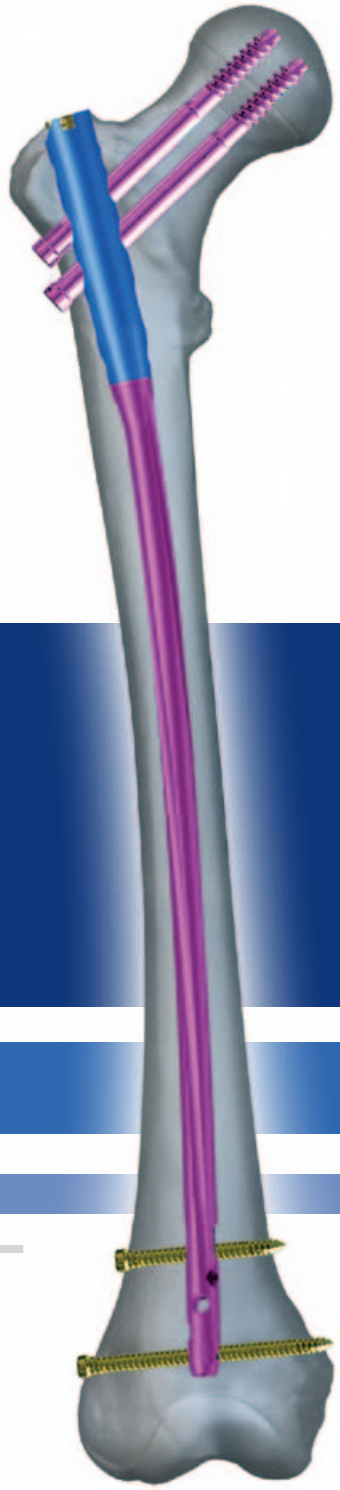
REGIONAL PROGRAMME
NATIONAL COHESION STRATEGY
Podlaskie
EUROPEAN UNION
EUROPEAN REGIONAL DEVELOPMENT FUND

*instruction*

# INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR WITH ANATOMICAL FEMORAL NAILS



- IMPLANTS
- INSTRUMENT SET 40.5500.500
- SURGICAL TECHNIQUE

CHARFIX system 2

34C

CE 0197
ISO 9001
ISO 13485

ChM®

REGIONAL PROGRAMME
NATIONAL COHESION STRATEGY


EUROPEAN UNION
EUROPEAN REGIONAL
DEVELOPMENT FUND

Project co-financed by the European Union
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Marshall Office of Podlaskie Voivodship – Institution Managing ROPPV

Edition 34C dated 02.08.2010, reviewed 29.10.2013

CHARFIX system 2

- a new system of intramedullary locking nails designed on the basis of existing ***CHARFIX*** system of **ChM** Ltd.,
- combines experience of **ChM** Ltd. 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.

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

- implants *(intramedullary nails, reconstructive screws, locking screws, compression screws and end caps)*,
- Instruments for implantation and implants removal after finished treatment,
- Instruction 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 system)*,
- static, using reconstructive screw,
- static.
-


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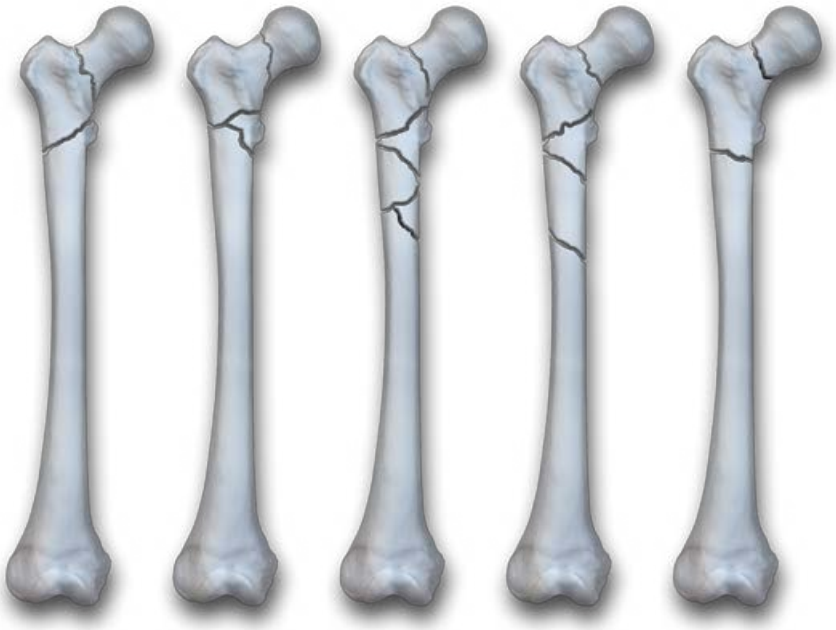
# I. METHODS OF OSTEOSYNTHESIS USING ANATOMICAL FEMORAL NAILS

## 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 reconstructive 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:

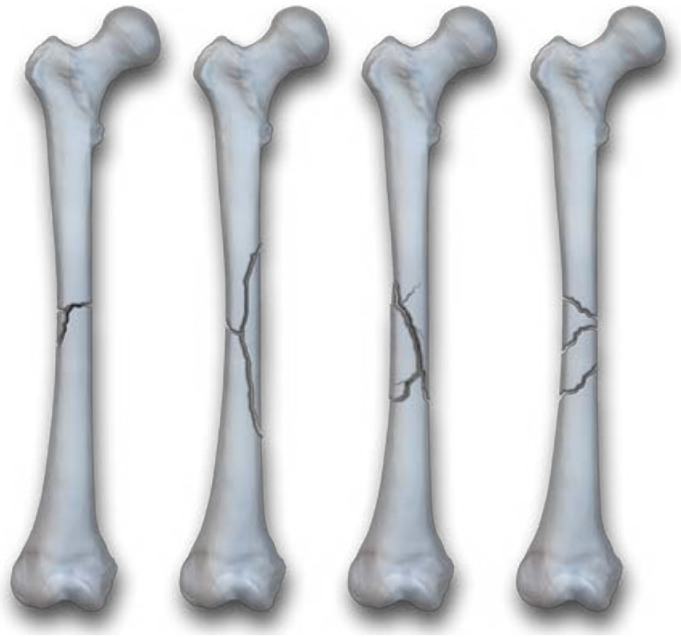


## I.2. STATIC METHOD USING RECONSTRUCTIVE SCREW

Construction of anatomical femoral nail includes additional angular reconstructive 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:





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## I.3. COMPRESSION METHOD

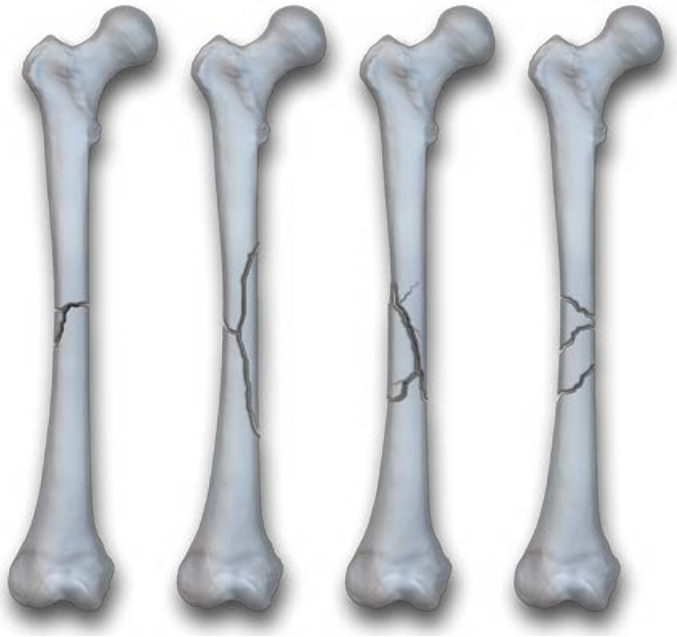
Compression of fragments can be performed with use of compression screw *(implant)*, or intraoperatively using compression screw *(instrument)*.

Anatomical femoral nail allows also 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 and nail, which is necessary in classical compression method. This solution allows to obtain final static system through use of the intraoperative fragments compression, also reducing the operative time.

Compressive locking.

Examples of fractures treated with this method:

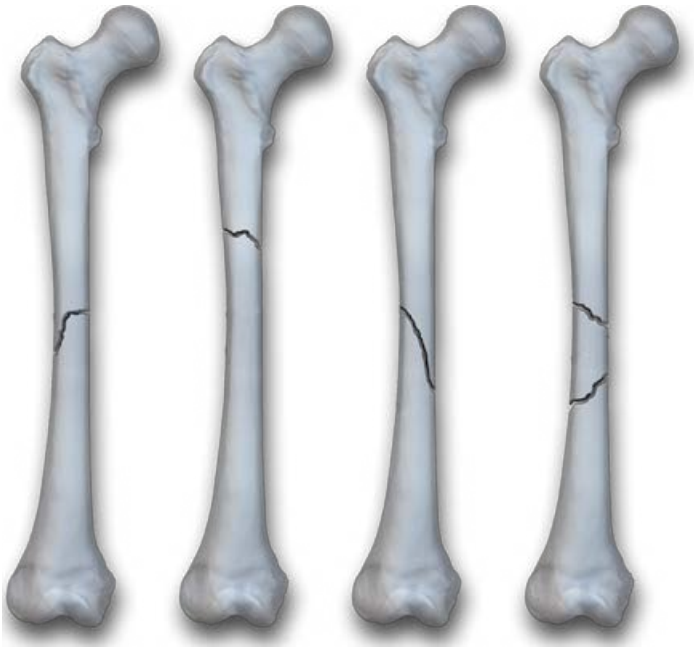


## I.4. DYNAMIC METHOD

Locking the nail in proximal part in compression hole, however 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:





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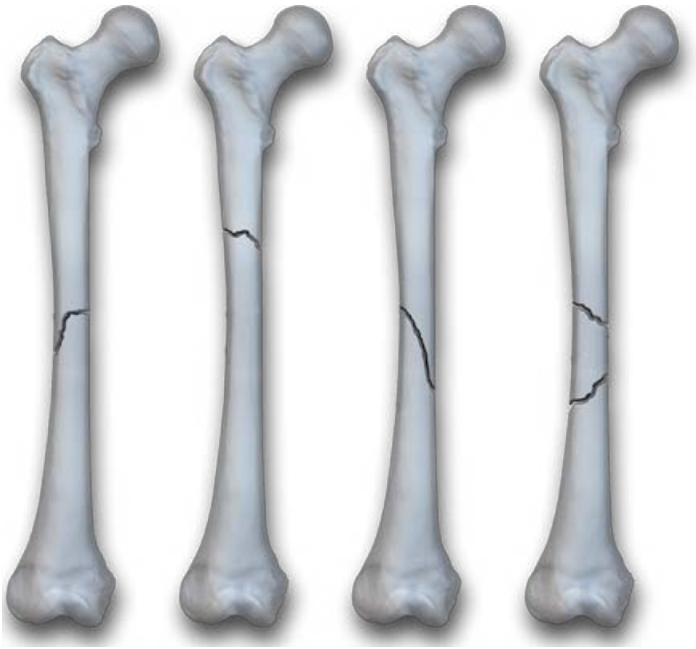
## I.5. SECONDARY DYNAMIZATION METHOD

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

Dynamization of static system.

Examples of fractures treated with this method:

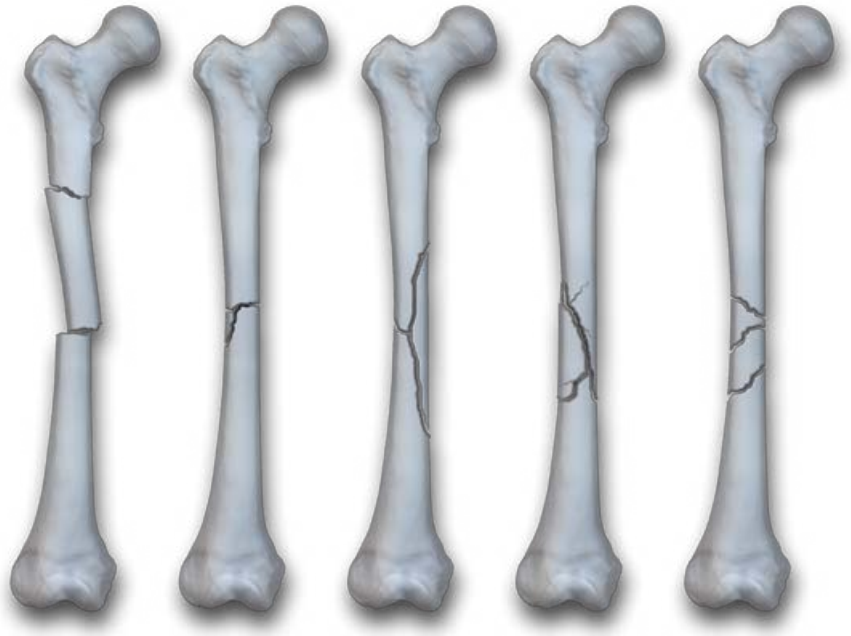


## I.6. STATIC LOCKING

Static locking of the nail is used to eliminate or reduce the movements in bone-nail-screws system. Construction of the implant allows for multiplain 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:





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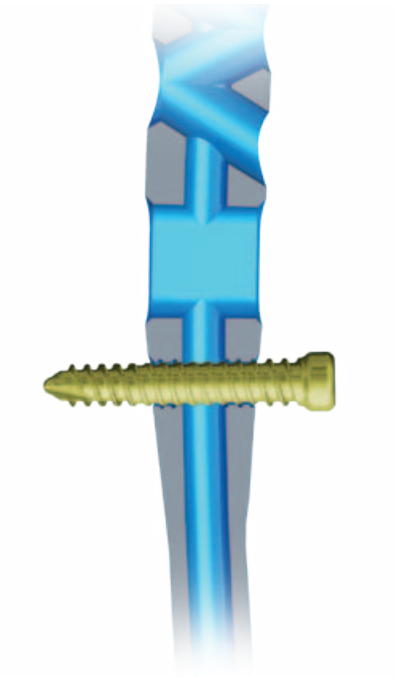
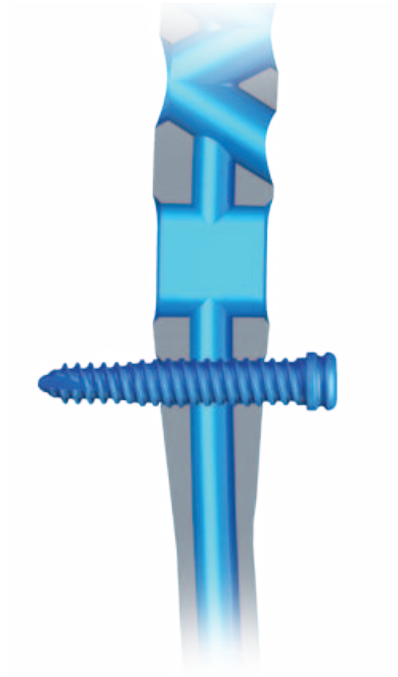
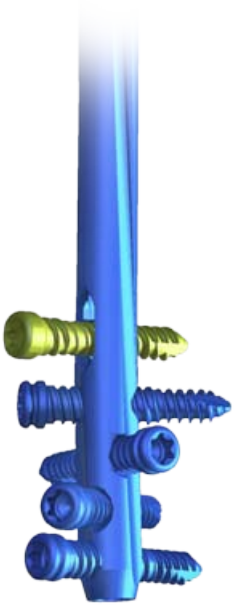
Threaded holes allow optional locking using:
- locking screw 5.0



- locking screw 5.0 to prevent angular displacement of the bone fragments *(using threaded hole in the nail)*.



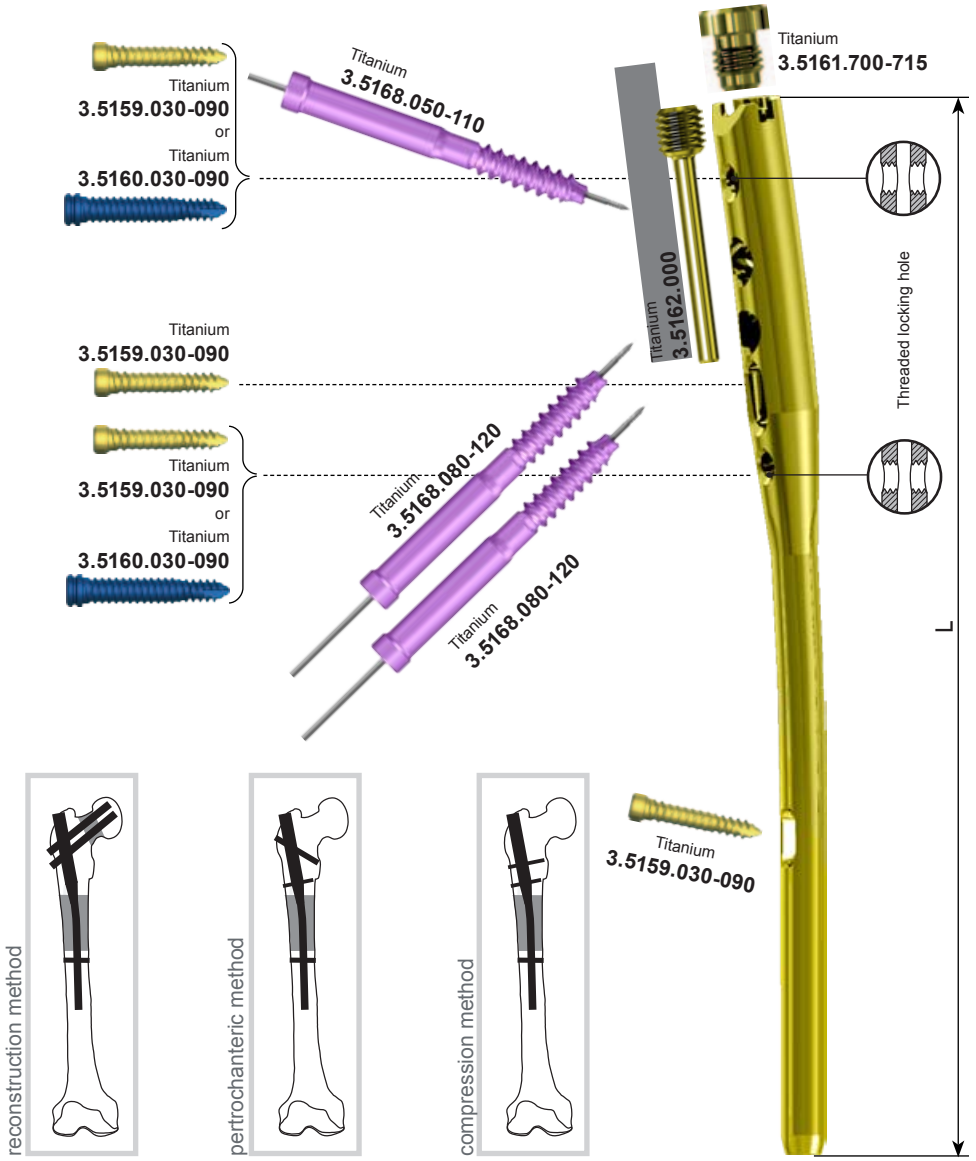


| | Diameter of intramedullary nail | |
|---|---|---|
| | 10 mm and larger | |
| | Standard locking | Standard locking with angular stabilization |
| **Round Hole** ○ | screw 5.0 *(gold)*  | screw 5.5 *(blue)*  |
| **Oval Hole** ⬭ | screw 5.0 *(gold)*  | |

# II. IMPLANTS

CHARFIX system 2

## ANATOMICAL FEMORAL NAIL SHORT




| L mm | Ø | Titanium |
|---|---|---|
| 180<br>200 | 10 | 3.5178.180<br>3.5178.200 |
| 180<br>200 | 11 | 3.5179.180<br>3.5179.200 |
| 180<br>200 | 12 | 3.5180.180<br>3.5180.200 |

| available | |
|---|---|
| Ø mm<br>pitch 1 mm | 10÷12 |
| L mm<br>pitch 5 mm | 180÷240 |

Titanium

| Ø10 | Ø11 | Ø12 |
|---|---|---|
| | | |
| colours | | |



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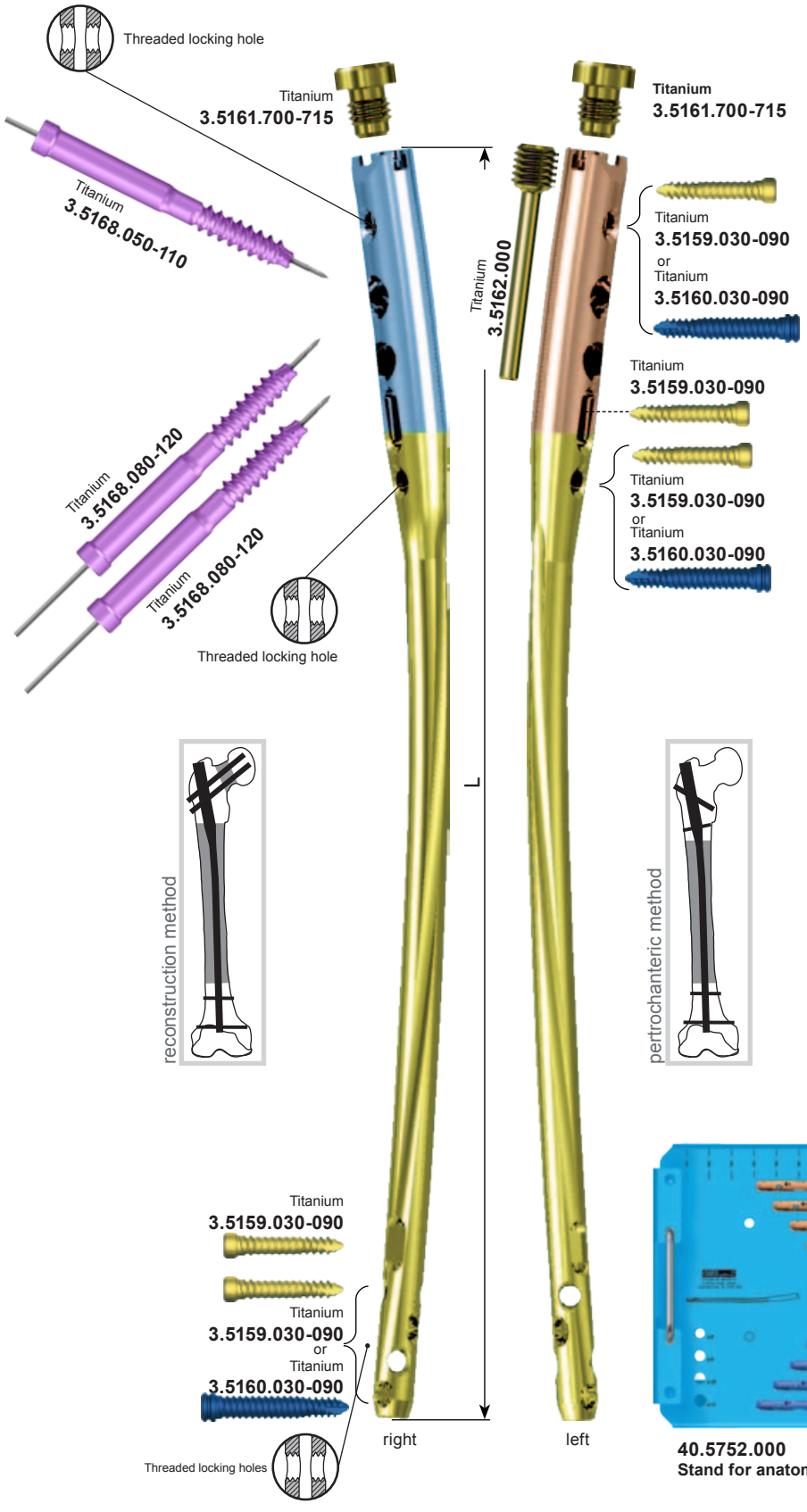
## ANATOMICAL FEMORAL NAIL




| Titanium | | | |
|---|---|---|---|
| L mm | Ø | left | right |
| 340 | 10 | 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 |
| 340 | 11 | 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 |
| 340 | 12 | 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 |

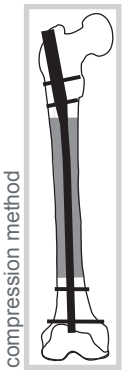
| available | |
|---|---|
| **Ø mm** pitch 1 mm | 10÷14 |
| **L mm** pitch 5 mm | 280÷600 |

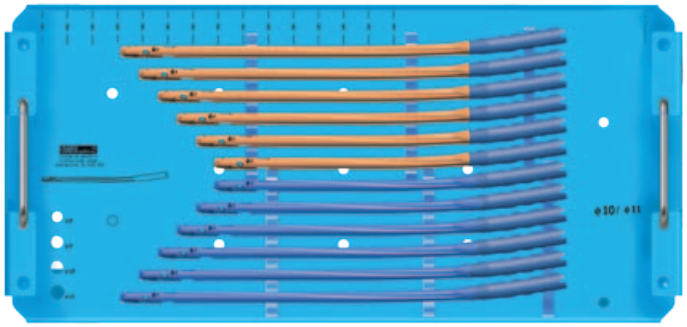
| Titanium | Ø10 | Ø11 | Ø12 |
|---|---|---|---|
| left | | | |
| right | | | |
| colours | | | |









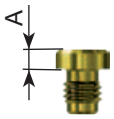



**40.5752.000**
**Stand for anatomical nails** *(implants not included)*

CHARFIX system 2

## LOCKING ELEMENTS

### End cap M10x1.5




| A | Catalogue no. Titanium |
|---|---|
| 0 | 3.5161.700 |
| +5 | 3.5161.705 |
| +10 | 3.5161.710 |
| +15 | 3.5161.715 |

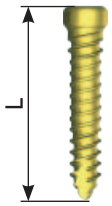
### Compression screw M10x1.5

| Catalogue no. Titanium |
|---|
| 3.5162.000 |

### T30 Cannulated reconstructive screw Ø7.5

| L mm | Catalogue no. Titanium |
|---|---|
| 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 |

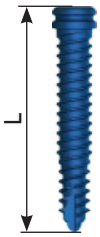
### T25 Distal screw Ø5.0




| L mm | Catalogue no. Titanium |
|---|---|
| 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 |

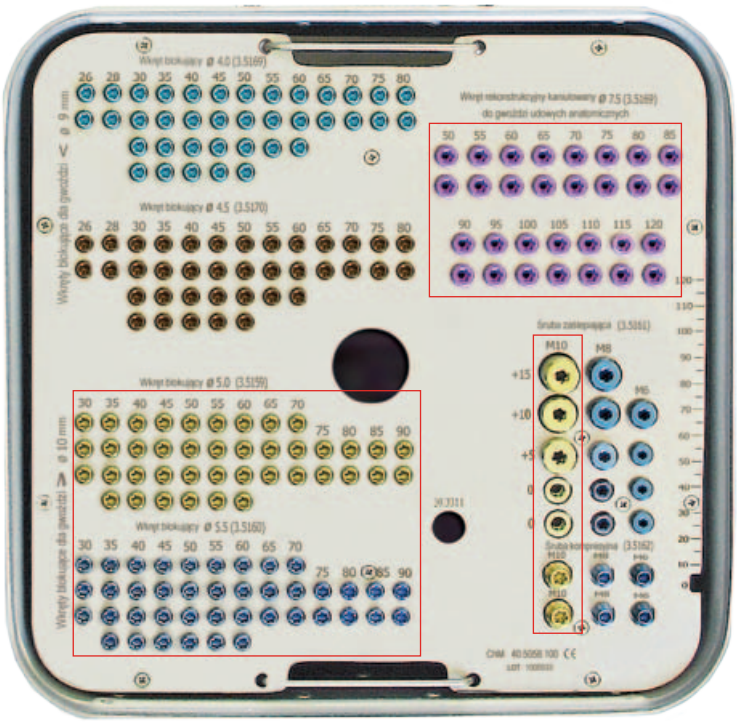
| available L mm | 16÷90 |
|---|---|

### T25 Distal screw Ø5.5




| L mm | Catalogue no. Titanium |
|---|---|
| 30 | 3.5160.030 |
| 35 | 3.5160.035 |
| 40 | 3.5160.040 |
| 45 | 3.5160.045 |
| 50 | 3.5160.050 |
| 55 | 3.5160.055 |
| 60 | 3.5160.060 |
| 65 | 3.5160.065 |
| 70 | 3.5160.070 |
| 75 | 3.5160.075 |
| 80 | 3.5160.080 |
| 85 | 3.5160.085 |
| 90 | 3.5160.090 |

| available L mm | 16÷90 |
|---|---|



**40.5058.000**
**Stand for Charfix2 locking elements**
*(set with box without implants)*



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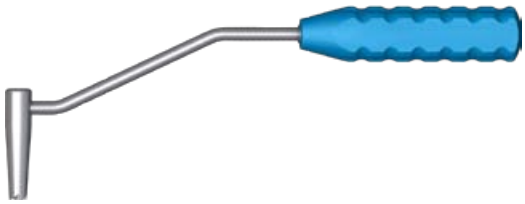
## III. INSTRUMENTS

Instrument set **[40.5500.500]** is used to perform fixation of bone fragments of trochanteric and shaft part of femur and for implants removal 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:

| No. | | Name | Catalogue no. | Pcs. |
|---|---|---|---|---|
| 1 |  | Arm target | 40.5501.000 | 1 |
| 2 |  | Target B | 40.5502.100 | 1 |
| 3 |  | Distal target D | 40.5503.300 | 1 |
| 4 |  | Connecting screw M10x1.5 | 40.5504.000 | 1 |
| 5 |  | Impactor-extractor | 40.5507.000 | 1 |
| 6 |  | Guide 9/2.8 | 40.5508.000 | 1 |
| 7 |  | Set block 9/5.0 | 40.5509.100 | 2 |
| 8 |  | Trocar 9 | 40.3327.100 | 1 |
| 9 |  | Protective guide 11/9 | 40.3328.000 | 2 |
| 10 |  | Protective guide 9/7 | 40.5510.200 | 2 |
| 11 |  | Drill guide 7/3.5 | 40.5511.200 | 1 |
| 12 |  | Connector M10x1.5/M12 | 40.5512.000 | 1 |
| 13 |  | Gradual cannulated drill 7.5/2.8 | 40.5513.200 | 1 |
| 14 |  | Compression screw | 40.5517.000 | 1 |
| 15 |  | Curved awl 8.0 | 40.5523.000 | 1 |
| 16 |  | Wrench S10 | 40.5526.100 | 1 |
| 17 |  | Handle guide rod | 40.1351.000 | 1 |

| No. | | Name | Catalogue no. | Pcs. |
|---|---|---|---|---|
| 18 |  | Screw length measure | 40.5530.100 | 1 |
| 19 |  | Guide rod 2.8/385 | 40.5531.000 | 4 |
| 20 |  | Guide rod 3.0/580 | 40.3925.580 | 1 |
| 21 |  | 3,5/350Drill with scale 3.5/300 | 40.5339.002 | 2 |
| 22 |  | Nail length measure | 40.4798.500 | 1 |
| 23 |  | Cannulated screwdriver T30 | 40.5574.100 | 1 |
| 24 |  | Screwdriver T25 | 40.5575.100 | 1 |
| 25 |  | Target D | 40.1344.100 | 1 |
| 26 |  | Drill guide short 7/3.5 | 40.1358.100 | 2 |
| 27 |  | Trocar short 7 | 40.1354.100 | 1 |
| 28 |  | Trocar 6.5 | 40.5534.100 | 1 |
| 29 |  | Cannulated screw length measure | 40.4724.100 | 1 |
| 30 |  | Mallet | 40.3667.000 | 1 |
| 31 |  | Teflon pipe guide | 40.1348.000 | 1 |
| 32 |  | Insertion target 9.0 | 40.5065.009 | 2 |
| 33 |  | Insertion target 11.0 | 40.5065.011 | 2 |
| 34 |  | Protective guide 17/14 | 40.5518.100 | 1 |
| 35 |  | Cannulated drill 14/3,5 | 40.5515.100 | 1 |



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| No. | | Name | Catalogue no. | Pcs. |
|---|---|---|---|---|
| 36 |  | Stand for instruments anatomic femur nails | 40.5519.500 | 1 |

# IV. SURGICAL TECHNIQUE

**NOTE: The following description includes main steps of procedure during implantation of intramedullary anatomical femoral nails, however it does not comprise the 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, 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 possibility of its 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. It should be always verified if the arthroplasty of hip or knee join has been ever performed before.

Procedure should be performed at traction table and patient positioned supine or in lateral decubitus position.

Advantage of lateral decubitus position is easier access to the greater trochanter, which is significant 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.

Thanks to the possibility of locking the nail with screws there is no need to exactly fit the medullary canal. In case of nailing without reaming the medullary canal Ø10 and 11 mm nails are used.

Nails with diameter of Ø12, 13, 14 mm are intended for the cases in which reaming cannot be avoided. It should be noticed, that diameter of reamed hole should be about 1,5÷2 mm greater than nail diameter.

However, in each case, in proximal metaphysial section, for Ø10, 11, 12, 13, 14 mm nails the hole should be reamed for diameter of Ø15 mm and depth of 9 cm. This facilitates penetration of nail's proximal end, which is wider in this section. Surgeon decides about reaming on the basis of medullary canal shape and fracture type.

Reaming of medullary canal is contraindicated in patients with chest injury due to risk of fat embolism.

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

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

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


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## IV.2. PATIENT POSITIONING

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

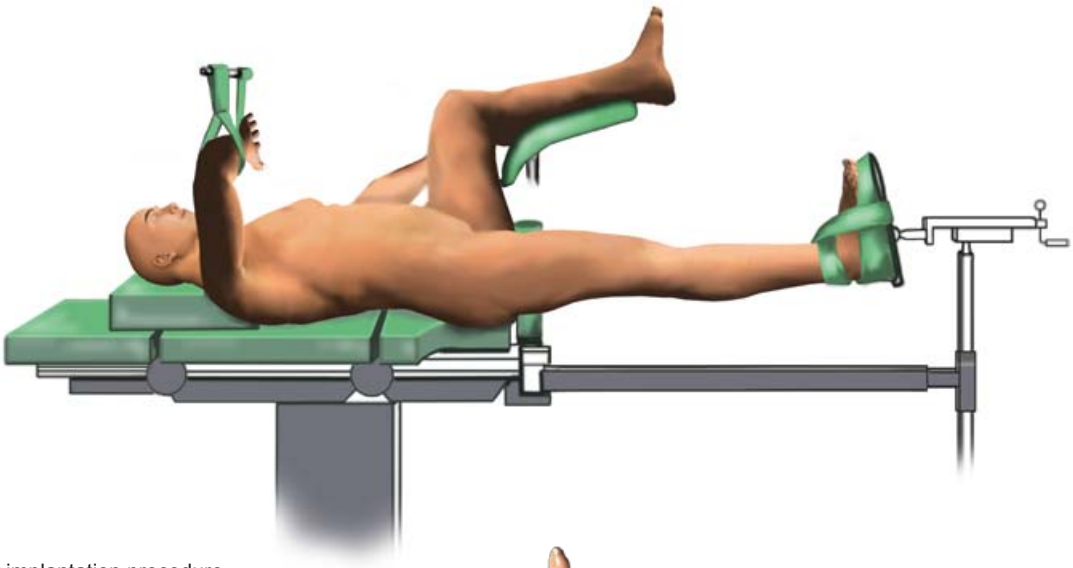
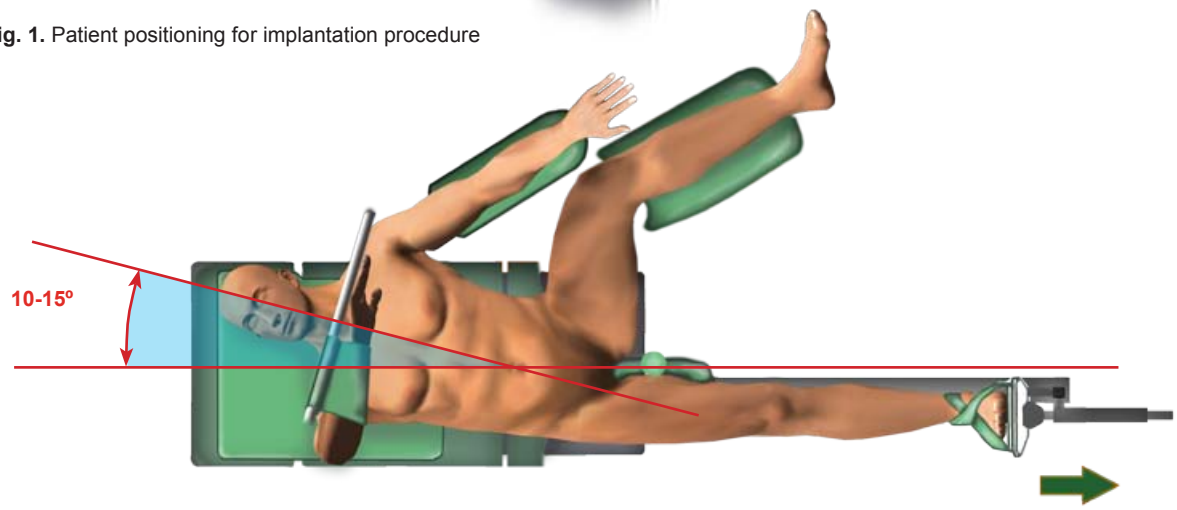


**Fig. 1.** Patient positioning for implantation procedure




## 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 reposition.

## 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 way ensuring precise imaging in AP and lateral position [Fig. 2.].

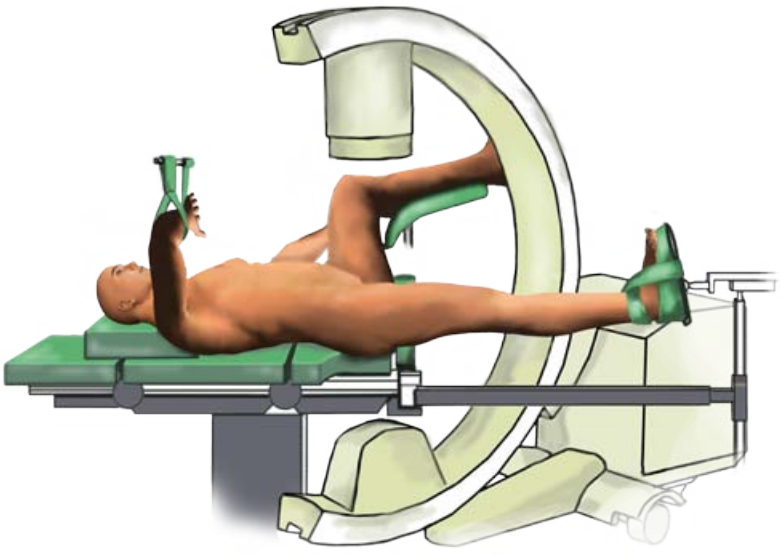
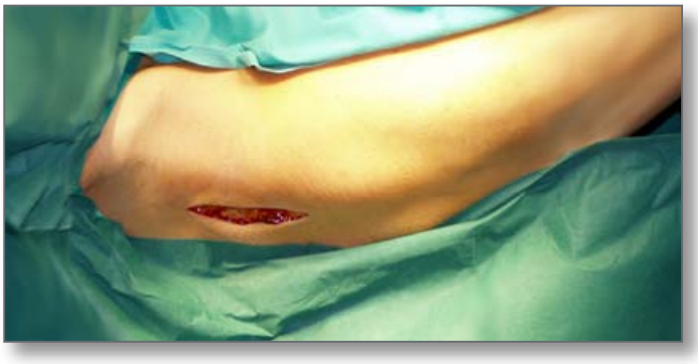


**Fig. 2.** Positioning of intraoperative X-Ray unit with C-arm

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

Watson-Jones lateral approach is recommended. Palpate the greater trochanter. Then, perform 3÷5 cm lateral incision in 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.



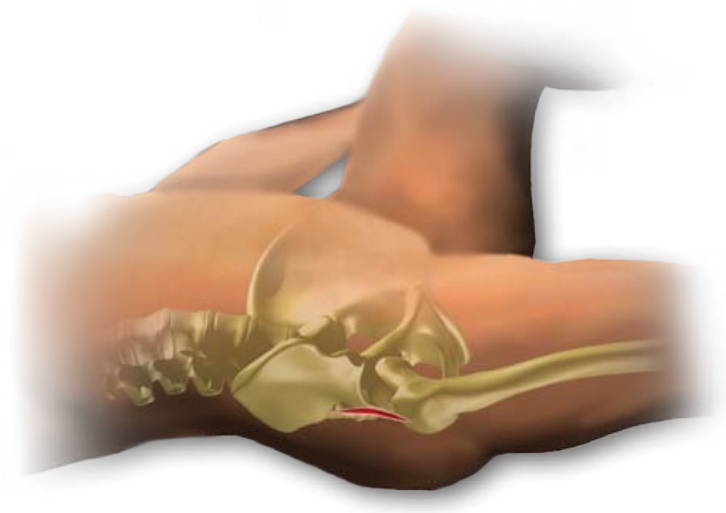


**Fig.3.** Determination of incision site

## 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 intramedullary canal [Fig. 4.].
Entry hole should be performed using sharp ended Curved Awl **[40.5523]**. Precise preparation of entry hole ensures right nail insertion.

The surgeon determines length, diameter and type of the nail on the basis of injured femur X-Ray and X-Ray of opposite intact femur with gauge.

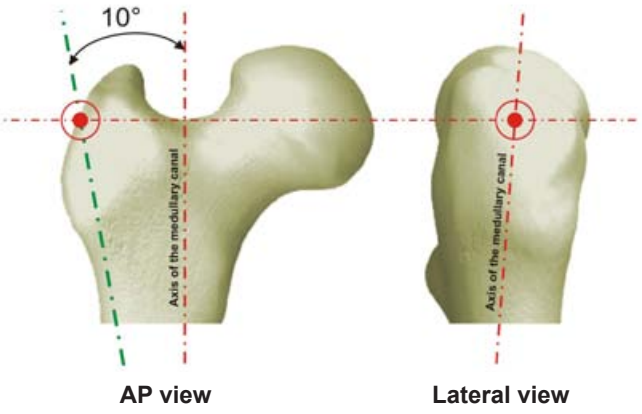
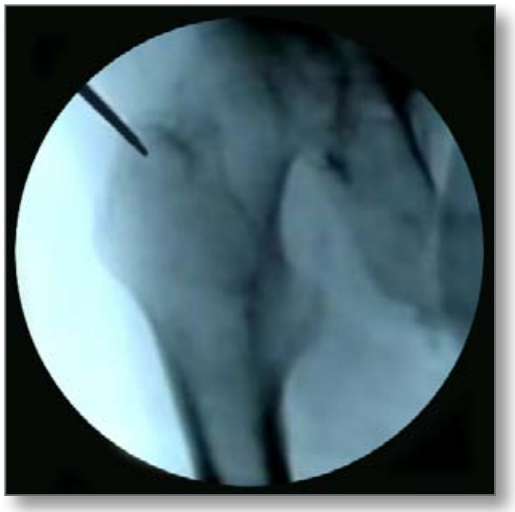



**Fig. 4.** Entry point



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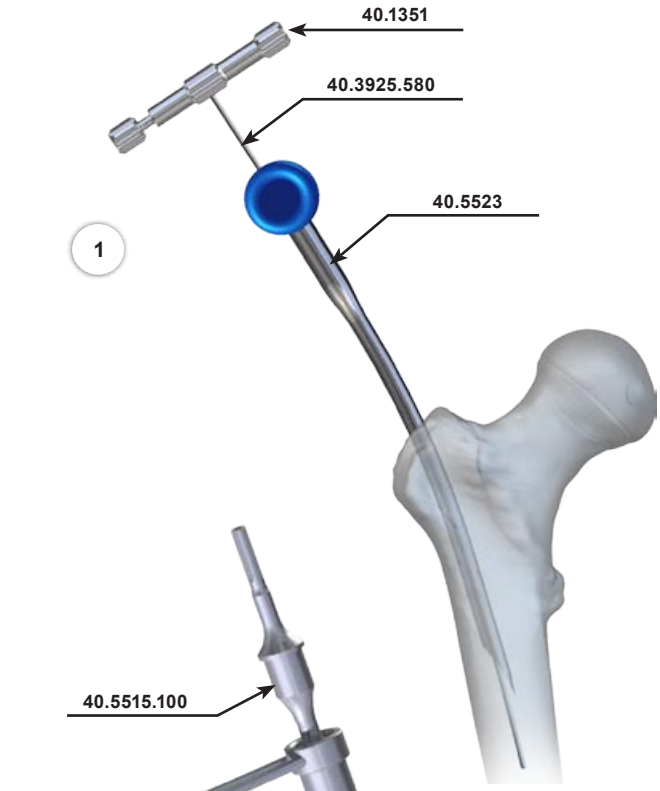
## IV.6. OPENING AND PREPARATION OF MEDULLARY CANAL AND NAIL INSERTION

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

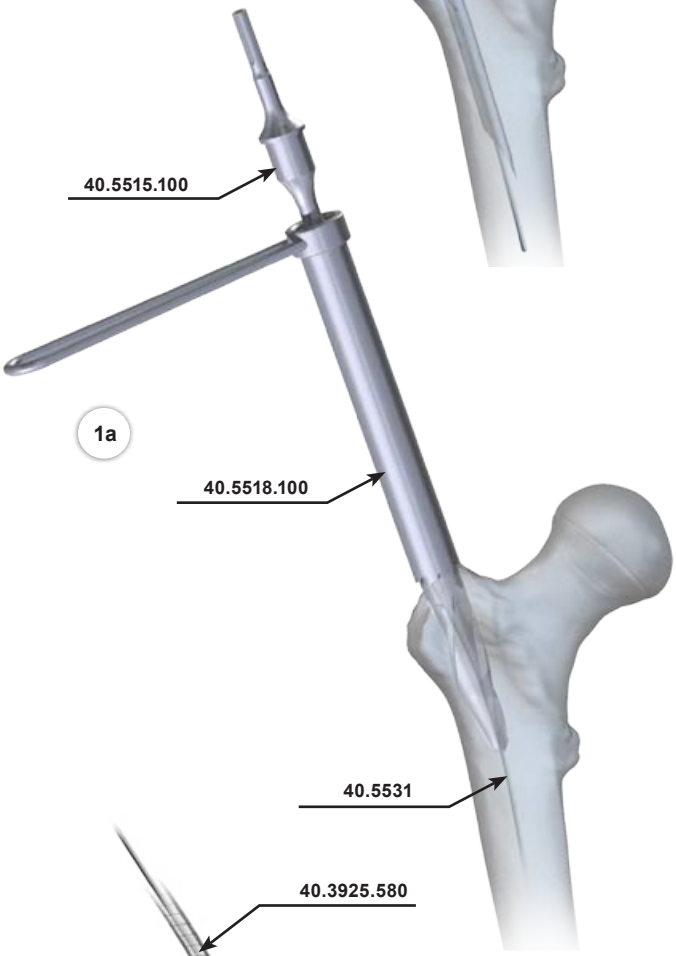
1 Make a skin incision near the tip of trochanter major.
After localizing the entry point for the nail, open the medullary canal using Curved awl 8.0 **[40.5523]**. Penetrate the awl in trochanter with angle equal to angle of proximal end deflexion against the main axis of the nail *(approximately 10º)*, paying attention not to perforate opposite cortex. Continue awl penetration while spare of the awl is in line with intramedullary canal axis, enabling correct introduction of guiding wire.
Mount the Guide rod 3.0/580 **[40.3925.580]** in Handle guide rod **[40.1351]** and introduce into medullary canal through cannulated hole of curved awl **[40.5523]**, at depth required for correct fragments fixation. During rod introduction the fracture reduction should be monitored and the attention must be paid to pass with the guide rod through all fragments.

**Described operations should be performed under the X-Ray image intensifier.**

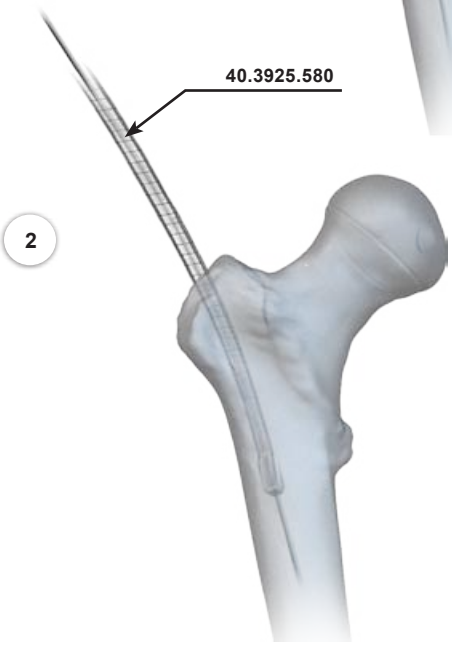



1a After locating insertion point, use the driver to insert the Guide rod 2.8/385 **[40.5531]** into the medullary canal.
The Guide rod is as the guide for the Cannulated drill 14/3.5 **[40.5515.100]** lead in the Protective guide 17/14 **[40.5518.100]**.
Slowly ream the medullary canal using the cannulated drill until the resistance.
Remove the Cannulated drill with the Guide rod 2.8/385.
Insert into the medullary canal the Guide rod 3.0/580 **[40.3925.580]**.

**The process shall be done under X-Ray control.**




2 Detach handle guide rod **[40.1351]** from the guide rod. Remove curved awl 8,0 **[40.5523]** from intramedullary canal, leave the guide rod.




Ream the medullary canal in proximal part using flexible reamer Ø15 mm, guided over the guide rod 3.0/580 **[40.3925.580]**, for approximate depth of 9 cm.

In case of nail implantation 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 with 0,5 mm diameter graduation obtain hole 1,5÷2 mm greater than nail diameter, with depth not lesser than nail length.

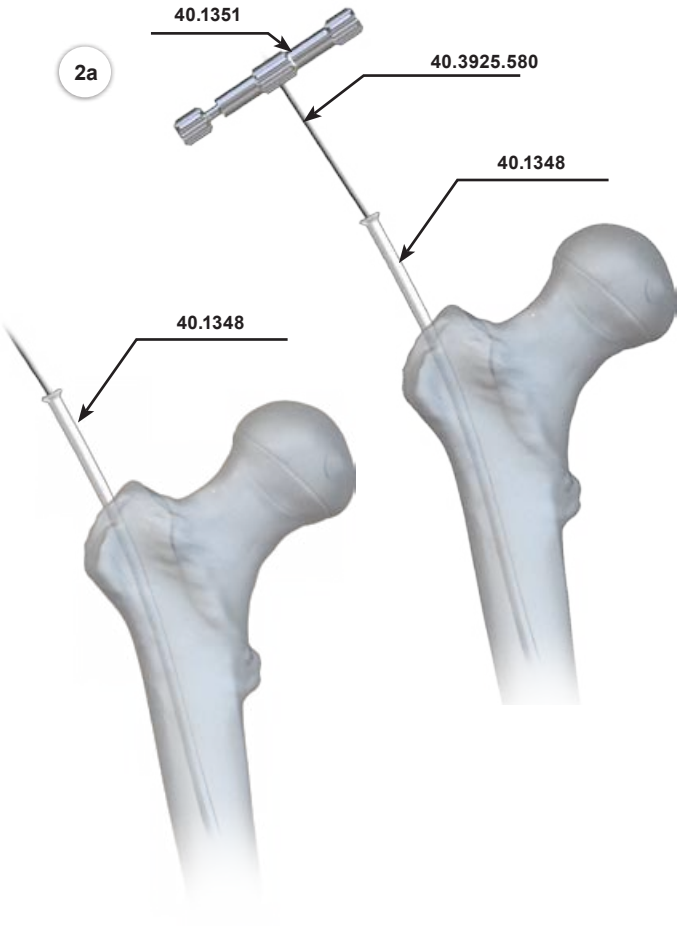
*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

**In case of using the reamer guide other than the one included in the instrument set [40.5500], use the Teflon pipe guide [40.1348]** *(white teflon pipe)* **to ream the intramedullary canal and follow the steps of given instruction.**

2a Introduce the Teflon pipe guide **[40.1348]** over the flexible reamer guide deep into the medullary canal, until the end of reamed canal in distal part of femur is reached.

Remove the flexible reamer guide.

Mount the Guide rod 3.0/580 **[40.3925.580]** in Handle guide rod **[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 handle guide rod **[40.1351]** of the guide rod.
Remove the Teflon pipe guide **[40.1348]** from the intramedullary canal, leave the guide rod.
Next, make the measurement described in step 5.




3 Introduce the Nail length measure **[40.4798.500]** over the guide rod, to contact its end with bone. Read the nail length from the scale. Remove the nail length measure from the guide rod. The intramedullary canal is prepared for nail insertion.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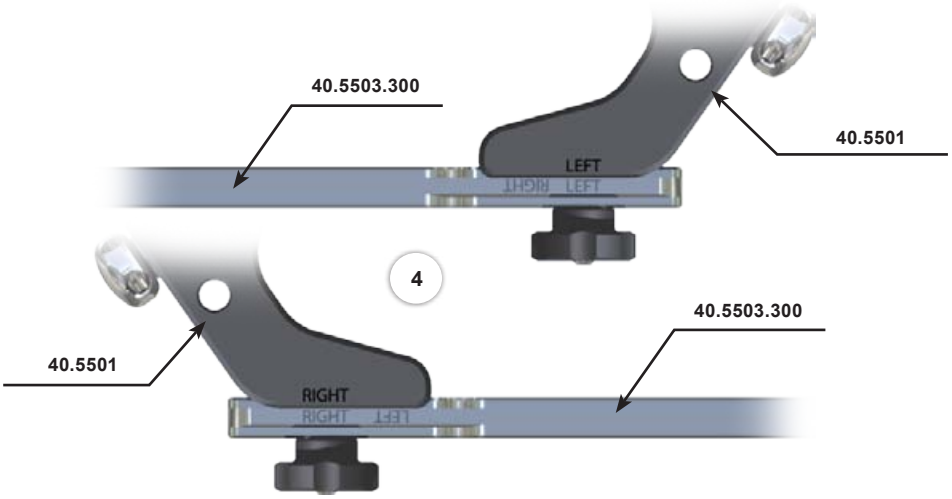
### IV.6.2. Connecting the nail with Targeter B and determination of Targeter D slider position

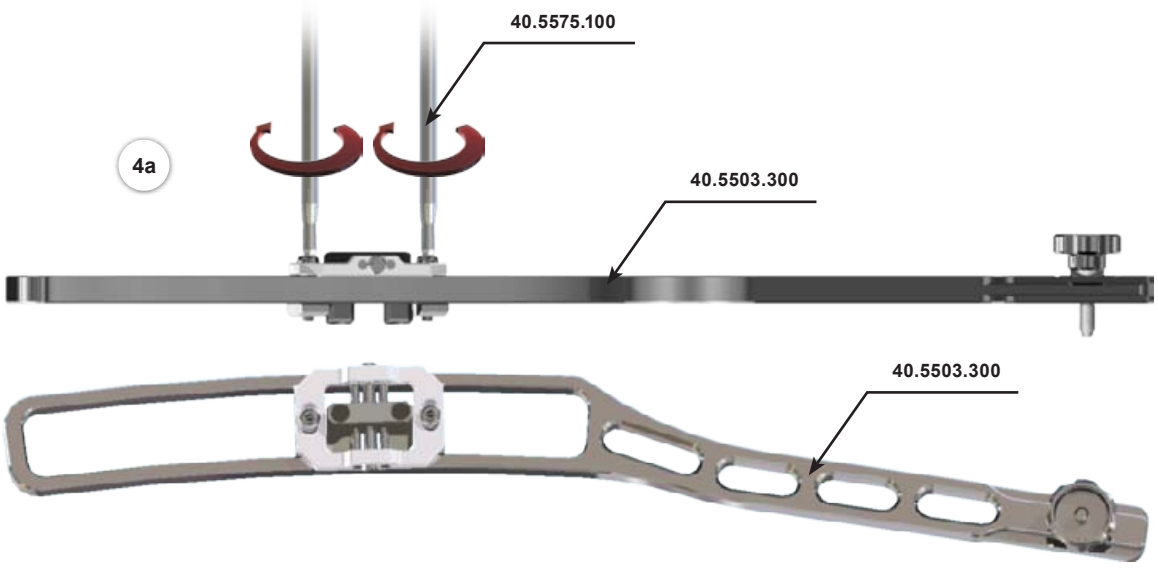
Distal targeter D **[40.5503.300]** cannot be used with short anatomical femoral nails. In this case step 6.2 shall be passed.

4 Prepare the Distal targeter D for connecting with Targeter arm of targeter B.
Distal targeter D **[40.5503.300]** has a targeting slider and a screw for targeter B **[40.5501]** attachment, reversed regarding operating site, before attachment with Targeter arm.

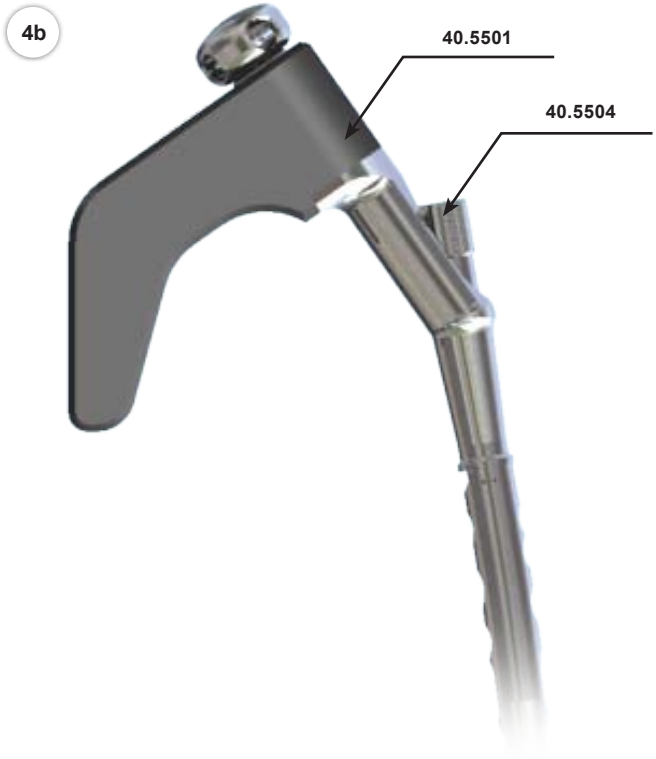
**If both targeters are connected correctly, the reading planes of RIGHT or LEFT sign should be compatible.**




4a **Note!**
The screw joining Distal targeter D with Targeter arm of Targeter B *(proximal)* 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.



**4b** Mount the selected nail to the Targeter arm **[40.5501]** using Connecting screw M10x1.5 driven by Wrench S10 **[40.5526.100]**. Attach the Distal targeter D **[40.5503.300]** to the Targeter arm, in accordance with steps 4 - 4a.

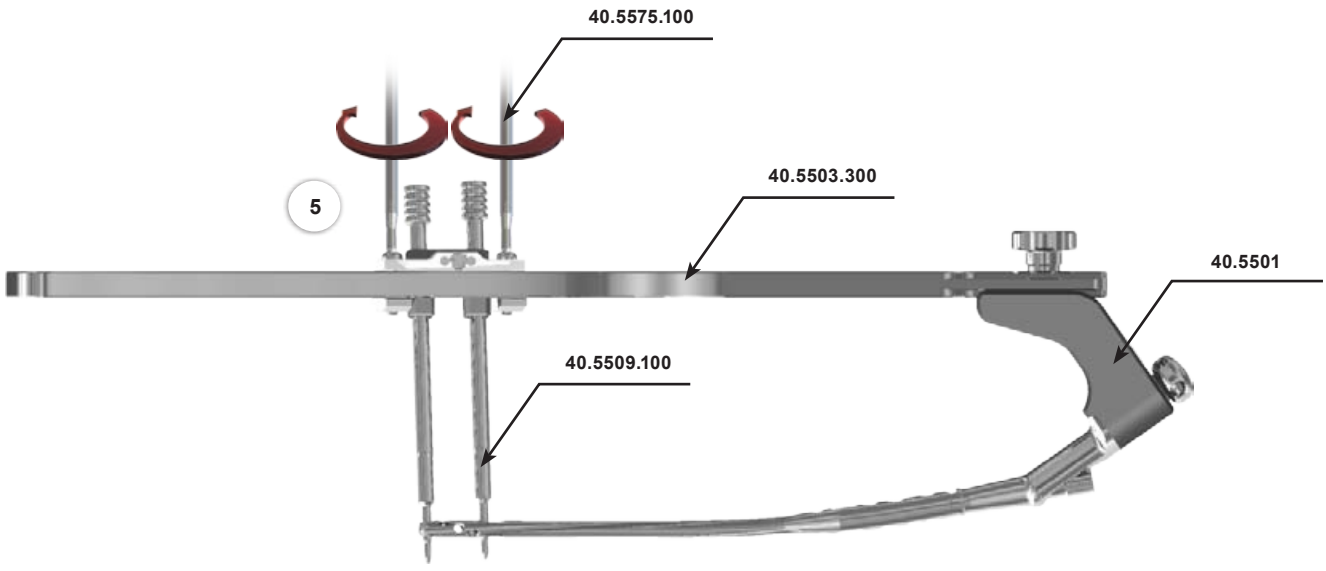



**4c** Loose the slider's setting screw *(in order to allow movement of the slider along the Targeter D beam)* and shift the slider nearby the holes in distal part of the nail.

**5** Set the suitable slider position in relation to the locking holes in distal part of the nail using two Set blocks 9/5.0 **[40.5509.100]**. Fix slider position using the Screwdriver T25 **[40.5575.100]**.

**IMPORTANT!**
**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 Distal targeter D of the Targeter arm.

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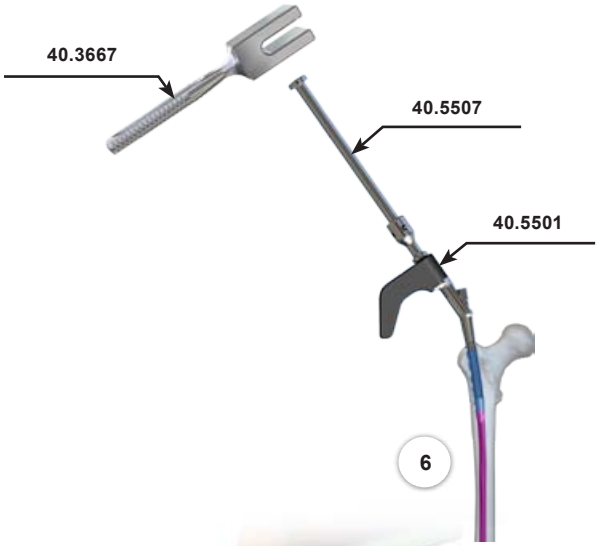
### IV.6.3. Nail insertion into the medullary canal

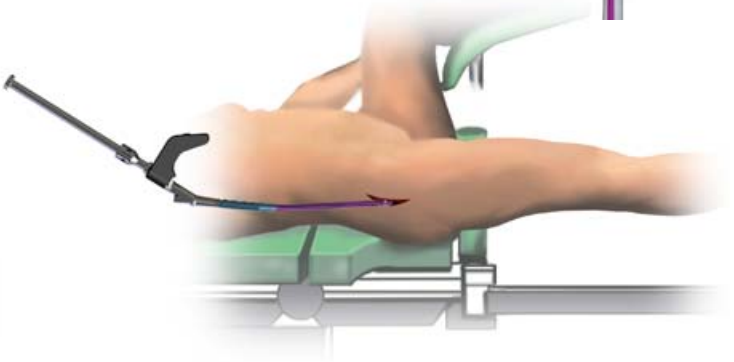
6 Join the Targeter arm **[40.5501]** with Impactor-extractor **[40.5507]**. Position the system in plane perpendicular to the AP plane and introduce the nail into the intramedullary canal using Mallet **[40.3667]**. While introducing, the nail rotates and moves along the medullary canal at once. In the end phase of insertion Targeter arm rotates with the nail at 90º from the initial position.

Remove the Guide rod **[40.3925.580]**.
Detach the Impactor-extractor **[40.5507]** of the Targeter arm **[40.5501]**.

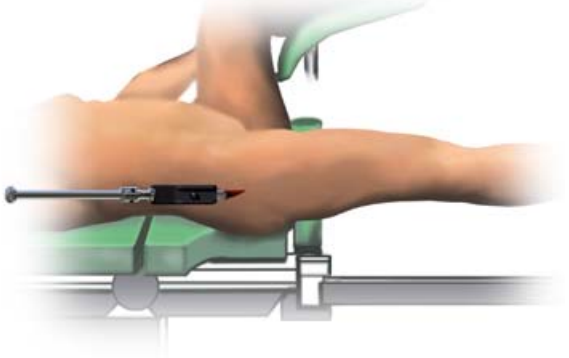


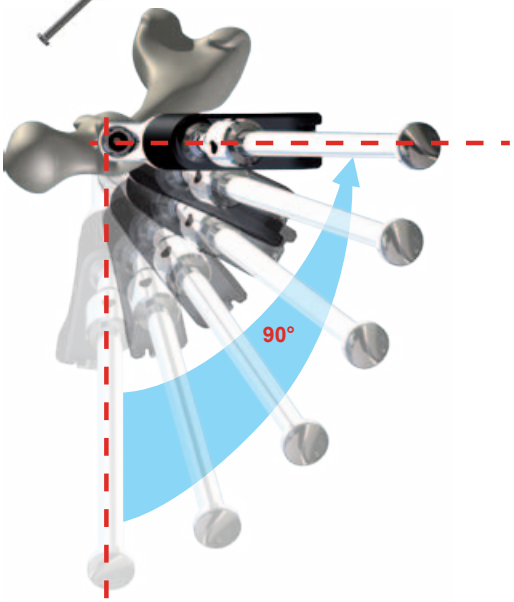


1a


1b


2a


2b




6a **NOTE!**
**Connection of Targeter arm and impactor-extractor is possible after mallet head removal.**

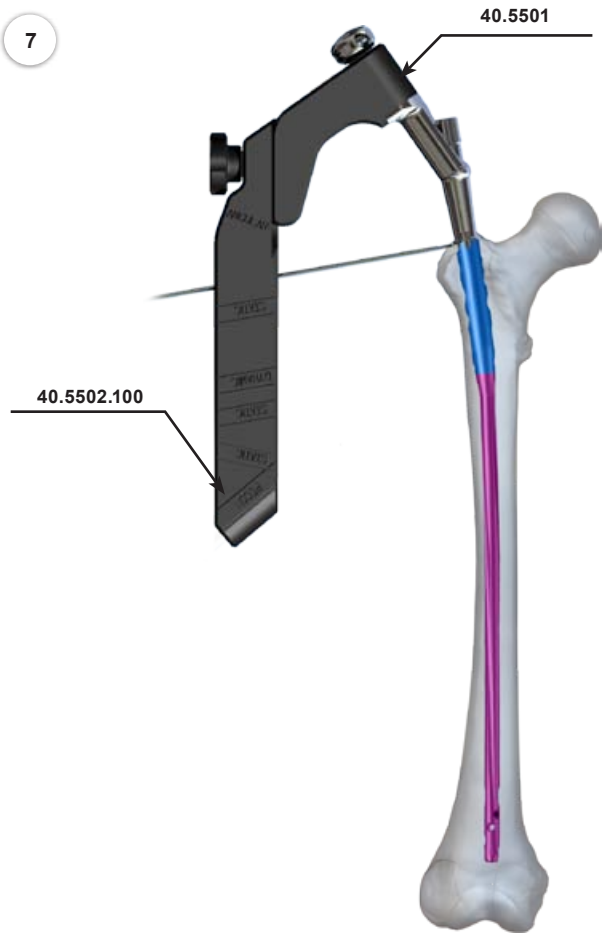
6b **NOTE!**
If the nail did not move from anterior to lateral position, then it should be removed from intramedullary canal and reinserted, with targeter rotated a few degrees laterally in relation to AP plane.

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

7 Correctness of nail penetration inside femur can be checked using K-wire introduced in Targeter B **[40.5502.100]** hole signed *"0"*.

Therefore attach Targeter B **[40.5502.100]** to the Targeter arm **[40.5501]**, then introduce K-wire in hole signed *"0"*. End of the wire 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 K-wires *(introducing K-wires in holes signed "5" ÷ "25" and performing the X-Ray)*, then select the suitable height of the end cap in order to protect the nail against bone overgrowth.

7




## IV.7. LOCKING THE NAIL

### IV.7.1. Reconstruction method

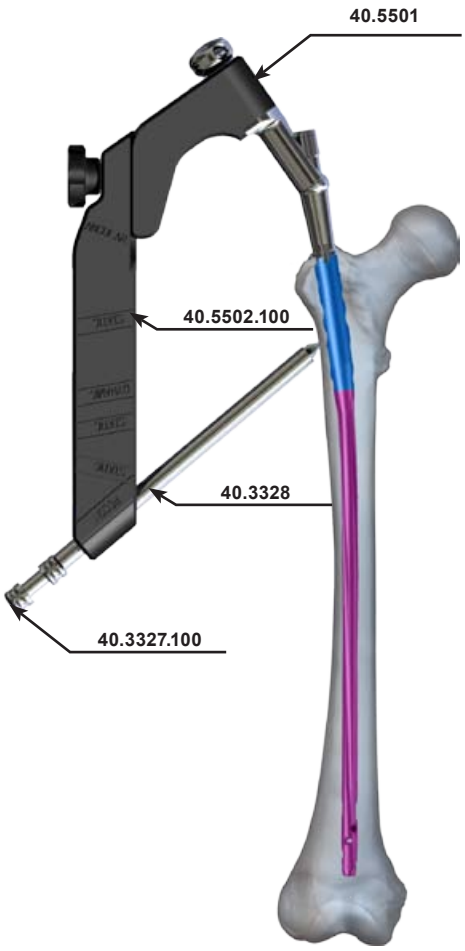
#### *IV.7.1.1. Locking the nail with cannulated reconstructive screws in proximal part*

**NOTE! In reconstruction method the nail should be always fixed with two reconstructive screws.**

8 Introduce Protective guide **[40.3328]** together with Trocar **[40.3327.100]** in distal reconstructive 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.

8

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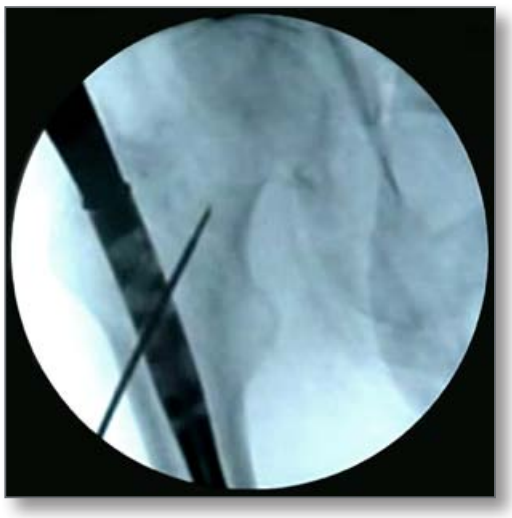
9 Introduce Guide 9/2.8 **[40.5508]** into Protective guide **[40.3328]**.
Mount the Guide rod 2.8/385 **[40.5531]** in the drive.
Drill in the femoral neck with guide rod leaded in Guide 9/2.8, so as not to perforate the cortex of femoral neck and head.

9a **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 reconstructive screw introduction without femoral neck cortex infringement.**
**Repeat the operation should the incorrect Guide rod introduction occur.**

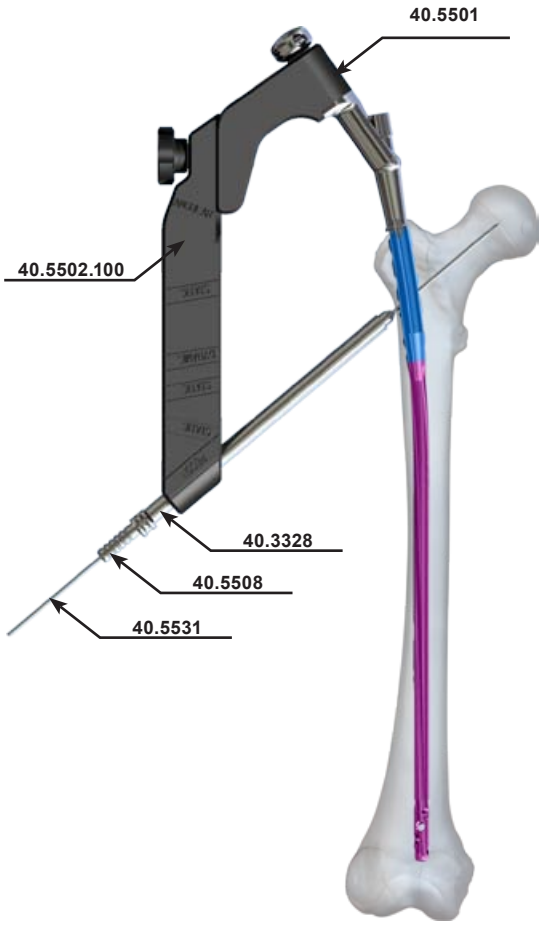
Leave the Guide rod 2.8/385, Guide 9/2.8 and Protective guide 11/9 in the targeter hole.



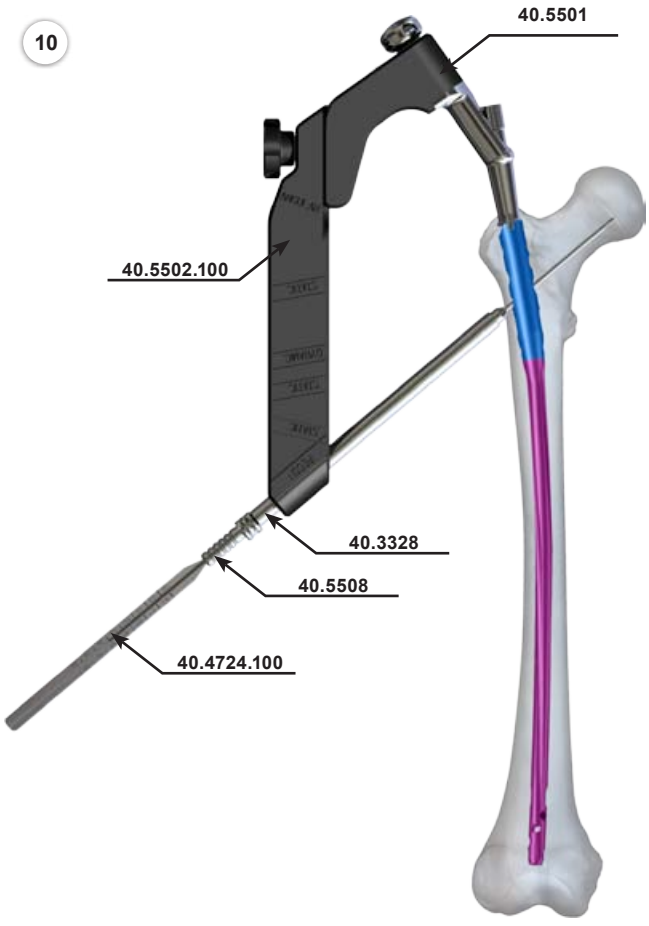
10 Introduce Cannulated screw length measure **[40.4724.100]** onto guide rod introduced in femoral neck, in way that its tapered end contact with the protective guide. Read length of cannulated reconstructive screw from the measure's scale, that is pointed by end of guide rod. Protective guide 11/9 **[40.3328]** 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]**.
Leave the guide rod.

9



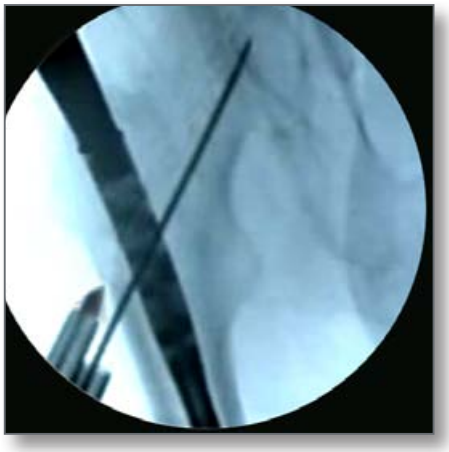

10

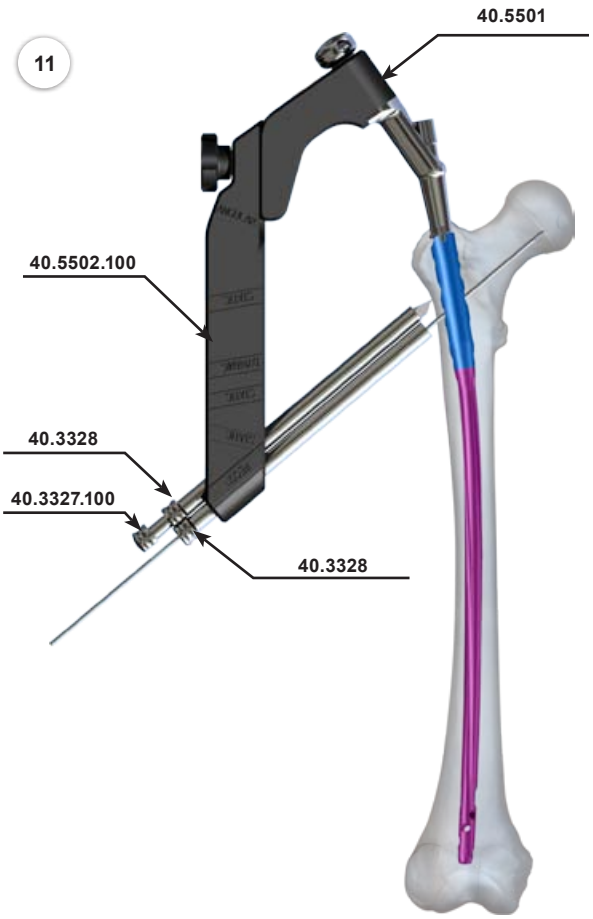



*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

11 Introduce Protective guide **[40.3328]** together with Trocar **[40.3327.100]** in proximal reconstructive 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.

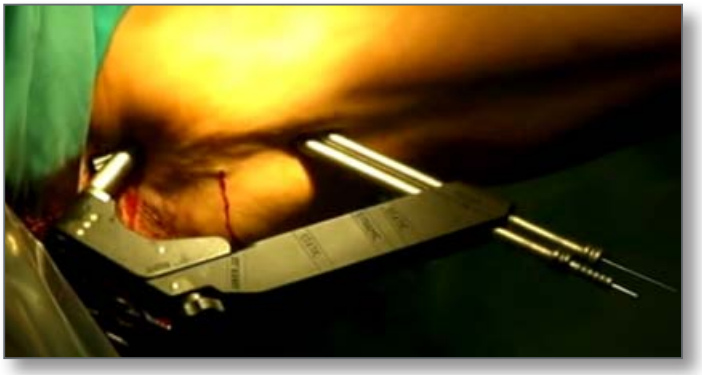


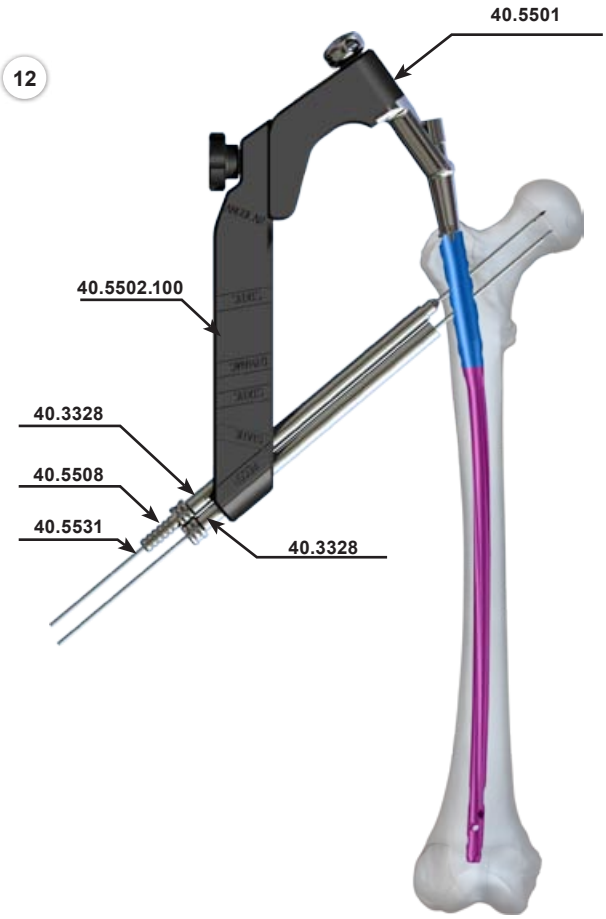



12 Introduce Guide 9/2.8 **[40.5508]** into Protective guide **[40.3328]**.
Mount the Guide rod 2.8/385 **[40.5531]** in the drive.
Drill in the femoral neck with guide rod leaded in Guide 9/2.8, so as not to perforate the cortex of femoral neck and head.

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's 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.



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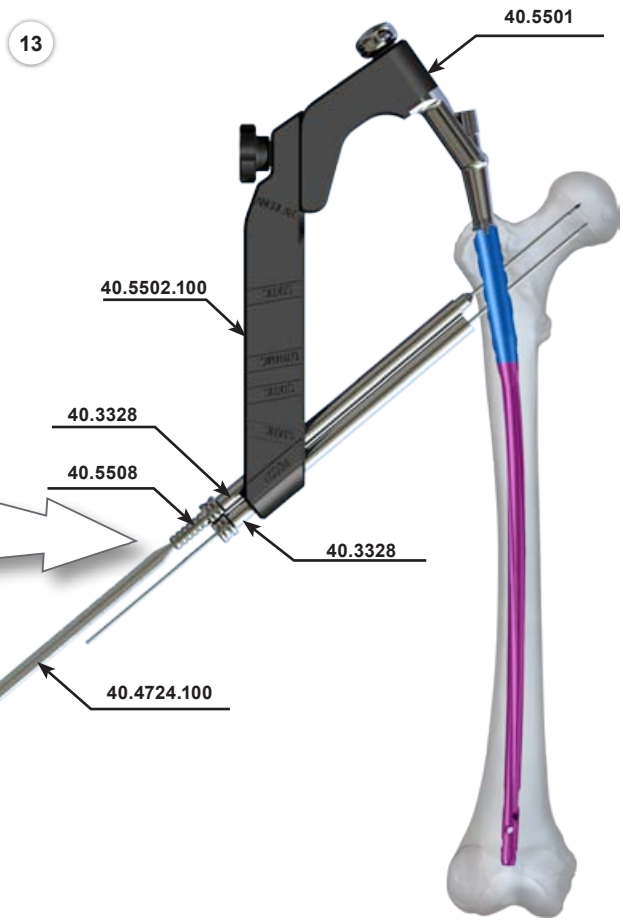
13 Introduce Cannulated screw length measure **[40.4724.100]** onto guide rod introduced in femoral neck, in way that its tapered end contact with the protective guide. Read length of cannulated reconstructive screw from the measure's scale, that is pointed by end of guide rod. Protective guide 11/9 **[40.3328]** should be in contact with cortical bone during the measurement.

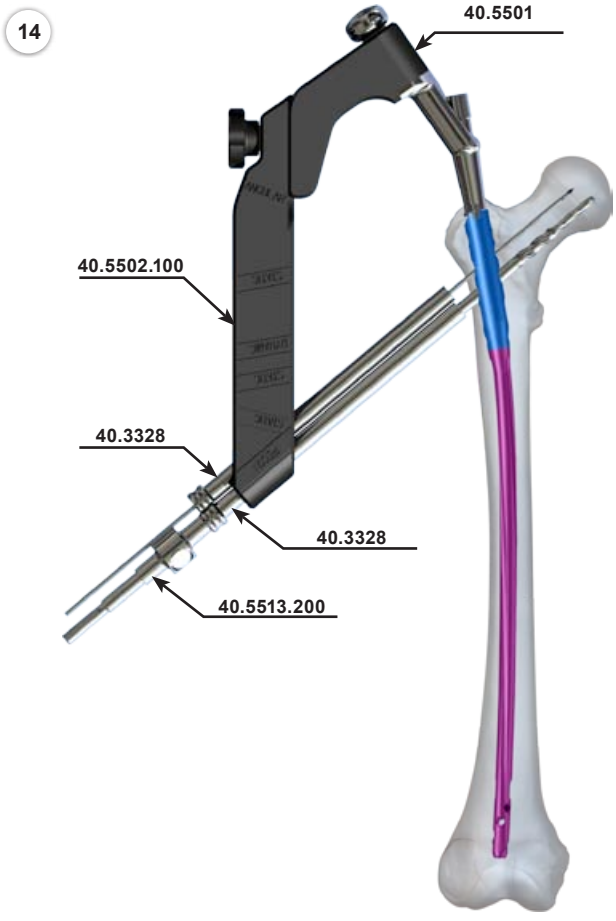
Remove the Cannulated screw length measure **[40.4724.100]** and Guide 9/2.8 **[40.5508]**.
Leave the guide rod.


14 Set the drilling depth, corresponding with length of selected reconstructive 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 lean against Protective guide **[40.3328]**, leading the drill over the guide rod and inside the Protective guide **[40.3328]** *(located in distal hole of the targeter)*.

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

Remove the Gradual cannulated drill.
In the case of cannulated screws application leave the protective guide and guide rod inside the targeter hole.
In the case of solid screws application remove the guide rod, leaving the protective guide.

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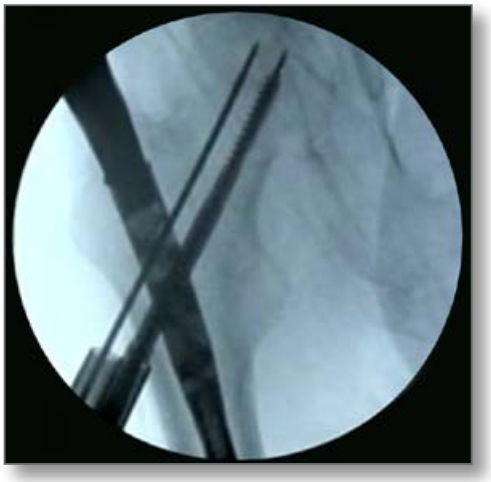
**15** Mount on the tip of Cannulated screwdriver T30 **[40.5574.100]** the reconstructive screw with selected length *(set on the Gradual cannulated drill using setting slider or from measurement with cannulated screw length measure)*. Insert the set in Protective guide **[40.3328]** and leading over 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 from distal hole of the Targeter. Guide Rod 2.8/385 **[40.5531]** is single use instrument.

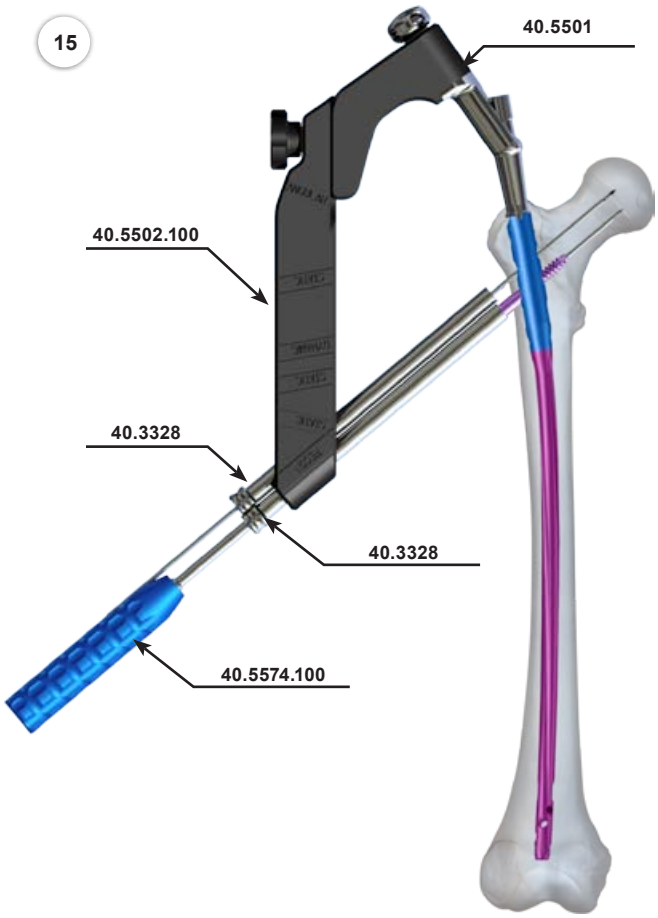


**16** Set the drilling depth, corresponding with length of selected reconstructive screw, on the Gradual cannulated drill 7.5/2.8 **[40.5513.200]** using setting slider. Mount the gradual cannulated drill in the drive, then drill the hole until slider set on the drill lean against protective guide **[40.3328]**, leading the drill over the guide rod and inside the Protective guide **[40.3328]** *(located in proximal hole of the targeter)*.
**Drilling hole should be performed under the X-Ray image intensifier control.**

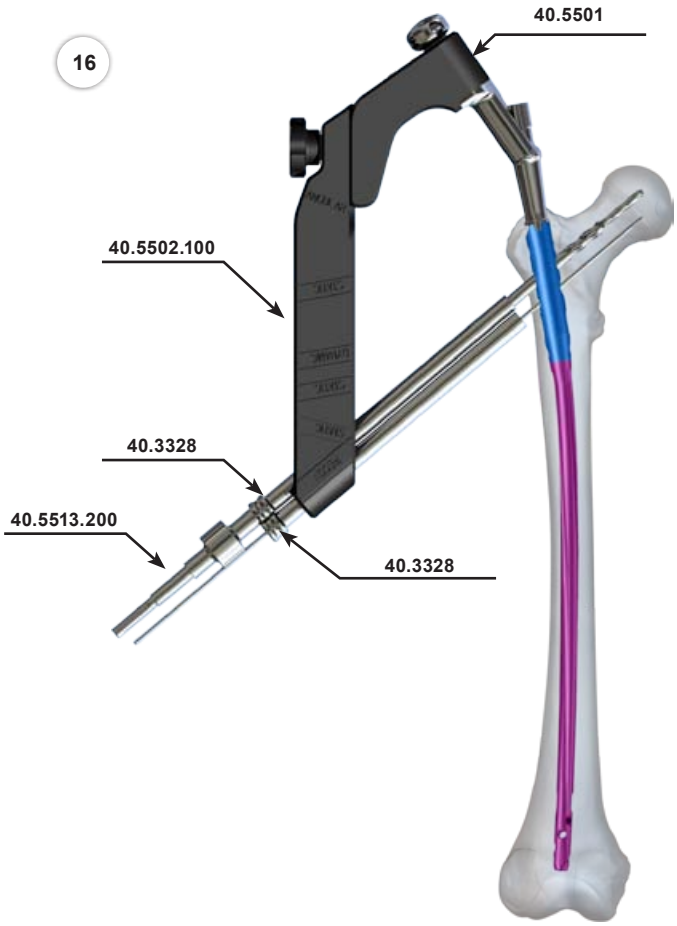
Remove the gradual cannulated drill.

In case of cannulated screws application leave the protective guide and guide rod inside the target's hole.
In case of solid screws application remove the guide rod, leaving the protective guide.

**15**




**16**

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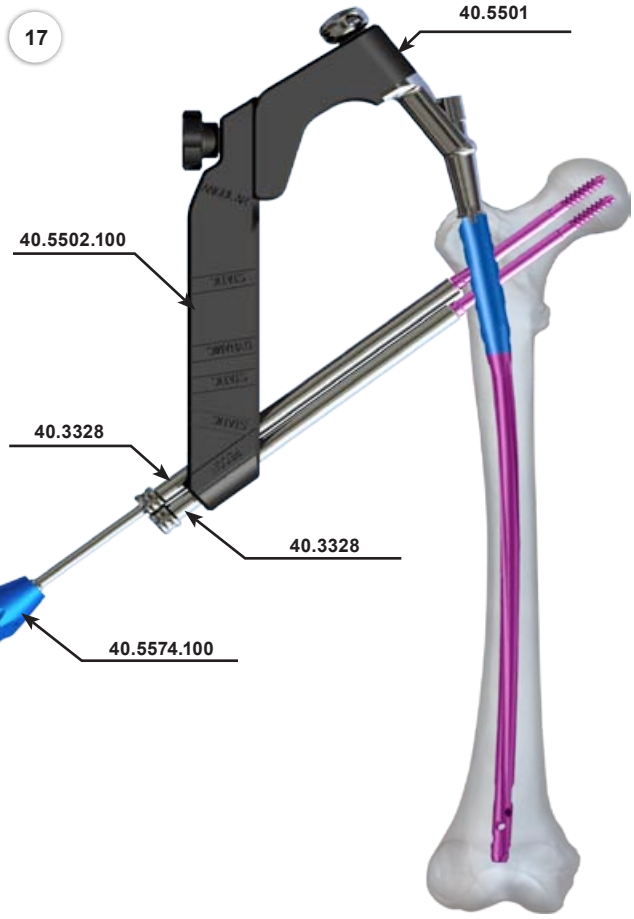
17 Mount on the tip of Cannulated screwdriver T30 **[40.5574.100]** the reconstructive screw with selected length *(set on the gradual cannulated drill using setting slider or from measurement with cannulated screw length measure)*. Insert the set in Protective guide **[40.3328]** and leading over the 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 from distal hole of the targeter. Guide Rod 2.8/385 **[40.5531]** is single use instrument.

17




18 Remove both Protective guides 11/9 **[40.3328]** from reconstructive 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.

Regarding 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 than 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.

18


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

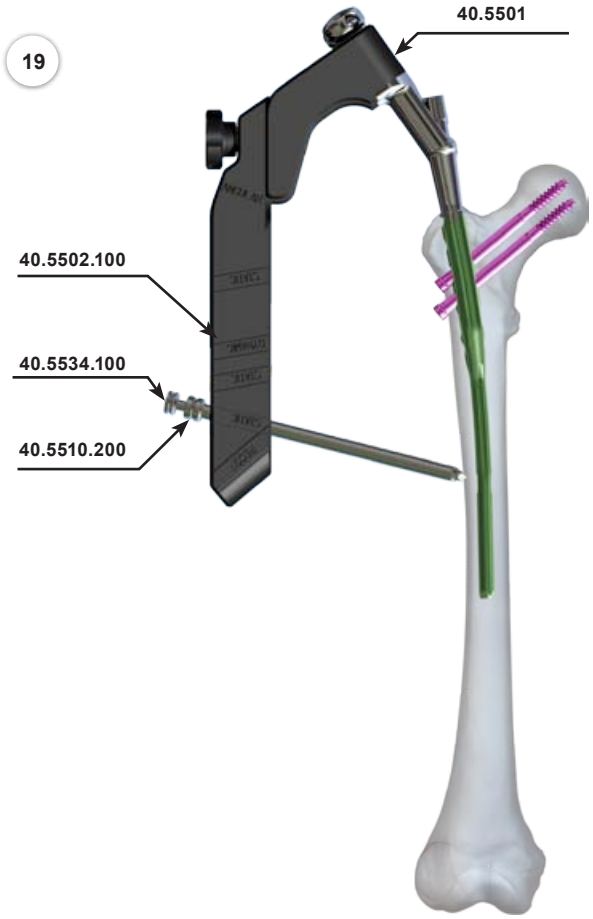
### *IV.7.1.2. Locking the short nail in distal part*

Anatomical femoral nails have a locking hole in distal part that is situated in fixed distance from nail's beginning, independently from total nail length.
Short nails are universal and can be applied in right and left extremity.

From the previous step there should remain the Targeter arm **[40.5501]** connected with Targeter B **[40.5502.100]**.

19 In angular hole of Targeter B **[40.5502.100]** signed *"STATIC"* introduce Protective guide 9/7 **[40.5510.200]** together with Trocar 6.5 **[40.5534.100]**.
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 occurs.

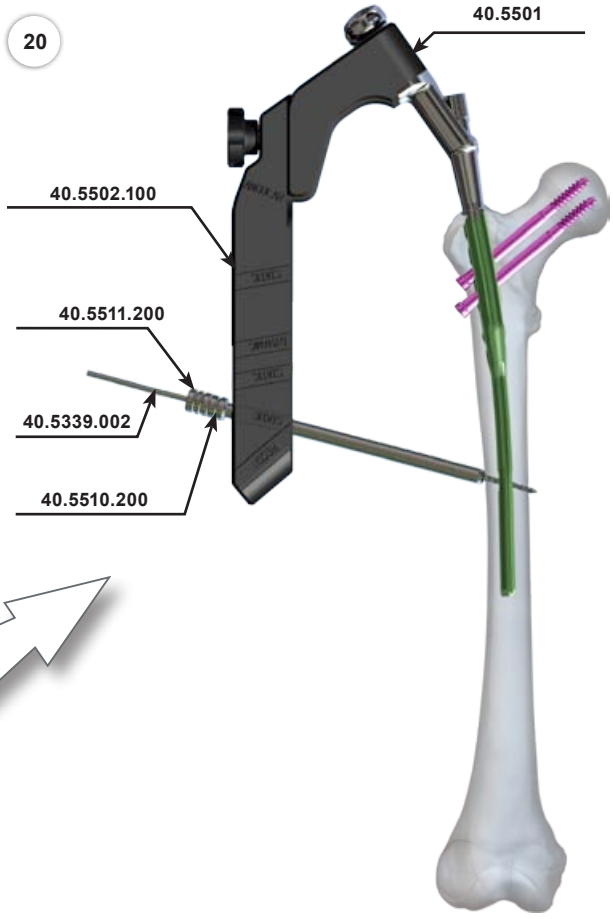
Remove the trocar.
Leave the protective guide inside the Targeter B **[40.5502.100]** hole.

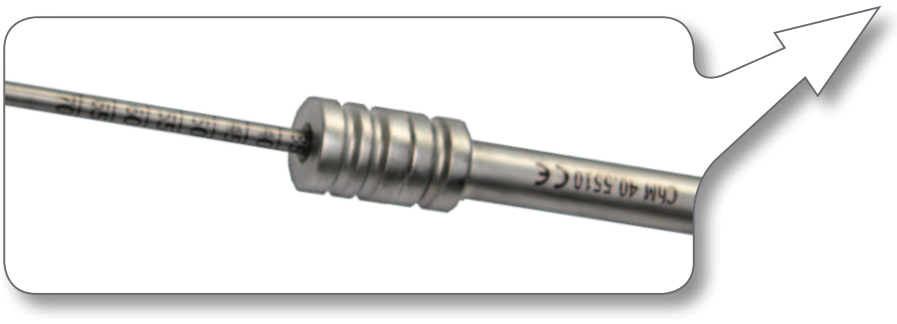



20 In left protective guide introduce Drill guide 7/3.5 **[40.5511.200]**. Drill with scale 3.5/350 **[40.5339.002]** mount in drive and then leading the drill in drill guide drill a hole in femur through its both cortexes and hole in the nail. Scale on the drill shows the length of locking element.

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

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



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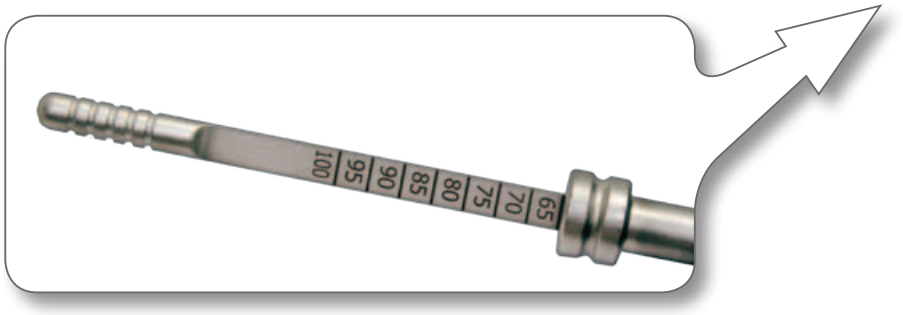
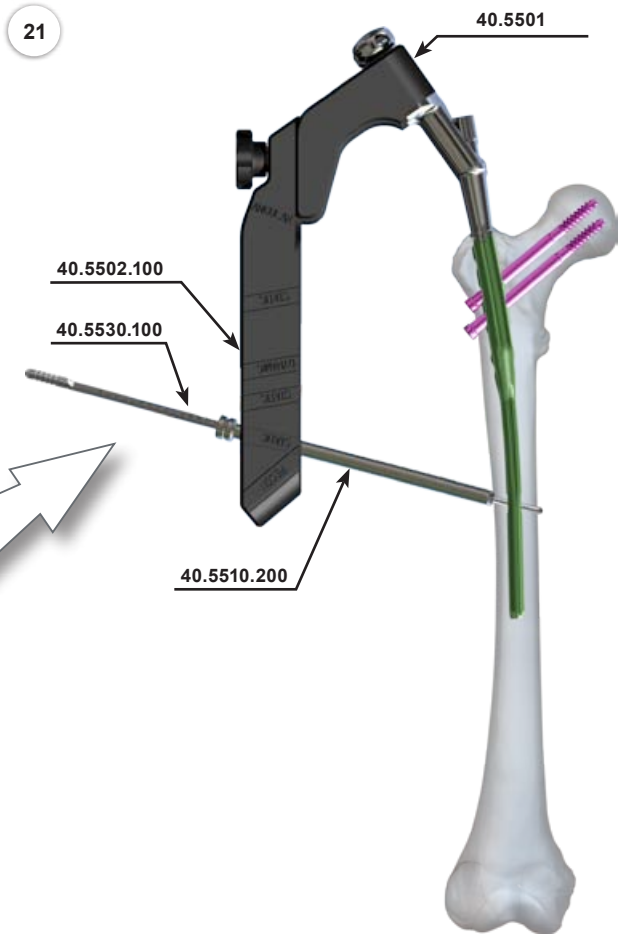
**21** Introduce Screw length measure **[40.5530.100]** through protective guide, in the hole drilled in the bone, until the hook of measuring tip reaches the far cortex. From the B-D scale of measure read the locking element length. During measurement the protection guide should be pressed against the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

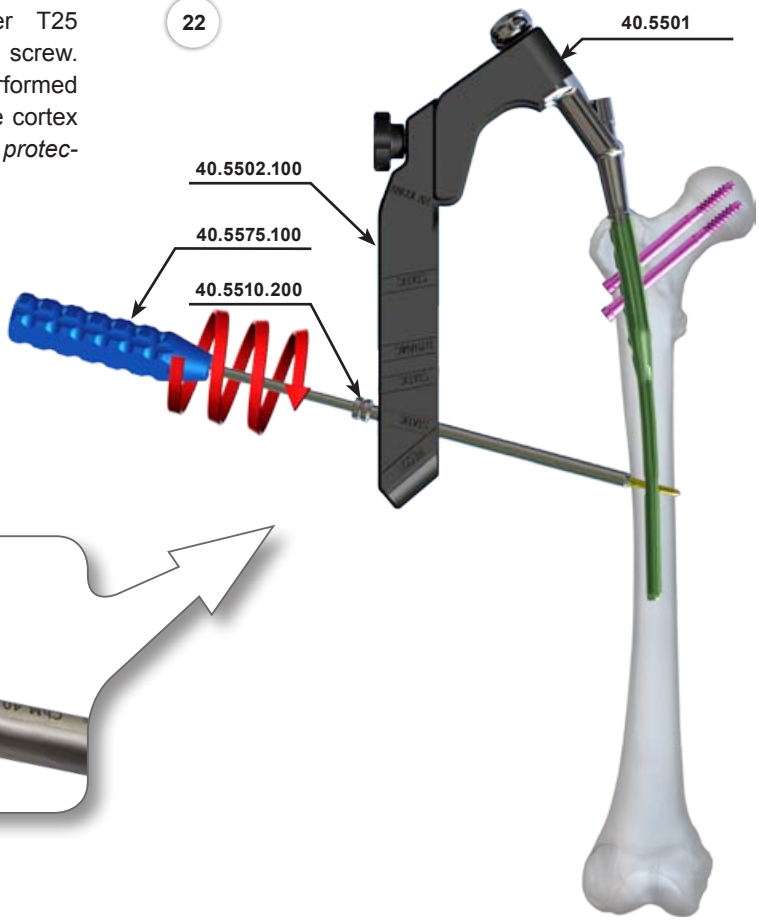
Remove the screw length measure.
Leave the protective guide in the targeter hole.




**22** Introduce the tip of Cannulated screwdriver T25 **[40.5575.100]** in the socket of specific locking screw. The set through protective guide drive in previously performed 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.

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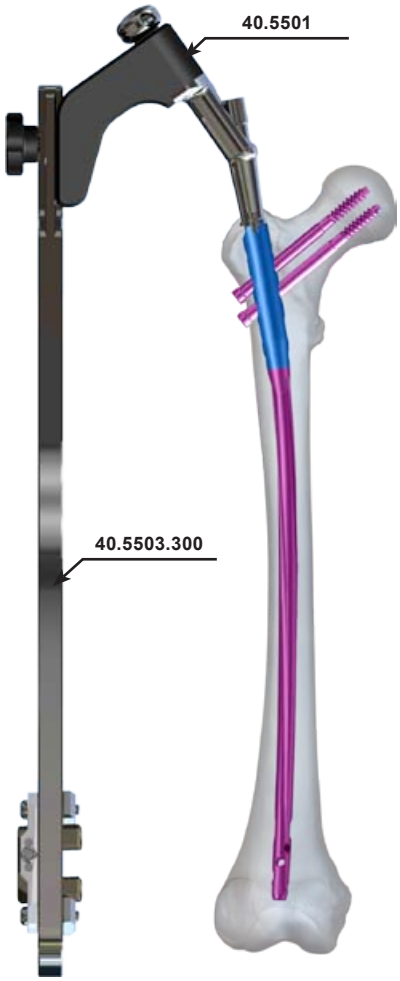
### *IV.7.1.3. Locking the left/right nail in distal part*

23 Couple Targeter arm **[40.5501]** with Targeter D **[40.5503.300]** using screw described in step 1a.

23a **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.
In order to perform correction of mutual holes position in the nail and slider, using adjustment screw's knob of Targeter D **[40.5503.300]** slider, shift the adjustable slider to obtain correct holes configuration.

23b **NOTE!**
Previously set 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 proceed according to step 23a, 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 cover and form a circular profile.

23

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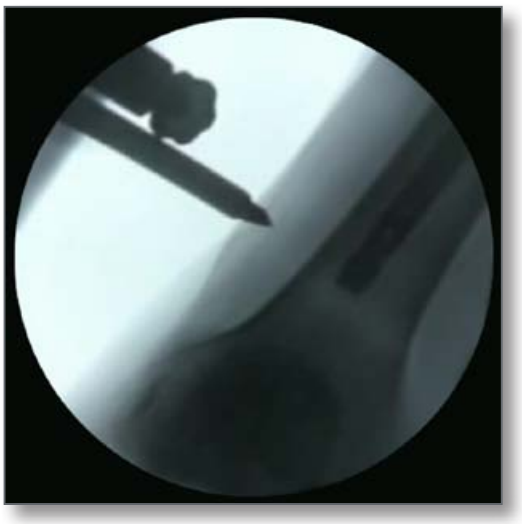
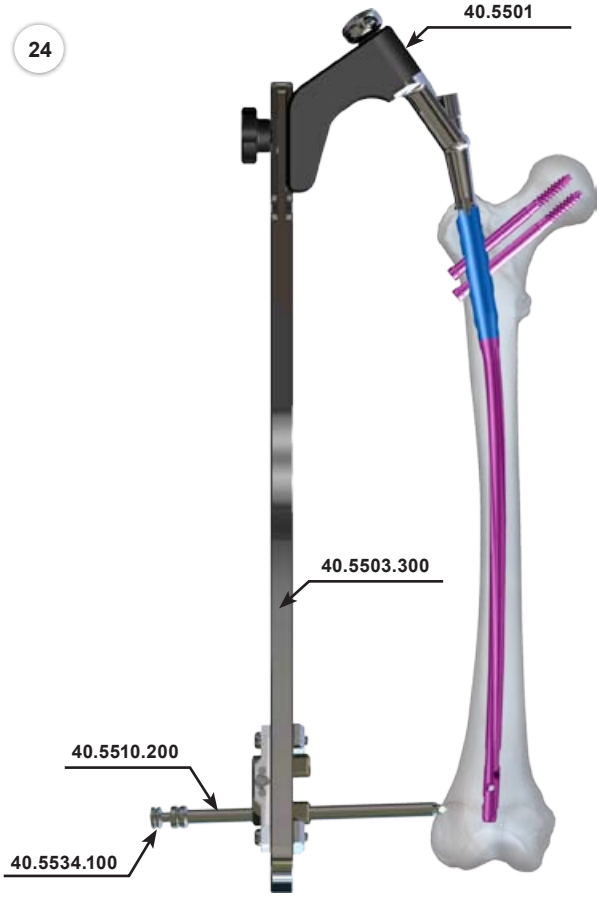
**24** In distal hole of Targeter D **[40.5503.300]** introduce Protective guide 9/7 **[40.5510.200]** together with Trocar 6.5 **[40.5534.100]**. After marking the screw's entry point on the skin, perform incision of soft tissues.
Trocar should penetrate to the cortex and mark the entry point for the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

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

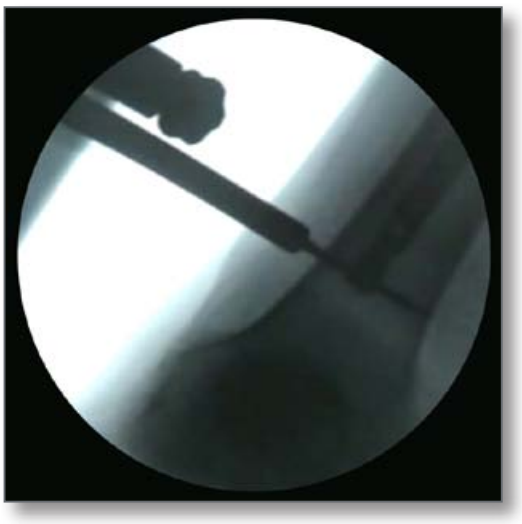


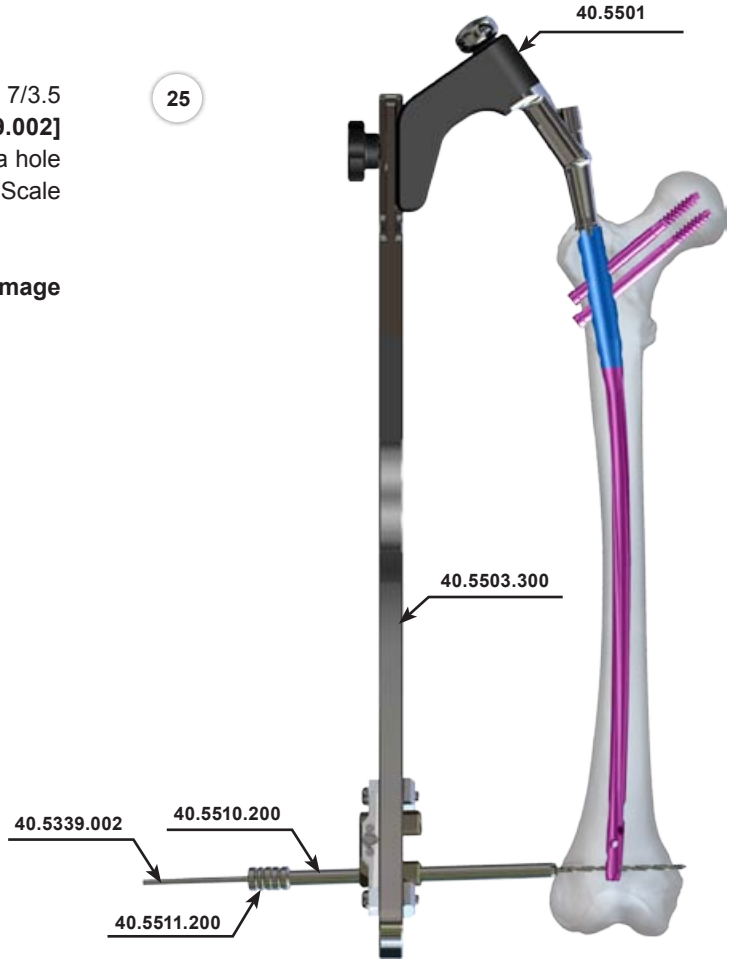



**25** In protective guide that was left introduce Drill guide 7/3.5 **[40.5511.200]**. Drill with scale 3.5/350 **[40.5339.002]** mount in drive and then leading the drill in drill guide drill a hole in femur through its both cortexes and hole in the nail. Scale on the drill shows the length of locking 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.



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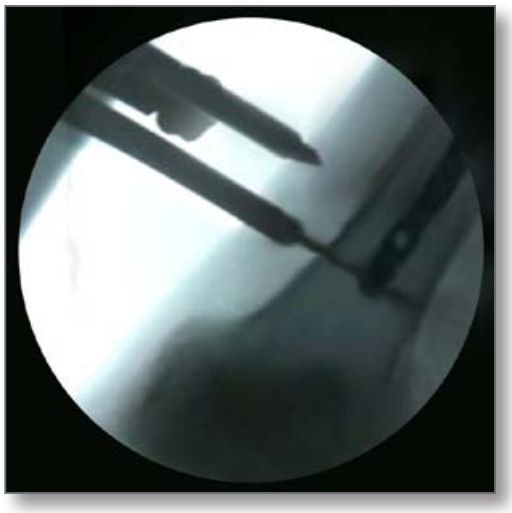
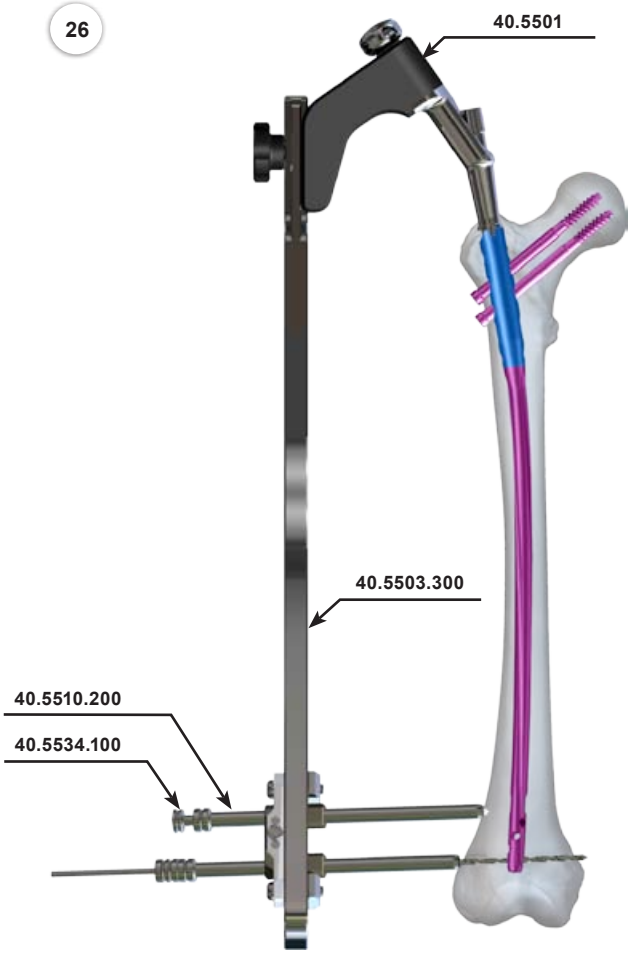
**26** In proximal hole of Targeter D **[40.5503.300]** introduce Protective guide 9/7 **[40.5510.200]** together with Trocar 6.5 **[40.5534.100]**. After marking the screw's entry point on the skin, perform incision of soft tissues.
Trocar should penetrate to the cortex and mark the entry point for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

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

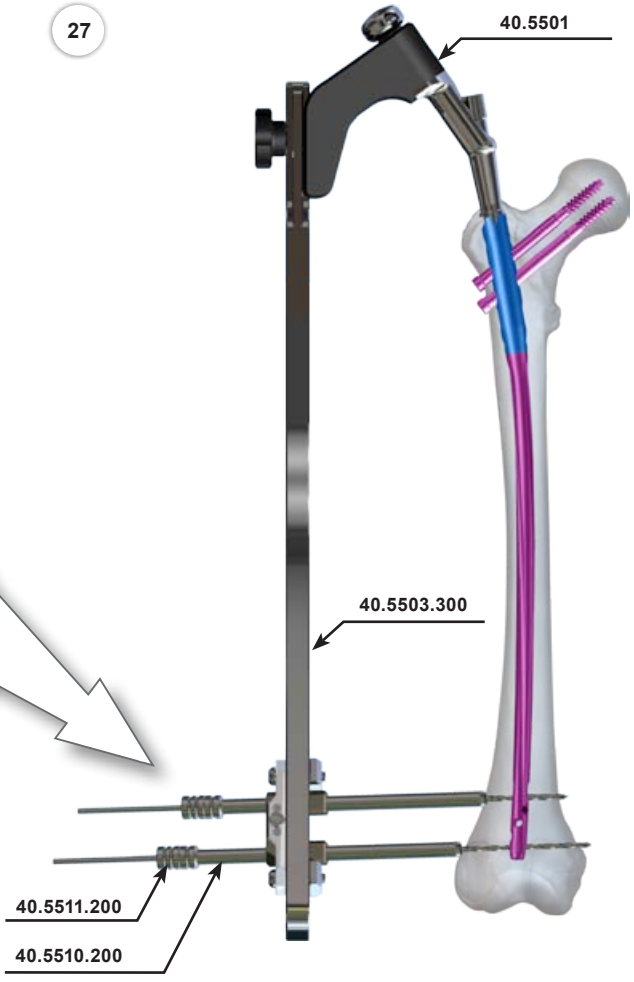





**27** In left protective quide introduce Drill guide 7/3.5 **[40.5511.200]**. Mount Drill with scale 3.5/350 **[40.5339.002]** in drive and then leading the drill in drill guide drill a hole in femur through its both cortexes and hole in the nail. Scale on the drill shows the length of locking element.

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

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

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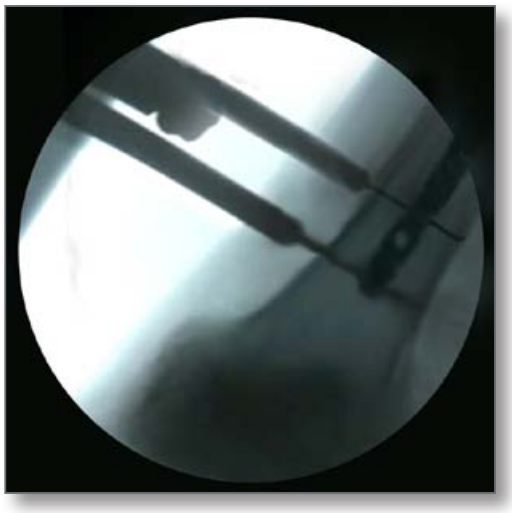
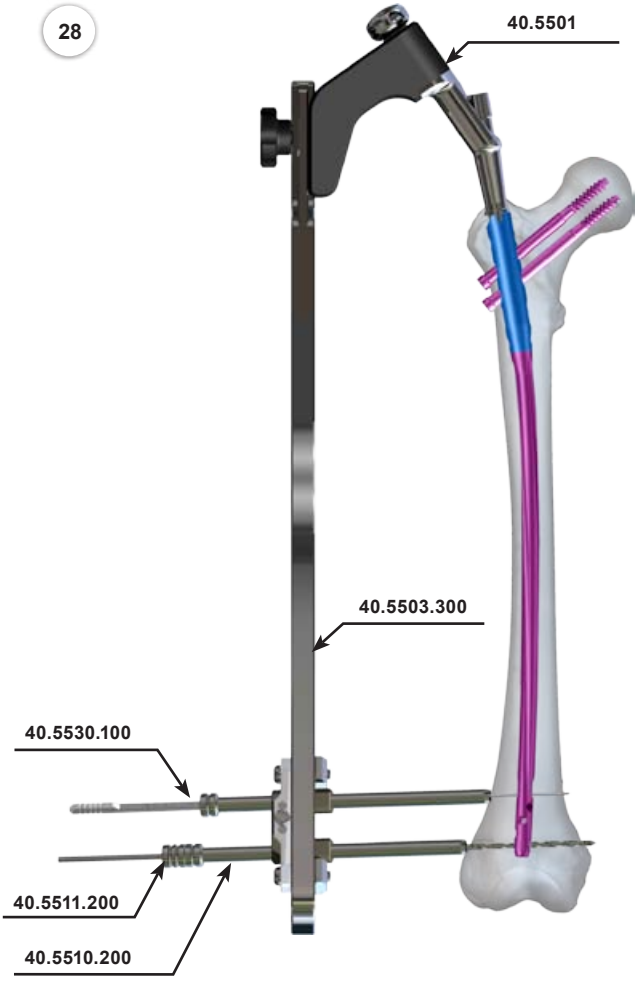
**28** Introduce Screw length measure **[40.5530.100]** through protective guide, in the hole drilled in the bone, until the hook of measuring tip reaches the far cortex. From the B-D scale read the locking element length. During measurement the protection guide should be pressed against the cortex.

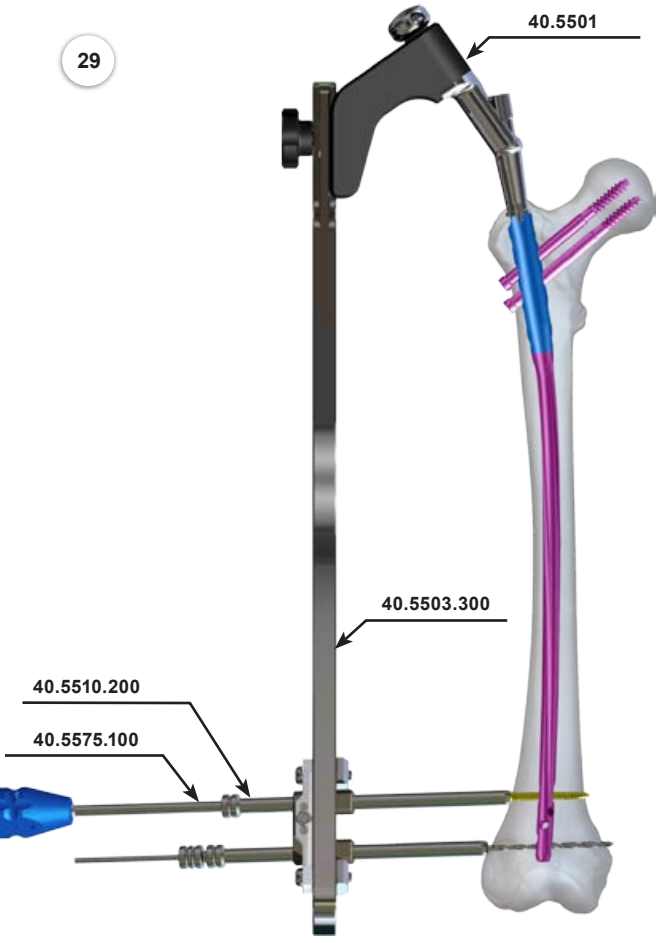
Remove the screw length measure.
Leave the protective guide in the targeter hole.






**29** Introduce the tip of Cannulated screwdriver T25 **[40.5575.100]** in the socket of specific locking screw. The set through Protective guide drive in previously performed 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)*.

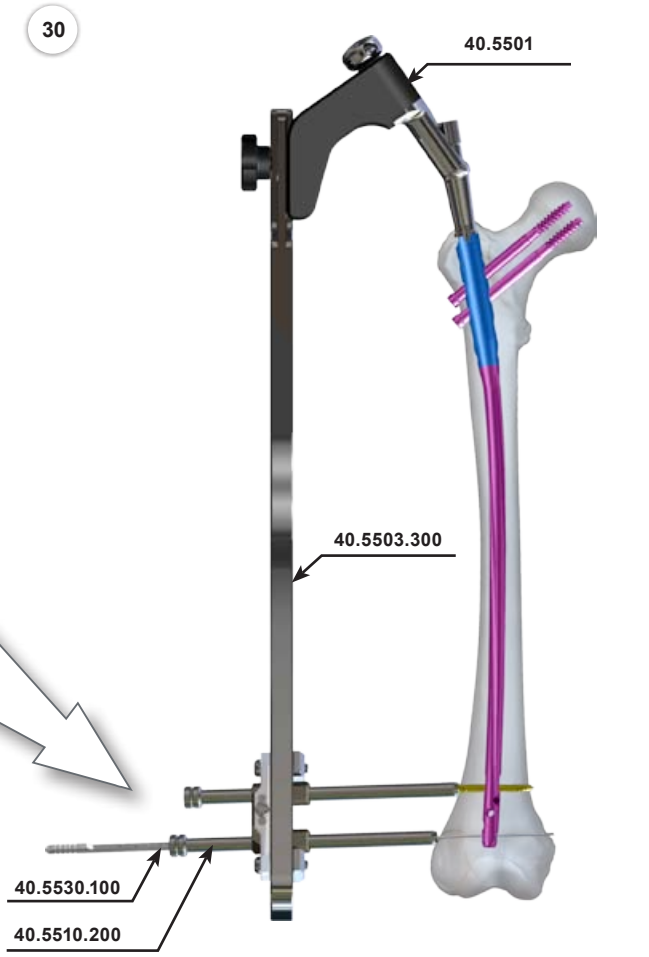
Remove the screwdriver.




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

**30** Remove the drill and drill guide from the proximal hole of Targeter D slider. Leave the protective guide 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.

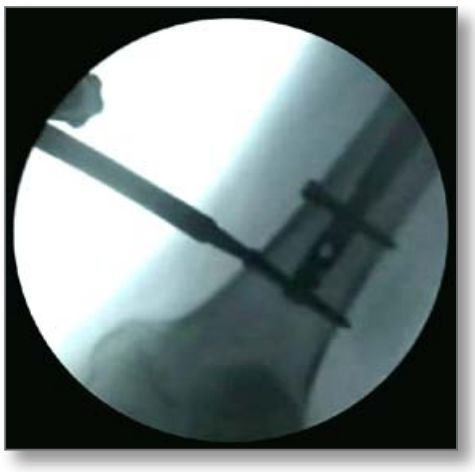
Remove the screw length measure.
Leave the protective guide in the targeter hole.

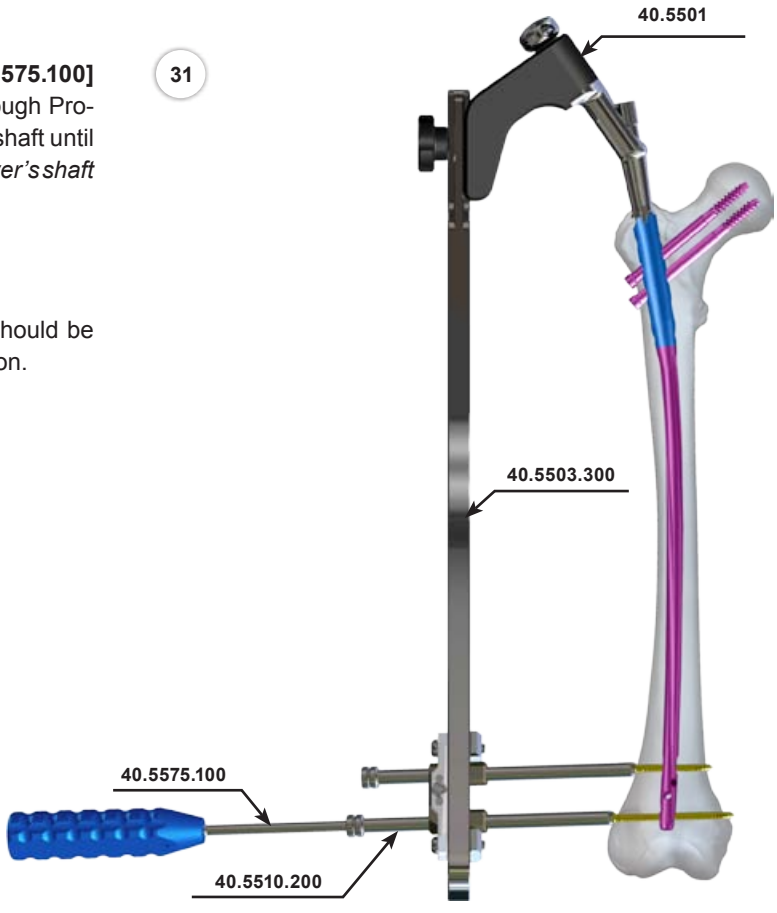



**31** Introduce the tip of Cannulated screwdriver T25 **[40.5575.100]** in the socket of specific locking screw. The set through Protective guide drive in previously performed hole in femoral shaft until the screw's head reaches the cortex *(groove on the screwdriver's shaft meets with end of the protective guide)*.

Remove the screwdriver.

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



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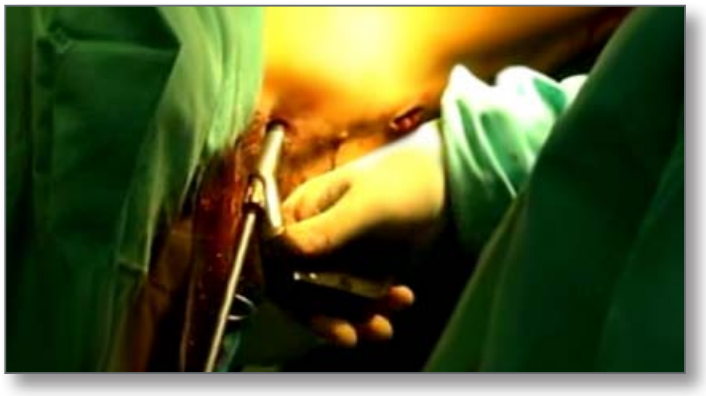
### *IV.7.1.4. Targeter removal and placing the end cap*

32 Drive out 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 intramedullary canal.

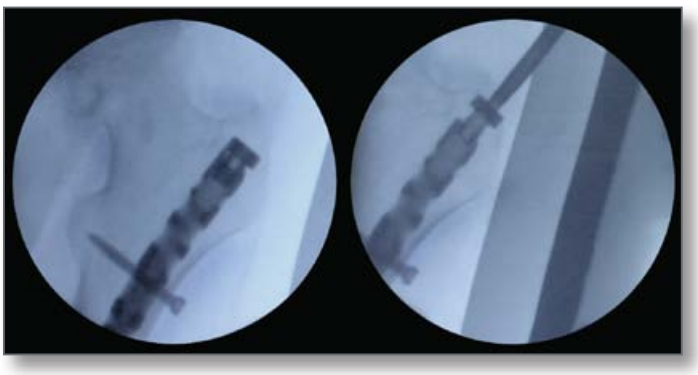


32



33

33 In order to protect the internal thread of the nail against bone tissue overgrowth, drive in the nail's shaft the End cap M10x1.5 *(implant)* using Cannulated screwdriver T30 **[40.5574.100]**.



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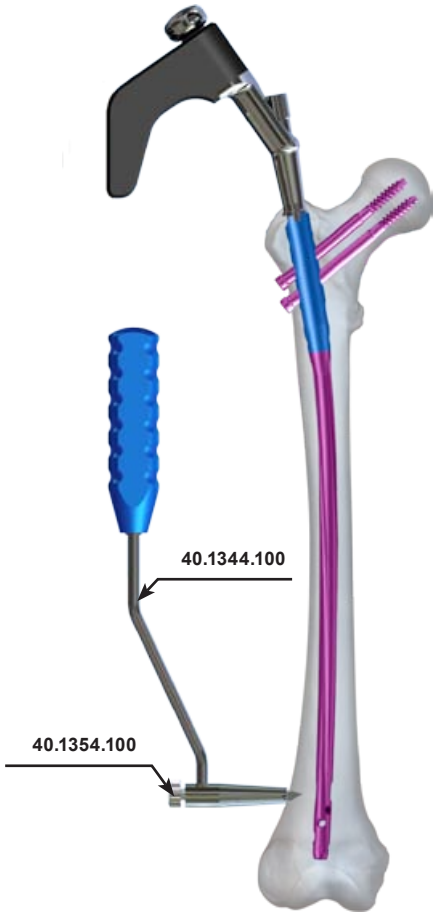
### *IV.7.1.5. ALTERNATIVE: Locking the nail in distal part using "free-hand" technique*

Instant radiographic control is necessary in this method for determination of the drilling points and during the drilling operation. Angular attachment of the drive is recommended for drilling the holes, so operators hands will be outside the direct X-Ray influence. 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.

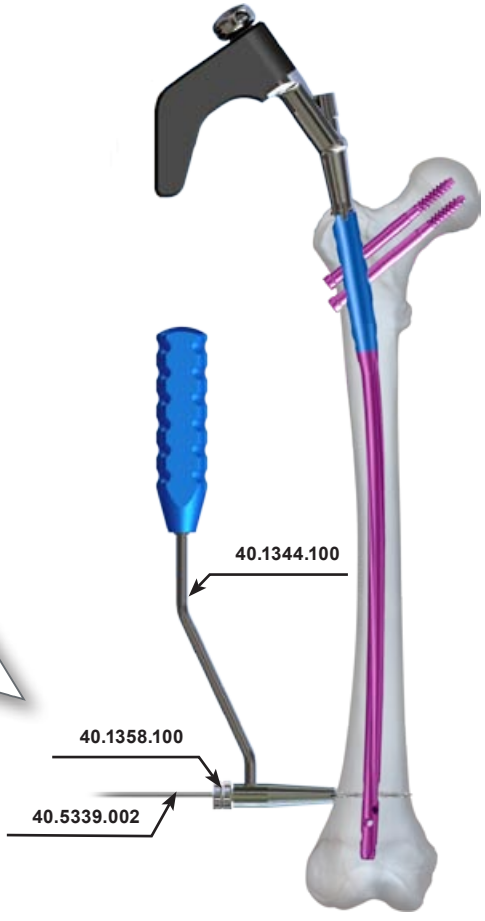
34




34 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 **[40.1354.100]** in the targeter hole, penetrate the trocar to the cortex and mark the entry point for the drill.

Remove the trocar
Leave the targeter in place.

35




35 In targeter hole introduce the Short drill guide 7/3.5 **[40.1358.100]**. Drill a hole using Drill with scale 3.5/350 **[40.5339.002]** *(guided inside the Drill guide)* through both cortexes 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.

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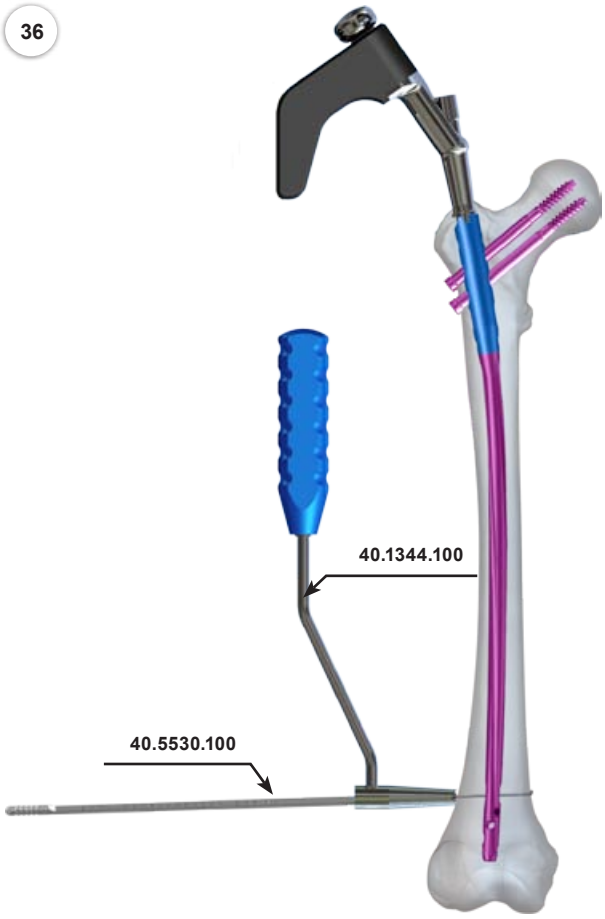
**36** Introduce the Screw length measure **[40.5530.100]** through targeter hole, in the hole drilled in the bone, until the hook of measuring tip reaches the far cortex. From the D scale read the locking screw length.

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

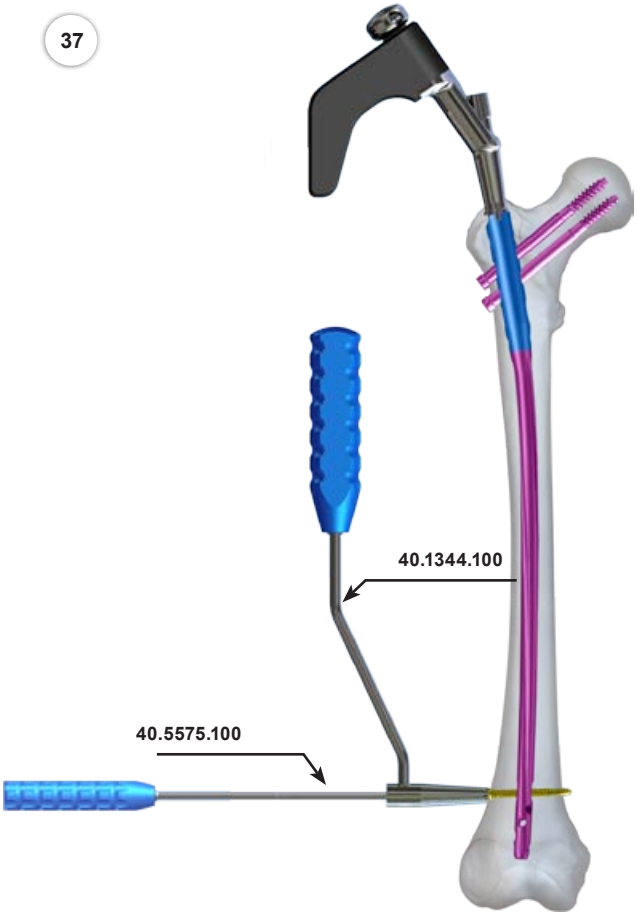
**36**




**37** Introduce the tip of Cannulated screwdriver T25 **[40.5575.100]** in the socket of specific locking screw. the set through protective guide drive in previously performed hole in femoral shaft until the screw's head reaches the cortex.

Remove the screwdriver and the Targeter D.

**37**



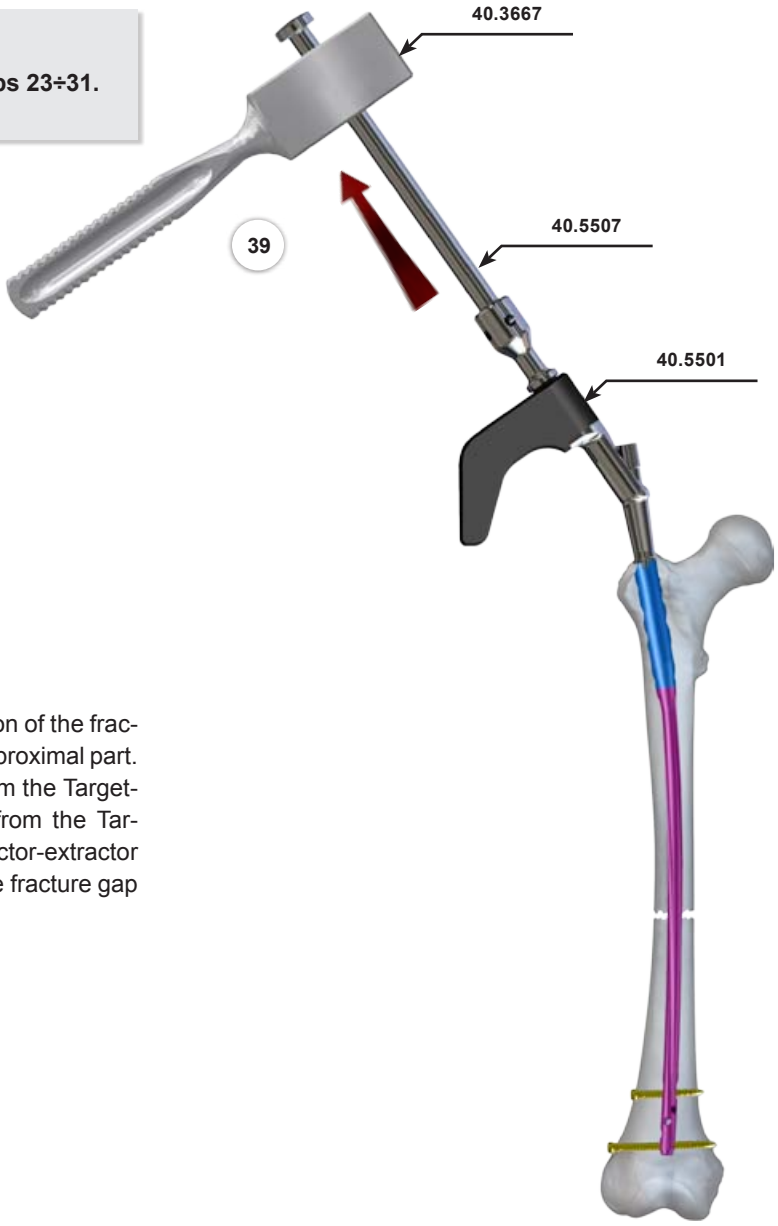

*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

### IV.7.2. Compression method

#### *IV.7.2.1. Locking the nail in distal part*

38 Mount the Targeter D **[40.5503.300]** to the Targeter arm **[40.5501]** using screw described in step 4a. Verify the position of Targeter D slider according to step 23a and 23b.

**Attention!**
**Further proceeding according to steps 23÷31.**




39 After locking the nail in distal part the reduction of the fracture 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 head from the Targeter arm, while in exposed hole screw the impactor-extractor **[40.5507]**. Slightly backstroke the nail to reduce the fracture gap using Mallet **[40.3667]**.

Detach the impactor-extractor from Targeter arm.
Screw in the targeter arm hole the mallet head.

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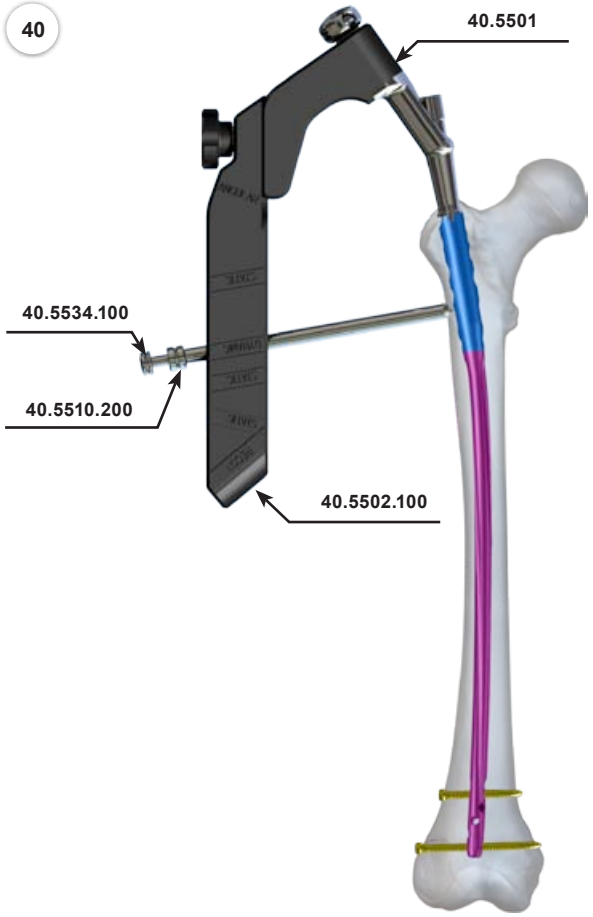
### *IV.7.2.2. Locking the nail in proximal part*

**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)*

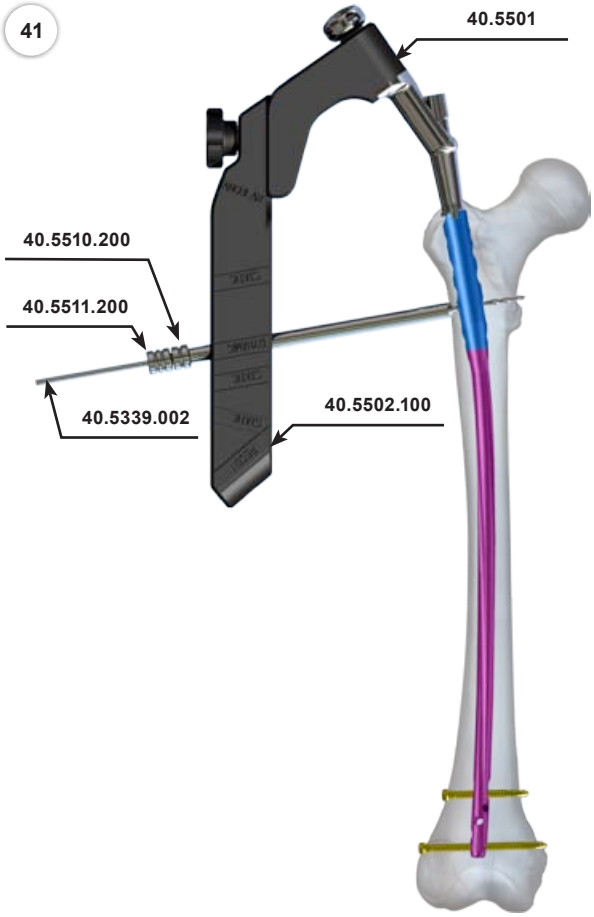
**40** Attach Targeter B **[40.5502.100]** to the Targeter arm **[40.5501]**. In hole of Targeter B **[40.5502.100]** signed *"DYNAMIC"* introduce Protective guide 9/7 **[40.5510.200]** together with Trocar 6.5 **[40.5534.100]**. After marking the screw's entry point on the skin, perform 1,5 cm long 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.




**41** In protective guide that was left introduce Drill guide 7/3.5 **[40.5511.200]**. Drill with scale 3.5/350 **[40.5339.002]** mount in drive and then leading the drill in drill guide drill a hole in femur through its both cortexes and hole in the nail. Scale on the drill shows the length of locking element.

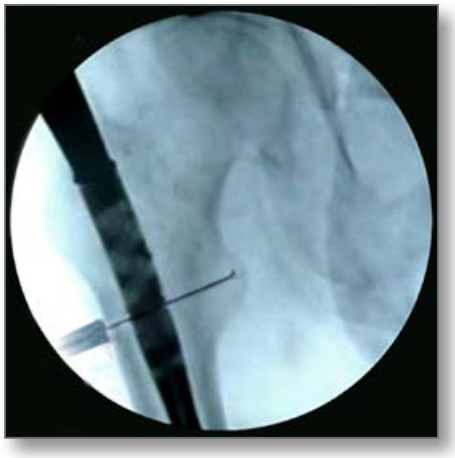
Remove the drill and drill guide.
Leave the protective guide in the Targeter hole.

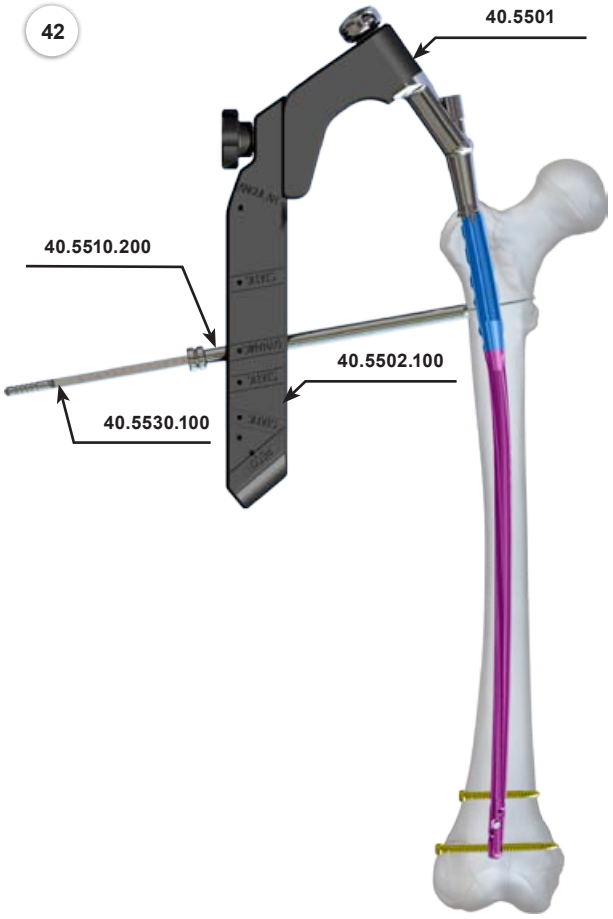



*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

**42** 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 B-D scale read the locking screw length. During measurement the protection guide should be pressed against the cortex.

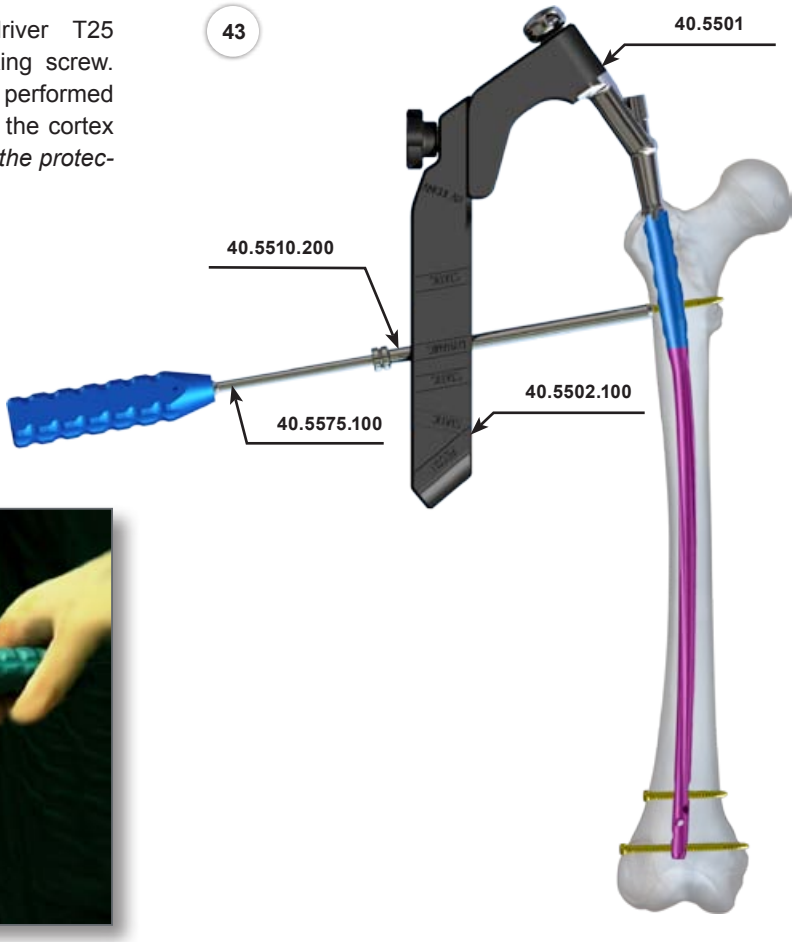
Remove the screw length measure.
Leave the protective guide in the Targeter hole.






**43** Introduce the tip of Cannulated screwdriver T25 **[40.5575.100]** in the socket of specific locking screw. The set through protective guide drive in previously performed 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.

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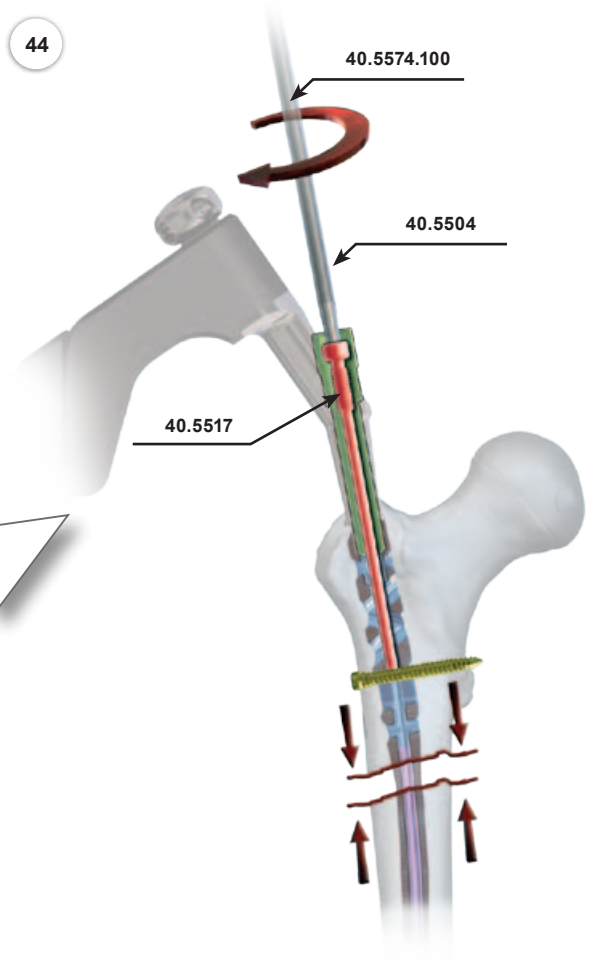
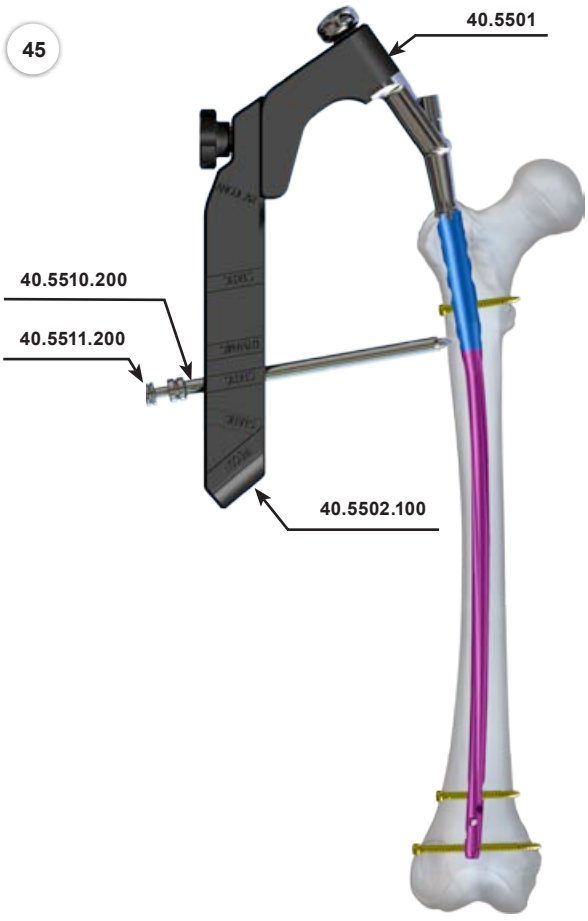
44 In order to perform intraoperative compression drive the Compression screw **[40.5517]** in Connecting screw M10x1.5 **[40.5504]**, that joins the intramedullary nail with Targeter arm **[40.5501]**, using Cannulated screwdriver T30 **[40.5574.100]**. When face of the compression screw meets the shaft of the locking screw a perceptible resistance occurs, from this moment on, a further compression screw insertion will result in bone fragments compression.

**The operation perform under the X-Ray image intensifier control, monitoring the inter-fragmental gap.**




45 In order to keep the fragments compression additional locking screw should be introduced in one of static holes of the nail *(distal hole is preferred)*. For this purpose, In hole of Targeter B **[40.5502.100]** signed *"STATIC"* introduce Protective guide 9/7 **[40.5510.200]** together with Trocar 6.5 **[40.5534.100]**. 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.

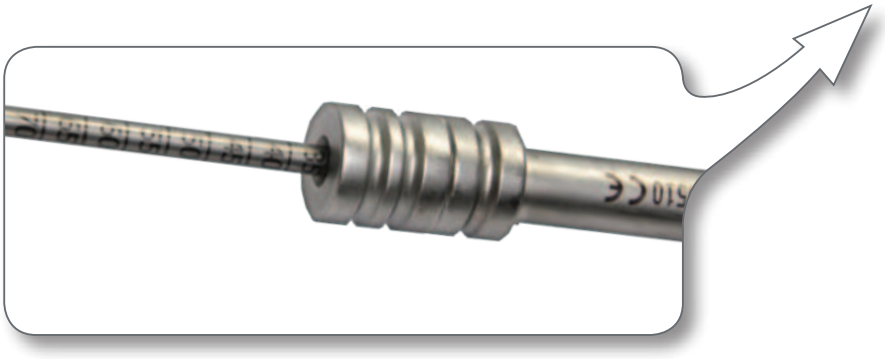
Remove the trocar.
Leave the protective guide inside the targeter hole.

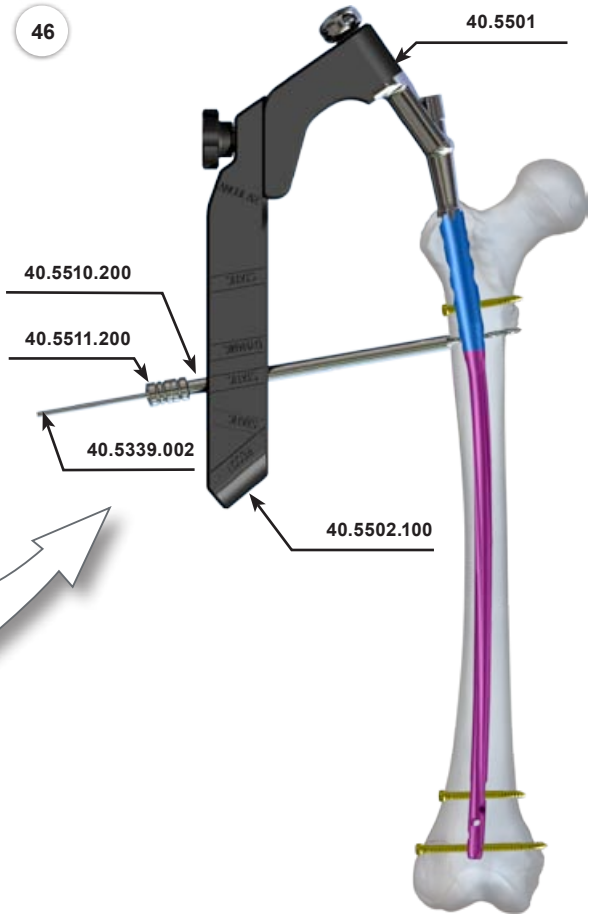



*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

46 In protective guide that was left introduce Drill guide 7/3.5 **[40.5511.200]**. Drill with scale 3.5/350 **[40.5339.002]** mount in drive and then leading the drill in drill guide drill a hole in femur through its both cortexes and hole in the nail. Scale on the drill shows the length of locking element.

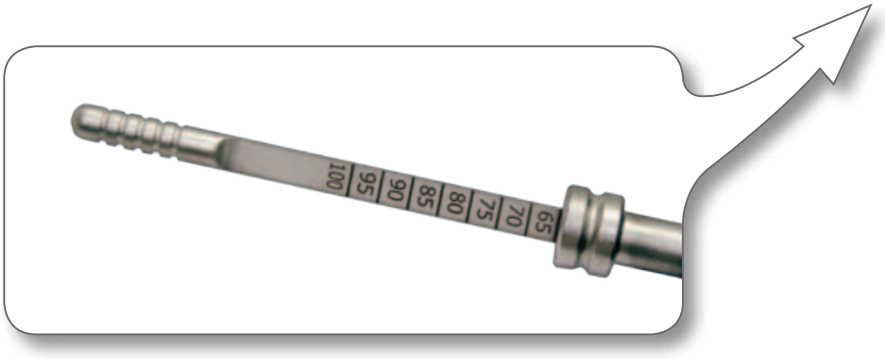
Remove the drill and drill guide.
Leave the protective guide in the targeter hole.

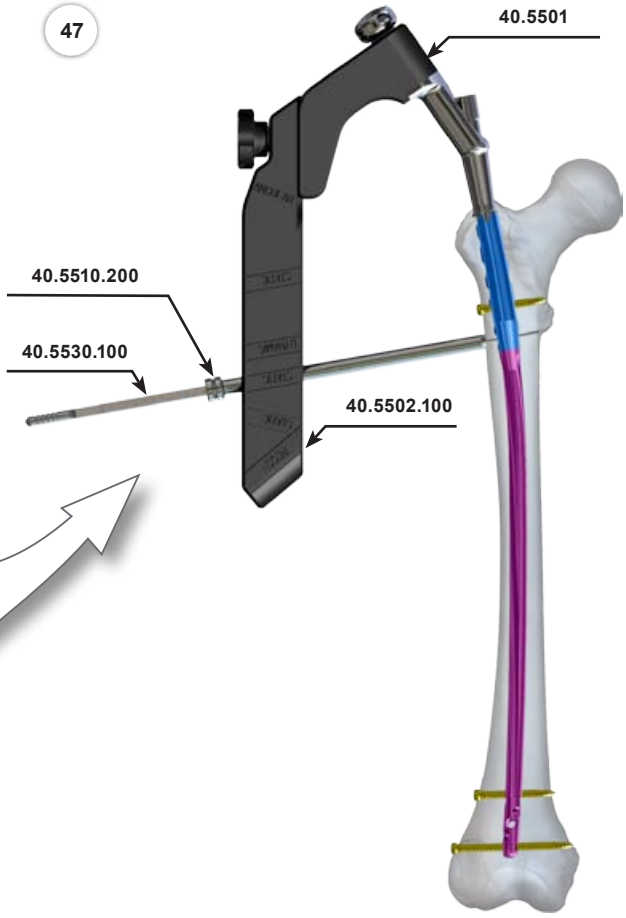





47 Introduce the Screw length measure **[40.5530.100]** through the protective guide, in the hole drilled in the bone, until the hook of measuring tip grasp the far cortex. From the B-D scale read the locking screw length. During measurement the protection guide should be pressed against the cortex.

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

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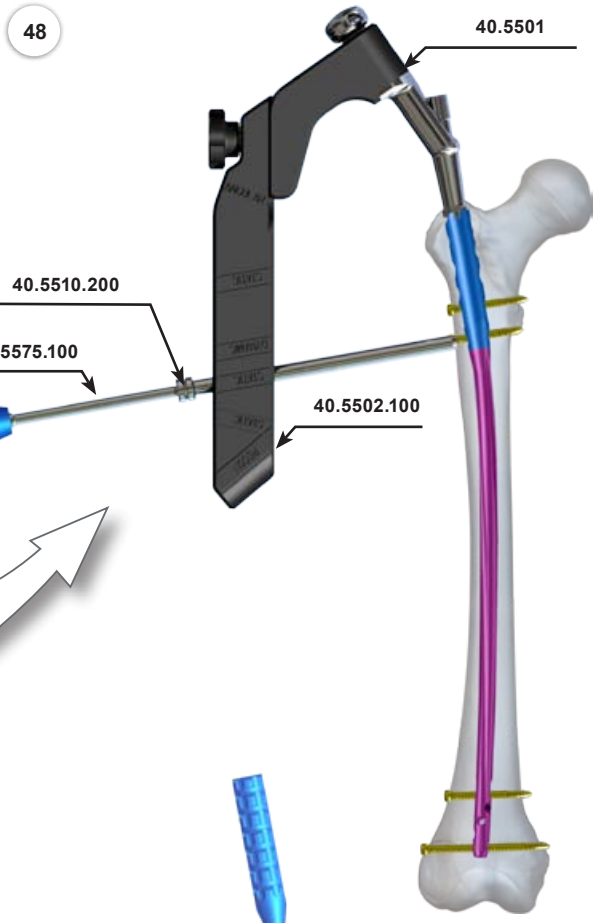
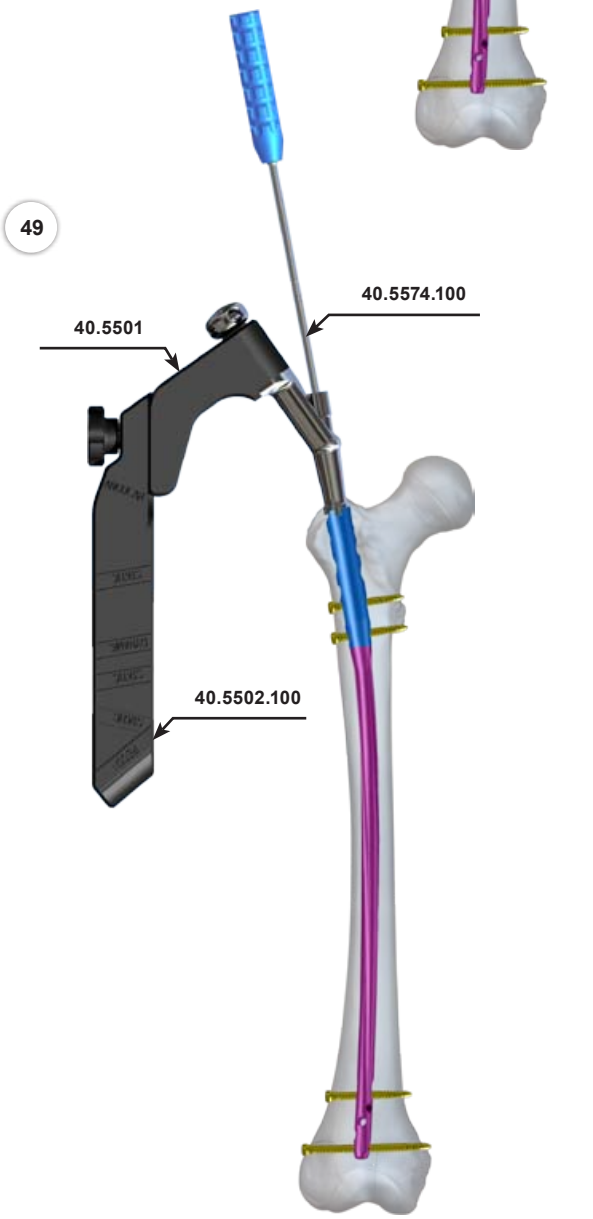
**48** Introduce the tip of Cannulated screwdriver T25 **[40.5575.100]** in the socket of specific locking screw. The set through protective guide drive in previously performed hole in femoral shaft until the screw's head reaches the cortex *(groove on the screwdriver's shaft meets with end of the protective guide)*.

Remove the screwdriver and the protective guide.




**49** Drive out of the Connecting screw the Compression screw using Cannulated screwdriver T30 **[40.5574.100]**.




**Attention!**

**Further proceeding according to steps described in section IV.7.3.3.**

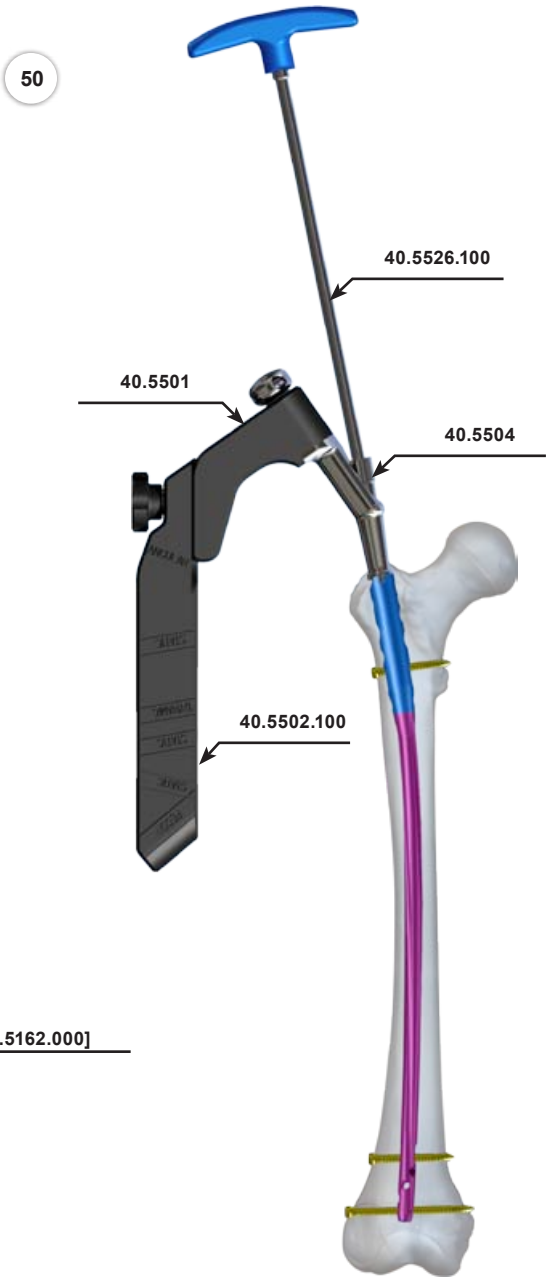
*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

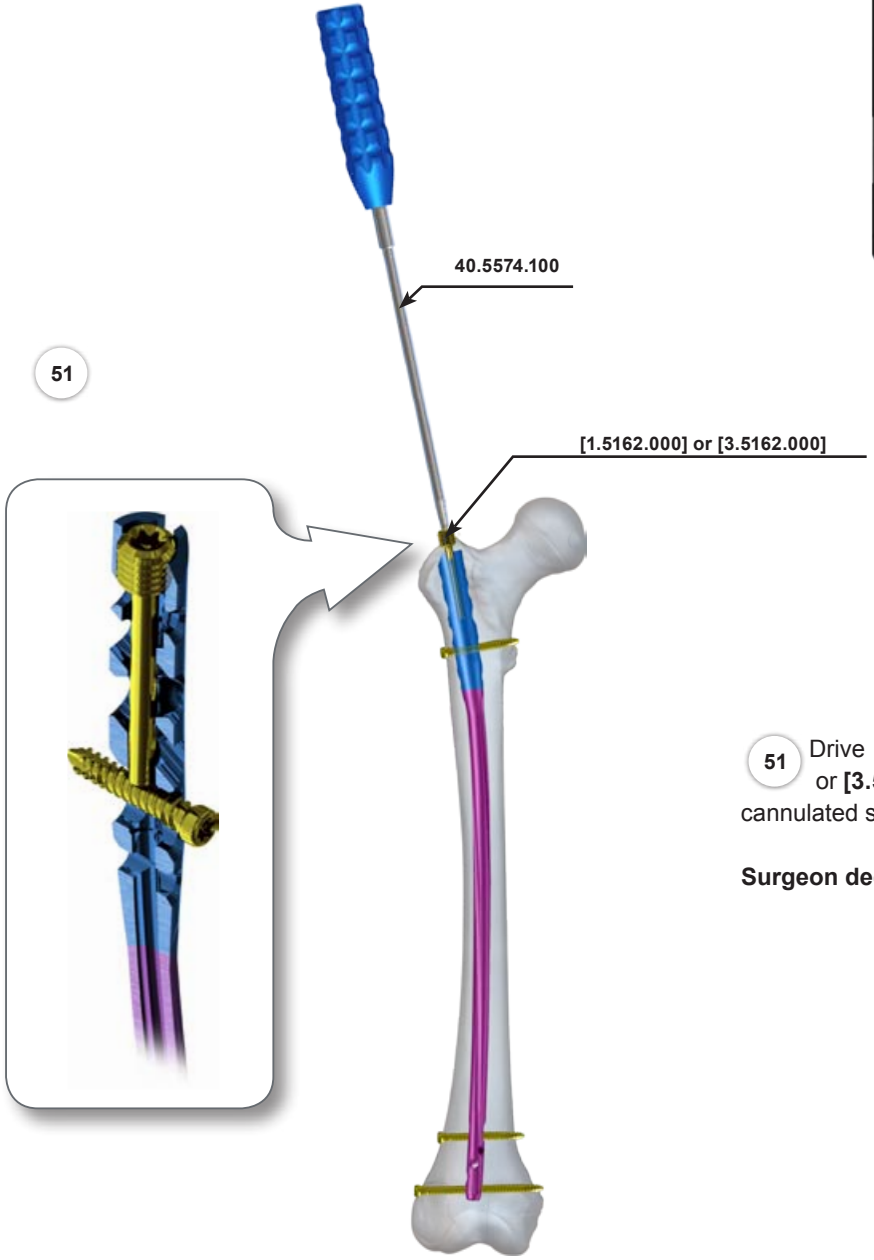
### *IV.7.2.2b. OPTION II: Compression of fragments using compression screw M10x1,5* [1.5162.000] *or* [3.5162.000] *(implant)*

Option of compressive locking in proximal part with use of Compressive screw M10x1.5 *(implant)* should be performed according to steps 40÷43, then according to procedure described in section IV.7.2.3.

### *IV.7.2.3. Targeter removal and placing the compression screw*

50 Drive out 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 intramedullary canal.




51 Drive in the Compression screw **[1.5162.000]** or **[3.5162.000]** in threaded hole of nails shaft using cannulated screwdriver T30 **[40.5574.100]**.

**Surgeon decides about the compression rate.**

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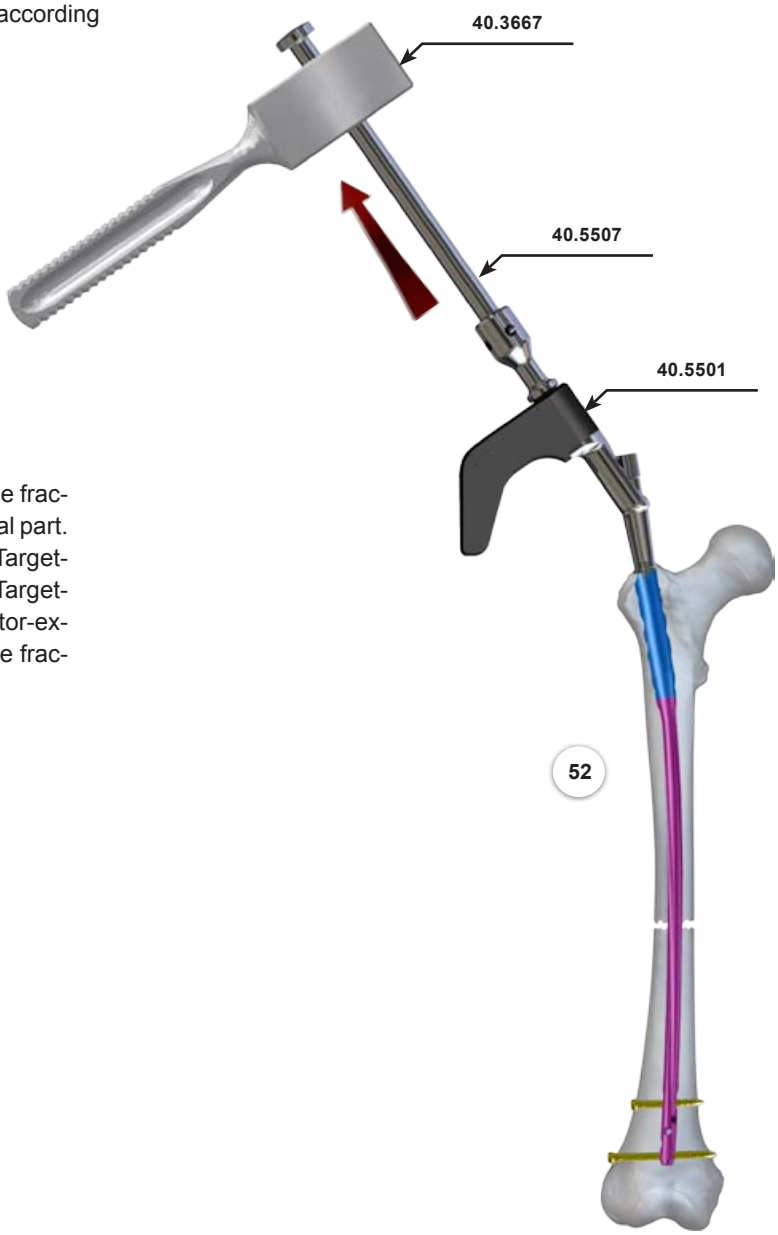
**IV.7.3. Dynamic method**

***IV.7.3.1. Locking the nail in distal part***

Locking the nail in distal part in dynamic method perform according to steps 23÷31.




52 After locking the nail in distal part the reduction of the fracture 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 head from the Targeter arm **[40.5501]**, while in exposed hole screw the Impactor-extractor **[40.5507]**. Slightly backstroke the nail to reduce the fracture gap using Mallet **[40.3667]**.

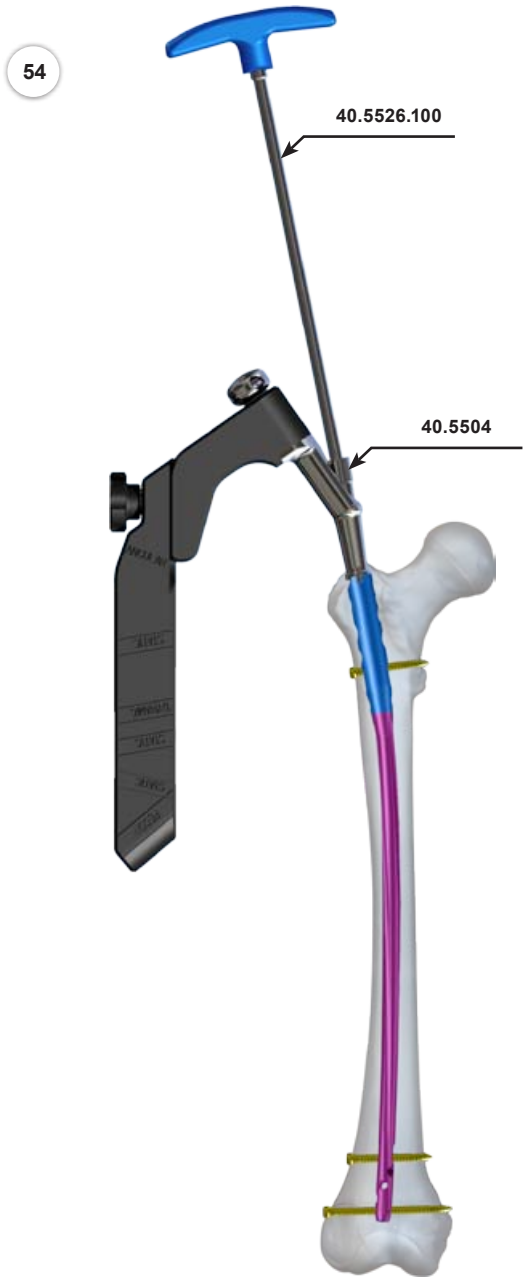
Detach the impactor-extractor from targeter arm.
Screw in the targeter arm hole the mallet head.

***IV.7.3.2. Locking the nail in proximal part***

53 Locking the nail in proximal part in dynamic method perform according to steps 40÷43.

### *IV.7.3.3. Targeter removal and placing the end cap*

54 Drive out 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 intramedullary canal.





55 In order to protect the connecting thread of the nail against bone tissue overgrowth, drive in the nail's threaded hole the End cap M10x1.5 **[1.5161.7xx]** or **[3.5161.7xx]** using Cannulated screwdriver T30 **[40.5574.100]**.

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### 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 23÷31.

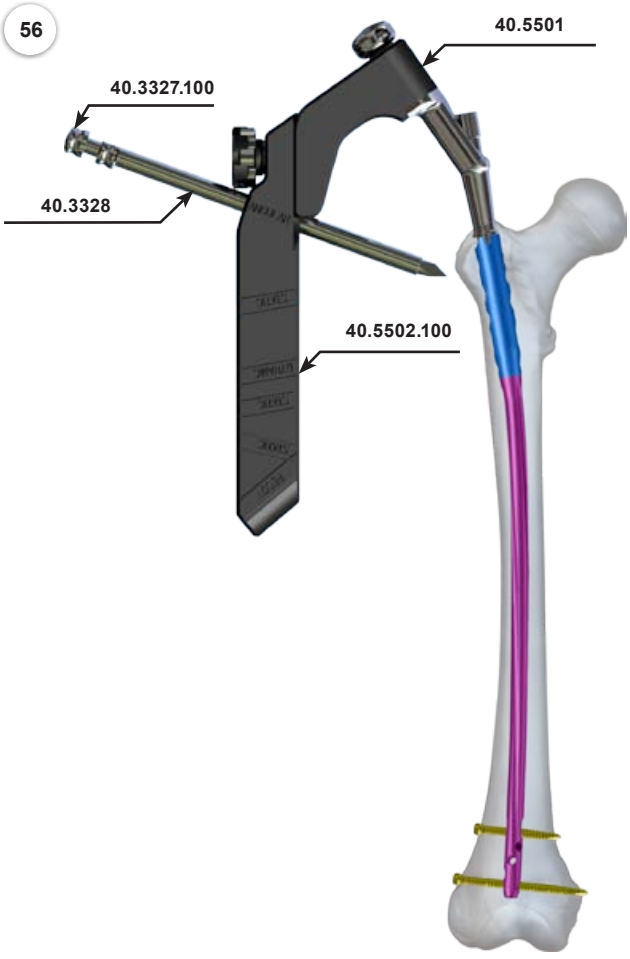
#### *IV.7.4.2. Locking the nail in proximal part*

#### *IV.7.4.2a. OPTION I: Locking the nail with reconstructive screw*

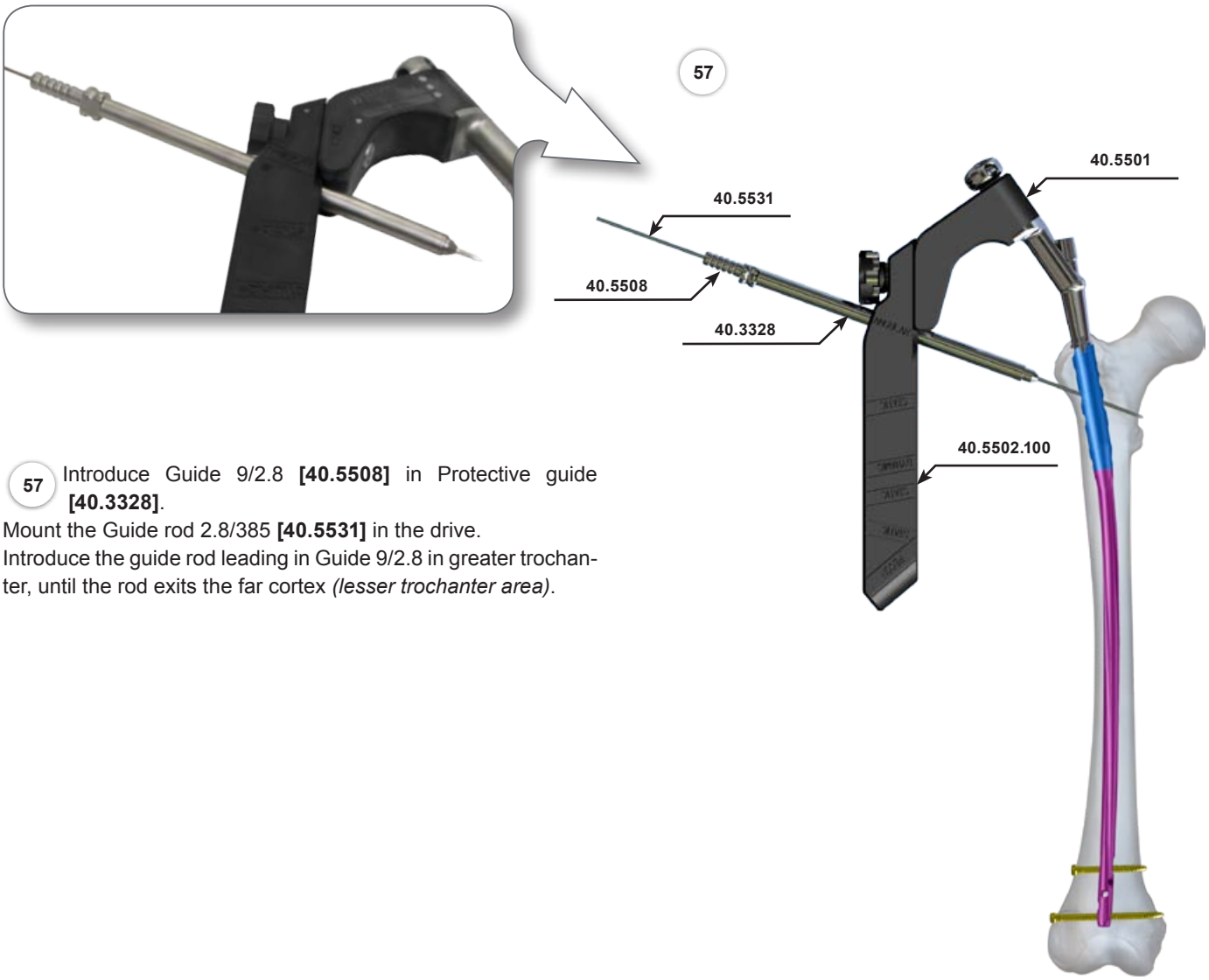
Locking the anatomical femoral nail with reconstructive screw in static method allows to reduce operative wound, because this solution enables to perform one incision for nail introduction into the intramedullary canal and for locking in proximal part. Besides, angular screw position ensures stabile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

56 Attach Targeter B **[40.5502.100]** to the Targeter arm **[40.5501]**. In hole of Targeter B **[40.5502.100]** signed *"ANGULAR"* introduce Protective guide 11/9 **[40.3328]** together with Trocar 6.5 **[40.3327.100]**. 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 near to the bone as possible.

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




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




57 Introduce Guide 9/2.8 **[40.5508]** in Protective guide **[40.3328]**.
Mount the Guide rod 2.8/385 **[40.5531]** in the drive.
Introduce the guide rod leading in Guide 9/2.8 in greater trochanter, until the rod exits the far cortex *(lesser trochanter area)*.

58 **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.

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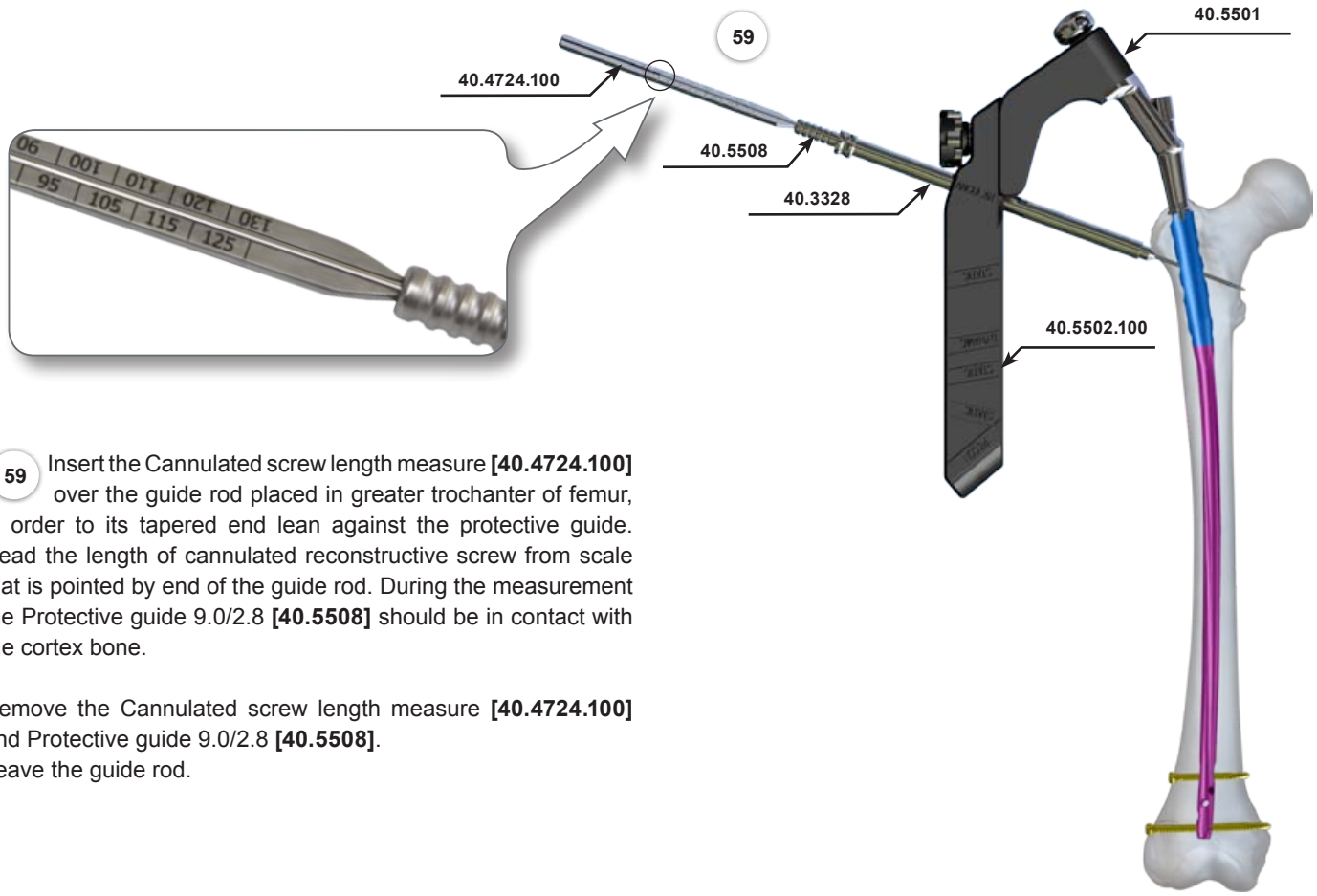
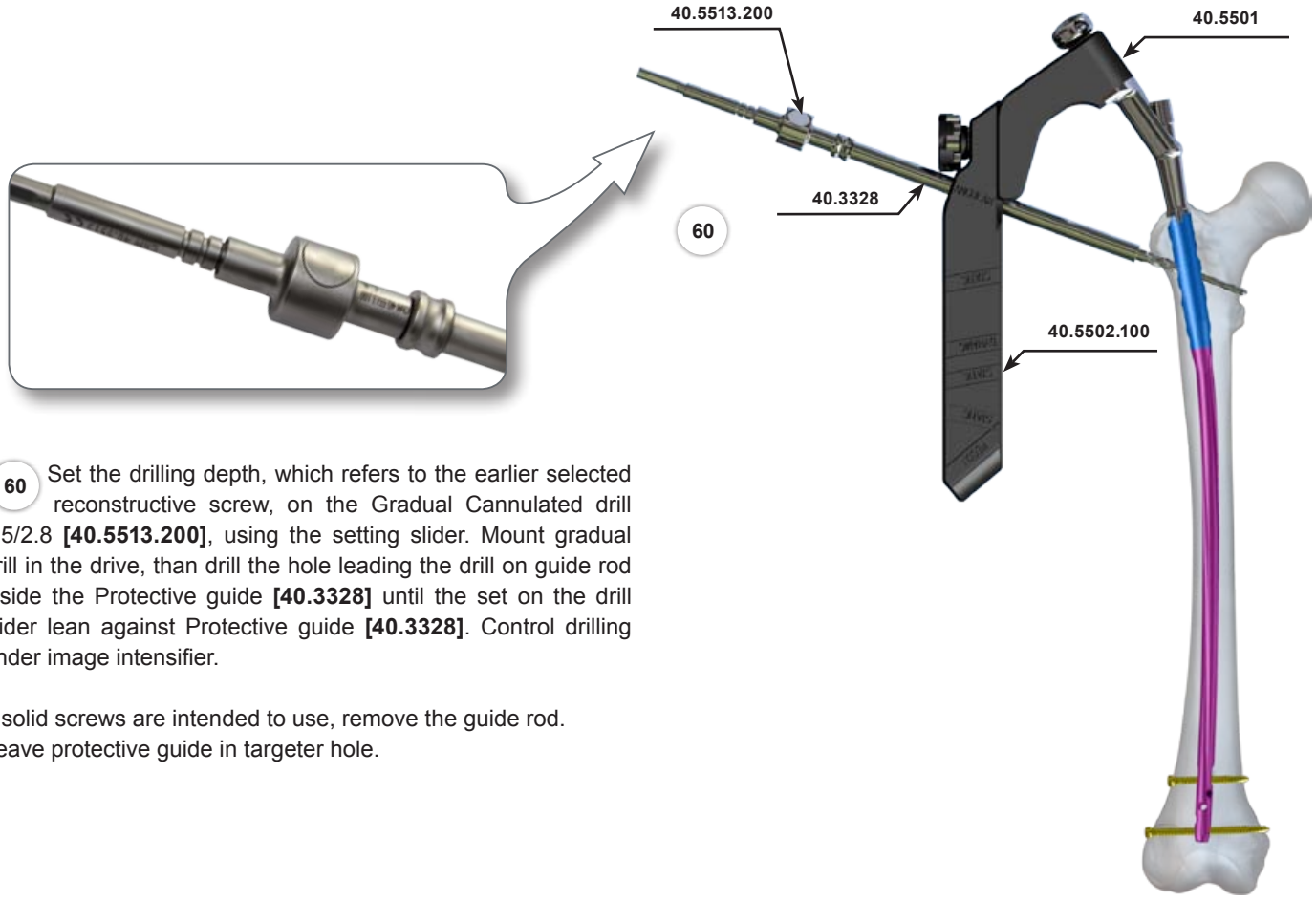



59 Insert the Cannulated screw length measure **[40.4724.100]** over the guide rod placed in greater trochanter of femur, in order to its tapered end lean against the protective guide. Read the length of cannulated reconstructive screw from scale that is pointed by end of the guide rod. During the measurement the Protective guide 9.0/2.8 **[40.5508]** should be in contact with the cortex bone.

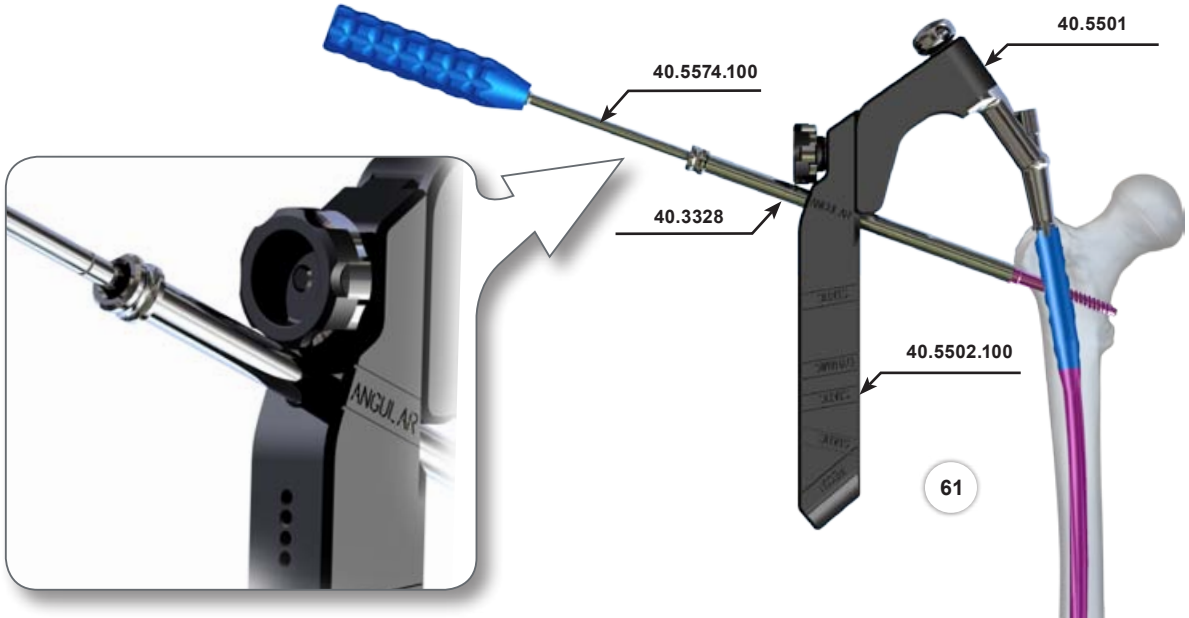
Remove the Cannulated screw length measure **[40.4724.100]** and Protective guide 9.0/2.8 **[40.5508]**.
Leave the guide rod.




60 Set the drilling depth, which refers to the earlier selected reconstructive screw, on the Gradual Cannulated drill 7.5/2.8 **[40.5513.200]**, using the setting slider. Mount gradual drill in the drive, than drill the hole leading the drill on guide rod inside the Protective guide **[40.3328]** until the set on the drill slider lean against Protective guide **[40.3328]**. Control drilling under image intensifier.

If solid screws are intended to use, remove the guide rod.
Leave protective guide in targeter hole.

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




61 Mount reconstructive screw with previously matched length *(set on the Cannulated drill using the setting slider or determined with Cannulated screw length measure)* on the tip of Cannulated screwdriver T30 **[40.5574.100]**. That Coupled system introduce in Protective guide **[40.3328]** and drive into previously prepared hole in femur neck, 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 screw and protective guide.

**Holes in distal part lock according to point IV.7.1.3.**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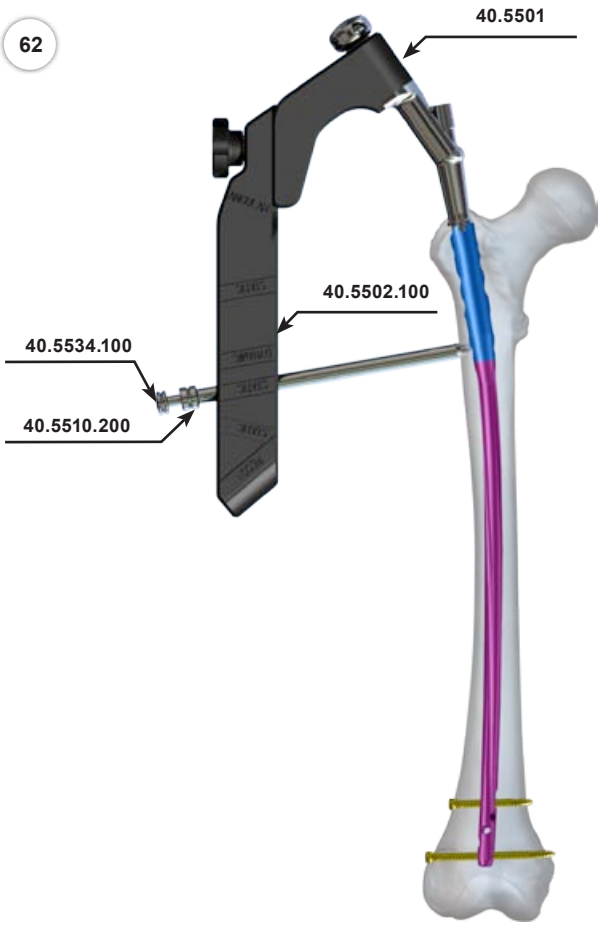
### *IV.7.4.2b. OPTION II: Locking the nail with locking screws*

Construction of anatomical femoral nail and instrumentarium 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.

**Holes in distal part, lock according to point IV.7.1.3.**

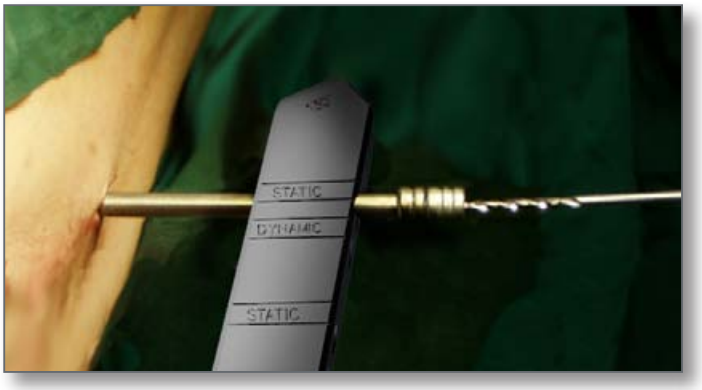
62 Introduce the Protective guide **[40.5510.200]** together with Trocar **[40.5534.100]** in distal static hole of Targeter B. Perform 1,5cm long incision of soft tissues in a place defined as entry point for locking screw. Reach the cortex with the trocar and mark the drill entry point. The protective guide should penetrate together with trocar, in order to place its end as close to the bone as possible.

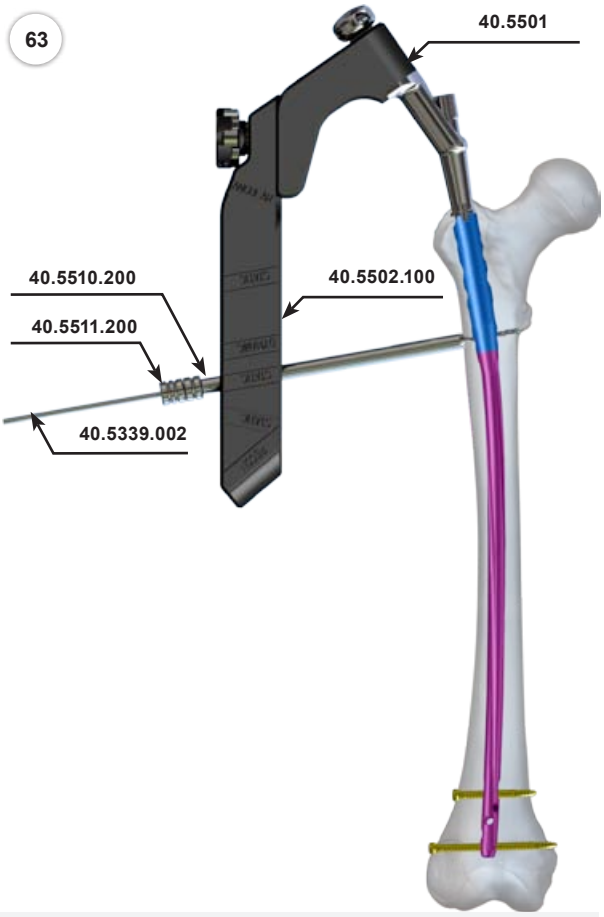
Remove the trocar.
Leave the protective guide in targeter hole.




63 Into protective guide left introduce drill Guide 7/3.5 **[40.5511.200]**. Drill with scale 3.5/350 **[40.5339.002]** mount in the drive, than leading the drill through both guides drill the hole in femur, through both cortexes and hole in the nail. Scale on the drill indicates length of locking element.

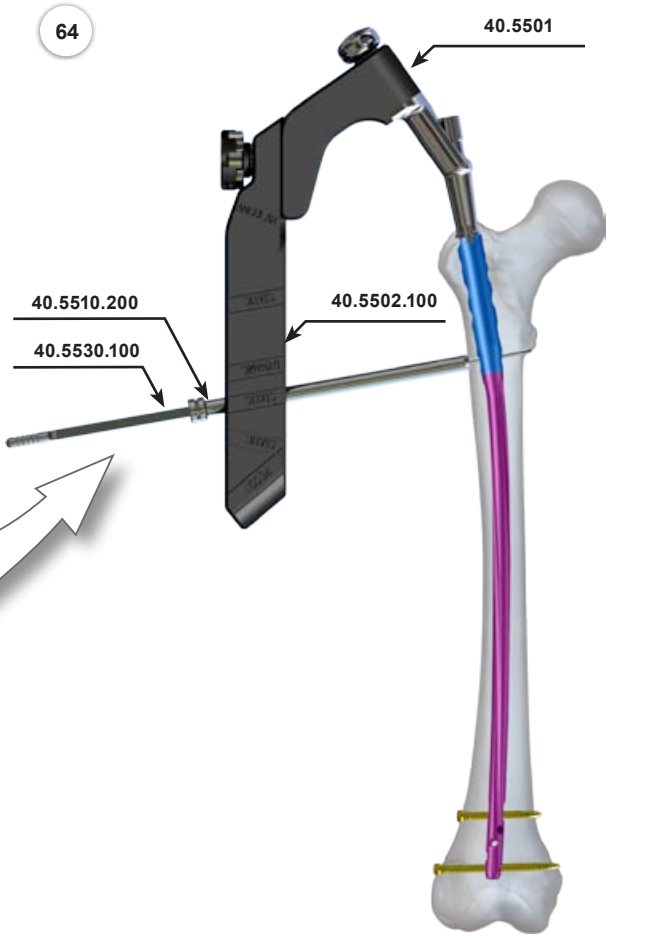
Remove the Drill Guide and Drill.
Leave the Protective Guide.



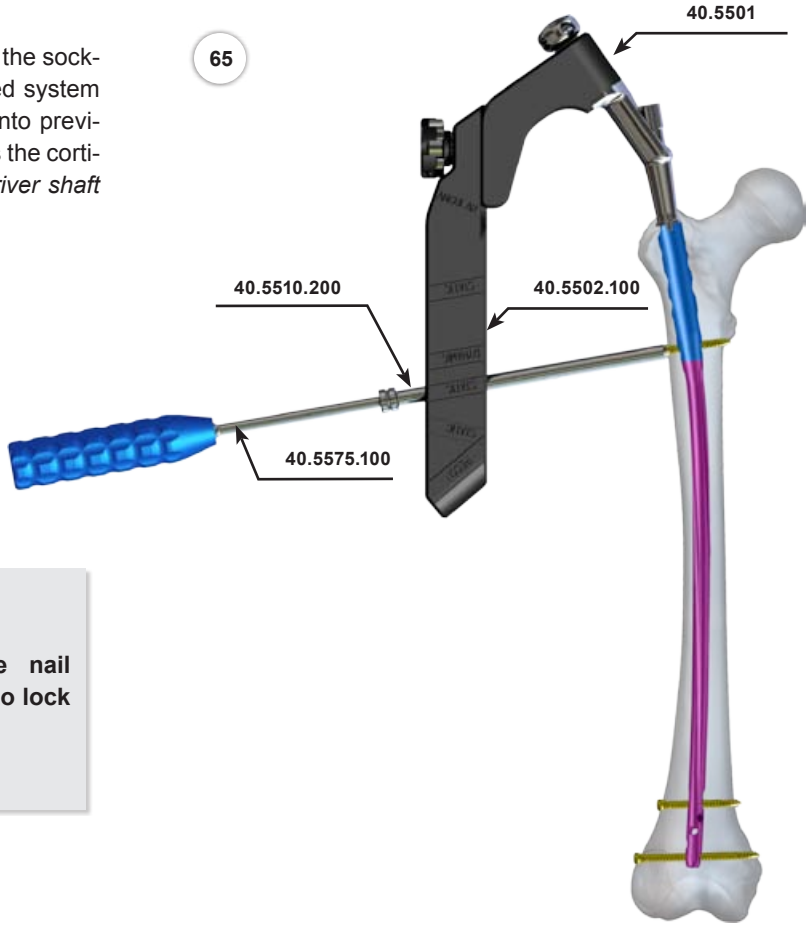

*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

64 Through the Protective guide **[40.5510.200]** introduce the Screw length measure **[40.5530.100]** into hole drilled in the bone, until the catch of measuring tip reaches 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 targeter block.


65 Tip of the screwdriver **[440.5575.100]** insert into the socket of particular locking screw. Next, that coupled system insert 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.




**ATTENTION!**

**If the surgeon decides to lock the nail in the proximal part using two screws - to lock using second screw follow steps 62-65.**

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### *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.

**66** 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 consist 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.

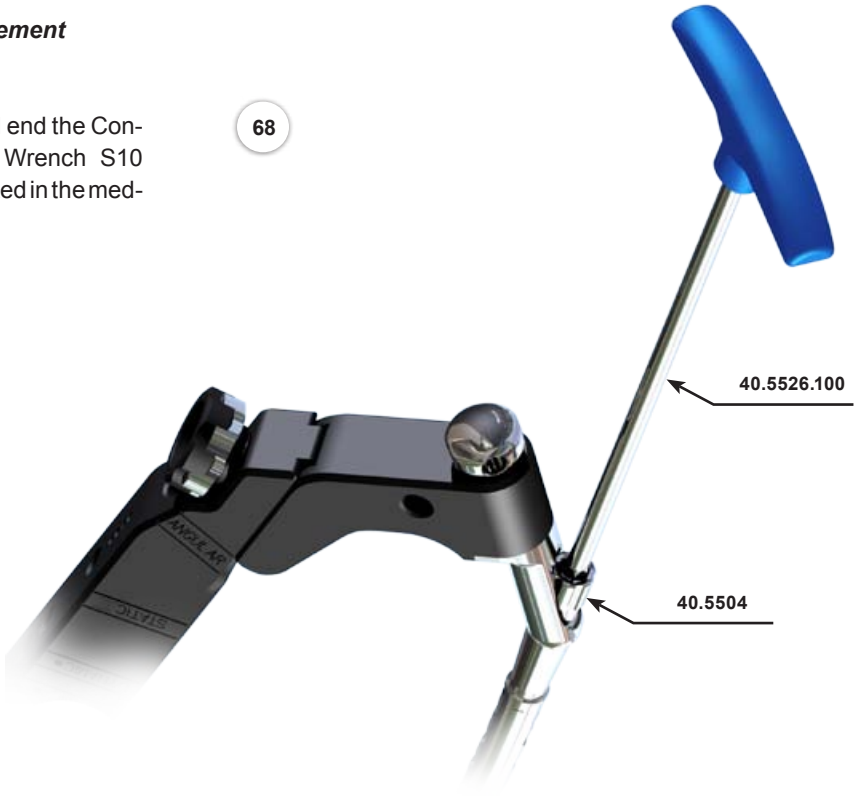
**67** Perform the 1,5cm long incision over the head of screw inserted in the locking hole. Introduce the tip of Screwdriver T25 into the screw's socket, through the surgical wound. Drive the screw out of nail's locking hole, leave the screw placed in the compression hole.

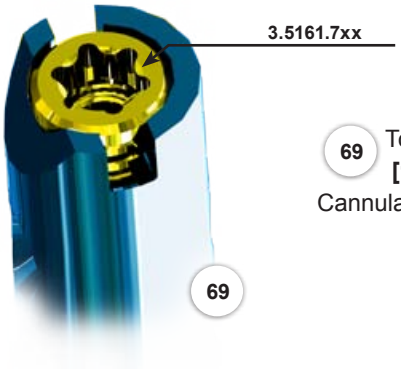
**66**

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

### *IV.7.4.3. Targeter detachment and End cap placement*

68 Drive out of the intramedullary nail's proximal end the Connecting Screw M10x1.5 **[40.5504]** using Wrench S10 **[40.5526.100]** and detach the targeter of the nail locked in the medullary canal.

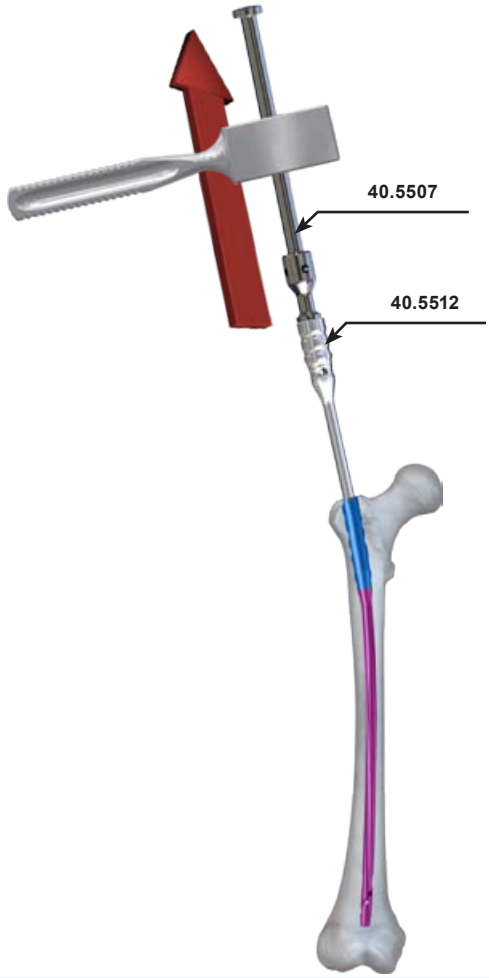



69 To secure the connecting thread of the nail against bone overgrowth, screw the End cap **[1.5161.7xx]** or **[3.5161.7xx]** guided via K-wire into threaded hole in nail's shank using Cannulated Screwdriver T30 **[40.5574.100]**.

## IV.8. NAIL REMOVAL

70 Drive out the end cap or compression screw out of intramedullary nail using Cannulated Screwdriver T30 **[40.5574.100]**. Drive the Connector M10x1,5/M12 **[40.5512]** into the threaded hole in proximal end of the intramedullary nail. Than, screw out all locking screws using Screwdriver T25 **[40.5575.100]**, while reconstructive screws using Cannulated screwdriver T30 **[40.5574.100]**. Attach the Impactor-extractor **[40.5507]** to the Connector. Remove the nail of the medullary canal using Mallet.

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# REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

Instruments manufactured by **ChM** Ltd. are made of steel, aluminium alloys and plastics according to ISO standards. Each medical instrument is exposed to occurrence of corrosion, stains and damage if not treated with special care and recommendations provided below.

**MATERIALS**

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

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

Devices made of aluminium with processed layer have a good corrosion resistance. The contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference on the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: POM-C *(Polyoxymethylene Copolymer)*, PEEK *(Polyetheretherketone)* and teflon *(PTFE)*. The above mentioned materials can be processed *(washed, cleaned, sterilized)* at temperatures not higher than 140°C, they are stable in aqueous solution of washing-disinfecting agents with pH values from 4 to 9.5.

*If the material of the device cannot be specified, please contact* **ChM** *Ltd. company representative.*

**DISINFECTION AND CLEANING**

Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quality of used detergent, the technique of cleaning *(manual/machine)*, the correct rinsing and drying, the proper preparation of the instrument, the time, the temperature. Internal procedures of sterilization rooms, recommendations of cleaning and disinfecting agents, as well as recommendations for cleaning and sterilization in automatic machines shall be observed.

*Read and follow the instructions and restrictions specified by the manufacturers of the agents used for disinfection and cleaning procedures.*

1. Before the first use, the product has to be thoroughly washed in the warm water with washing-disinfecting detergent. It is important to follow the instructions and restrictions specified by the producer of those detergents. It is recommended to use water solutions of cleaning-disinfecting agents with a neutral pH.
2. After use, for at least 10 minutes the product has to be immediately soaked in an aqueous disinfectant solution of enzyme detergent with a netural pH *(with a disinfecting properties)* normally used for reusable medical devices *(remember to prevent drying out of any organic remains on the product surface)*. Follow all the instructions specified by the producer of those enzyme detergents.
3. Carefully scrub/clean the surfaces and crevices of the product using a soft cloth without leaving threads, or brushes made of plastic, the nylon brushes are recommended. Do not use brushes made of metal, bristles or another damaging material as they can cause physical or chemical corrosion.
4. Next, thoroughly rinse the instrument under the warm running water, paying particular attention to rinse the slots carefully. Use nylon brushes making multiple moves back and forth on the surface of the product. It is recommended to rinse under demineralized water, in order to avoid water stains and corrosion caused by chlorides, found in the ordinary water, and to avoid forming the stains on the surface *(e.g. anodized one)*. During the rinsing, manually remove the adherent remains.
5. Visually inspect the entire surface of the product to ensure that all contaminants are removed.

*If there are any residues of human tissue or any other contamination, repeat all stages of the cleaning process.*

6. Then, the instrument has to undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for reusable medical devices and instruments)*.

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

**STERILIZATION**

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

*Devices manufactured out of plastics (PEEK, PTFE, POM-C) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.*

Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards. It is recommended to sterilize in steam sterilizers where sterilizing agent is water vapour. Recommended parameters of the sterilization method: temperature min. 134°C, overpressure: 2 atm. of pressure above atmospheric.

*Please strictly observe the above-mentioned parameters of sterilization.*

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

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