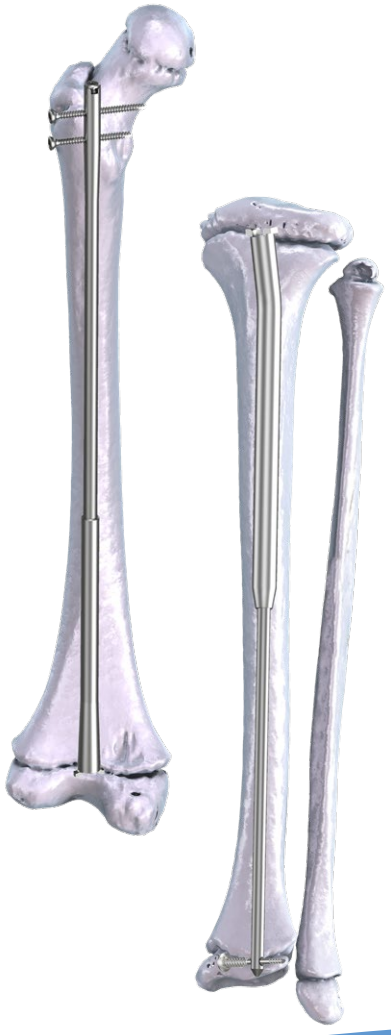
ST/17C

ChM®

INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR AND TIBIA WITH TELESCOPIC NAILS

- *IMPLANTS*
- *INSTRUMENT SET 40.4580.500*
- *INSTRUMENT SET 40.5080.500*
- *SURGICAL TECHNIQUE*



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SYMBOLS DESCRIPTION

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

	Caution - pay attention to a special procedure.
	Perform the activity under X-Ray control.
	Information about the next stages of a procedure.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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The manufacturer reserves the right to introduce design changes.
Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu

1. INTRODUCTION

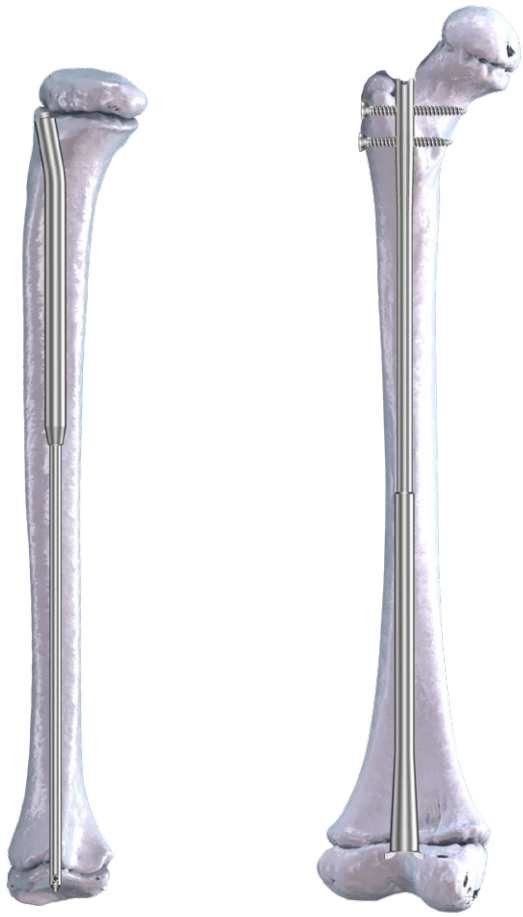
The presented range of implants is made of implantable steel in accordance with ISO 5832 standard. Compliance with the requirements of quality management systems and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered implants.

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*) in growing children and youth. 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 the system to be kept in the body for a 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 strength. Therefore, the stabilization becomes more reliable.

Implants for femur and tibia osteosynthesis with telescopic nails provide:

- stabilization with solid osteosynthesis of proximal and distal fragment, preventing migration of the rod ends,
- high mechanical strength, not lower than for the already used Rush nails,
- self-lengthening of implant for minimum of 5cm,
- possibility of nail components replacement for longer elements.

Tibial nail is to be placed near the tibial tuberosity in proximal epiphysis, whereas distally - in the epiphyseal plate.



Femoral nails are seated in the peritrochanteric area on the one side and near femoral condyle, in its distal end, on the other. Telescopic femoral and tibial nails are placed in epiphyseal plates, so that implants length changes with bone growth (*the nail comes out of the sleeve*); thereby, the interoperative period increases considerably decreasing child's exposition to reoperation and postoperative trauma.
It is possible to keep the correct positioning 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.

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 the epiphyseal plate.
The intramedullary telescopic nail system used for tibia and femur osteosynthesis consists of:

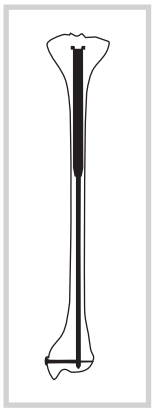
- implants for tibia (*telescopic tibial nail, tibial nail sleeve, locking screws, end cap, limiter screw*),
- implants for femur (*telescopic femoral nail, femoral nail sleeve, locking screw, end cap*),
- Surgical technique.

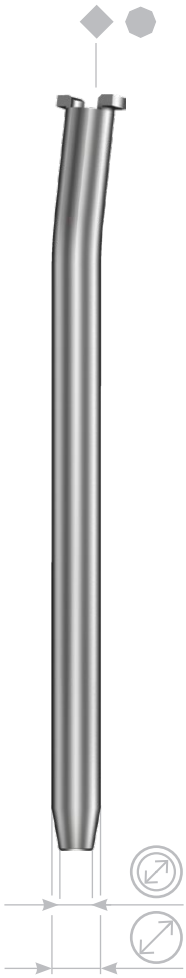
2. IMPLANTS

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]**,
- cortical self-tapping screw 1.5/2.7 **[1.1022.010÷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.





TELESCOPIC TIBIAL NAIL-SLEEVE

		Len	St
6.0	3.0	80	1.2542.080
		90	1.2542.090
		100	1.2542.100
		110	1.2542.110
		120	1.2542.120
		130	1.2542.130
		140	1.2542.140
		150	1.2542.150
6.5	3.5	80	1.2543.080
		90	1.2543.090
		100	1.2543.100
		110	1.2543.110
		120	1.2543.120
		130	1.2543.130
		140	1.2543.140
		150	1.2543.150
7.0	4.0	80	1.2544.080
		90	1.2544.090
		100	1.2544.100
		110	1.2544.110
		120	1.2544.120
		130	1.2544.130
		140	1.2544.140
		150	1.2544.150
7.5	4.5	80	1.2545.080
		90	1.2545.090
		100	1.2545.100
		110	1.2545.110
		120	1.2545.120
		130	1.2545.130
		140	1.2545.140
		150	1.2545.150
8.0	5.0	80	1.2546.080
		90	1.2546.090
		100	1.2546.100
		110	1.2546.110
		120	1.2546.120
		130	1.2546.130
		140	1.2546.140
		150	1.2546.150

available			pitch	
		2.5 ÷ 6		0.5
	Len	80 ÷ 150		5

	St				
	1.2530.000	✓			◆
	1.2529.005	✓			⬢

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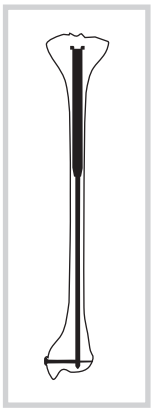
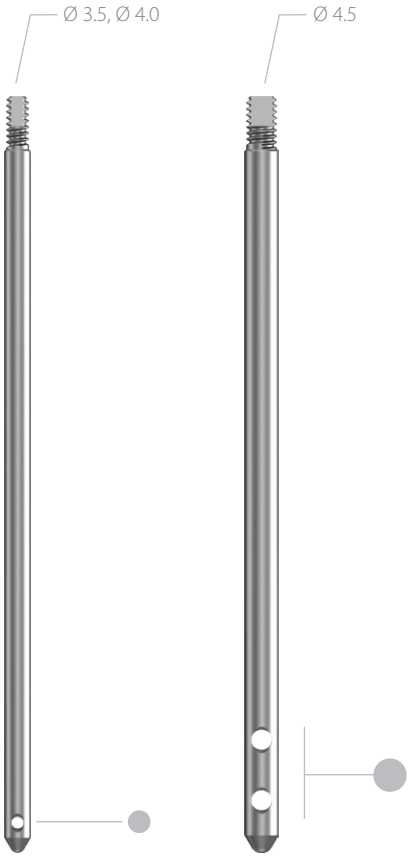
TELESCOPIC TIBIAL NAIL





Ster
Non Ster

	Len	St
3.5	180	1.2533.180
	190	1.2533.190
	200	1.2533.200
	210	1.2533.210
	220	1.2533.220
	230	1.2533.230
	240	1.2533.240
	250	1.2533.250
	260	1.2533.260
	270	1.2533.270
	280	1.2533.280
	290	1.2533.290
	300	1.2533.300
4.0	180	1.2534.180
	190	1.2534.190
	200	1.2534.200
	210	1.2534.210
	220	1.2534.220
	230	1.2534.230
	240	1.2534.240
	250	1.2534.250
	260	1.2534.260
	270	1.2534.270
	280	1.2534.280
	290	1.2534.290
	300	1.2534.300
4.5	180	1.2535.180
	190	1.2535.190
	200	1.2535.200
	210	1.2535.210
	220	1.2535.220
	230	1.2535.230
	240	1.2535.240
	250	1.2535.250
	260	1.2535.260
	270	1.2535.270
	280	1.2535.280
	290	1.2535.290
	300	1.2535.300

available	Len	2.5 ÷ 6	pitch 0.5
		180 ÷ 300	5

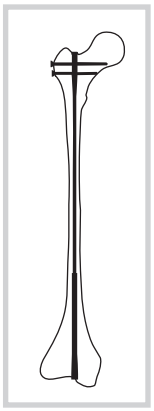
	St				
	1.1022.xxx	✓		1.5/2.7	10÷70
	1.1203.xxx	✓		2.7	6÷45

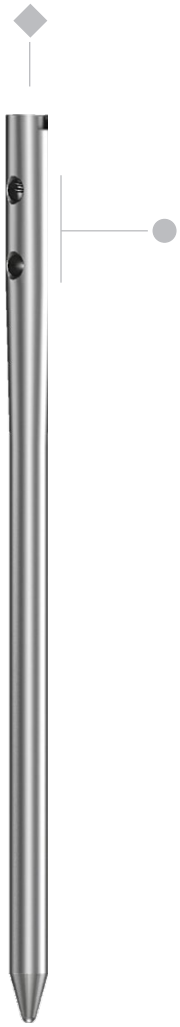
The set for femur osteosynthesis consists of:

- telescopic femoral nail d/L, **[1.2511.xxx]**-**[1.2516.xxx]**,
- telescopic femoral nail - sleeve d/L, **[1.2521.xxx]**-**[1.2526.xxx]**,
- cortical self-tapping screw 2.7 **[1.1203.006÷045]**,
- end cap M4 **[1.2104.004]**.

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

TELESCOPIC FEMORAL NAIL





Ster
Non Ster

St	Len	
3.5	180	1.2512.180
	190	1.2512.190
	200	1.2512.200
	210	1.2512.210
	220	1.2512.220
	230	1.2512.230
	240	1.2512.240
	250	1.2512.250
	260	1.2512.260
	270	1.2512.270
	280	1.2512.280
	290	1.2512.290
	300	1.2512.300
4.0	180	1.2513.180
	190	1.2513.190
	200	1.2513.200
	210	1.2513.210
	220	1.2513.220
	230	1.2513.230
	240	1.2513.240
	250	1.2513.250
	260	1.2513.260
	270	1.2513.270
	280	1.2513.280
	290	1.2513.290
	300	1.2513.300
4.5	180	1.2514.180
	190	1.2514.190
	200	1.2514.200
	210	1.2514.210
	220	1.2514.220
	230	1.2514.230
	240	1.2514.240
	250	1.2514.250
	260	1.2514.260
	270	1.2514.270
	280	1.2514.280
	290	1.2514.290
	300	1.2514.300

available			pitch
	Len	3 ÷ 6	0.5
		120 ÷ 350	5

St				
1.1203.xxx	✓		2.7	6÷45
1.2104.004	✓			

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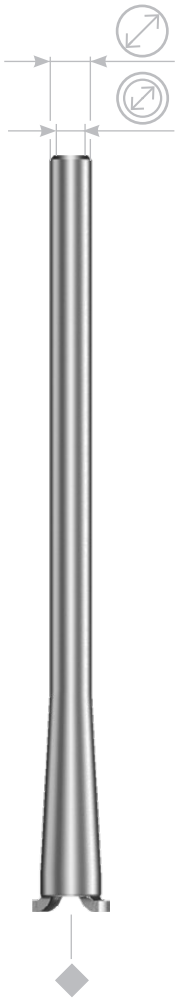
TELESCOPIC FEMORAL NAIL - SLEEVE



Ster
Non Ster

		Len	St
5.5	3.5	120	1.2522.120
		125	1.2522.125
		130	1.2522.130
		135	1.2522.135
		140	1.2522.140
		145	1.2522.145
		150	1.2522.150
6.0	4.0	120	1.2523.120
		125	1.2523.125
		130	1.2523.130
		135	1.2523.135
		140	1.2523.140
		145	1.2523.145
		150	1.2523.150
6.5	4.5	120	1.2524.120
		125	1.2524.125
		130	1.2524.130
		135	1.2524.135
		140	1.2524.140
		145	1.2524.145
		150	1.2524.150
7.0	5.0	120	1.2525.120
		125	1.2525.125
		130	1.2525.130
		135	1.2525.135
		140	1.2525.140
		145	1.2525.145
		150	1.2525.150

available			pitch
	3 ÷ 6		0.5
Len	80 ÷ 150		5

St				
1.2530.000	✓			◆

LOCKING ELEMENTS

St Ster Non Ster

Cortical self-tapping screw 2.7

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

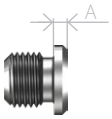
6 ÷ 45

Cortical self-tapping screw 1.5/2.7

12	1.1022.012
14	1.1022.014
16	1.1022.016
18	1.1022.018
20	1.1022.020
22	1.1022.022
24	1.1022.024
26	1.1022.026
28	1.1022.028
30	1.1022.030

10 ÷ 70

CHARFIX End cap M4x0.7



+2.5	1.2104.004

End cap M5

	1.2530.000

Limiter screw M5

	1.2529.005

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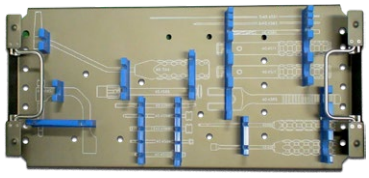
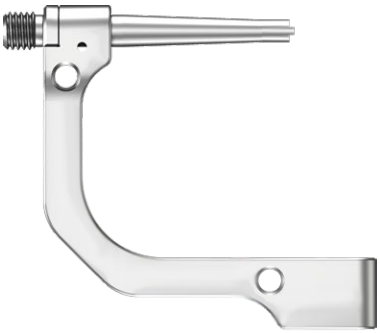
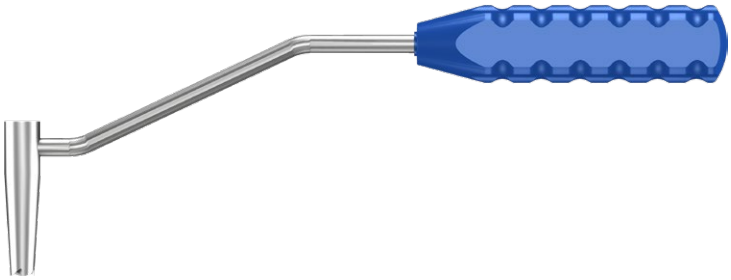
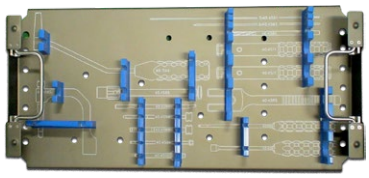
3. INSTRUMENT SET

To perform the fixation of fragments of femur/tibia with the telescopic nail and to remove the implants when the treatment is complete - 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 in the instrument set are placed 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 in the instrument set:

40.5080.500	Name	Catalogue no.	Pcs
	Kirschner wire 1.0/200	40.4814.200	4
	Holder with clamp M5	40.5081.000	1
	Holder M4	40.5082.000	1
	Nail guide	40.5083.000	1
	Nail guide M4 (*tibial*)	40.5084.000	1
	Nail guide M2.5 (*tibial*)	40.5085.000	1
	Container with solid bottom 1/1 595x275x86mm	12.0750.100	1
	Stand	40.5089.500	1
	Perforated aluminum lid 1/1 595x275x15mm Gray	12.0750.200	1

Instrument set for forearm and fibula bones 40.4580.500	Name	Catalogue no.	Pcs
	Proximal targeter B	40.4585.000	1
	Clamping screw M4	40.4586.000	1
	Socket wrench S6	40.4587.000	1
	Impactor-extractor	40.4588.000	1
	Protective guide 7/5	40.4589.000	1

Instrument set for forearm and fibula bones 40.4580.500	Name	Catalogue no.	Pcs
	Kirschner guide B 5/2	40.4590.000	1
	Screw length measure	40.4591.000	1
	Targeter D	40.1344.000	1
	Mallet	40.4595.000	1
	Connector M4	40.4596.000	1
	Hexagonal screwdriver S2.5	40.0321.000	1
	Nail trial	40.4581.000	5
	Bender	40.4511.000	2
	Kirschner wire 2.0	40.4583.000	3
	Cannulated drill 6.0/2.2/150	40.4584.000	1
	Kirschner wire 1.5/180	40.4592.180	3
	Perforated aluminum lid 1/1 595x275x15mm Gray	12.0750.200	1
	Stand for instrument set of small bone	40.4597.500	1
	Container with solid bottom 1/1 595x275x86mm	12.0750.100	1

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4. SURGICAL TECHNIQUE - TIBIAL NAIL

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

4.1. SURGERY PLANNING

Each surgery must be carefully planned. X-Ray visualization of the fractured bone should be performed in AP and lateral position in order to define the proper nail size. It is recommended to make the X-Ray visualization of the healthy extremity as well.

Nail length should fit the medullary canal on the maximal possible length. Whereas nail diameter should maximally fill the medullary canal.

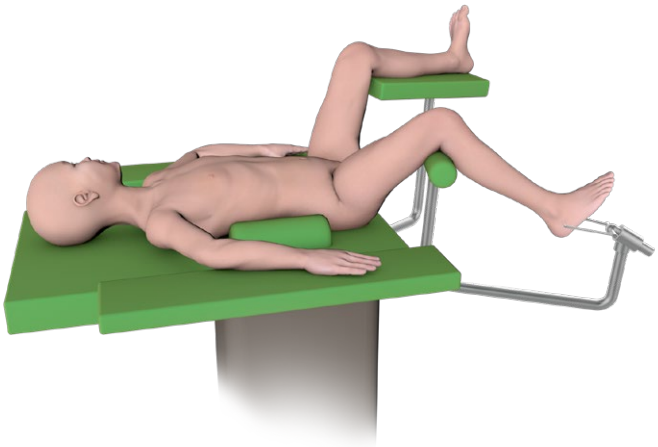
Nail insertion can be performed with two methods:

- separate insertion of telescopic nail and sleeve - **Method I**,
- combined system insertion - **Method II**.

The implantation should be performed on an operating table equipped with image intensifier.

4.2. SURGICAL APPROACH

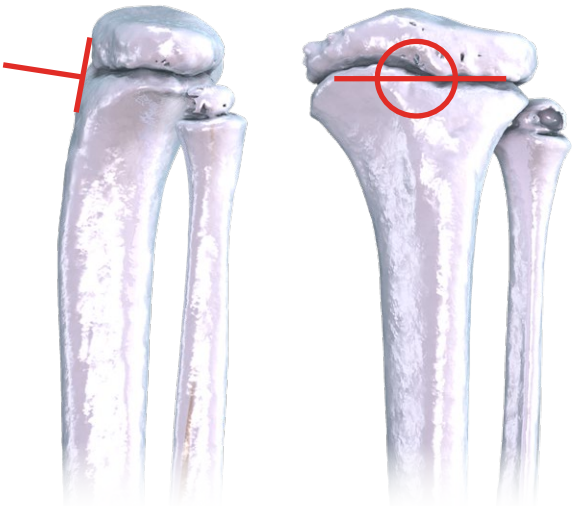
When patient is placed supine, the operated leg should be flexed in hip joint at 70 to 90 degrees, abducted at 10 to 20 degrees, and flexed at 80 to 90 degrees in the knee joint, while the ankle joint should stay in neutral position (*foot perpendicular to the tibia*).



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 the tendon lateral retraction.

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



4.3. OPENING OF THE MEDULLARY CANAL

1 Having prepared the surgery approach and insertion point, insert the Kirschner wire 2.0 **[40.4583]**) into the medullary canal at the angle of about 10°.

40.4583.000

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

Kirschner wire is a disposable device.

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

Remove the drill and Kirschner wire.

40.4584.000

40.4583.000

3 Proximal section of the canal at the depth of 5÷6 cm must be widened about 0.5mm more than the sleeve diameter (*see point II IMPLANTS*).

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 the surgeon's preferences and equipment available in the surgical theater.

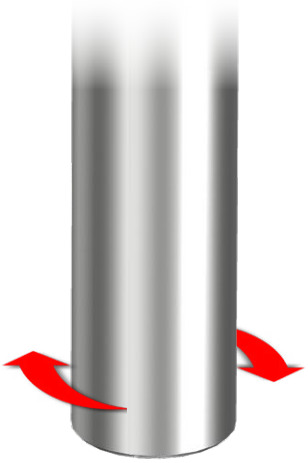
4.4. METHOD I

4.4.1. 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 M2.5 (*tibial*) **[40.5085]**,
- for Ø3.0 - 4.0 nail – nail guide **[40.5083]**,
- for Ø4.5 - 6.0 nail – nail guide M4 (*tibial*) **[40.5084]**.

	40.5085.000
	40.5083.000
	40.5084.000



5 Insert the coupled system (*the nail and nail guide*) into prepared medullary canal under the image intensifier control. An operator should pay attention to insert the nail deep into the medullary canal to leave some space (*about 3cm*) 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.

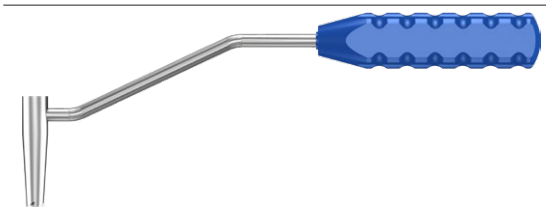
4.4.2. DISTAL LOCKING OF THE TELESCOPIC NAIL

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

For nails 3.0 – 4.0 use cortical self-tapping screws 1.5/2.7 [1.1022.010-070].
For nails 4.5 – 6.0 use cortical self-tapping screws 2.7 [1.1203.006-045].

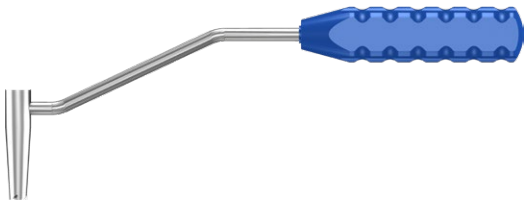
6 Use X-Ray machine to determine the location of the hole in the nail. Having marked the drilling points on the skin, make approx. 1.5cm incision of soft tissues passing through these points.
Use the X-Ray machine to position the targeter D **[40.1344]** in relation to the hole in the intramedullary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

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



40.1344.000

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



40.1344.000

40.4589.000

40.4590.000

8 Use surgical drive and Kirschner guide B 5/2 to drill the hole through both cortical layers with the aid of Kirschner wire 1.0/200 **[40.4814.200]** (*or [40.4583] when screws 2.7mm are used*).

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

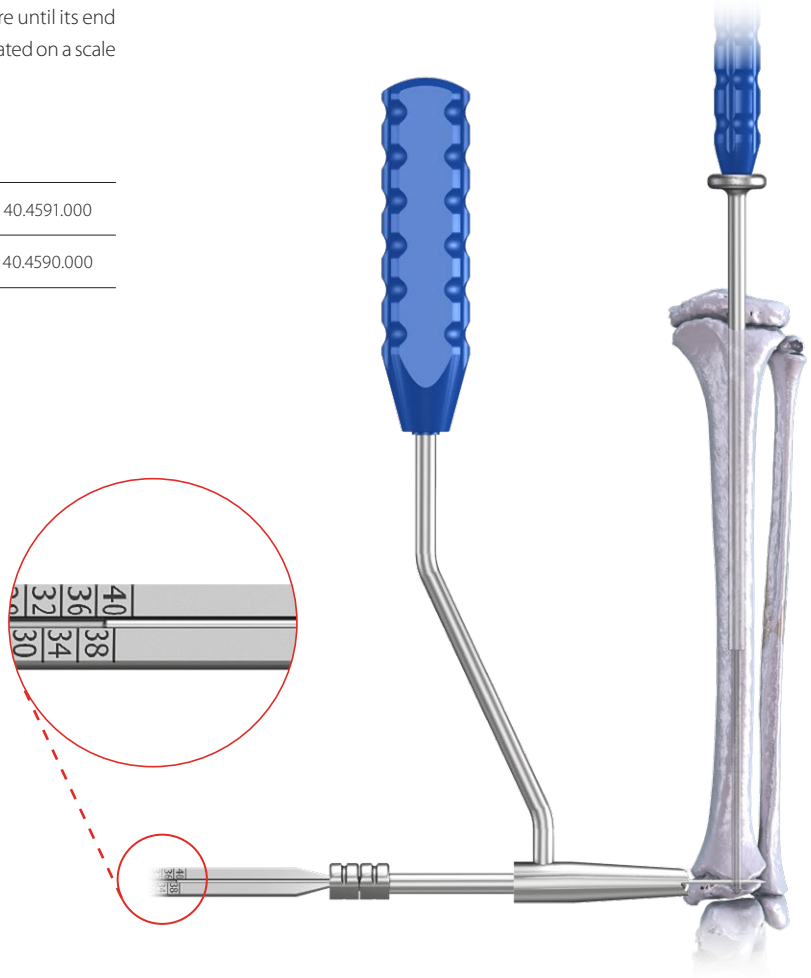
40.4814.200


40.4590.000

9 Apply screw length measure **[40.4591]** on the Kirschner wire until its end rests on the guide. Read the length of the locking screw indicated on a scale by the end of the Kirschner wire.
Remove the Kirschner guide B 5/2 and Kirschner wire.
Leave the targeter D and protective guide 7/5 in place.


40.4591.000


40.4590.000



10 Insert the tip of the screwdriver S2.5 **[40.0321]** into the socket of the locking screw and then into the protective guide 7/5 **[40.4589]**. Insert the screw until its head reaches the cortex. Remove the screwdriver, targeter D, protective guide and the nail guide.

	40.0321.000
	40.4589.000
	40.5085.000
	40.5083.000
	40.5084.000

Make sure the locking screw diameter matches the nail diameter!
(*See the beginning of section: 4.4.2. Distal locking of the telescopic nail*)

4.4.3. TELESCOPIC TIBIAL NAIL-SLEEVE INSERTION

Make sure the suitable sleeve diameter that matches the nail size has been chosen, e.g. sleeve 3.5 **[1.2543.xxx]** should be used only with nail 3.5 **[1.2533.xxx]**.
(*See: Tab. 1. Nail and sleeve selection*)

Tab 1. Nail and sleeve selection

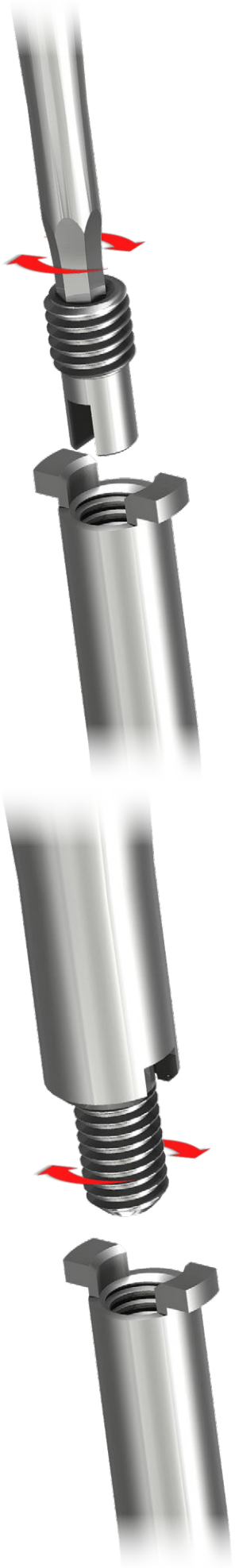
	Tibial nail			Telescopic tibial nail-sleeve
	steel			steel
3.5	1.2533.xxx	→	3.5	1.2543.xxx
4.0	1.2534.xxx	→	4.0	1.2544.xxx
4.5	1.2535.xxx	→	4.5	1.2545.xxx

11 Prior to sleeve implantation, insert limiter screw M5 **[1.2529.005]** into the sleeve using screwdriver S2.5 **[40.0321]**.

40.0321.000

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

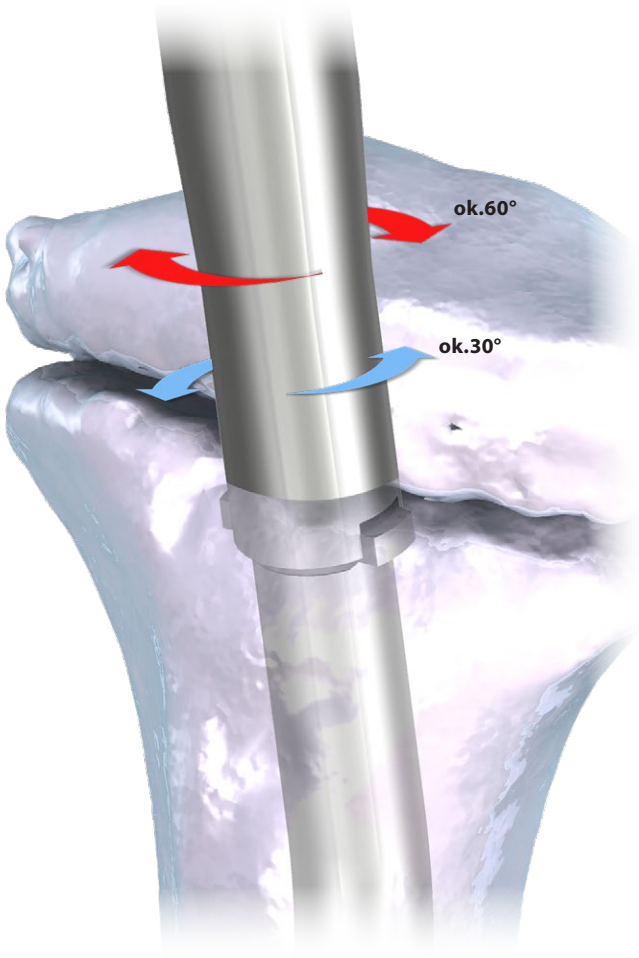
40.5081.000



13 Slide the sleeve over the nail so that the nail is located in front of the limiter screw. The screw prevents undesirable locking of the nail in the bent part of the sleeve.

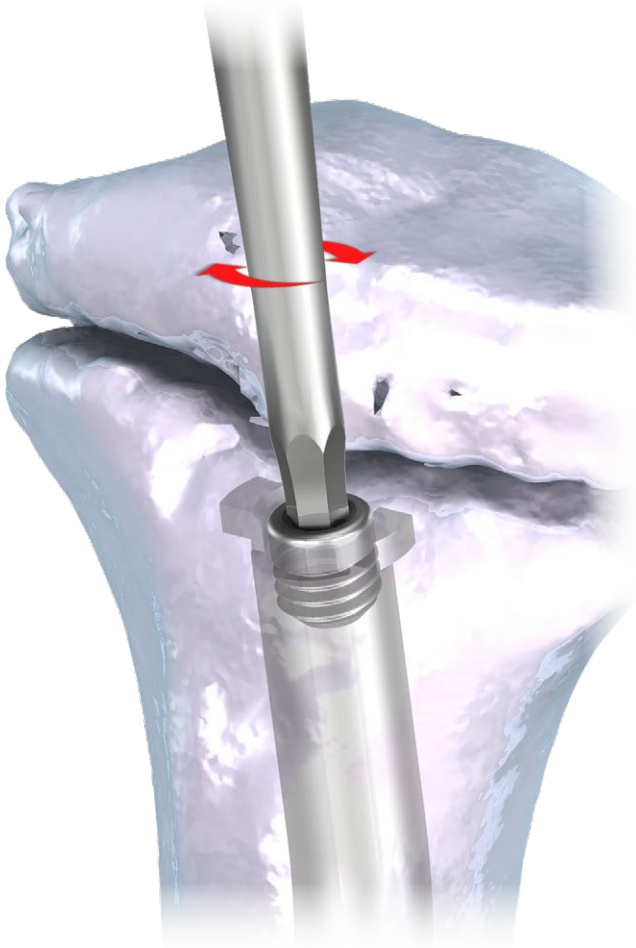
14 Insert the holder with clamp M5 with attached sleeve into the medullary canal, until the sleeve end rests on the intercondylar tissues. Gently turn left until resistance is felt (*about 30°*) and with adequate force, press the sleeve catches into tissues. Next turn the sleeve right until the resistance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

40.5081.000



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.

40.0321.000



4.5. METHOD II

Method II allows for insertion of a coupled set of implants: nail + sleeve + limiter screw into medullary canal.

4.5.1. 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 then, insert an appropriate nail into the sleeve (*according to Tab.1., section 4.4.3 of this technique*), so the cut of the limiter screw coincides with flat part of the telescopic nail end. Verify the connection by turning the sleeve against the nail. If the nail and sleeve rotate simultaneously, the connection is correct.

40.5081.000

17 The set is prepared for insertion into the medullary canal. Using holder with clamp M5 **[40.5081]**, insert the nail and sleeve into medullary canal, so the sleeve catches rest on the intercondylar tissues. Gently turn left until resistance (*about 30°*) and press the sleeve catches into tissues with adequate force. Next turn the sleeve right until resistance (*about 60°*), locking sleeve catches in epiphyseal plate. After locking the sleeve, remove the holder with clamp M5 **[40.5081]**. Make sure the hole in the nail (*for locking screw*) is in the correct position.

40.5081.000

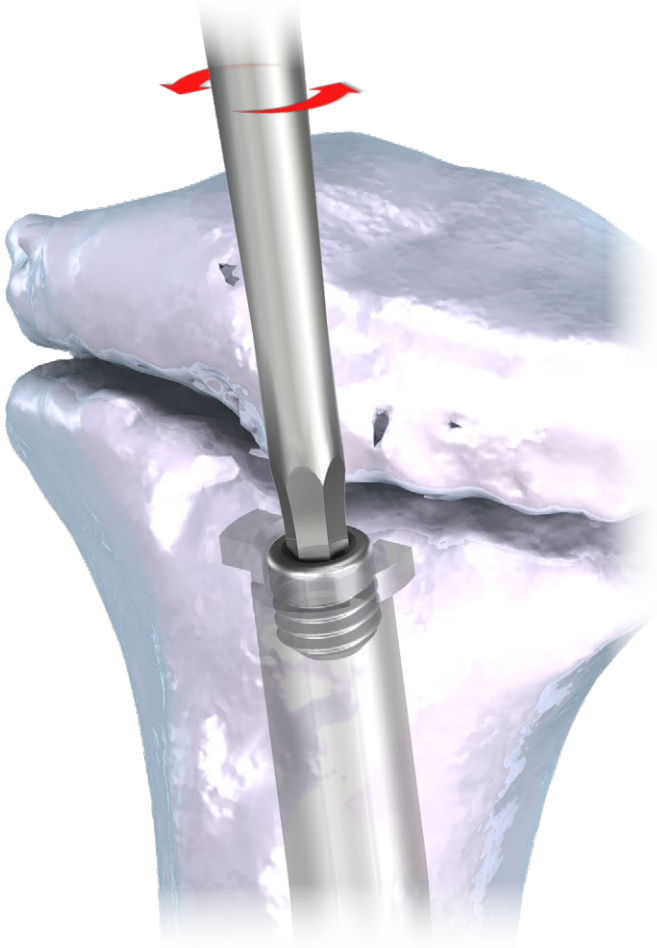
4.5.2. DISTAL LOCKING OF THE TELESCOPIC NAIL

Distal locking of the telescopic nail should be performed according to steps 6-10 of section 4.4.2.

4.6. TELESCOPIC NAIL REMOVAL

18 Use screwdriver S2.5 **[40.0321]** to remove the end cap M5 **[1.2530.000]** from the sleeve.

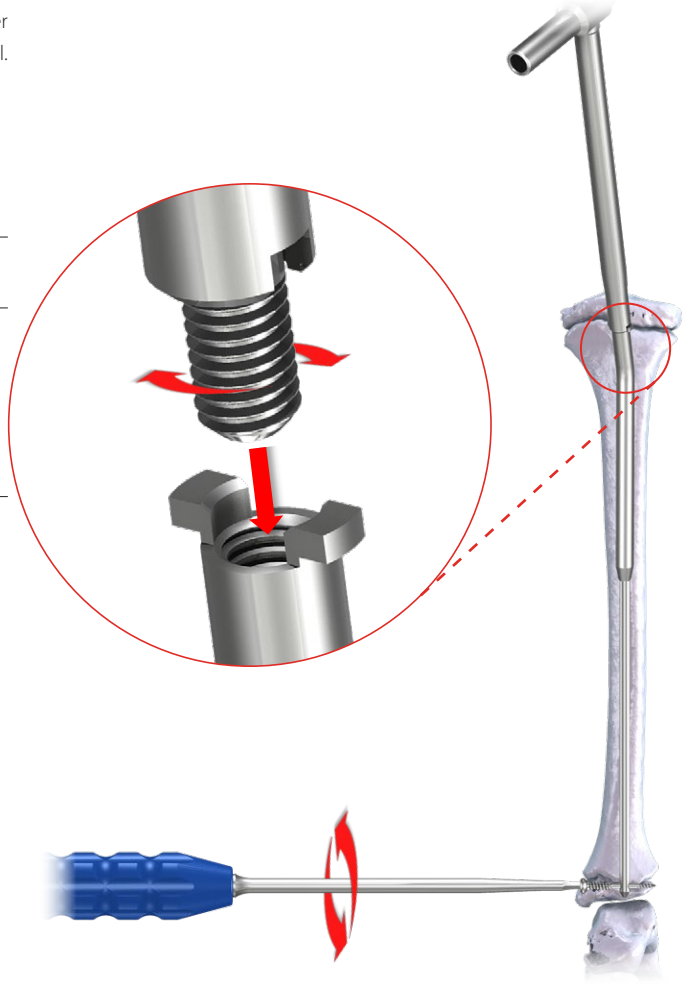
40.0321.000



19 Use screwdriver S2.5 **[40.0321]** to remove distal locking screw. Use holder with clamp M5 **[40.5081]** to remove the sleeve from the medullary canal.

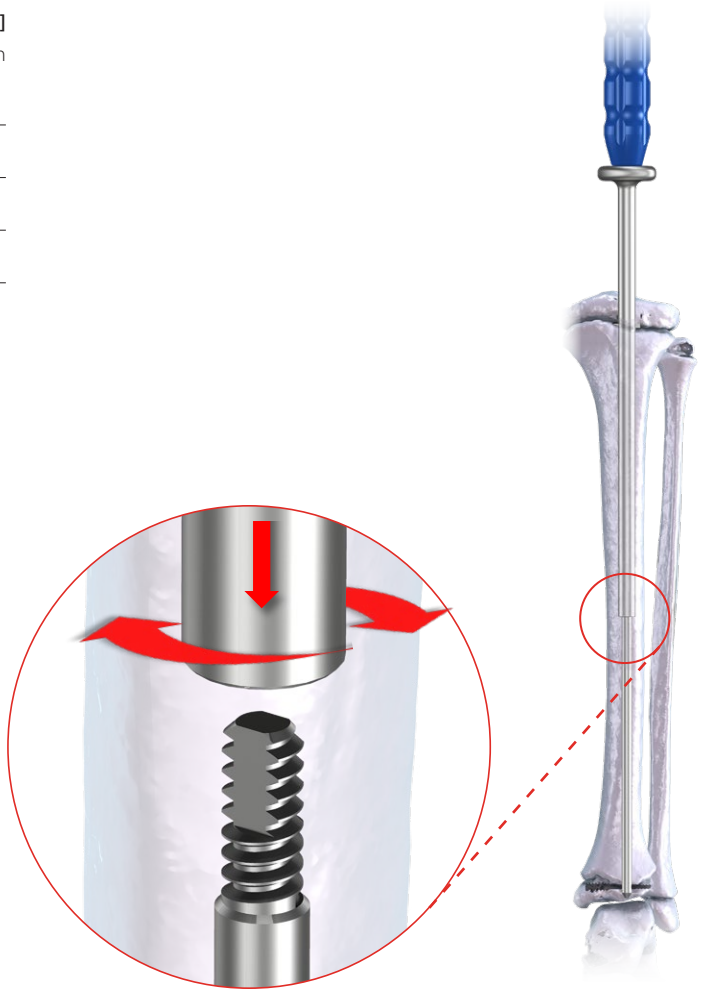
40.0321.000

40.5081.000



20 Attach an appropriate nail guide **[40.5083]**, **[40.5084]** or **[40.5085]** to the threaded end of telescopic nail and remove the nail from the medullary canal.

	40.5085.000
	40.5083.000
	40.5084.000



5. SURGICAL TECHNIQUE – FEMORAL NAIL

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

5.1. SURGERY PLANNING

Each surgery must be carefully planned. X-Ray visualization of the fractured bone should be performed in AP and lateral position in order to define the proper nail size. It is recommended to place the patient supine with direct traction applied to the femoral condyles of the operated limb. Nail length should fit the medullary canal on the maximal possible length. Whereas nail diameter should maximally fill the medullary canal. The implantation should be performed on an operating table equipped with image intensifier.

5.2. SURGICAL APPROACH

Lateral surgical approach should be used. Start the incision near the trochanter major apex, and lead it along the femur long axis for 8cm. The incision should be longer in overweight patients. When reached, cut the fascia the way the skin was incised. Next, the dissection of gluteus maximus muscle fibres should be performed. Back from gluteus medius muscle, access to trochanter major apex is enabled. Nail entry hole location must coincide with medullary canal axis. The point can be navigated with the following method. If trochanter apex is found with forefinger, then the entry point is located a bit medially (*towards the neck of femur basis*) and a bit anteriorly, in a place sensible with forefinger tip as a fossette (*fossa piriformis*).

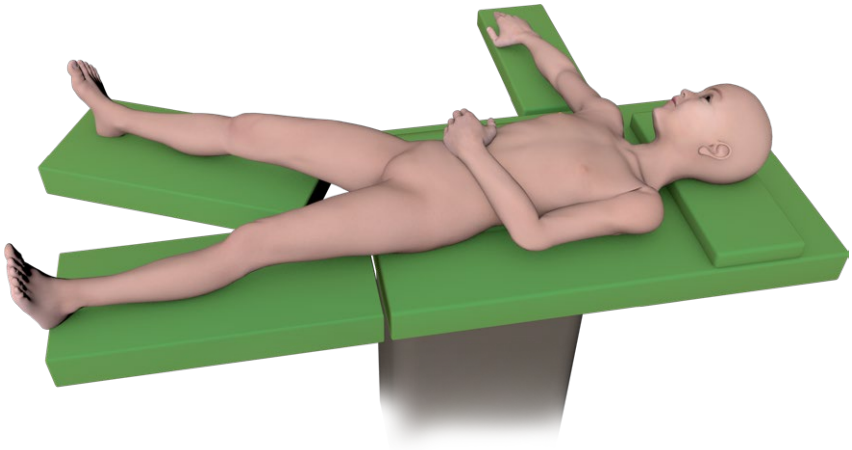


Fig.1. Supine positioning of a patient

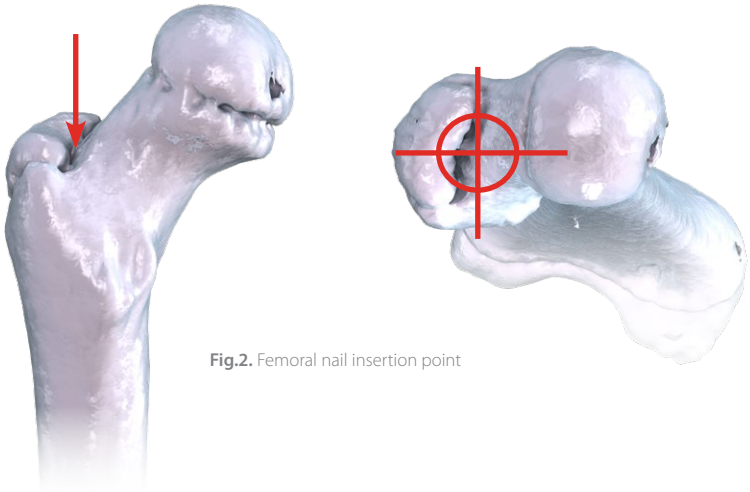
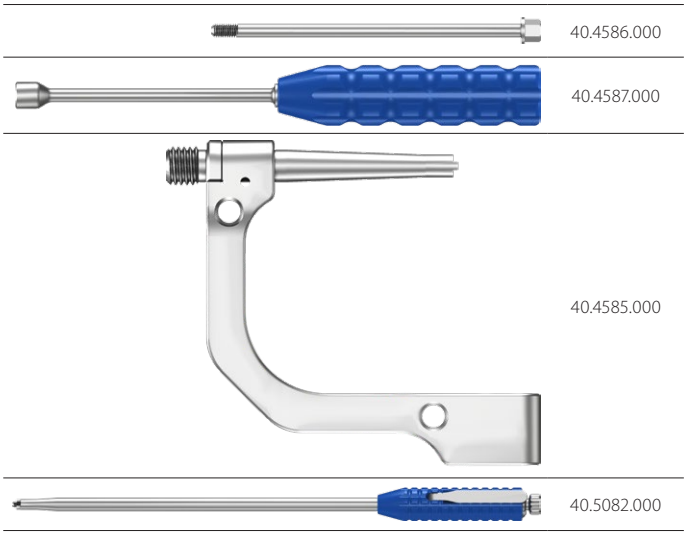


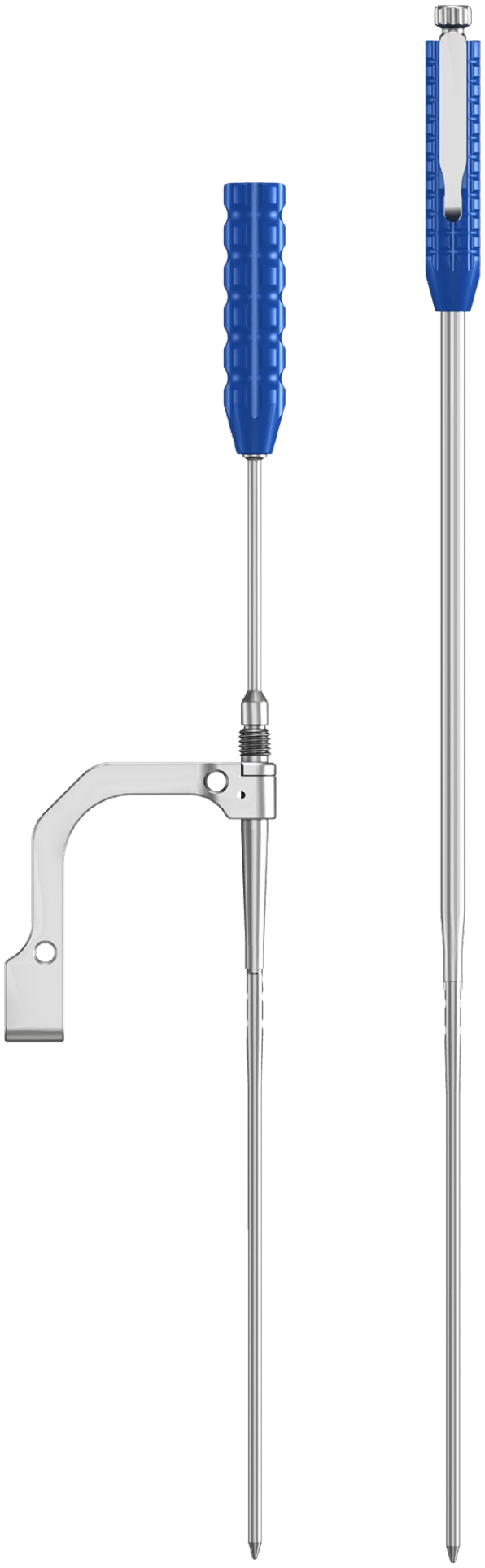
Fig.2. Femoral nail insertion point

5.3. NAIL PREPARATION FOR INSERTION INTO MEDULLARY CANAL

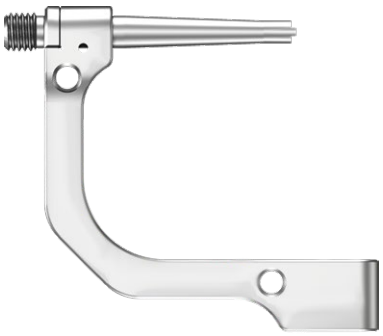
1 After taking X-Ray of the bone to be implanted with a nail (*it is recommended to take an X-Ray of the healthy leg as well*), nail length and diameter should be defined.

2 Use clamping screw M4 **[40.4586]** and socket wrench S6 **[40.4587]** to attach the 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, the use of the impactor-extractor shall be omitted.





3 Before implantation, make sure the hole in the proximal targeter B **[40.4585]** and hole in the telescopic nail overlap. For that purpose insert the protective guide 7/5 **[40.4589]** with Kirschner guide B 5/2 **[40.4590]** into the distal hole of the proximal targeter B. When the nail is attached correctly, the Kirschner wire **[40.4583]** should easily pass through the nail hole.



40.4585.000

40.4589.000

40.4590.000

40.4583.000

5.4. OPENING OF THE MEDULLARY CANAL

4 Having prepared the surgery approach and insertion point, use the drive to insert the Kirschner wire 2.0 **[40.4583]**) into the medullary canal.

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

Kirschner wire is a disposable device.

40.4583.000

5 Use the cannulated drill 6.0/2.2/150 **[40.4584]**, drive and Kirschner wire to open the medullary canal.

Remove the drill and Kirschner wire.

It is recommended to open the medullary canal using the procedure defined in step 4. However, the choice of operation technique depends on the surgeon's preferences and equipment available in the surgical theater.

40.4584.000

6 Use the X-Ray to define nail location in the medullary canal in its distal portion. Perform the tissue incision over the patella ligament middle, or to its medial side. Expose the intercondylar area (*unfibre longitudinal ligament or retract laterally*). Mark the insertion point for Kirschner wire on the bone. Perforate the cortical layer and insert the Kirschner wire 2.0 **[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 a disposable device.

40.4583.000

7 Use the cannulated drill 6.0/2.2/150 **[40.4584]**, drive and Kirschner wire to open the medullary canal for the length of about 6cm.

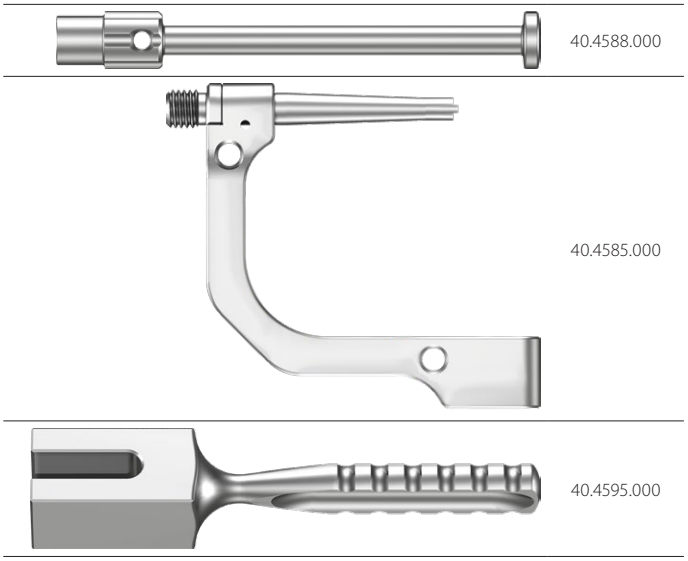
Remove the drill and Kirschner wire.


40.4584.000

40.4583.000

5.5. NAIL INSERTION INTO MEDULLARY CANAL

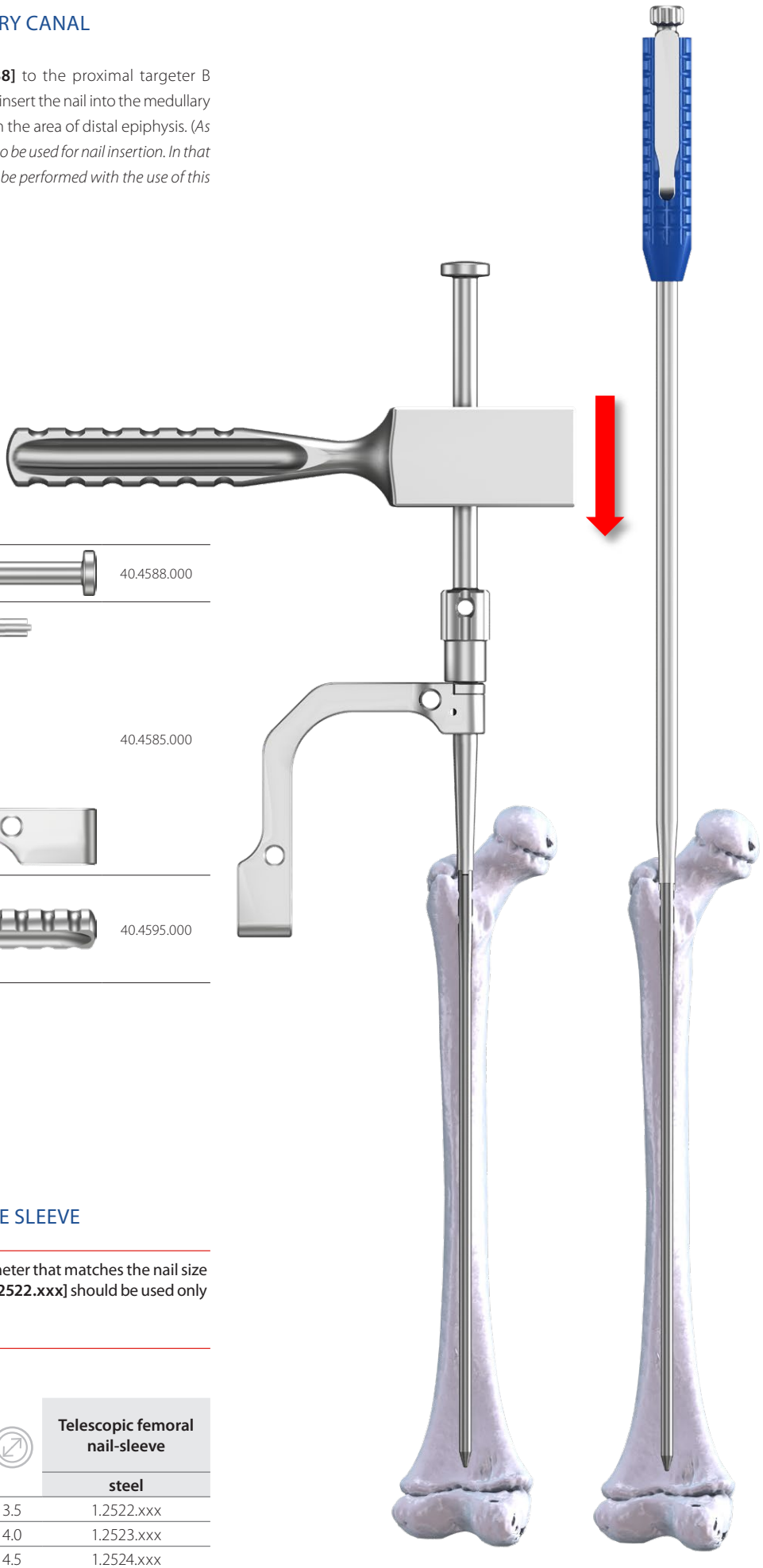
8 Attach the impactor-extractor **[40.4588]** to the proximal targeter B **[40.4585]**. Use mallet **[40.4595]** to gently insert the nail into the medullary canal, as deep as possible, until its end is placed in the area of distal epiphysis. (*As mentioned above, the holder with clamp M4 may also be used for nail insertion. In that case any manipulation related to nail insertion is to be performed with the use of this device only*).



40.4588.000

40.4585.000

40.4595.000



5.6. INSERTION AND LOCKING OF THE SLEEVE

Make sure the suitable sleeve diameter that matches the nail size has been chosen, e.g. sleeve 3.5 **[1.2522.xxx]** should be used only with nail 3.5 **[1.2512.xxx]**.
(*See: Tab. 2. Nail and sleeve selection*)

Tab. 2. Nail and sleeve selection

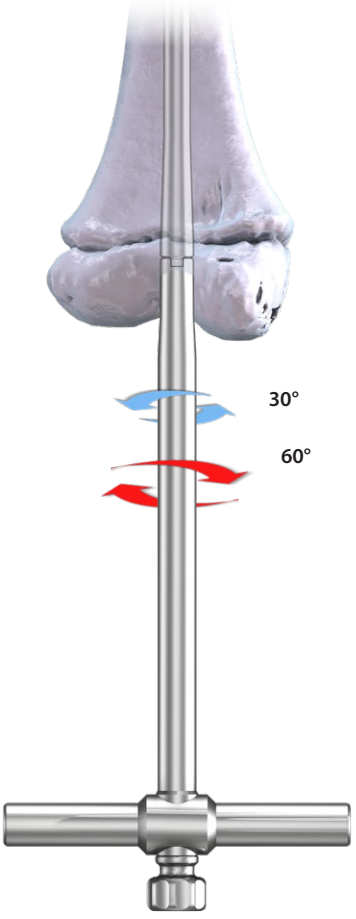
	Femoral nail			Telescopic femoral nail-sleeve	
	steel			steel	
3.5	1.2512.xxx	→	3.5	1.2522.xxx	
4.0	1.2513.xxx	→	4.0	1.2523.xxx	
4.5	1.2514.xxx	→	4.5	1.2524.xxx	

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

40.5081.000

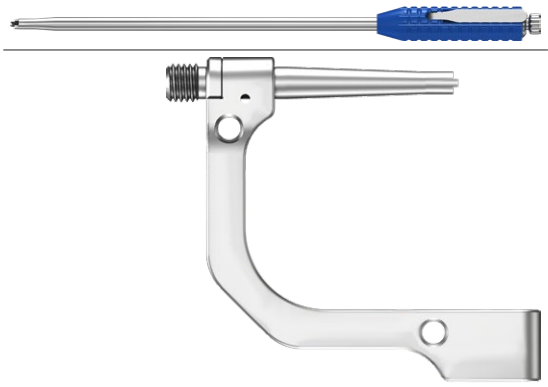
10 Insert the holder with clamp M5 with attached sleeve into the medullary canal, until the sleeve end rests on the intercondylar tissues. Gently turn left until resistance is felt (*about 30°*) and with adequate force, press the sleeve catches into tissues. Next turn the sleeve right until the resistance is felt (*about 60°*), locking the sleeve catches in the epiphyseal plate. After locking the sleeve, remove the holder with clamp M5 **[40.5081]**.

40.5081.000



5.7. LOCKING THE INTRAMEDULLARY NAIL

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



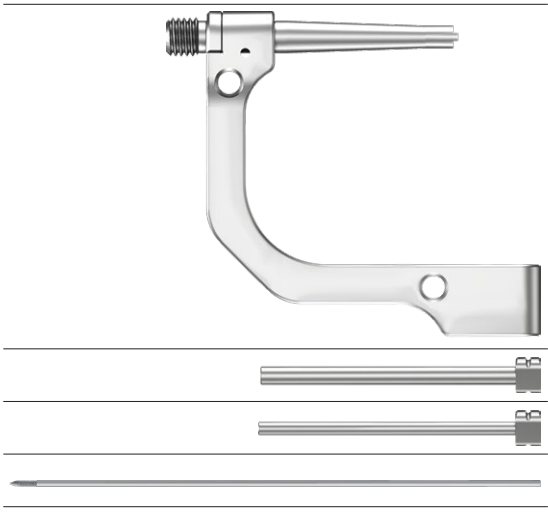
40.5082.000

40.4585.000

12 Insert the protective guide 7/5 **[40.4589]** and Kirschner guide B 5/2 **[40.4590]** into the distal hole of proximal targeter B **[40.4585]**. Use the surgical drive and Kirschner wire 2.0 **[40.4583]** to drill the hole in the bone through both cortexes, until the wire end slightly protrudes from the bone.

Drilling process shall be controlled under image intensifier.

Leave the wire and guides in the hole.

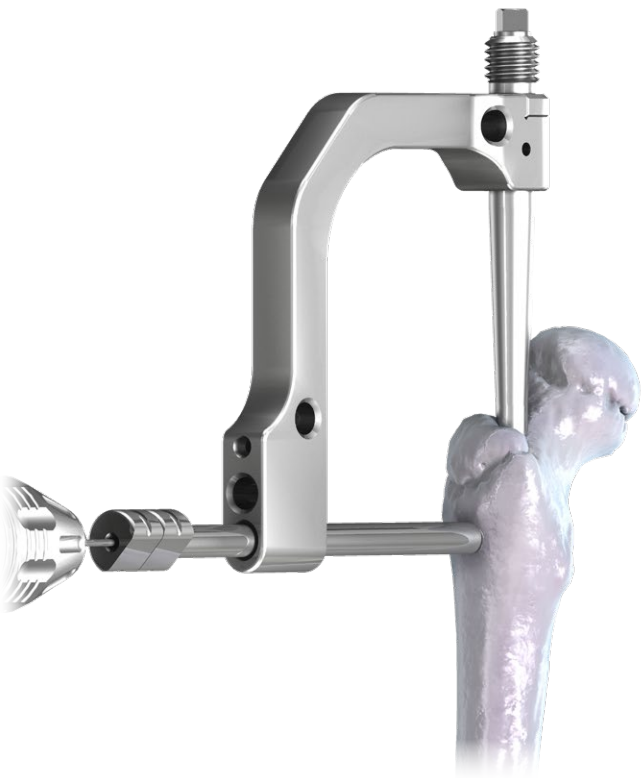


40.4585.000

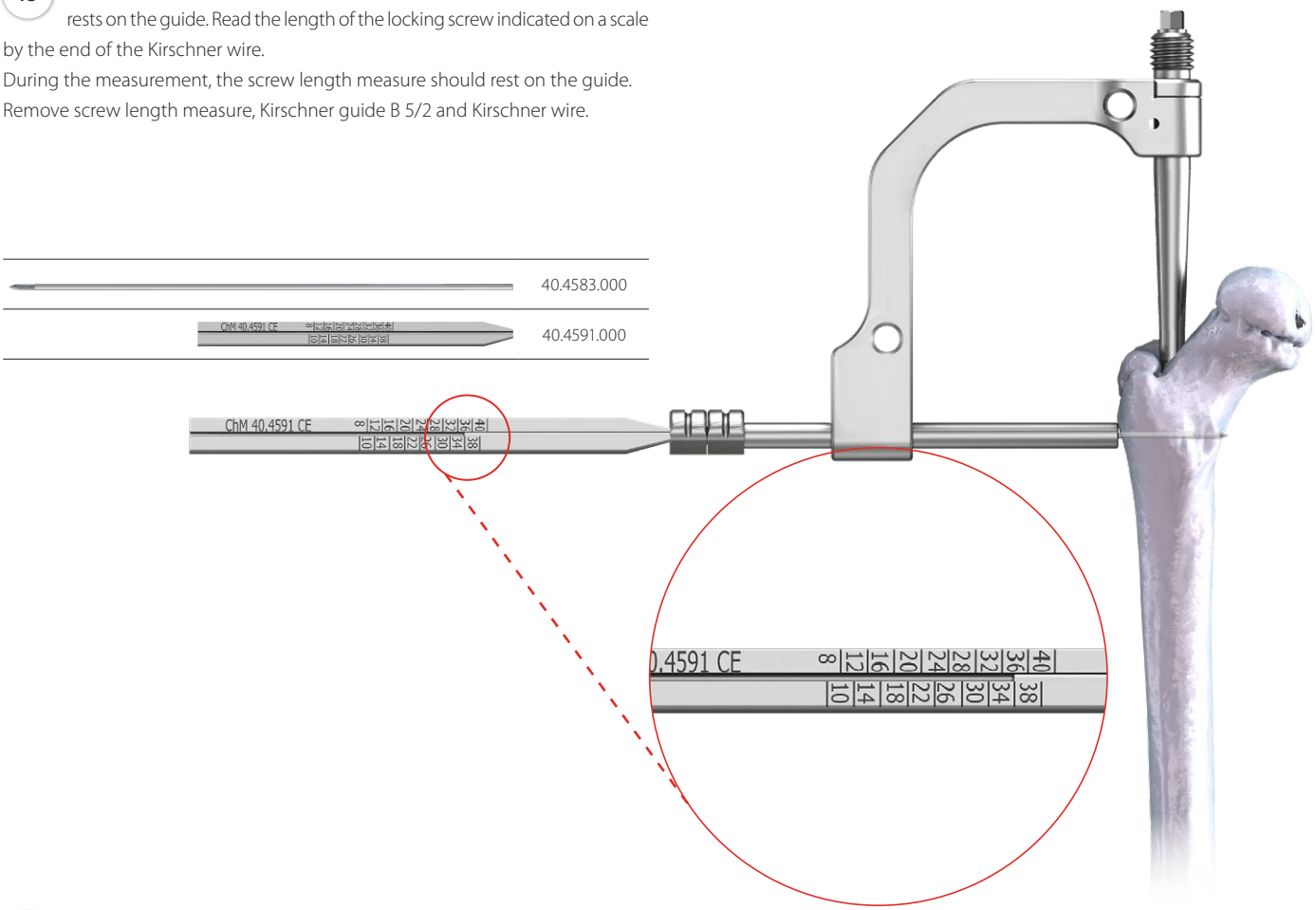
40.4589.000

40.4590.000

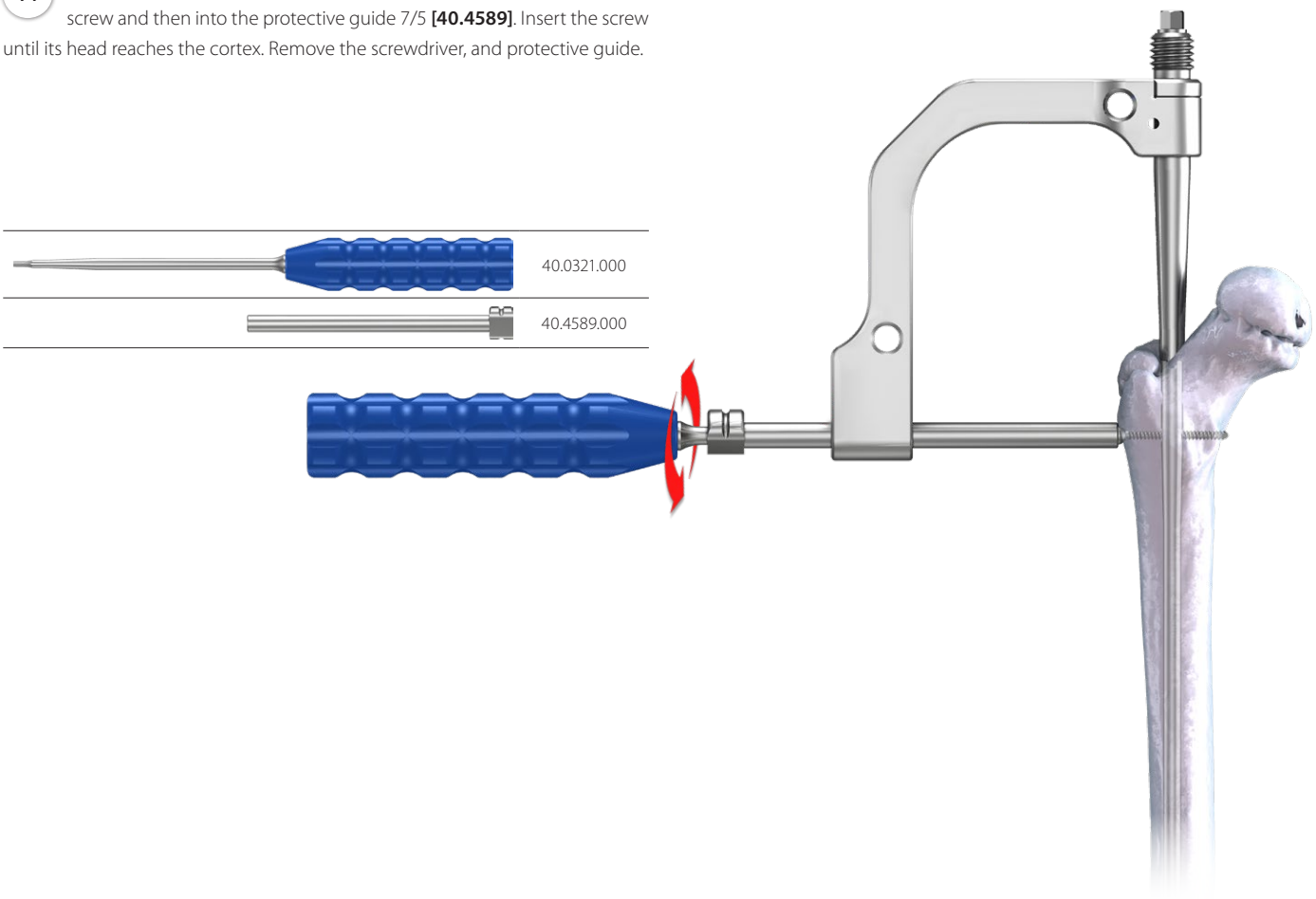
40.4583.000



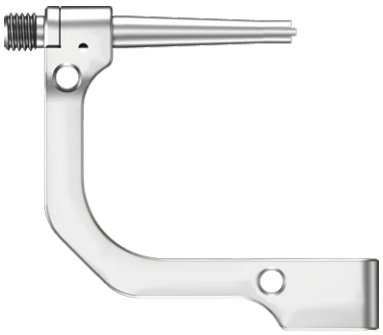
13 Apply screw length measure **[40.4591]** on the Kirschner wire until its end rests on the guide. Read the length of the locking screw indicated on a scale by the end of the Kirschner wire.
During the measurement, the screw length measure should rest on the guide.
Remove screw length measure, Kirschner guide B 5/2 and Kirschner wire.



14 Insert the tip of the screwdriver S2.5 **[40.0321]** into the socket of the locking screw and then into the protective guide 7/5 **[40.4589]**. Insert the screw until its head reaches the cortex. Remove the screwdriver, and protective guide.



15 Lock the nail with the other screw using the proximal hole of the proximal targeter B **[40.4585]** according to the steps 12 to 14 of this technique.



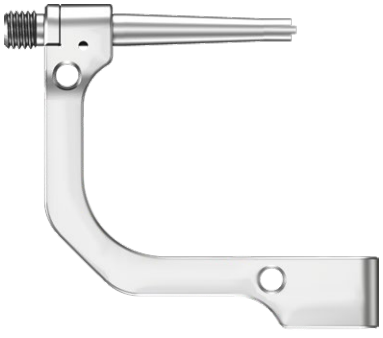
40.4585.000

5.8. END CUP INSERTION

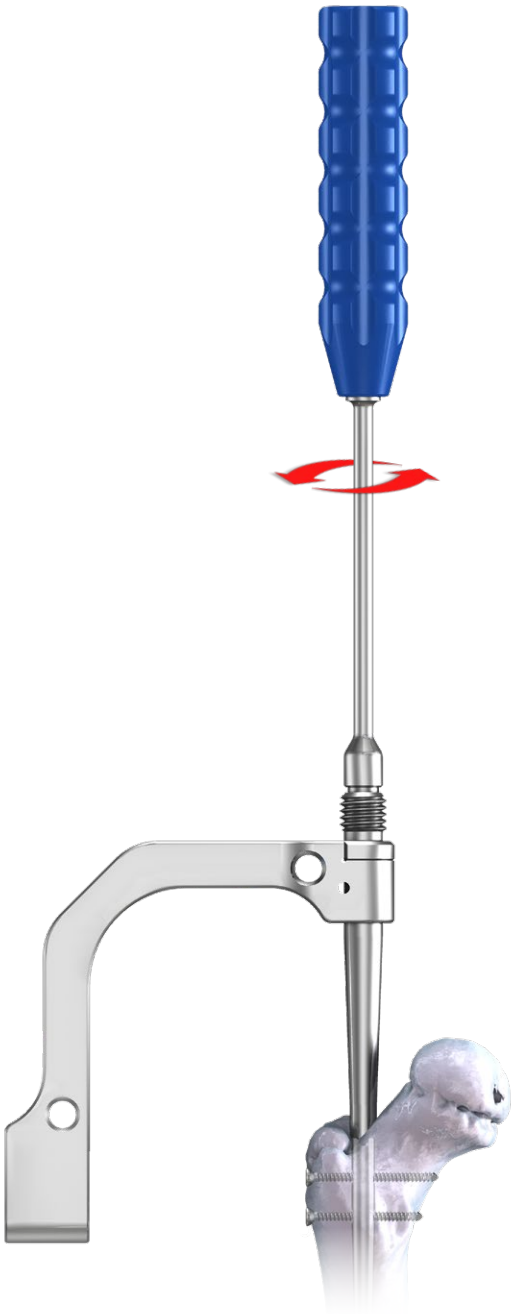
16 Use socket wrench S6 **[40.4587]** to remove the clamping screw M4 **[40.4586]** from the nail shaft. Remove the proximal targeter B **[40.4585]** from the nail locked in the medullary canal.

40.4587.000

40.4586.000



40.4585.000



17 To secure the threaded hole of the nail from bone ingrowth, use the screwdriver S2.5 **[40.0321]** to insert the end cap M4 **[1.2104.004]**.

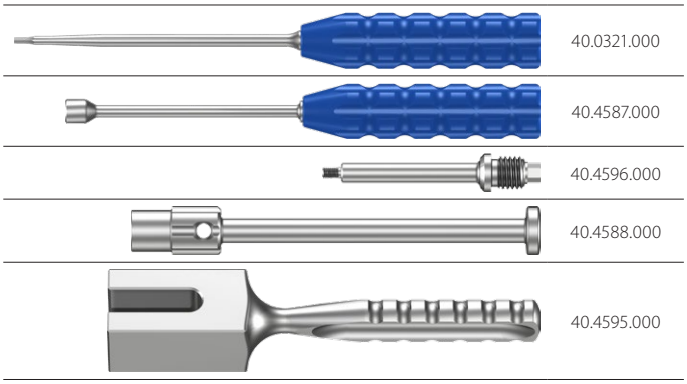
40.0321.000

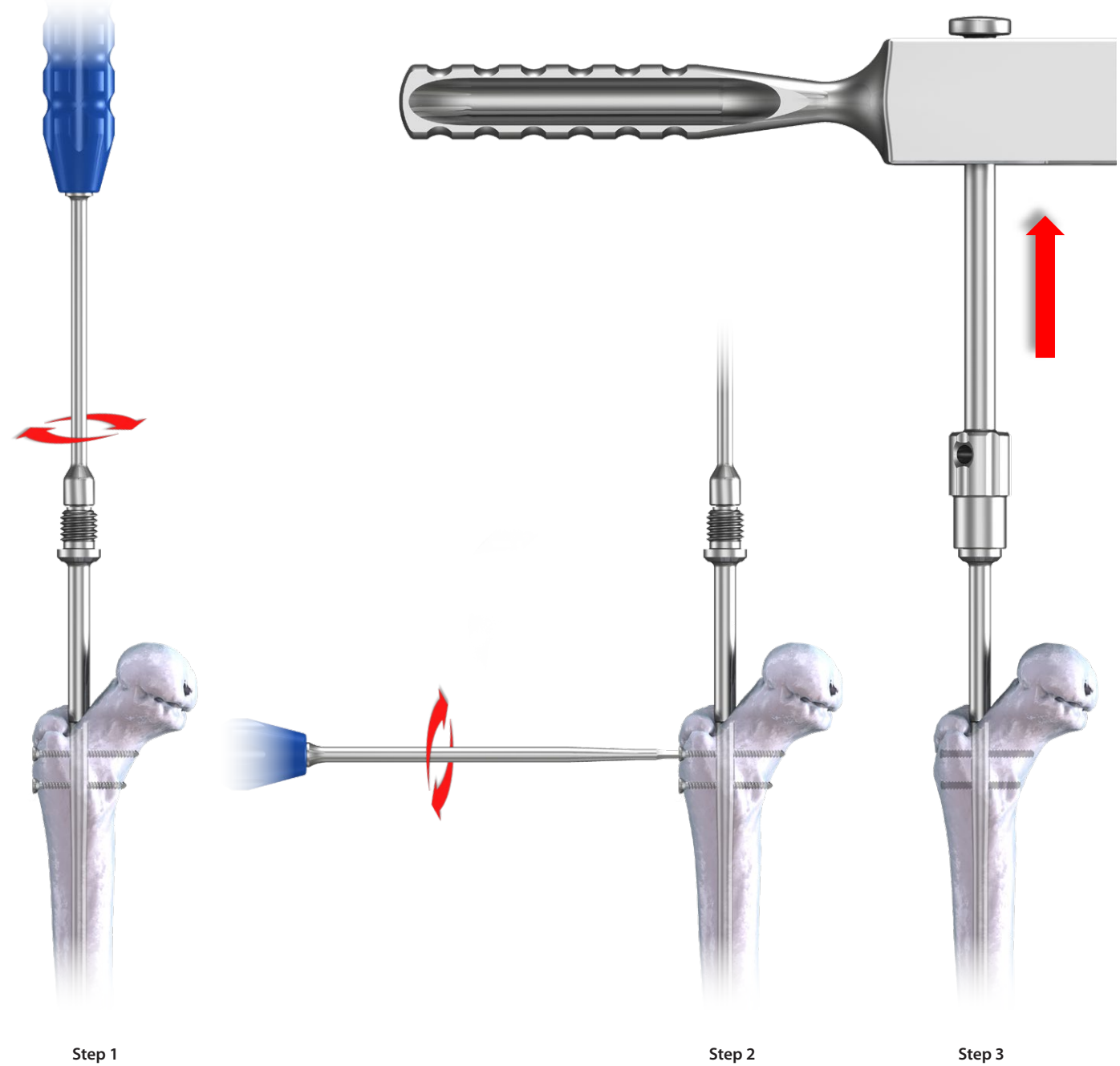
18 Analogous procedure should be performed for the nail sleeve - insert the end cap M5 **[1.2530]** using the screwdriver S2.5 **[40.0321]**.

40.0321.000

5.9. TELESCOPIC NAIL REMOVAL

19 Use screwdriver S2.5 **[40.0321]** to remove the end cap M4 **[1.2104.004]** from nail. Use the socket wrench S6 **[40.4587]** to insert the connector M4 **[40.4596]** into the threaded hole of the nail shaft. Remove all locking screws using the screwdriver S2.5. Attach impactor-extractor **[40.4588]** to the connector and use mallet **[40.4595]** to remove the nail from the medullar canal.





Step 1 Step 2 Step 3

20 Use screwdriver S2.5 **[40.0321]** to remove the end cap M5 **[1.2530]** from the nail sleeve, then use the holder with clamp M5 **[40.5081]** to turn the sleeve left of about 90°, loosen and remove from the medullary canal.


40.0321.000


40.5081.000

Step 1

Step 2

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