ST/34C

ChM®

CHARFIX system 2

INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR WITH ANATOMICAL FEMORAL NAILS

- *IMPLANTS*
- *INSTRUMENT SET 40.5500.500*
- *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
	Locking
	Cannulated
	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.

CHARFIX system 2

- a new system of intramedullary locking nails designed on the basis of existing **CHARFIX** system of **ChM** sp. z o.o,
- combines experience of **ChM** sp. z o.o with up-to-date, innovative design solutions in intramedullary osteosynthesis,
- enables complex supply of long bones fractures using methods of intramedullary static, dynamic, compression and reconstruction osteosynthesis.

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

CHARFIX system 2 – intramedullary osteosynthesis of femur with anatomical femoral nails, composes of:

- implants *(intramedullary nails, reconstruction screws, locking screws, compression screws and end caps)*,
- instruments for implantation and implants removal after finished treatment,
- instructions for Use.

CHARFIX system 2 – intramedullary osteosynthesis of femur with anatomical femoral nails enables, depending on femur fracture type, intramedullary fixation of its fragments with the following methods:

- reconstruction,
- compression,
- compression with intra-operative compression,
- dynamic,
- secondary dynamization *(dynamization of static fixation)*,
- static, using reconstruction screw,
- static.

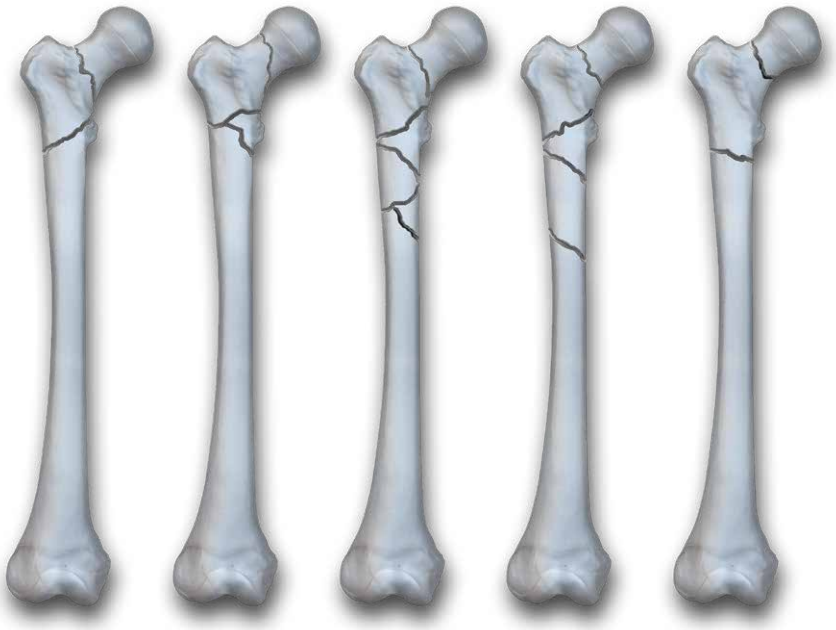
I. METHODS OF OSTEOSYNTHESIS USING ANATOMICAL FEMORAL NAILS

I.1. RECONSTRUCTION METHOD

Reconstruction method of locking the anatomical femoral nail is used in intramedullary osteosyntheses of proximal femur, in femoral neck and trochanteric fractures, also combined with femoral shaft fractures. As a result of angular positioning of reconstruction screws, anatomical positioning of femoral head and trochanteric region in relation to femoral shaft is obtained. Right and left version of the nail are used, accordingly for right and left extremity.

Reconstructive locking.

Examples of fractures treated with this method:

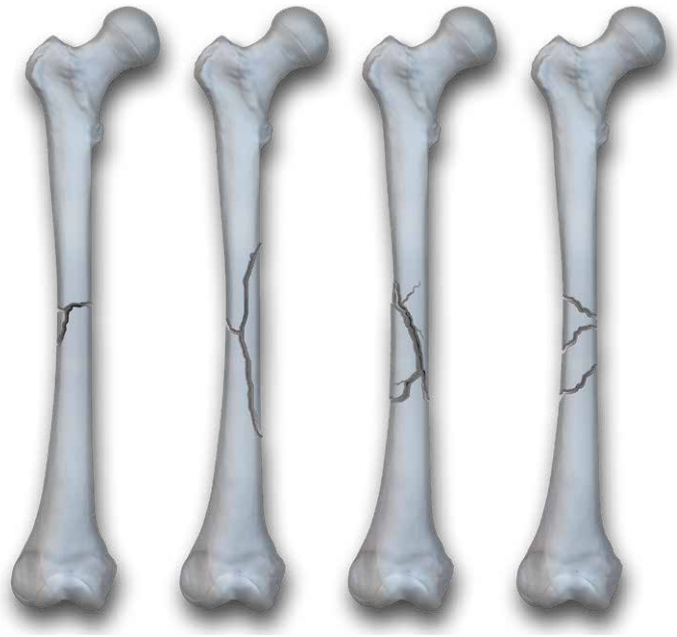


I.2. STATIC METHOD USING RECONSTRUCTION SCREW

Construction of anatomical femoral nail includes additional angular reconstruction hole directed to distal part of femur *(so-called* "antegrade") used in subtrochanteric static fixations of femoral shaft. This solution allows locking with static method using one screw in proximal part and performing only one incision in proximal part.

„Antegrade" locking.

Examples of fractures treated with this method:



I.3. COMPRESSION METHOD

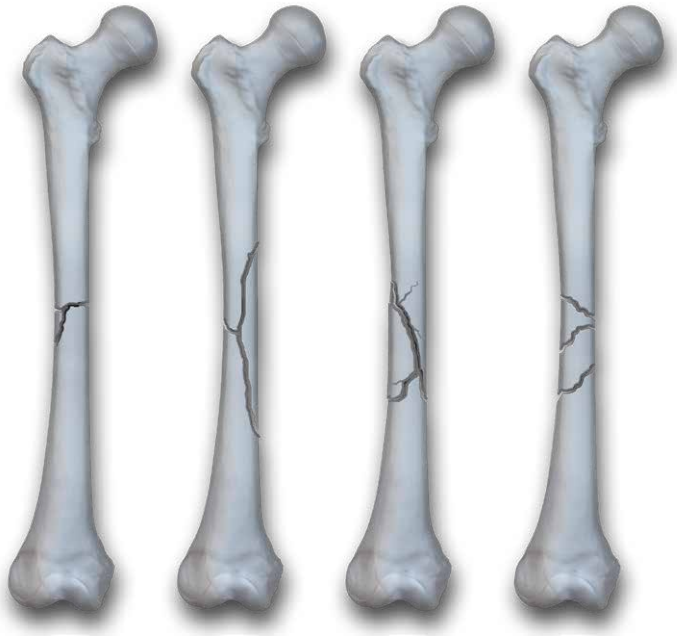
Compression of fragments can be performed with use of compression screw *(implant)*, or intraoperatively using compression screw *(instrument)*.

Anatomical femoral nail allows fragments compression through their movement along axis of the nail until their edges contact. Purpose of that procedure is to restore shape of the bone and stimulation of bone tissue growth in fracture site. It is necessary to use compression screw to obtain the compression.

Compression of fragments can be performed intraoperatively without disconnecting the targeter from the nail, which is necessary in classical compression method. This solution allows to obtain final static fixation through use of the intraoperative fragments compression, also reducing the operative time.

Compressive locking.

Examples of fractures treated with this method:

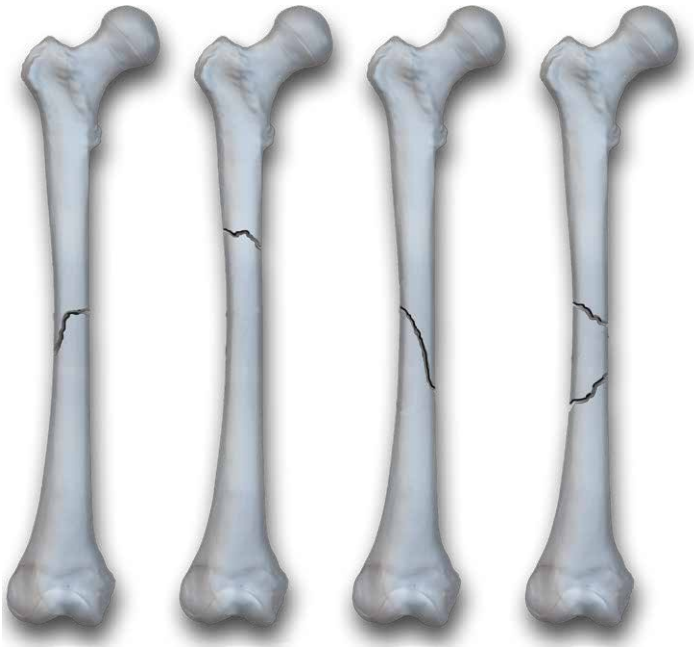


I.4. DYNAMIC METHOD

Locking the nail in proximal part in compression hole without compression allows for dynamic fixation of bone fragments. This solution is used in case, when continuous mobility of fragments is required for stimulation of ossification process.

Dynamic locking

Examples of fractures treated with this method:

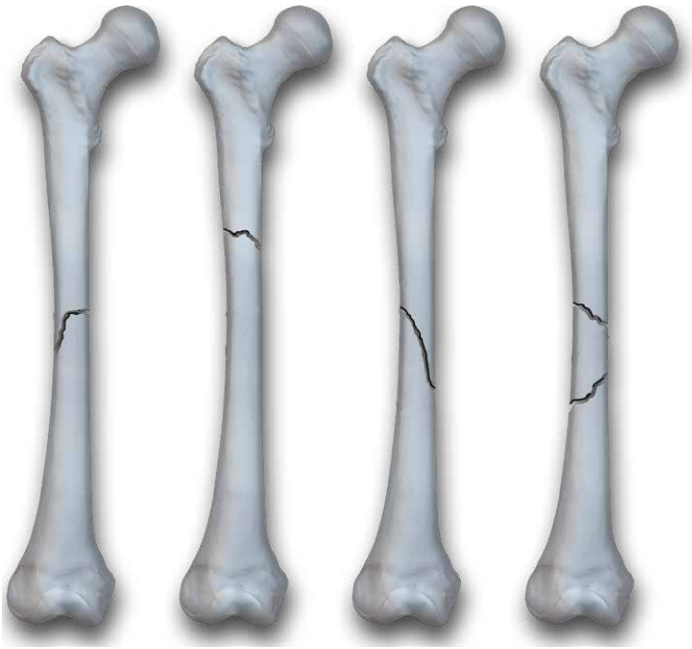


I.5. SECONDARY DYNAMIZATION METHOD

Construction of anatomical femoral nail includes possibility of static fixation dynamization through screw removal from static hole in distal part of the nail, and leaving one screw in compression hole. Dynamization procedure is performed when necessity for bone tissue stimulation occurs *(for example, non-union in fracture site)*.

Dynamization of static fixation.

Examples of fractures treated with this method:

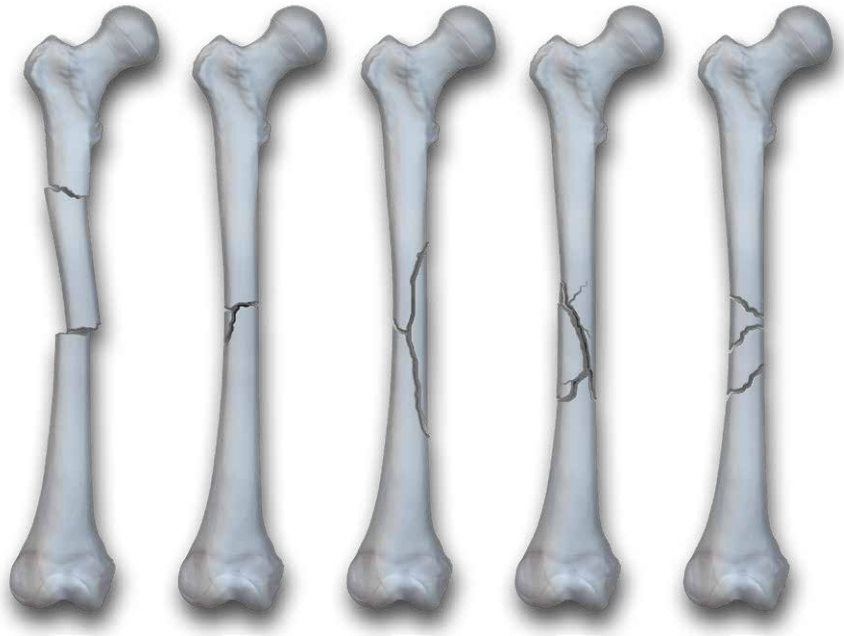


I.6. STATIC LOCKING

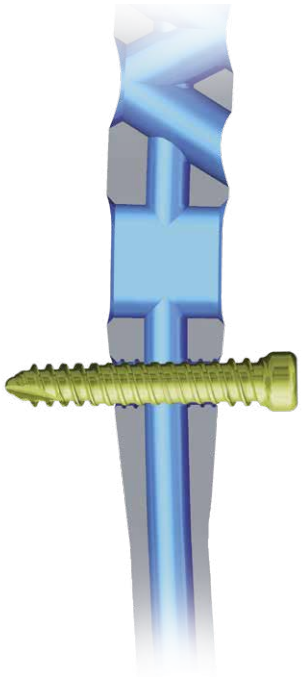
Static locking of the nail is used to eliminate or reduce the movements in bone-nail-screws system. Construction of the implant allows for multiplane locking in 5 holes in distal part and for locking with 1, 2 or 3 screws in proximal part.

Static locking.

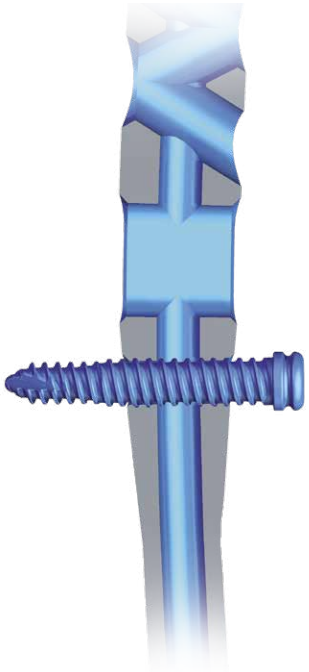
Examples of fractures treated with this method:

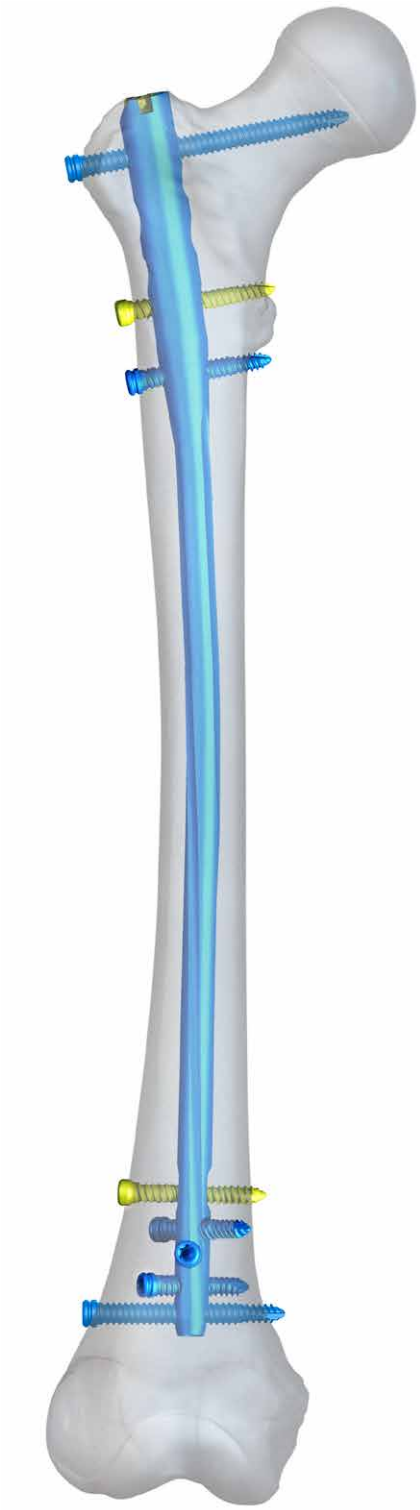


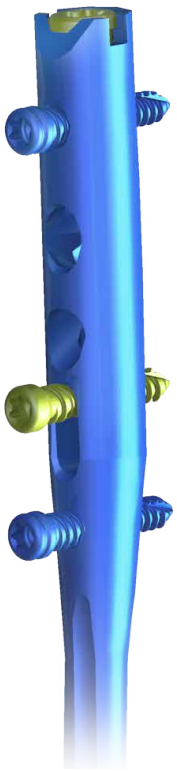
Threaded holes allow optional locking using:
- **CHARFIX2** Distal screw 5.0

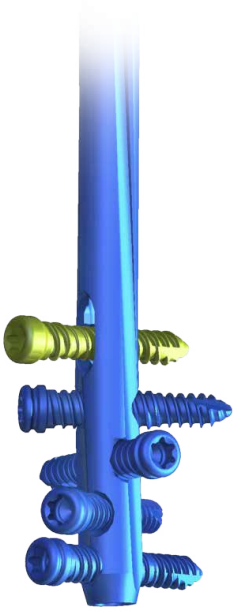


- **CHARFIX2** Distal screw 5.5 to prevent angular displacement of the bone fragments *(using threaded hole in the nail)*.





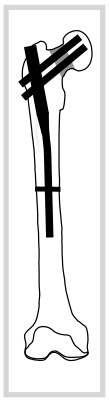


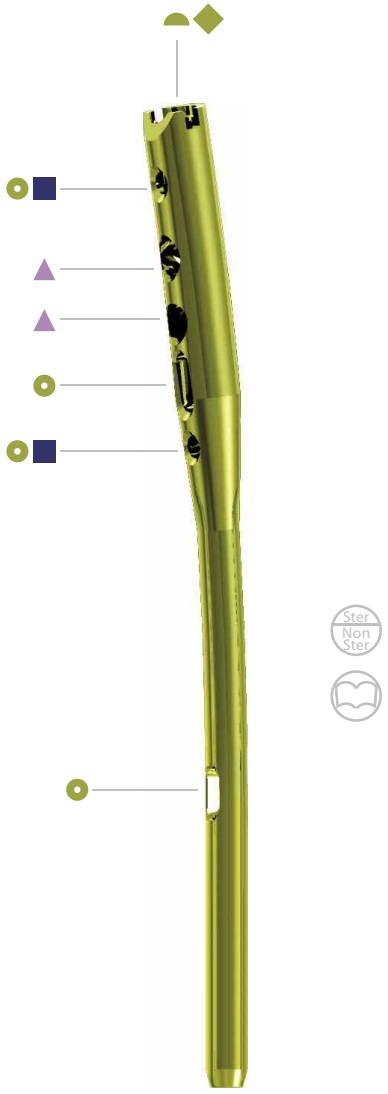


II. IMPLANTS

CHARFIX2 ANATOMICAL FEMORAL NAIL SHORT

CHARFIX system 2





	Len	Ti
10	180	3.5178.180
	200	3.5178.200
11	180	3.5179.180
	200	3.5179.200
12	180	3.5180.180
	200	3.5180.200

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

	Ti					
3.5168.xxx	✓		✓	7.5	50÷120	▲
3.5160.xxx	✓	✓		5.5	30÷90	■
3.5159.xxx	✓			5.0	30÷90	●
3.5162.000	✓					◗
3.5161.xxx	✓		✓		0÷15	◆

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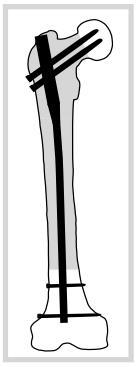
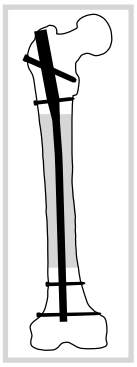
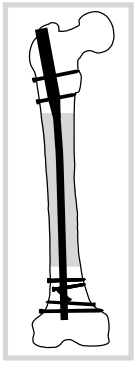
CHARFIX2 ANATOMICAL FEMORAL NAIL

CHARFIX system 2



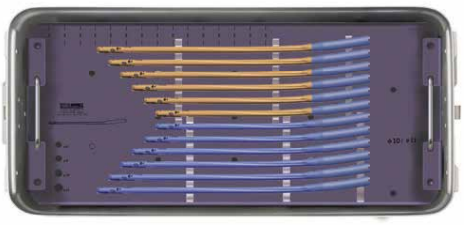




	Len	L	R
10	340	3.5105.340	3.5106.340
	360	3.5105.360	3.5106.360
	380	3.5105.380	3.5106.380
	400	3.5105.400	3.5106.400
	420	3.5105.420	3.5106.420
	440	3.5105.440	3.5106.440
	460	3.5105.460	3.5106.460
11	340	3.5107.340	3.5108.340
	360	3.5107.360	3.5108.360
	380	3.5107.380	3.5108.380
	400	3.5107.400	3.5108.400
	420	3.5107.420	3.5108.420
	440	3.5107.440	3.5108.440
	460	3.5107.460	3.5108.460
12	340	3.5109.340	3.5110.340
	360	3.5109.360	3.5110.360
	380	3.5109.380	3.5110.380
	400	3.5109.400	3.5110.400
	420	3.5109.420	3.5110.420
	440	3.5109.440	3.5110.440
	460	3.5109.460	3.5110.460

available	Ø	10 mm ÷14 mm	pitch	1 mm
	L	280 mm ÷ 600 mm		5 mm

	Ti					
3.5168.xxx	✓		✓	7.5	50÷120	▲
3.5160.xxx	✓	✓		5.5	30÷90	■
3.5159.xxx	✓			5.0	30÷90	●
3.5162.000	✓					◡
3.5161.xxx	✓		✓		0÷15	◆



Stand for anatomical femoral nails (set with a box without implants) 40.5752.000

LOCKING ELEMENTS

Ti Ster Non Ster

CHARFIX system 2

CHARFIX2 DISTAL SCREW 5.0

30	3.5159.030
35	3.5159.035
40	3.5159.040
45	3.5159.045
50	3.5159.050
55	3.5159.055
60	3.5159.060
65	3.5159.065
70	3.5159.070
75	3.5159.075
80	3.5159.080
85	3.5159.085
90	3.5159.090

16 ÷ 90

CHARFIX2 DISTAL SCREW 5.5

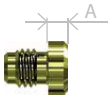
30	3.5160.030
35	3.5160.035
40	3.5160.040
45	3.5160.045
50	3.5160.050
55	3.5160.055
60	3.5160.060
65	3.5160.065
70	3.5160.070
75	3.5160.075
80	3.5160.080
85	3.5160.085
90	3.5160.090

16 ÷ 90

CHARFIX2 RECONSTRUCTION CANNULATED SCREW 7.5

50	3.5168.050
55	3.5168.055
60	3.5168.060
65	3.5168.065
70	3.5168.070
75	3.5168.075
80	3.5168.080
85	3.5168.085
90	3.5168.090
95	3.5168.095
100	3.5168.100
105	3.5168.105
110	3.5168.110
115	3.5168.115
120	3.5168.120

CHARFIX2 END CAP M10X1.5



A	
0	3.5161.700
+5	3.5161.705
+10	3.5161.710
+15	3.5161.715

CHARFIX2 COMPRESSION SCREW M10X1.5

	3.5162.000

Stand for CHARFIX2 nail locking elements (set with a box without implants) 40.5058.200

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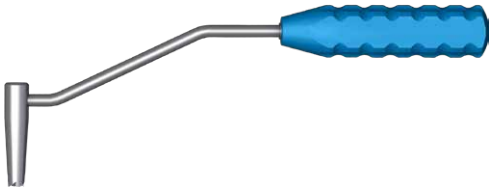
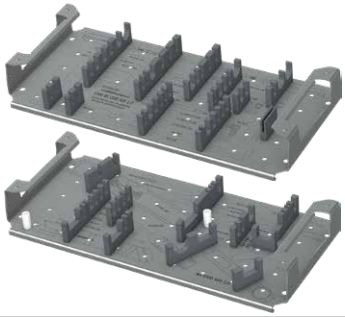
III. INSTRUMENT SET

Instrument set **[40.5500.500]** is used to perform fixation of bone fragments of trochanteric and shaft part of femur and to remove implants after finished treatment. Instruments that are part of the instrument set are placed on the stand and covered with its lid, so storage and transportation for operating suite is facilitated.

Instrument set consists of the following instruments:

INSTRUMENT SET FOR ANATOMICAL FEMORAL NAILS 40.5500.500	Name	Pcs	Catalogue No.
	Targeter arm	1	40.5501.000
	Targeter B	1	40.5502.100
	Targeter D	1	40.5503.300
	Connecting screw M10x1.5 L=53	1	40.5504.000
	Impactor-extractor	1	40.5507.000
	Guide 9/2.8	1	40.5508.200
	Set block 9/5.0	2	40.5509.100
	Trocar 9	1	40.3327.100
	Protective guide 11/9	2	40.3328.200
	Protective guide 9/7	2	40.5510.200
	Drill guide 7/3.5	1	40.5511.200
	Connector M10x1.5/M12	1	40.5512.000
	Gradual cannulated drill 7.5/2.8	1	40.5513.200
	Compression screw	1	40.5517.000
	Curved awl 8.0	1	40.5523.000
	Wrench S10	1	40.5526.100
	Guide rod handle	1	40.1351.000
	Screw length measure	1	40.5530.100
	Guide rod 2.8/385	4	40.5531.000
	Guide rod 3.0/580	1	40.3925.580
	Drill with scale 3.5/350	2	40.5339.002
	Nail length measure	1	40.4798.500

INSTRUMENT SET FOR ANATOMICAL FEMORAL NAILS 40.5500.500	Name	Pcs	Catalogue No.
	Cannulated screwdriver T30	1	40.5574.300
	Screwdriver T25	1	40.5575.400
	Targeter D	1	40.1344.100
	Drill guide short 7/3.5	2	40.1358.100
	Trocar short 7	1	40.1354.100
	Trocar 6.5	1	40.5534.100
	Cannulated screw length measure	1	40.4724.100
	Mallet	1	40.3667.000
	Teflon pipe guide	1	40.1348.000
	Aiming insert 9.0	2	40.5065.009
	Aiming insert 11.0	2	40.5065.011
	Protective guide 17/14	1	40.5518.100
	Cannulated drill 14/3,5	1	40.5515.100
	Perforated aluminum lid 1/1 595x275x15mm Gray	1	12.0750.200
	Stand for instr. set of anatomical femoral nails	1	40.5519.500
	Container with solid bottom 1/1 595x275x185mm	1	12.0750.103

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IV. SURGICAL TECHNIQUE

NOTE: The following description includes main steps of procedure during implantation of intramedullary anatomical femoral nails, however it does not comprise a detailed instruction of conduct. The surgeon decides on choosing the surgical technique and its application in every individual case.

IV.1. PLANNING THE PROCEDURE

Every surgical procedure should be properly planned. It is necessary to perform X-Ray imaging of whole femur with adjacent joints in ap and lateral plane as to avoid missing its damage in proximal and distal part. It is especially important while nailing the pathological fractures of subtrochanteric area.

Special attention should be paid to coexisting femoral neck fractures and comminuted fractures of proximal epiphysis of femur, and also to the possibility of their occurrence during nail insertion.

Further fragmentation of main fragments may occur during procedure. Dynamic fixation must be replaced with static fixation in such cases.

Attention should be also paid to hip joint condition. In serious arthrosis or contraction nailing can be very difficult, or even impossible.

Procedure should be performed on traction table with a patient positioned supine or in lateral position.

Advantage of lateral position is easier access to the greater trochanter which is especially important in obese patients. In supine position access to the greater trochanter is more difficult, however further phases of procedure *(especially correction of rotational displacement)* are definitely easier.

If a patient cannot be operated at the day of femur injury, it is recommended to retract the fragments through application of very strong traction for 2-3 days. This will facilitate further reduction and insertion of the nail significantly.

Patient positioning on operating table is an integral part of surgical procedure.
Intramedullary osteosynthesis with presented method requires intraoperative imaging.

IV.2. PATIENT POSITIONING

In presented method of intramedullary osteosynthesis of femur with anatomical femoral nail, a supine patient position is recommended [Fig.1.]. To increase access to greater trochanter, the patient's body shall be bent in the opposite direction to fracture. If the access is still insufficient, the fractured leg shall be adducted. The limb adduction shall be reduce before the nail implantation, in order to obtain adequate fragments' position.

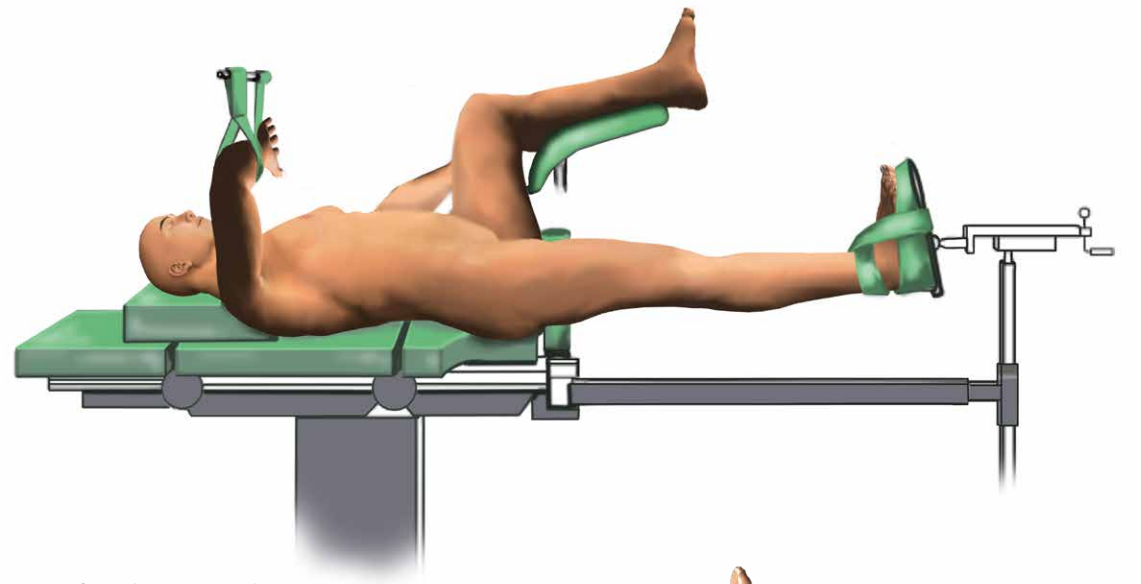
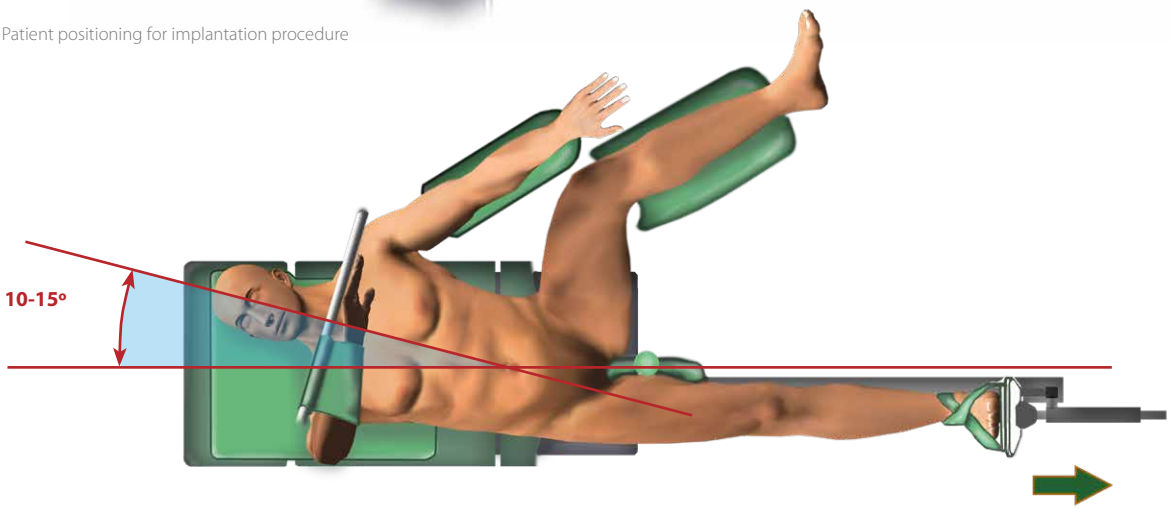


Fig. 1. Patient positioning for implantation procedure



IV.3. REDUCTION OF FRACTURE

Fracture reduction should be performed before implantation, according to surgical technique adequate for fracture being reduced.

Orthopedic surgeon decides on fragments reduction method. It is recommended to aim at anatomical positioning of fragments during repositioning.

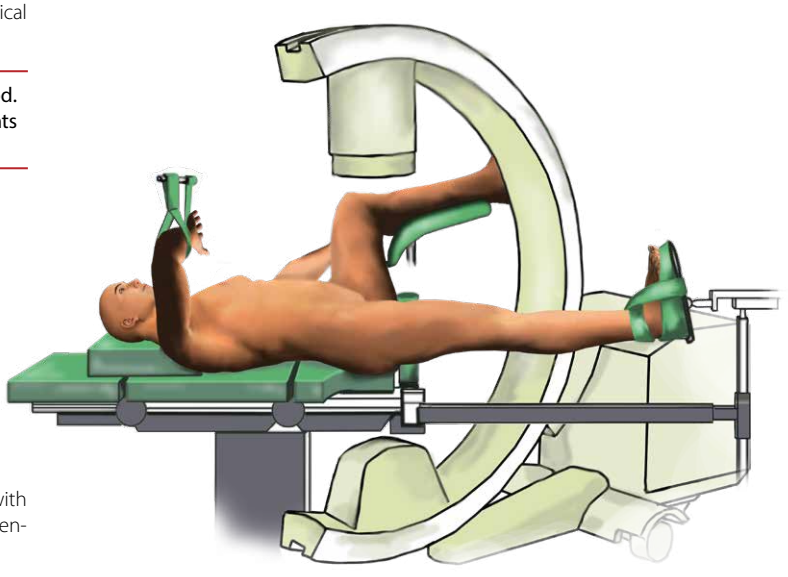


Fig. 2. Positioning of intraoperative X-Ray unit with C-arm

IV.4. SURGICAL APPROACH

The procedure can be performed with use of intraoperative image intensifier with C-arm. C-arm of X-Ray unit should be placed laterally to the patient, in a way ensuring precise imaging in AP and lateral position [Fig. 2.].

Watson-Jones lateral approach is recommended. Palpate the greater trochanter. Then, perform 3÷5 cm lateral incision at the distance of 2÷6 cm from tip of the greater trochanter, in line with medullary canal axis [Fig. 3.]. The incision should be extended 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.

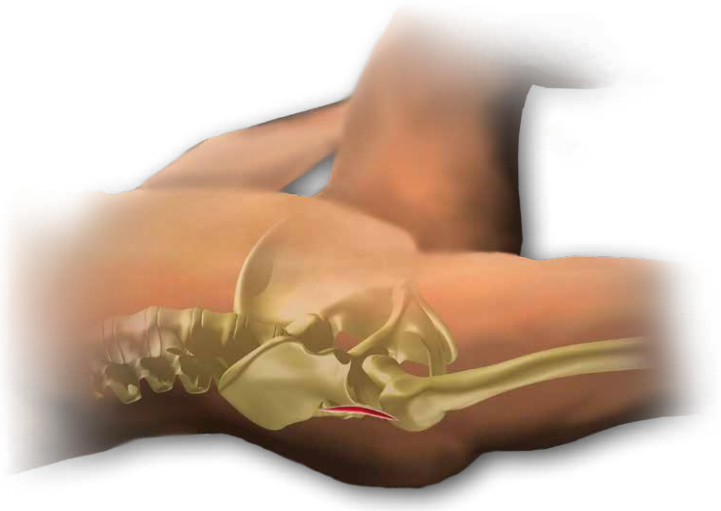
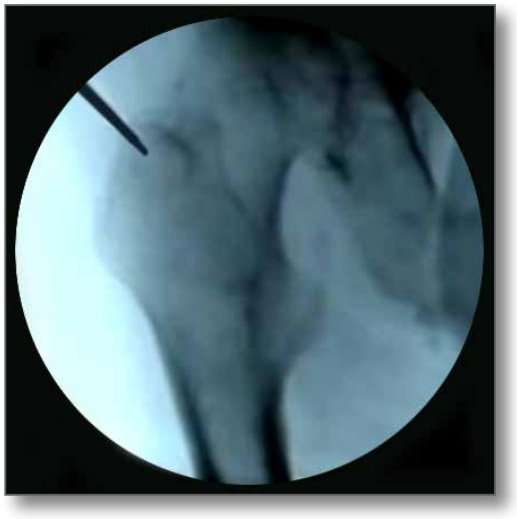


Fig.3. Determination of incision site

IV.5. ENTRY POINT

In AP plane, entry point is located at line angled from medullary canal axis of about 10º, at level of fossa trochanterica. In lateral plane, entry point is in line with the axis of the medullary canal [Fig. 4.].
Having localized the nail entry point, using the drive, insert the guide rod 2.8/385 **[40.5531]** into the medullary canal. Precise guide rod introduction ensures proper nail implantation.
The surgeon determines length and diameter of the nail
on the basis of injured femur X-Ray and X-Ray of opposite intact femur.

40.5531



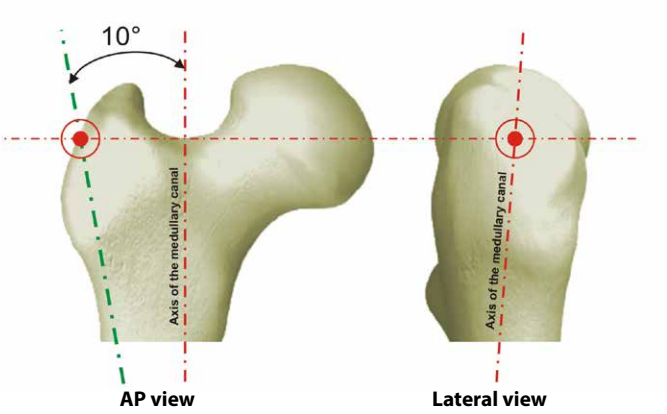


Fig. 4. Entry point

IV.6. OPENING AND PREPARATION OF MEDULLARY CANAL AND NAIL INSERTION

IV.6.1. Opening and preparation of medullary canal for nail insertion

1 Using guide rod 2.8/385 **[40.5531]**, insert into the medullary canal curved awl 8.0 **[40.5523]** to the depth at which the awl blade goes along the medullary canal, allowing proper insertion of guide rod 3.0/580 **[40.3925.580]**.
Having opened medullary canal, remove guide rod 2.8/385 **[40.5531]**.
Mount guide rod 3.0/580 **[40.3925.580]** to guide rod handle **[40.1351]** 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.


40.5531


40.5523

40.3925.580


40.1351

2 Remove guide rod handle **[40.1351]** and curved awl 8.0 **[40.5523]**. Leave guide rod 3.0/580 **[40.3925.580]** in place.
Open the medullary canal using cannulated drill 14/3.5 **[40.5515.100]** inserted into protective guide 17/14 **[40.5518.100]** via guide rod 3.0/580 **[40.3925.580]**.
Slowly ream the medullary canal using cannullated drill until it rests on the protective guide.
Remove protective guide, cannullated drill.


The process shall be controlled with X-Ray.


40.1351


40.5523

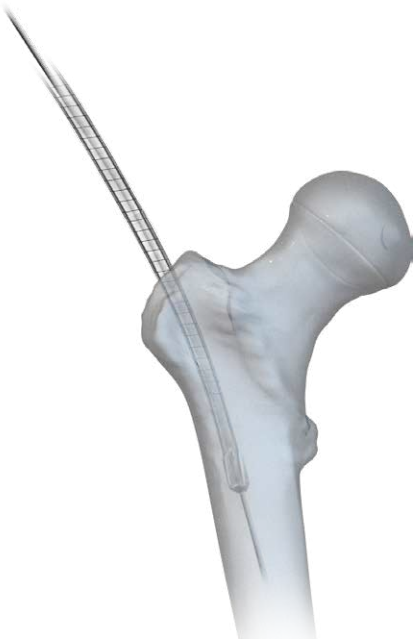
40.3925.580


40.5515.100


40.5518.100

3 In case nail implantation is preceded with reaming the intramedullary canal, the canal should be gradually enlarged with flexible reamers guided over the guide rod 3.0/580 **[40.3925.580]**. Reaming should begin with Ø8 mm reamer and should continue with 0.5 mm diameter graduation until a hole 1.5÷2 mm greater than nail diameter, with depth not lesser than nail length is achieved.
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 15 mm to a depth of about 9 cm.
Remove flexible reamer.

40.3925.580



In case of using a reamer guide *(guide rod)* other than the one included in the instrument set **[40.5500.500]**, use the teflon pipe guide **[40.1348]** *(white teflon pipe)* to ream the intramedullary canal and follow the steps of given instruction.

4 Introduce the teflon pipe guide **[40.1348]** over the flexible reamer guide *(guide rod)* deep into the medullary canal, until the end of reamed canal in distal part of femur is reached.

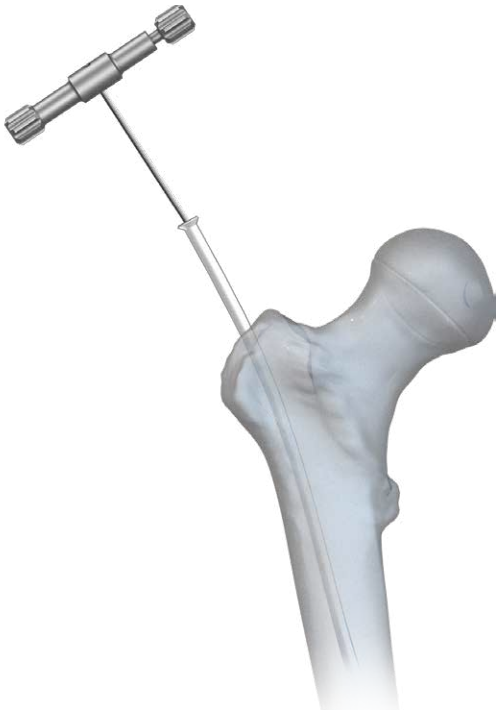
Remove the flexible reamer guide *(guide rod)*.

Mount the guide rod 3.0/580 **[40.3925.580]** in guide rod handle **[40.1351]** and introduce entire construction into the medullary canal, through the teflon pipe guide, until the end of reamed canal in distal part of femur is reached.
Detach the guide rod handle **[40.1351]** of the guide rod.
Remove the teflon pipe guide **[40.1348]** from the medullary canal, leave the guide rod.

40.1348

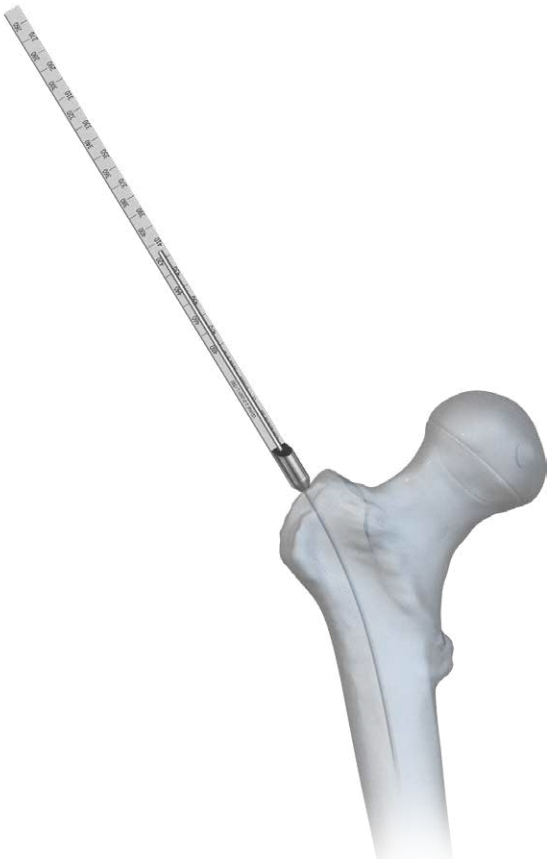
40.3925.580


40.1351



5 Introduce the nail length measure **[40.4798.500]** via the guide rod until it reaches the bone. Read the nail length from the scale. Remove the nail length measure from the guide rod. The medullary canal is prepared for nail insertion.

40.4798.500



IV.6.2. Connecting the nail with targeter arm and determination of targeter D slider position

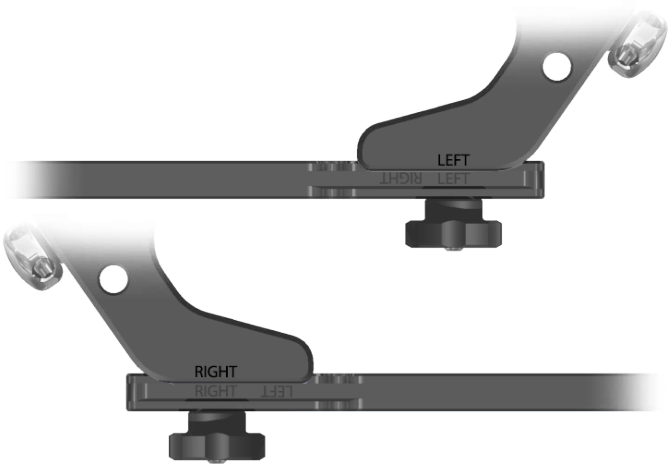
Targeter D **[40.5503.300]** cannot be used with short anatomical femoral nails. In this case, step 6.2 shall be omitted.

6 Targeter D **[40.5503.300]** has a targeting slider and a screw for targeter arm **[40.5501]** attachment, reversed regarding operating site before attaching targeter arm.

If both targeters are connected correctly, the reading planes of RIGHT or LEFT sign should be compatible.

40.5503.300

40.5501

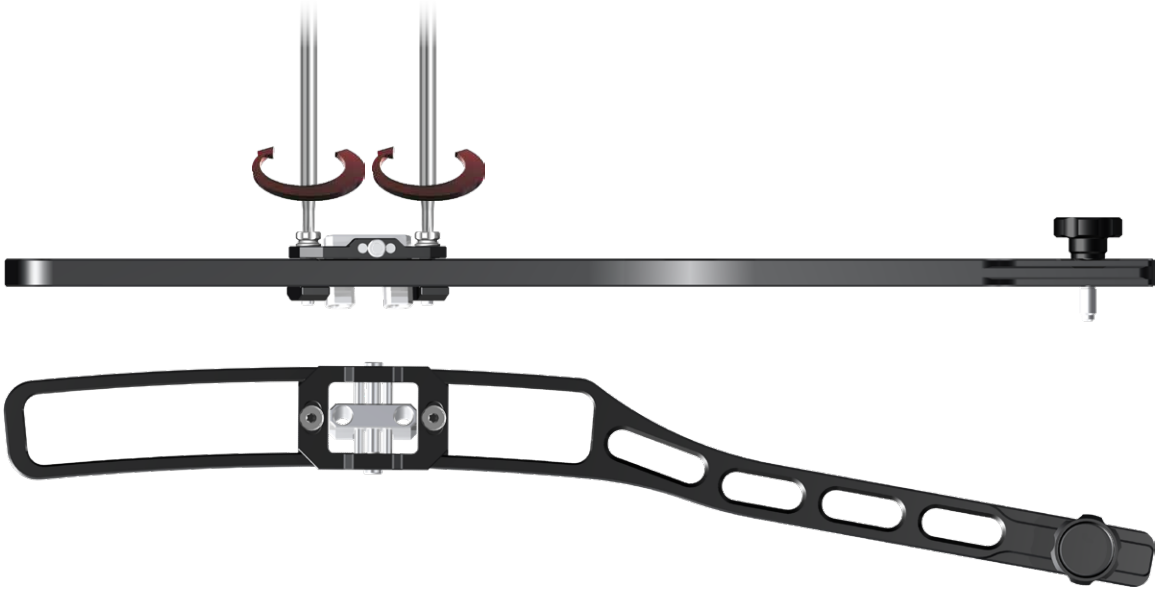


7

NOTE! The screw joining targeter D with targeter arm shall always be placed outside the targeter *(in relation to the nail)*. In order to reverse the screw, pull the knob, what will result in system decoupling. Then the screw should be reversed for suitable site and pressed into the targeter hole. Specific *"click"* determines correct system connection. Slider of targeter D should be always placed in such a way as to make its fixation possible at external site *(in relation to the nail)* using T25 screwdriver. Moreover, the setting of the screw knob should always be directed upward.

40.5503.300

40.5501



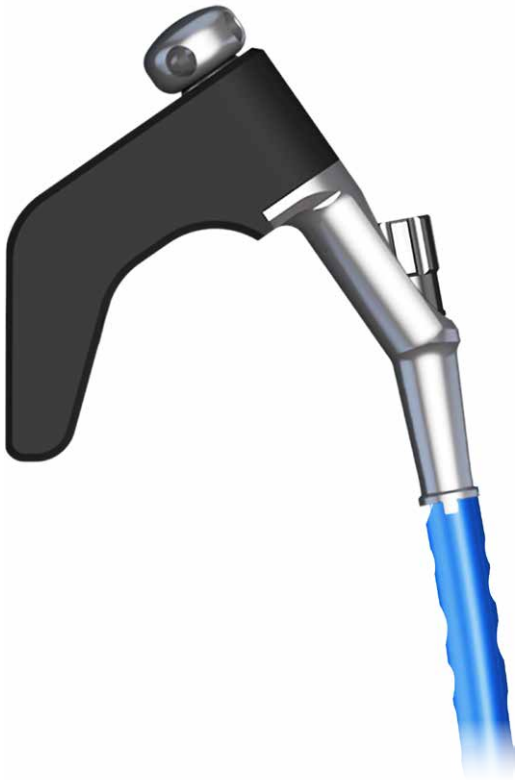
8 Mount the selected nail to the targeter arm **[40.5501]** using connecting screw M10x1.5 L=55 **[40.5504]** inserted by wrench S10 **[40.5526.100]**. Attach the targeter D **[40.5503.300]** to the targeter arm, in accordance with steps 6 and 7.


40.5504


40.5501


40.5526.100


40.5503.300

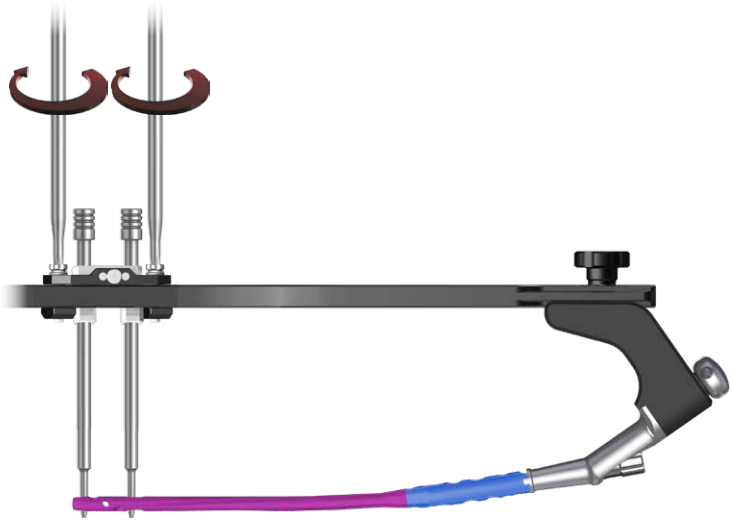


9 Loosen the slider's setting screws *(in order to allow movement of the slider along the targeter D beam)* and shift the slider close to the holes in distal part of the nail.


40.5503.300

10 Set the correct slider position in relation to the holes in distal part of the nail using two set blocks 9/5.0 **[40.5509.100]**.
Fix slider position using the screwdriver T25 **[40.5575.400]**.

Check: slider is set and fixed correctly if the set blocks hit smoothly in the holes of the nail.



Remove the set blocks from the targeter slider.
Detach the targeter D of the targeter arm.


40.5503.300


40.5509.100


40.5575.400

IV.6.3. Nail insertion into the medullary canal

11 Join the targeter arm **[40.5501]** with impactor-extractor **[40.5507]**.

NOTE! In order to connect targeter arm with impactor-extractor, remove the mallet screw from the targeter arm.

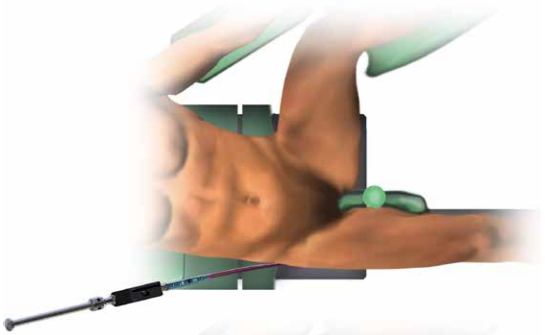
Position the system in plane perpendicular to the AP plane and introduce the nail into the medullary canal using mallet **[40.3667]**. While introducing, the nail rotates and moves along the medullary canal. In the end phase of insertion, targeter arm rotates with the nail at 90º from the initial position.


40.5501


40.5507


40.3667

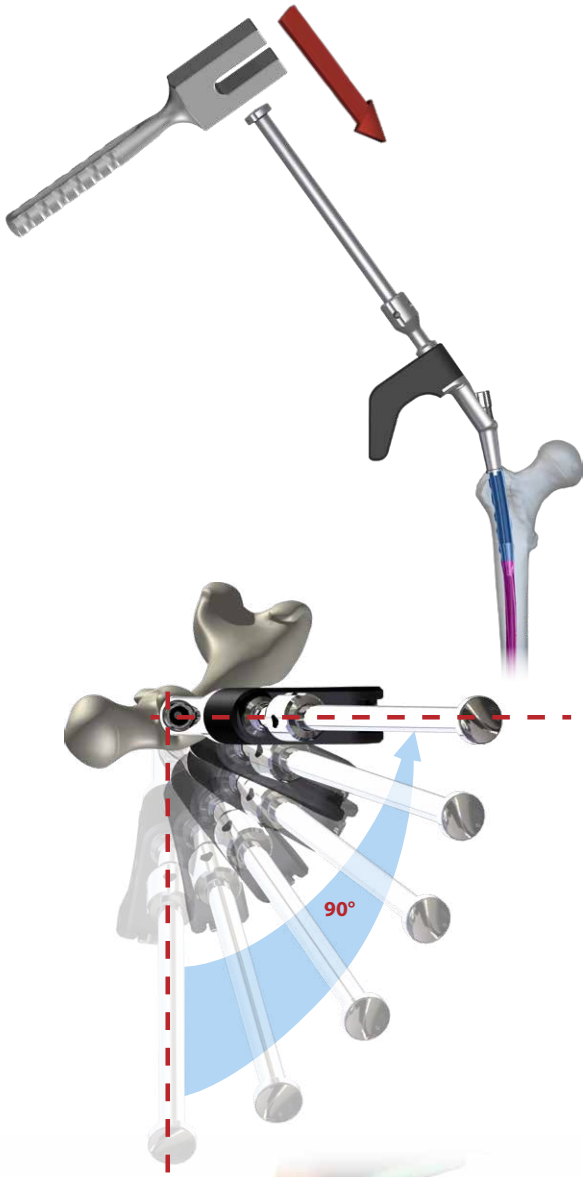
NOTE! If the nail did not move from anterior to lateral position, then it should be removed from medullary canal and reinserted, with targeter rotated a few degrees laterally in relation to AP plane.

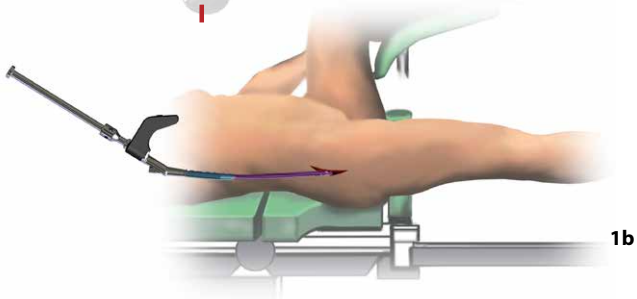

1a

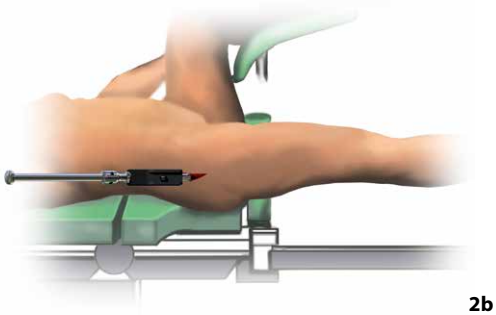

2a

Remove the guide rod **[40.3925.580]**.
Detach the impactor-extractor **[40.5507]** of the targeter arm **[40.5501]**.

40.3925.580

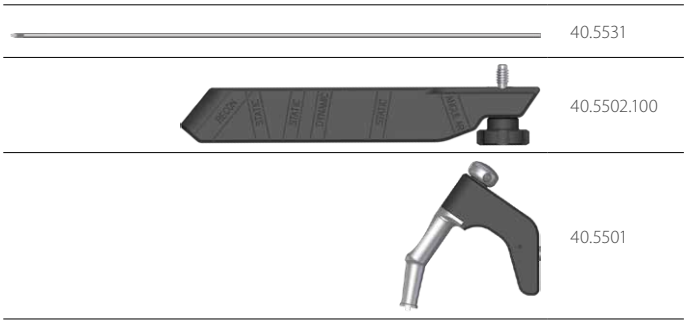


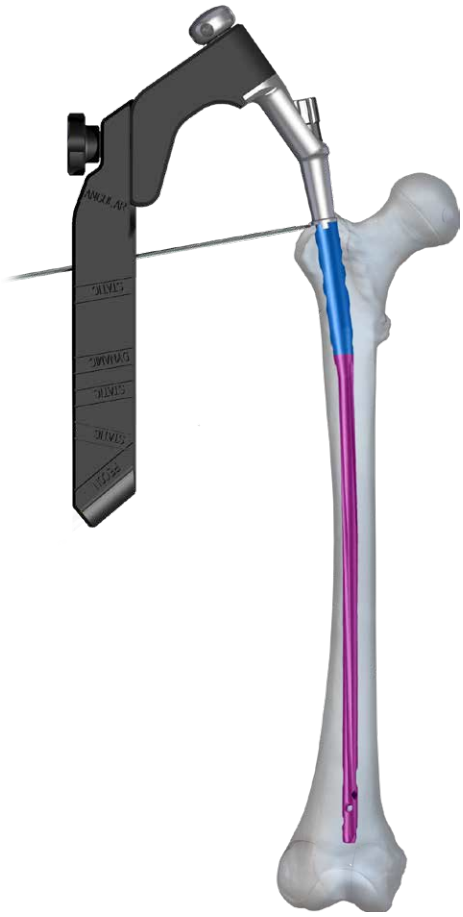

1b


2b

12 Correctness of nail penetration inside femur can be checked using guide rod 2.8/385 **[40.5531]** introduced in targeter B **[40.5502.100]** hole marked *"0"*.

Attach targeter B **[40.5502.100]** to the targeter arm **[40.5501]**, then introduce guide rod 2.8/385 **[40.5531]** in hole marked *"0"*. End of the rod will point the proximal end of the nail. If necessity of deeper nail insertion occurs, the depth of insertion can be determined using other holes prepared for guide rods *(introducing guide rods in holes marked "5" ÷ "15" and taking the X-Ray)*. Then select the suitable height of the end cap in order to protect the nail against bone overgrowth.





IV.7. LOCKING THE NAIL

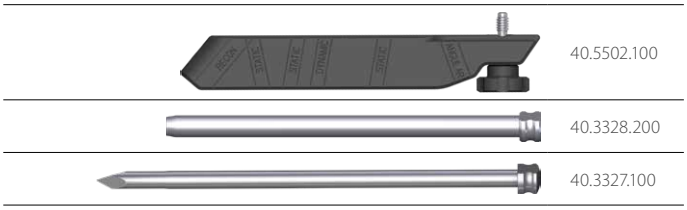
IV.7.1. Reconstruction method

IV.7.1.1. Locking the nail with reconstruction cannulated screws in proximal part

NOTE! In reconstruction method the nail should be always locked with two reconstruction screws.

13 Introduce protective guide 11/9 **[40.3328.200]** together with trocar 9 **[40.3327.100]** in the most distal reconstruction *(RECON)* hole of targeter B **[40.5502.100]**.
After marking the screw's entry point on the skin, perform incision of soft tissues. Trocar should penetrate to the cortex and mark the entry point for the drill.
The protective guide should penetrate together with the trocar until reaching the bone.

Remove the trocar.
Leave the protective guide inside the targeter hole.



14 Introduce guide 9/2.8 **[40.5508.200]** into protective guide **[40.3328.200]**.
Mount the guide rod 2.8/385 **[40.5531]** in the drive.
Drill in the femoral neck with guide rod led in guide 9/2.8, so as not to perforate the cortex of femoral neck and head.

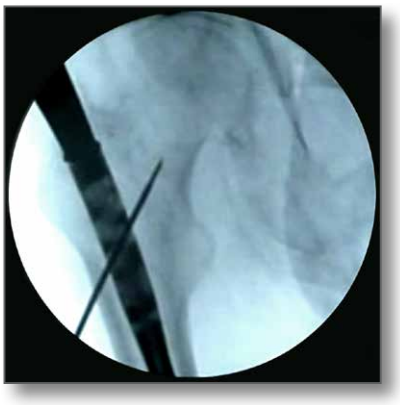

40.3328.200


40.5508.200

40.5531


NOTE! Described operations should be performed under the X-Ray image intensifier control in AP projection. Check the guide rod position in femoral neck in lateral projection. Its position should ensure reconstruction screw introduction without femoral neck cortex infringement.
Repeat the operation should the incorrect guide rod introduction occur.

Leave the guide rod 2.8/385, guide 9/2.8 and protective guide 11/9 in the targeter hole.



15 Introduce cannulated screw length measure **[40.4724.100]** onto guide rod introduced in femoral neck, in way that its tapered end contact with protective guide. Read length of reconstruction cannulated screw from the measure's scale, that is pointed by end of guide rod. Guide 9/2.8 **[40.5508.200]** should be in contact with cortical bone during the measurement.

Remove the cannulated screw length measure **[40.4724.100]** and guide 9/2.8 **[40.5508.200]**.
Leave the guide rod.

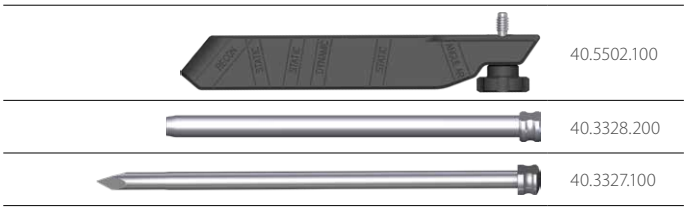
40.5531

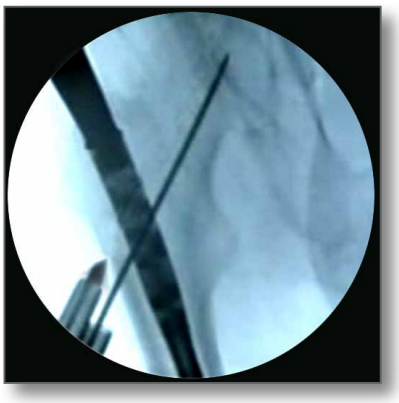

40.4724.100

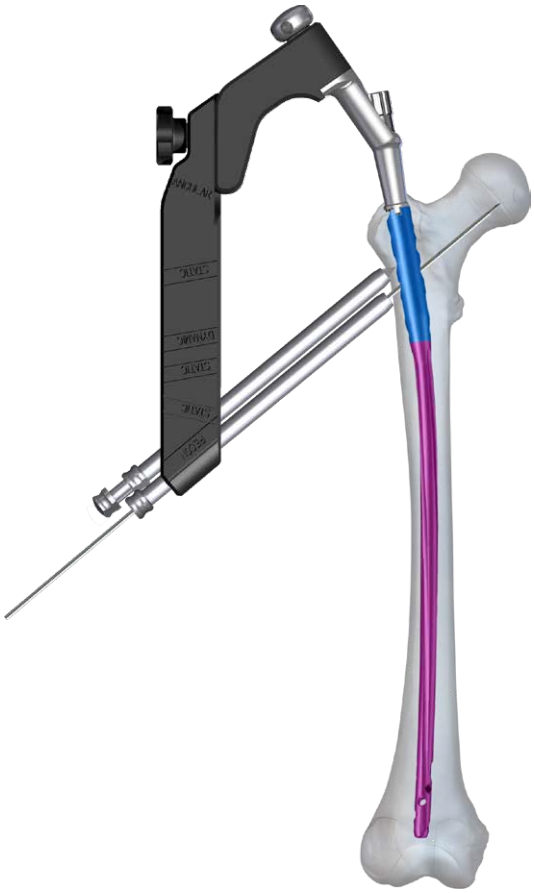

40.5508.200

16 Introduce protective guide 11/9 **[40.3328.200]** together with trocar 9 **[40.3327.100]** in proximal reconstruction *(RECON)* hole of targeter B **[40.5502.100]**.
After marking the screw's entry point on the skin, perform incision of soft tissues. Trocar should penetrate to the cortex and mark the entry point for the drill.
The protective guide should penetrate together with the trocar until contact with the bone occures.

Remove the trocar.
Leave the protective guide inside the targeter hole.



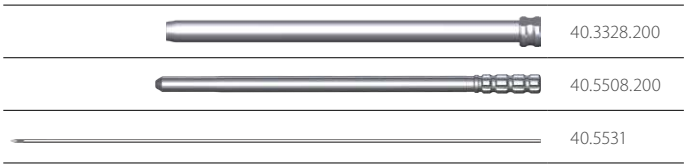


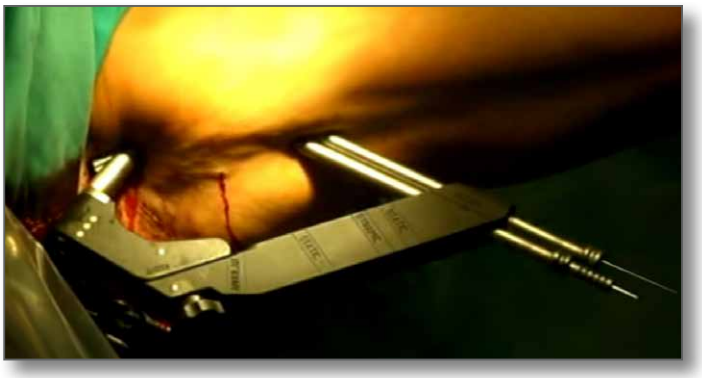


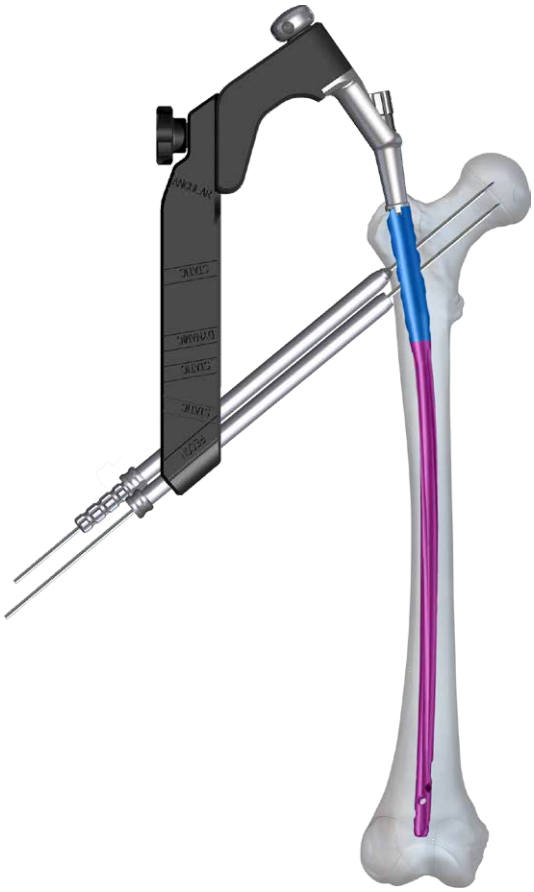
17 Introduce guide 9/2.8 **[40.5508.200]** into protective guide **[40.3328.200]**.
Mount the guide rod 2.8/385 **[40.5531]** in the drive.
Drill in the femoral neck with guide rod led in guide 9/2.8, so as not to perforate the cortex of femoral neck and head.

Described operations should be performed under the X-Ray image intensifier control in AP projection. Check the guide rod position in femoral neck in lateral projection. Its position should ensure reconstructive screw introduction without femoral neck cortex infringement.
Repeat the operation in the case of incorrect guide rod introduction.

Leave the guide rod 2.8/385, guide 9/2.8 and protective guide 11/9 in targeter hole.







18 Introduce cannulated screw length measure **[40.4724.100]** onto guide rod introduced in femoral neck, in way that its tapered end contact with the protective guide. Read length of reconstruction cannulated screw from the measure's scale, that is pointed by end of guide rod. Guide 9/2.8 **[40.5508.200]** should be in contact with cortical bone during the measurement.

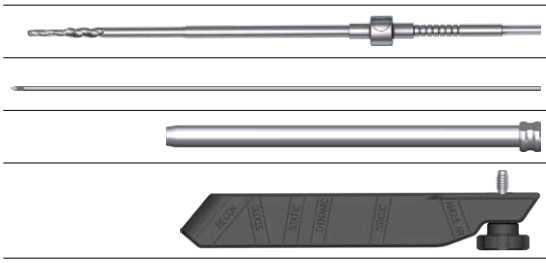
Remove the cannulated screw length measure **[40.4724.100]** and guide 9/2.8 **[40.5508.200]**.
Leave the guide rod.

40.5531
40.4724.100
40.3328.200
40.5508.200

19 Set the drilling depth, corresponding with length of selected reconstruction screw, on the gradual cannulated drill 7.5/2.8 **[40.5513.200]** using setting slider. Mount the gradual cannulated drill in the drive, then drill the hole until slider set on the drill leans against protective guide **[40.3328.200]**, leading the drill over the guide rod and inside the protective guide **[40.3328.200]** *(located in distal hole of the targeter)*.

Hole drilling should be performed under the X-Ray image intensifier control.

Remove the gradual cannulated drill.
Leave the protective guide and guide rod inside the targeter hole.



40.5513.200
40.5531
40.3328.200
40.5502.100

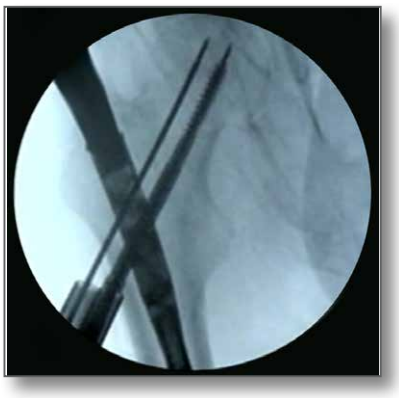
20 Insert the tip of cannulated screwdriver T30 **[40.5574.300]** into the head of reconstruction cannulated screw with selected length *(set on the gradual cannulated drill using setting slider or from measurement with cannulated screw length measure)*. Insert the set in protective guide **[40.3328.200]** and leading over the guide rod 2.8/385 **[40.5531]** drive in previously performed hole in femoral neck until the screw's head reaches the cortex *(groove on the screwdriver's shaft meets with end of the protective guide)*.

Remove the cannulated screwdriver and guide rod from distal hole of the targeter. Guide rod 2.8/385 **[40.5531]** is a single use instrument.


40.5574.300


40.3328.200

40.5531



21 Set the drilling depth, corresponding with length of selected reconstruction screw, on the gradual cannulated drill 7.5/2.8 **[40.5513.200]** using setting slider. Mount the gradual cannulated drill in the drive, then drill the hole until slider set on the drill leans against protective guide **[40.3328.200]**, leading the drill over the guide rod and inside the protective guide **[40.3328.200]** *(located in proximal hole of the targeter)*.

Hole drilling should be performed under the X-Ray image intensifier control.

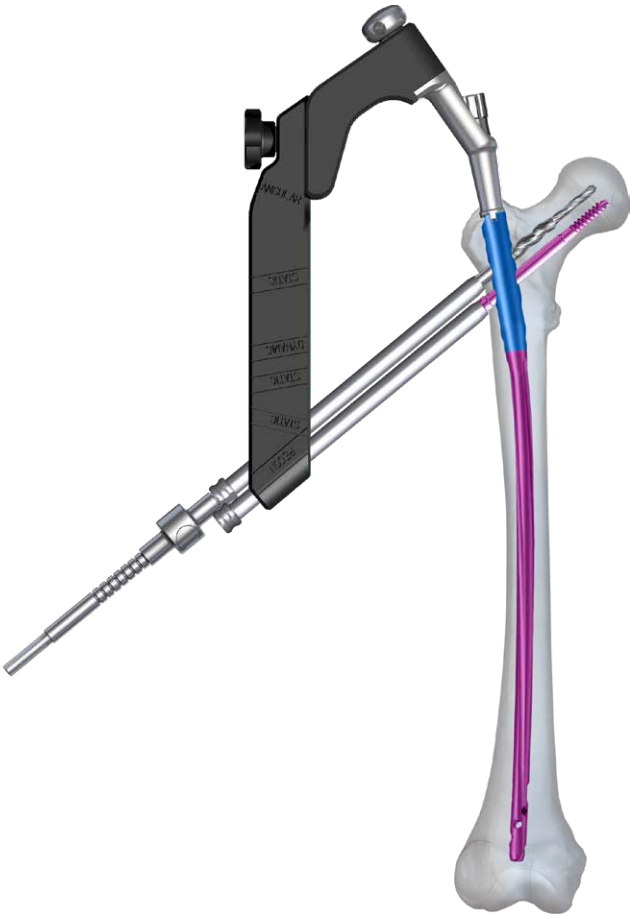
Remove the gradual cannulated drill.
Leave the protective guide and guide rod inside the target's hole.


40.5513.200

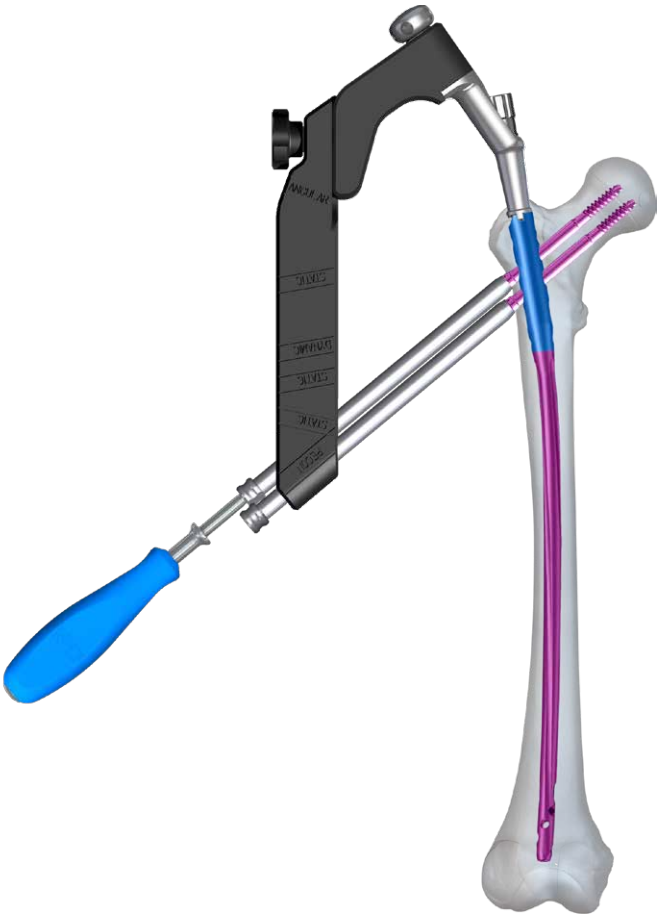
40.5531


40.3328.200


40.5502.100



22 Insert the tip of cannulated screwdriver T30 **[40.5574.300]** into the head of reconstruction screw with selected length *(set on the gradual cannulated drill using setting slider or from measurement with cannulated screw length measure)*. Insert the set in protective guide **[40.3328.200]** and leading over the guide rod 2.8/385 **[40.5531]** drive in previously performed hole in femoral neck until the screw's head reach the cortex *(groove on the screwdriver's shaft meets with end of the protective guide)*.



Remove the cannulated screwdriver and guide rod. Guide rod 2.8/385 **[40.5531]** is a single use instrument.


40.5574.300


40.3328.200

40.5531

23 Remove both protective guides 11/9 **[40.3328.200]** from reconstruction *(RECON)* holes in targeter B.

In the case of short nail application, leave targeter arm **[40.5501]** and targeter B **[40.5502.100]** coupled.

Correctness of performed fixation of femoral neck fracture should be verified by taking a X-Ray image in AP and lateral projection.

With small overall dimensions of targeter B additionally deflected with anteversion angle, it is possible to take a X-Ray image in lateral projection *(C-arm is then positioned under slight angle in relation to the **targeter**)*. Radiographic image of nail with locking elements can be helpful while confirmation of correctness of performed locking.


40.3328.200


40.5502.100


40.5501

IV.7.1.2. Locking the short nail in distal part

Anatomical femoral nails have a locking hole in distal part that is situated in a fixed distance from nail's beginning, independently from total nail length.

Short nails are universal and can be applied in right and left extremity.

24 Introduce protective guide 9/7 **[40.5510.200]** together with trocar 6.5 **[40.5534.100]** in the most distal angular hole of targeter B **[40.5502.100]** signed *"STATIC"*.
After marking the screw's entry point on the skin, perform incision of soft tissues. Trocar should penetrate to the cortex and mark the entry point for the drill.
The protective guide should penetrate together with the trocar until contact with the bone occurs.

Remove the trocar.
Leave the protective guide inside the targeter B **[40.5502.100]** hole.

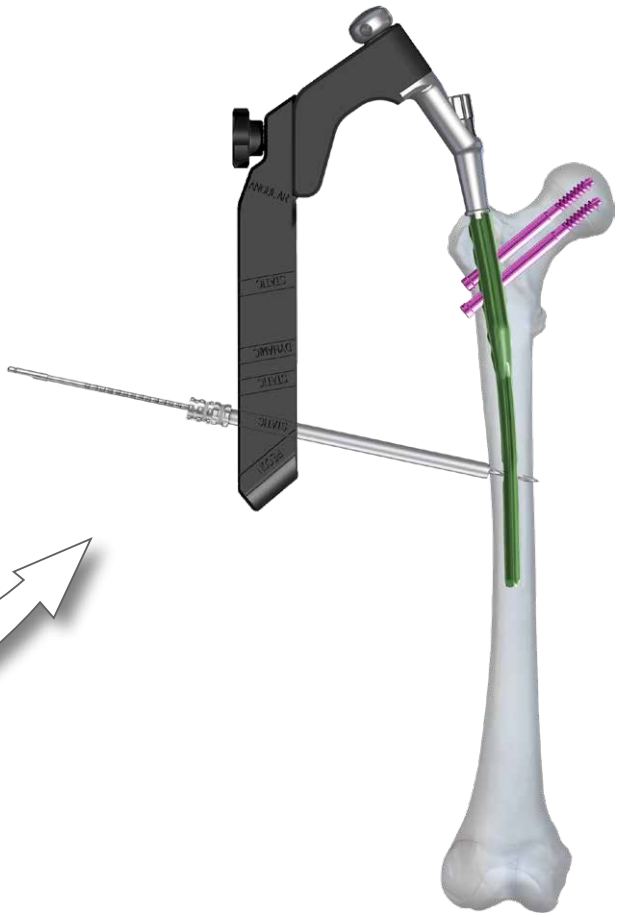

40.5502.100


40.5510.200


40.5534.100

25 Introduce Drill guide 7/3.5 **[40.5511.200]** in left protective guide 9/7. Attach drill with scale 3.5/350 **[40.5339.002]** to the drive and leading it in drill guide, drill a hole in femur through its both cortices and hole in the nail. Scale on the drill shows the length of locking element.

Hole drilling should be performed under the X-Ray image intensifier control.

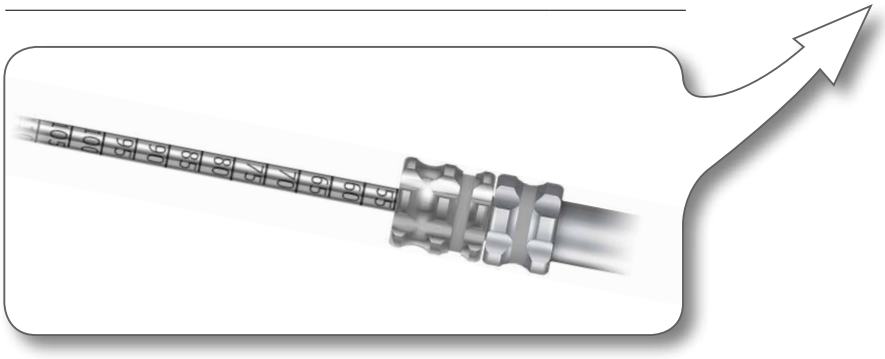


Detach drive of the drill.
Remove the drill guide and the drill.


40.5510.200

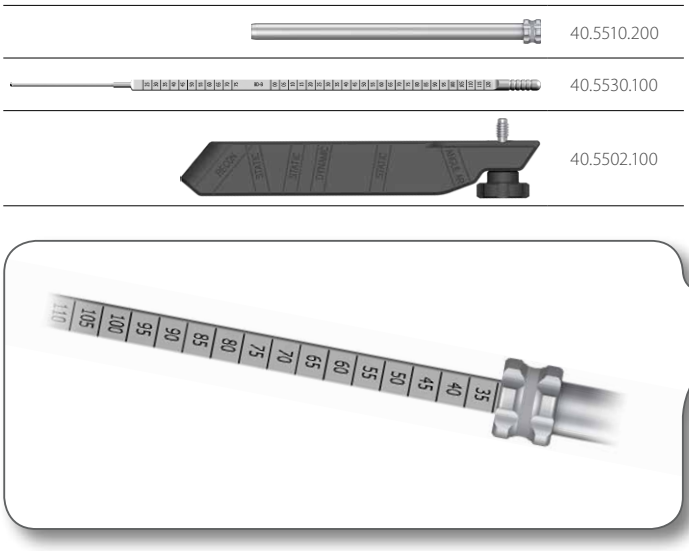

40.5511.200

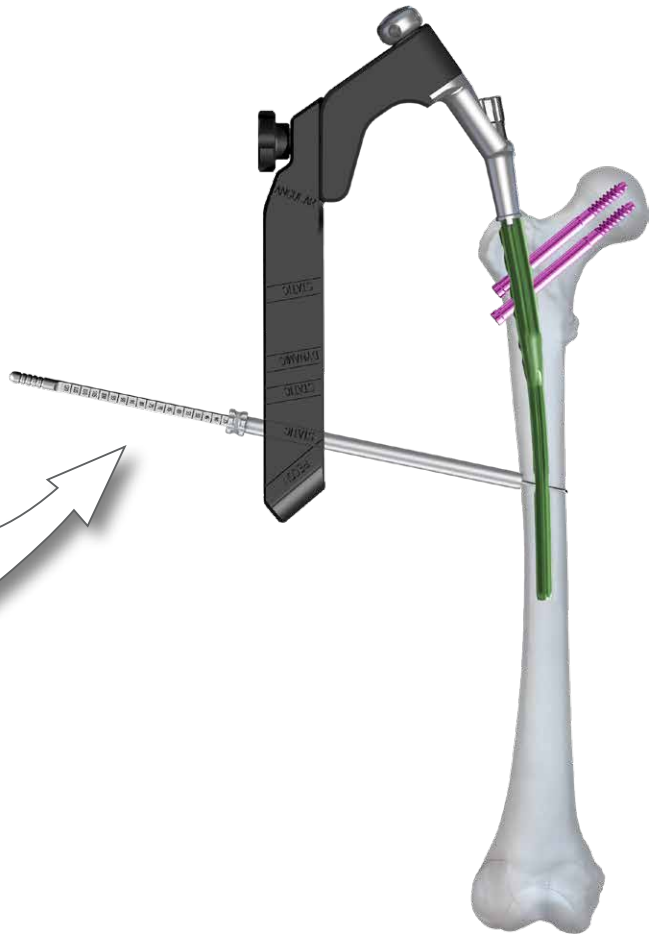
40.5339.002



26 Introduce screw length measure **[40.5530.100]** through protective guide 9/7 in the hole drilled in the bone, until the hook of measuring tip reaches the far cortex. From the B-D scale of measure, read the locking element length. During measurement the protective guide should be pressed against the cortex.

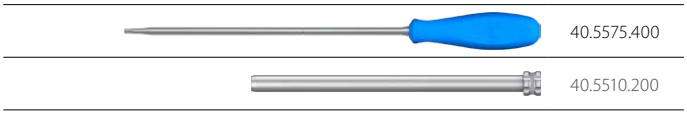
Remove the screw length measure.
Leave the protective guide in the targeter hole.





27 Introduce the tip of cannulated screwdriver T25 **[40.5575.400]** in the socket of defined locking screw. Insert the system, through protective guide, into the already prepared hole in femoral shaft until the screw's head reaches the cortex *(groove on the screwdriver's shaft meets with end of the protective guide)*.

Remove the screwdriver and the protective guide.



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

IV.7.1.3. Locking the left/right nail in distal part

When using long left/right nail, remove targeter B **[40.5502.100]** from targeter arm **[40.5501]**.

40.5502.100

40.5501

28 Couple targeter arm **[40.5501]** with targeter D **[40.5503.300]** using screw described in step 7 on page 23.

40.5501

40.5503.300

NOTE! Regarding possibility of incorrect positioning of targeter D slider's holes in relation to holes in the nail, the slider has been provided with adjustment screw used for correction of holes configuration.
The alignment of the holes in the nail and the slider should be performed with the adjustment screw of the targeter D slider which allows for the part of the slider to move along the screw until the correct position is reached.

NOTE! The position of targeter D **[40.5503.300]** slider can be verified taking X-Ray image in AP and lateral projections.
If slider positioning requires correction, re-position the slider using the adjustment screw, until correct configuration of holes in the nail and the slider of targeter D is obtained.
Holes in the nail and slider of targeter should overlap and form a circular profile.

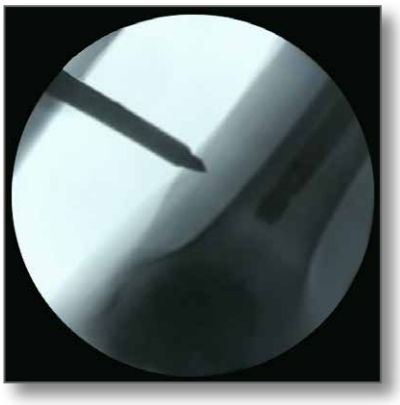
29 Introduce protective guide 9/7 **[40.5510.200]** together with trocar 6.5 **[40.5534.100]** in distal hole of targeter D **[40.5503.300]**. After marking the screw's entry point on the skin, perform incision of soft tissues.
Trocar should penetrate to the cortex and mark the entry point for the drill.
The protective guide should penetrate together with the trocar until contact with the bone occurs.

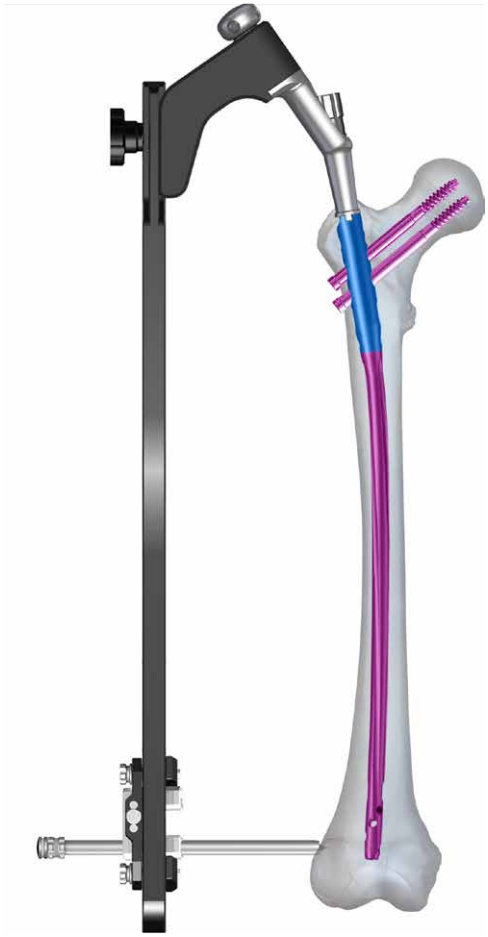
Remove the trocar.
Leave the protective guide inside the targeter D hole.


40.5503.300


40.5510.200


40.5534.100





30 Introduce drill guide 7/3.5 **[40.5511.200]** in the left protective guide 9/7. Attach drill with scale 3.5/350 **[40.5339.002]** to the drive and leading it in drill guide, drill a hole in femur through its both cortices and hole in the nail. Scale on the drill shows the length of locking element.

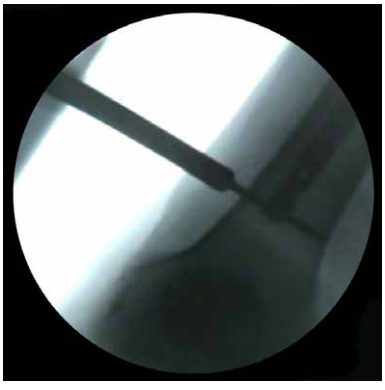

Hole drilling should be performed under the X-Ray image intensifier control.

Detach drive of the drill.
Remove the drill guide and the drill.


40.5510.200


40.5511.200

40.5339.002



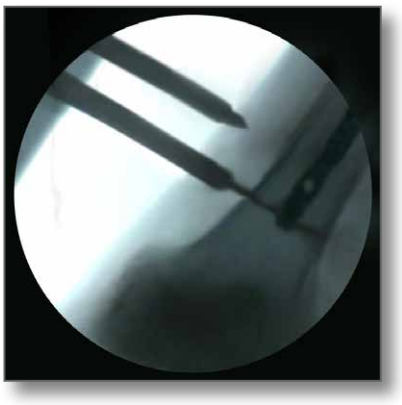
31 Introduce protective guide 9/7 **[40.5510.200]** together with trocar 6.5 **[40.5534.100]** in proximal hole of targeter D slider **[40.5503.300]**. After marking the screw's entry point on the skin, perform incision of soft tissues. Trocar should penetrate to the cortex and mark the entry point for the drill. The protective guide should penetrate together with the trocar until contact with the bone occurs.

Remove the trocar.
Leave the protective guide inside the targeter D hole.


40.5503.300


40.5510.200


40.5534.100



32 Introduce drill guide 7/3.5 **[40.5511.200]** in the left protective guide 9/7. Mount drill with scale 3.5/350 **[40.5339.002]** in drive and then leading the drill in drill guide drill a hole in femur through its both cortices and hole in the nail. Scale on the drill shows the length of locking element.

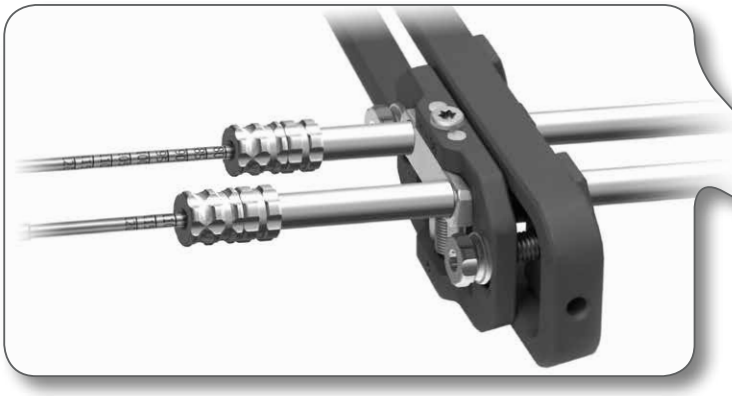

Drilling hole should be performed under the X-Ray image intensifier control.

Detach drive of the drill.
Remove the drill guide and the drill.


40.5510.200


40.5511.200

40.5339.002

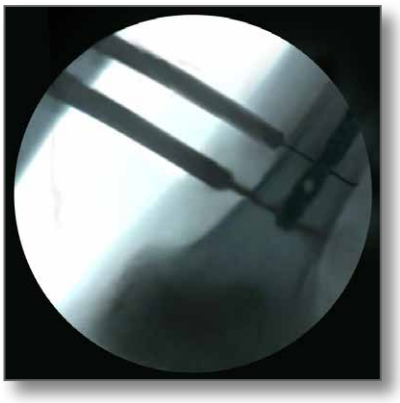


33 Introduce screw length measure **[40.5530.100]** through protective guide, in the hole drilled in the bone, until the hook of measuring tip reaches the far cortex. From the B-D scale read the locking element length. During measurement the protection guide should be pressed against the cortex.

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


40.5510.200


40.5530.100



34 Introduce the tip of screwdriver T25 **[40.5575.400]** in the socket of defined locking screw. Insert the system, through protective guide, into the already prepared hole in femoral shaft until the screw's head reaches the cortex *(groove on the screwdriver's shaft meets with end of the protective guide)*.

Remove the screwdriver.


40.5575.400


40.5510.200

35 Remove the drill and drill guide from the distal hole of targeter D slider. Leave the protective guide 9/7 in hole of targeter D slider. Introduce screw length measure **[40.5530.100]** through protective guide, in the hole drilled in the bone, until the hook of measuring tip reaches the far cortex. From the B-D measure scale read the locking element length. During measurement the protection guide should be pressed against the cortex.

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

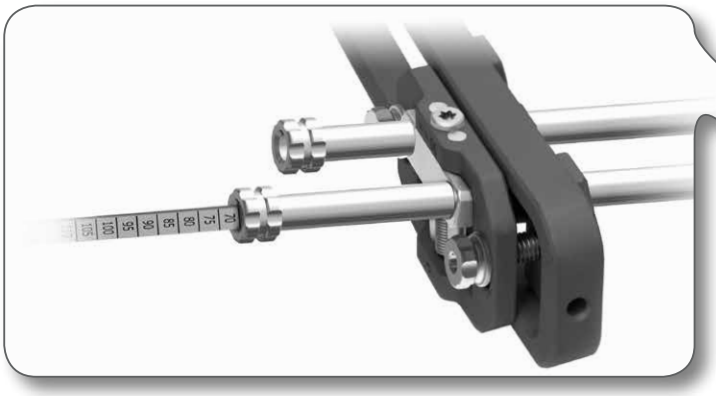

40.5503.300

40.5339.002


40.5511.200


40.5510.200

40.5530.100



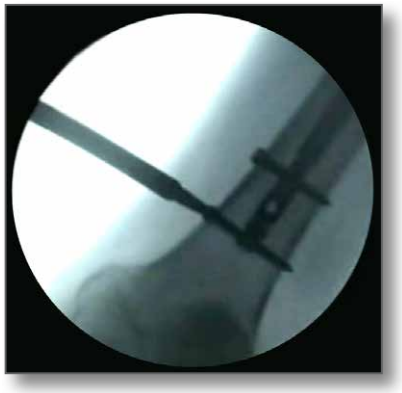
36 Introduce the tip of screwdriver T25 **[40.5575.400]** in the socket of defined locking screw. Insert the system, through protective guide, into the already prepared hole in femoral shaft until the screw's head reaches the cortex *(groove on the screwdriver's shaft meets with end of the protective guide)*.

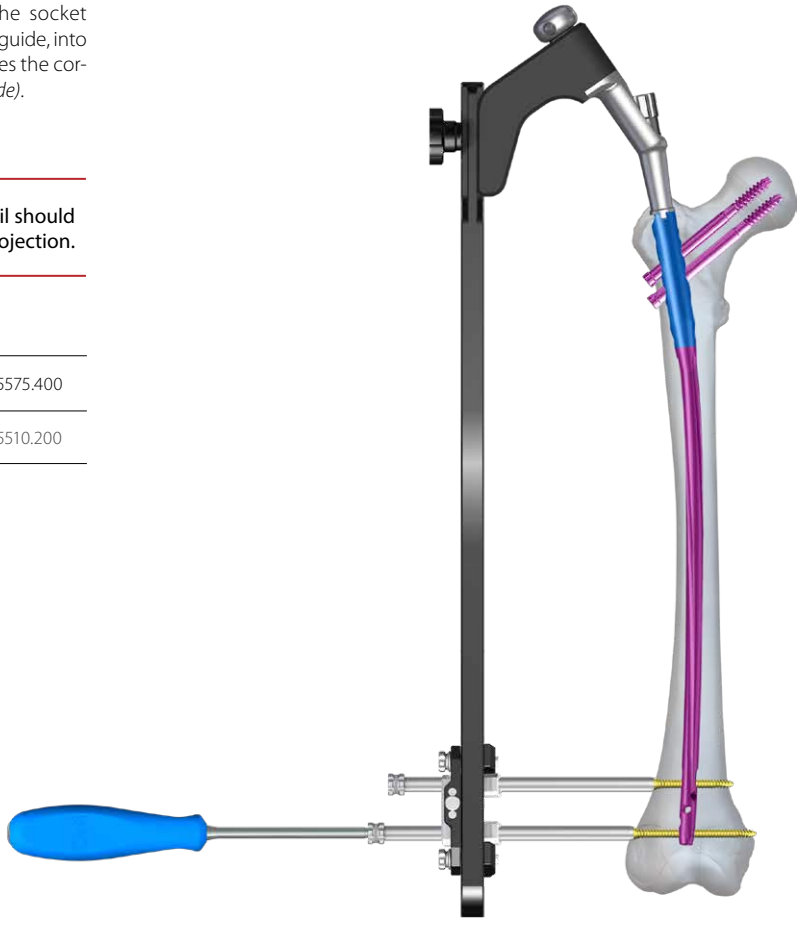
Remove the screwdriver and protective guides.

Correctness of screws insertion in distal part of the nail should be verified by taking a X-Ray image in AP and lateral projection.


40.5575.400

40.5510.200





IV.7.1.4. Targeter removal and placing the end cap

37 Remove the connecting screw M10x1.5 **[40.5504]** from the proximal end of the intramedullary nail using wrench S10 **[40.5526.100]** and detach the targeter arm from the nail fixed in the medullary canal.

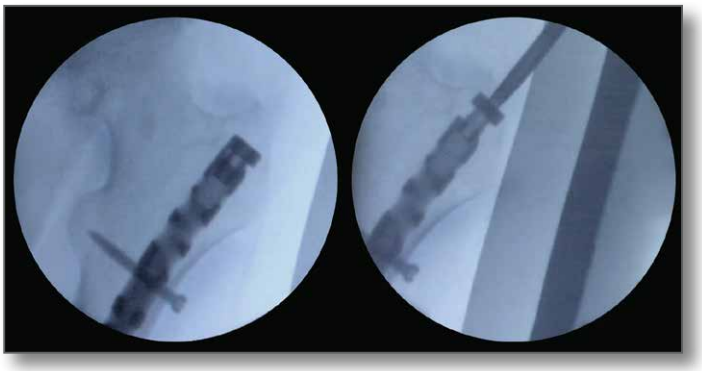

40.5526.100


40.5504


40.5501

38 In order to protect the internal thread of the nail against bone tissue overgrowth, insert in the nail's shaft **CHARFIX2** End cap M10x1.5 *(implant)* using cannulated screwdriver T30 **[40.5574.300]**.


40.5574.300

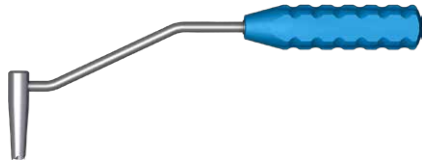


IV.7.1.5. ALTERNATIVE: Locking the nail in distal part using "free-hand" technique

Instant radiographic control is necessary in this method for determination of the drilling points and during the drilling procedure. Angular attachment of the drive is recommended for drilling the holes, so the operator's hands will be outside the direct X-Ray exposure. After marking on the skin the drill entry points for drilling the holes in femoral shaft, perform incision of soft tissues for approximately 1,5 cm.

39 Determine under the X-Ray the targeter D position in relation to the hole in the intramedullary nail. The holes in nail and the targeter shall coincide. Edges of the targeter shall penetrate the cortex. Introduce the short trocar 7 **[40.1354.100]** in the targeter hole, penetrate the cortex with the trocar and mark the entry point for the drill.

Remove the trocar
Leave the targeter in place.



40.1344.100

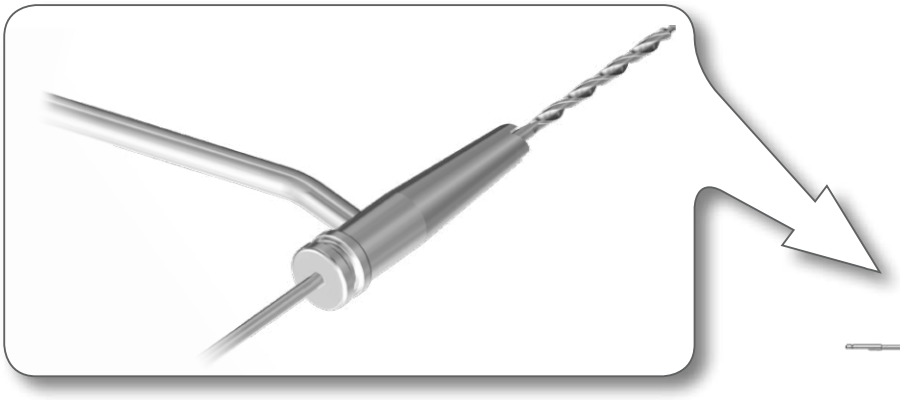
40.1354.100

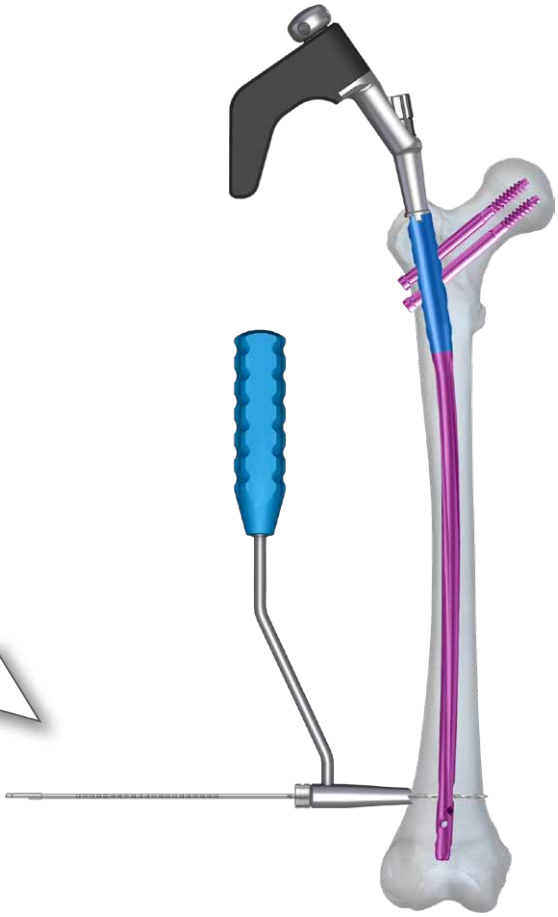
40 Introduce the short drill guide 7/3.5 **[40.1358.100]** in the targeter hole. Drill a hole using drill with scale 3.5/350 **[40.5339.002]** *(guided inside the drill guide)* through both cortices and hole in the nail. Scale on the drill shows the length of locking element.

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

40.1358.100

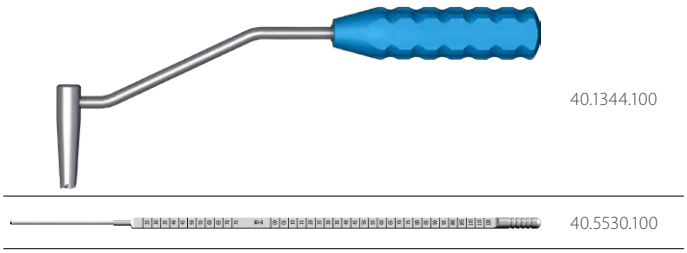
40.5339.002

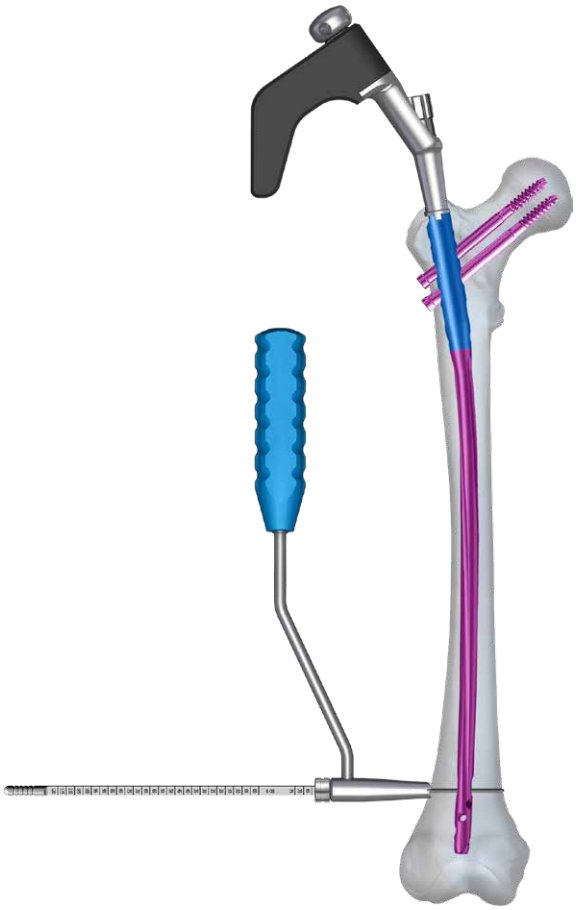




41 Introduce the screw length measure **[40.5530.100]** through targeter hole, in the hole drilled in the bone, until the hook of measuring tip reaches the far cortex. From the D scale read the locking screw length.

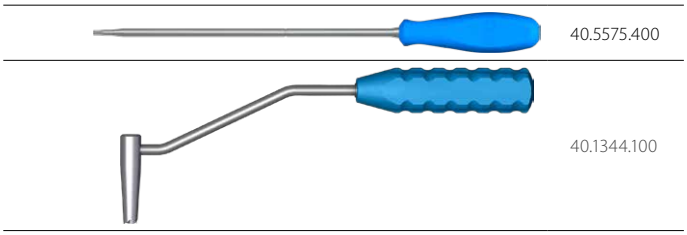
Remove the screw length measure.
Leave the targeter in place.

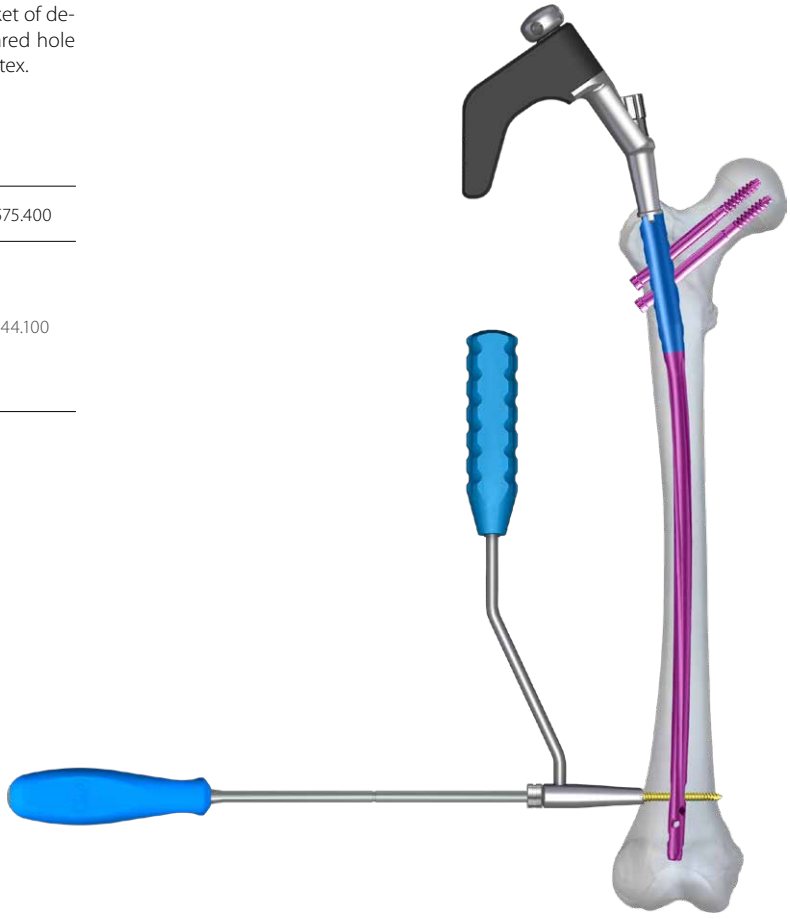




42 Introduce the tip of screwdriver T25 **[40.5575.400]** in the socket of defined locking screw. Insert the system, into the already prepared hole in femoral shaft *(via targeter hole)* until the screw's head reaches the cortex.

Remove the screwdriver and the targeter D.





IV.7.2. Compression method

IV.7.2.1. Locking the nail in distal part

43 Mount the targeter D **[40.5503.300]** to the targeter arm **[40.5501]** using screw described in step 7 on page 23.

Verify the position of targeter D slider according to step 28 on page 34.


40.5501.000


40.5503.300

Further proceeding according to steps 28÷36.

44 After locking the nail in distal part, the reduction of the fracture gap can be performed and further locking in proximal part.
Therefore detach the targeter D **[40.5503.300]** from the targeter arm **[40.5501]** and screw out the mallet screw from the targeter arm. Attach impactor-extractor **[40.5507]**. Slightly backstroke the nail to reduce the fracture gap using Mallet **[40.3667]**.

Detach the impactor-extractor from targeter arm.
Re-attach the mallet screw in the targeter arm hole.


40.5503.300


40.5501


40.5507


40.3667

IV.7.2.2. Locking the nail in proximal part

IMPORTANT! In compression method, for locking the anatomical femoral nail, hole in targeter B **[40.5502.100]** signed *"DYNAMIC"* is used.

IV.7.2.2a. OPTION I: Intra-operative compression of fragments using compression screw **[40.5517]** *(instrument)*

40.5517

45 Attach targeter B **[40.5502.100]** to the targeter arm **[40.5501]**. Introduce protective guide 9/7 **[40.5510.200]** together with trocar 6.5 **[40.5534.100]** in the hole of targeter B **[40.5502.100]** signed *"DYNAMIC"*. After marking the screw's entry point on the skin, perform 1,5 cm long incision of soft tissues.
Trocar should penetrate to the cortex and mark the entry point for the drill.
The protective guide should penetrate together with the trocar until contact with the bone occurs.

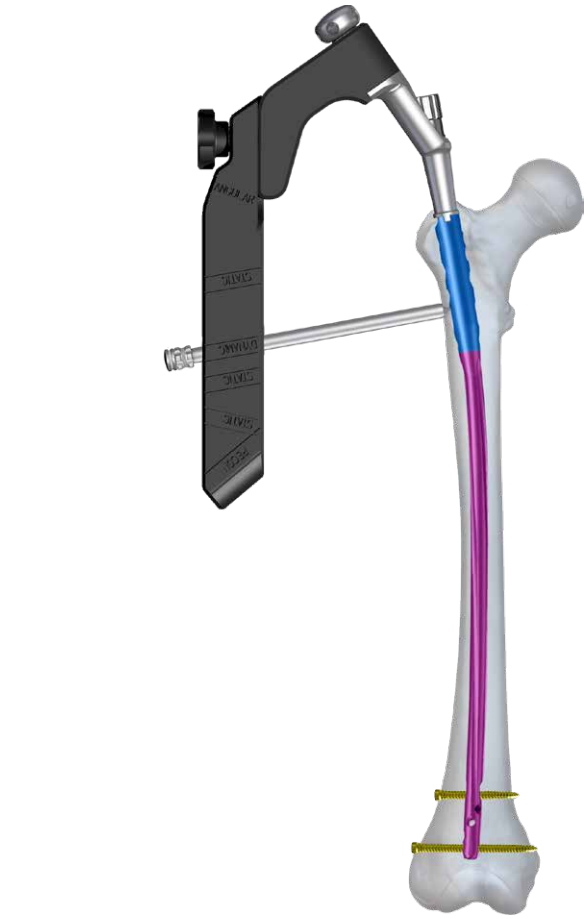
Remove the trocar.
Leave the protective guide inside the targeter B hole.


40.5502.100


40.5501


40.5510.200


40.5534.100

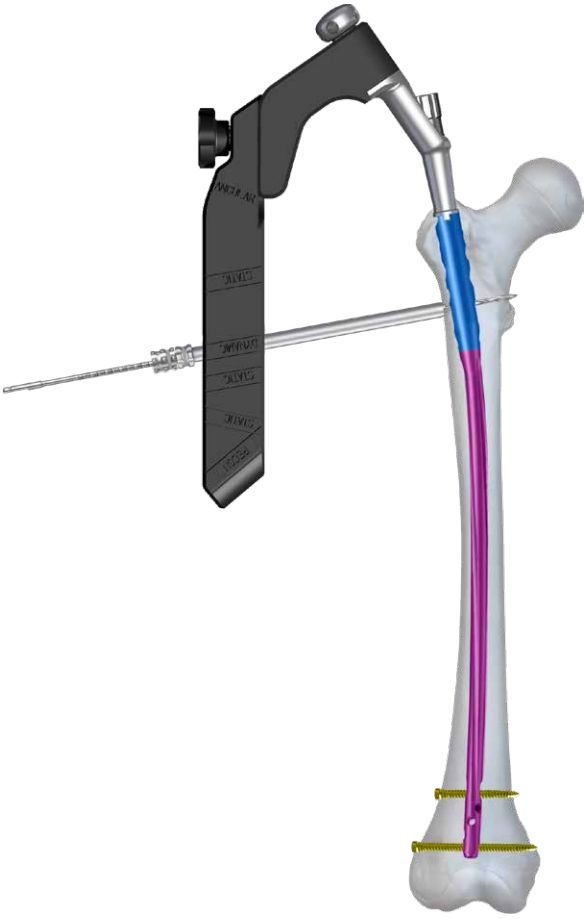


46 Introduce drill guide 7/3.5 **[40.5511.200]** in the left protective guide. Attach drill with scale 3.5/350 **[40.5339.002]** to the drive and leading it in drill guide, drill a hole in femur through its both cortices and hole in the nail. Scale on the drill shows the length of locking element.

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


40.5511.200

40.5339.002

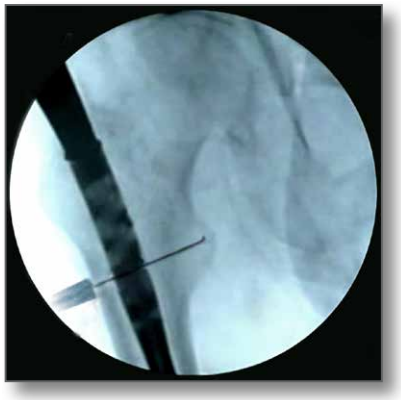


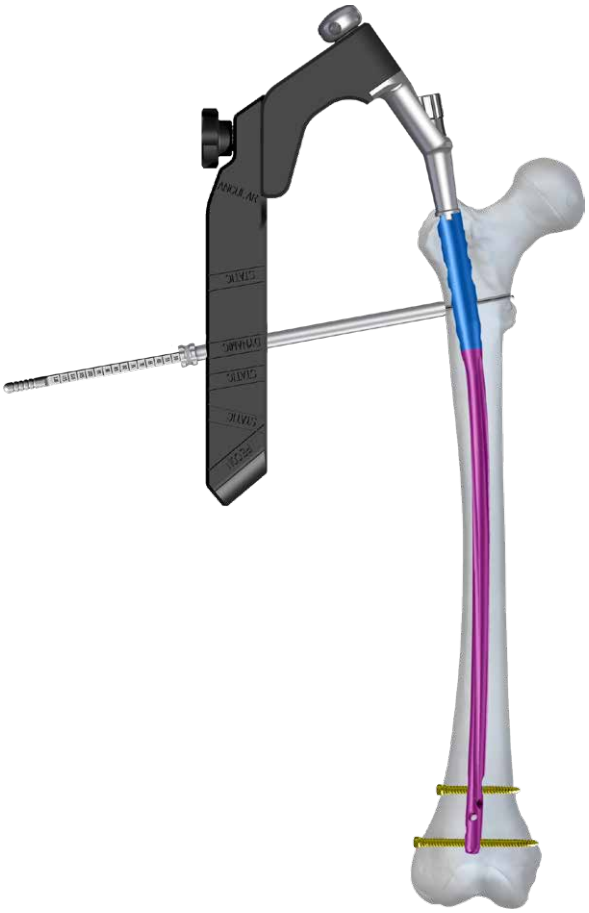
47 Introduce the screw length measure **[40.5530.100]** through protective guide 9/7 **[40.5510.200]**, in the hole drilled in the bone, until the hook of measuring tip reaches the far cortex. From the B-D scale read the locking screw length. During measurement the pretective guide should be pressed against the cortex.

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


40.5510.200


40.5530.100

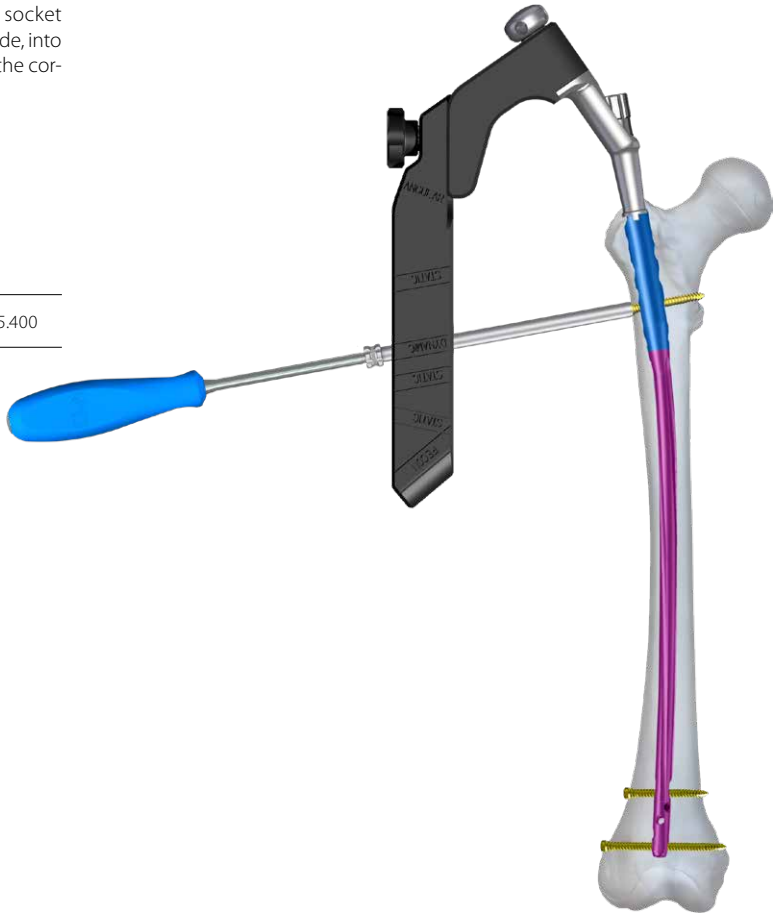




48 Introduce the tip of screwdriver T25 **[40.5575.400]** in the socket of defined locking screw. Insert the system, through protective guide, into the already prepared hole in femoral shaft until the screw's head reaches the cortex *(groove on the screwdriver's shaft meets with end of the protective guide)*.

Remove the screwdriver and the protective guide.


40.5575.400



49 In order to perform intraoperative compression, insert the compression screw **[40.5517]** in connecting screw M10x1.5 **[40.5504]**, that joins the intramedullary nail with targeter arm **[40.5501]**, using cannulated screwdriver T30 **[40.5574.300]**. When face of the compression screw meets the shaft of the locking screw, a perceptible resistance occurs. From this moment on, a further compression screw insertion will result in bone fragments compression.

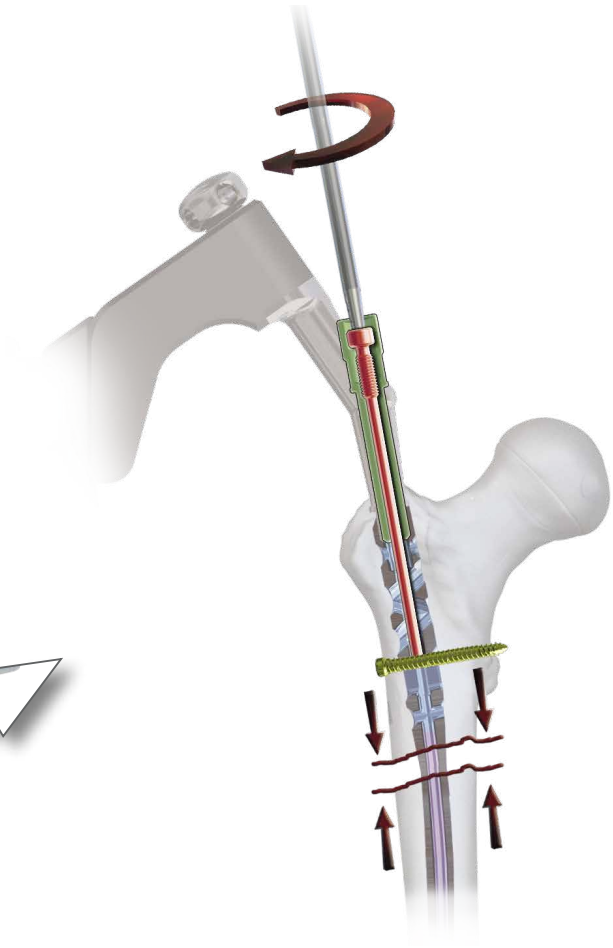
Perform the insertion under the X-Ray image intensifier control, monitoring the inter-fragmental gap.


40.5574.300


40.5517


40.5504


40.5501



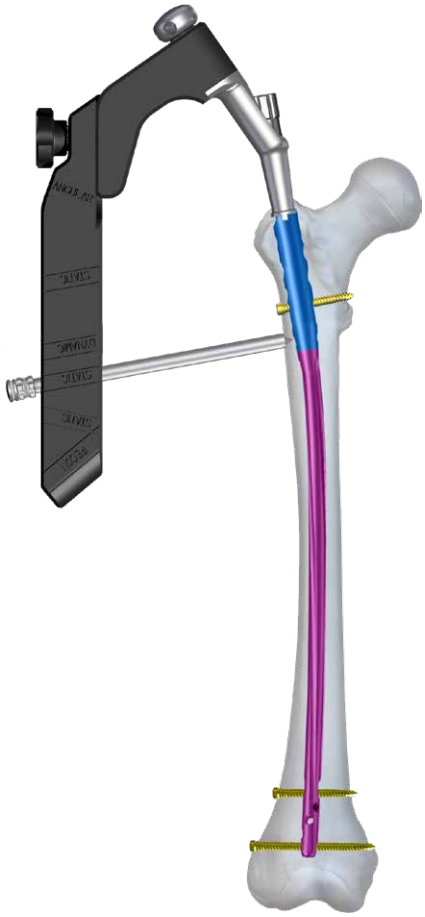
50 In order to keep the fragments compression, static locking of the nail should be performed. For this purpose, introduce protective guide 9/7 **[40.5510.200]** together with trocar 6.5 **[40.5534.100]** in the distal hole of targeter B **[40.5502.100]** signed *"STATIC"*.
After marking the screw's entry point on the skin, perform 1,5 cm long incision of soft tissues.
Trocar should penetrate to the cortex and mark the entry point for the drill.
The protective guide should penetrate together with the trocar so as to place its end as close to the bone as possible.

Remove the trocar.
Leave the protective guide inside the targeter hole.


40.5502.100

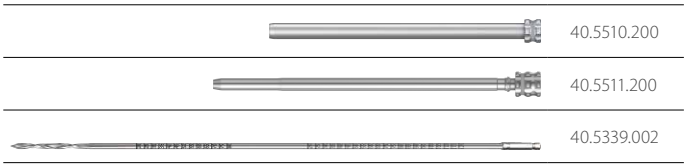

40.5510.200

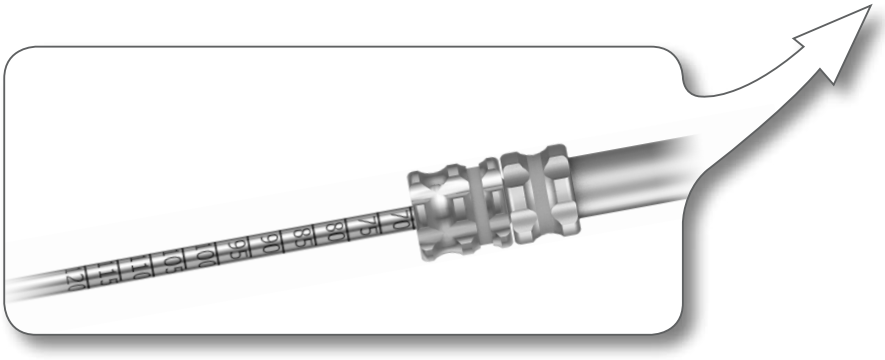

40.5534.100

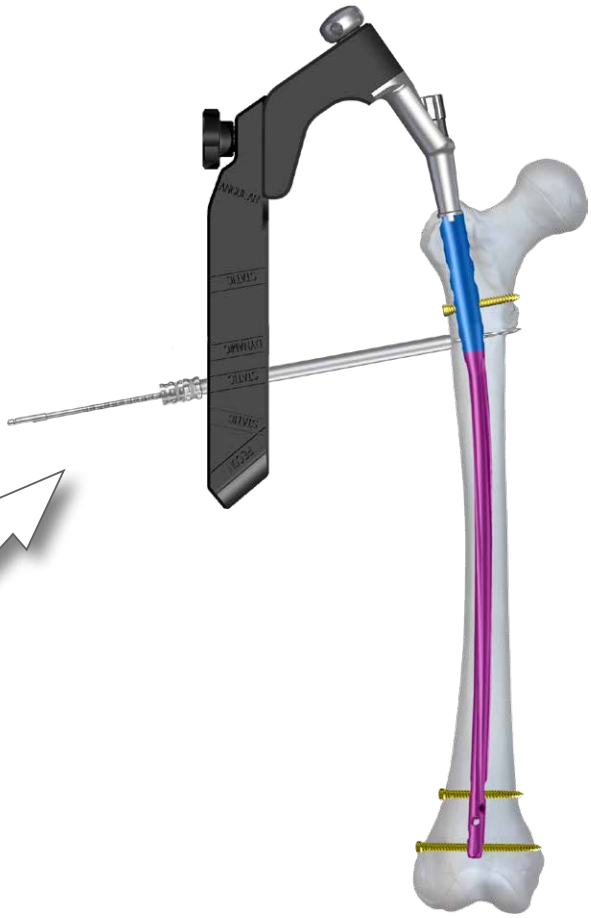


51 Introduce drill guide 7/3.5 **[40.5511.200]** in the left protective guide 9/7. Attach drill with scale 3.5/350 **[40.5339.002]** to the drive and leading it in drill guide, drill a hole in femur through its both cortices and hole in the nail. Scale on the drill shows the length of locking element.

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

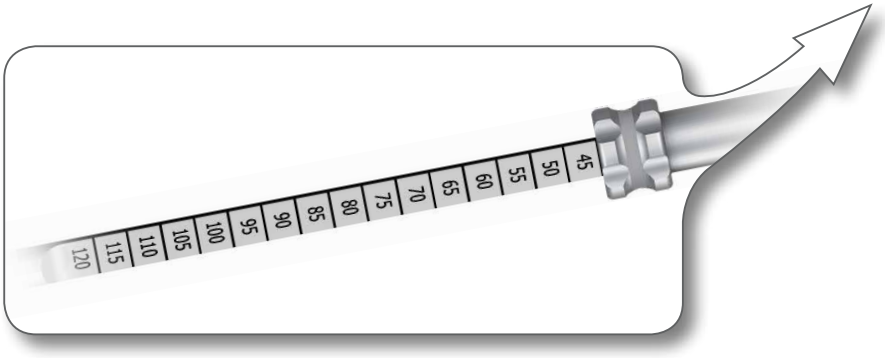


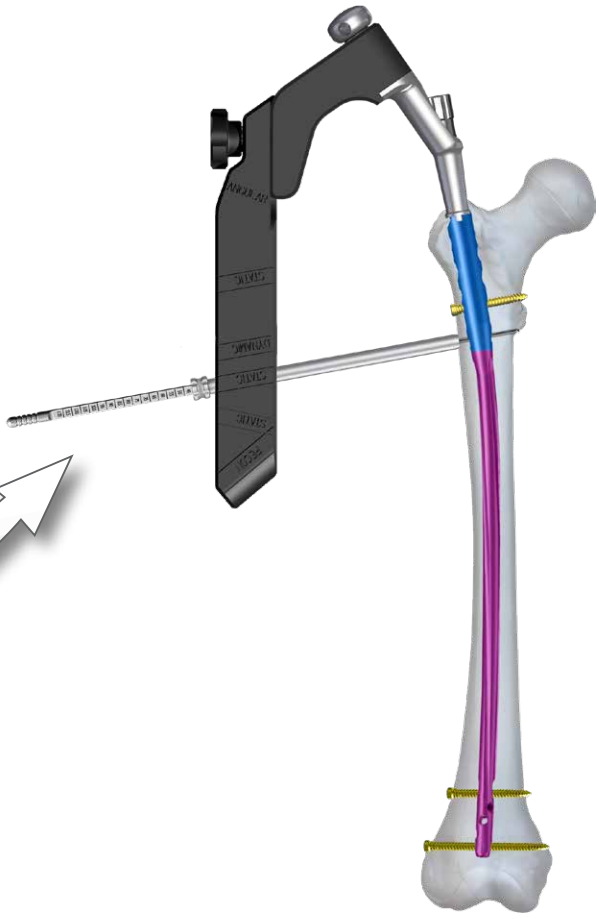




52 Introduce the screw length measure **[40.5530.100]** through the protective guide, in the hole drilled in the bone, until the hook of measuring tip grasps the far cortex. From the B-D scale read the locking screw length. During measurement the protection guide should be pressed against the cortex.

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





53 Introduce the tip of screwdriver T25 **[40.5575.400]** in the socket of defined locking screw. Insert the system, through protective guide, into the already prepared hole in femoral shaft until the screw's head reaches the cortex *(groove on the screwdriver's shaft meets with end of the protective guide)*.

Remove the screwdriver and the protective guide.

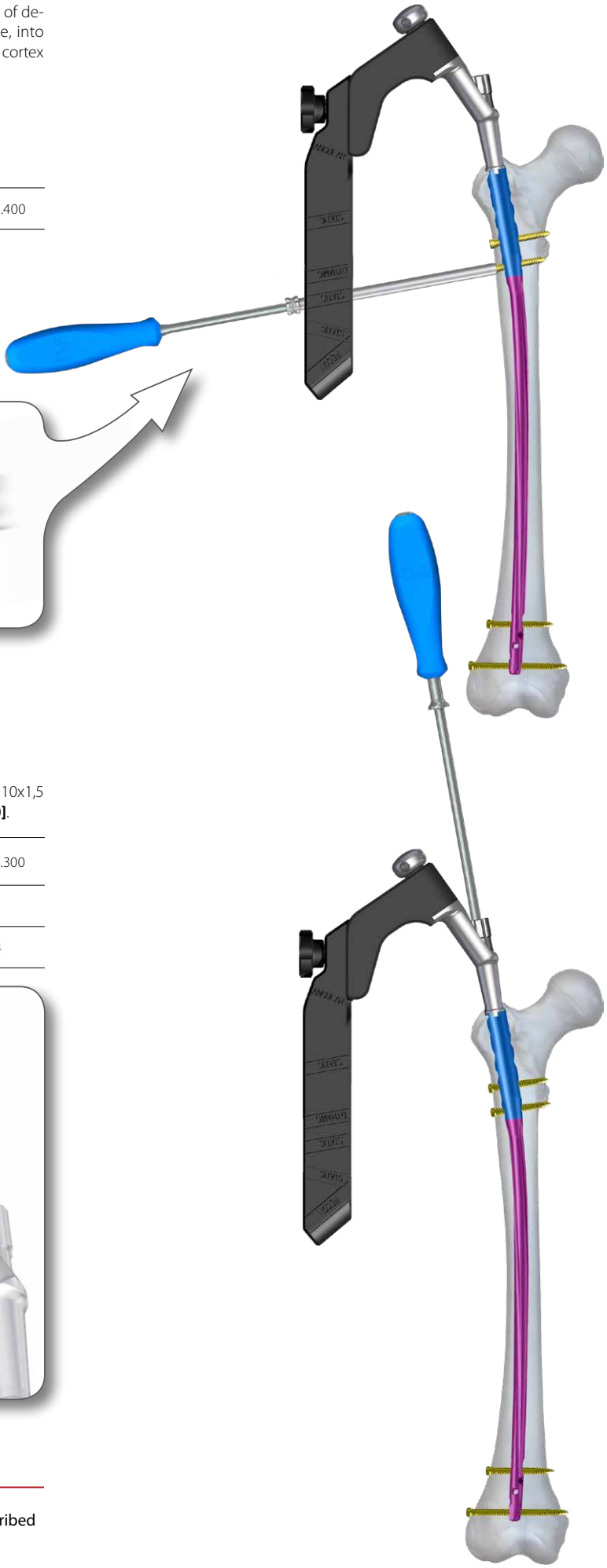

40.5575.400

54 Remove compression screw **[40.5517]** from connecting screw M10x1,5 L=53 **[40.5504]** using cannulated screwdriver T30 **[40.5574.300]**.


40.5574.300


40.5517


40.5504



ATTENTION! Further proceeding according to steps described in section IV.7.3.3.

IV.7.2.2b. OPTION II: Compression of fragments using CHARFIX2 Compression screw M10x1,5 **[3.5162.000]** *(implant)*

Option of compressive locking in proximal part with use of **CHARFIX2** Compression screw M10x1.5 *(implant delivered separately)* should be performed according to steps 45÷48, then according to procedure described in section IV.7.2.3.


3.5162

IV.7.2.3. Targeter removal and placing the compression screw

55 Remove targeter B **[40.5502.100]** form targeter arm **[40.5501]**. Remove connecting screw M10x1.5 **[40.5504]** from the proximal end of the intramedullary nail using wrench S10 **[40.5526.100]** and detach the targeter arm from the nail fixed in the medullary canal.


40.5502.100


40.5501


40.5526.100

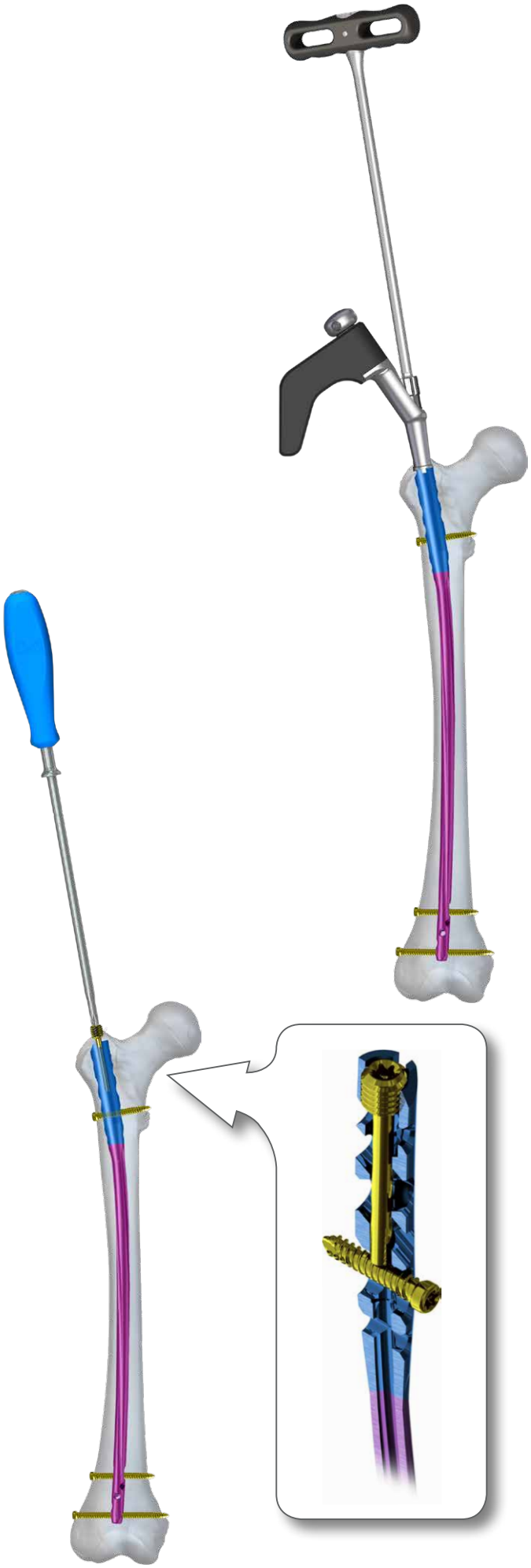

40.5504

56 Drive in **CHARFIX2** Compression screw M10x1.5 **[3.5162]** in threaded hole of nail shaft using cannulated screwdriver T30 **[40.5574.300]**.

Surgeon decides about the compression rate.


40.5574.300


3.5162



IV.7.3. Dynamic method

IV.7.3.1. Locking the nail in distal part

Locking the nail in distal part in dynamic method perform according to steps 28÷36.

57 After locking the nail in distal part the reduction of the fracture gap can be performed and further locking in proximal part.
Remove targeter D **[40.5503.300]** from the targeter arm **[40.5501]** and screw out the mallet screw from the targeter arm **[40.5501]**. Attach impactor-extractor **[40.5507]**. Slightly backstroke the nail to reduce the fracture gap using mallet **[40.3667]**.

Detach the impactor-extractor from targeter arm.
Re-attach mallet screw to the targeter arm.


40.5503.300


40.5501


40.5507


40.3667

IV.7.3.2. Locking the nail in proximal part

58 Locking the nail in proximal part in dynamic method perform according to steps 45÷48.

IV.7.3.3. Targeter removal and placing the end cap

59 Remove targeter B **[40.5502.100]** form targeter arm **[40.5501]**. Remove connecting screw M10x1.5 **[40.5504]** from the proximal end of the intramedullary nail using wrench S10 **[40.5526.100]** and detach the targeter arm from the nail fixed in the medullary canal.


40.5502.100


40.5501

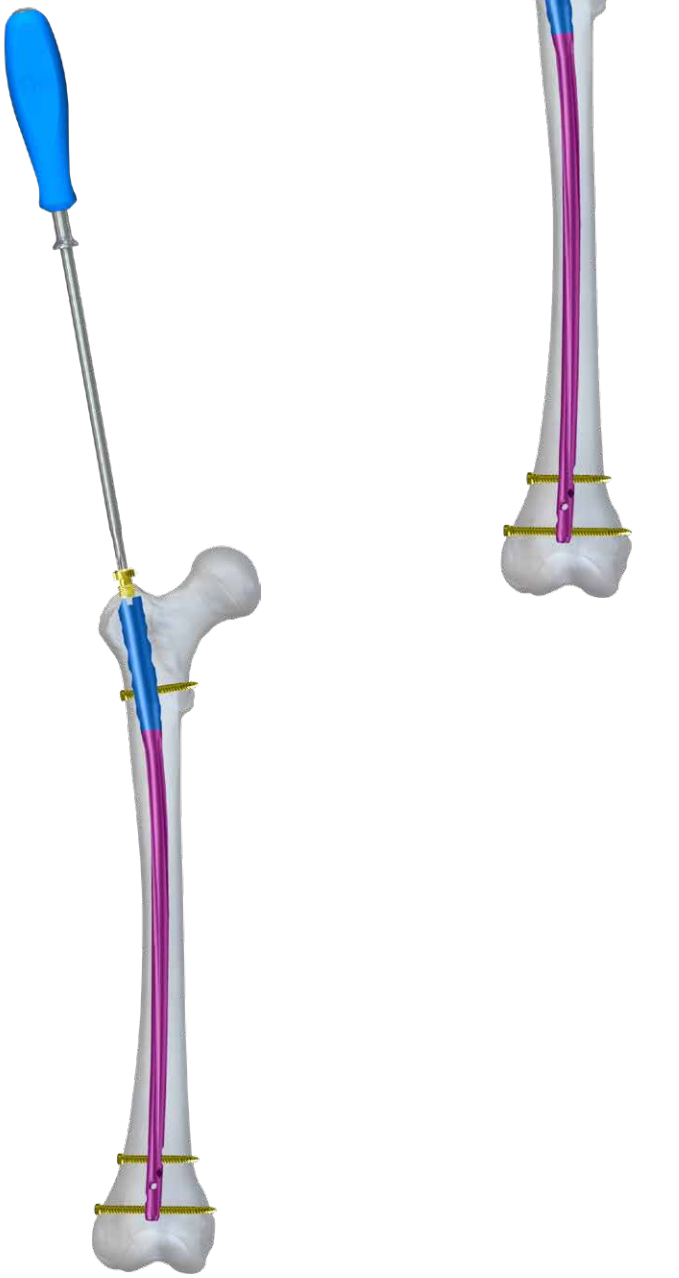

40.5526.100


40.5504

60 In order to protect the connecting thread of the nail against bone tissue overgrowth, insert in the nail's threaded hole **CHARFIX2** End cap M10x1.5 *(implant delivered separately)* **[3.5161.7xx]** using cannulated screwdriver T30 **[40.5574.300]**.


40.5574.300


3.5161.7xxx



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

IV.7.4. Static method

IV.7.4.1. Locking the nail in distal part

Locking the nail in distal part in static method perform according to steps 28÷36.

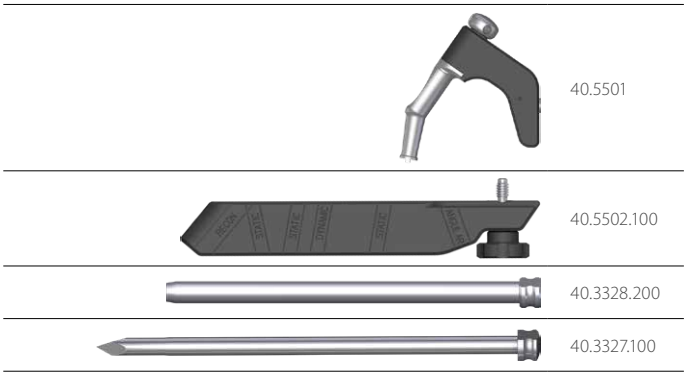
IV.7.4.2. Locking the nail in proximal part

IV.7.4.2a. OPTION I: Locking the nail with reconstruction screw

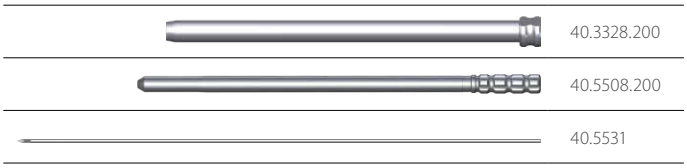
Locking the anatomical femoral nail with reconstruction screw in static method allows to reduce operative wound, because this solution enables to perform one incision for nail introduction into the medullary canal and for locking in proximal part. Besides, angular screw position ensures stabile locking, therefore, application of additional locking screws is not necessary.

61 Attach targeter B **[40.5502.100]** to the targeter arm **[40.5501]**. Introduce protective guide 11/9 **[40.3328.200]** together with trocar 6.5 **[40.3327.100]** in hole of targeter B **[40.5502.100]** signed "ANGULAR. After marking the screw's entry point on the skin, perform incision of soft tissues.
Trocar should penetrate to the cortex and mark the entry point for the drill.
The protective guide should penetrate together with the trocar so as to place its end as near to the bone as possible.

Remove the trocar.
Leave the protective guide inside the targeter hole.



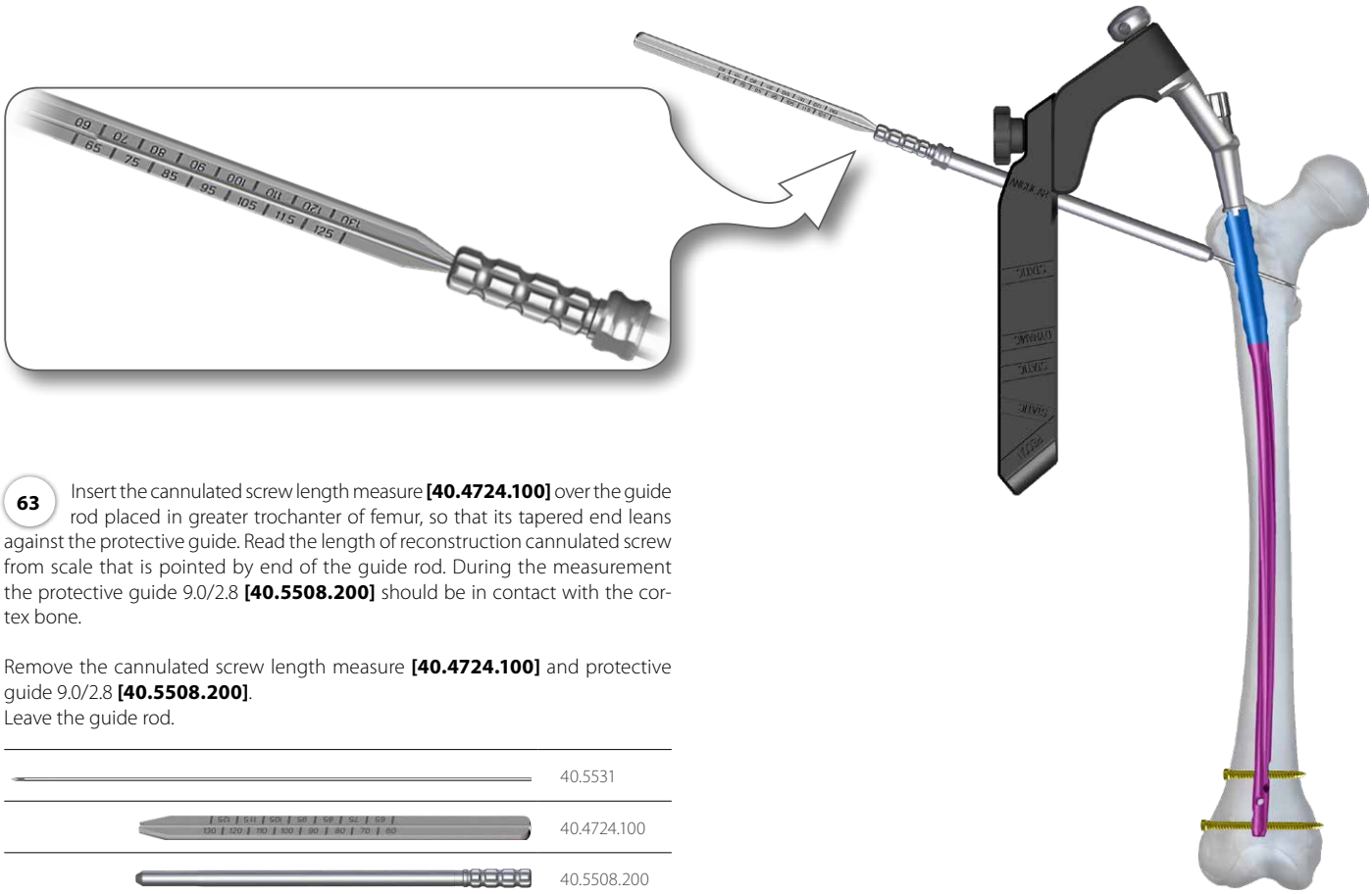
62 Introduce guide 9/2.8 **[40.5508.200]** in protective guide **[40.3328.200]**. Mount the guide rod 2.8/385 **[40.5531]** in the drive.
Leading in guide 9/2.8, introduce the guide rod in greater trochanter, until the rod exits the far cortex *(lesser trochanter area)*.



NOTE! Described operations should be performed under the X-Ray image intensifier control in AP and lateral projection.

Repeat the operation in the case of incorrect guide rod introduction.

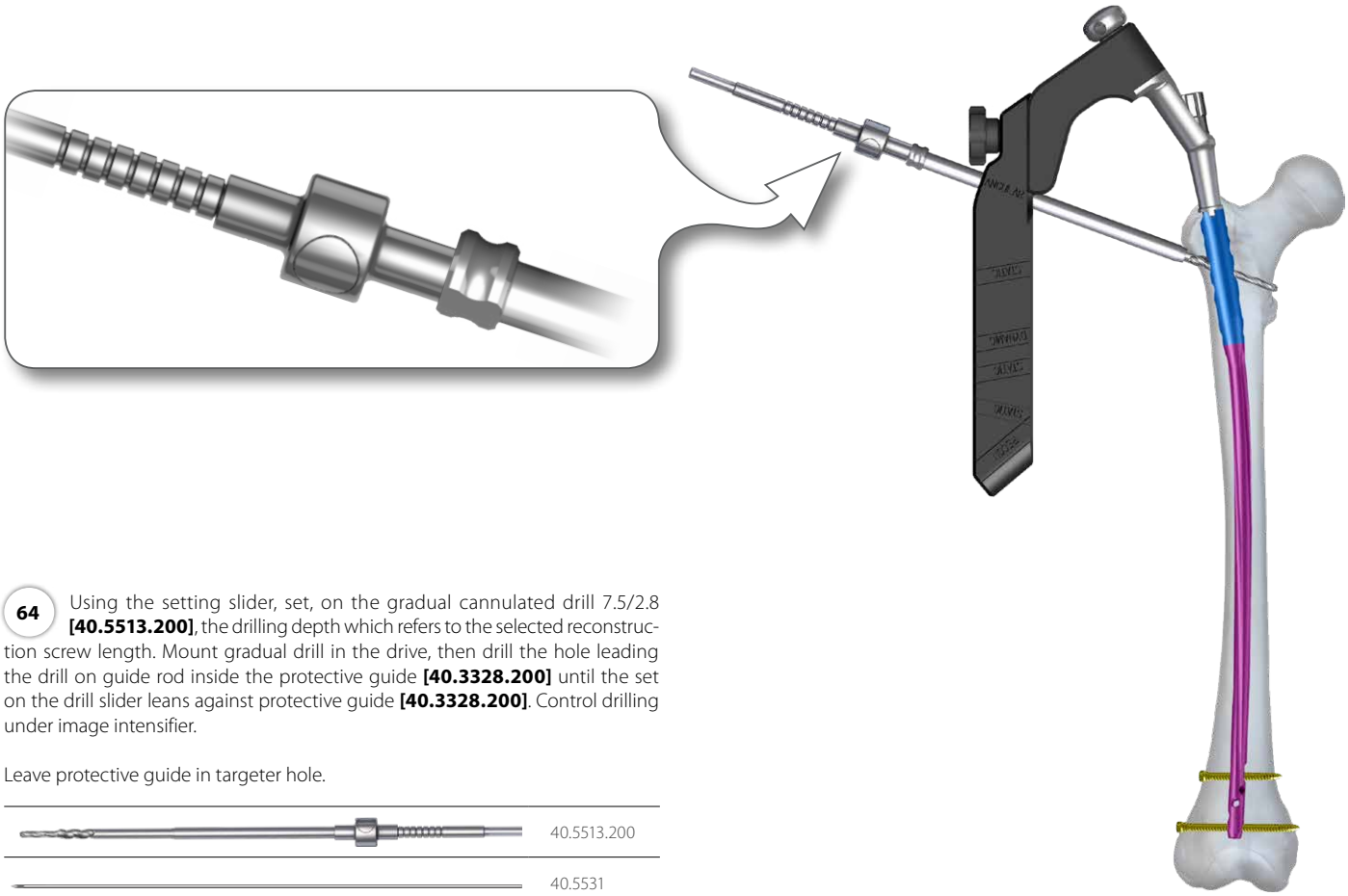
Leave the guide rod 2.8/385, guide 9/2.8 and protective guide 11/9 in the targeter hole.



63 Insert the cannulated screw length measure **[40.4724.100]** over the guide rod placed in greater trochanter of femur, so that its tapered end leans against the protective guide. Read the length of reconstruction cannulated screw from scale that is pointed by end of the guide rod. During the measurement the protective guide 9.0/2.8 **[40.5508.200]** should be in contact with the cortex bone.

Remove the cannulated screw length measure **[40.4724.100]** and protective guide 9.0/2.8 **[40.5508.200]**.
Leave the guide rod.

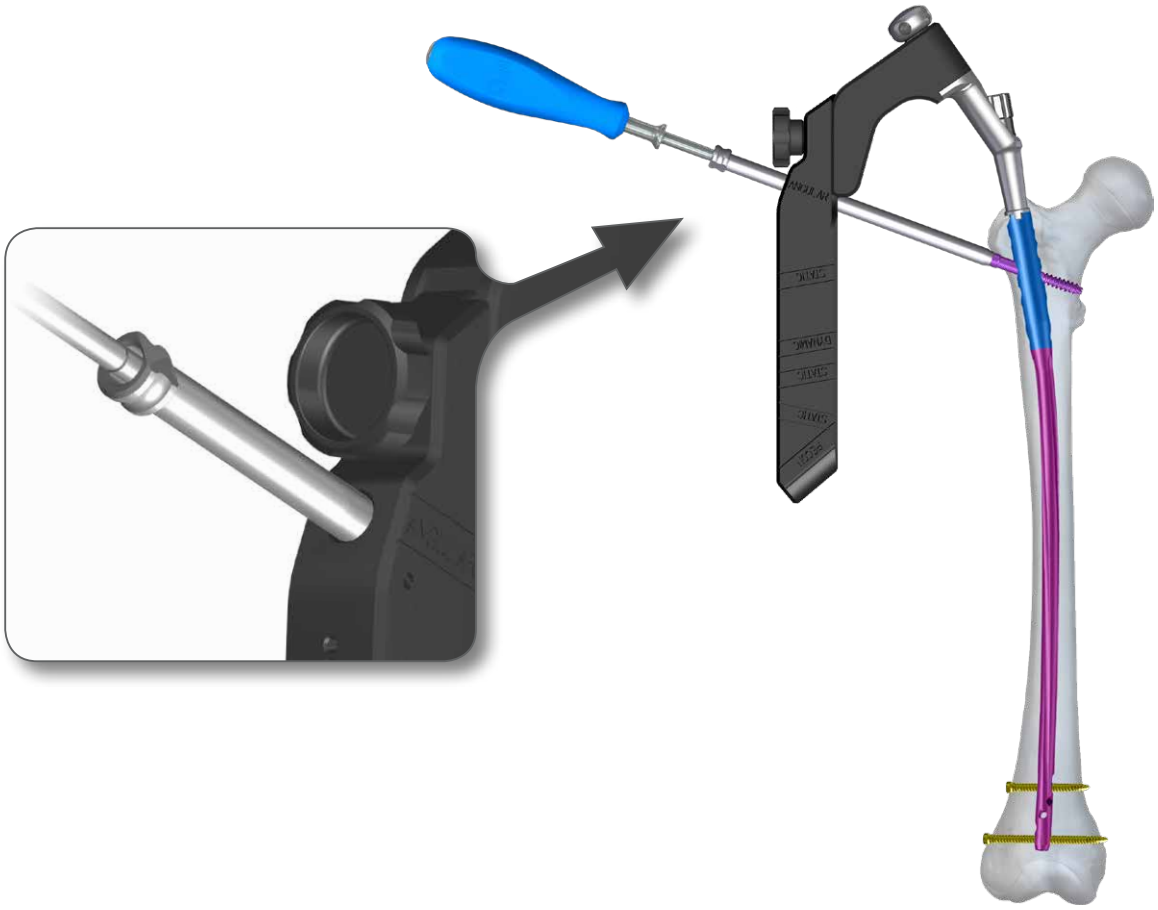
	40.5531
	40.4724.100
	40.5508.200



64 Using the setting slider, set, on the gradual cannulated drill 7.5/2.8 **[40.5513.200]**, the drilling depth which refers to the selected reconstruction screw length. Mount gradual drill in the drive, then drill the hole leading the drill on guide rod inside the protective guide **[40.3328.200]** until the set on the drill slider leans against protective guide **[40.3328.200]**. Control drilling under image intensifier.

Leave protective guide in targeter hole.

	40.5513.200
	40.5531
	40.3328.200



65 Mount reconstruction screw with previously defined length *(set on the cannulated drill using the setting slider or determined with cannulated screw length measure)* on the tip of cannulated screwdriver T30 **[40.5574.300]**. Introduce the system in protective guide **[40.3328.200]** and drive into previously prepared hole until the screws head reaches the cortex bone layer *(circumferential groove on the screwdriver shaft will align with the front of protective guide)*.

Remove the cannulated screwdriver and protective guide.

	40.5574.300
	40.3328.200

IV.7.4.2b. OPTION II: Locking the nail with locking screws

Construction of anatomical femoral nail and instrument set provides two holes in proximal part for static locking with use of locking screws. Holes in targeter B **[40.5502.100]** are marked STATIC.

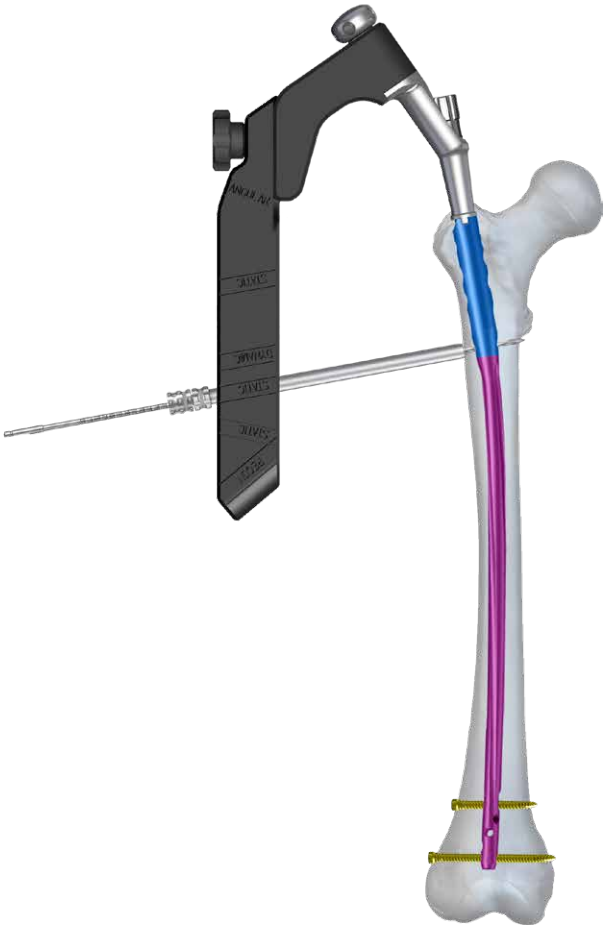
66 Introduce the protective guide **[40.5510.200]** together with trocar **[40.5534.100]** in distal static *(STATIC)* hole of targeter B. Perform 1,5cm long incision of soft tissues in a place defined as entry point for locking screw. Reach the cortex with the trocar and mark the drill entry point. The protective guide should penetrate together with trocar, in order to be placed as close to the bone as possible.

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


40.5502.100


40.5510.200


40.5534.100



67 Introduce drill guide 7/3.5 **[40.5511.200]** into left protective guide. Mount drill with scale 3.5/350 **[40.5339.002]** in the drive, then leading the drill through both guides drill the hole in femur, through both cortices and hole in the nail. Scale on the drill indicates length of locking element.

Remove the drill guide and drill.
Leave the protective guide.


40.5510.200


40.5511.200

40.5339.002

68 Introduce the screw length measure **[40.5530.100]** through the protective guide **[40.5510.200]** into hole drilled in the bone, until the end of measuring tip reaches the end of the hole. From the B-D scale of the screw length measure read the locking screw length. During the measurement the tip of the protective guide should rest on the cortex bone. Remove the screw length measure. Leave the protective guide in hole of the targeter.


40.5510.200

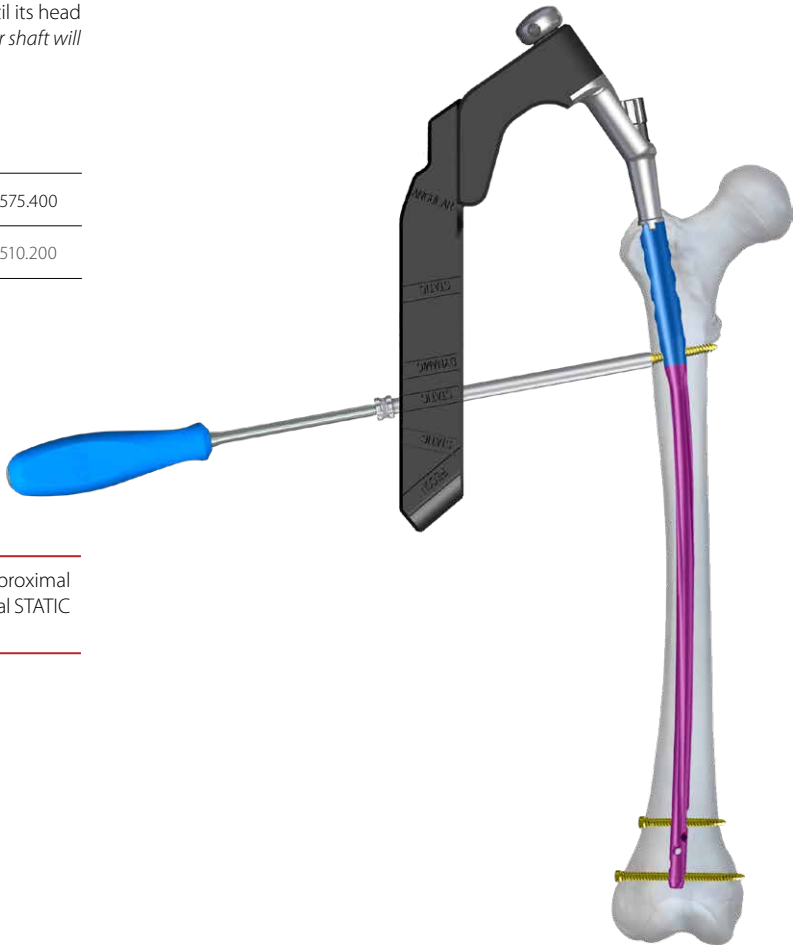

40.5530.100

69 Insert the tip of the screwdriver **[40.5575.400]** into the socket of defined locking screw. Next, insert such coupled system into protective guide. Drive the locking screw into previously drilled hole in femoral shaft, until its head reaches the cortical bone layer *(circumferential groove on the screwdriver shaft will align with the front of protective guide)*.

Remove the screwdriver and protective guide.


40.5575.400


40.5510.200



ATTENTION! If the surgeon decides to lock the nail in the proximal part using two screws - to lock using second screw (proximal STATIC hole) follow steps 66÷69.

IV.7.4.2c. OPTION III: Postoperative dynamization of static osteosynthesis

Construction of the anatomical femoral nail allows dynamization of static osteosynthesis, owing to application of compression hole in distal or proximal part. Option of locking with secondary dynamization can be used in the case of transverse, rotationally stabile fractures.

70 For the dynamization to occur, at least one compression hole for locking the nail in static method needs to be used. Dynamization of static osteosynthesis consists in driving all screws out of static holes in one end of the nail, and leaving the screw in compression hole.
Dynamization of static osteosynthesis is used in postoperative period, so possibility of its application should be considered.

71 Perform the 1,5cm long incision over the head of screw inserted in the locking hole. Introduce the tip of screwdriver T25 into the screw's socket, through the surgical wound. Drive the screw out of nail's locking hole, leave the screw placed in the compression hole.

40.5575.400

IV.7.4.3. Targeter detachment and end cap placement

72 Remove targeter B **[40.5502.100]** form targeter arm **[40.5501]**. Remove connecting screw M10x1.5 **[40.5504]** from the proximal end of the nail using wrench S10 **[40.5526.100]** and detach the targeter of the nail locked in the medullary canal.


40.5502.100


40.5501


40.5526.100


40.5504

73 To secure the connecting thread of the nail against bone overgrowth, insert **CHARFIX2** End cap *(implant delivered separately)* **[3.5161.7xx]** guided via guide rod 2.8/385 **[40.5531]** into threaded hole in nail's shank using cannulated screwdriver T30 **[40.5574.300]**.


40.5574.300


3.5161.7xx

40.5531

IV.8. NAIL REMOVAL

74 Remove the end cap or compression screw from intramedullary nail using cannulated screwdriver T30 **[40.5574.300]**. Insert the connector M10x1,5/M12 **[40.5512]** into the threaded hole in proximal end of the intramedullary nail. Then, remove all locking screws using screwdriver T25 **[40.5575.400]**, while reconstruction screws using cannulated screwdriver T30 **[40.5574.300]**. Attach the impactor-extractor **[40.5507]** to the connector. Remove the nail of the medullary canal using mallet.


40.5574.300


40.5512


40.5575.400


40.5507


40.3667

GB

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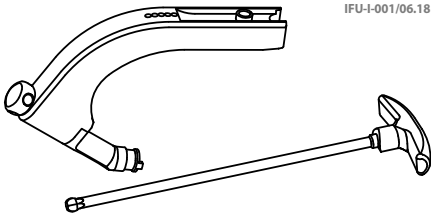
IFU-I-001/06.18



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INSTRUCTIONS FOR USE

REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

1 INDICATIONS

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

2 DESCRIPTION

1. The unit package contains one piece of the product in non-sterile condition. Clear plastic bags are a typical packaging material. The products may also be supplied as a complete set *(arranged on palettes and placed into specially designed sterilization containers)*. This Instructions For Use is attached both to the unit packages and the sets.
2. The package is equipped with the product label. The label *(as a primary label)* contains, among others:
   1) Logo ChM and the address of the manufacturer.
   2) Catalogue number *(REF)*, e.g.: 40.XXXX.XXX, and device name and size.
   3) Production batch number *(LOT)*, e.g. XXXXXXX.
   4) NON-STERILE sign - indicates non-sterile product.
   5) Information symbols *(described in the footer of this Instructions For Use)*.
   6) CE conformity mark.
3. Depending on the size or type of the product, the following information may be marked on its surface: manufacturer's logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.

3 MATERIALS

1. For the production of instruments, ChM sp. z o.o. uses mainly: steel, aluminum alloys and plastics, approved for use in surgical instruments and in accordance with applicable procedures.
2. Instruments are produced of corrosion-resistant steel. The protective layer *(passive layer)* against corrosion is formed on the surface of the device due to high content of chromium.
3. Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as e.g. handles. The protective oxide layer which may be dyed or stays in natural colour *(silvery-grey)* is formed on the aluminium as an effect of electrochemical treatment of its surface.
4. Devices made of aluminium with processed layer have good corrosion resistance. However, the contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference with the processed aluminium surface, shall be avoided.
5. Devices produced of plastics are mainly stands, palettes, cuvettes and some parts of instruments such as e.g. handles. Plastics used in the manufacture of instruments are mainly: PPSU *(Polyphenylsulfone)*, PEEK *(Polyetheretherketone)*, teflon *(PTFE - Polytetrafluoroethylene)* and silicone. The above-mentioned materials can be processed *(washed, cleaned, sterilized)* at temperatures not higher than 140°C. They are stable in aqueous solution of washing-disinfecting agents with a pH value from 4 to 10.8.
6. Steel surgical instruments with a hardened insert are more durable than steel products. The advantage of the product is the sintered carbide insert placed in the working part of the instrument. This insert is characterized by great hardness and abrasion resistance.
7. If the material of the device cannot be specified, please contact ChM sp. z o.o. representative.

4 WARNINGS AND PRECAUTIONS

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

5 CLEANING, DISINFECTION, STERILIZATION

1. Prior to use of a non-sterile device, the following rules apply:
   1) The device must undergo cleaning, disinfection and sterilization procedures.
   2) Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of cleaning *(manual, automated)*, the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process, etc.
   3) The hospital facility remains responsible for the effectiveness of the conducted cleaning, packaging and sterilization processes with the use of existing equipment, materials and properly trained personnel.
2. Preparation at the place of use.
   1) Immediately after use, remove from instrument blood and other contaminants with disposable cloth or paper towels. Additionally, it is recommended to rinse the instrument under running water or to place it in the aqueous disinfectant solution. Do not let blood, tissues, body fluids or other biological impurities dry out on the surface of the device.
   2) In order to prevent blood and debris from drying out on the instrument surface, transport the product to the processing area in a closed container or covered with a damp cloth.
   3) In order to avoid contamination during transportation, the dirty instruments should be separated from the clean ones.
3. Preparation for washing and disinfection *(for all methods)*.
   1) The used instruments should be reprocessed as soon as possible.
   2) If the instrument can be disassembled, it must be done before cleaning processes.
   3) Rinse under running water and remove surface debris using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*. Particular attention should be paid to openings and places difficult to be cleaned. Very dirty devices should be soaked in an aqueous solution of a detergent or a washing-disinfecting agent, e.g. neodisher® MediClean forte, at temperature of 40+/- 2°C and pH of 10.4-10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
   4) CAUTION: It is forbidden to use brushes made of metal, bristles or materials which could damage the product.
4. Cleaning and disinfection process.
   1) This Instructions for Use describes two ChM-approved cleaning and disinfection methods: manual with ultrasound cleaning and automated method. It is recommended to use automated cleaning and disinfection procedures *(in a washer-disinfector)*.
   2) The chosen washing and disinfecting agents must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of those cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 10.4 and 10.8. ChM used the following materials during the validation process of the described recommendations for cleaning and disinfection. It is allowed to use other materials than those listed below which may also give a comparable effect:
      a) detergent - Dr.Weigert *(producer)* neodisher® MediClean forte *(name of the detergent)*;
      b) disinfectant - Dr.Weigert *(producer)* neodisher® Septo Active *(name of disinfectant)*.
   3) To prevent product damage *(pitting, rust, discoloration)*, do not use aggressive cleaning agents *(NaOH, NaOCl)*, saline solutions and unsuitable cleaning agents.
   4) Where possible, it is recommended to use demineralized water to avoid the formation of spots and stains caused by chlorides and other compounds present in ordinary water.
   5) Manual with ultrasound cleaning.
      a) Equipment and materials: a device for ultrasound cleaning, soft, lint-free cloths, plastic brushes, syringes, aqueous solutions of cleaning agent.
      b) Manual cleaning: Initial manual cleaning must be performed prior to ultrasound cleaning.
      c) Rinse under running water until the product is visually clean. Use plastic brushes to remove heavy or large debris.
      d) Soak the product for at least 10 minutes in an aqueous solution of a detergent at temperature of 40+/- 2°C and pH of 10.4-10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
      e) Rinse the product under cold water for at least 2 minutes, paying particular attention to the holes and places difficult to be cleaned.
      f) Prepare fresh washing solution. Clean the surfaces and gaps of the product, carefully. Use suitable brushes to clean the holes. Clean the product immersed in the solution.
      g) Rinse the product thoroughly under warm running water for at least 2 minutes, paying special attention to the gaps, blind holes, hinges and joints. When cleaning, use brushes and perform multiple reciprocating movements on the surface of the product.
      h) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-h until the product is visually clean.
      i) Ultrasound cleaning: prepare an aqueous cleaning solution at a temperature of 40 +/- 2°C and pH of 10.4 - 10.8 *(follow the information contained in the instructions prepared by the manufacturer of the cleaning agent, in respect of temperature, concentration, exposure time and water quality)*. Immerse fully the product in the aqueous cleaning solution and have it washed in ultrasounds for 15 minutes.
      j) Rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
      k) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-k until the product is visually clean.
      l) Use demineralized water for final rinsing of the device.
      m) Dry the device thoroughly using disposable, soft, lint-free cloth or compressed air.
      n) Prepare an aqueous solution of disinfecting agent at a temperature of 20+/-2 °C using 20g of the agent per 1 liter of water. Immerse the product in the solution, exposure time – 15min *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
      o) After the exposure time, rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
      p) The cannulated instruments should be treated using a compressed air or air supplied from the syringe.
      q) Dry the device thoroughly. It is recommended to dry the product in a dryer at a temperature ranging from 90°C to 110°C.
      r) Visually inspect the entire surface of the device.
      s) CAUTION: If the obstruction in the cannula cannot be removed as indicated in the Instructions for Use, the device should be considered at the end of its useful life and should be discarded in accordance with facility procedures and guidelines.
   6) The automated method using a washer - disinfector.
      a) Equipment and materials: a washer - disinfector, aqueous solutions of cleaning agent.
      b) Cleaning in the washer-disinfector must be preceded by a manual and ultrasound cleaning, following the procedure described in subsections c-h of paragraph 5.
      c) CAUTION: The equipment used for washing/disinfection should meet the requirements of ISO 15883. Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washer-disinfector manufacturer, and instructions for use prepared by the washing-disinfecting agent manufacturer.
      d) The device should undergo the process of machine washing in the washer-disinfector using the following cycle parameters: *(1)* - pre-washing in cold tap water, duration – 2min; *(2)* - washing in an aqueous solution of cleaning agent at 55+/-2°C and pH of 10.4 - 10.8, duration – 10min; *(3)* - rinsing under demineralized water, duration – 2min; *(4)* - thermal disinfection in demineralised water at 90°C, minimal duration – 5min; *(5)* - drying at the temperature ranging from 90°C to 110°C, duration - 40min.
5. Inspection
   1) Each time before re-use and re-sterilization, all medical devices should be inspected.
   2) All parts of the product should be checked for visible dirt and corrosion. Particular attention should be paid to:
      b) Holes, grooves and gaps the debris could have been pressed into during use.
      a) Places where dirt can be found, such as joints, latches, etc.
   3) Generally unmagnified visual inspection under good light conditions is sufficient.
   4) Each time before re-use and re-sterilization, the functional check of the product should be performed, consisting of:
      a) Verifying the connections in the mating instruments, such as tips, shafts and quick coupling devices.
      b) Verifying the correct functioning of mechanisms, e.g. screw, ratchet, snap mechanism, etc.
      c) Verifying all rotating devices for straightness *(this can be simply achieved by rolling the device on a flat surface)*.
      d) Verifying cutting edges for sharpness.
      e) Verifying instruments for damage to material structure *(cracks, dents, peels, etc.)*.
   5) Damaged or defective product cannot be approved for further use.
   6) Prior to storage, the instrument must be checked for dryness.
   7) CAUTION:
      a) The ChM sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful and proper use reduces the risk of damage to the product and extends its serviceable life.
      b) The manufacturer does not recommend using any preservatives on medical devices.
6. Packaging
   1) Washed and dried devices shall be stored *(if possible)* in suitable stands placed in special sterilization containers. Separate items should be packed in a packaging intended for the recommended steam sterilization. Sterilization containers, item packaging and packaging process itself have to meet the requirements of ISO 11607 standards. The packaging procedure must be performed in controlled purity conditions. The device must be packed so that during its removal from the packaging, when used, there is no risk for its re-contamination
7. Sterilization
   1) Washed, disinfected, and dried device shall undergo the sterilization process. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:
      a) temperature: 134°C,
      b) minimum exposure time: 7 min,
      c) minimum drying time: 20 min.
   2) CAUTION:
      a) The sterilization process must be validated and routinely monitored in accordance with the requirements of EN ISO 17665-1.
      b) Sterilization must be effective and in accordance with requirements of the EN 556-1 standard to ensure the required level of guaranteed sterility SAL 10^{-6} *(where SAL stands for Sterility Assurance Level)*.
      c) Device must not be sterilized in the packaging in which it was delivered, except specially designed sterilization containers.
      d) The method of sterilization using ethylene oxide, gas plasma and dry heat should not be used, unless the Instructions for Use for the product contains sterilization recommendations using these methods.
      e) The sterilization temperature for plastic products *(PPSU, PEEK, PTFE, silicone)* cannot be higher than 140°C.

6 STORAGE

1. The devices should be properly stored. When storing surgical instruments, it is recommended that they never be stacked together. It may lead to damage of cutting edges *(nick or dull)* and/or initiation of corrosion centers. Instruments should be stored in a clean and dry room, at room temperature and off the direct sunlight. If possible, instruments should be stored in suitable palettes placed into specially designed sterilization containers.

7 CALIBRATION

1. Regular calibration is required in case of torque wrenches, handles and connectors. Torque instruments are factory-calibrated, the nominal torque of a calibrated instrument is marked on the device *(e.g. 4 Nm)*. To maintain a high level of safety and accuracy of operation of a torque instrument, it is necessary to follow the calibration deadline which is marked on the device.
2. Instrument calibration is performed by the manufacturer. Any attempt of unauthorized modifications to the construction or factory setting of the torque devices can lead to a potential injury or damage to the product and is prohibited.

8 COMPATIBILITY

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

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

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

IFU-I-001/06.18; Date of verification: June 2018

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

	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
STERILIZE	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterilizzare
	Do not use if package is damaged • Nie używać jeśli opakowanie jest uszkodzone • Не использовать при повреждённой упаковке • No utilizar si el envase está dañado • Nicht verwenden falls Verpackung beschädigt ist • Nepoužívejte, pokud je obal poškozen • Non utilizzare se la confezione è danneggiata
	Consult Instructions for Use • Zajrzyj do instrukcji używania • Обратитесь к инструкции по применению • Consultar instrucciones de uso • Siehe die Gebrauchsanweisung • Řiďte se návodem k použití • Consultare le istruzioni per l'uso
NON STERILE	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Avvertenza
STERILE R	Sterilized using irradiation • Sterylizowany przez napromieniowanie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione
STERILE VH2O2	Sterilized using hydrogen peroxide • Sterylizowany nadtlenkiem wodoru • Стерилизован перекисью водорода • Esterilizado con peróxido de hidrógeno • Sterilisiert mit Wasserstoffperoxid • Sterilizováno s peroxidem vodíku • Sterilizzato mediante perossido di idrogeno
REF	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo
LOT	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto
Mat:	Material • Materiał • Материал • Material • Materiál • 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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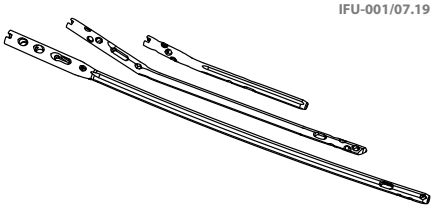
IFU-001/07.19



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INSTRUCTIONS FOR USE

Important product information for

INTERLOCKING NAIL SYSTEM

CHARFIX system | CHARFIX system 2

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

1 PURPOSE AND INDICATIONS

1. Bone nails of CHARFIX, CHARFIX2, ChFN, ChFN2 systems are intended for osteosynthesis of long bone fractures. There are the following indications for bone treatment: transverse and short oblique fractures, trochanteric zone fractures *(per-, inter-, sub-trochanteric)*, comminuted fractures, open fractures of I, II, IIIA degree Gustillo-Anderson, pathologic fractures, disturbance of union *(false joint)* after treatment using other methods, corrective osteotomies, neck base region fractures. Bone nails of CHARFIX FN system and femoro-tibial nails are used to treat diseases associated with the knee joint, in particular: failed arthroplasty, periprosthetic fractures, post-traumatic state which does not allow for implantation of the knee prosthesis, post-infection state, neoplastic transformations, loss of or damage to the knee extensor, knee arthrodesis.
2. Bone nail locking elements: locking screws, reconstruction screws, locking sets, setting screws, compression screw, join screws, end cap, spiral screw and nuts, are used to lock the nails of the above-mentioned systems in the treatment of long bone fractures by means of intramedullary fixation method.
3. Stable osteosynthesis of bone fragments is obtained by locking the appropriate nail in the medullary canal with the use of locking elements suitable for the given nail and fixation method used.
4. Nails and telescopic sleeves are intended for fracture treatment in children and adolescents with congenital osteogenesis imperfecta.
5. Calcaneal nail of CHARFIX2 system is used to treat fractures of the calcaneus and for subtalar arthrodesis.
6. When using CHARFIX2 FN nails combined with knee joint resection, use spacers.
7. The radial nail is intended for treatment of distal radius fractures.
8. For the implantation of the aforementioned products, ChM's specialist instrument sets are dedicated. Along with the instrument set, illustrated surgical technique is also provided. Surgical technique is not a detailed instruction of conduct. This is the physician that determines the proper technique and detailed surgical procedure for a particular patient.

2 CONTRAINDICATIONS

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

3 ADVERSE EFFECTS

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

4 WARNINGS

1. The important medical information provided in this document should be given to the patient.
2. The selection of proper shape and size of the implant appropriate for a specific patient is crucial to achieve the success of the surgery. The surgeon is responsible for this choice.
3. Preoperative and operating procedures, including knowledge of surgical techniques, and correct placement of implants are important and shall be considered by the surgeon in order to achieve success during operation.
4. No implant can withstand body loads without the biomechanical continuity of the bone.
5. During normal use all surgical implants are subjected to repeated stresses which can result in material fatigue and failure of the implant.
6. To avoid excessive stress on the implant which could lead to non-union or implant failure and associated clinical problems, the surgeon must inform the patient about the physical activity limitations during the treatment period.
7. If the patient is involved in an occupation or activity *(e.g.: substantial walking, running, weights lifting, muscles strain)* which may apply excessive stress on the implant, the surgeon must inform the patient that resultant forces can cause implant failure.
8. A successful result is not always achieved in every surgical case. This fact is especially true in the case where other patient's conditions may compromise the results.
9. The proper patient selection, compliance of the patient and observance of post-operative recommendations will greatly affect the results. The bone union is less likely to occur among smoking patients. These patients should be informed about this fact and warned of this consequence.
10. Overweight may cause additional stresses and strains within implant which can lead to fatigue and deformation of the implant.
11. Patients who are overweight, malnourished and/or abuse alcohol or drugs, with weak muscles and low quality bones and/or with nerve palsy are not the best candidates for the procedure of surgical stabilization. These patients are not able or not ready to observe the post-operative recommendations and limitations.
12. The implants are intended as an aid to the healing process and are NOT intended to replace body structures or bear the body weight when the treatment process has not yet finished.
13. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
14. The surgeon must warn the patient that the device cannot and does not restore the function and efficiency of a healthy bone.
15. In the case of delayed union or non-union, the load or weight bearing may eventually cause the implant bending, loosening, disassembling or fatigue breakage.
16. The surgeon should inform the patient of the resulting total stiffening of the limb when using CHARFIX2 FN implants and femoro-tibial nails.

5 PACKAGING AND STORAGE

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

6 IMPLANT MATERIAL

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

7 PRE-OPERATIVE RECOMMENDATIONS

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

8 RECOMMENDATIONS FOR IMPLANTS PROVIDED STERILE

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

9 RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE

1. The following recommendations apply to unused non-sterile implants. An implant that has been implanted must not be re-processed and re-used.
2. The implant which has not been used but got contaminated by contact with the blood, tissue and/or body fluids/materials, should not be used again. The implant should be handled in accordance with applicable hospital protocol. ChM does not recommend re-processing of contaminated implants. Should the contaminated implant be re-processed, ChM bears no responsibility.
3. Prior to use of a non-sterile device, the following rules apply:
1) The device must undergo cleaning, disinfection and sterilization procedures.
2) Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of cleaning *(manual, automated)*, the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process.
3) The hospital facility remains responsible for the effectiveness of the conducted cleaning, packaging and sterilization processes with the use of existing equipment, materials and properly trained personnel.
4. Preparation for washing and disinfection *(for all methods)*
1) Prior to cleaning, remove the implant from the original unit packaging. Dispose of the packaging. Protect patient labels, provided with the implant, against accidental loss or damage.
2) To avoid contamination, the implants should not have contact with the contaminated devices/instruments.
3) Rinse under running water and remove possible surface dirt *(resulting from e.g.: damage to the unit packaging)* using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*.
4) CAUTION: It is forbidden to use brushes made of metal, bristles or materials which could damage the implant.
5. Cleaning and disinfection process
1) This Instructions for Use describes two validated by ChM cleaning and disinfection methods: manual with ultrasound cleaning and automated method. It is recommended to use automated procedures for cleaning and disinfection *(in the washer-disinfector)*.
2) The chosen washing and disinfecting agents must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of those cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 10.4 and 10.8. ChM used the following materials during the validation process of the described recommendations for cleaning and disinfection. It is allowed to use other materials than those listed below which may also give a comparable effect:
a) detergent - Dr.Weigert *(producer)* neodisher® MediClean forte *(name of the detergent)*;
b) disinfectant - Dr.Weigert *(producer)* neodisher® Septo Active *(name of disinfectant)*.
3) Manual with ultrasound cleaning
a) Equipment and materials: a device for ultrasound cleaning, soft, lint-free cloths, plastic brushes, aqueous solutions: of cleaning agent, disinfecting agent or washing – disinfecting agent.
b) Prepare an aqueous solution of cleaning agent at temperature of 40+/-2 °C and a pH of 10.4 - 10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
c) Immerse the implant in the aqueous solution of the cleaning agent and subject it to ultrasound cleaning for 15 minutes.
d) Rinse the implant thoroughly under running water, paying particular attention to the holes and places difficult to be cleaned. It is recommended to rinse with demineralized water.
e) Visually inspect the entire surface of the device for debris and impurity. Damaged implants must be removed. For dirty implants, the cleaning process should be repeated.
f) Dry the device thoroughly using disposable, soft, lint-free cloth.
g) Prepare an aqueous solution of disinfecting agent at a temperature of 20+/-2 °C using 20g of the agent per 1 liter of water. Immerse the implant in the solution, exposure time – 15min *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
h) After the exposure time, rinse the product thoroughly under running water, paying particular attention to the holes and places difficult to be cleaned. It is recommended to rinse with demineralized water.
i) Dry the device thoroughly. It is recommended to dry the implant in a dryer at a temperature ranging from 90°C to 110°C.
j) Visually inspect the entire surface of the device.
4) The automated method using a washer - disinfector
a) Equipment and materials: a washer - disinfector, aqueous solutions of cleaning agent.
b) CAUTION: The equipment used for washing/disinfection should meet the requirements of ISO 15883. Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and Instructions for Use prepared by the washing-disinfecting agent manufacturer.

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

6. Packaging

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

7. Sterilization

1) Washed, disinfected, and dried device shall undergo the sterilization process in accordance with the applicable procedures of the customer. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:
   a) temperature: 134°C,
   b) minimum exposure time: 7 min,
   c) minimum drying time: 20 min.
2) CAUTION
   a) The sterilization process must be validated and routinely monitored in accordance with the requirements of EN ISO 17665-1.
   b) Sterilization must be effective and in accordance with requirements of the EN 556-1 standard to ensure the required level of guaranteed sterility SAL 10^{-6} *(where SAL stands for Sterility Assurance Level)*.
   c) The implant cannot be sterilized in the unit package in which it was delivered.
   d) The method of sterilization using ethylene oxide, gas plasma and dry heat should not be used, unless the Instructions for Use for the product contains sterilization recommendations using these methods.
   e) The above-mentioned principles for cleaning and sterilization must be applied to all implants intended for implantation.
   f) The surgical instruments used for implants insertion should also be covered by cleaning and sterilization procedure.

10 RE-STERILIZATION

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

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

11 PRECAUTIONS

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

1) screwdriver should be set in the screw axis,
2) apply proper axial pressure to ensure that the screwdriver goes as deep in the head of the bone screw as possible,
3) the final phase of tightening shall be performed carefully.

12 POST-OPERATIVE RECOMMENDATIONS

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

13 CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER TREATMENT

1. When bone union is achieved, the implants serve no functional purpose and their removal is recommended. The possibility of another surgical procedure and associated risks must be analysed and discussed with the patient. The final decision on implant removal is up to the surgeon. In most patients, removal is indicated because the implants are not intended to transfer forces developed during normal activities.
2. If the device is not removed following completion of its intended use, one or more complications may occur, in particular:

1) Corrosion and local tissue reaction or pain.
2) Migration of the implant, possibly resulting in injury.
3) Risk of additional injury from postoperative trauma.
4) Bending, loosening, or breakage, which could make implant removal difficult or impossible.
5) Pain, discomfort, or abnormal sensation due to the presence of the implant.
6) Increased risk of infection.
7) Bone loss due to the stress shielding.
8) Potentially unknown and/or unexpected long term effects.

3. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
4. Implantable stainless steel implant shall be removed after period of not more than two years after its implantation.
5. Remove CHARFIX2 FN implants and femoro-tibial nails only in the case of complications.

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

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

IFU-001/07.19; Date of verification: July 2019

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

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

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