ST/52D

ChM®

Charfix Femoral Nail
ChFN system 2

INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR WITH TROCHANTERIC NAILS

- *IMPLANTS*
- *INSTRUMENT SET 40.6340.600*
- *INSTRUMENT SET 40.6340.510*
- *SURGICAL TECHNIQUE*

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SYMBOLS DESCRIPTIONS

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

	Caution - pay attention to 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.

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The manufacturer reserves the right to introduce design changes.

I. INTRODUCTION

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

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

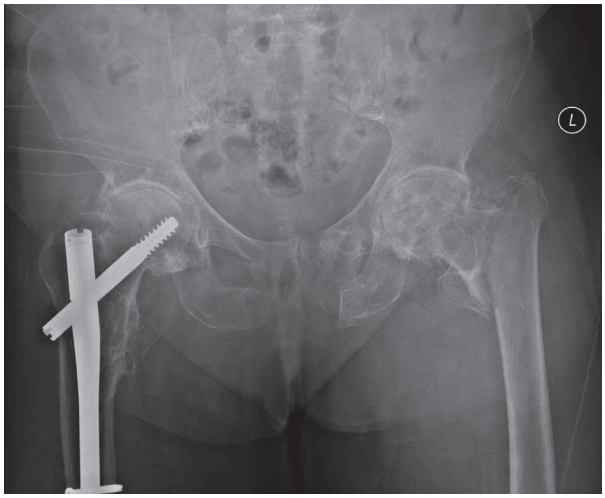
Intramedullary osteosynthesis of femur with trochanteric nails allows for stable reduction of femur pertrochanteric fractures. Application of two join screws eliminates rotation of the femur neck.

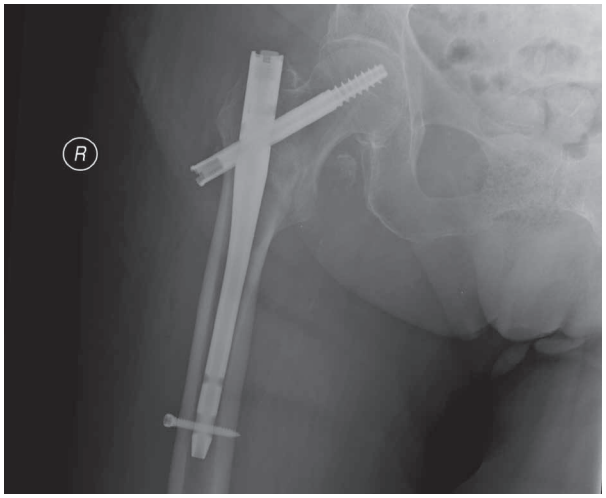
The presented range of implants is made of titanium and its alloys and implantable steel in accordance with ISO 5832 standard. Compliance with the requirements of quality management systems and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered implants.

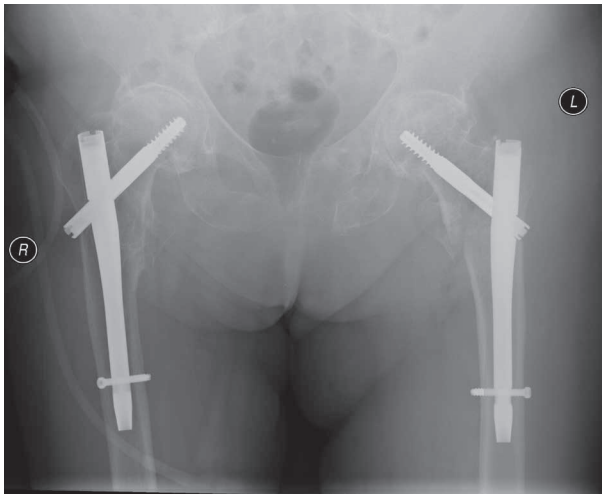
Indicated use:

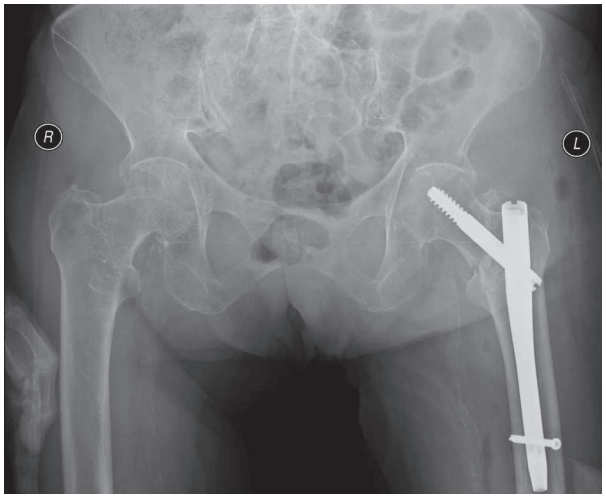
- subtrochanteric fractures,
- intertrochanteric fractures,
- pertrochanteric fractures.

Examples of femur fractures treated with trochanteric nails.









Good results are also obtained in the case of:

- Pathological (*one-place*) and ipsilateral damage of intertrochanteric region,
- Pathological (*one-place*) and ipsilateral damage of femoral shaft.

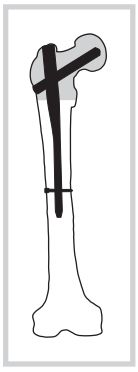
Trochanteric nails are also used in the case of:

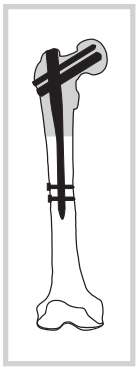
- Multifragmentary fractures of trochanteric-subtrochanteric region,
- Fractures of the femur neck located near the trochanter.

II. IMPLANTS

ChFN2 TROCHANTERIC NAIL

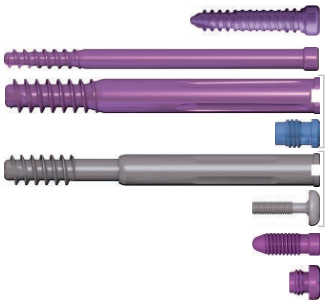
Charfix Femoral Nail
ChFN system 2





		Len	Ti
130°	10	180	3.5651.180
		200	3.5651.200
	11	180	3.5652.180
		200	3.5652.200
	12	180	3.5653.180
		200	3.5653.200
130°	Recommended		

available	Ø 10 mm ÷12 mm	pitch	1 mm
	L 170 mm ÷ 240 mm		5 mm



Ti					
3.5159.5xx	✓			5.0	30÷60
3.5805.xxx	✓			5.0	70÷110
3.5804.xxx			✓	10.5	80÷120
3.5161.003	✓		✓		
3.5961.xxx			✓	10.5	80÷120
3.5962.000	✓				
3.5808.000	✓				
3.5161.6xx	✓		✓		0÷15

* Available sterile only

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ChFN2 TROCHANTERIC NAIL

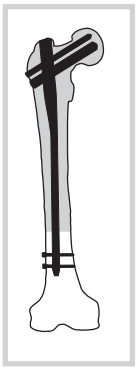
Charfix Femoral Nail
ChFN system 2

		Len	Ti
125°	10	180	3.5639.180
		200	3.5639.200
	11	180	3.5640.180
		200	3.5640.200
	12	180	3.5641.180
		200	3.5641.200
135°	10	180	3.5663.180
		200	3.5663.200
	11	180	3.5664.180
		200	3.5664.200
	12	180	3.5665.180
		200	3.5665.200

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

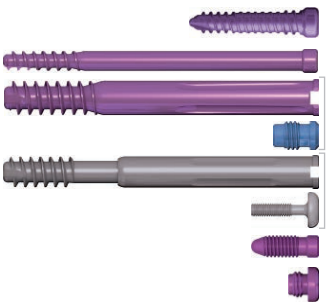
ChFN2 TROCHANTERIC NAIL

Charfix Femoral Nail
ChFN system 2



		Len	L	R
130°	10	340	3.5761.340	3.5762.340
		360	3.5761.360	3.5762.360
		380	3.5761.380	3.5762.380
		400	3.5761.400	3.5762.400
		420	3.5761.420	3.5762.420
	11	340	3.5763.340	3.5764.340
		360	3.5763.360	3.5764.360
		380	3.5763.380	3.5764.380
		400	3.5763.400	3.5764.400
		420	3.5763.420	3.5764.420
	12	340	3.5765.340	3.5766.340
		360	3.5765.360	3.5766.360
		380	3.5765.380	3.5766.380
		400	3.5765.400	3.5766.400
		420	3.5765.420	3.5766.420
130°	Recommended			

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



Ti					
3.5159.5xx	✓			5.0	30÷80
3.5805.xxx	✓			5.0	70÷110
3.5804.xxx			✓	10.5	80÷120
3.5161.003	✓		✓		
3.5961.xxx			✓	10.5	80÷120
3.5962.000	✓				
3.5808.000	✓				
3.5161.6xx	✓		✓		0÷15

* Available sterile only

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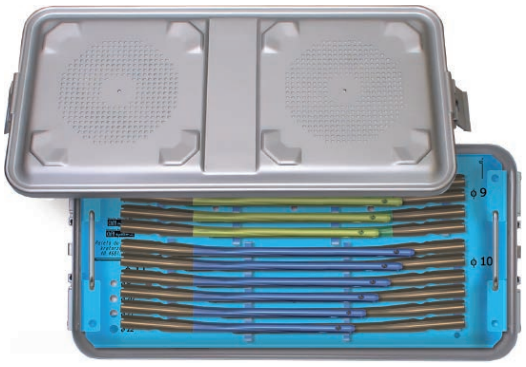
ChFN2 TROCHANTERIC NAIL

Charfix Femoral Nail
ChFN system 2

		Len	L	R
125°	10	340	3.5737.340	3.5738.340
		360	3.5737.360	3.5738.360
		380	3.5737.380	3.5738.380
		400	3.5737.400	3.5738.400
		420	3.5737.420	3.5738.420
	11	340	3.5739.340	3.5740.340
		360	3.5739.360	3.5740.360
		380	3.5739.380	3.5740.380
		400	3.5739.400	3.5740.400
		420	3.5739.420	3.5740.420
	12	340	3.5741.340	3.5742.340
		360	3.5741.360	3.5742.360
		380	3.5741.380	3.5742.380
		400	3.5741.400	3.5742.400
		420	3.5741.420	3.5742.420
135°	10	340	3.5785.340	3.5786.340
		360	3.5785.360	3.5786.360
		380	3.5785.380	3.5786.380
		400	3.5785.400	3.5786.400
		420	3.5785.420	3.5786.420
	11	340	3.5787.340	3.5788.340
		360	3.5787.360	3.5788.360
		380	3.5787.380	3.5788.380
		400	3.5787.400	3.5788.400
		420	3.5787.420	3.5788.420
	12	340	3.5789.340	3.5790.340
		360	3.5789.360	3.5790.360
		380	3.5789.380	3.5790.380
		400	3.5789.400	3.5790.400
		420	3.5789.420	3.5790.420

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



Palette for trochanteric nails (implants not included) 40.4681.100

LOCKING ELEMENTS

Ti Ster Non Ster

Charfix Femoral Nail ChFN system 2

CHARFIX2 DISTAL SCREW 5.0
CHARFIX2 ВИНТ ДИСТАЛЬНЫЙ 5,0

30	3.5159.530
35	3.5159.535
40	3.5159.540
45	3.5159.545
50	3.5159.550
55	3.5159.555
60	3.5159.560
65	3.5159.565
70	3.5159.570
75	3.5159.575
80	3.5159.580

16 ÷ 90

ChFN2 JOIN SCREW 10.5
ChFN2 ВИНТ ФИКСАЦИОННЫЙ 10,5

80	3.5804.080
85	3.5804.085
90	3.5804.090
95	3.5804.095
100	3.5804.100
105	3.5804.105
110	3.5804.110
115	3.5804.115
120	3.5804.120

ChFN2 JOIN TELESCOPIC SCREW 10.5 *
ChFN2 ВИНТ ТЕЛЕСКОПИЧЕСКИЙ ФИКСАЦИОННЫЙ

80	3.5961.080
85	3.5961.085
90	3.5961.090
95	3.5961.095
100	3.5961.100
105	3.5961.105
110	3.5961.110
115	3.5961.115
120	3.5961.120

* Available sterile only

ChFN2 JOIN SCREW 5.0
ChFN2 ВИНТ ФИКСАЦИОННЫЙ

70	3.5805.070
75	3.5805.075
80	3.5805.080
85	3.5805.085
90	3.5805.090
95	3.5805.095
100	3.5805.100
105	3.5805.105
110	3.5805.110

CHARFIX2 END CAP M8
CHARFIX2 ВИНТ СЛЕПОЙ M8

A	
+3	3.5161.003

ChFN2 COMPRESSION SCREW
ChFN2 ВИНТ КОМПРЕССИОННЫЙ

	3.5962.000

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LOCKING ELEMENTS

Charfix Femoral Nail ChFN system 2

Ti Ster Non Ster

ChFN2 SETTING SCREW M6
ChFN2 ВИНТ УСТАНОВОЧНЫЙ M6

	3.5808.000

ChFN2 END CAP M12X1.75
ChFN2 ВИНТ СЛЕПОЙ M12X1,75

A	
0	3.5161.600
+5	3.5161.605
+10	3.5161.610
+15	3.5161.615

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

III. INSTRUMENT SET

INSTRUMENT SET FOR ChFN2 TROCHANTERIC NAILS 40.6340.600	Name	Pcs	Catalogue No.
	Targeter arm	1	40.6341.000
	Targeter 120/130	1	40.6342.100
	Targeter 125/135	1	40.6343.100
	Connecting screw M12x1.75	1	40.6305.000
	Drill guide 14/11.5	1	40.6346.100
	Protective guide 11.5/3.2	1	40.6347.000
	Drill guide 11.0/6.0	1	40.6348.100
	Protective guide 6.0/3.2	1	40.6349.000
	Trocar 3.2	1	40.6350.000
	Gradual drill 10.5/7	1	40.6351.000
	Drill 5.0	1	40.6352.000
	Cannulated drill 16.0	1	40.6313.000
	Protective guide 16.0	1	40.6314.000
	Guide 16/3.2	1	40.6315.000
	Guide rod 3.2/500	4	40.6356.100
	Compression wrench	1	40.6357.000
	Cannulated screw length measure	1	40.6548.000
	Wrench for self-aligning joint S7	1	40.6319.000

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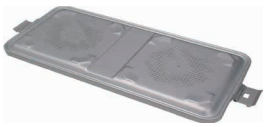
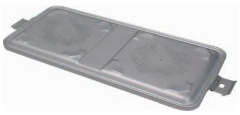
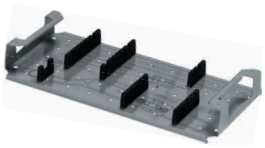
INSTRUMENT SET FOR ChFN2 TROCHANTERIC NAILS 40.6340.600	Name	Pcs	Catalogue No.
	Wrench for self-aligning joint T25	1	40.6320.000
	Screwdriver T25 with holder	1	40.6361.000
	Protective guide 12/10	2	40.6353.000
	Drill guide 10/4	2	40.6362.000
	Trocar 10	1	40.6355.000
	Wrench S10	1	40.5526.100
	Drill with scale 4.0	2	40.5346.002
	Mallet	1	40.3667.000
	Impactor-extractor	1	40.5507.000
	Curved awl 8.0	1	40.5523.000
	Guide 11.5/6	1	40.6363.000
	Screw length measure	1	40.6358.000
	Guide rod 3.0/580	1	40.3925.580
	Steinmann handle	1	40.0987.200
	Perforated aluminum lid 1/1 595x275x15mm Gray	1	12.0750.200
	Stand for instrument set for **ChFN2** trochanteric nails	1	40.6369.600
	Container with solid bottom 1/1 595x275x185mm	1	12.0750.103

INSTRUMENT SET FOR ChFN2 TROCHANTERIC NAILS - II 40.6340.510	Name	Pcs	Catalogue No.
	Distal targeter D	1	40.6344.000
	**ChFN2** trial	1	40.6360.000
	Set block 12/5.0/4.0	2	40.6359.000
	Connector of extractor M12x1.75	1	40.6345.000
	Nail length measure	1	40.5098.000
	Teflon pipe guide	1	40.1348.000
	Protective guide short	1	40.5871.000
	Drill guide short 7/4.0	1	40.6365.000
	Drill with scale 4.0/150	1	40.5348.002
	Perforated aluminum lid 1/1 595x275x15mm Gray	1	12.0750.200
	Stand for instrument set for **ChFN2** trochanteric nails - II	1	40.6368.500
	Container with solid bottom 1/1 595x275x86mm	1	12.0750.100

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IV. SURGICAL TECHNIQUE

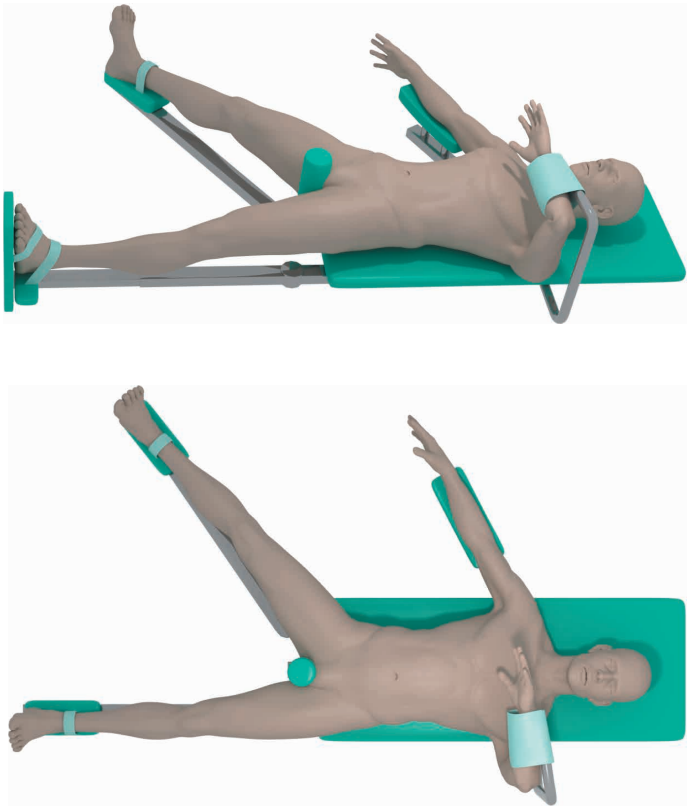
The following description covers the most important stages of the implantation of the femoral trochanteric intramedullary nails; however, it is not a detailed instruction of conduct.
The surgeon decides about choosing the operating procedure and its application in each individual case.

IV.1. INTRODUCTION

When the patient cannot be operated at the day of femoral fracture, it is recommended to apply direct traction for 2 to 3 days to spread the fragments. This will considerably facilitate fracture reduction and nail insertion. Positioning of the patient on the traction table is an integral part of the operating procedure. Presented method of intramedullary osteosynthesis requires image intensifier control.

Each operating procedure must be carefully planned. X-Ray imaging of the entire femur and adjacent joints (*in AP and lateral position*) is essential in order to not overlook the injuries in its proximal or distal part. It is especially important in the cases of pathological subtrochanteric fractures. Special attention should be paid to concurrent neck fractures or proximal epiphysis multifragmental fractures, and the possibility of its occurrence during the procedure. On the basis of the images of fractured femur and the healthy one (*the other one*) using a trial, the physician determines the angle, length and diameter of the nail.

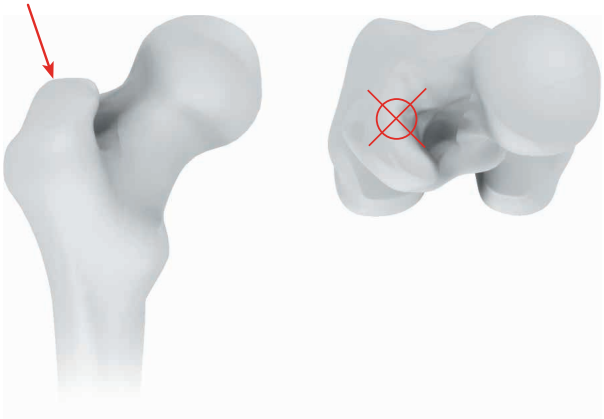
During the operation, secondary fractures of main fragments may occur.
The condition of hip joint is also important.
In advanced arthrosis or contracture, nailing may be difficult or even impossible to perform.
The procedure has to be carried out on the operating table with traction with the patient placed supine or on the side. Side position facilitates the approach to the greater trochanter which is especially important with overweight patients. Supine position provides less favorable access to the greater trochanter but makes all other stages of the operation considerably easier (*especially rotary corrections*). In the below method supine position of a patient is presented with traction applied on the condyles of the operated femur.



Patient positioning

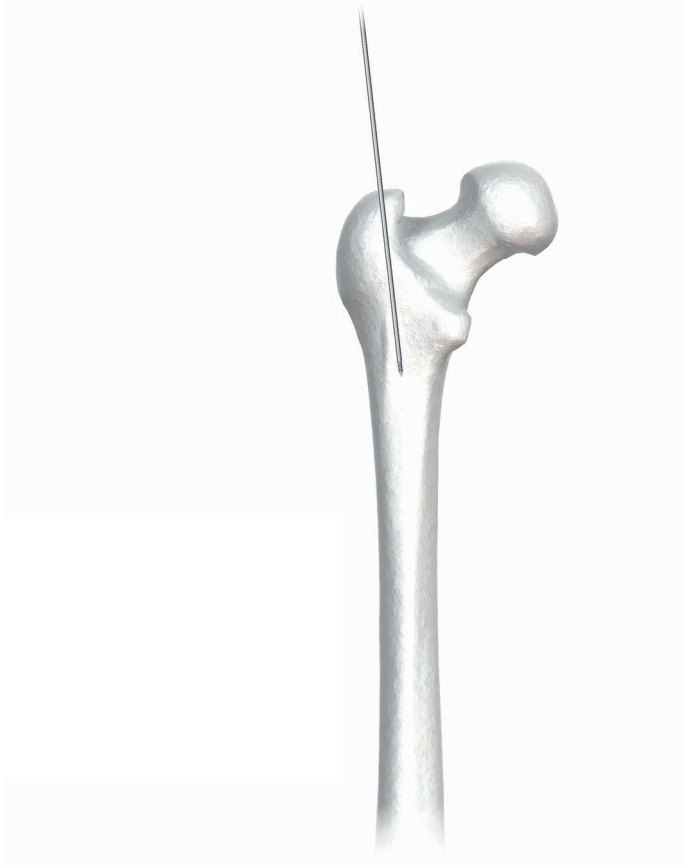
Lateral surgical approach shall be applied starting the incision near the tip of the greater trochanter in line with the femoral shaft axis for 8 cm. The incision should be longer in obese patients. When the fascia is reached, cut it along the skin incision line. Next the dissection of gluteus maximus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

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



Location of the entry point for trochanteric nail

IV.2. OPENING AND PREPARATION OF MEDULLARYCANAL FOR TROCHANTERIC NAIL INSERTION (*SHORTAND LONG NAILS*)



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

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

40.6356.100

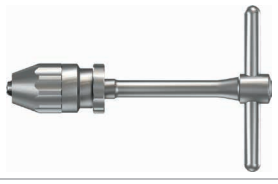
2 Using guide rod 3.2/500 **[40.6356.100]**, insert into the medullary canal curved awl 8.0 **[40.5523]** to the depth at which the awl blade goes along the medullary canal, allowing proper insertion of guide rod 3.0/580 **[40.3925.580]**. Having opened medullary canal, remove guide rod 3.2/500 **[40.6356.100]**. Mount guide rod 3.0/580 **[40.3925.580]** to Steinmann handle **[40.0987.200]** and enter the guide into the medullary canal through curved awl 8.0 **[40.5523]** cannulated hole to the depth required for the proper fixation of bone fragments. While guide rod insertion, control the fracture reduction and make sure the guide rod passes through all the bone fragments.

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

40.6356.100


40.5523

40.3925.580


40.0987.200

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

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

Remove the cannulated drill and protective guide.

40.6314

40.6315

40.6313

40.3925.580

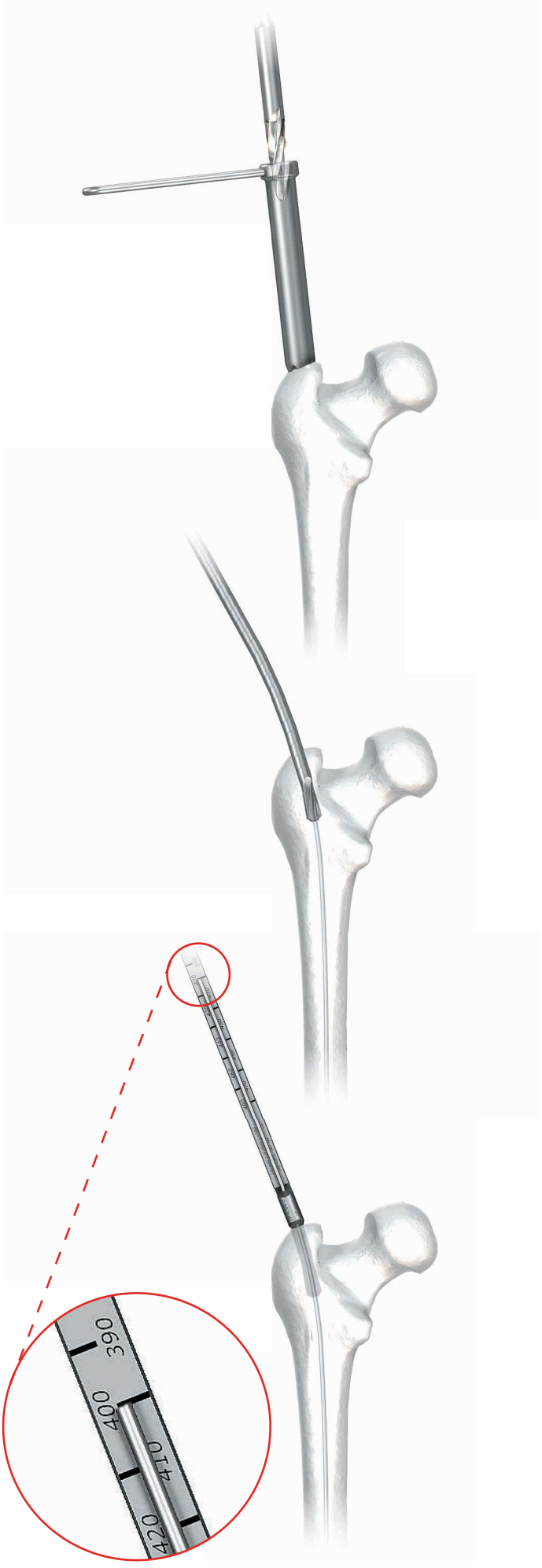
3 When reaming the medullary canal of femur shaft, the process should be performed gradually using reamers 0.5 mm thicker than the previous one until the diameter of the opening is 1.5 ÷ 2 mm greater than the diameter of the nail for a depth of not less than its length.
Whether the medullary canal of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

Remove the reamer.

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

The medullary canal is ready for nail implantation.

40.5098



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

IV.3. NAIL-TARGETER CONNECTING, NAIL INSERTION

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

A fork screw has been inserted in the nail.
Do not change its position in the nail.

40.6341

40.6305

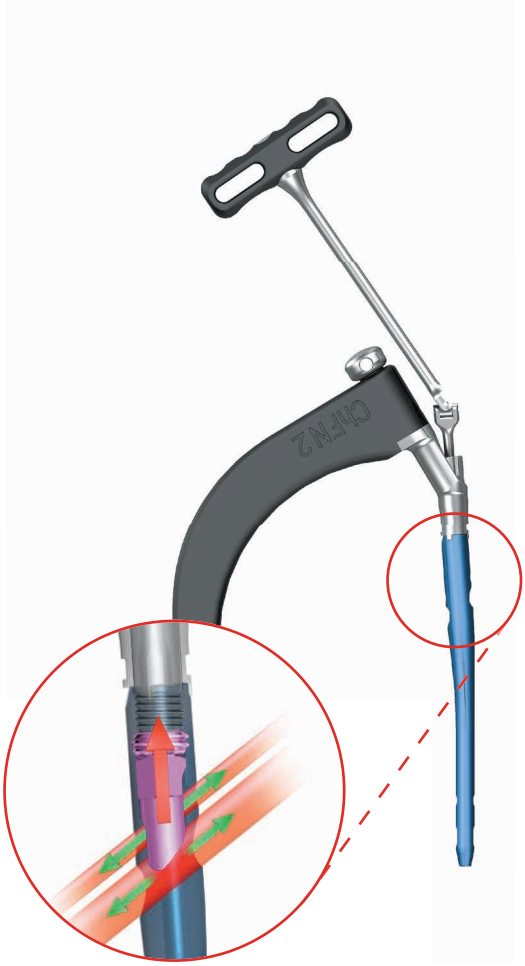
40.5526.100

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

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

40.6305

40.6319



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

6 For long nails attach distal targeter D **[40.6344]** to the targeter arm **[40.6341]** and set the correct position of the slider in relation to the locking holes of the nail in its distal part using two set blocks 12/5.0/4.0 **[40.6359]**. Lock the slider using the screwdriver T25 with holder **[40.6361]**.

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

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

40.6341

40.6344

40.6359

40.6361

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

40.6341

40.5507

40.3667

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

40.6356.100

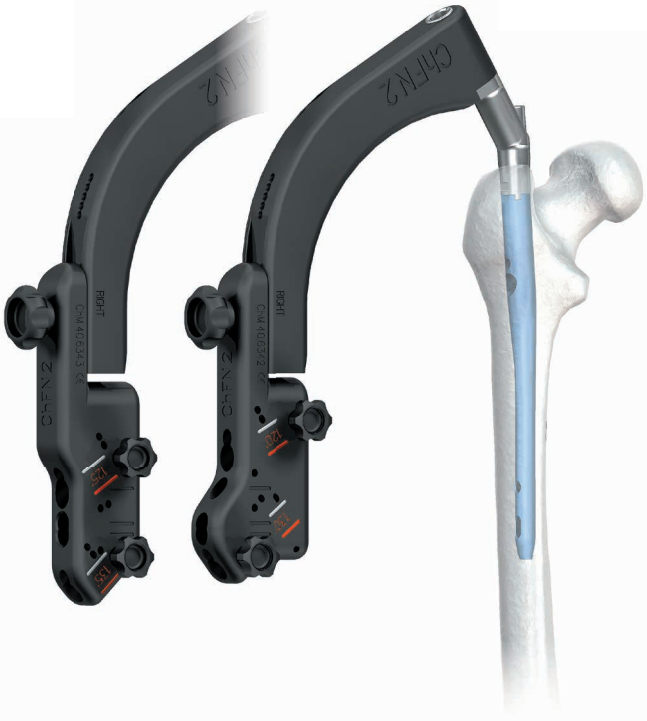
IV.4. PROXIMAL LOCKING OF THE TROCHANTERIC NAIL USING JOIN SCREWS

9 Attach chosen targeter 120/130 **[40.6342.100]** or targeter 125/135 **[40.6343.100]** to the targeter arm.

- for the nails 120° and 130° - targeter 120/130 **[40.6342.100]** shall be used,
- for the nails 125° and 135° - targeter 125/135 **[40.6343.100]** shall be used.


40.6342.100

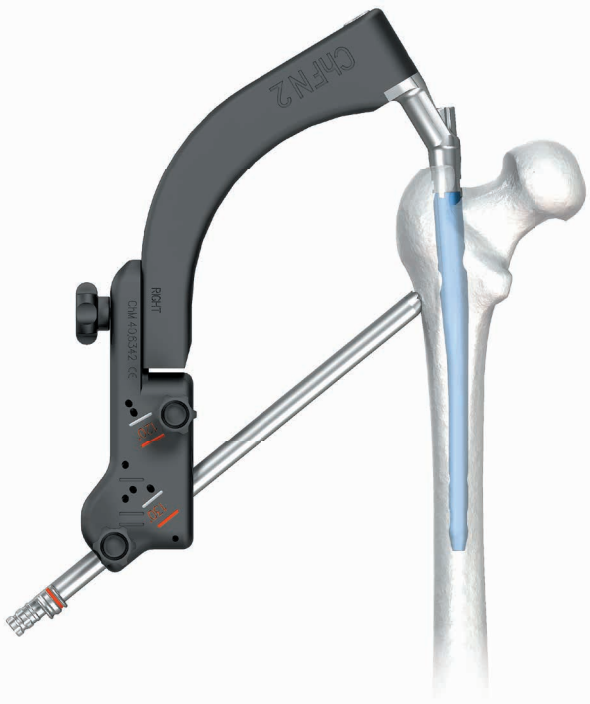

40.6343.100



10 Insert protective guide 11.5/3.2 **[40.6347]** into the drill guide 14/11.5 **[40.6346.100]** and then insert this system into the larger hole of the targeter until it rests on the skin.


40.6346.100


40.6347

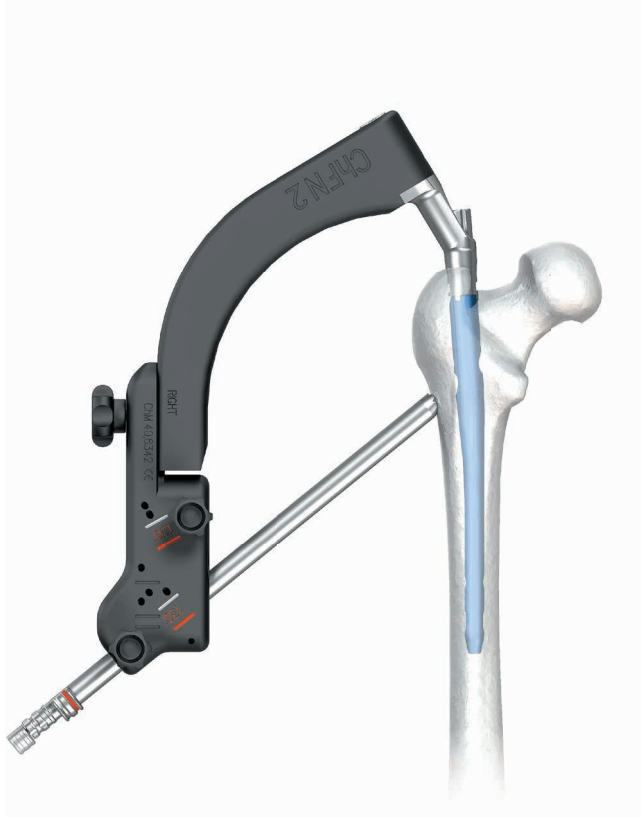


11 Insert the trocar 3.2 **[40.6350]** in the protective guide 11.5/3.2 **[40.6347]**. Mark on the skin the entry point for the join screw and perform soft tissue incision. Use the trocar to mark in the cortex the entry point for the drill.
At the same time advance the protective guide as close to the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

Remove the trocar and protective guide.


40.6347


40.6350



12 Insert the protective guide 6.0/3.2 **[40.6349]** in the drill guide 11.0/6.0 **[40.6348.100]** and then insert this system in the smaller hole of the proximal targeter until it rests on the skin.

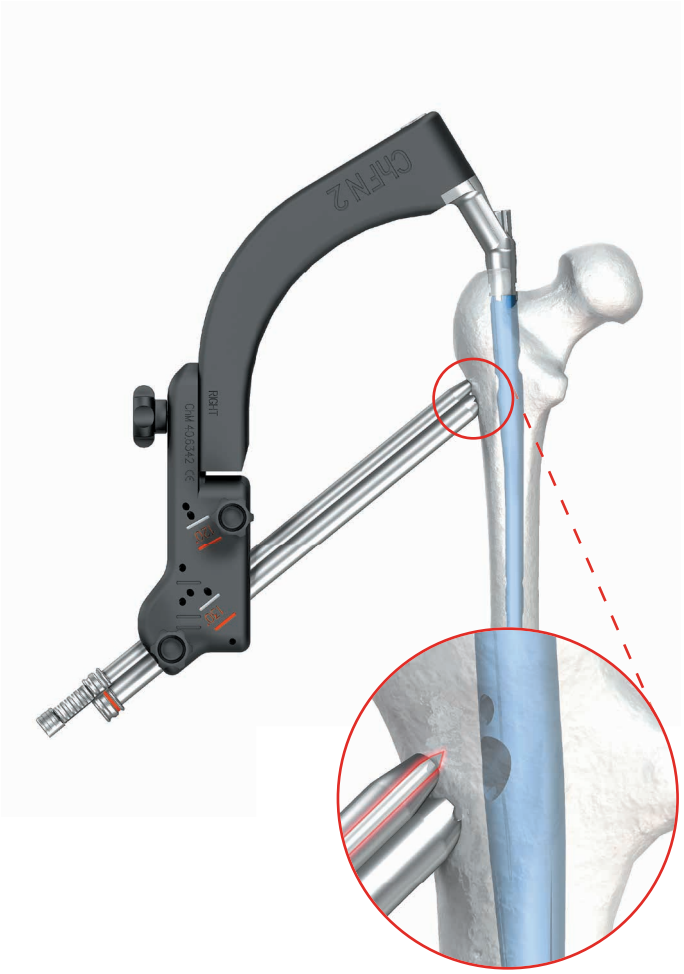
Insert the trocar 3.2 **[40.6350]** in the protective guide 6.0/3.2 **[40.6349]**. Mark on the skin the entry point for the join screw and perform soft tissue incision. Use the trocar to mark in the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as possible.

Remove the trocar and protective guide 6.0/3.2


40.6348.100


40.6349


40.6350



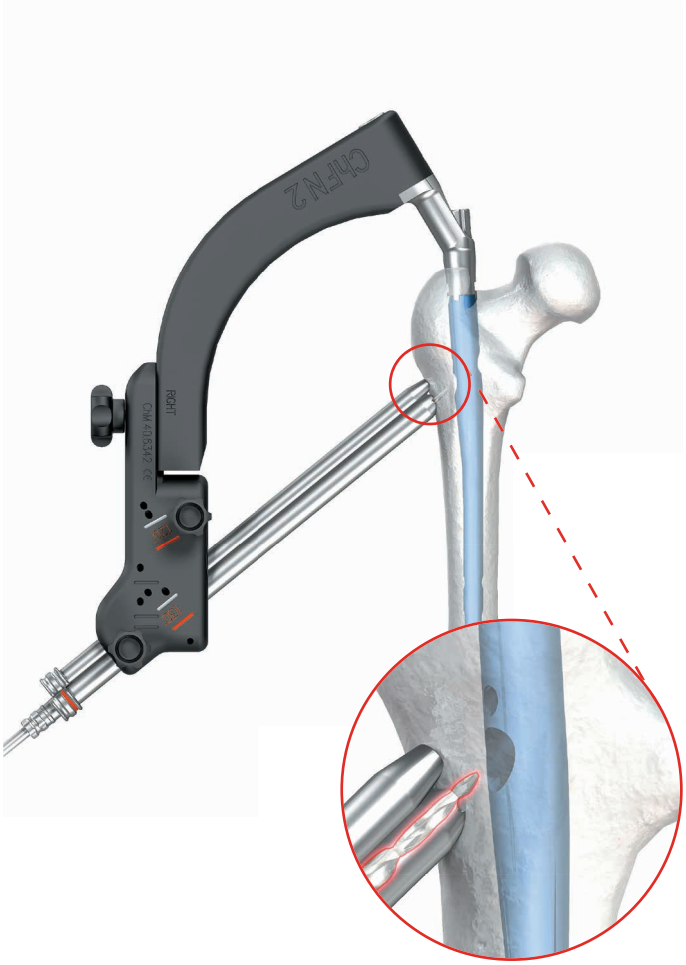
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

13 Insert the guide 11.5/6 **[40.6363]** into the drill guide 14/11.5 **[40.6346.100]**. Then, use the drill 5.0 **[40.6352]** mounted in the drive to drill the bone to a depth of approximately 3 mm.

Remove the drill and guide 11.5/6.


40.6363

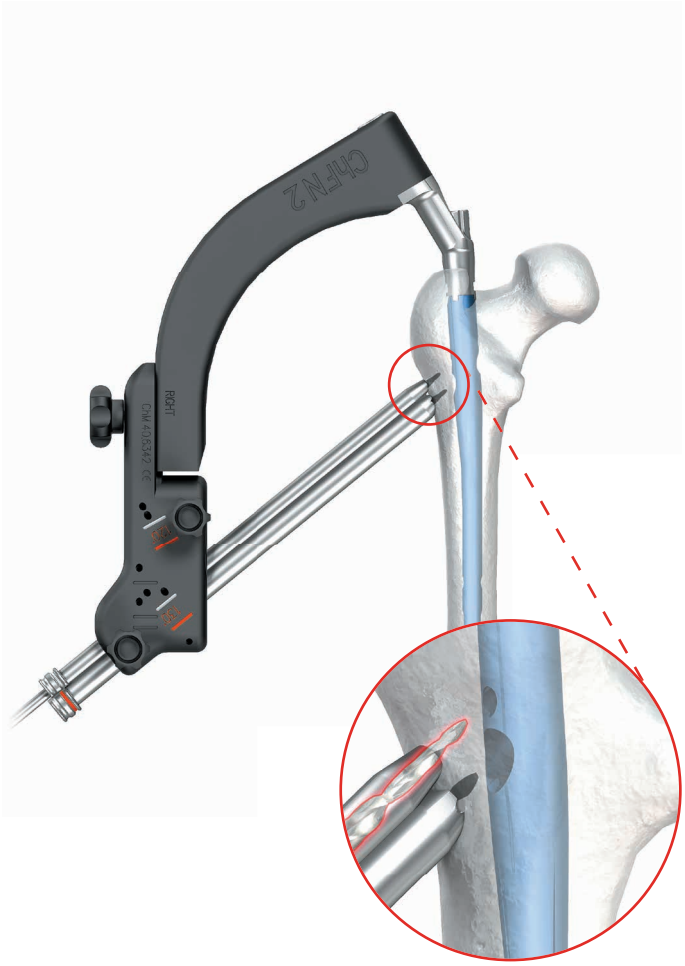
40.6352



14 Insert the drill 5.0 **[40.6352]** mounted in the drive to the drill guide 11.0/6.0 **[40.6348.100]**. Then, drill the bone to a depth of approximately 3 mm.

Remove the drill.

40.6352



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

15 Insert the protective guide 11.5/3.2 **[40.6347]** into the drill guide 14/11.5 **[40.6346.100]**. Then, insert the guide rod 3.2/500 **[40.6356.100]** mounted in the drive.

Guide insertion should be controlled with X-Ray imaging.

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


40.6347

40.6356.100

16 Insert the guide 6.0/3.2 **[40.6349]** into the drill guide 11,0/6.0 **[40.6348.100]**. Then, insert the guide rod 3.2/500 **[40.6356.100]** mounted in the drive.

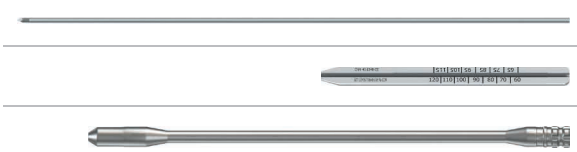

40.6349

40.6356.100

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

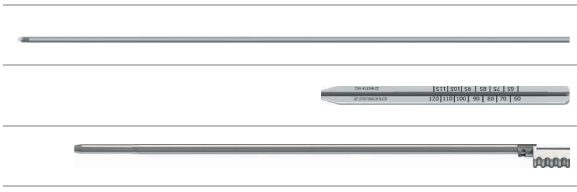
17 Insert the cannulated screw length measure **[40.6548]** via the guide rod **[40.6356.100]** (*placed into the protective guide 11.5/3.2 [40.6347]*) until its end rests on the protective guide 11.5/3.2. Read the length of the join screw 10.5 on the scale indicated by the end of the guide rod.
During the measurement, the tip of the cannulated screw length measure should rest on the protective guide 11.5/3.2, and the guide on cortex.

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



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

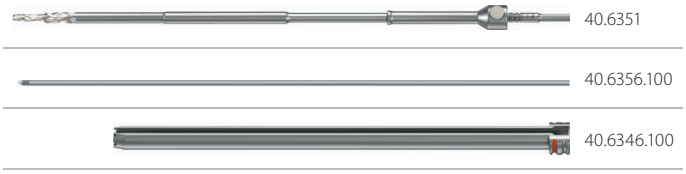
Remove the cannulated screw length measure and the protective guide 6.0/3.2. Leave the guide rod in place.



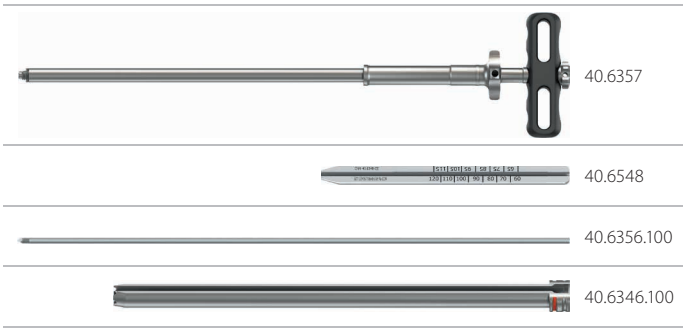
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

19 Set the drilling depth corresponding to the length of previously selected join screw on the gradual drill 10.5/7 **[40.6351]** using the setting latch. Mount the gradual drill in the drive and insert on the guide rod **[40.6356.100]** placed in the femoral neck. Drill a hole until the latch rests on drill guide 14/11.5 **[40.6346.100]**.

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



20 Set the nut of the compression wrench at "*0*" acc. to the scale.
Attach the join screw 10.5 of the length earlier determined by the cannulated screws length measure **[40.6548]** to the compression wrench **[40.6357]**. Insert the join screw on the guide rod **[40.6356.100]**. Using the compression wrench that is led on the guide rod, insert the join screw in the neck of the femur until the nut of the wrench rests on the drill guide 14/11.5 **[40.6346.100]**.



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

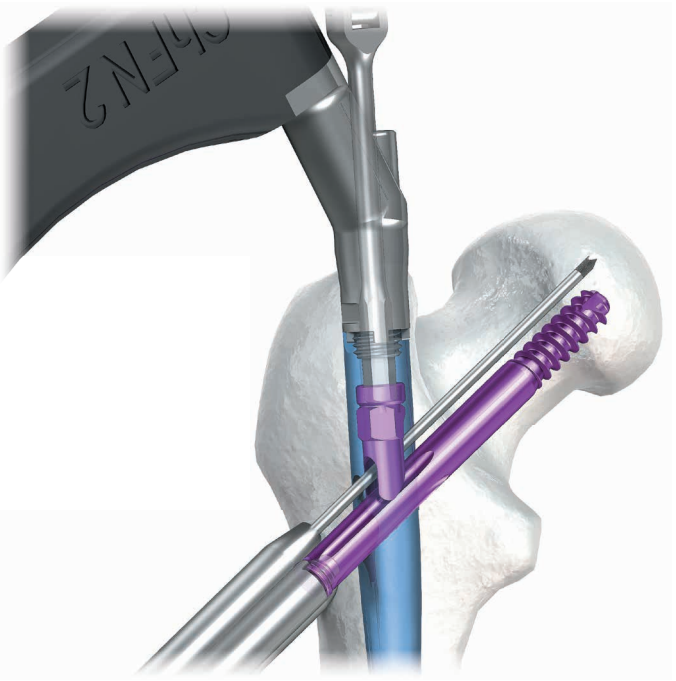
21 If fracture compression is intended, do the following:

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

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

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

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



Remove the compression wrench, guide rod and protective guide.

Guide rod [40.6356.100] is a disposable device.

40.6357

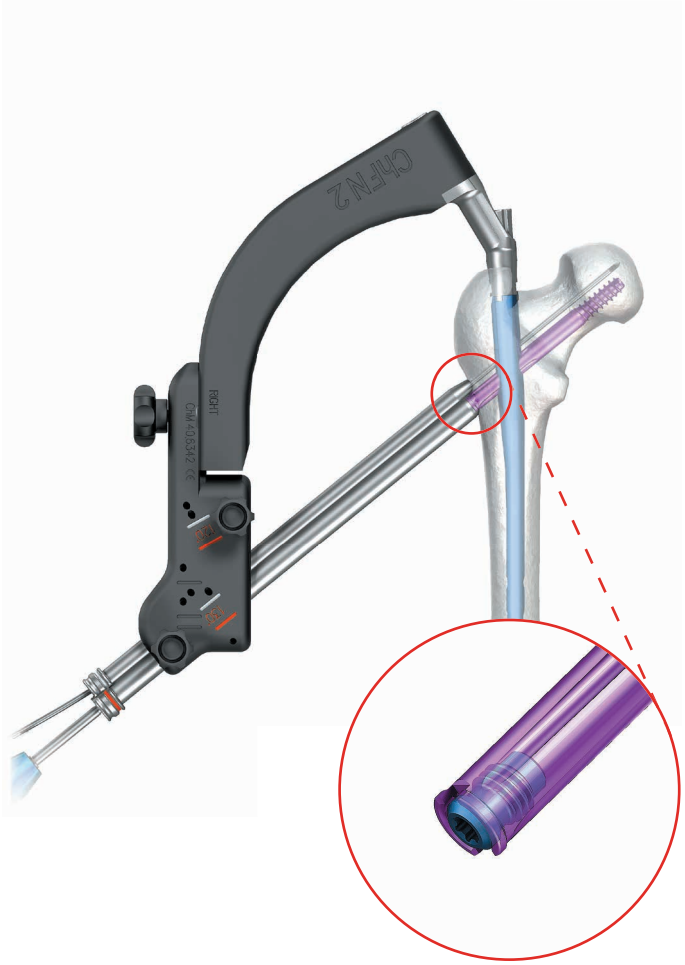
40.6319

40.6356.100

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


40.6361

The holder of screwdriver T25 **[40.6361]** must not be used with the drill guide 14/11.5 **[40.6346.100]**. Remove the holder.



In the case of locking the nail using a single join screw 10.5, omit the steps 24-26.

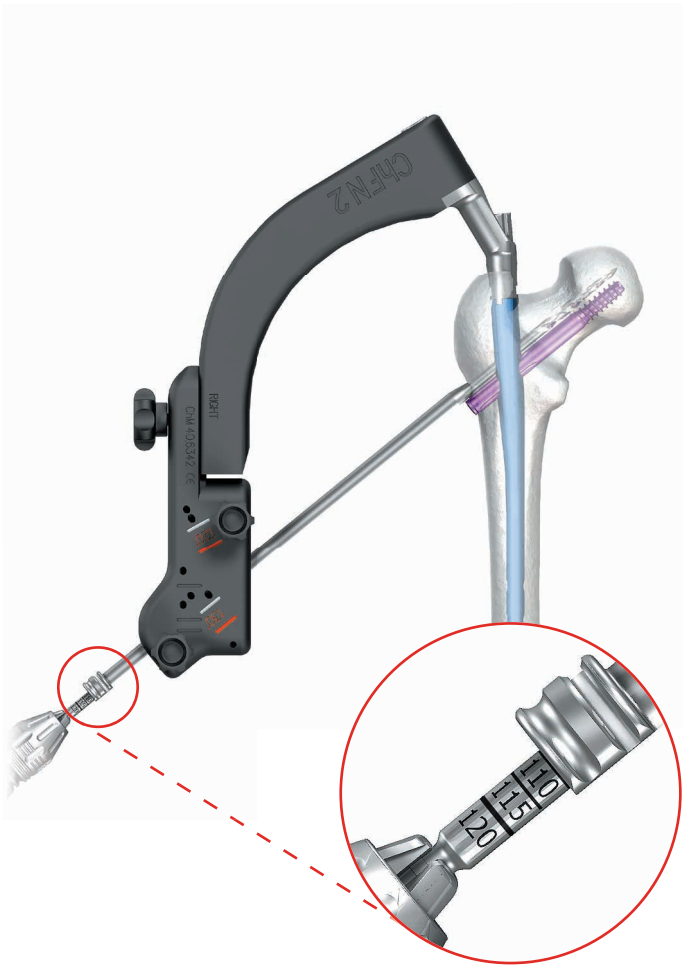
24 Remove the guide rod.

Mount the drill 5.0 **[40.6352]** in the drive, insert it in the drill guide 11.0/6.0 **[40.6348]** and deepen the hole in the first cortical layer (*up to the intramedullary nail*).

Remove the drill.

40.6352


40.6348.100



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

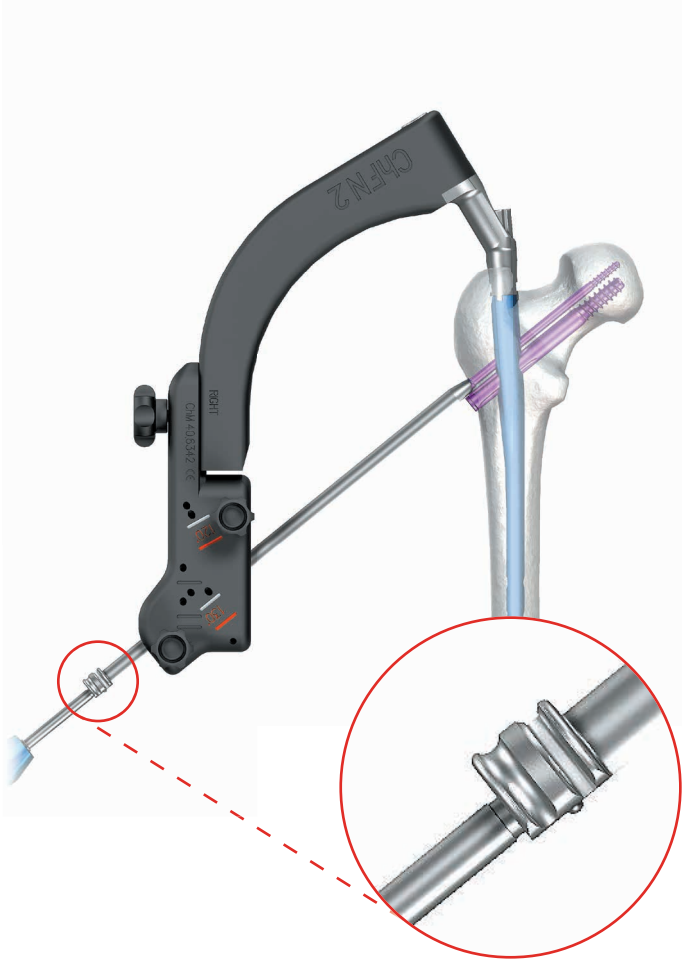
25 Insert the tip of the screwdriver T25 **[40.6361]** into the socket of the specified join screw 5.0 and then into drill guide 11.0/6.0 **[40.6348100]**.

Insert the join screw 5.0 in the previously drilled hole until its head reaches the cortex (*the groove on the screwdriver shaft matches the end of the protective guide*). Remove screwdriver T25 and protective guide.

The holder of screwdriver T25 **[40.6361]** must not be used with the drill guide 11.0/6.0 **[40.6348.100]**. Remove the holder.

40.6361

40.6348.100

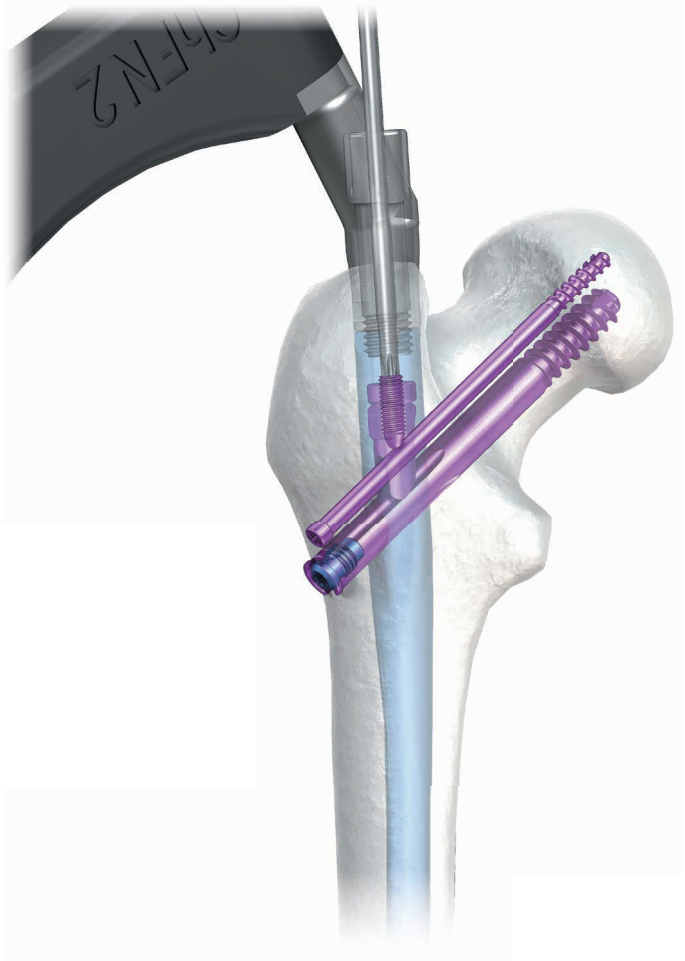


26 Join screw 5.0 locking:

Attach the setting screw (*implant*) to the wrench for self-aligning joint T25 **[40.6320]**. Insert the wrench for self-aligning joint T25 **[40.6320]** with the setting screw in the connecting screw located in the targeter arm. Tighten the setting screw until immobilization of join screw 5.0 occurs.

Remove the wrench for self-aligning joint T25.

40.6320



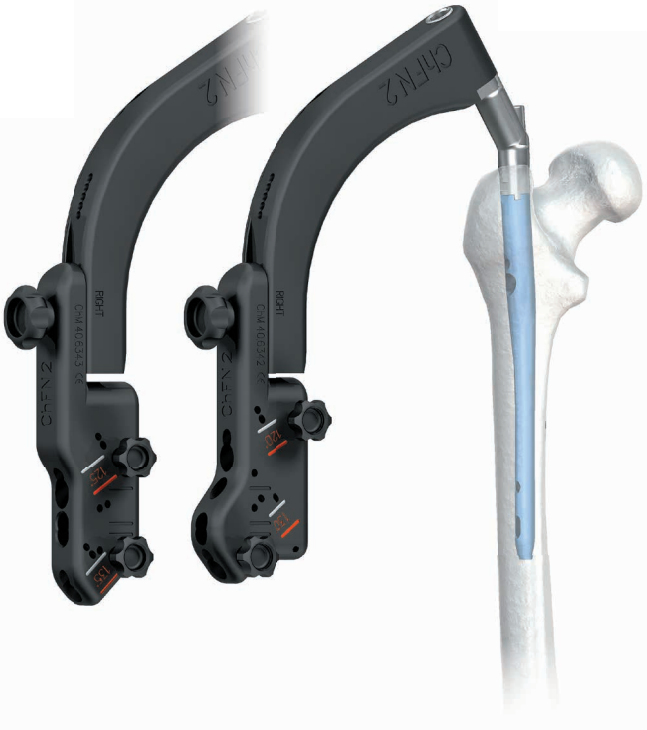
IV.5. PROXIMAL TROCHANTERIC NAIL LOCKING USING JOIN TELESCOPIC SCREW 10.5

27 Attach chosen targeter 120/130 **[40.6342.100]** or targeter 125/135 **[40.6343.100]** to the targeter arm.

- for the nails 120° and 130° - targeter 120/130 **[40.6342.100]** shall be used,
- for the nails 125° and 135° - targeter 125/135 **[40.6343.100]** shall be used.


40.6342.100

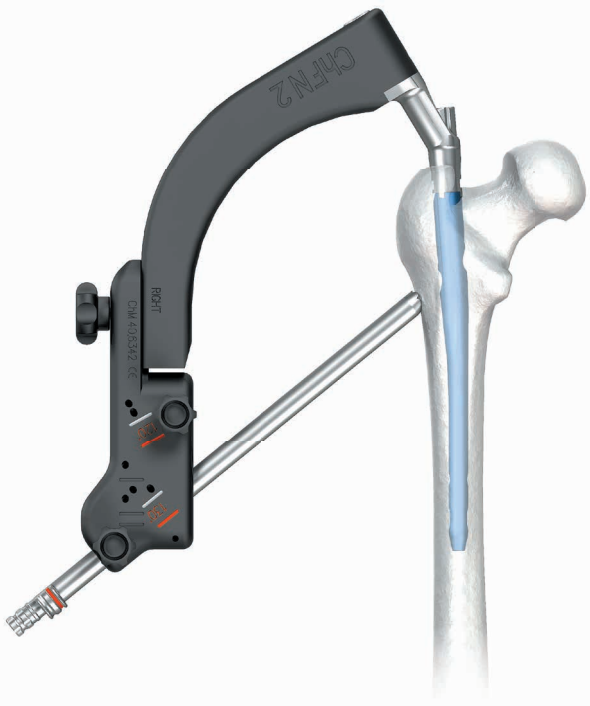

40.6343.100



28 Insert protective guide 11.5/3.2 **[40.6347]** into the drill guide 14/11.5 **[40.6346.100]** and then insert this system into the larger hole of the targeter until it rests on the skin.


40.6346.100


40.6347



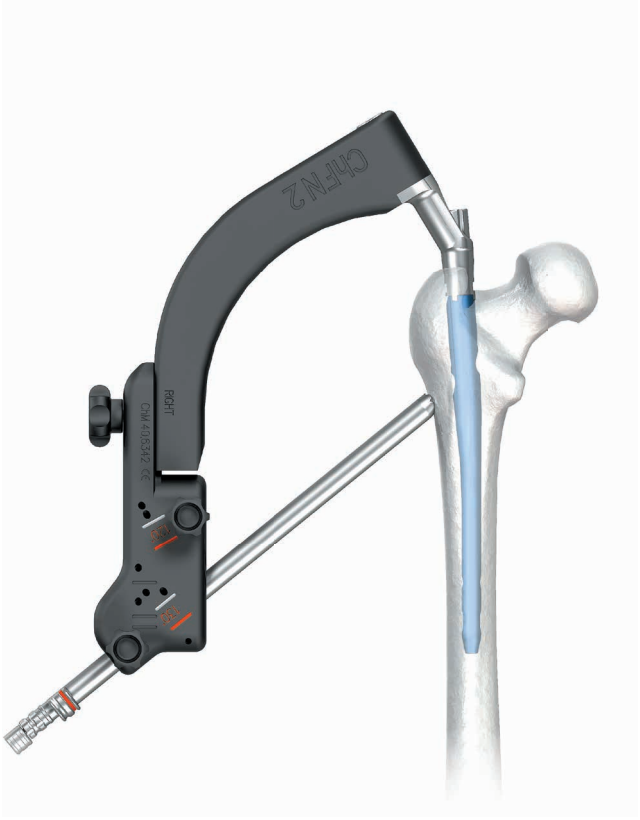
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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

Remove trocar and protective guide.


40.6347


40.6350



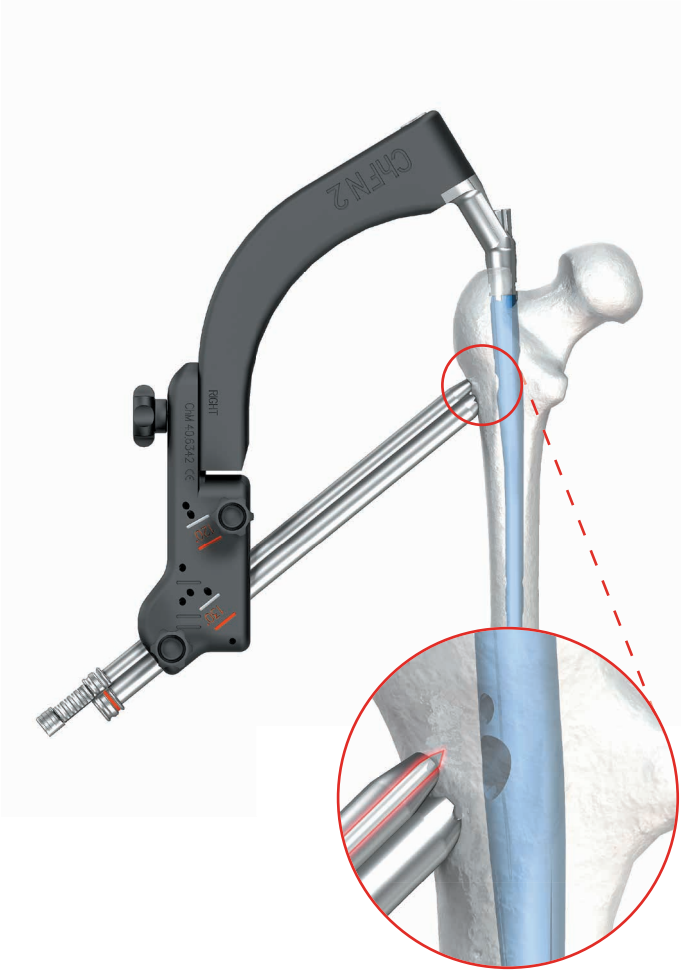
30 Insert the protective guide 6.0/3.2 **[40.6349]** in the drill guide 11.0/6.0 **[40.6348.100]** and then insert this system in the smaller hole of the chosen targeter.
Insert the trocar 3.2 **[40.6350]** in the protective guide 6.0/3.2 **[40.6349]**. Mark on the skin the entry point for the join screw and perform soft tissue incision.
Use the trocar to mark in the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as possible.

Remove trocar and protective guide 6.0/3.2.


40.6348.100


40.6349


40.6350



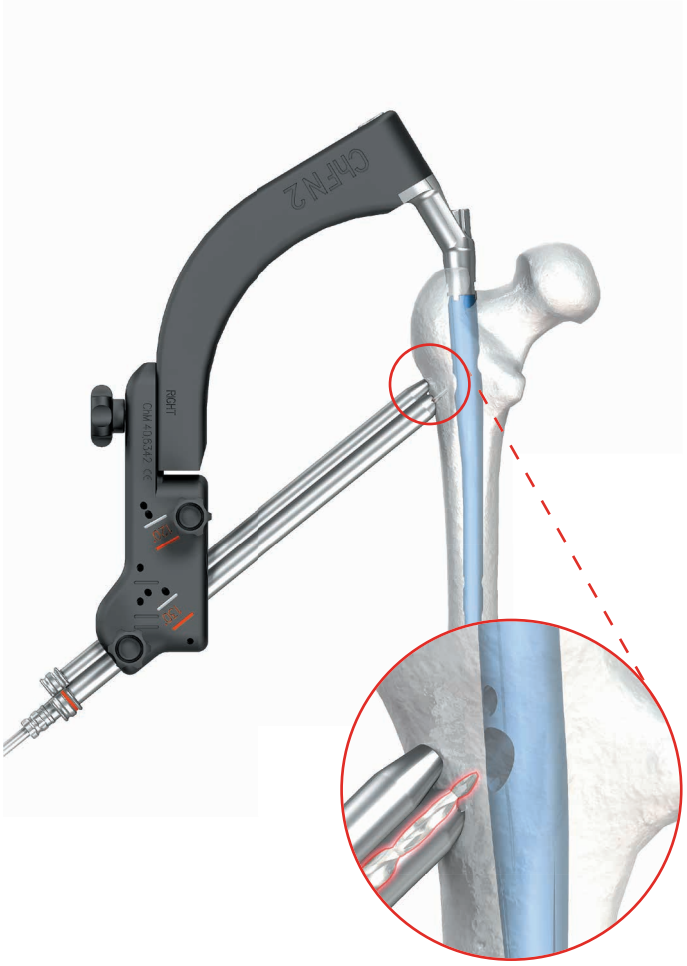
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

31 Insert the guide 11.5/6 **[40.6363]** into the drill guide 14/11.5 **[40.6346.100]**. Use the drive and drill 5.0 **[40.6352]** to drill a hole in the bone to a depth of about 3mm.

Remove the drill and guide 11.5/6.


40.6363

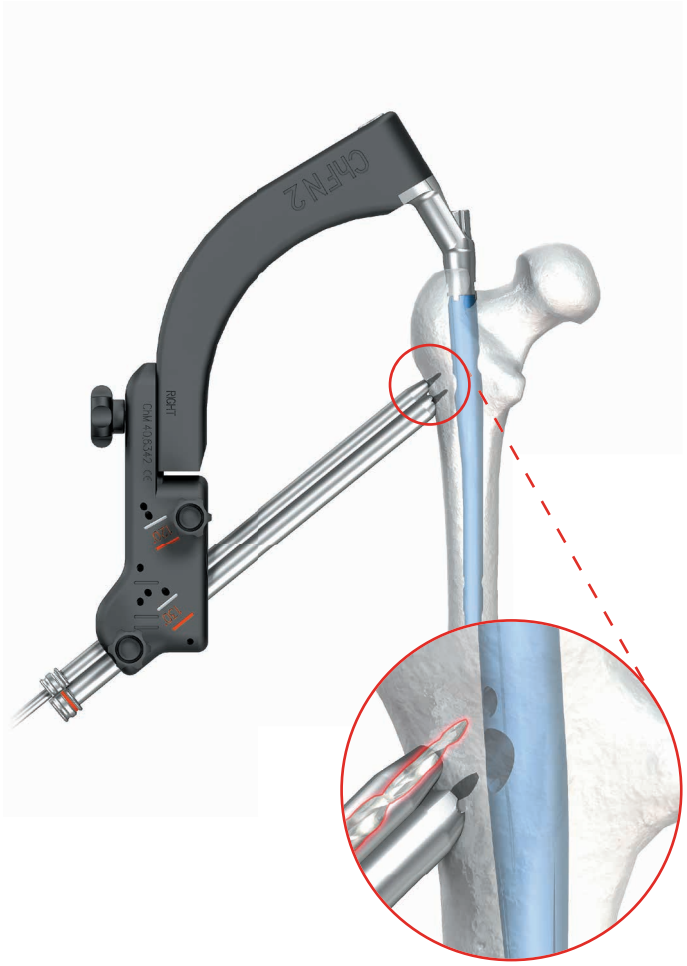
40.6352



32 Insert the drill 5.0 **[40.6352]** into the drill guide 11.0/6.0 **[40.6348]** and drill a hole in the bone to a depth of about 3mm.

Remove the drill.

40.6352



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

33 Insert protective guide 11.5/3.2 **[40.6347]** into drill guide 14/11.5 **[40.6346.100]**. Connect the guide rod 3.2/500 **[40.6356.100]** to the drive and advance it into the femoral head.

Guide rod insertion should be performed under X-Ray control.

Insert the guide rod 3.2/500 **[40.6356.100]** into the femoral head. at the depth of about 5÷10 mm from articular cartilage for join screw 10.5 and at the depth of about 15-20 mm for the join screw 5.0.

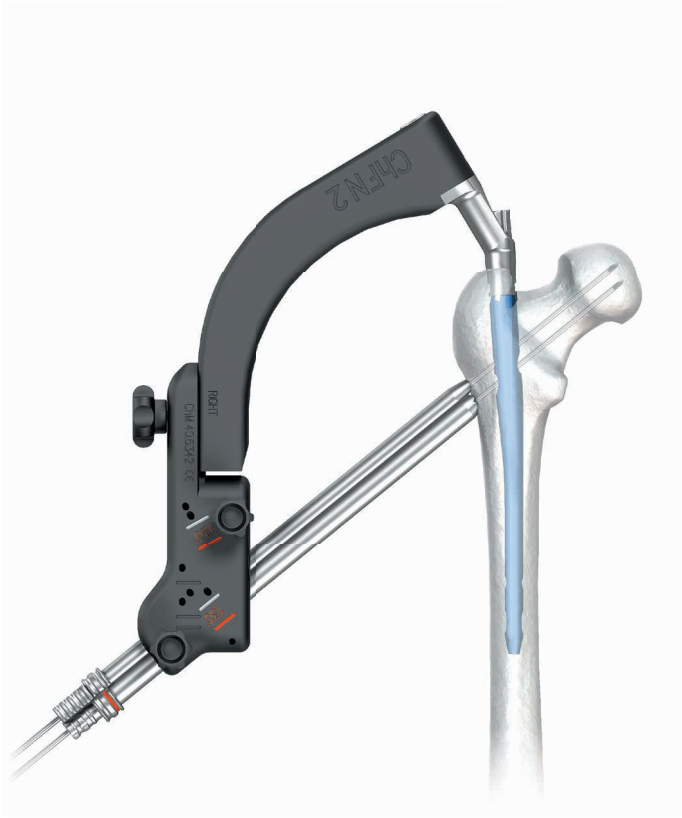

40.6347

40.6356.100

34 Insert the guide 6.0/3.2 **[40.6349]** into the drill guide 11.0/6.0 **[40.6348.100]**.
Attach the guide rod 3.2/500 **[40.6356.100]** to the drive and advance into the femoral head.


40.6349

40.6356.100

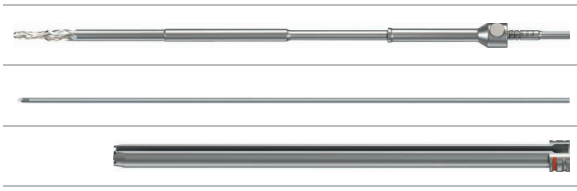


35 Insert the cannulated screw length measure **[40.6548]** via the guide rod **[40.6356.100]** (*placed into the protective guide 11.5/3.2 [40.6347]*) until its end rests on the protective guide 11.5/3.2 **[40.6347]**. Read the length of the join telescopic screw on the scale indicated by the end of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

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

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

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



37 Set the nut of the compression wrench at "*0*" acc. to the scale.
Attach the join telescopic screw 10.5 of the length earlier determined by the cannulated screws length measure **[40.6548]** to the compression wrench **[40.6357]**. Insert the join screw on the guide rod **[40.6356.100]**. Using the compression wrench that is led on the guide rod, insert the join telescopic screw in the neck of the femur until the nut of the wrench rests on the drill guide 14/11.5 **[40.6346.100]**.

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


40.6357


40.6548

40.6356.100


40.6346.100

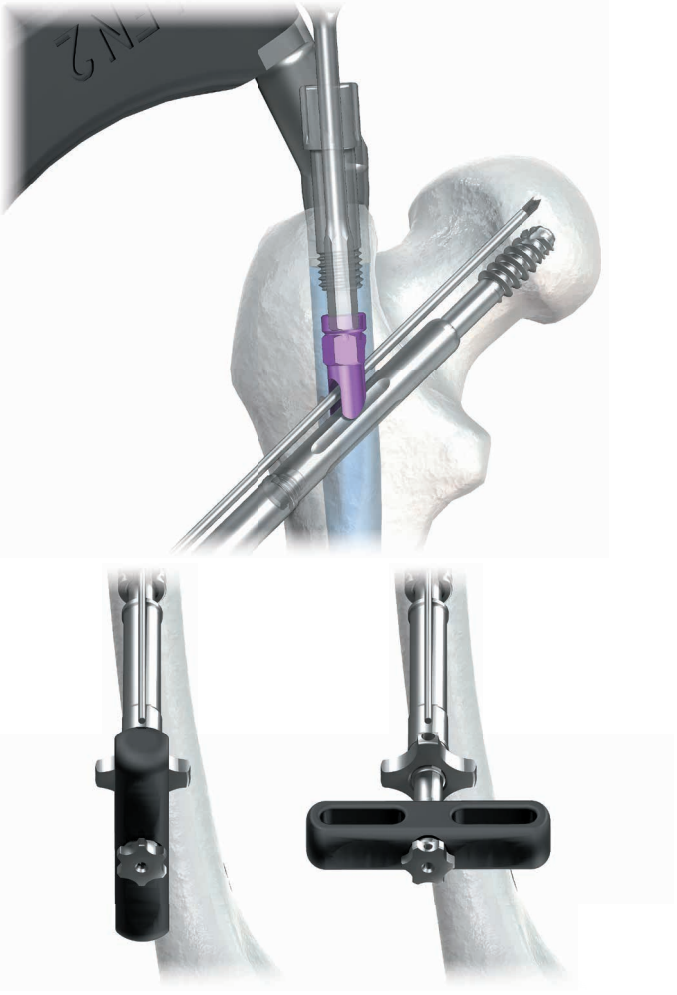
38 Set the combined join screw 10.5 with compression wrench so that the handle of the wrench is positioned parallel or perpendicular to the longitudinal axis of the nail. Insert the wrench for self-aligning joint S7 **[40.6319]** in the connecting screw located in the targeter arm. Tighten the fork screw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

Guide rod **[40.6356.100]** is a disposable device.


40.6357


40.6319

40.6356.100

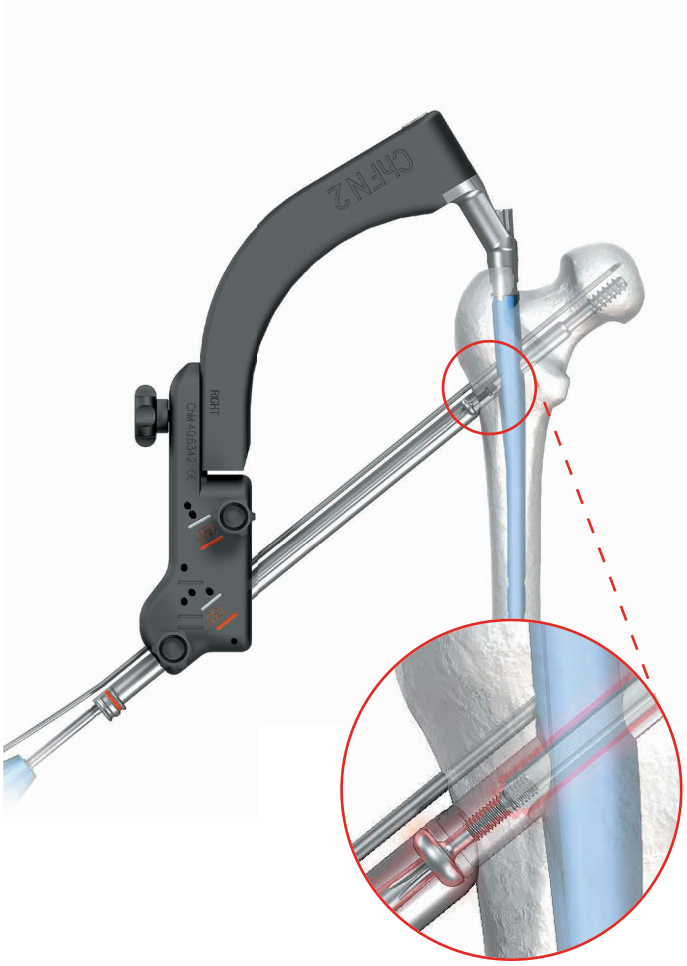


39 If fracture compression is intended, do the following:

- insert the compression screw (*implant*) into the join telescopic screw using screwdriver T25 **[40.6361]**,
- perform compression.

40.6361

The holder of screwdriver T25 **[40.6361]** must not be used with the drill guide 14/11.5 **[40.6346.100]**. Remove the holder.



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

Nails of the length of 170 or 180 can only be locked with one distal screw using the 12 mm proximal hole of the targeter **[40.6342.100]** or **[40.6343.100]**.

40 Insert the trocar 10 **[40.6355]** in the protective guide 12/10 **[40.6353]** and insert this system in the proximal 12 mm hole of the targeter **[40.6342.100]** or **[40.6343.100]**. Mark on the skin the entry point for the distal screw and perform soft tissue incision. Use the trocar to mark in the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as possible.

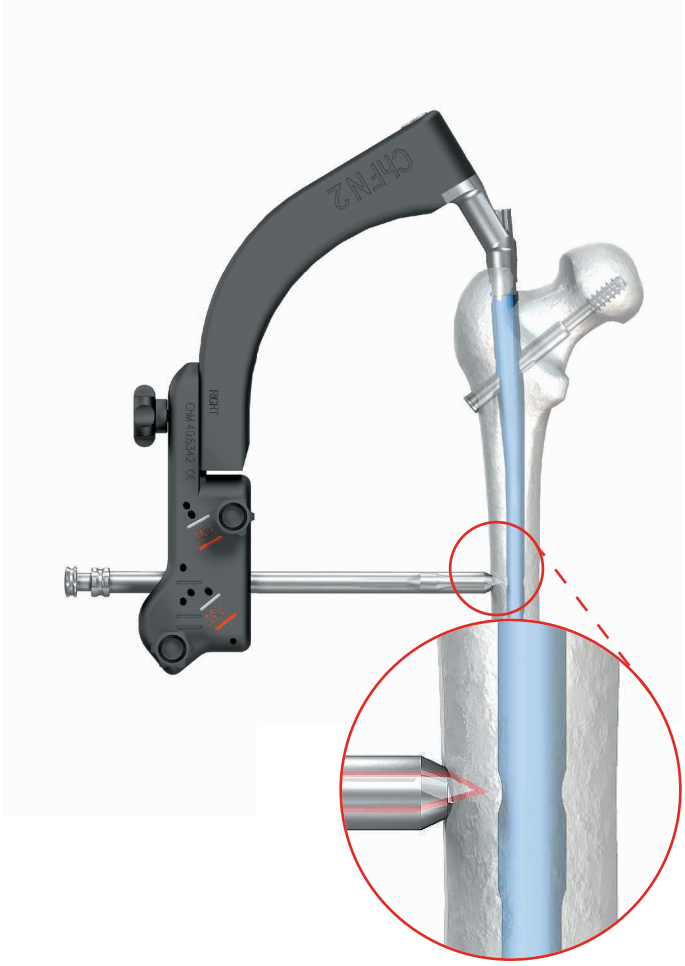
Remove the trocar.
Leave protective guide in place.


40.6342.100


40.6343.100


40.6353


40.6355



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

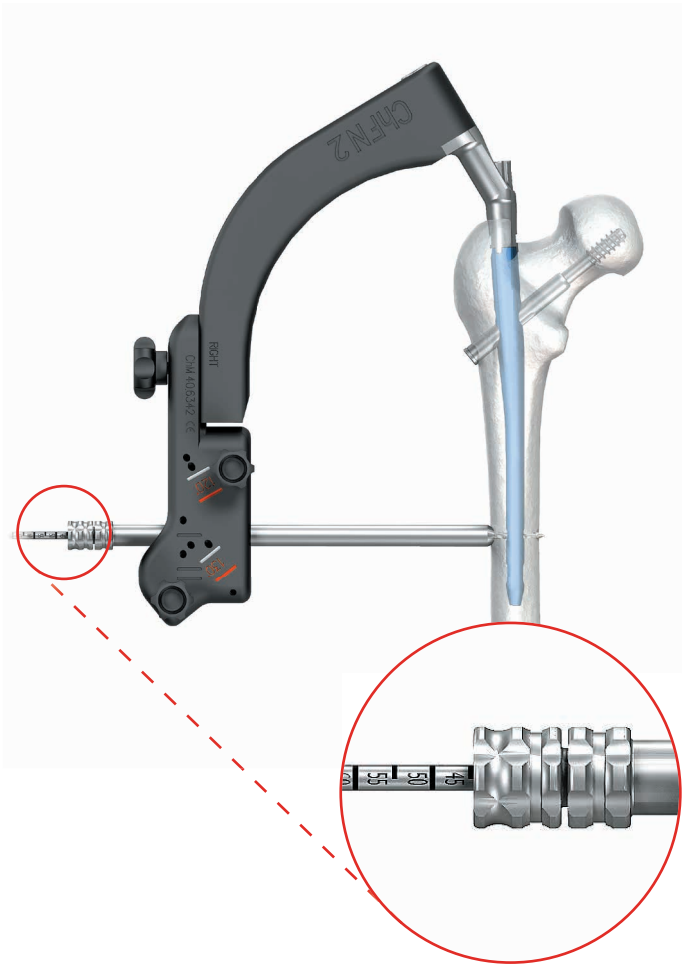
The drilling process should be done under X-Ray with visual track control.

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


40.6353


40.6362

40.5346.002

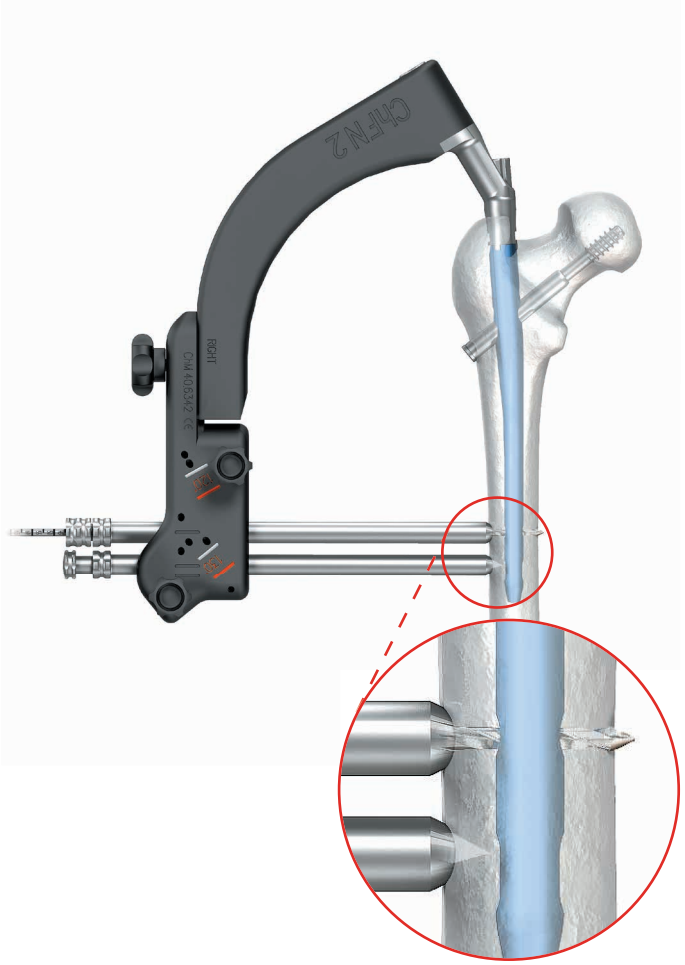


42 Insert the trocar 10 **[40.6355]** in the protective guide 12/10 **[40.6353]** and then insert this system in the other (*distal*) hole of the proximal targeter. Use the trocar to mark in the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as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

Remove the trocar.
Leave protective guide in place.


40.6353


40.6355



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

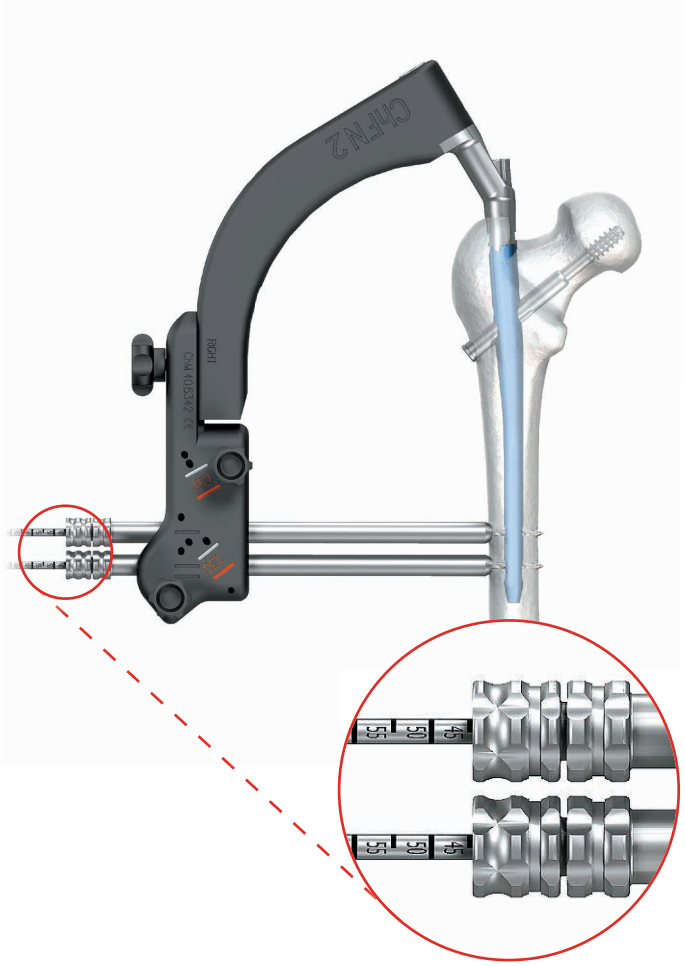

The drilling process should be done under X-Ray with visual track control.

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


40.6353


40.6362

40.5346.002



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

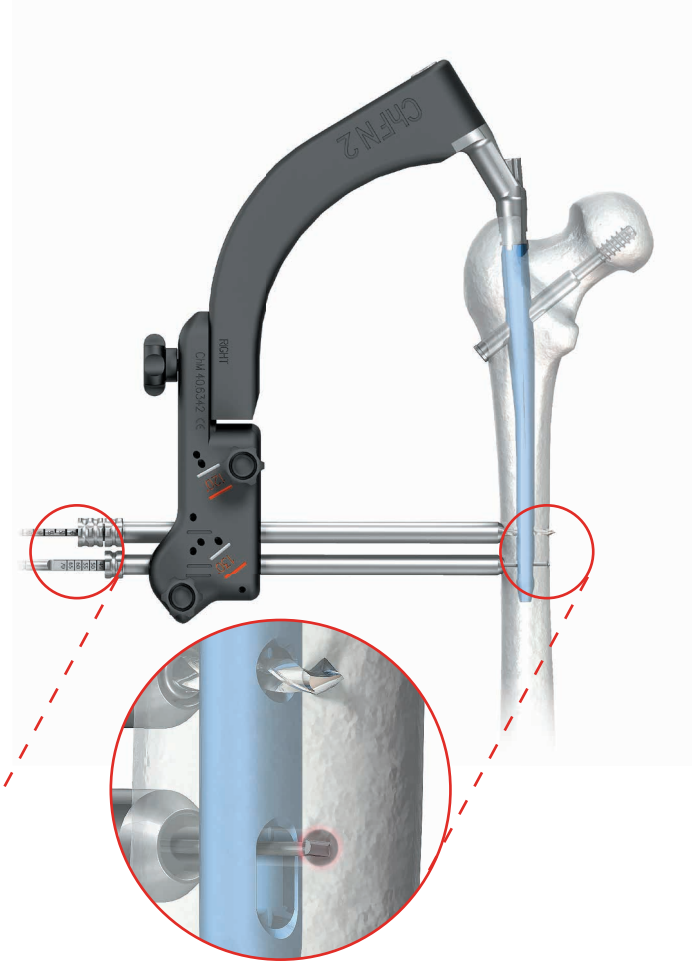
44 Insert the screw length measure **[40.6358]** through the protective guide 12/10 **[40.6353]** into drilled hole until its hook reaches the exit hole.
Read the length of distal screw on the B-D scale.

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

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


40.6353

40.6358



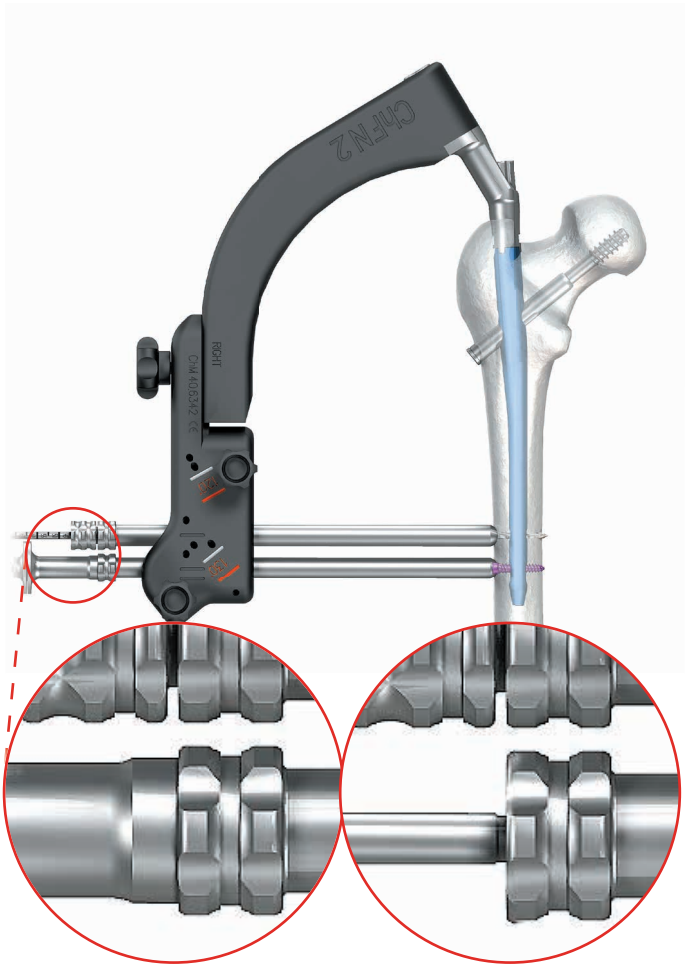
45 Insert the tip of the screwdriver T25 with holder **[40.6361]** into the socket of selected distal screw. Slide the holder on the screw head. Then advance both into the protective guide 12/10 **[40.6353]**.
Insert the distal screw in the prepared hole until the head of the screw reaches the cortex of the bone (*the collar of the holder rests against the protective guide 12/10 and the holder detaches from the screw head*).

Remove the screwdriver and protective guide.

Screw insertion should be controlled with X-Ray imaging.


40.6361


40.6353



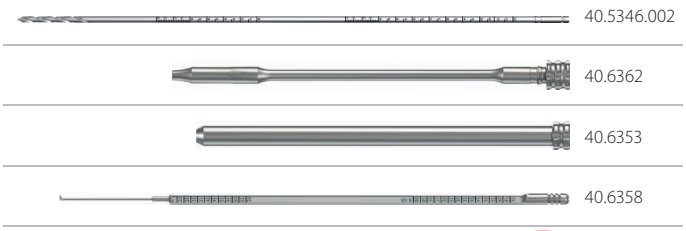
The distal screw can be inserted also using screwdriver T25 **[40.6361]** with the holder removed. When the groove on the screwdriver shaft matches the edge of protective guide 12/10 **[40.6353]**, the screw head reaches the cortex of the bone.

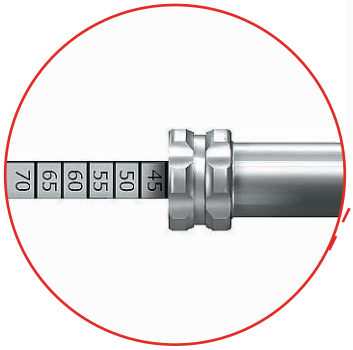
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

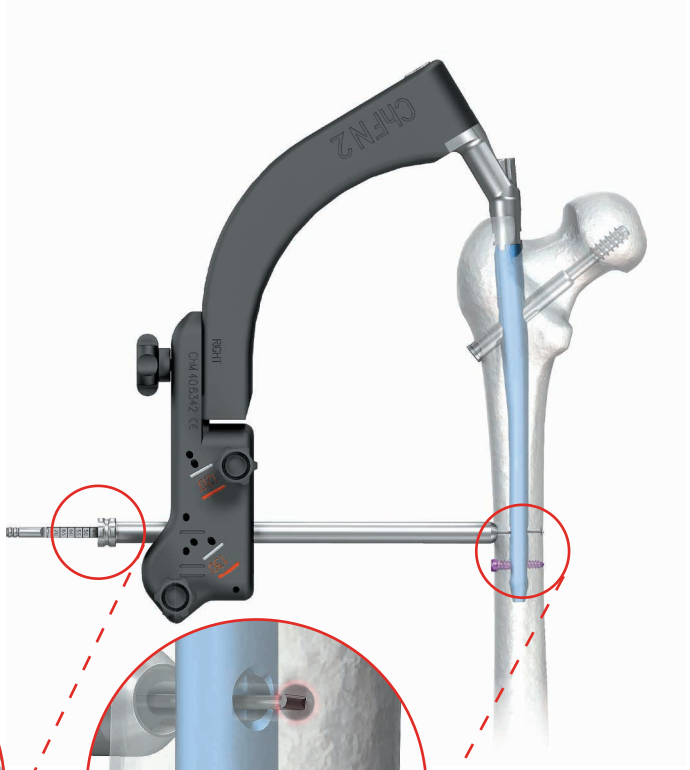
46 Remove drill with scale 4.0 **[40.5346.002]** and the drill guide 10/4.0 **[40.6362]** from the proximal hole of the targeter. Leave the protective guide 12/10 **[40.6353]** in the targeter hole. Insert the screw length measure **[40.6358]** through the protective guide 12/10 **[40.6353]** into drilled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

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

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



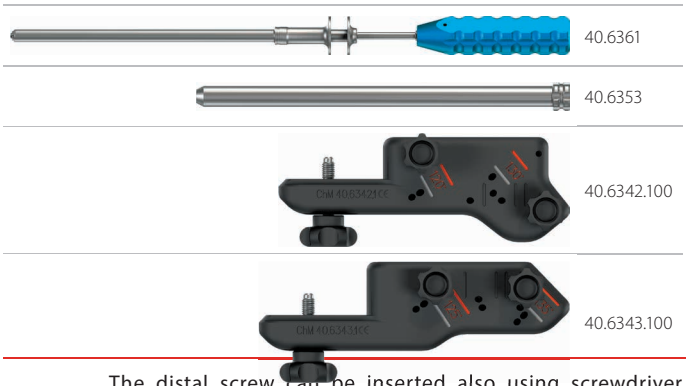




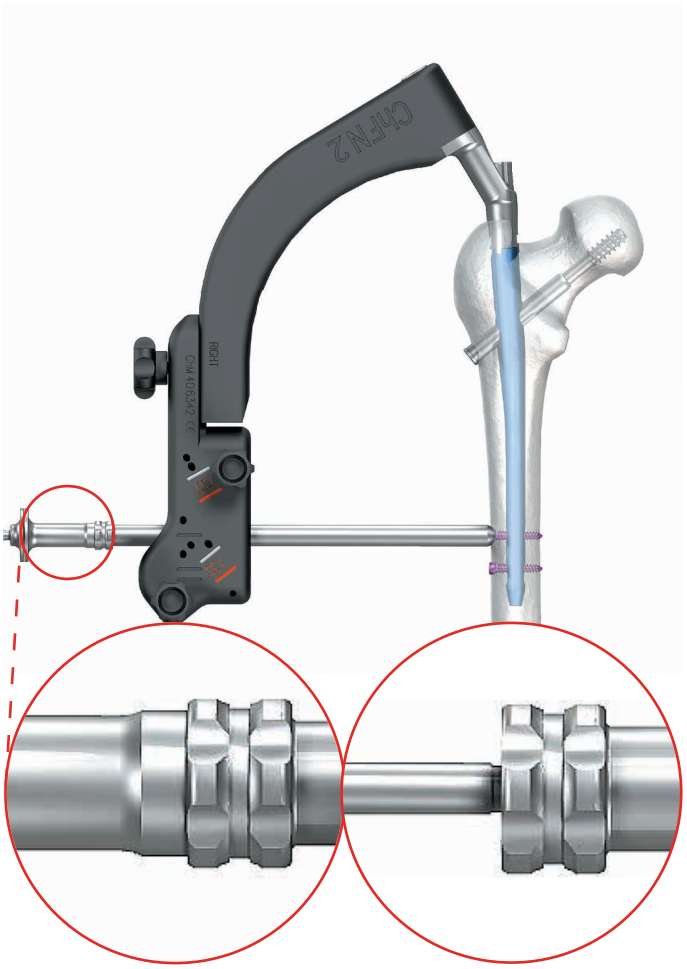
47 Insert the tip of the screwdriver T25 with holder **[40.6361]** into the socket of selected distal screw. Slide the holder on the screw head. Then advance both into the protective guide 12/10 **[40.6353]**.
Insert the distal screw in the prepared hole until the head of the screw reaches the cortex of the bone (*the collar of the holder rests against the protective guide 12/10 and the holder detaches from the screw head*).

Remove the screwdriver, protective guide and the targeter **[40.6342.100]** or **[40.6343.100]**.

Screw insertion should be controlled with X-Ray imaging.



The distal screw can be inserted also using screwdriver T25 **[40.6361]** with the holder removed. When the groove on the screwdriver shaft matches the edge of protective guide 12/10 **[40.6353]**, the screw head reaches the cortex of the bone.



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

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

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

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

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


40.6342.100

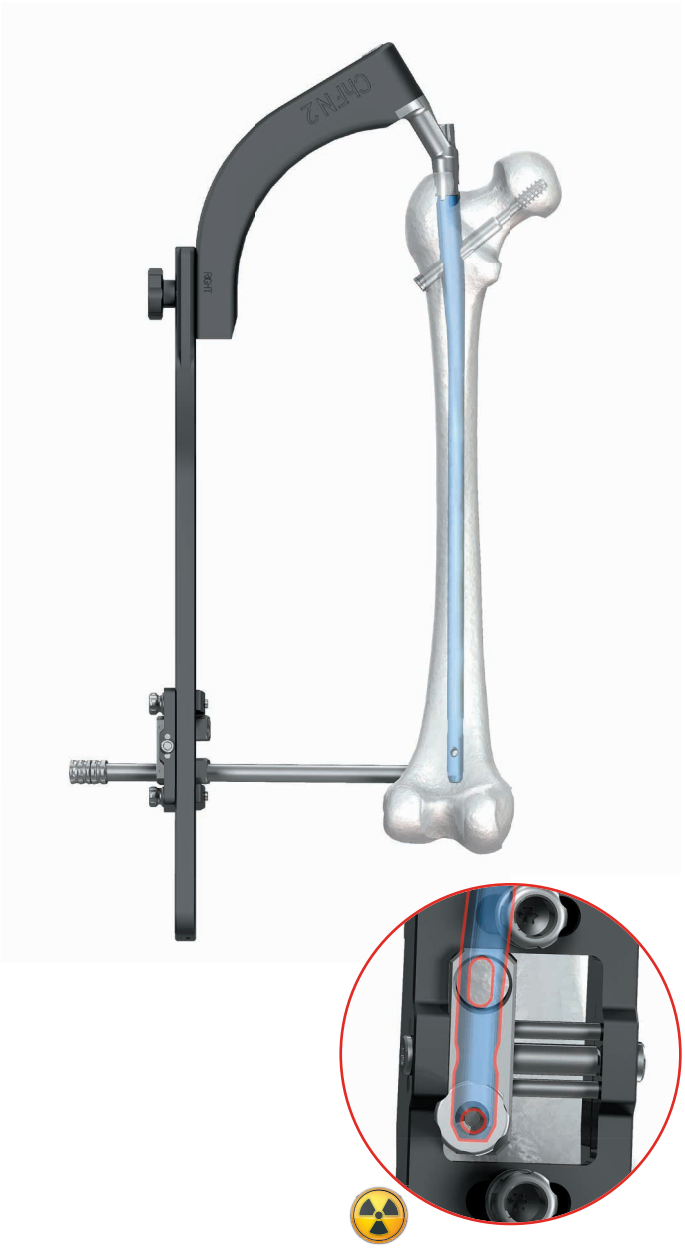

40.6343.100


40.6344


40.6341


40.6353


40.6362



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

Remove the trocar.
Leave protective guide in place.


40.6353


40.6362


40.6355

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

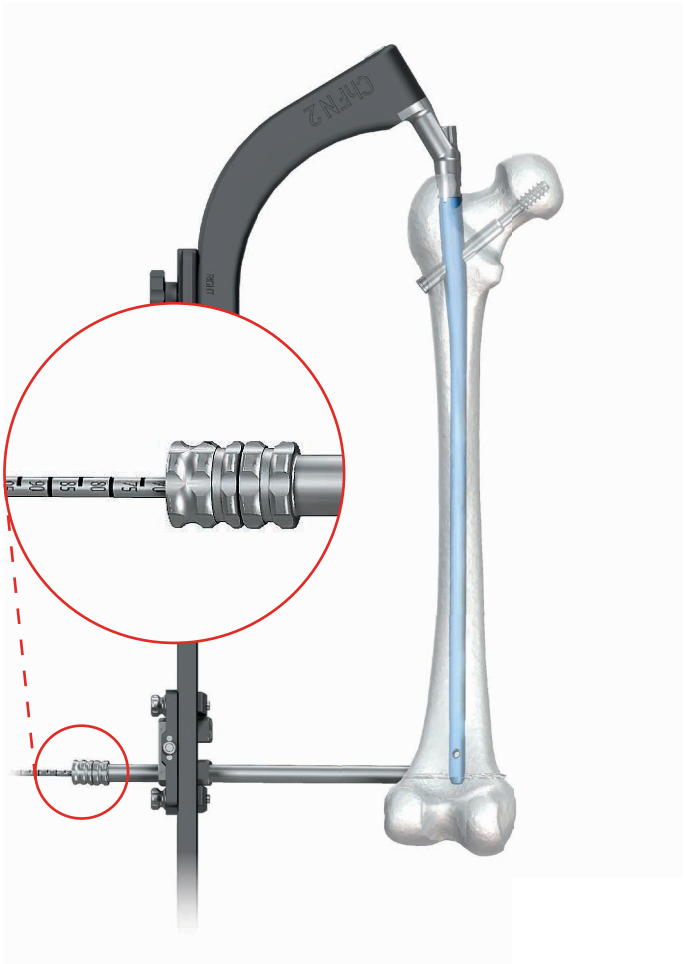

The drilling process should be done under X-Ray with visual track control.

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


40.6353


40.6362


40.5346.002



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

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

Remove the trocar.
Leave protective guide in place.


40.6353


40.6355

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

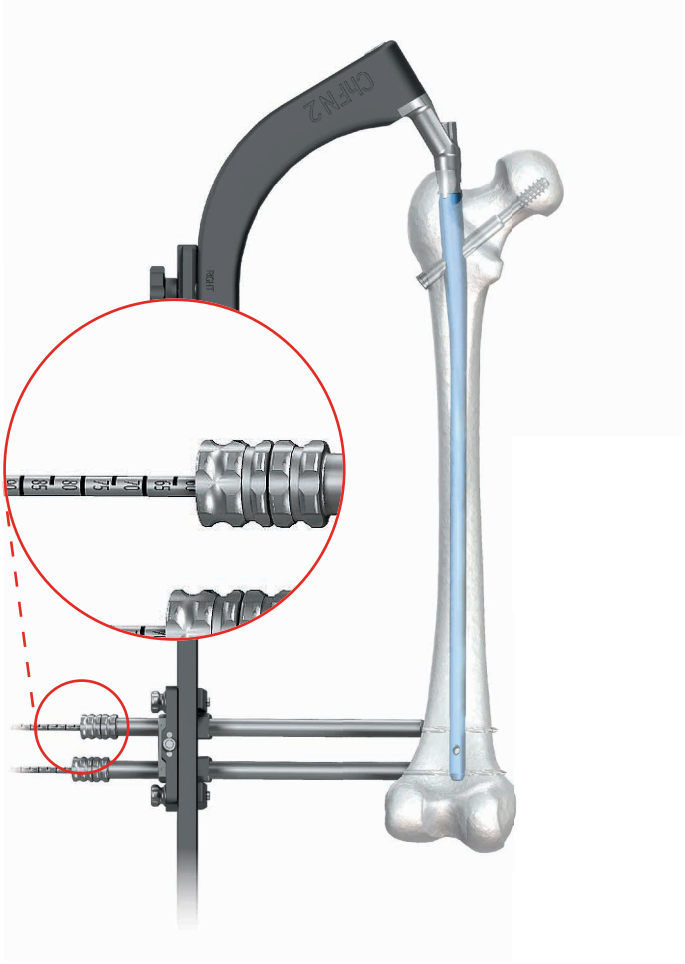
The drilling process should be done under X-Ray with visual track control.

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


40.6353


40.6362

40.5346.002

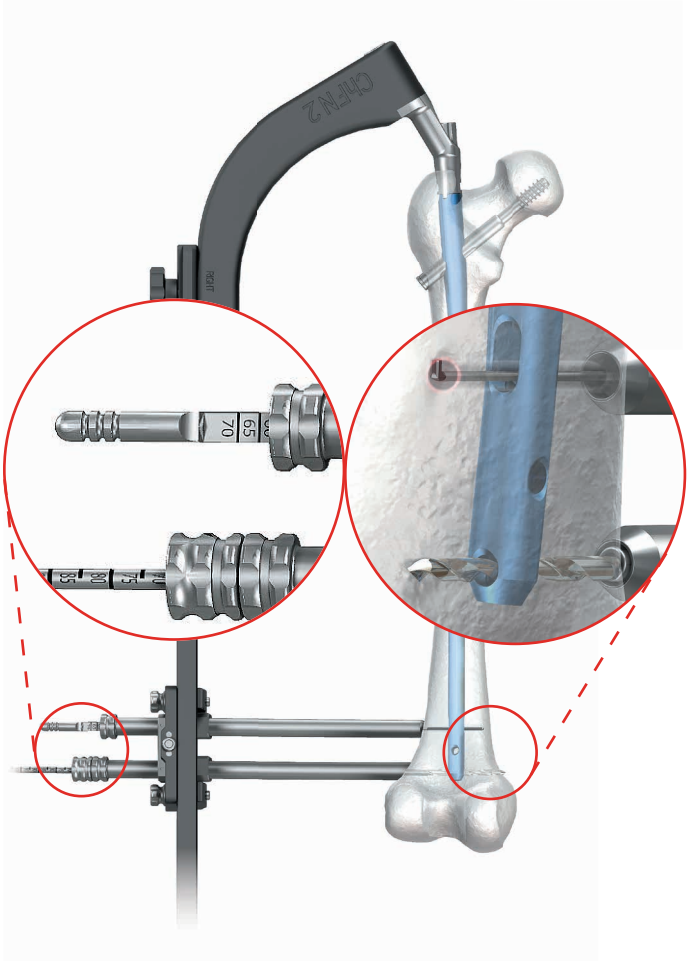


53 Insert the screw length measure **[40.6358]** through the protective guide 12/10 **[40.6353]** into drilled hole until its hook reaches the exit hole.
Read the length of distal screw on the B-D scale.
During measurements the tip of protective guide 12/10 should rest on the cortex bone.

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


40.6353

40.6358



54 Insert the tip of the screwdriver T25 with holder **[40.6361]** into the socket of selected distal screw. Slide the holder on the screw head. Then advance both into the protective guide 12/10 **[40.6353]**.
Insert the distal screw in the prepared hole until the head of the screw reaches the cortex of the bone (*the collar of the holder rests against the protective guide 12/10 and the holder detaches from the screw head*).

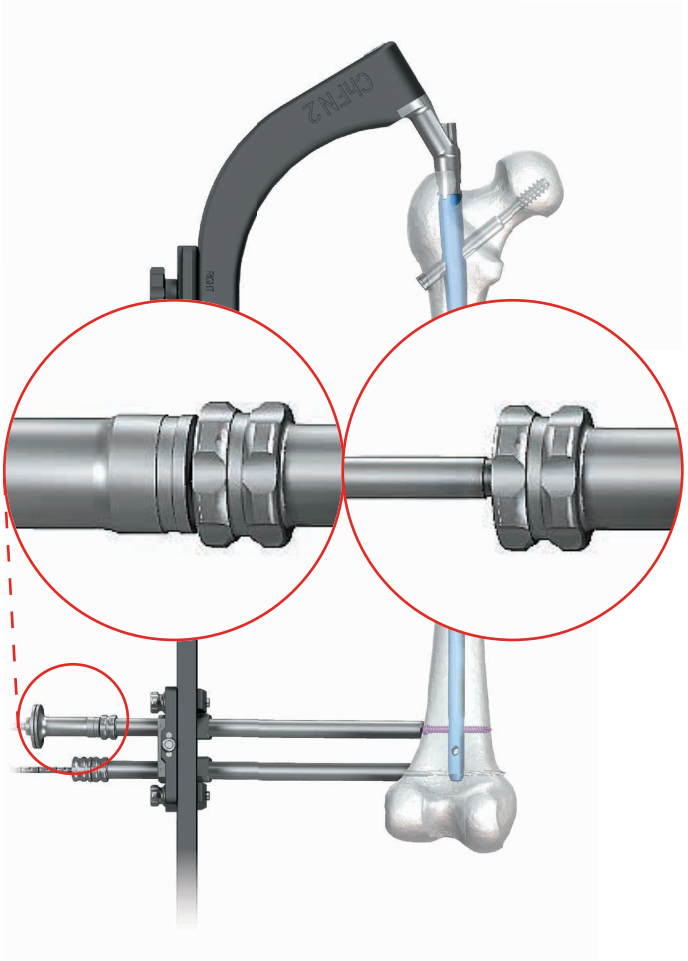
Remove the screwdriver and the protective guide.

Screw insertion should be controlled with X-Ray imaging.


40.6361


40.6353

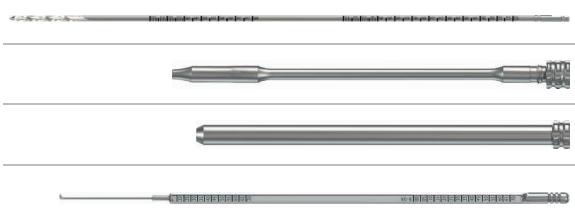
The distal screw can be inserted also using screwdriver T25 **[40.6361]** with the holder removed. When the groove on the screwdriver shaft matches the edge of protective guide 12/10 **[40.6353]**, the screw head reaches the cortex of the bone.

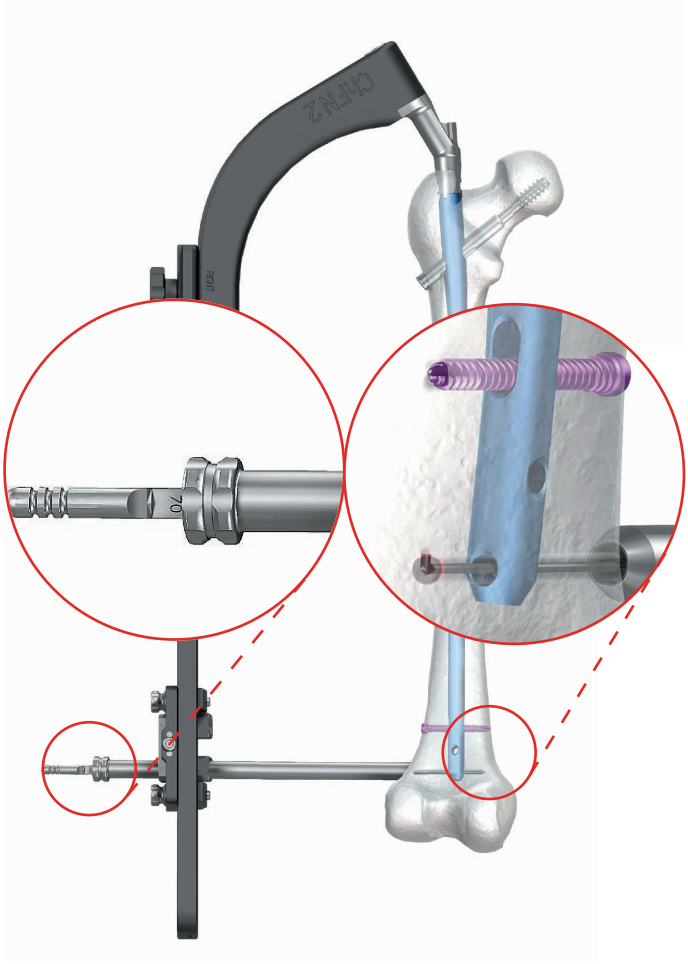


55 Remove drill with scale 4.0 **[40.5346.002]** and the drill guide 10/4.0 **[40.6362]** from the distal hole of the targeter. Leave the protective guide 12/10 **[40.6353]** in the targeter hole. Insert the screw length measure **[40.6358]** through the protective guide 12/10 **[40.6353]** into drilled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

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

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

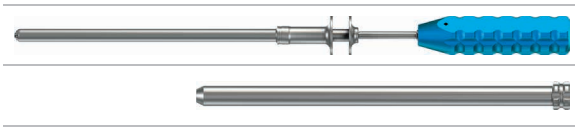


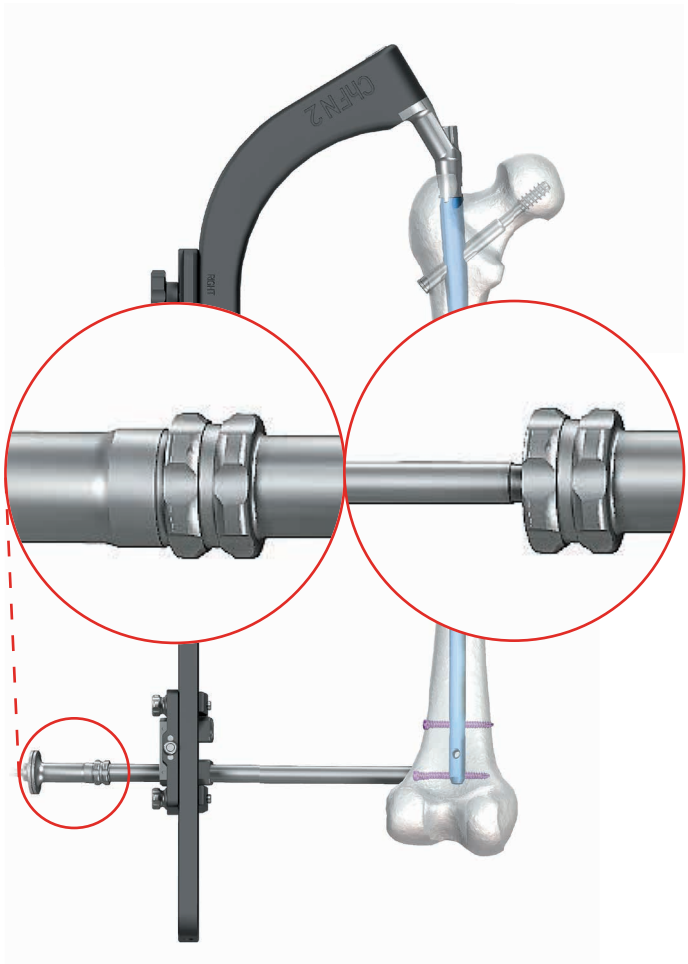


56 Insert the tip of the screwdriver T25 with holder **[40.6361]** into the socket of selected distal screw. Slide the holder on the screw head. Then advance both into the protective guide 12/10 **[40.6353]**.
Insert the distal screw in the prepared hole until the head of the screw reaches the cortex of the bone (*the collar of the holder rests against the protective guide 12/10 and the holder detaches from the screw head*).

Remove the screwdriver, protective guide and the distal targeter D.

Screw insertion should be controlled with X-Ray imaging.





The distal screw can be inserted also using screwdriver T25 **[40.6361]** with the holder removed. When the groove on the screwdriver shaft matches the edge of protective guide 12/10 **[40.6353]**, the screw head reaches the cortex of the bone.

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

40.5526.100

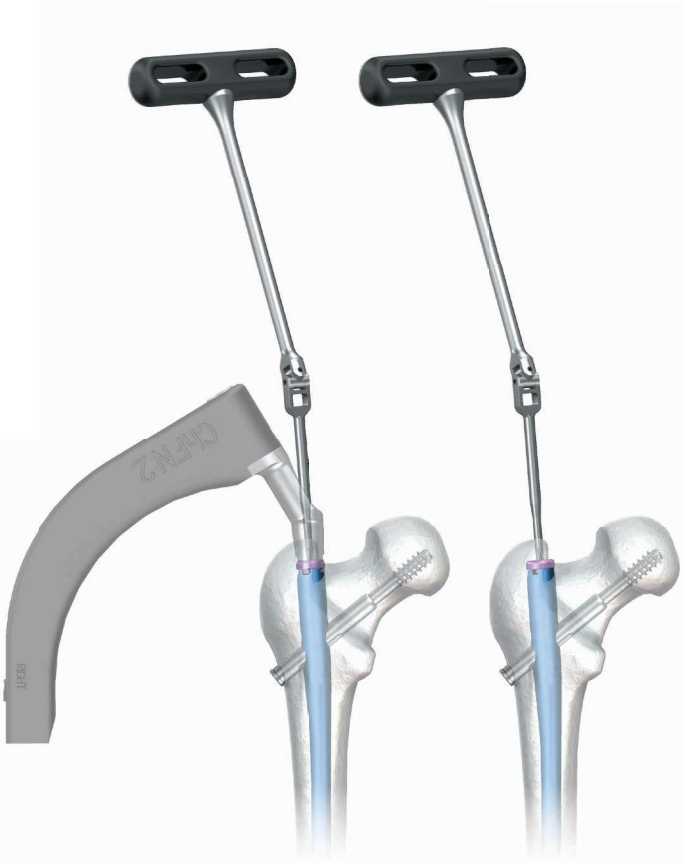
40.6305

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

End cap "*0*" [3.5161.600] may be inserted via the targeter arm [40.6341] after removing the connecting screw.

40.6320

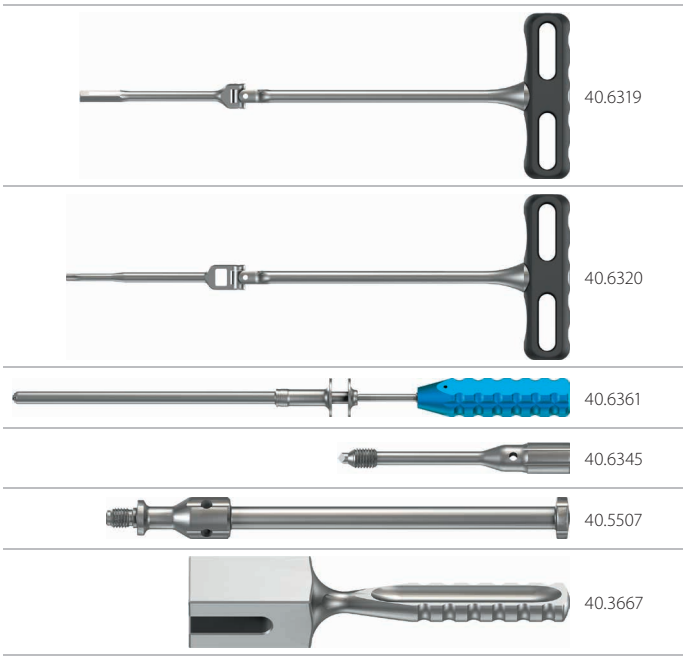
40.6341

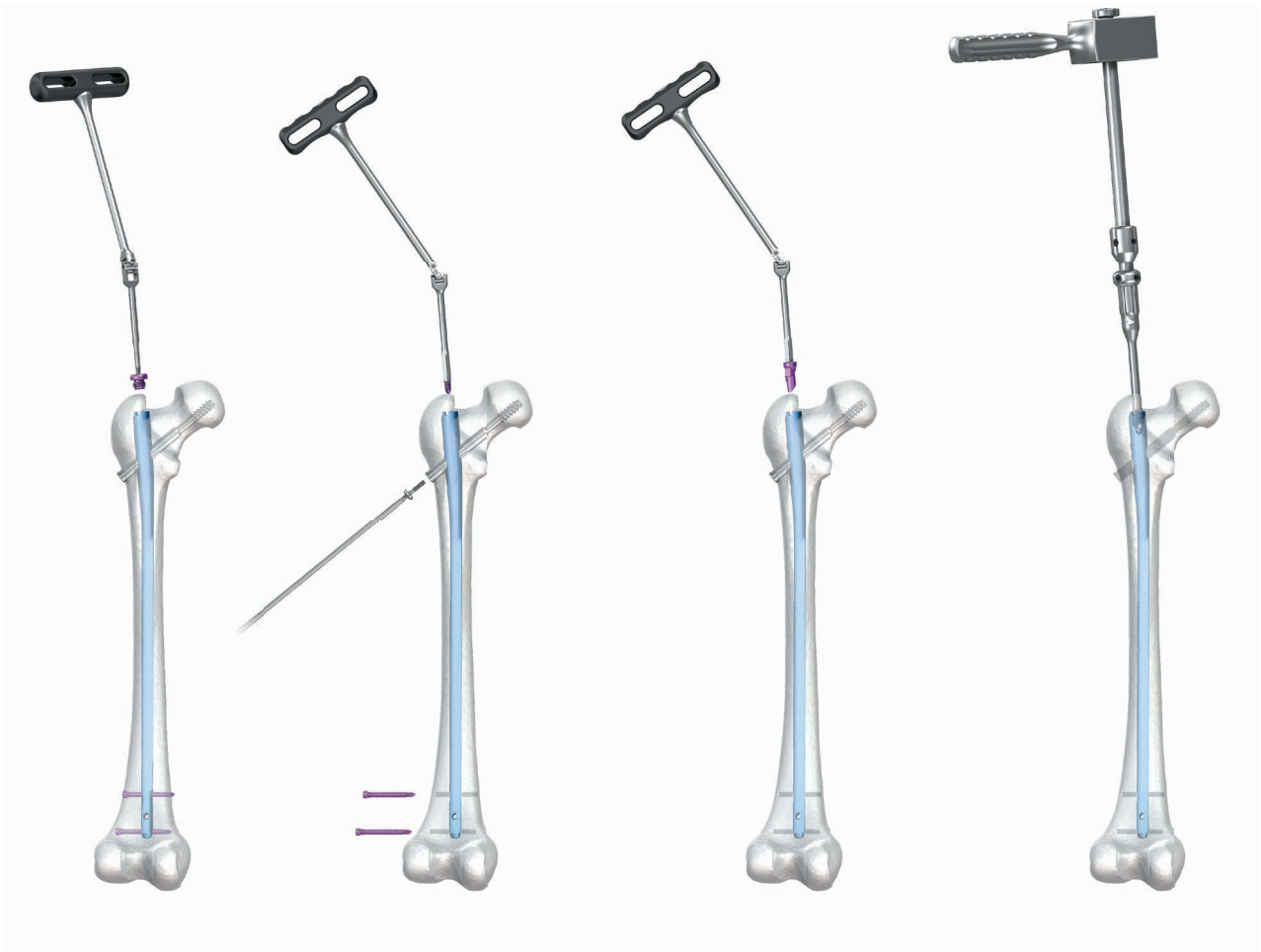


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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

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





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

V. INSTRUCTIONS FOR USE

GB

ChM®

CE 0197

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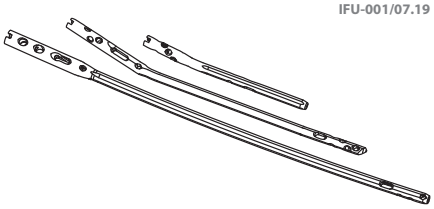
IFU-001/07.19



GB

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	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.
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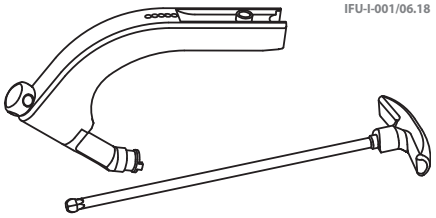

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INSTRUCTIONS FOR USE

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 unmagnifed 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**

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

	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
STERILE	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 envace 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	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

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