instructions for use

INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR AND TIBIA TELESCOPIC NAIL

- IMPLANTS
- INSTRUMENT SET 40.5080.500
- SURGICAL TECHNIQUE

17C

CE 0197
ISO 9001
ISO 13485

ChM®

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I. INTRODUCTION

ChM telescopic nails are intended for stable femoral and tibial bone osteosynthesis. The nails are used to treat or to prevent fractures and deformation in the case of bone congenital fragility *(Osteogenesis Imperfecta)* of children and youth in their growth phase. The telescopic nails have been designed to modernize the treatment methods using Rush nails. Implant design is based on bicomponential telescopic system which includes nail and sleeve. Telescopic nail replaces Rush nail and the sleeve is a stabilizing component which allows for leaving the system in the body for longer period of time. Using the maximal possible length of the nail, the strengthening of the bone on the greatest length is provided, whereas implantation of the nail with its maximal diameter increases its endurance. Therefore, the stabilization becomes more reliable.
Implants for femoral and tibial osteosynthesis with telescopic nails provide:
- stabilization with correct union of proximal and distal fragment, preventing migration of the rod ends,
- high mechanical endurance, not lower than for the already used Rush nails,
- self-protraction of implant of minimum 5cm, that eliminates necessity of surgical intervention for the term of 2 years,
- possibility of nail components replacement for longer elements.

Tibial nail is to be placed near the tibial tuberosity in proximal epiphysis, whereas in distal extremity - near its end.

Fig. 1. Implants placement in the tibia

Femoral nails are seated in the peritrochanter area on the one side and near femoral condyle, in its distal end, on the other. Telescopic femoral and tibial nails are placed in growth tissues, so implants length changes with bone accretion. Thereby the interoperative period increases considerably decreasing child's exposition for reoperation and postoperative trauma.
It is possible to keep correct location of the bone that prevents deformation of the lower extremity due to strengthening of the bone by the implant. Additionally, telescopic nails allow for greater motor activity of the patient.

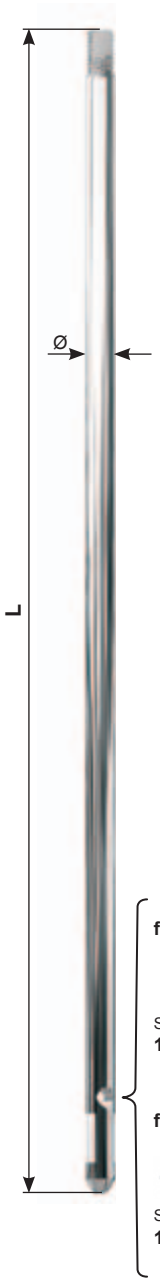
The limiter screw M5 placed in tibial nail sleeve is meant to reduce rotational motion between nail and sleeve what significantly facilitates the manipulation of the nail using the sleeve when locking in distal end. Additionally, the limiter screw M5 prevents wedging of the nail in the telescopic sleeve. The limiter screw M5 allows already joined components to be inserted directly into medullary canal and allows for nail manipulation using the sleeve.
Telescopic nails are locked by the self-tapping cortical screws, while the telescopic sleeve is locked by its hooks.
The telescopic sleeve shall be placed in growth tissues
The intramedullary telescopic nail system used for tibial and femoral osteosynthesis consists of:
- implants for tibia *(telescopic tibial nail, tibial nail sleeve, locking screws, end cap, limiter screw)*,
- implants for femur *(telescopic femoral nail, femoral nail sleeve, locking screw, end cap)*,
- instruments instructions for use.

II. IMPLANTS

The set for tibia osteosynthesis consists of:
- telescopic tibial nail d/L, **[1.2531.xxx]** - **[1.2538.xxx]**,
- telescopic tibial nail - sleeve d/L, **[1.2541.xxx]** - **[1.2548.xxx]**,
- locking screws 1.5/2.7, **[1.1022.014÷070]**, 2.7 **[1.1203.008÷018]**,
- limiter screw M5 **[1.2529.005]**,
- end cap M5 **[1.2530.000]**.

All implants are made of implantable steel according to ISO 5832-9 standard.

TELESCOPIC TIBIAL NAIL



L [mm]	Ø	Steel	L [mm]	Ø	Steel	L [mm]	Ø	Steel
180	3.5	1.2533.180	180	4	1.2534.180	180	4.5	1.2535.180
190		1.2533.190	190		1.2534.190	190		1.2535.190
200		1.2533.200	200		1.2534.200	200		1.2535.200
210		1.2533.210	210		1.2534.210	210		1.2535.210
220		1.2533.220	220		1.2534.220	220		1.2535.220
230		1.2533.230	230		1.2534.230	230		1.2535.230
240		1.2533.240	240		1.2534.240	240		1.2535.240
250		1.2533.250	250		1.2534.250	250		1.2535.250
260		1.2533.260	260		1.2534.260	260		1.2535.260
270		1.2533.270	270		1.2534.270	270		1.2535.270
280		1.2533.280	280		1.2534.280	280		1.2535.280
290		1.2533.290	290		1.2534.290	290		1.2535.290
300		1.2533.300	300		1.2534.300	300		1.2535.300

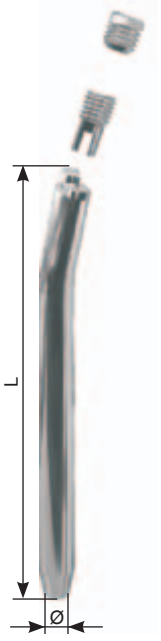
available	
Ø [mm] pitch 1 mm	2.5÷6
L [mm] pitch 5 mm	180÷300

for nails Ø3.5 - 4.0

Steel
1.1022.014-40

for nails Ø4.5

Steel
1.1203.008-045



Telescopic tibial nail sleeve

L [mm]	Ø	Steel	L [mm]	Ø	Steel	L [mm]	Ø	Steel
80	3.5	1.2543.080	80	4	1.2544.080	80	4.5	1.2545.080
90		1.2543.090	90		1.2544.090	90		1.2545.090
100		1.2543.100	100		1.2544.100	100		1.2545.100
110		1.2543.110	110		1.2544.110	110		1.2545.110
120		1.2543.120	120		1.2544.120	120		1.2545.120
130		1.2543.130	130		1.2544.130	130		1.2545.130
140		1.2543.140	140		1.2544.140	140		1.2545.140
150		1.2543.150	150		1.2544.150	150		1.2545.150

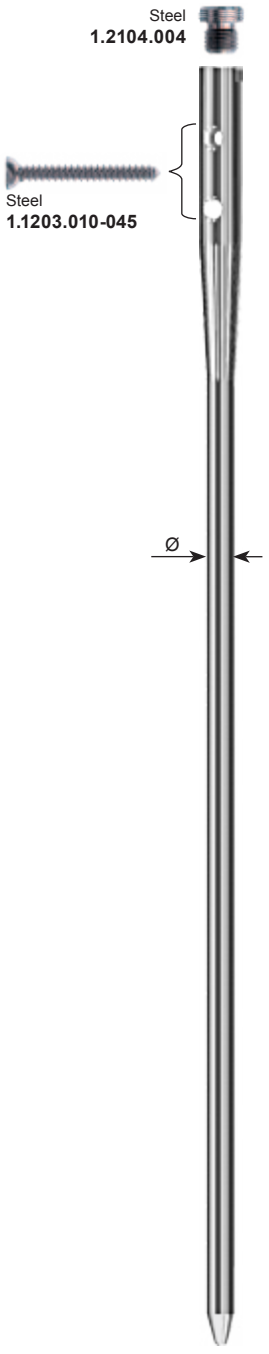
available	
Ø [mm] pitch 1 mm	2.5÷6
L [mm] pitch 5 mm	180÷150

Use with instrument set **[40.5080.500]** and **[40.4580.500]**

The set for femur osteosynthesis consists of:
- telescopic femoral nail d/L, **[1.2511.xxx]**-**[1.2516.xxx]**,
- telescopic femoral nail - sleeve d/L, **[1.2521.xxx]**-**[1.2526.xxx]**,
- locking screws 2.7 **[1.1203.008÷018]**,
- end cap M4 **[1.2104.004]**.

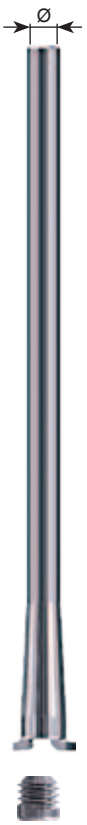
All implants are made of implantable steel according to ISO 5832-9 standard.

TELESCOPIC FEMORAL NAIL



L [mm]	Ø	Steel	L [mm]	Ø	Steel	L [mm]	Ø	Steel
180		1.2512.180	180		1.2513.180	180		1.2514.180
190		1.2512.190	190		1.2513.190	190		1.2514.190
200		1.2512.200	200		1.2513.200	200		1.2514.200
210		1.2512.210	210		1.2513.210	210		1.2514.210
220		1.2512.220	220		1.2513.220	220		1.2514.220
230		1.2512.230	230		1.2513.230	230		1.2514.230
240	3.5	1.2512.240	240	4	1.2513.240	240	4.5	1.2514.240
250		1.2512.250	250		1.2513.250	250		1.2514.250
260		1.2512.260	260		1.2513.260	260		1.2514.260
270		1.2512.270	270		1.2513.270	270		1.2514.270
280		1.2512.280	280		1.2513.280	280		1.2514.280
290		1.2512.290	290		1.2513.290	290		1.2514.290
300		1.2512.300	300		1.2513.300	300		1.2514.300

available	○
Ø [mm] pitch 1 mm	3÷6
L [mm] pitch 5 mm	180÷350



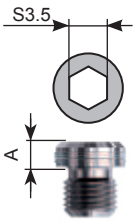
Telescopic femoral nail - sleeve

L [mm]	Ø	Steel	L [mm]	Ø	Steel	L [mm]	Ø	Steel
120		1.2522.120	120		1.2523.120	120		1.2524.120
125		1.2522.125	125		1.2523.125	125		1.2524.125
130		1.2522.130	130		1.2523.130	130		1.2524.130
135	3.5	1.2522.135	135	4	1.2523.135	135	4.5	1.2524.135
140		1.2522.140	140		1.2523.140	140		1.2524.140
145		1.2522.145	145		1.2523.145	145		1.2524.145
150		1.2522.150	150		1.2523.150	150		1.2524.150

available	○
Ø [mm] pitch 1 mm	3÷6
L [mm] pitch 5 mm	100÷150

Use with instrument set **[40.5080.500]** and **[40.4580.500]**

LOCKING ELEMENTS



End cap M4

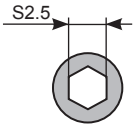
	Catalogue no.
A	**Steel**
+2.5	1.2104.004

End cap M5

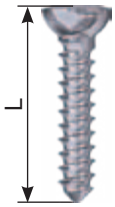
	Catalogue no.
A	**Steel**
+2.5	1.2530.000

Limiter screw M5

Catalogue no.
Steel
1.2529.005



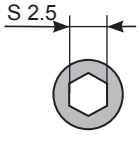
Cortical self - tapping screw Ø2.7



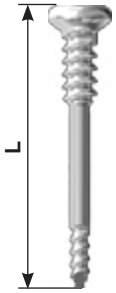
	Catalogue no.
L [mm]	**Steel**
8	1.1203.008
10	1.1203.010
12	1.1203.012
14	1.1203.014
16	1.1203.016
18	1.1203.018
20	1.1203.020
22	1.1203.022
24	1.1203.024
26	1.1203.026
28	1.1203.028
30	1.1203.030
32	1.1203.032
34	1.1203.034
36	1.1203.036
38	1.1203.038
40	1.1203.040
45	1.1203.045

available

L [mm]	6÷45



Distal screw Ø1.5/2.7



	Catalogue no.
L [mm]	**Steel**
14	1.1022.014
16	1.1022.016
18	1.1022.018
20	1.1022.020
22	1.1022.022
24	1.1022.024

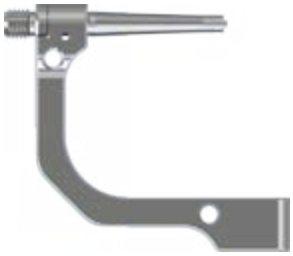
III. INSTRUMENT SET

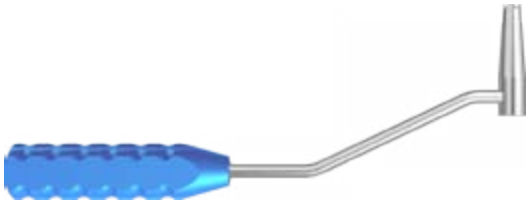
To perform the fixation of fragments in femur/tibia with a telescopic nail and to remove the implants at the end of treatment - use the instrument set **[40.5080.500]** - instrument set for tibial and femoral telescopic nails together with instrument set **[40.4580.500]** - instrument set for forearm and fibula bones. All instruments which are included into the instrument set are put on a stand, which is inside a sterilization box, therefore the storage and transporation of the instruments to the operating theatre is facilitated.
The following devices are included into the instrument set:

40.5080.500

No.		Name	Catalogue no.	Pcs
1		Kirschner wire 1.0/200	40.4814.200	4
2		Holder with clamp M5	40.5081.000	1
3		Holder M4	40.5082.000	1
4		Nail guide	40.5083.000	1
5		Nail guide M4 *(tibial)*	40.5084.000	1
6		Nail guide M2.5 *(tibial)*	40.5085.000	1
7		Stand	40.5089.500	1

40.4580.500

No.		Name	Catalogue no.	Pcs
1		Proximal targeter B	40.4585	1
2		Clamping screw M4	40.4586	1
3		Socket wrench S6	40.4587	1
4		Impactor-extractor	40.4588	1
5		Protective guide 7/5	40.4589	1
6		Kirschner guide B 5/2	40.4590	1
7		Screw length measure	40.4591	1

No.		Name	Catalogue no.	Pcs
8		Targeter D	40.1344	1
9		Mallet	40.4595	1
10		Connector M4	40.4596	1
11		Hexagonal screwdriver S2.5	40.0321	1
12		Nail template	40.4581	5
13		Bender	40.4511	2
14		Kirschner wire 2/200	40.4583	3
15		Cannulated drill 6.0/2.2/150	40.4584	1
16		Stand	40.4597.500	1

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IV. SURGICAL TECHNIQUE - TIBIAL NAIL

The following description details the most important steps regarding telescopic tibial nail insertion; nonetheless, these are not detailed instructions for use. The surgeon decides about surgical technique and its use in each individual case.

IV.1. INTRODUCTION

Each surgery must be carefully planned. X-Ray visualization of fractured bone should be done in AP and lateral position in order to define proper nail size. It is recommended to make the X-Ray visualization of healthy extremity as well. Nail length should match the medullary canal on the maximal possible length. Whereas nail diameter should be matched to maximally fill the lumen of the medullary canal.
Nail insertion can be performed with two methods:
- separate insertion of telescopic nail and sleeve - **METHOD I**,
- combined system insertion - **METHOD II**.

The implantation should be done on operating table equipped with traction and image intensifier.

IV.2. SURGICAL APPROACH

When patient is placed supine, operated leg should be flexed in hip joint at 70 to 90 degrees and abducted at 10 to 20 degrees, and flexed at 80 to 90 degrees in the knee joint, while the ankle joint should stay in neutral position *(foot perpendicular to shin)*. *(Fig. 2)*

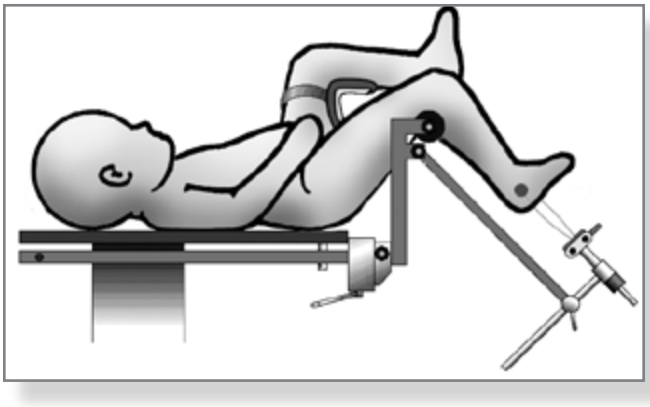


Fig. 2. Patient positioning *(AP and lateral X-Ray control)*

Surgery approach is prepared by:
- longitudinal incision from lower patella end to the point situated a bit medially from tibial tuberosity,
- performing the incision along medial margin of patella tendon and its lateral retraction.

Nail insertion point *(Fig. 3)* is situated on prolongation of line that passes through the medullary canal *(X-Ray in AP position)* and it is located between tibial tuberosity and tibial epiphysis anterior margin.

Fig. 3. Tibial nail insertion point

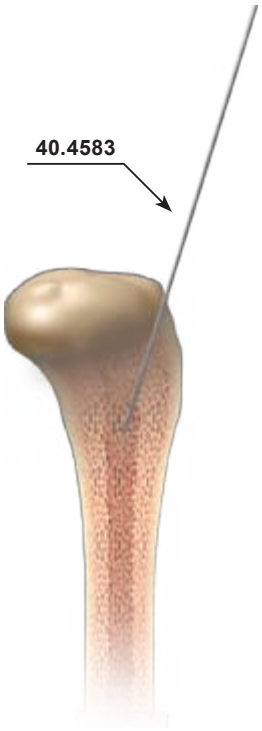
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.3. MEDULLARY CANAL INCISION

1 After preparation of the surgery approach and insertion point, Kirschner wire *(recommended Kirschner wire size is 2/200 [40.4583])* shall be inserted into medullary canal, at the angle corresponding to the nail diversion angle from the main nail axis *(about 10°)*.

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

Kirschner wire is disposable.



2 Use the cannulated drill 6.0/2.2/150 **[40.4584]** via Kirschner wire to open the medullary canal.

Remove the cannulated drill and Kirschner wire.

3 Proximal section of the canal at the depth of 5÷6 cm must be widened about 0.5mm more than the sleeve diameter *(it is related to a larger diameter of the nail sleeve)*.

It is recommended to open the medullary canal using the procedure defined in step 1 and 2. However, the choice of operation technique depends on surgeon's preference and equipment available in surgical suit.

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

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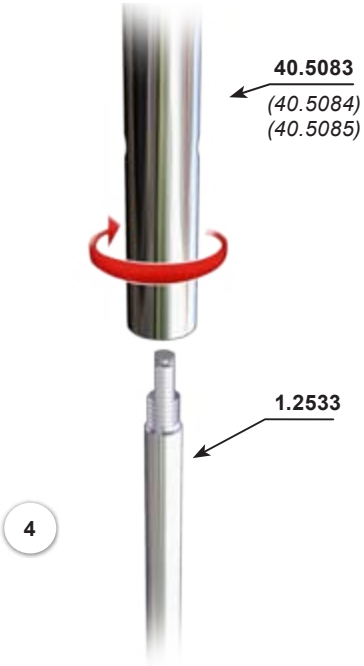
IV.4. METHOD I

IV.4.1. Nail insertion into medullary canal



4 Insert a suitable nail guide on the threaded end of a telescopic nail.

- for Ø2.5 nail – nail guide **[40.5085]**,
- for Ø3.0 - 4.0 nail – nail guide **[40.5083]**,
- for Ø4.5 - 6.0 nail – nail guide **[40.5084]**.

5 Insert the coupled system *(the nail and nail guide)* into prepared medullary canal under the image intensifier control. Operator should pay attention to insert the nail into the medullary canal and to leave some space in proximal section for telescopic nail sleeve to be inserted later on the nail.
The hole in the nail *(for locking screw)* should be in the right position.

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

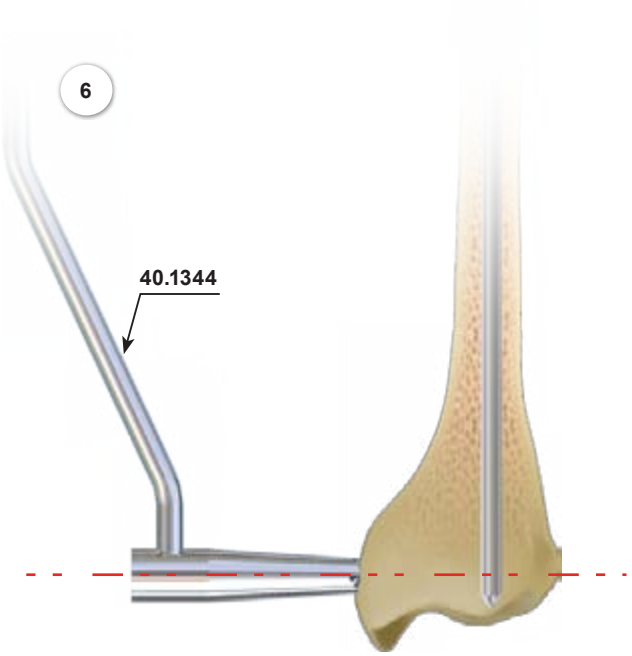
IV.4.2. Locking the telescopic nail in distal section

The *"free hand"* technique is used to lock the nail in the distal part. It is necessary to use the image intensification to define the place of drilling. It is recommended to use the drill angle attachment, so the operator's hands are away from the direct X-Ray radiation area.

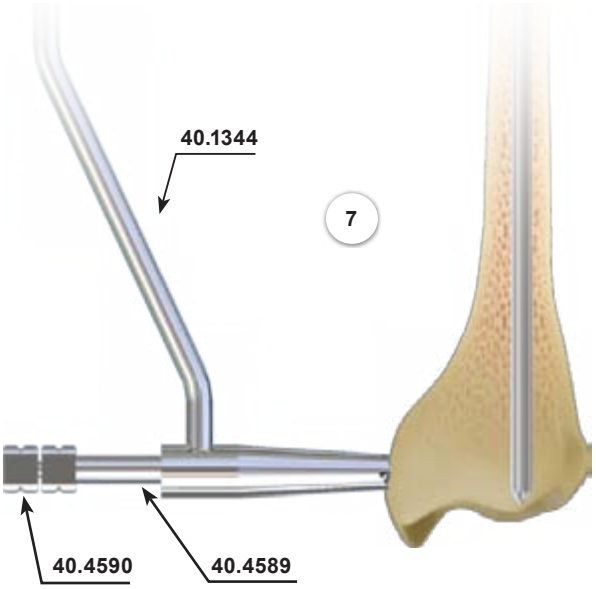
NOTE!
For nails 3.0 – 4.0 use screws 1.5/2.7mm [1.1022.014-070].
For nails 4.5 – 6.0 use screws 2.7mm [1.1203.008-018].

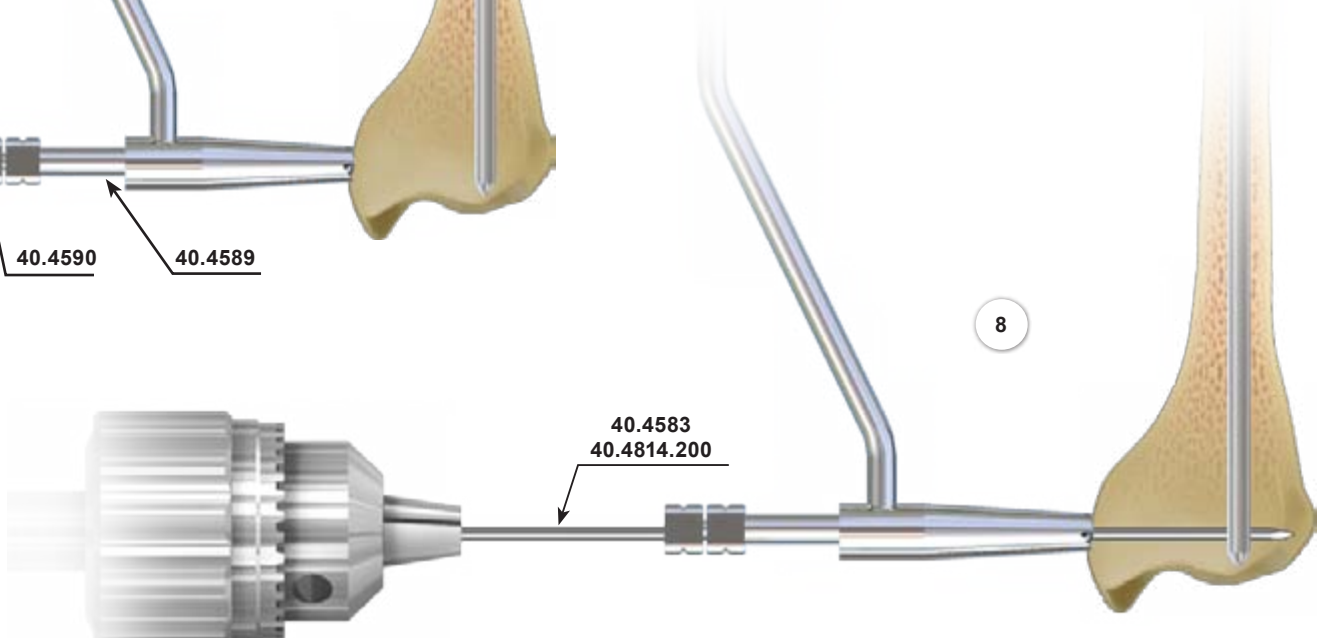
6 Use X-Ray to determine the location of nail holes. Having marked the drilling point on the skin, make approx. 1.5cm incision of soft tissues passing through the determined points. Use the X-Ray to determine the targeter D **[40.1344]** location in relation to the hole in the intramedullary nail.

NOTE!
Holes in nail and targeter D must coincide. Targeter blades should be immersed in cortical bone.



7 Insert the protective guide 7/5 **[40.4589]** with Kirschner guide B 5/2 **[40.4590]** into the targeter D **[40.1344]** hole.





8 Use the surgical drive to drill the hole through both cortical layers with the aid of Kirschner wire 1.0/200 **[40.4814.200]** *(or [40.4583] when locking screws 2.7 mm are used)* inside the Kirschner guide.

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

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

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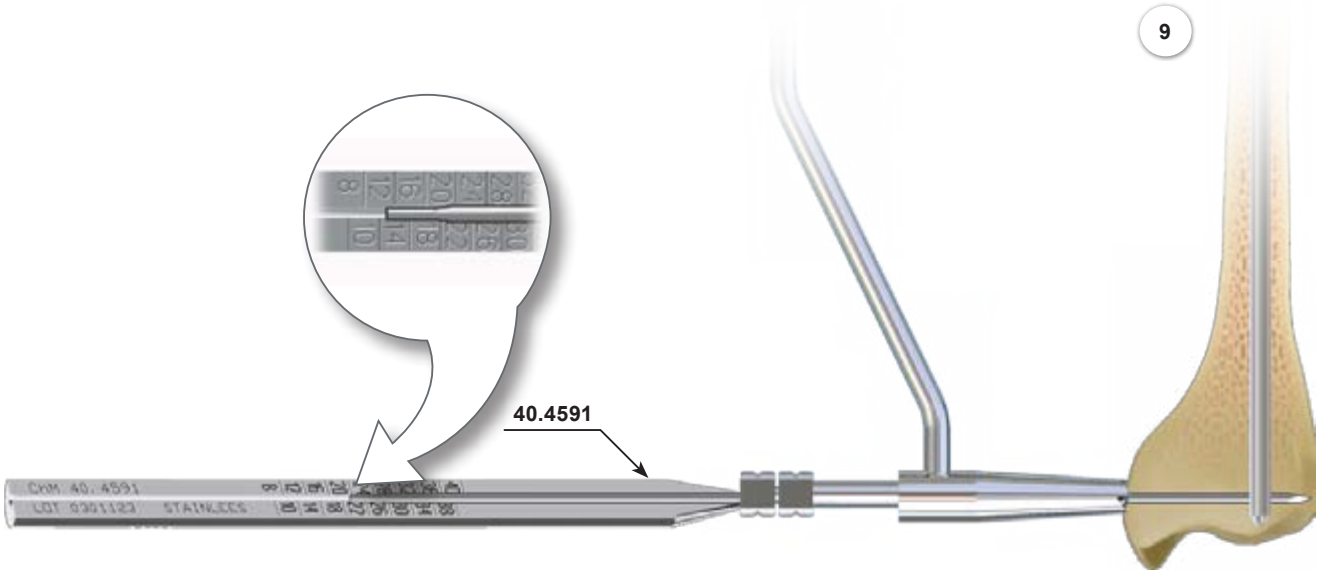
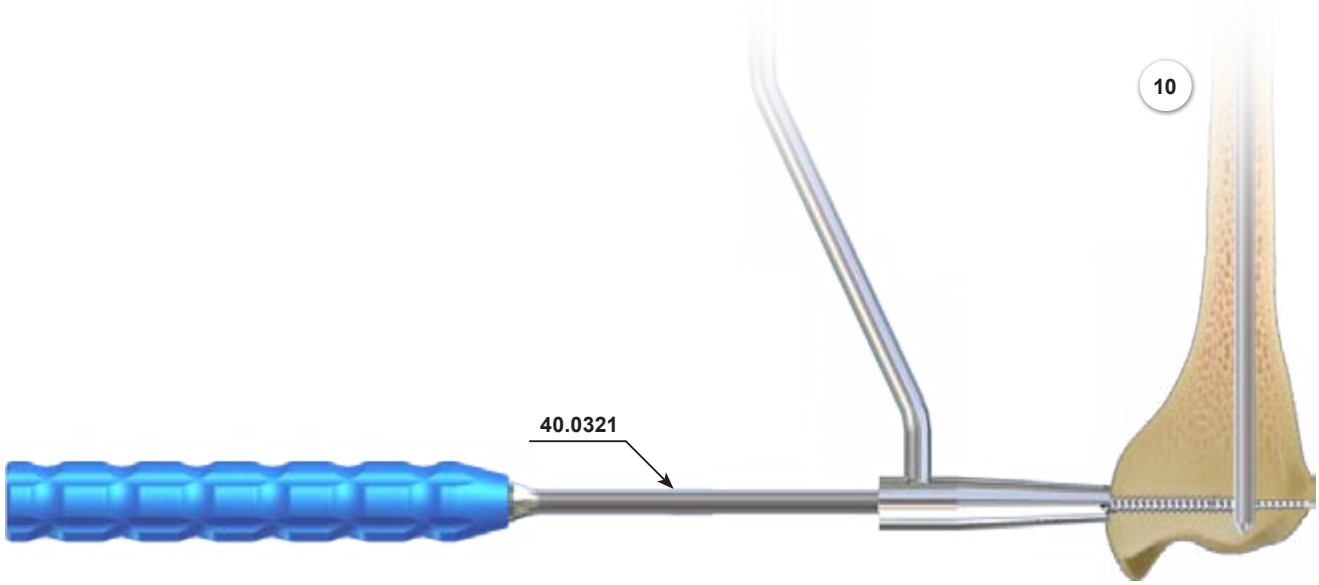
9 Apply the screw length measure **[40.4591]** via Kirschner wire *(placed into Kirschner guide [40.4590])* until its end rests on the guide. Read the length of locking screw indicated on a scale by the end of Kirschner wire.
Remove the Kirschner guide B and the Kirschner wire.
Leave the targeter D and the protective guide 7/5 in place.



10 Insert the tip of the screwdriver S2.5 **[40.0321]** into the hexagonal socket of the locking screw. Advance this coupled system the opening of protective guide 7/5 **[40.4589]** into prepared hole of the locking screw, until its head reaches the cortex. Remove the screwdriver, the targeter and the nail guide.



NOTE!
REMEMBER TO SELECT LOCKING SCREW DIAMETER MATCHING THE NAIL DIAMETER!
(See the beginning of section: IV.4.2. Locking the telescopic nail in distal section)

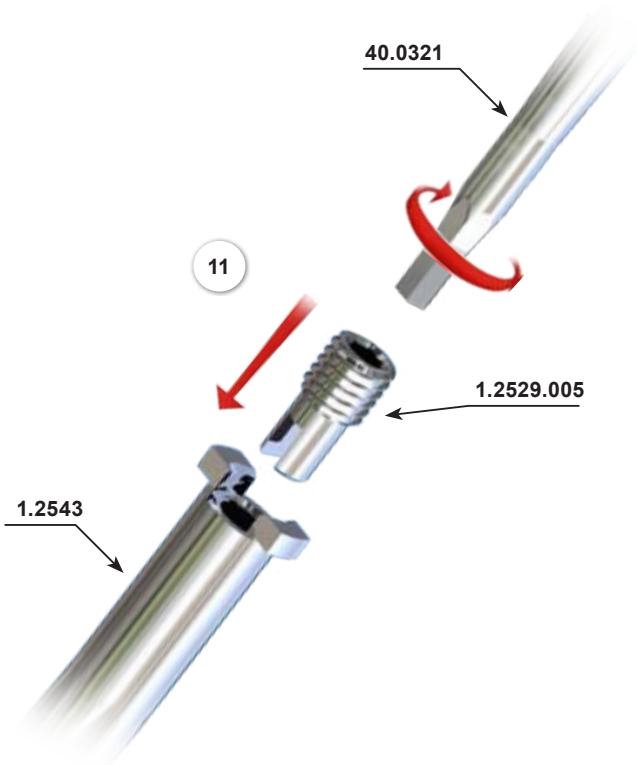
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.4.3. Telescopic sleeve insertion

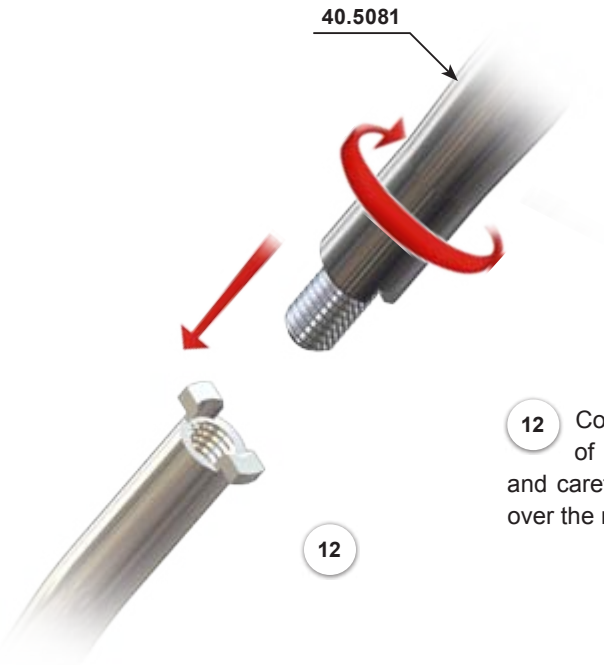
NOTE!
Pay particular attention while choosing the suitable sleeve diameter matching the nail size, e.g. sleeve 3.5 [1.2543.xxx] should be mounted only with nail 3.5 [1.2533.xxx].
(see: Tab. 1. Nail and sleeve selection)

Tab. 1. Nail and sleeve selection

Ø	Tibial nail steel		Ø	Tibial nail steel
3.5	1.2533.xxx	→	3.5	1.2543.xxx
4.0	1.2534.xxx	→	4.0	1.2544.xxx
4.5	1.2535.xxx	→	4.5	1.2545.xxx



11 Prior to sleeve implantation, insert limiter screw M5 **[1.2529.005]** into the sleeve with the aid of screwdriver 2.5 **[40.0321]**. Insert the tip of screwdriver into the hexagonal socket of limiter screw and screw it in to the limit.



12 Combine the holder with clamp M5 **[40.5081]** with tapped section of the sleeve, verify the nail end location with the image intensifier and carefully insert the system into medullary canal, until the sleeve slides over the nails shaft.

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

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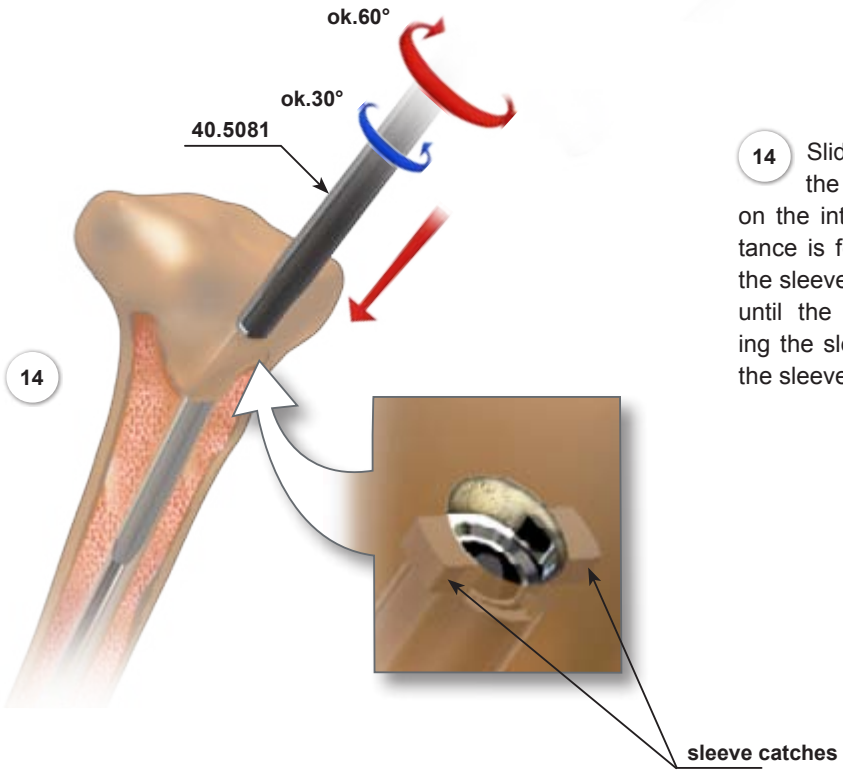
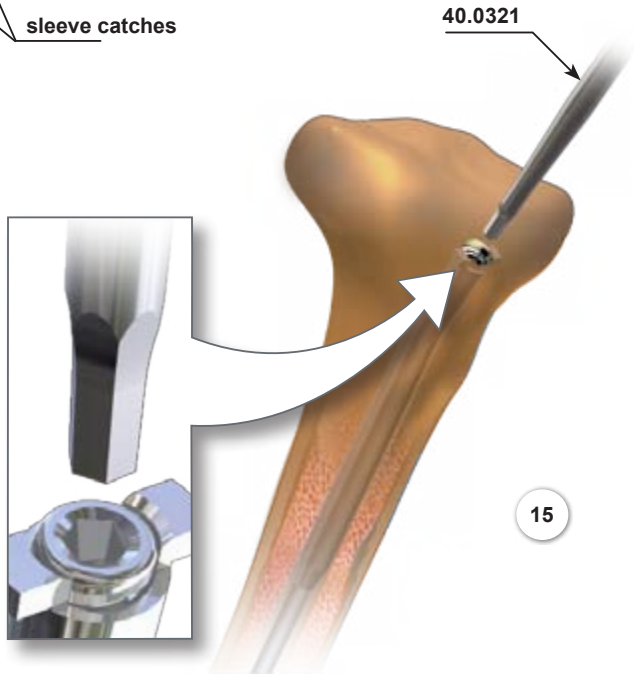
13 Slide over the sleeve, until the cut in the limiter screw coincides with flat part of the telescopic nail end.



14 Slide the holder with clamp M5 with the sleeve into the medullary canal, until the sleeve end rests on the intercondylar tissues. Gently turn left until resistance is felt *(about 30°)* and with adequate force press the sleeve catches into tissues. Next turn the sleeve right until the resistance *(about 60°)* is felt, thereby locking the sleeve catches into growth tissues. After locking the sleeve, unscrew the holder with clamp M5 **[40.5081]**.

15 Use the screwdriver S2.5 **[40.0321]** to insert the end cap **[1.2530.000]** into the sleeve in order to secure the threaded hole from bone ingrowth.



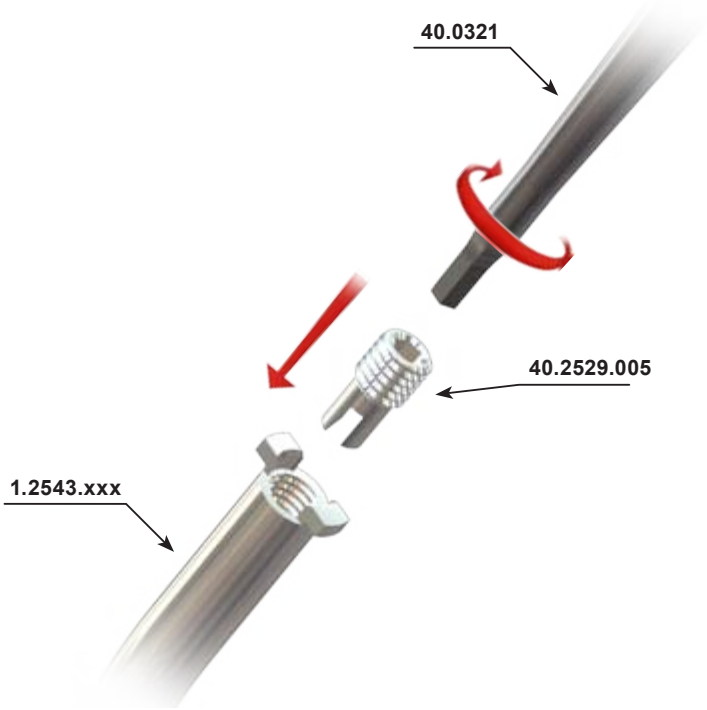
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

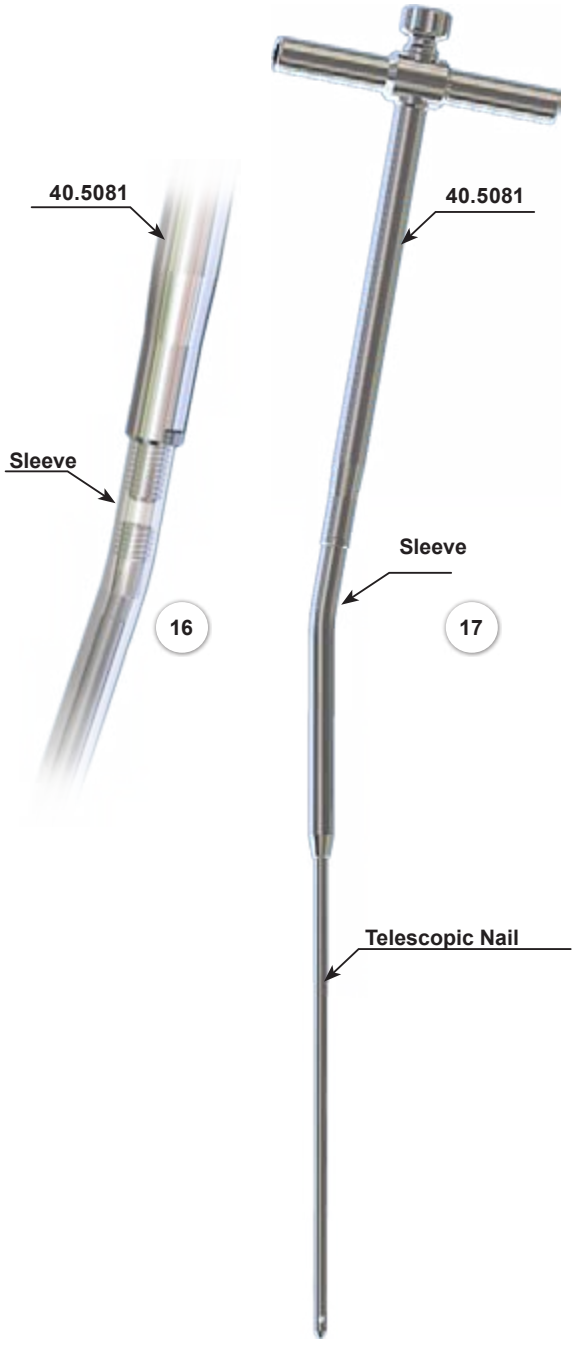
IV.5. METHOD II

METHOD II relies on an insertion to medullary canal of a coupled set of implants: nail + sleeve + limiter screw.

IV.5.1. Insertion of a coupled system into medullary canal

Insert the limiter screw into the sleeve, proceed according to step 11 from the METHOD I.





16 Couple the holder with clamp M5 **[40.5081]** with the sleeve tapped section, then, insert an appropriate nail into the sleeve *(according to Tab.1., section IV.4.3 of these Instructions)*, so the cut of the limiter screw coincides with flat part of the telescopic nail end. Check whether the system is connected correcly by turning the sleeve against the nail. If rotation does not occur, the connection is correct.

17 That coupled nail is ready for insertion into the medullary canal. Using the same holder with clamp M5 **[40.5081]**, slide the nail and sleeve into medullary canal, so the sleeve catches at its end rest on the intercondylar tissues. Gently turn left until sensible resistance occurs *(about 30°)* and press the sleeve catches into tissues with adequate force. Next turn the sleeve right until sensible resistance occurs *(about 60°)*, thereby locking sleeve catches in growth tissues. After locking the sleeve, remove *(unscrew)* the holder with clamp M5 **[40.5081]**.

IV.5.2. Locking the telescopic nail in distal section

Perform the telescopic nail locking in distal section according to steps 6-10 of section IV.4.2.

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

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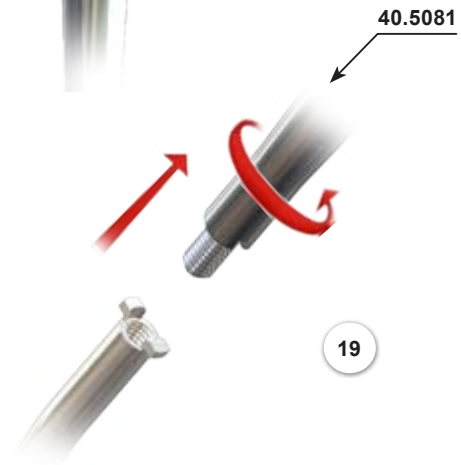
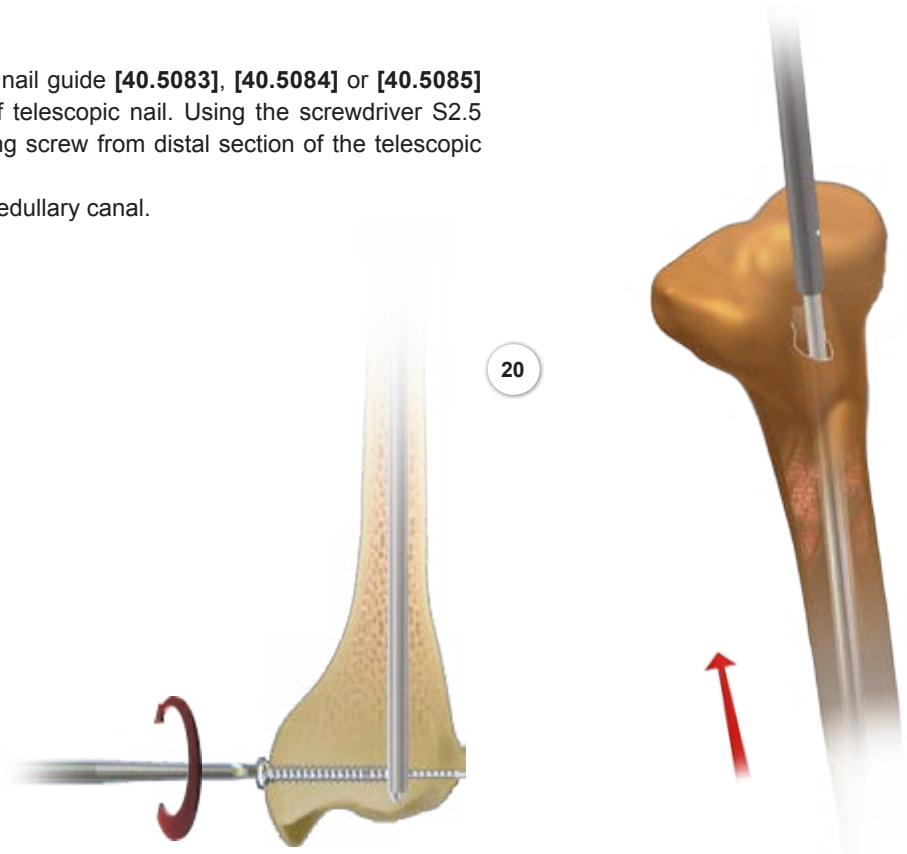
IV.6. TELESCOPIC NAIL REMOVAL

18 Using screwdriver S2.5 **[40.0321]** unscrew end cap M5 **[1.0105.005]** from telescopic sleeve.

19 Using the holder with clamp M5 **[40.5081]**, remove the sleeve from the medullary canal.



20 Insert an appropriate nail guide **[40.5083]**, **[40.5084]** or **[40.5085]** on a threaded end of telescopic nail. Using the screwdriver S2.5 **[40.0321]** remove the locking screw from distal section of the telescopic nail.
Remove the nail from the medullary canal.



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

V. SURGICAL TECHNIQUE – FEMORAL NAIL

The following description details the most important steps regarding telescopic femoral nail insertion; nonetheless, these are not detailed instructions for use. The surgeon decides about surgical technique and its use in each individual case.

V.1. INTRODUCTION

Each surgery must be carefully planned. X-Ray visualization of fractured bone should be done in AP and lateral position in order to define proper nail size and its flexion, that should be used for implantation. It is recommended to place the patient supine with direct traction over femur condyles of the operated leg. Nail length should match the medullary canal on the maximal possible length. Whereas nail diameter should be matched to maximally fill the lumen of the medullary canal.
The implantation should be done on operating table equipped with traction and image intensifier.

V.2. SURGICAL APPROACH

Lateral surgical approach should be used. Start the incision near the trochanter major apex, and lead it along the thigh long axis 8 cm long. The incision should be widened in the case of overweight patients. When reaching the fascia, cut it according to skin incision. Next the dissection of gluteus maximus muscle fibres should be performed. Back from gluteus medius muscle, approach to trochanter major apex is enabled. Entry hole axis location must coincide with medullary canal axis. This can be done with the following method. If trochanter apex is found with forefinger, then the sought after point is located a bit medially *(towards the neck of femur basis)* and a bit anteriorly, in place sensible with forefinger tip as a fossette *(fossa piriformis)*.

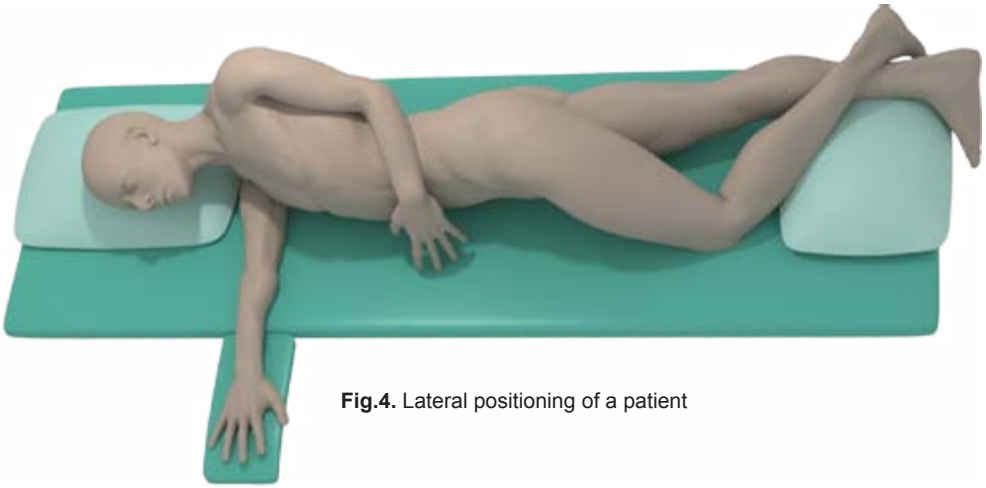


Fig.4. Lateral positioning of a patient

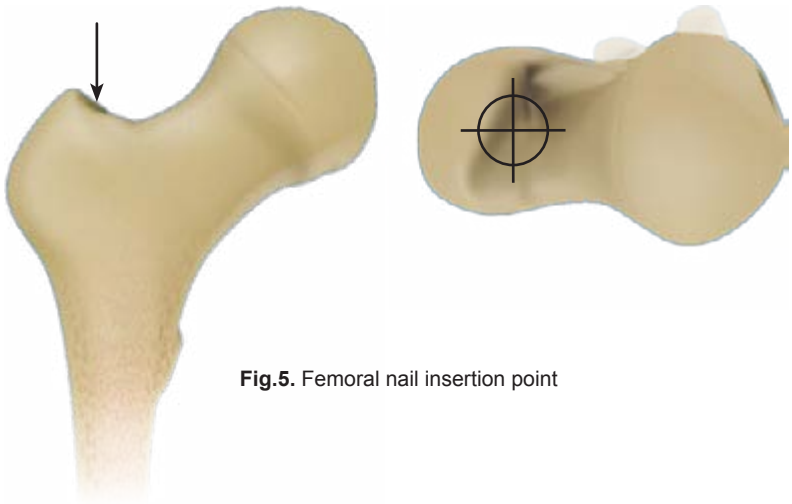


Fig.5. Femoral nail insertion point

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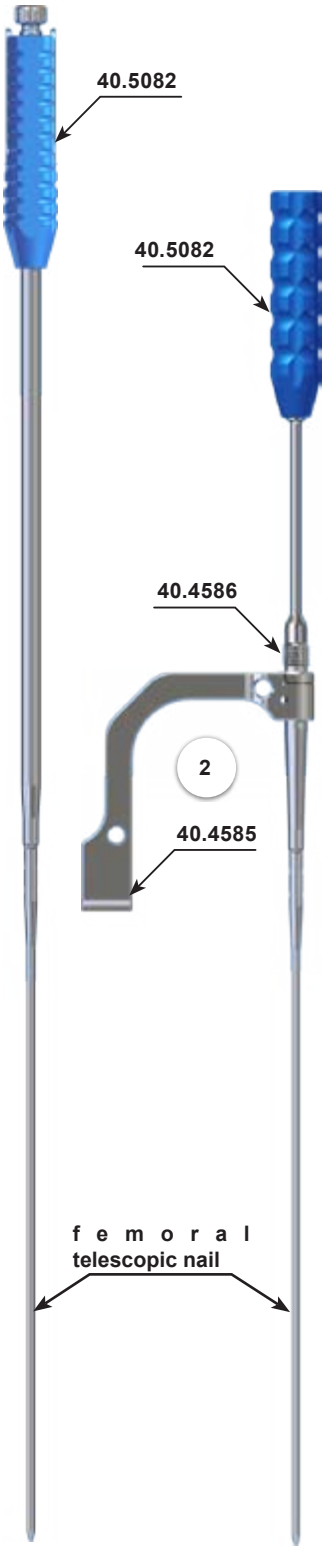
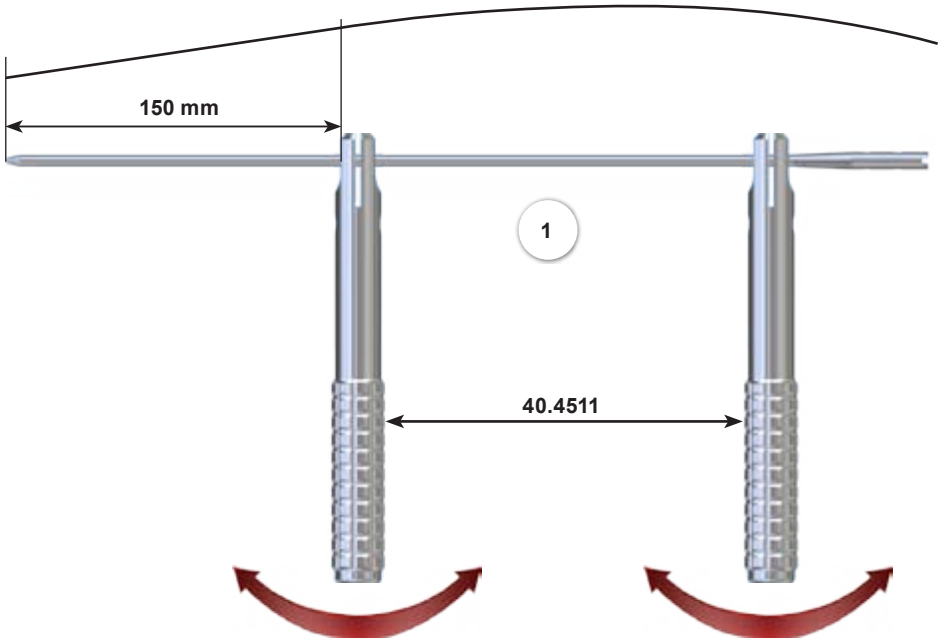
V.3. NAIL PREPARATION FOR INSERTION IN MEDULLARY CANAL

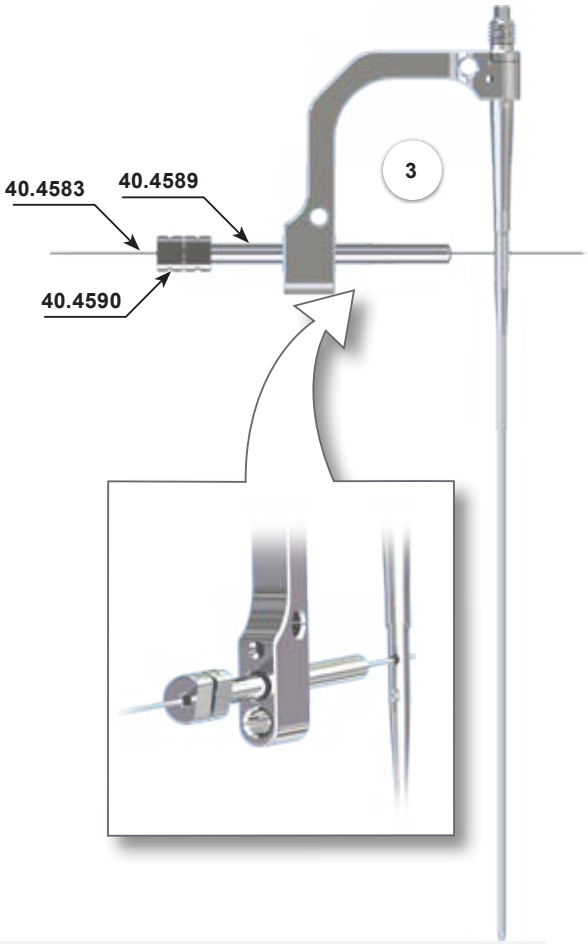
1 After taking X-Ray of the bone to be implanted with a nail *(it is recommended to take an X-Ray of healthy leg as well)*, nail length and shape should be defined. Nail flexion is acquired with use of two benders **[40.4511]**. Nail should be gripped with benders and bend properly with the use of hands force.

ATTENTION! Straight sector 150 mm of length should remain unbent.





2 With the clamping screw M4 **[40.4586]**, using the socket wrench S6 **[40.4587]**, attach intramedullary nail to the proximal targeter B **[40.4585]**. Alternatively, for the same purpose the holder with clamp M4 **[40.5082]** can be used. In such case, use of the impactor-extractor shall be omitted.



3 Before implantation, coincidence of hole in the proximal targeter B **[40.4585]** and hole in the telescopic nail should be verified. For that purpose insert the protective guide 7/5 **[40.4589]** with Kirschner guide B **[40.4590]** into the distal hole of the proximal targeter B. When system is correctly connected Kirschner wire **[40.4583]** should easily hit the nail hole.

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

V.4. OPENING THE MEDULLARY CANAL

4 After preparation of the surgery approach and location of the nail insertion point into the medullary canal, insert Kirschner wire 2/200 **[40.4583]** with the help of surgical drive.

Process shall be done under the image intensifier control.

Kirschner wire is disposable.

5 Use the cannulated drill 6.0/2.2/150 **[40.4584]** mounted on a surgical drive and led by Kirschner wire to open the medullary canal.
Remove the drill and Kirschner wire.

ATTENTION!
It is recommended to open the medullary canal with procedure defined in step 4. The operator can choose other medullary canal opening technique depending on the equipment available in the operating theater.

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

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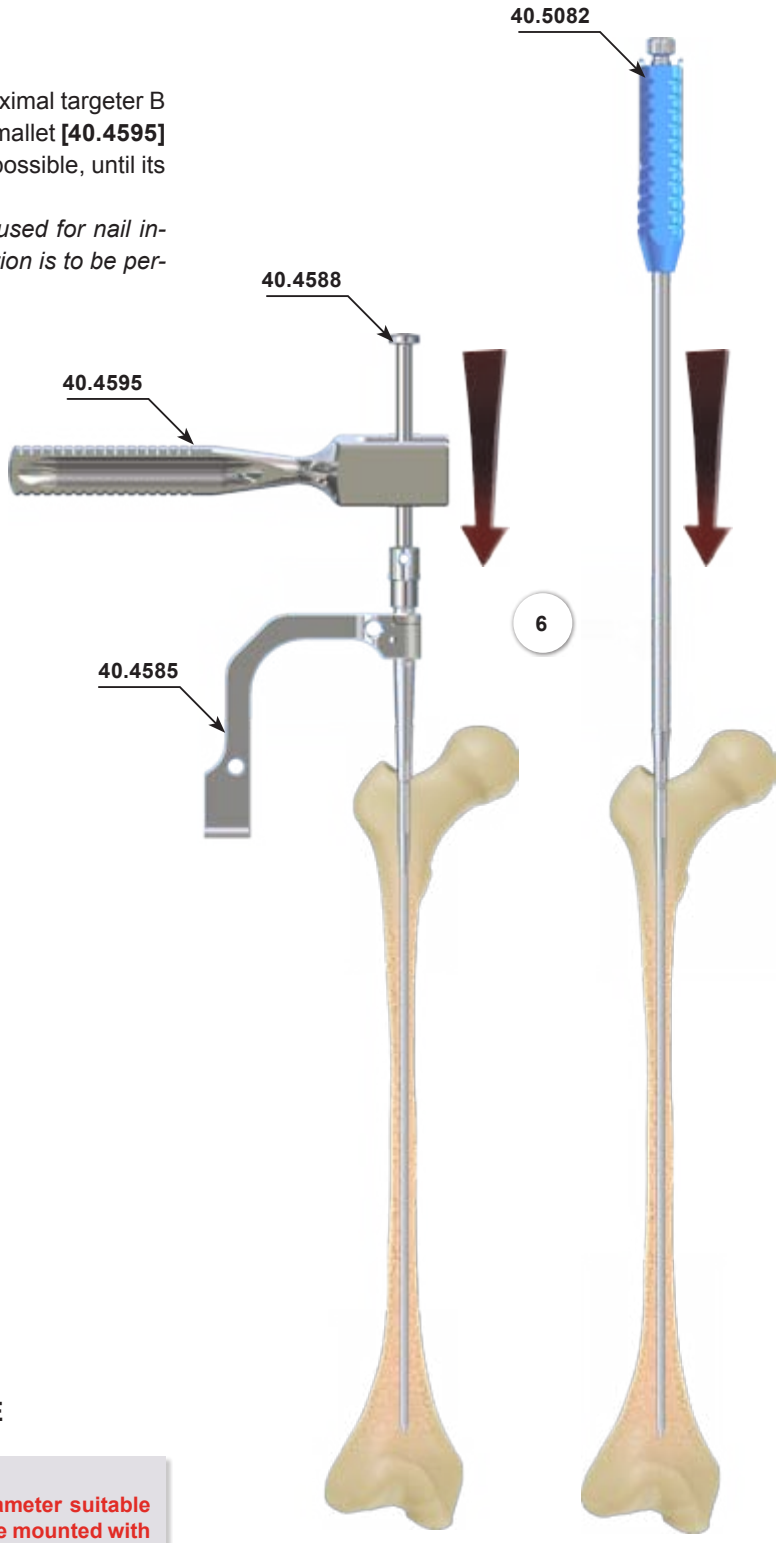
V.5. NAIL INSERTION INTO MEDULLARY CANAL

6 Connect the impactor-extractor **[40.4588]** to the proximal targeter B **[40.4585]** *(by putting it on a tapped end)*. Using the mallet **[40.4595]** gently insert the nail into the medullary canal, as deep as possible, until its end is placed in the area of distal section of the epiphysis.
(As mentioned above, the holder with clamp M4 can be used for nail insertion. In that case any manipulation related to nail insertion is to be performed with the use of this device).



V.6. INSERTION AND LOCKING OF NAIL SLEEVE

ATTENTION!
Attention must be paid to the selected sleeve diameter suitable to the nail size, e.g. sleeve 3.5 [1.2522.xxx] must be mounted with the nail 3.5 [1.2512. xxx].
(see: Tab. 2. Nail and sleeve selection)

Tab. 2. Nail and sleeve selection

Ø	Femoral nail steel		Ø	Femoral sleeve steel
3.5	1.2512.xxx	→	3.5	1.2522.xxx
4.0	1.2513.xxx	→	4.0	1.2523.xxx
4.5	1.2514.xxx	→	4.5	1.2524.xxx

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

7 Use the X-Ray to define nail location in the medullary canal. Perform the tissue incision over the patella ligament middle, or on its medial side. Expose the intercondylar area *(unfibre longitudinal ligament or retract on lateral side)*. Mark the insertion point for Kirschner wire on the bone. Perforate the cortical layer and insert Kirschner wire 2/200mm **[40.4583]** into the medullary canal.

This process must be performed under image intensifier control.

Kirschner wire is a guide for the cannulated awl.
Kirschner wire is disposable.

8 Open the medullary canal at the depth of about 6 cm with the help of cannulated drill 6.0/2.2/150 **[40.4584]** mounted in a drive and led via Kirschner wire. Remove the drill and Kirschner wire.

9 Connect the holder with clamp M5 **[40.5081]** with threaded section of the telescopic sleeve, then checking the end nail location with X-Ray, gently insert the coupled device into the medullary canal, so the sleeve slides on the nail shaft.

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

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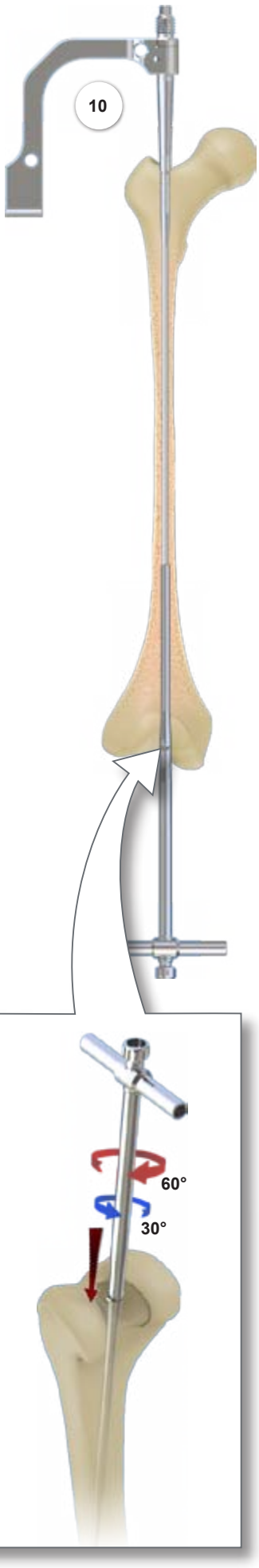
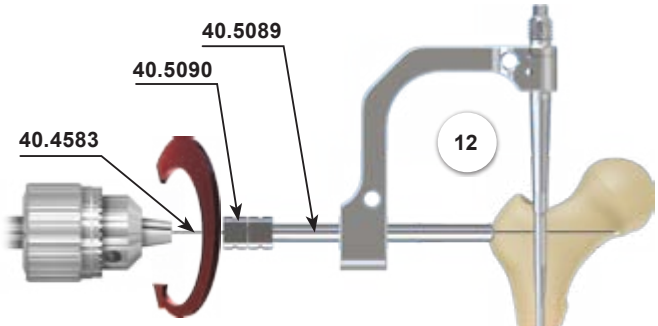
10 Slide the coupled holder with clamp M5 **[40.5081]** and sleeve into the medullary canal, until the sleeve catches rest on the intercondylar tissues. Gently turn left until the resistance is felt *(around 30°)* and press the sleeve catches into the tissues with appropriate force. Next turn right the sleeve until sensible resistance occurs *(about 60°)* locking the sleeve catches into growth tissues. After locking the sleeve, remove *(unscrew)* the holder with clamp M5 **[40.5081]**.



V.7. LOCKING THE INTRAMEDULLARY NAIL

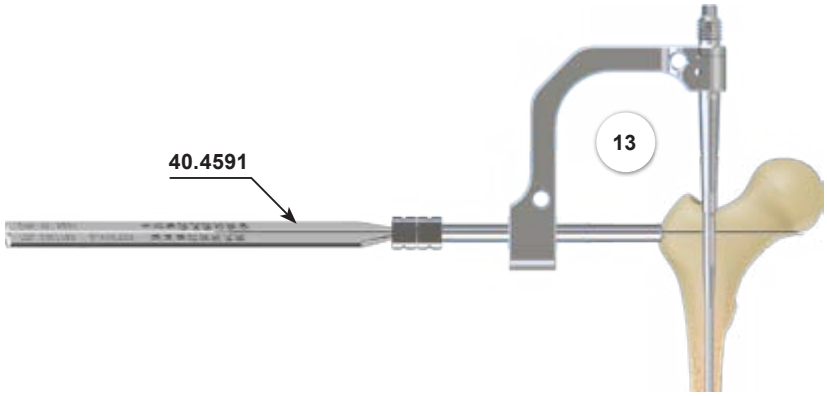
11 Withdraw the nail to locking position. If the holder with clamp M4 was used for the nail insertion, it should be removed from nail socket, then connect the intramedullary nail with the proximal targeter B *(according to the procedure describen in point 2 of section V.3 of these Instructions)*..



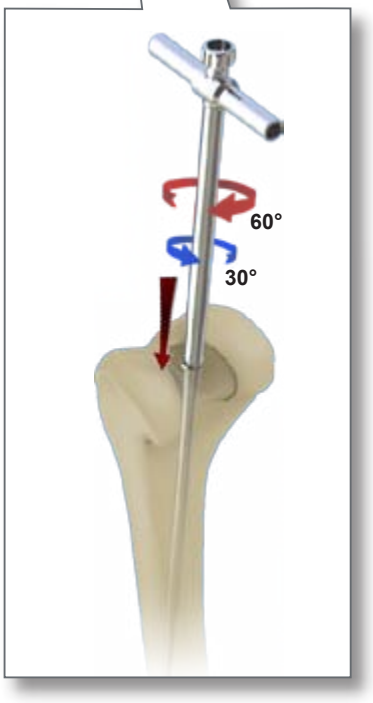
12 Insert the protective guide 7/5 **[40.4589]** and Kirschner guide B **[40.4590]** into the distal hole of targeter B **[40.4585]**. Use the surgical drive while leading the Kirschner wire 2/200 **[40.4583]** in the Kirschner guide to drill the hole in the bone through both cortexes, until the drill end slightly protrudes from the bone.

Drilling process shall be controlled under image intensifier.

Leave the nail and guides in the hole.

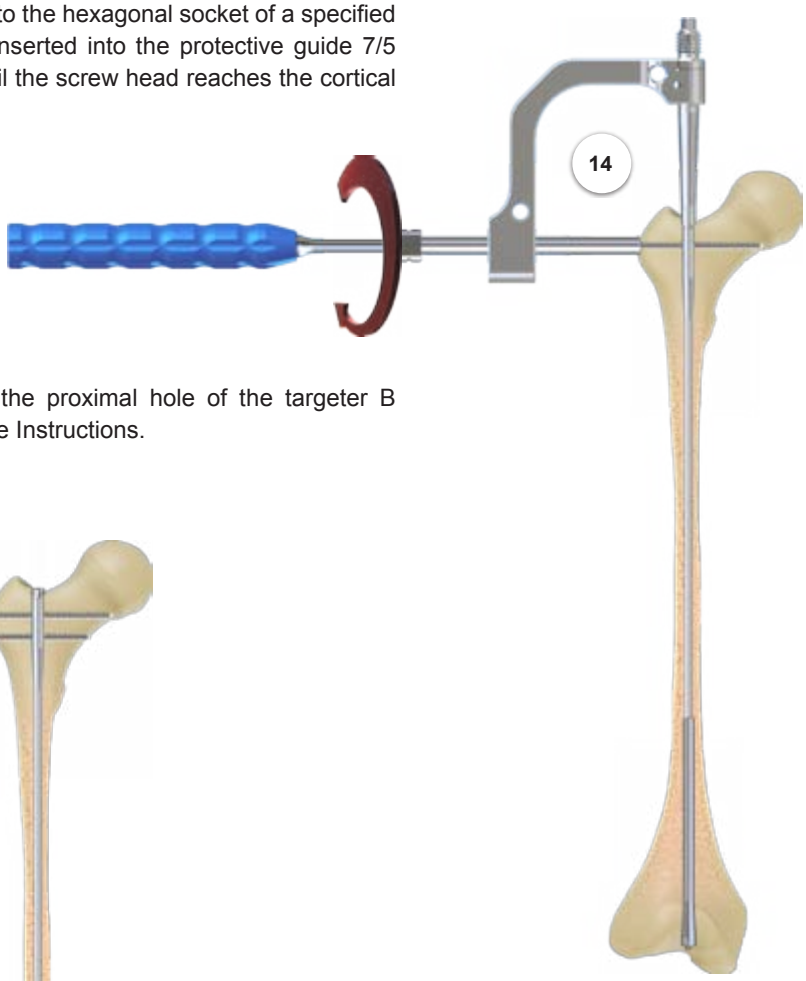


13 Apply the screw length measure **[40.4591]** on a Kirschner wire **[40.4583]** inserted into the bone shaft *(in a Kirschner guide [40.4590])* untill its end rests on the guide. Read the locking screw length indicated on a screw length measure scale by Kirschner wire tip. During the measurement, the screw length measure should rest upon the guide.
Remove the screw length measure, Kirschner wire and Kirschner guide.

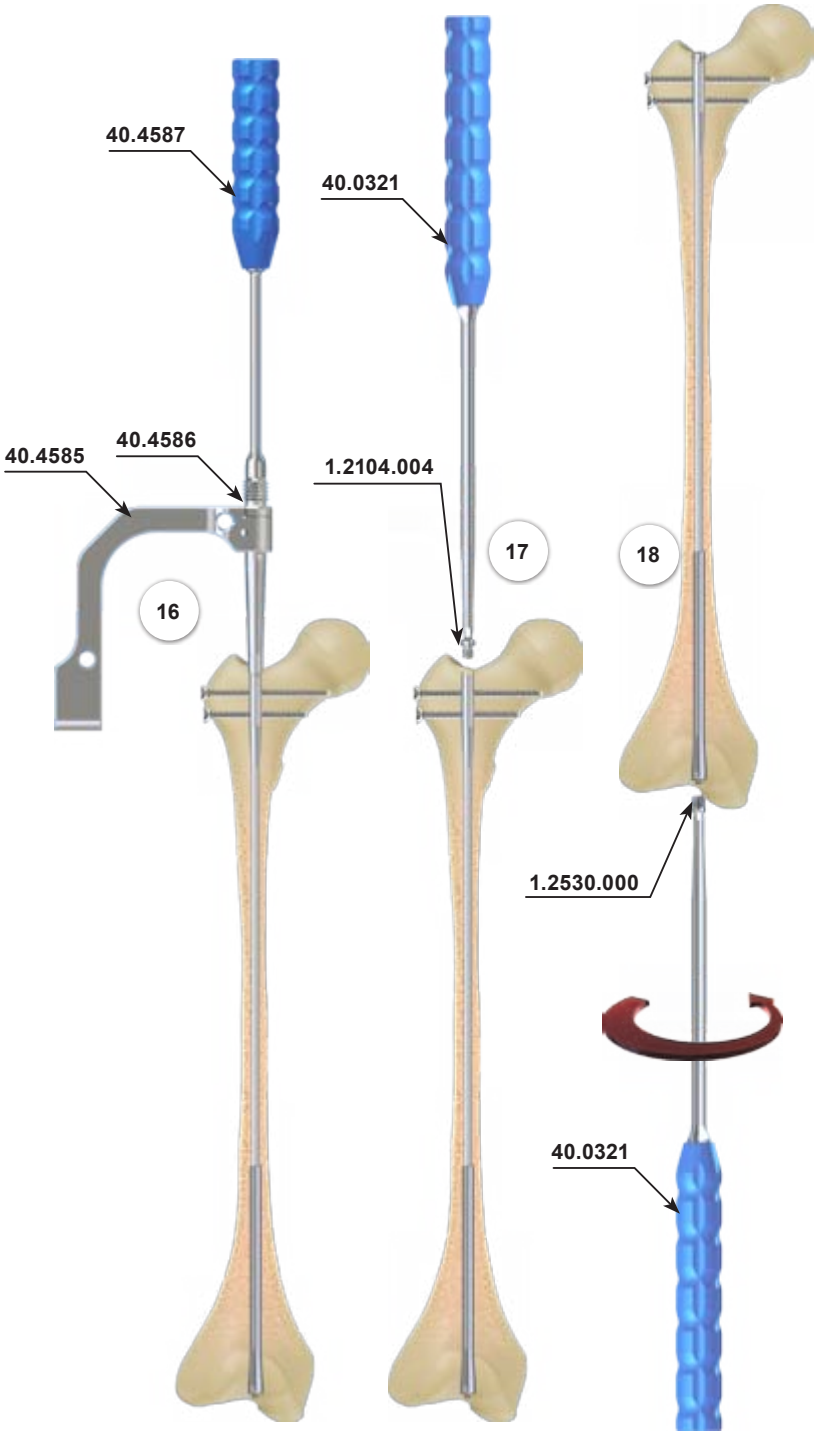


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

14 Insert the tip of the screwdriver S2.5 **[40.0321]** into the hexagonal socket of a specified locking screw. This combined system shall be inserted into the protective guide 7/5 **[40.4589]** and advanced in a hole prepared earlier, until the screw head reaches the cortical bone layer.
Remove the screwdriver and the protective guide.



15 Lock the nail with the second screw, through the proximal hole of the targeter B **[40.4585]** according to the steps 11 to 13 of these Instructions.



V.8. END CUP INSERTION

16 Use the socket wrench S6 **[40.4587]** to remove the clamping screw M4 **[40.4586]** from the nail shaft. Disconnect the targeter B **[40.4585]** from the nail locked in the medullary canal.

17 To secure the threaded hole of the nail from bone ingrowth, use the screwdriver S2.5 **[40.0321]** to insert the end cap.

18 Analogical procedure should be performed in the case of the nail sleeve - insert the end cap using the screwdriver S2.5 **[40.0321]**.

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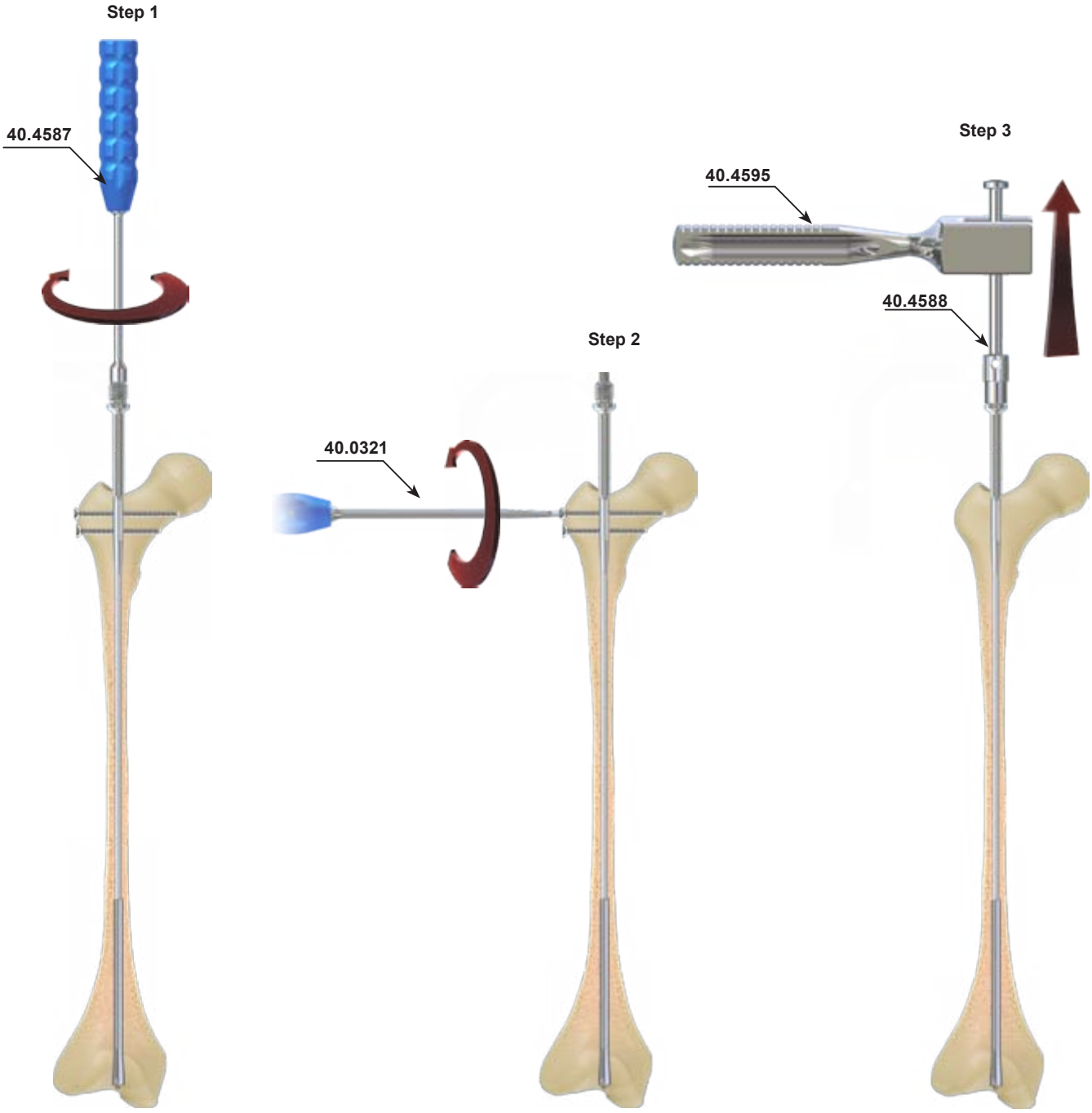
V.9. TELESCOPIC NAIL REMOVAL

19 Using the screwdriver S2.5 **[40.0321]** remove the end cap from nail. Use the socket wrench S6 **[40.4587]** to insert the connector M4 into the threaded hole of the nail shaft. Unscrew all locking screws using the screwdriver. Insert the impactor-extractor **[40.4588]** on the connector and use the mallet **[40.4595]** to remove the nail from the medullar canal.



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

20 Use the screwdriver S2.5 **[40.0321]** to remove the end cap from the nail sleeve, then use the holder with clamp M5 **[40.5081]** to make left turn of about 90°, dismount and remove the sleeve from the medullary canal.

Step 1

Step 2

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

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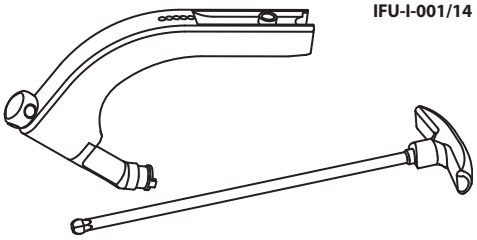

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INSTRUCTIONS FOR USE

REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

Instruments manufactured by **ChM** sp. z o.o. 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 according to 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** *sp. z o.o. 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 neutral pH *(with 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.*

ATTENTION! *The manufacturer does not recommend using any preservatives on surgical and orthopedic devices.*

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: 134°C,
- pressure: 2 atm. of pressure above atmospheric *(overpressure)*,
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

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.

If this instruction 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-001/14; Date of verification: September 2014

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

Do not reuse Nie używać powtórnie Не использовать повторно No reutilizar Nicht wiederverwenden Nepoužívejte opakovaně	Do not resterilize Nie sterylizować ponownie Не стерилизовать повторно No reesterilizar Nicht resterilisieren Nepoužívejte resterilizaci	Do not use if package is damaged Nie używać jeśli opakowanie jest uszkodzone Не используйте при поврежденной упаковке No utilizar si el envase está dañado Nicht verwenden falls Verpackung beschädigt ist Nepoužívejte, pokud je obal poškozen
Sterilized using irradiation Sterylizowany przez napromieniowanie Стерилизация облучением Esterilizado mediante radiación Sterilisiert durch Bestrahlung Sterilizovat zářením STERILE R	Sterilized using ethylene oxide Sterylizowany tlenkiem etylenu Стерилизация окисью этилена Esterilizado mediante óxido de etileno Sterilisiert mit Ethylenoxid Sterilizovat ethylenoxidem STERILE EO	Non-sterile Niesterylny Нестерильно No estéril Unsteril Nesterilní
Catalogue number Numer katalogowy Номер по каталогу Número de catálogo Katalognummer Katalogové číslo REF	Batch code Kod partii Код партии Código de lote Chargennummer Číslo šarže LOT	Consult instructions for use Zajrzyj do instrukcji używania Смотри инструкцию по применению Consultar instrucciones de uso Siehe die Gebrauchsanweisung Řiďte se návodem k použití
Material Material Материал Material Material Materiál Mat:	Quantity Ilość Количество Cantidad Menge Množství Qty:	Use by Użyć do Срок годности Fecha de caducidad Verwenden bis Použijte do
	Caution Ostrzeżenie Предупреждение Advertencia Vorsicht Varování	

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