ChM®

Charfix Femoral Nail
ChFN system

INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR WITH ChFN TROCHANTERIC NAILS

- *IMPLANTS*
- *INSTRUMENT SET 40.5520.600*
- *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.
	Before using the product, carefully read the Instructions for Use supplied with the product. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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

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The manufacturer reserves the right to introduce design changes.

I. INTRODUCTION 5

II. IMPLANTS 5

III. SURGICAL TECHNIQUE 15

III.1. INTRODUCTION 15

III.2. PREPARATION FOR IMPLANTATION OF SHORT TROCHANTERIC NAIL 120°,125°,130° OR 135° 16

III.3. POSITIONING OF TARGETER D SLIDER 17

III.4. OPENING AND PREPARING THE MEDULLARY CANAL FOR INSERTION OF TROCHANTERIC NAIL (*SHORT AND LONG*) 17

III.5. NAIL INSERTION INTO MEDULLARY CANAL (*SHORT AND LONG NAILS*) 19

III.6. LOCKING THE TROCHANTERIC NAIL IN THE PROXIMAL PART 20

III.6A. LOCKING THE TROCHANTERIC NAIL (*SHORT AND LONG*) IN THE PROXIMAL PART USING TWO JOIN SCREWS 20

III.6B. LOCKING THE TROCHANTERIC NAIL IN THE PROXIMAL PART USING THE JOIN SCREW WITH ANTIROTARY PROTECTION 25

III.7. LOCKING THE SHORT TROCHANTERIC NAIL IN DISTAL PART 28

III.8. LOCKING THE LONG TROCHANTERIC NAIL IN THE DISTAL PART 31

III.9. THE NAIL EXTRACTION (*LONG AND SHORT*) 33

I. INTRODUCTION

Intramedullary Osteosyntesis of Femur with **CHARFIX FEMORAL NAIL** consists of:

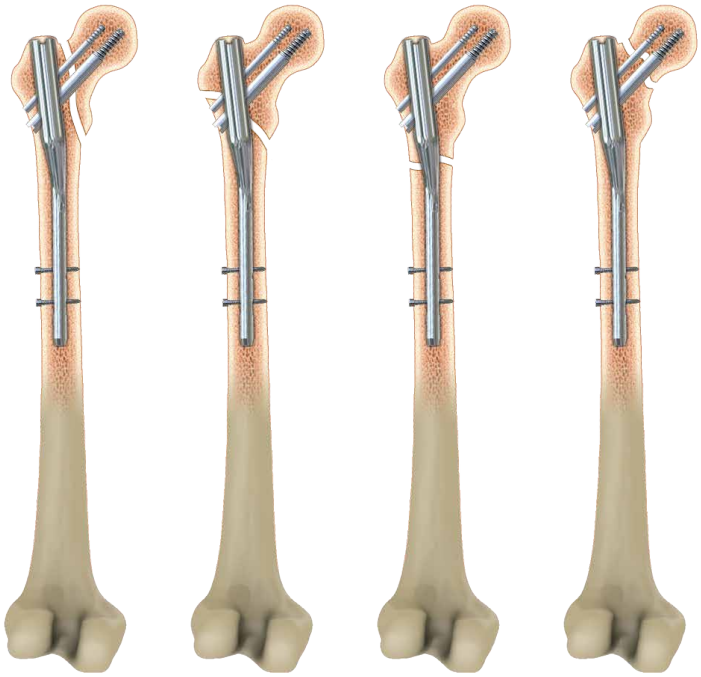
- implants (*intramedullary nails, locking screws, join screws, end caps*),
- instrument sets for implants insertion and removal,
- Instructions for Use

Intramedullary osteosynthesis of femur with **ChFN** nails allows for stable reduction 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 and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered implants.

Application of the nail:

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



Examples of femur fractures treated with ChFN nail

Good result are obtained for:

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

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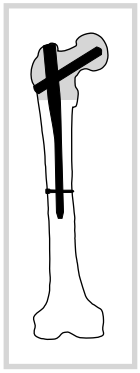

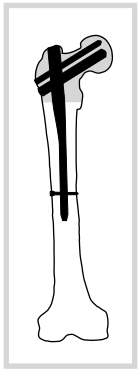

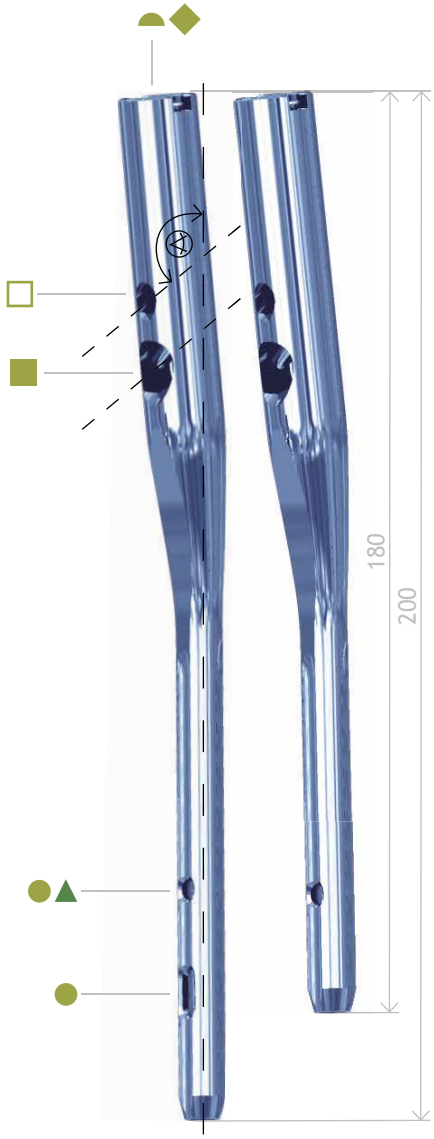

		Len	Ti
130°	10	180	3.4876.180
		200	3.4876.200
	11	180	3.4877.180
		200	3.4877.200
	12	180	3.4878.180
		200	3.4878.200
130°	Recommended		

available	Ø 10 mm ÷12 mm	pitch	1 mm
	L 180 mm ÷ 240 mm		5 mm

	Ti						
	3.1938.xxx			✓	11	70÷120	■
	3.2104.003	✓		✓			
	3.1935.xxx	✓		✓	6.5	70÷120	□
	3.1657.xxx	✓	✓		5.0	30÷60	▲
	3.1654.xxx	✓			4.5	30÷60	●
	3.2106.008	✓					◗
	3.2104.6xx	✓		✓		0÷15	◆

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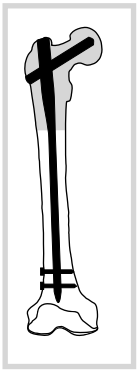
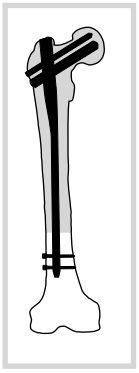
		Len	Ti
125°	10	180	3.4864.180
		200	3.4864.200
	11	180	3.4865.180
		200	3.4865.200
	12	180	3.4866.180
		200	3.4866.200
135°	10	180	3.4888.180
		200	3.4888.200
	11	180	3.4889.180
		200	3.4889.200
	12	180	3.4890.180
		200	3.4890.200

available	Ø	10 mm ÷12 mm	pitch	1 mm
	L	180 mm ÷ 240 mm		5 mm

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

Charfix Femoral Nail
ChFN system





		Len	L	R
130°	10	340	3.4951.340	3.4950.340
		360	3.4951.360	3.4950.360
		380	3.4951.380	3.4950.380
		400	3.4951.400	3.4950.400
		420	3.4951.420	3.4950.420
	11	340	3.4953.340	3.4952.340
		360	3.4953.360	3.4952.360
		380	3.4953.380	3.4952.380
		400	3.4953.400	3.4952.400
		420	3.4953.420	3.4952.420
	12	340	3.4955.340	3.4954.340
		360	3.4955.360	3.4954.360
		380	3.4955.380	3.4954.380
		400	3.4955.400	3.4954.400
		420	3.4955.420	3.4954.420
130°	Recommended			

available	Ø	10 mm ÷12 mm	pitch	1 mm
	L	280 mm ÷ 480 mm		5 mm

	3.1938.xxx			✓	11	70÷120	■
	3.2104.003	✓		✓			
	3.1935.xxx	✓		✓	6.5	70÷120	□
	3.1657.xxx	✓	✓		5.0	30÷80	▲
	3.1654.xxx	✓			4.5	30÷80	●
	3.2106.008	✓					◗
	3.2104.6xx	✓		✓		0÷15	◆

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		Len	L	R
125°	10	340	3.4927.340	3.4926.340
		360	3.4927.360	3.4926.360
		380	3.4927.380	3.4926.380
		400	3.4927.400	3.4926.400
		420	3.4927.420	3.4926.420
	11	340	3.4929.340	3.4928.340
		360	3.4929.360	3.4928.360
		380	3.4929.380	3.4928.380
		400	3.4929.400	3.4928.400
		420	3.4929.420	3.4928.420
	12	340	3.4931.340	3.4930.340
		360	3.4931.360	3.4930.360
		380	3.4931.380	3.4930.380
		400	3.4931.400	3.4930.400
		420	3.4931.420	3.4930.420
135°	10	340	3.4975.340	3.4974.340
		360	3.4975.360	3.4974.360
		380	3.4975.380	3.4974.380
		400	3.4975.400	3.4974.400
		420	3.4975.420	3.4974.420
	11	340	3.4977.340	3.4976.340
		360	3.4977.360	3.4976.360
		380	3.4977.380	3.4976.380
		400	3.4977.400	3.4976.400
		420	3.4977.420	3.4976.420
	12	340	3.4979.340	3.4978.340
		360	3.4979.360	3.4978.360
		380	3.4979.380	3.4978.380
		400	3.4979.400	3.4978.400
		420	3.4979.420	3.4978.420

available		Ø	10 mm ÷12 mm	pitch 1 mm
		L	280 mm ÷ 480 mm	5 mm

Ti Ster Non Ster

Charfix Femoral Nail
ChFN system
CHARFIX system

CHARFIX DISTAL SCREW 4.5

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

16 ÷ 100

CHARFIX DISTAL SCREW 5.0

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

16 ÷ 100

ChFN JOIN CANNULATED TROCHANTERIC SCREW WITH COLLAR 6.5

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 WITH COLLAR 11

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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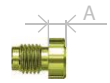
ChFN END CAP M12X1.75



A	
0	3.2104.600
+5	3.2104.605
+10	3.2104.610
+15	3.2104.615

ChFN END CAP M8X1.25

	3.2104.003

ChFN COMPRESSION SCREW M8X1.25

	3.2106.008

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40.5520.600	Name	Pcs.	Catalogue no.
	Targeter arm	1	40.5541.000
	Targeter 120/130	1	40.5542.100
	Targeter 125/135	1	40.5543.100
	Distal targeter D	1	40.5546.000
	Drill guide 14/12	1	40.5544.100
	Protective guide 12/2.8	1	40.5545.100
	Connecting screw M12x1.75 L-34	1	40.5547.000
	Drill guide 9.0/7.0	1	40.5537.100
	Protective guide 7.0/2.8	1	40.5538.100
	Drill with scale 3.5/350	2	40.5339.001
	Drill guide 7/3.5	2	40.5511.100
	Protective guide 9/7	2	40.5510.100
	Compression wrench	1	40.5532.300
	Screwdriver S3.5	1	40.5525.100
	Cannulated screwdriver S4	1	40.5524.300
	Drill 6.5	1	40.5529.000
	Gradual drill 11/6.5	1	40.5528.000

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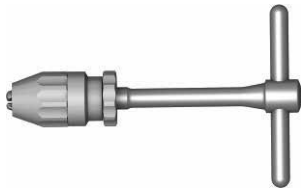
Charfix Femoral Nail ChFN system

40.5520.600	Name	Pcs.	Catalogue no.
	Screwdriver S10	1	40.5521.000
	Mallet	1	40.3667.000
	Wrench S10	1	40.5526.100
	Impactor-extractor	1	40.5507.000
	Curved awl 8.0	1	40.5523.000
	Protective guide 20.0/17.0	1	40.4711.000
	Guide 17.0/2.8	1	40.4712.100
	Set block 9/4.5	2	40.5533.000
	Cannulated drill 17.0	1	40.4715.000
	Connector of extractor M12x1.75	1	40.4731.000
	Trocar 2.8	1	40.5527.000
	Trocar 6.5	1	40.5534.000
	Screw length measure	1	40.5530.000
	Cannulated screw length measure	1	40.4724.000
	Nail length measure	1	40.4798.500
	Teflon pipe guide	1	40.1348.000
	Guide rod 3.0/580	1	40.3925.580
	Guide rod 2.8/385	4	40.5531.000

Charfix Femoral Nail ChFN system

40.5520.600	Name	Pcs.	Catalogue no.
	Steinmann handle	1	40.0987.200
	Wrench for self-aligning joint S4	1	40.5540.000
	Perforated aluminumcover 1/1 595x275x15mm gray	1	12.0750.200
	Stand f/instr.set of ChFN trochanteric nails	1	40.5549.600
	Container with solid bottom 1/1 595x275x185mm	1	12.0750.103

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III. SURGICAL TECHNIQUE

III.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 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 is essential as 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-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 artrosis 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.

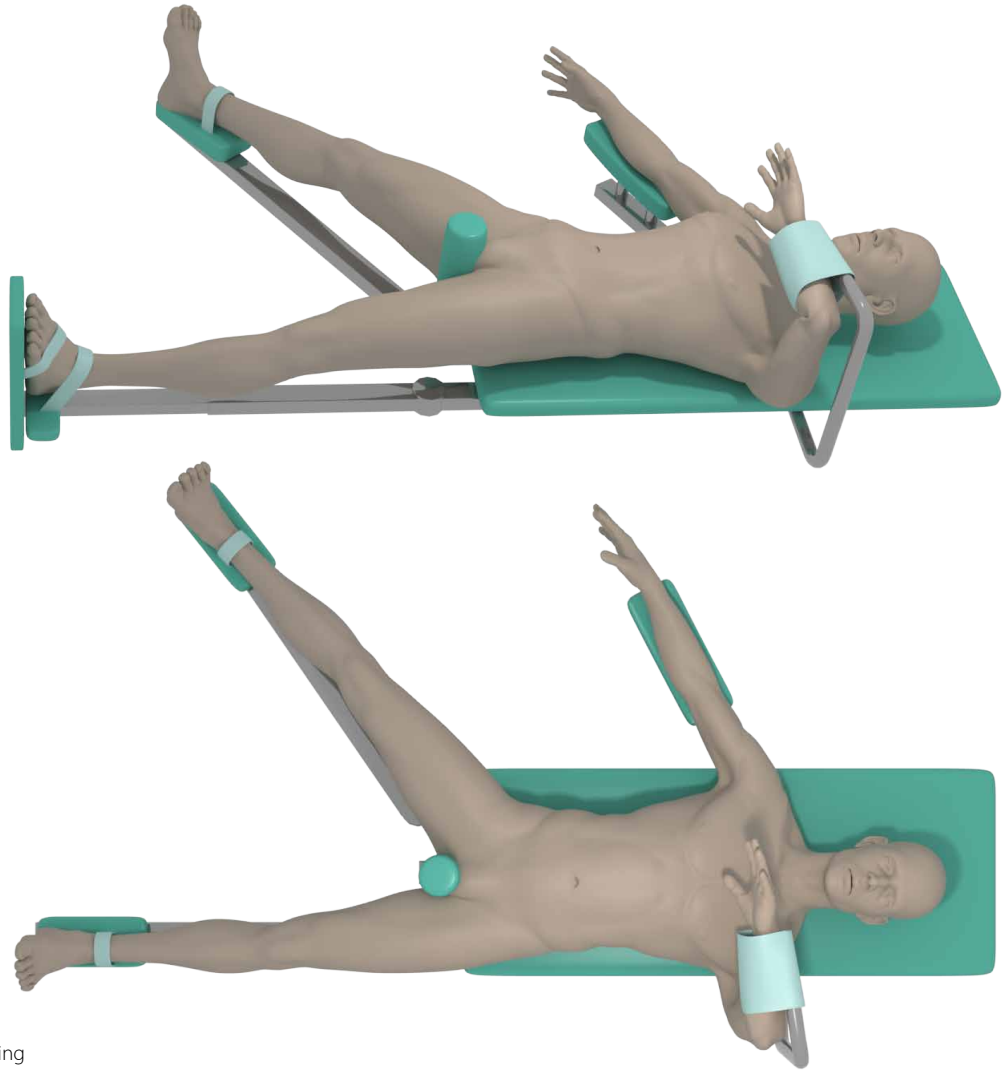


Fig.1. Patient positioning

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.

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

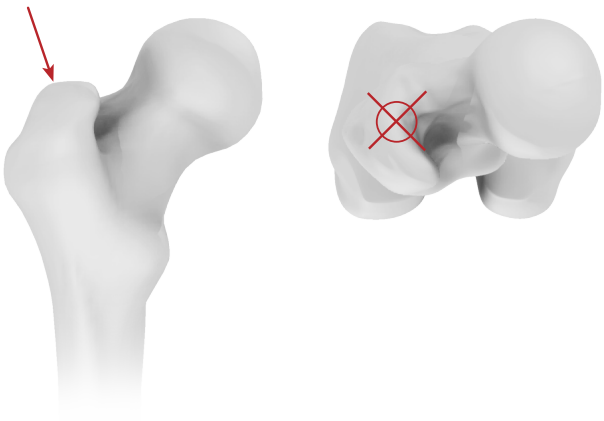


Fig.2. Location of the entry point for femoral nail

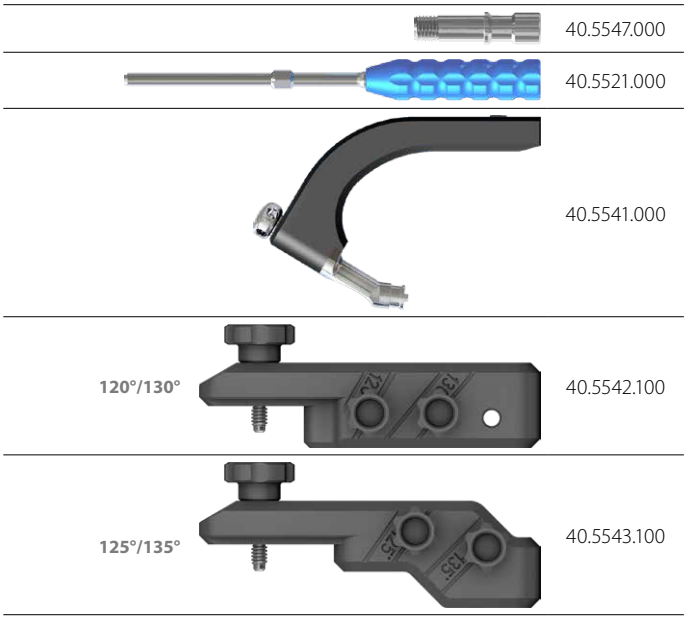
The following paragraphs describe most important steps during implantation of ChFN trochanteric nails; nevertheless it is not a detailed instruction of use. The surgeon decides about choosing the surgical technique and its application in each individual case.

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

1 Mount trochanteric nail to the targeter arm **[40.5541]** using the connecting screw M12x1.75 L-34 **[40.5547]** and the screwdriver S10 with pilot **[40.5521]**.

Mount specified targeter onto the targeter arm depending on selected nail angle.

- for nail 120° and 130° use targeter 120/130 **[40.5542.100]**,
- for nail 125° and 135° use targeter 125/135 **[40.5543.100]**.



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

III.3. POSITIONING OF TARGETER D SLIDER

2 In case of long nail implantation, mount the distal targeter D **[40.5546]** to the targeter arm **[40.5541]**. 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 **[40.5525.100]**.

CHECK: **Correctly positioned and locked slider should allow easy insertion of the set blocks into the nail holes.**

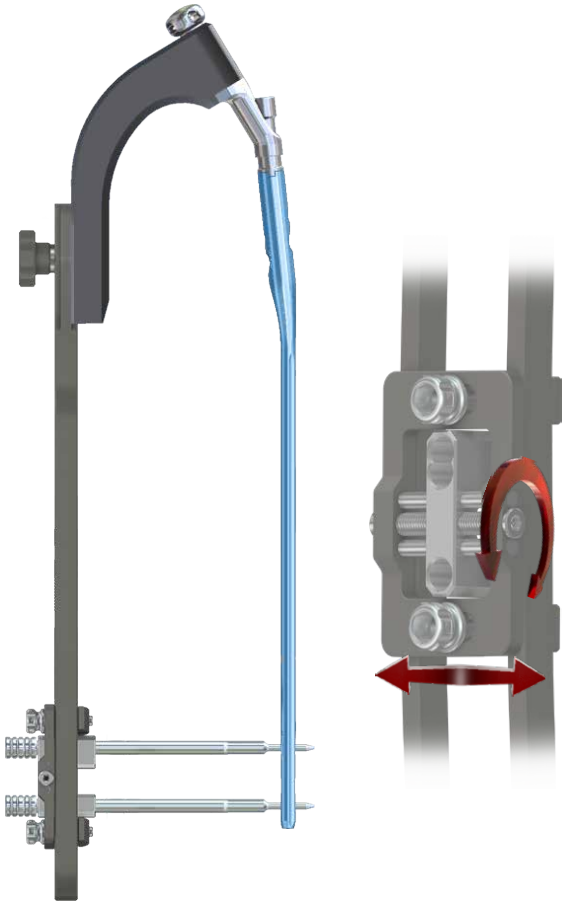
Remove the set blocks.
Dismount the distal targeter D from the targeter arm.

40.5541.000

40.5546.000

40.5533.000

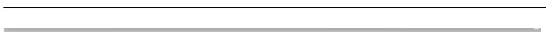
40.5525.100



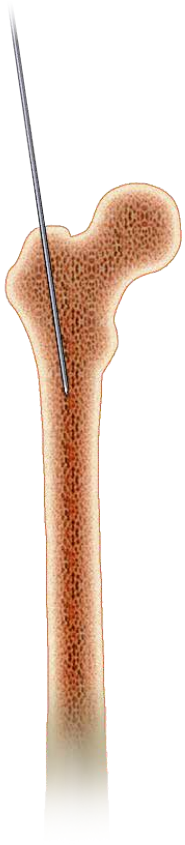
III.4. OPENING AND PREPARING THE MEDULLARY CANAL FOR INSERTION OF TROCHANTERIC NAIL *(SHORT AND LONG)*

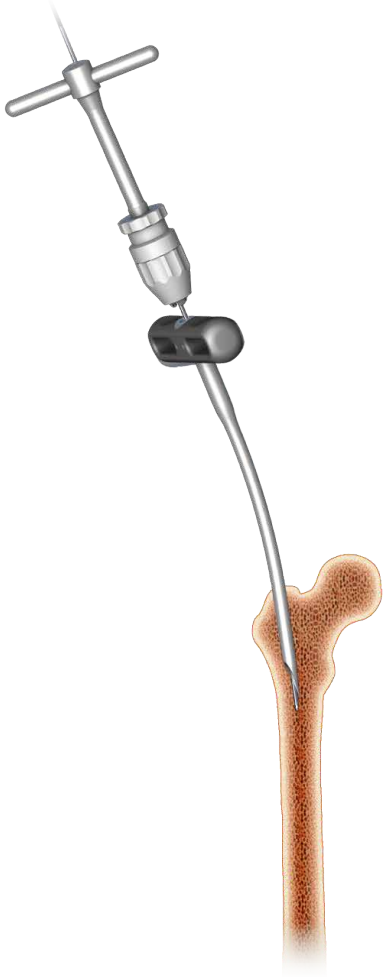
3 Make the skin incision near the tip of a grater trochanter.
Having localized the nail entry point, using the drive insert the guide rod 2.8/385 **[40.5531]** into the medullary canal. The rod should be inserted in the angle corresponding to the deviation angle of the nail shaft from the main axis (*about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

The process should be controlled with image intensifier.



40.5531.000





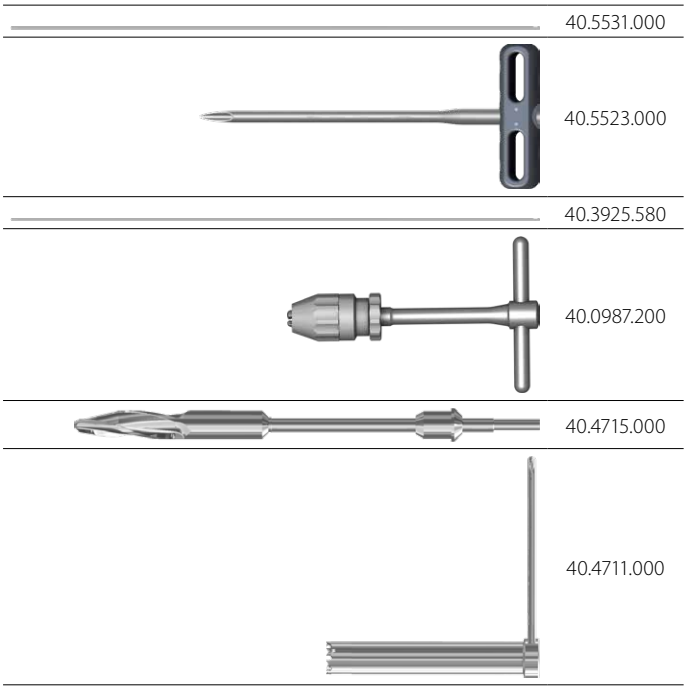
4 Using guide rod 2.8/385 **[40.5531]**, insert into the medullary canal curved awl 8.0 **[40.5523]** to the depth at which the awl blade goes along the medullary canal, allowing proper insertion of guide rod 3.0/580 **[40.3925.580]**. Having opened medullary canal, remove guide rod 2.8/385 **[40.5531]**.

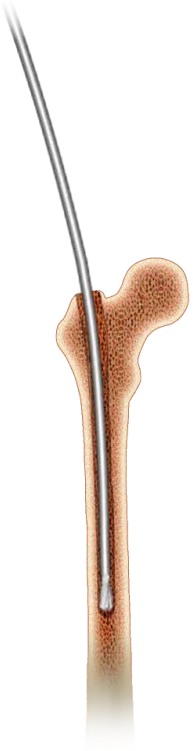
Mount guide rod 3.0/580 **[40.3925.580]** to Steinmann handle **[40.0987.200]** and enter the guide into the medullary canal through curved awl 8.0 **[40.5523]** cannulated hole to the depth required for the proper fixation of bone fragments. While guide rod insertion, control the fracture reduction 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*).

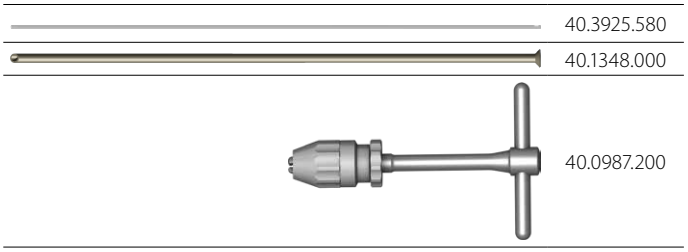
In both cases, when the medullary canal was reamed or not, the proximal part of the canal should be reamed using 17 mm reamer to the depth of approx. 6 cm.

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



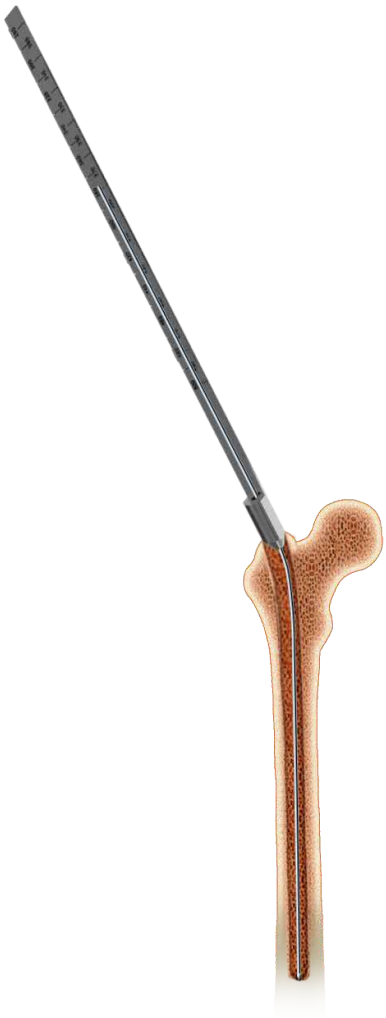
The below step concerns long trochanteric nails.

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.


40.4798.500



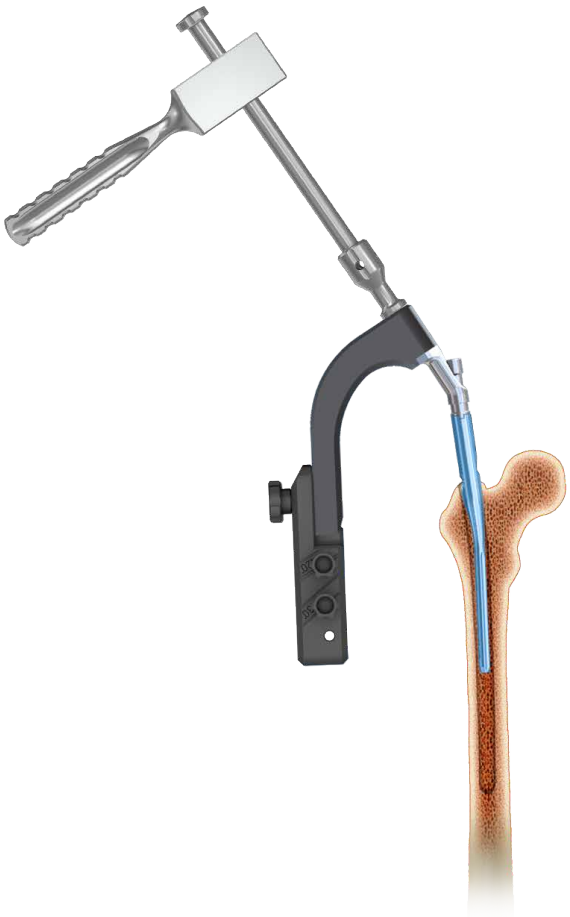
III.5. NAIL INSERTION INTO MEDULLARY CANAL *(SHORT AND LONG NAILS)*

6 Connect the targeter arm **[40.5541]** with the impactor-extractor **[40.5507]** and using the mallet **[40.3667]** insert the nail into the medullary canal. Remove the guide rod.


40.5541.000


40.5507.000


40.3667.000

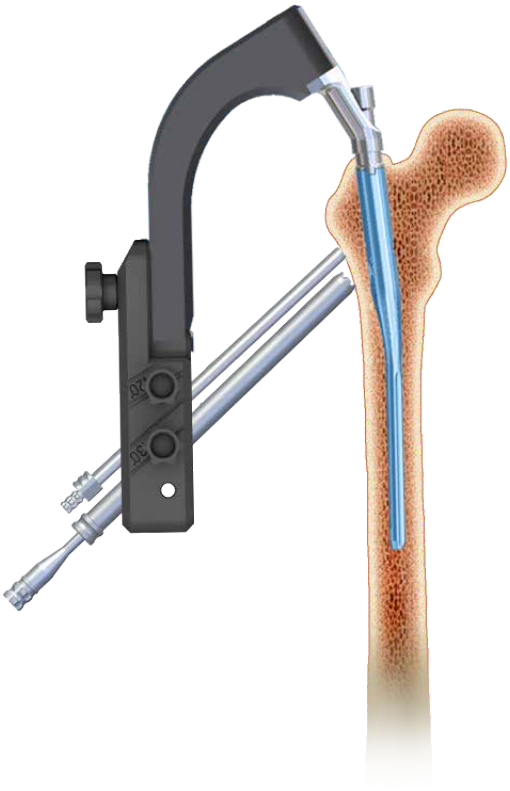


III.6. LOCKING THE TROCHANTERIC NAIL IN THE PROXIMAL PART

III.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 120/130 **[40.5542.100]** or targeter 125/135 **[40.5543.100]** to the targeter arm. Insert the drill guide 9.0/7.0 **[40.5537.100]** and the protective guide 7.0/2.8 **[40.5538.100]**, and trocar 2.8 **[40.5527]** into the smaller hole of the targeter. Advance the trocar until it reaches the cortex and mark the entry point for the guide rod. Advance the drill guide **[40.5537.100]** together with the trocar in such a way that its end is placed as close to the bone as possible. Remove the trocar. Insert the drill guide 14/12 **[40.5544.100]** and the protective guide 12/2.8 **[40.5545.100]**, and trocar 2.8 **[40.5527]** into the bigger hole of the targeter. Advance the trocar until it reaches the cortex and mark the entry point for the guide rod. Advance the drill guide **[40.5544.100]** together with the trocar in such a way that its end is placed as close to the bone as possible. Remove the trocar.




40.5542.100


40.5543.100


40.5537.100

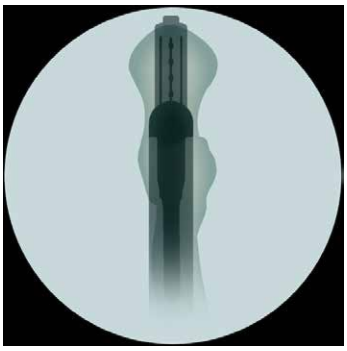

40.5538.100


40.5527.000


40.5544.100


40.5545.100

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 **[40.5540.100]** and position the nail under the control of image intensifier in two projections (*AP and lateral*).




40.5522.000

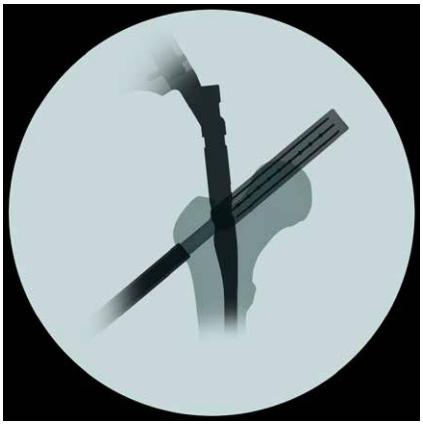
The instrument set does not include the screw position measure **[40.5522]**.

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.

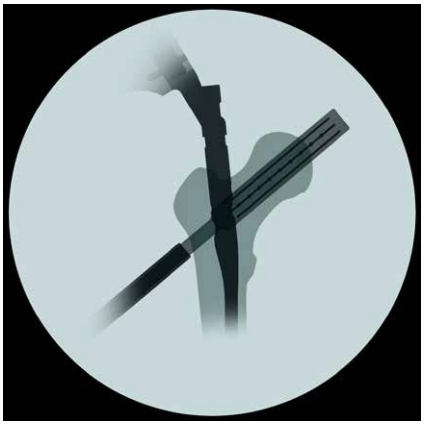
Rotate the nail with the targeter and set the nail in such way to enable insertion of join screws according to the angle of anteversion of femur neck.

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.

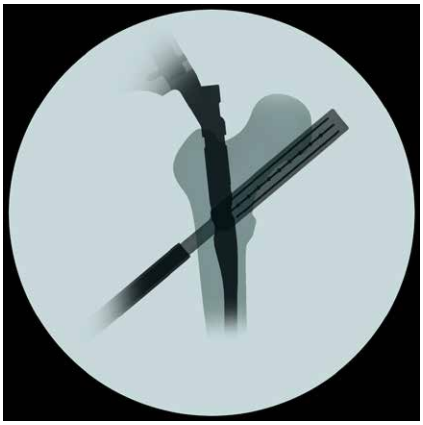
40.5522.000



IMPLANT PLACED TOO HIGH



CORRECT PLACEMENT

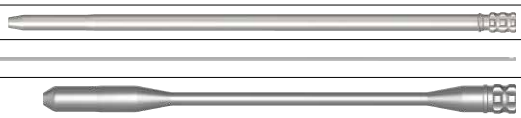


IMPLANT PLACED TOO LOW

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]**.

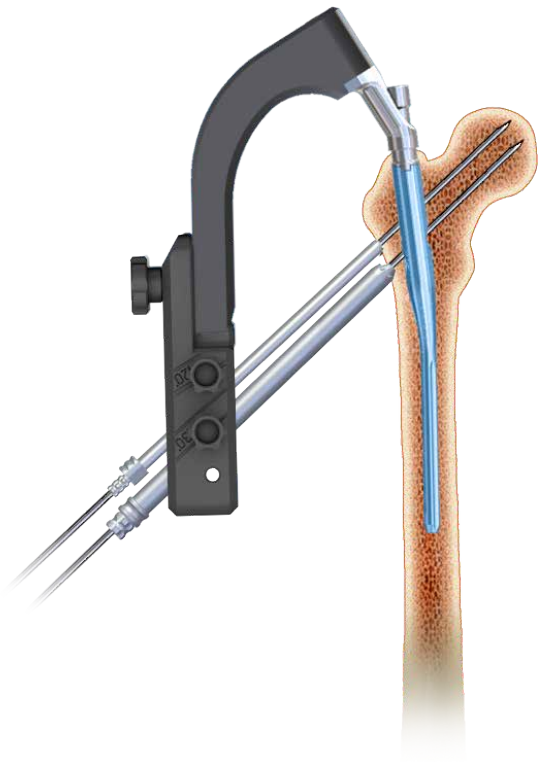
The guide rod [40.5531] shall be inserted into the femoral head at the distance of 5-10mm to the cartilage.



40.5538.100

40.5531.000

40.5545.100

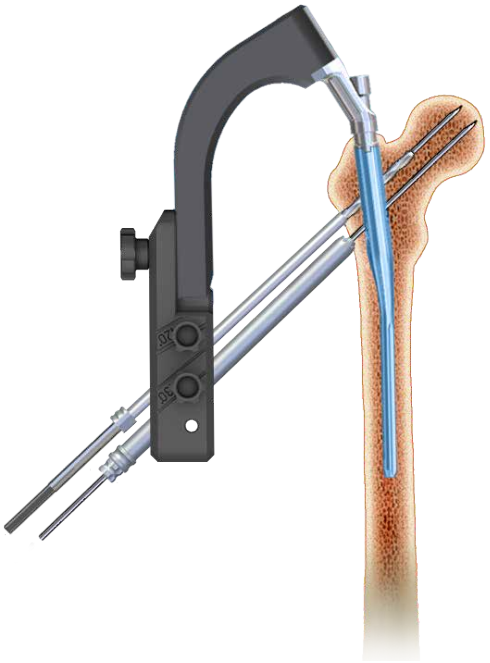


10 Insert the cannulated screw length measure **[40.4724]** via the guide rod 2.8/385 **[40.5531]** (*placed into the protective guide 7.0/2.8 [40.5538.100]*)
Read the length of the join screw on the scale indicated by end of the guide rod.
During the measurement the tip of the cannulated screw length 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.

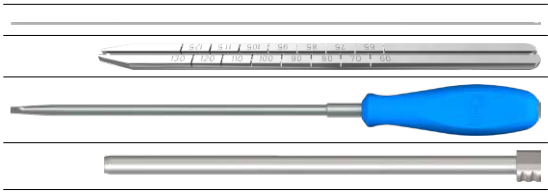
40.5531.000

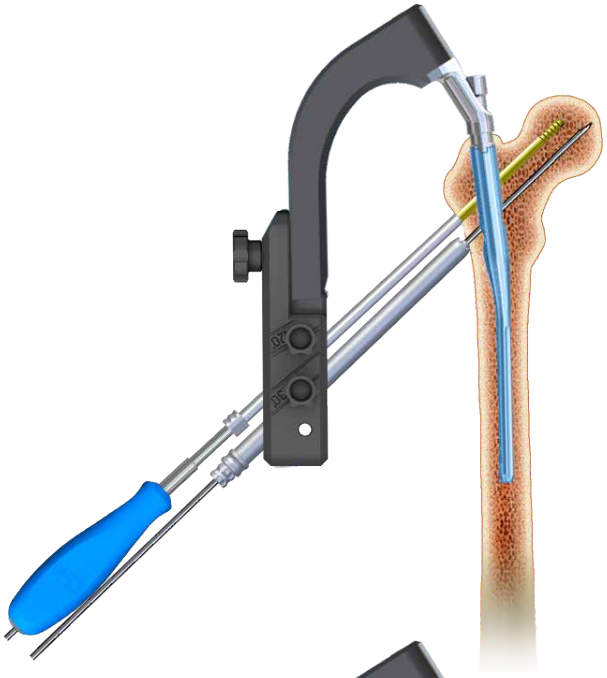
40.4724.000

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.

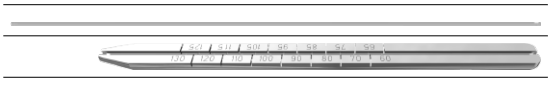


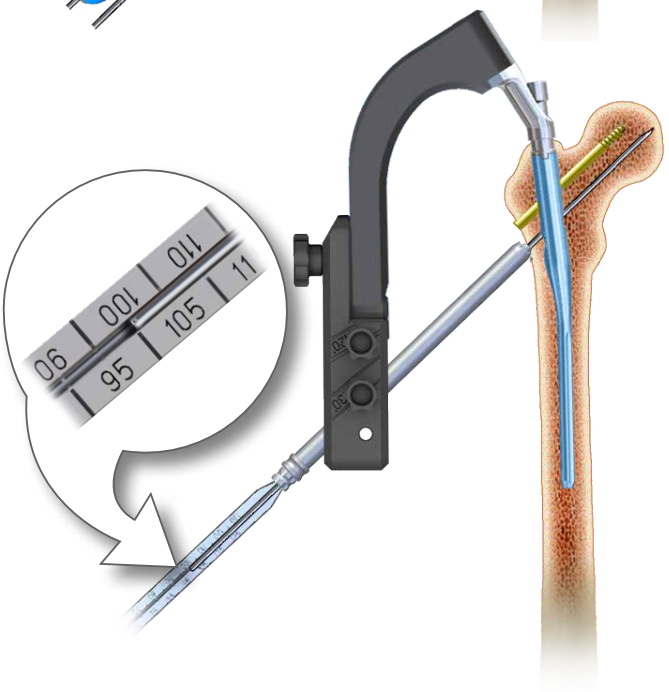
12 Insert the join cannulated screw 6.5, defined by the cannulated screw length measure **[40.4724]**, onto the guide rod 2.8/385 **[40.5531]**. Use the cannulated screwdriver S4 **[40.5524.300]** to advance the screw via the guide rod into the femur neck until the screwdriver tip rests on the drill 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 screws 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.





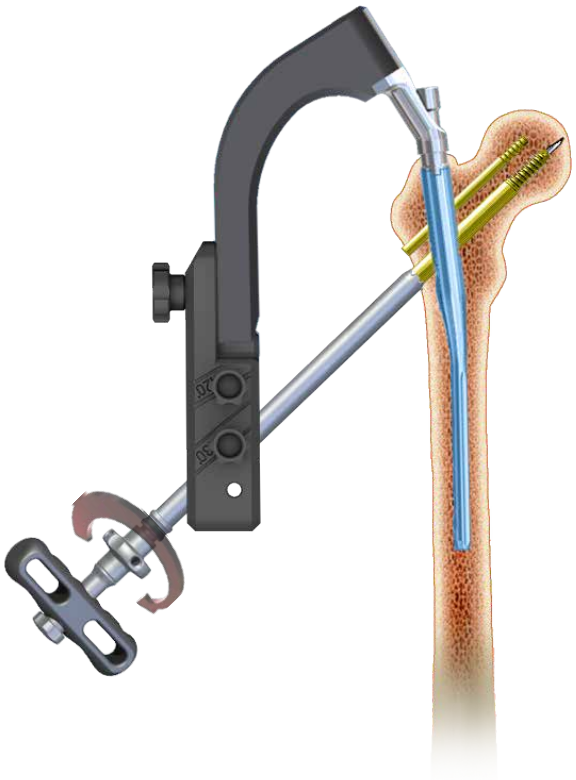
14 Use the adjusting bolt to set the depth of drilling (*corresponding to the join screw*) on the gradual drill 11/6.5 **[40.5528]**. Connect the gradual drill with electric drive, and advance such system onto the guide rod 2.8/385 **[40.5531]** until the bolt set rests on the drill guide 14/12 **[40.5544.100]**.
Remove the gradual drill.
Leave the guide rod and the drill guide.


40.5528.000

40.5531.000


40.5544.100

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 device




40.5532.300


40.4724.000

40.5531.000


40.5544.100

III.6B. LOCKING THE TROCHANTERIC NAIL IN THE PROXIMAL PART USING THE JOIN SCREW WITH ANTIROTARY PROTECTION

16 Mount previously chosen targeter **[40.5542.100]** or **[40.5543.100]** on the targeter arm. 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 protective guide 12/2.8 **[40.5545.100]** into bigger targeter hole.

40.5542.100

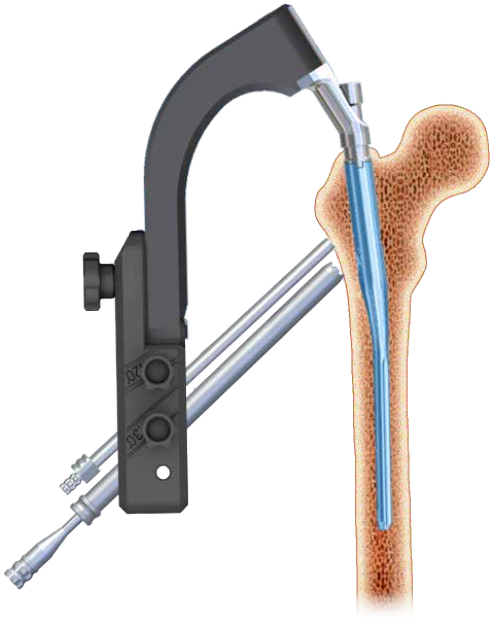
40.5543.100

40.5537.100

40.5538.100


40.5544.100


40.5545.100



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]**.

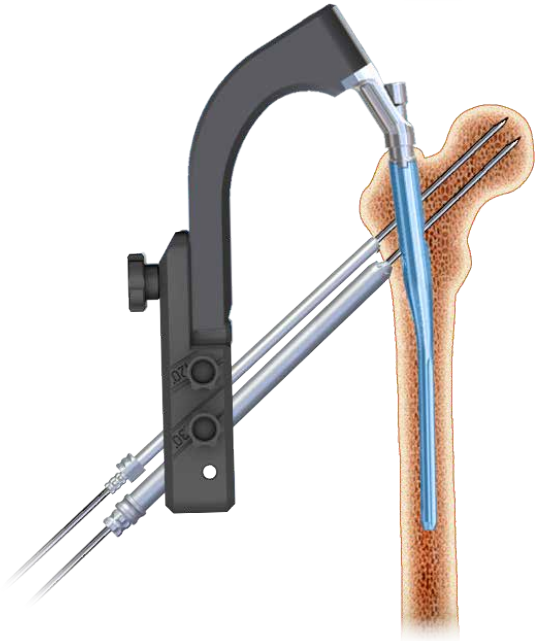
The guide rod [40.5531] shall be inserted into the femoral head at the distance of 5-10mm to the cartilage.

In the case of inappropriate positioning of the guide rod, repeat the step.
Leave the guide rod and guides in the holes.

40.5538.100

40.5531.000


40.5545.100



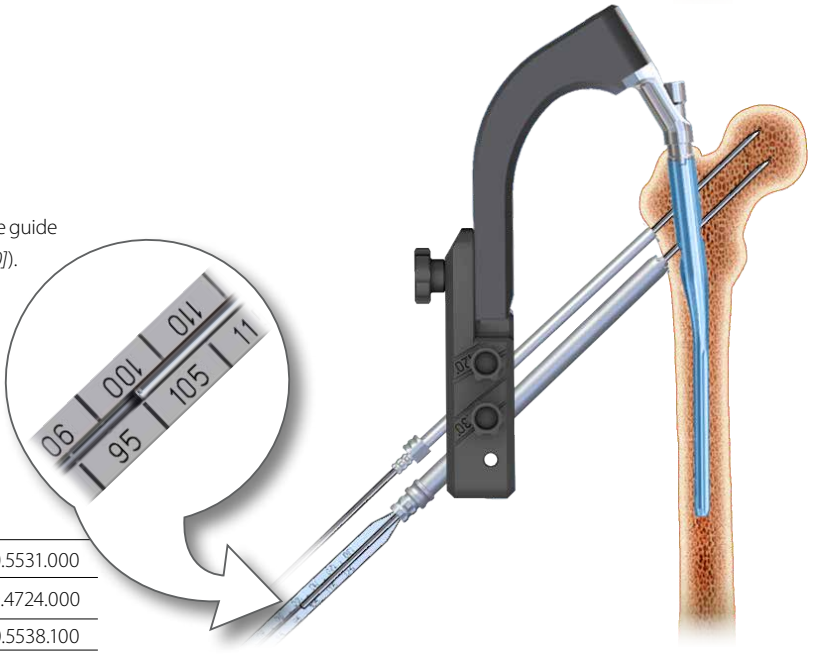
18 Insert the cannulated screw length measure **[40.4724]** onto the guide rod 2.8/385 **[40.5531]** (*placed into the guide 12/2.8 [40.5545.100]*).
Read the length of the join cannulated screw on the scale. The tip of the cannulated screw length measure should rest on the guide 12/2.8 during the measurement.

Remove the cannulated screw length measure, Guide 12/2.8 and protective guide 7,0/2.8 **[40.5538.100]**.
Leave the guide rod.

40.5531.000

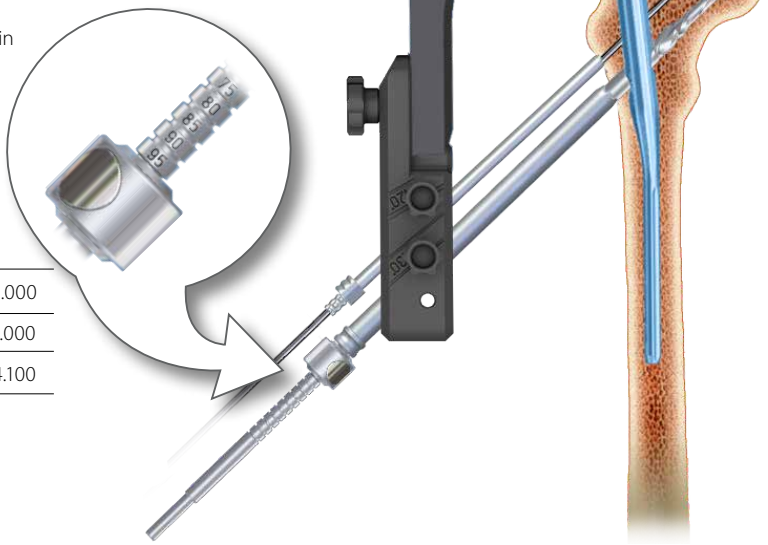

40.4724.000


40.5538.100



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

19 Define the drilling depth coresponding to the previously chosen join screw on drill 11/6.5 **[40.5528]** using the adjusting bolt. Connect the gradual 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.

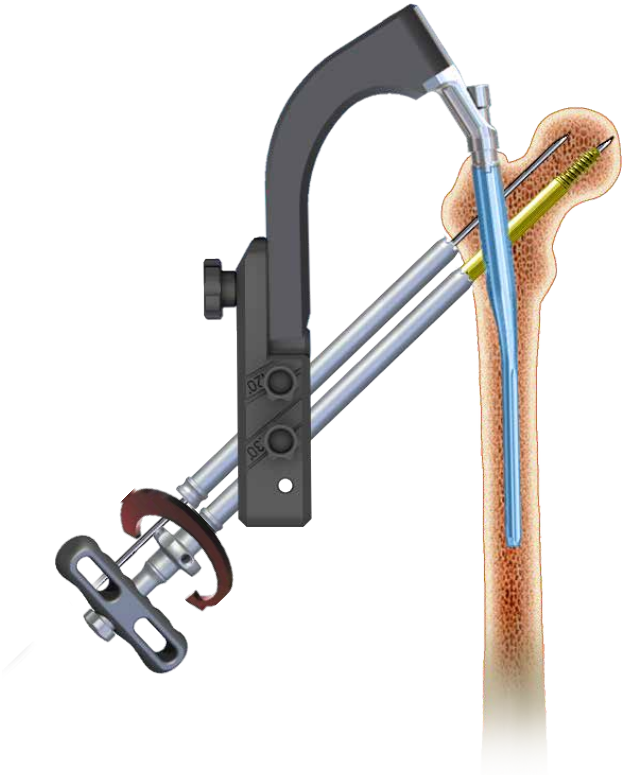



40.5528.000

40.5531.000


40.5544.100

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 guide rod.




40.5532.300


40.4724.000

40.5531.000

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 match 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 maximally tightened up, and next loosened by ¼ turn*)
• static - after interfragmental compression, compression screw is maximally tightened up.

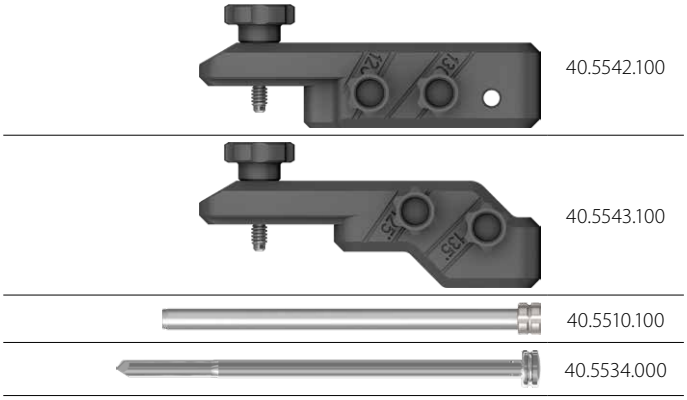
Remove the compression wrench, guide rod and drill guide.

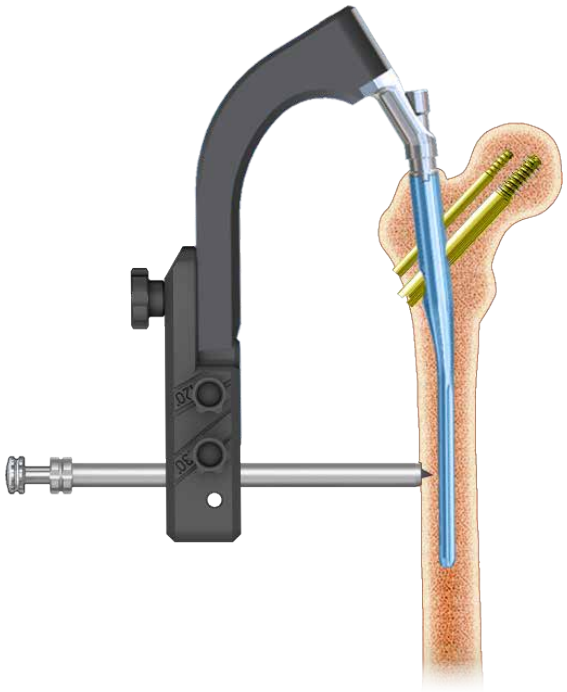
Secure the inner thread of the join screw against tissue overgrowth by insertion of end cap **[3.2104.003]** using screwdriver S3,5 **[40.5525.100]**.


40.5525.100

III.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 **[40.5534.100]** into the proximal hole of the targeter **[40.5542.100]** or **[40.5543.100]**. 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.

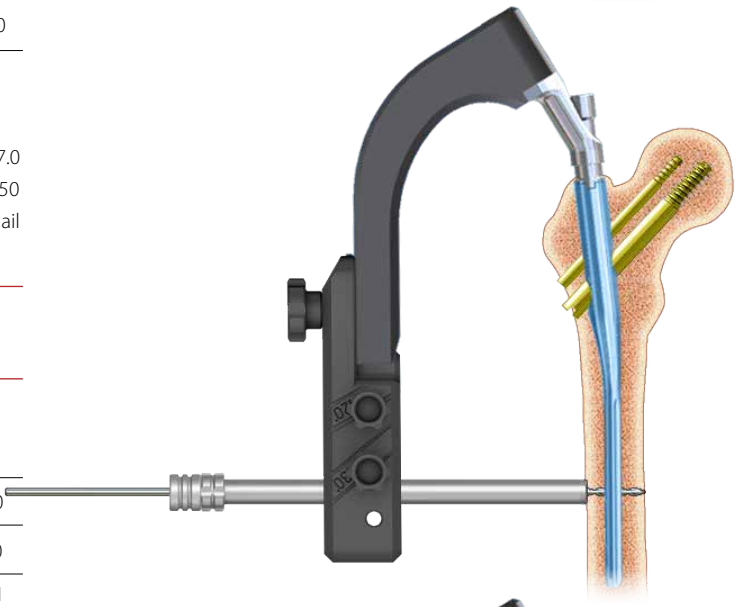




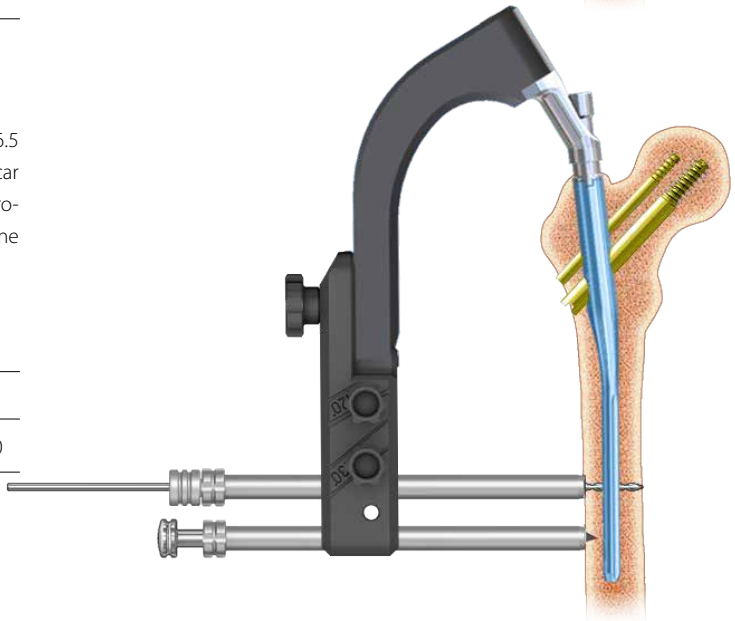
23 Insert the drill guide 7/3.5 **[40.5511.100]** into the protective guide 9.0/7.0 **[40.5510.100]**. Using electric drive, lead the drill with scale 3.5/350 **[40.5339.001]** into the drill guide and throughout both cortex layers and the nail hole. The scale on the drill indicates the length of locking 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 **[40.5339.001]** 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.

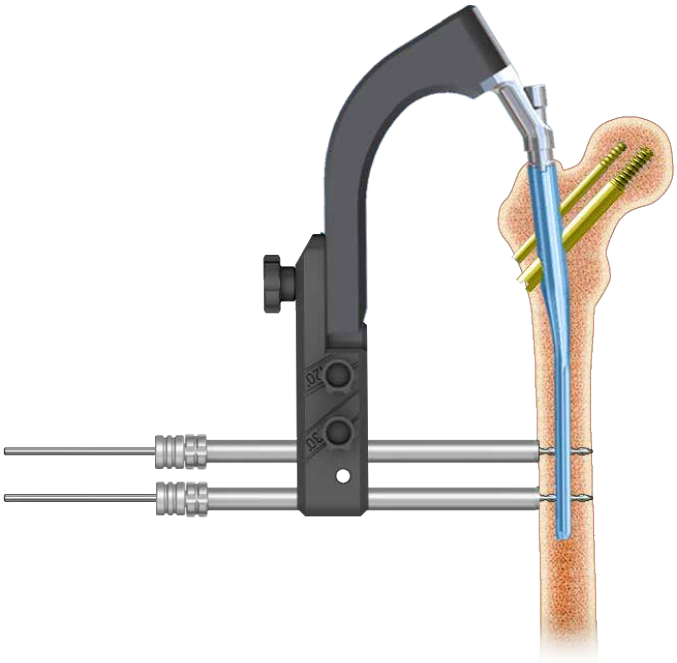
Drilling process should be controlled with image intensifer.

Remove the drill and the drill guide.
Leave the protective guide 9.0/7.0.


40.5510.100


40.5511.100

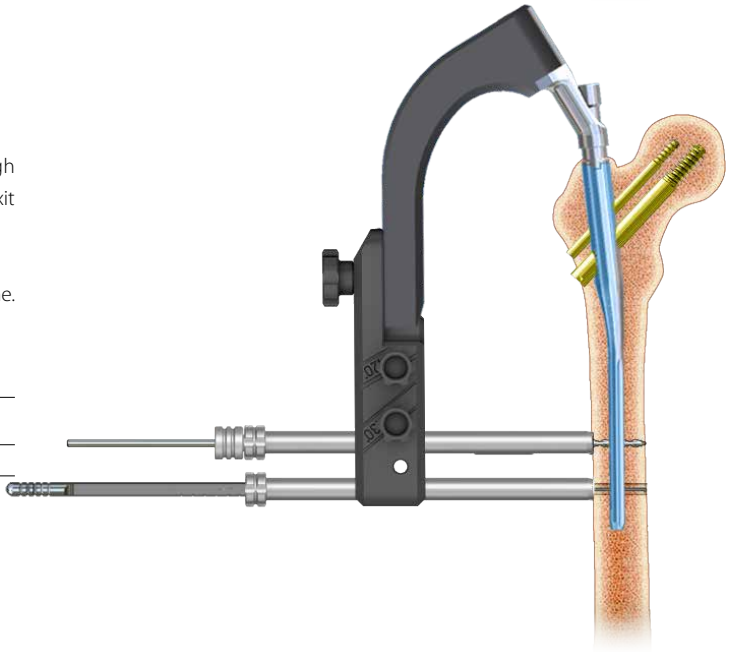

40.5339.001



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 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.


40.5510.100

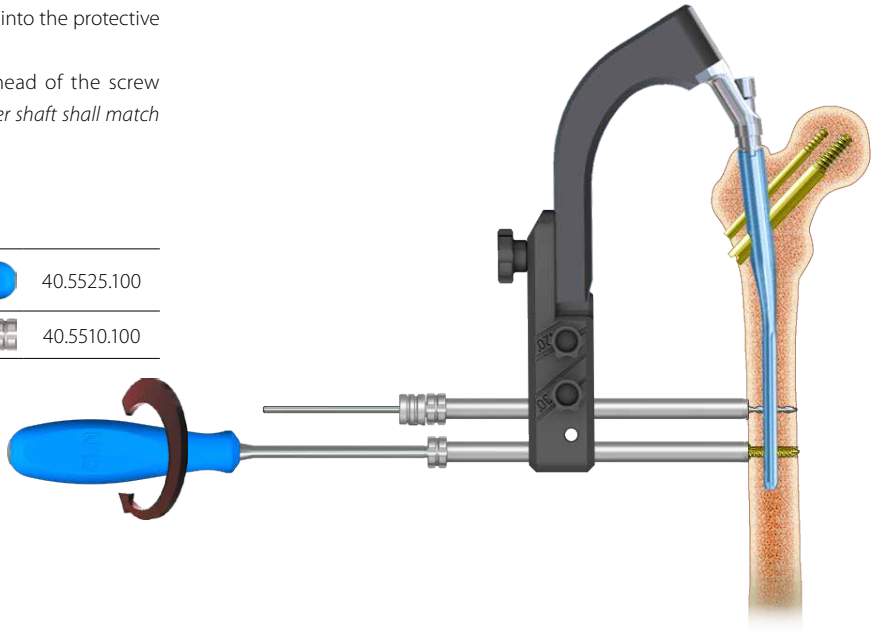

40.5530.000

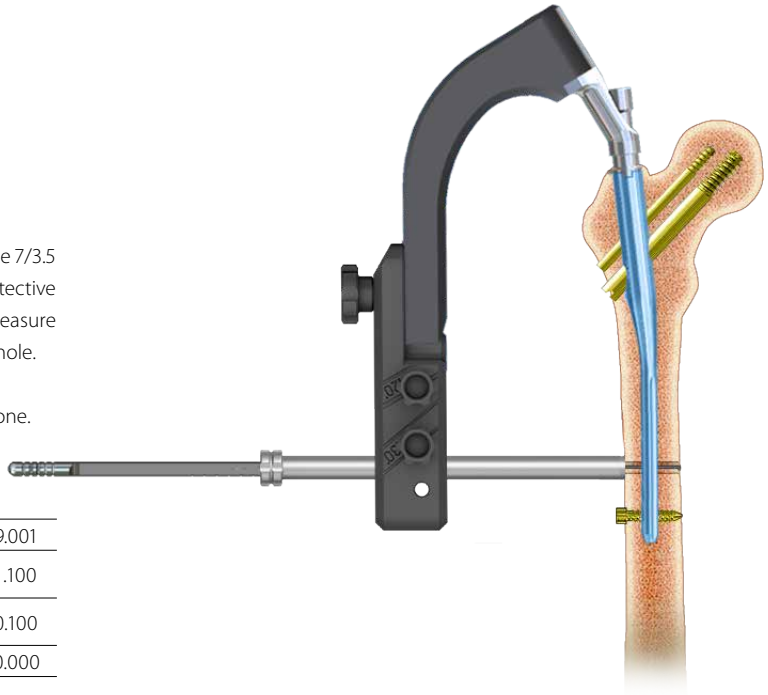


27 Insert the tip of the screwdriver S3.5 **[40.5525.100]** into the hexagonal socket of selected locking screw. Then advance both into the protective guide 9.0/7.0 **[40.5510.100]**.
Insert the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone (*the groove on the screwdriver shaft shall match the edge of protective guide*).
Remove the screwdriver and the protective guide 9.0/7.0.

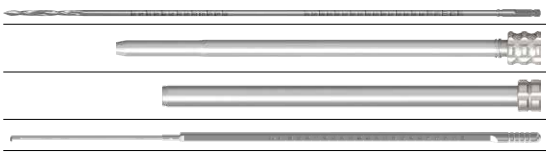

40.5525.100

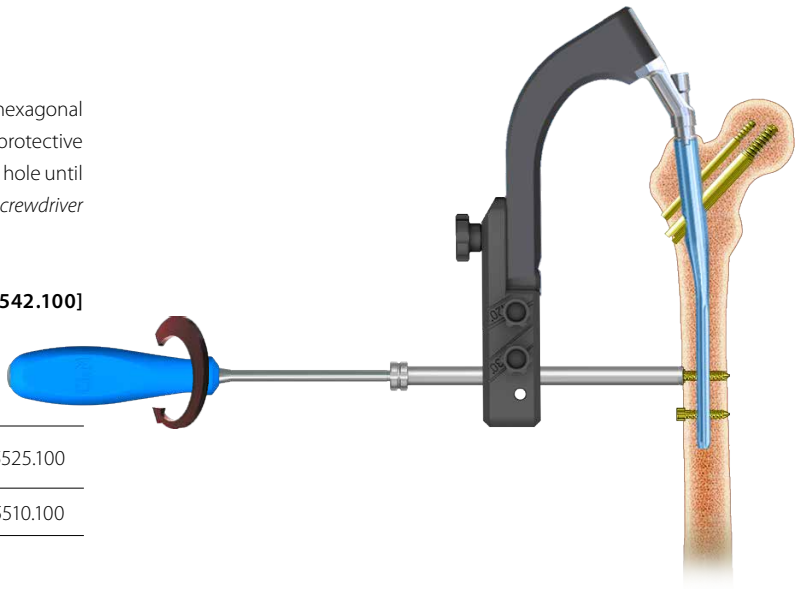

40.5510.100





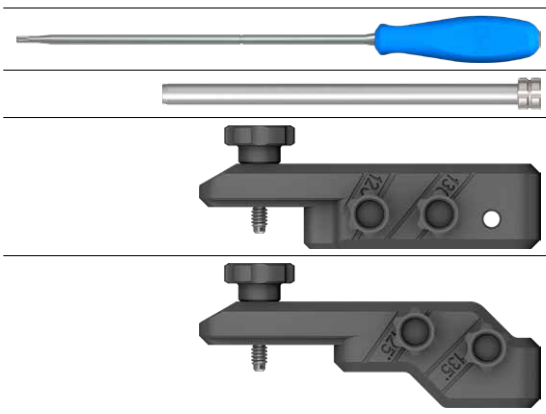
28 Remove the drill with scale 3.5/350 **[40.5339.001]** and the drill guide 7/3.5 **[40.5511.100]** out of proximal hole in the targeter. Leave the protective guide 9.0/7.0 **[40.5510.100]** in targeter hole. Insert the screw length measure **[40.5530]** into the drilled hole until its hook reaches 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 **[40.5525.100]** 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 **[40.5542.100]** or **[40.5543.100]**.



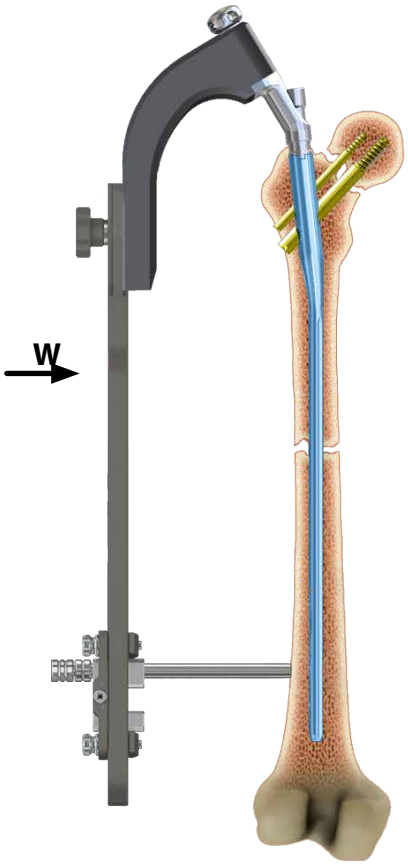
III.8. LOCKING THE LONG TROCHANTERIC NAIL IN THE DISTAL PART

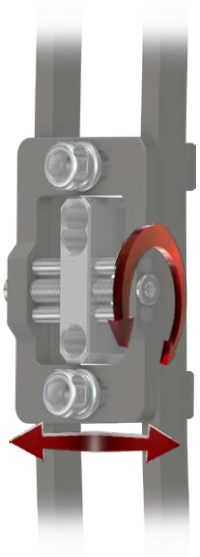
30 After locking the long trochanteric nail in proximal part and dismounting the targeter **[40.5542.100]** or **[40.5543.100]**; mount the distal targeter D **[40.5546]** onto the targeter arm **[40.5541]**. Verify with the image intensifier the position of the holes in targeter slider and distal holes 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.

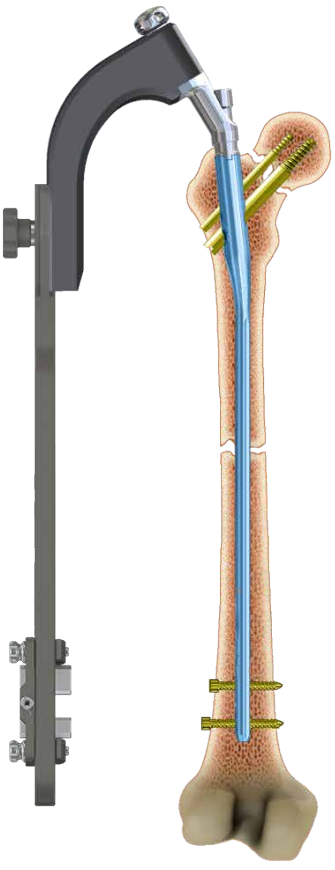
Insert the protective guide 9.0/7.0 **[40.5510.100]** and the drill guide **[40.5511.100]** into the slider hole of Distal targeter D.

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 appeared on the screen is not a circle, settings of D targeter must be corrected.

To do so, use the screw in the distal targeter D **[40.5546]** to move the slider (*turn the screw left or right*) until the circle appears on the screen (*image close to circle is acceptable*).








40.5542.100


40.5543.100


40.5541.000


40.5546.000


40.5510.100


40.5511.100

31 Remove the drill guide 7/3.5 **[40.5511.100]** out of the protective guide 9.0/7.0 **[40.5510.100]**.

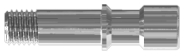
Locking the nail by the screws shall proceed in accordance with steps 22-29 presented on page 28.


40.5510.100

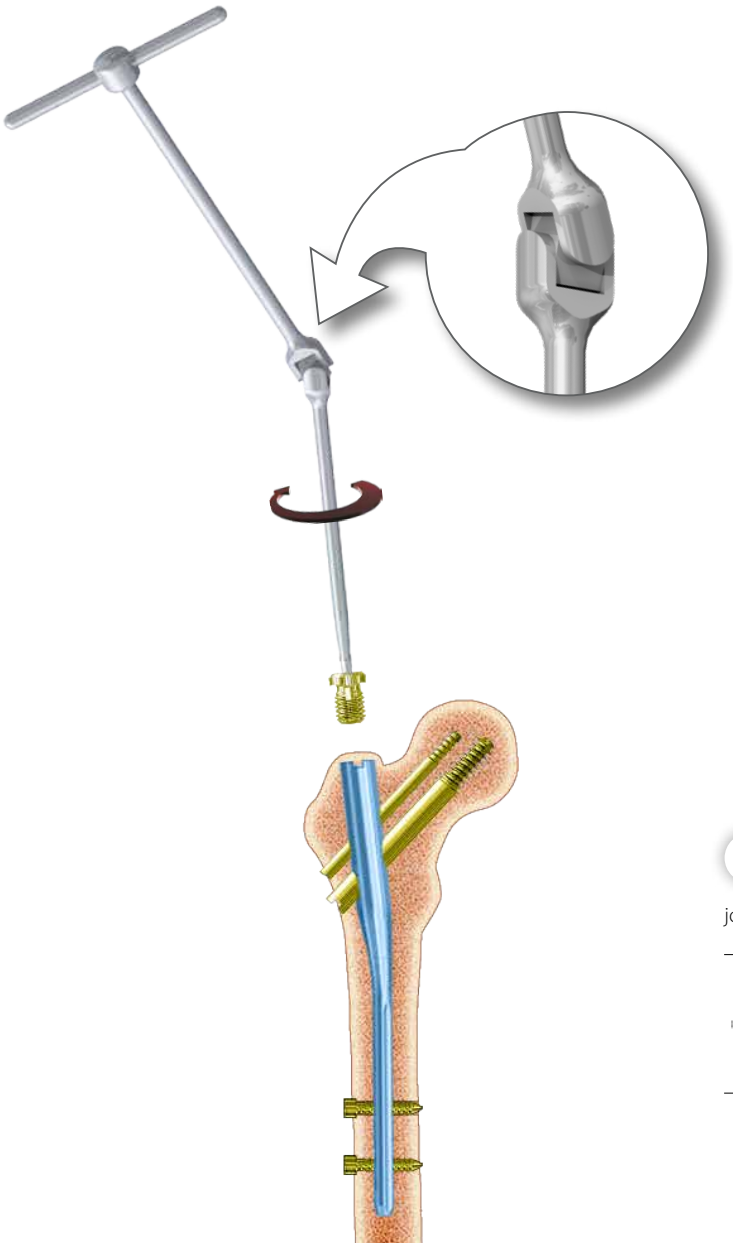

40.5511.100

32 Remove the connecting screw M12x1.75 L-34 **[40.5547]** from the nail using the wrench S10 **[40.5526]**. Dismount the targeter arm **[40.5541]** from the nail locked the medullary canal.


40.5526.100


40.5547.000


40.5541.000



33 In order to secure the inner thread of the nail form bone ingrowth, insert the end cap **[3.2104.600-615]** implant using the wrench for self-aligning joint S4 **[40.5540]**.


40.5540.000

III.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 **[40.5525.100]** 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]**.


40.5540.000

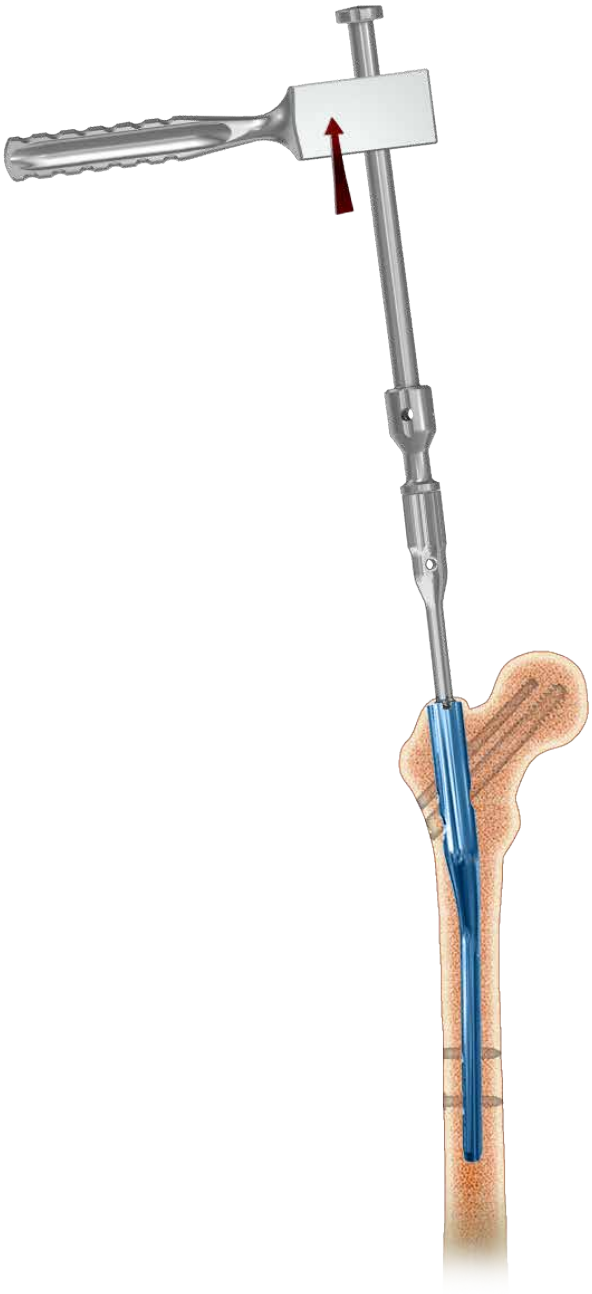

40.5525.100


40.4731.000


40.5532.300


40.5507.000


40.3667.000



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Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 86 86 100 fax: +48 85 86 86 101
e-mail: chm@chm.eu www.chm.eu

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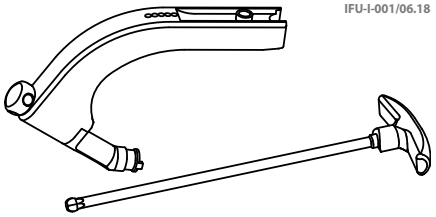

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INSTRUCTIONS FOR USE

REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

1 INDICATIONS

1. Surgical and orthopaedic instruments are intended for use only by skilled and trained medical professionals who are familiar with their use and application.

2 DESCRIPTION

1. The unit package contains one piece of the product in non-sterile condition. Clear plastic bags are a typical packaging material. The products may also be supplied as a complete set *(arranged on palettes and placed into specially designed sterilization containers)*. This Instructions For Use is attached both to the unit packages and the sets.
2. The package is equipped with the product label. The label *(as a primary label)* contains, among others:
   1) Logo ChM and the address of the manufacturer.
   2) Catalogue number *(REF)*, e.g.: 40.XXXX.XXX, and device name and size.
   3) Production batch number *(LOT)*, e.g. XXXXXXX.
   4) NON-STERILE sign - indicates non-sterile product.
   5) Information symbols *(described in the footer of this Instructions For Use)*.
   6) CE conformity mark.
3. 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.

3 MATERIALS

1. For the production of instruments, ChM sp. z o.o. uses mainly: steel, aluminum alloys and plastics, approved for use in surgical instruments and in accordance with applicable procedures.
2. Instruments are produced of corrosion-resistant steel. The protective layer *(passive layer)* against corrosion is formed on the surface of the device due to high content of chromium.
3. Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as e.g. handles. 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 of its surface.
4. Devices made of aluminium with processed layer have good corrosion resistance. However, 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.
5. Devices produced of plastics are mainly stands, palettes, cuvettes and some parts of instruments such as e.g. handles. Plastics used in the manufacture of instruments are mainly: PPSU *(Polyphenylsulfone)*, PEEK *(Polyetheretherketone)*, teflon *(PTFE - Polytetrafluoroethylene)* and silicone. 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 a pH value from 4 to 10.8.
6. Steel surgical instruments with a hardened insert are more durable than steel products. The advantage of the product is the sintered carbide insert placed in the working part of the instrument. This insert is characterized by great hardness and abrasion resistance.
7. If the material of the device cannot be specified, please contact ChM sp. z o.o. representative.

4 WARNINGS AND PRECAUTIONS

1. Instruments are intended for use only by skilled and trained medical professionals who are familiar with their use and application.
2. Improper, careless and inconsistent with the recommendations provided below handling of the instruments can lead to their chemical, electrochemical or mechanical damage which can adversely affect corrosion resistance and shorten the service life of the devices.
3. 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 to the instrument.
4. The surgeon should be familiar with all components of the device before use and should personally verify if all components and instruments are present before the surgery begins.
5. Before the procedure begins, all instruments should be carefully inspected for their condition and proper functioning. They should be undamaged and without any signs of corrosion. Blades and cutting edges should be sharp and undamaged. Damaged or corroded instruments should be immediately replaced. The use of bent, damaged or corroded instruments is not allowed.
6. Tissue structures close to the operative site must be protected.
7. Collision of the instrument with metal operating equipment, retractor or other device may cause damage that necessitates intraoperative replacement of that instrument.
8. Do not apply excessive force when using the instrument – it may lead to its permanent damage and, in consequences, to mal-function of the device.
9. Instruments are subject to constant wear processes. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive forces are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed. Should breakage occur, the instrument parts must be removed and disposed of immediately in accordance with valid medical facility procedures.
10. In order to confirm the removal of all undesired metal fragments from the surgical field, intraoperative X-Ray examination is recommended.
11. 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.
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.
13. Instrument which had contact with tissues or body fluids of another patient cannot be re-used prior to its reprocessing due to a potential risk of cross-infection caused by viruses, bacteria and prions.
14. Middle and working part of the surgical devices with hardened insert shall be used during the surgical procedure. Improper or inconsistent with the intended purpose usage of the product may lead to damage of the working part e.g. damage to the inserts.

5 CLEANING, DISINFECTION, STERILIZATION

1. Prior to use of a non-sterile device, the following rules apply:
   1) The device must undergo cleaning, disinfection and sterilization procedures.
   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, automated)*, the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process, etc.
   3) The hospital facility remains responsible for the effectiveness of the conducted cleaning, packaging and sterilization processes with the use of existing equipment, materials and properly trained personnel.
2. Preparation at the place of use.
   1) Immediately after use, remove from instrument blood and other contaminants with disposable cloth or paper towels. Additionally, it is recommended to rinse the instrument under running water or to place it in the aqueous disinfectant solution. Do not let blood, tissues, body fluids or other biological impurities dry out on the surface of the device.
   2) In order to prevent blood and debris from drying out on the instrument surface, transport the product to the processing area in a closed container or covered with a damp cloth.
   3) In order to avoid contamination during transportation, the dirty instruments should be separated from the clean ones.
3. Preparation for washing and disinfection *(for all methods)*.
   1) The used instruments should be reprocessed as soon as possible.
   2) If the instrument can be disassembled, it must be done before cleaning processes.
   3) Rinse under running water and remove surface debris using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*. Particular attention should be paid to openings and places difficult to be cleaned. Very dirty devices should be soaked in an aqueous solution of a detergent or a washing-disinfecting agent, e.g. neodisher® MediClean forte, at temperature of 40+/- 2°C and pH of 10.4-10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
   4) CAUTION: It is forbidden to use brushes made of metal, bristles or materials which could damage the product.
4. Cleaning and disinfection process.
   1) This Instructions for Use describes two ChM-approved cleaning and disinfection methods: manual with ultrasound cleaning and automated method. It is recommended to use automated cleaning and disinfection procedures *(in a washer-disinfector)*.
   2) The chosen washing and disinfecting agents 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 cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 10.4 and 10.8. ChM used the following materials during the validation process of the described recommendations for cleaning and disinfection. It is allowed to use other materials than those listed below which may also give a comparable effect:
      a) detergent - Dr.Weigert *(producer)* neodisher® MediClean forte *(name of the detergent)*;
      b) disinfectant - Dr.Weigert *(producer)* neodisher® Septo Active *(name of disinfectant)*.
   3) To prevent product damage *(pitting, rust, discoloration)*, do not use aggressive cleaning agents *(NaOH, NaOCl)*, saline solutions and unsuitable cleaning agents.
   4) Where possible, it is recommended to use demineralized water to avoid the formation of spots and stains caused by chlorides and other compounds present in ordinary water.
   5) Manual with ultrasound cleaning.
      a) Equipment and materials: a device for ultrasound cleaning, soft, lint-free cloths, plastic brushes, syringes, aqueous solutions of cleaning agent.
      b) Manual cleaning: Initial manual cleaning must be performed prior to ultrasound cleaning.
      c) Rinse under running water until the product is visually clean. Use plastic brushes to remove heavy or large debris.
      d) Soak the product for at least 10 minutes in an aqueous solution of a detergent at temperature of 40+/- 2°C and pH of 10.4-10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
      e) Rinse the product under cold water for at least 2 minutes, paying particular attention to the holes and places difficult to be cleaned.
      f) Prepare fresh washing solution. Clean the surfaces and gaps of the product, carefully. Use suitable brushes to clean the holes. Clean the product immersed in the solution.
      g) Rinse the product thoroughly under warm running water for at least 2 minutes, paying special attention to the gaps, blind holes, hinges and joints. When cleaning, use brushes and perform multiple reciprocating movements on the surface of the product.
      h) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-h until the product is visually clean.
      i) Ultrasound cleaning: prepare an aqueous cleaning solution at a temperature of 40 +/- 2°C and pH of 10.4 - 10.8 *(follow the information contained in the instructions prepared by the manufacturer of the cleaning agent, in respect of temperature, concentration, exposure time and water quality)*. Immerse fully the product in the aqueous cleaning solution and have it washed in ultrasounds for 15 minutes.
      j) Rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
      k) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-k until the product is visually clean.
      l) Use demineralized water for final rinsing of the device.
      m) Dry the device thoroughly using disposable, soft, lint-free cloth or compressed air.
      n) Prepare an aqueous solution of disinfecting agent at a temperature of 20+/-2 °C using 20g of the agent per 1 liter of water. Immerse the product in the solution, exposure time – 15min *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
      o) After the exposure time, rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
      p) The cannulated instruments should be treated using a compressed air or air supplied from the syringe.
      q) Dry the device thoroughly. It is recommended to dry the product in a dryer at a temperature ranging from 90°C to 110°C.
      r) Visually inspect the entire surface of the device.
      s) CAUTION: If the obstruction in the cannula cannot be removed as indicated in the Instructions for Use, the device should be considered at the end of its useful life and should be discarded in accordance with facility procedures and guidelines.
   6) The automated method using a washer - disinfector.
      a) Equipment and materials: a washer - disinfector, aqueous solutions of cleaning agent.
      b) Cleaning in the washer-disinfector must be preceded by a manual and ultrasound cleaning, following the procedure described in subsections c-h of paragraph 5.
      c) CAUTION: The equipment used for washing/disinfection should meet the requirements of ISO 15883. Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washer-disinfector manufacturer, and instructions for use prepared by the washing-disinfecting agent manufacturer.
      d) The device should undergo the process of machine washing in the washer-disinfector using the following cycle parameters: *(1)* - pre-washing in cold tap water, duration – 2min; *(2)* - washing in an aqueous solution of cleaning agent at 55+/-2°C and pH of 10.4 - 10.8, duration – 10min; *(3)* - rinsing under demineralized water, duration – 2min; *(4)* - thermal disinfection in demineralised water at 90°C, minimal duration – 5min; *(5)* - drying at the temperature ranging from 90°C to 110°C, duration - 40min.
5. Inspection
   1) Each time before re-use and re-sterilization, all medical devices should be inspected.
   2) All parts of the product should be checked for visible dirt and corrosion. Particular attention should be paid to:
      b) Holes, grooves and gaps the debris could have been pressed into during use.
      a) Places where dirt can be found, such as joints, latches, etc.
   3) Generally unmagnified visual inspection under good light conditions is sufficient.
   4) Each time before re-use and re-sterilization, the functional check of the product should be performed, consisting of:
      a) Verifying the connections in the mating instruments, such as tips, shafts and quick coupling devices.
      b) Verifying the correct functioning of mechanisms, e.g. screw, ratchet, snap mechanism, etc.
      c) Verifying all rotating devices for straightness *(this can be simply achieved by rolling the device on a flat surface)*.
      d) Verifying cutting edges for sharpness.
      e) Verifying instruments for damage to material structure *(cracks, dents, peels, etc.)*.
   5) Damaged or defective product cannot be approved for further use.
   6) Prior to storage, the instrument must be checked for dryness.
   7) CAUTION:
      a) The ChM sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful and proper use reduces the risk of damage to the product and extends its serviceable life.
      b) The manufacturer does not recommend using any preservatives on medical devices.
6. Packaging
   1) Washed and dried devices shall be stored *(if possible)* in suitable stands placed in special sterilization containers. Separate items should be packed in a packaging intended for the recommended steam sterilization. Sterilization containers, item packaging and packaging process itself have to meet the requirements of ISO 11607 standards. The packaging procedure must be performed in controlled purity conditions. The device must be packed so that during its removal from the packaging, when used, there is no risk for its re-contamination
7. 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.
   2) CAUTION:
      a) The sterilization process must be validated and routinely monitored in accordance with the requirements of EN ISO 17665-1.
      b) Sterilization must be effective and in accordance with requirements of the EN 556-1 standard to ensure the required level of guaranteed sterility SAL 10^{-6} *(where SAL stands for Sterility Assurance Level)*.
      c) Device must not be sterilized in the packaging in which it was delivered, except specially designed sterilization containers.
      d) The method of sterilization using ethylene oxide, gas plasma and dry heat should not be used, unless the Instructions for Use for the product contains sterilization recommendations using these methods.
      e) The sterilization temperature for plastic products *(PPSU, PEEK, PTFE, silicone)* cannot be higher than 140°C.

6 STORAGE

1. 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 a clean and dry room, at room temperature and off the direct sunlight. If possible, instruments should be stored in suitable palettes placed into specially designed sterilization containers.

7 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. Instrument calibration is performed by the manufacturer. Any attempt of unauthorized modifications to the construction or factory setting of the torque devices can lead to a potential injury or damage to the product and is prohibited.

8 COMPATIBILITY

1. ChM specialist instrument sets are designed for insertion of ChM implants. A specific, illustrated operating technique that describes the proper use of instruments included in the instrument set that is designed for particular implant system, is provided together with such instrument set. It is not allowed to combine ChM instruments with products from other manufacturers. The physician bears all responsibility for the use of the ChM instruments together with implants and instruments from other manufacturers.

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-001/06.18; Date of verification: June 2018

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 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 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.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 86 86 100 fax: +48 85 86 86 101
e-mail: chm@chm.eu www.chm.eu

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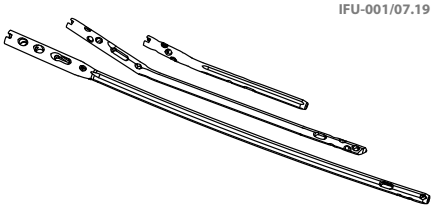
ChM®

CE 0197

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 86 86 100 fax: +48 85 86 86 101
e-mail: chm@chm.eu www.chm.eu

IFU-001/07.19



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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 short 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. Bone nails of CHARFIX FN system and femoro-tibial nails are used to treat diseases associated with the knee joint, in particular: failed arthroplasty, periprosthetic fractures, post-traumatic state which does not allow for implantation of the knee prosthesis, post-infection state, neoplastic transformations, loss of or damage to the knee extensor, knee arthrodesis.
2. Bone nail locking elements: locking screws, reconstruction screws, locking sets, setting screws, compression screw, join screws, end cap, spiral screw and nuts, are used to lock the nails of the above-mentioned systems 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. Calcaneal nail of CHARFIX2 system is used to treat fractures of the calcaneus and for subtalar arthrodesis.
6. When using CHARFIX2 FN nails combined with knee joint resection, use spacers.
7. The radial nail is intended for treatment of distal radius fractures.
8. For the implantation of the aforementioned products, ChM's specialist instrument sets are dedicated. Along with the instrument set, illustrated surgical technique is also provided. Surgical technique is not a detailed instruction of conduct. This is the physician that determines the proper technique and detailed surgical procedure for a particular patient.

2 CONTRAINDICATIONS

1. Contraindications may be relative or absolute. The choice of particular device must be carefully considered in terms of 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 application and may 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 the 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 of contraindications is not exhaustive.

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 below-mentioned list of adverse events is not exhaustive. 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 to foreign bodies e.g. possibility of tumour metaplasia, autoimmune disease and/or scarring.
5) Compression on the surrounding tissues or organs.
6) Infection.
7) Bone fractures or *"stress shielding"* phenomenon causing loss of bone above, below or at the operative site.
8) Haemorrhage 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 provided in this document should be given to the patient.
2. The selection of proper shape and size of the implant appropriate for a specific patient is crucial to achieve the 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, weights lifting, 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 patient 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 smoking patients. 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 abuse 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.
16. The surgeon should inform the patient of the resulting total stiffening of the limb when using CHARFIX2 FN implants and femoro-tibial nails.

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. Implants can be delivered in a unit package. The unit package of the product contains:
1) sterile version - one piece of the product in a sterile condition. A double packaging made of Tyvek-foil or a single blister are typical packaging material.
2) non-sterile version - one piece of the product. Plastic bags are a typical packaging material.
5. Implants can be delivered on stands, palettes *(non-sterile version only)*.
6. A sterility indicator is placed on the sterile package.
7. Products are delivered with a 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)*.
8. 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)*.
9. The package may contain: Instructions For Use and labels to be placed in a patient's medical record.
10. 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.
11. Implants should be stored in appropriate protective packagings, in a clean, dry place with a room 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:balance.
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:balance.
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:balance.
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:balance.
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 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 package is not intact. The package shall be carefully checked prior to use.
9. Implants are delivered in protective packagings. 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 must not be inserted into the body.

8 RECOMMENDATIONS FOR IMPLANTS PROVIDED STERILE

1. Sterile implant - is delivered in sterile packaging, 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 package 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 packagings in accordance with aseptic rules.

9 RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE

1. The following recommendations apply to unused non-sterile implants. An implant that has been implanted must not be re-processed and re-used.
2. The implant which has not been used but got contaminated by contact with the blood, tissue and/or body fluids/materials, should not be used again. The implant should be handled in accordance with applicable hospital protocol. ChM does not recommend re-processing of contaminated implants. Should the contaminated implant be re-processed, ChM bears no responsibility.
3. Prior to use of a non-sterile device, the following rules apply:
1) The device must undergo cleaning, disinfection and sterilization procedures.
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, automated)*, the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process.
3) The hospital facility remains responsible for the effectiveness of the conducted cleaning, packaging and sterilization processes with the use of existing equipment, materials and properly trained personnel.
4. Preparation for washing and disinfection *(for all methods)*
1) Prior to cleaning, remove the implant from the original unit packaging. Dispose of the packaging. Protect patient labels, provided with the implant, against accidental loss or damage.
2) To avoid contamination, the implants should not have contact with the contaminated devices/instruments.
3) Rinse under running water and remove possible surface dirt *(resulting from e.g.: damage to the unit packaging)* using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*.
4) CAUTION: It is forbidden to use brushes made of metal, bristles or materials which could damage the implant.
5. Cleaning and disinfection process
1) This Instructions for Use describes two validated by ChM cleaning and disinfection methods: manual with ultrasound cleaning and automated method. It is recommended to use automated procedures for cleaning and disinfection *(in the washer-disinfector)*.
2) The chosen washing and disinfecting agents 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 cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 10.4 and 10.8. ChM used the following materials during the validation process of the described recommendations for cleaning and disinfection. It is allowed to use other materials than those listed below which may also give a comparable effect:
a) detergent - Dr.Weigert *(producer)* neodisher® MediClean forte *(name of the detergent)*;
b) disinfectant - Dr.Weigert *(producer)* neodisher® Septo Active *(name of disinfectant)*.
3) Manual with ultrasound cleaning
a) Equipment and materials: a device for ultrasound cleaning, soft, lint-free cloths, plastic brushes, aqueous solutions: of cleaning agent, disinfecting agent or washing – disinfecting agent.
b) Prepare an aqueous solution of cleaning agent at temperature of 40+/-2 °C and a pH of 10.4 - 10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
c) Immerse the implant in the aqueous solution of the cleaning agent and subject it to ultrasound cleaning for 15 minutes.
d) Rinse the implant thoroughly under running water, paying particular attention to the holes and places difficult to be cleaned. It is recommended to rinse with demineralized water.
e) Visually inspect the entire surface of the device for debris and impurity. Damaged implants must be removed. For dirty implants, the cleaning process should be repeated.
f) Dry the device thoroughly using disposable, soft, lint-free cloth.
g) Prepare an aqueous solution of disinfecting agent at a temperature of 20+/-2 °C using 20g of the agent per 1 liter of water. Immerse the implant in the solution, exposure time – 15min *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
h) After the exposure time, rinse the product thoroughly under running water, paying particular attention to the holes and places difficult to be cleaned. It is recommended to rinse with demineralized water.
i) Dry the device thoroughly. It is recommended to dry the implant in a dryer at a temperature ranging from 90°C to 110°C.
j) Visually inspect the entire surface of the device.
4) The automated method using a washer - disinfector
a) Equipment and materials: a washer - disinfector, aqueous solutions of cleaning agent.
b) CAUTION: The equipment used for washing/disinfection should meet the requirements of 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 agent manufacturer.

c) The device should undergo a process of machine washing in the washer-disinfector using the following cycle parameters: *(1)* - pre-washing in cold tap water, duration – 2min; *(2)* - washing in an aqueous solution of cleaning agent at 55+/-2 °C and pH of 10.4 - 10.8, duration – 10min; *(3)* - rinsing under demineralized water, duration – 2min; *(4)* - thermal disinfection in demineralised water at 90°C, minimal duration – 5min; *(5)* - drying at a temperature ranging from 90°C to 110°C, duration - 40min.

6. Packaging

1) Washed and dried devices shall be packed in a packaging intended for the recommended steam sterilization. The packaging and packaging process have to meet the requirements of ISO 11607 standards. The packaging procedure must be performed in controlled purity conditions. The device must be packed in such a way that during its removal from the packaging, when used, there is no risk for its re-contamination.

7. Sterilization

1) Washed, disinfected, and dried device shall undergo the sterilization process in accordance with the applicable procedures of the customer. 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.
2) CAUTION
   a) The sterilization process must be validated and routinely monitored in accordance with the requirements of EN ISO 17665-1.
   b) Sterilization must be effective and in accordance with requirements of the EN 556-1 standard to ensure the required level of guaranteed sterility SAL 10^{-6} *(where SAL stands for Sterility Assurance Level)*.
   c) The implant cannot be sterilized in the unit package in which it was delivered.
   d) The method of sterilization using ethylene oxide, gas plasma and dry heat should not be used, unless the Instructions for Use for the product contains sterilization recommendations using these methods.
   e) The above-mentioned principles for cleaning and sterilization must be applied to all implants intended for implantation.
   f) The surgical instruments used for implants insertion should also be covered by cleaning and sterilization procedure.

10 RE-STERILIZATION

1. It is permitted to re-sterilize a device in case, when its sterile packaging has been damaged or opened. In this case, the product should be washed and sterilized in the manner described in the chapter RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE.

1) ATTENTION: Implant that has been in contact with body tissues or fluids of a patient cannot be re-sterilized or implanted to another patient.

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 re-use or re-implant 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. Misuse of instruments or implants may cause injury to the patient or operative personnel.
4. Avoid damaging implant surface and deforming its shape during the implantation; the damaged implant cannot be implanted or left in the patient's body.
5. 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.
6. 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.
7. 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.
8. 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 hole in the bone:

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 treatment period, 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 provide 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 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 and local 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.
5. Remove CHARFIX2 FN implants and femoro-tibial nails only in the case of complications.

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-001/07.19; Date of verification: July 2019

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 é 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 • 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 • 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 86 86 100 fax: +48 85 86 86 101
e-mail: chm@chm.eu www.chm.eu

ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Kościelny
Poland
tel. +48 85 86 86 100
fax +48 85 86 86 101
chm@chm.eu
www.chm.eu

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