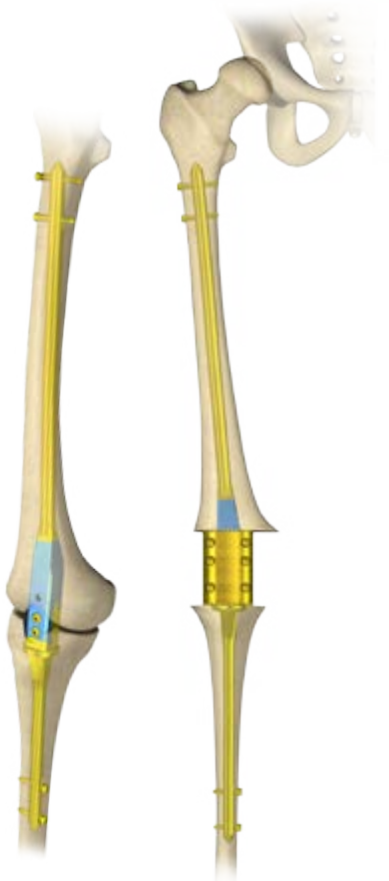
ST/69A

ChM®

CHARFIX system 2

CHARFIX2 FN NAIL

- *IMPLANTS*
- *INSTRUMENT SET 15.0427.100*
- *SURGICAL TECHNIQUE*



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SYMBOLS DESCRIPTIONS

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

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

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Document No ST/69A
Date of issue 21.01.2016
Review date P-003-06.06.2018

The manufacturer reserves the right to introduce design changes.

I. INTRODUCTION

CHARFIX2 FN Nail is used to join femur and tibia at the site of the knee resection or partially removed joint surfaces. The implant is a compound system which includes the following elements:

- **CHARFIX2** FN Nail - femur
- **CHARFIX2** FN Nail - tibia
- **CHARFIX2** FN Spacer
- **CHARFIX2** FN Screw T

Indications:

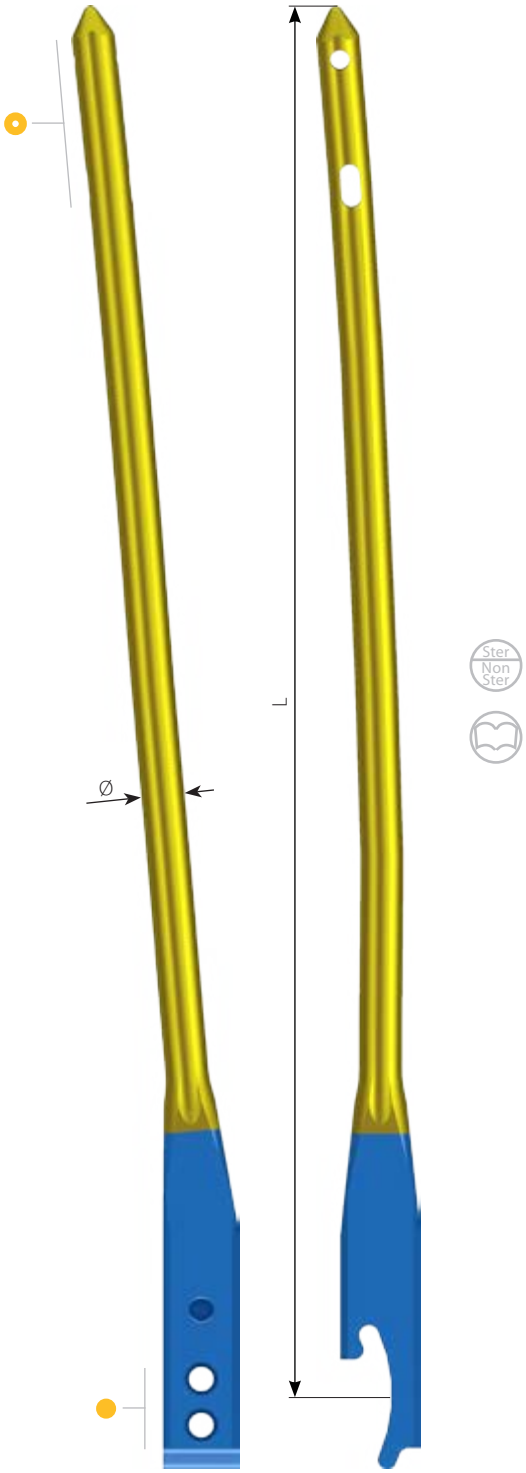
- Failed knee arthroplasty
- Post-infection state
- Periprosthetic fractures
- Post-traumatic state excluding knee prosthesis implantation
- Tumors in the knee area
- Loss of or damage to the extensor mechanism
- Oncological changes
- Arthroplasty of the knee joint

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

II. IMPLANTS

CHARFIX2 FN NAIL - FEMUR RIGHT

CHARFIX system 2



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	440	3.6322.440
	460	3.6322.460
	480	3.6322.480
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	400	3.6324.400
	420	3.6324.420
	440	3.6324.440
	460	3.6324.460
	480	3.6324.480

	R
10	
11	
12	

	Ti				
	3.5159.xxx	✓		5.0	26÷100
	3.6300.000	✓			

available		Ø	8 mm ÷ 19 mm	pitch	1 mm
		L	180 mm ÷ 480 mm		20 mm

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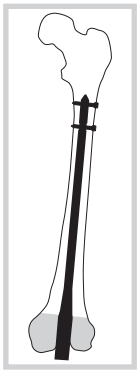
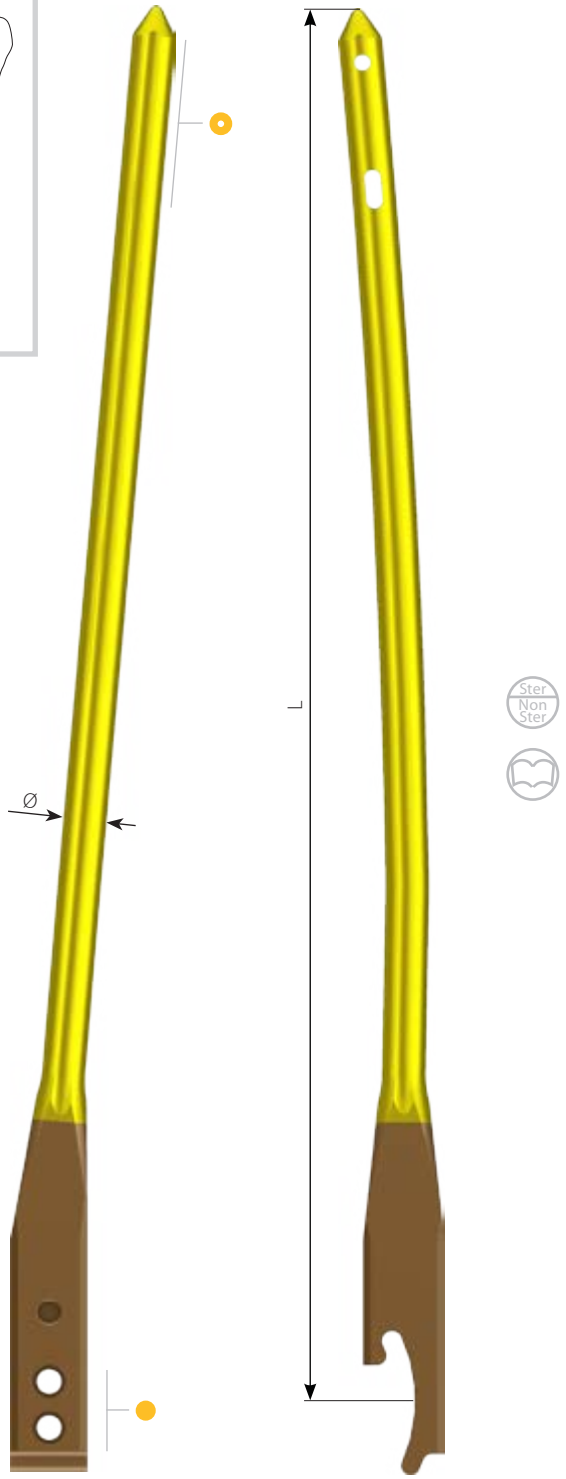
CHARFIX2 FN NAIL - FEMUR LEFT

CHARFIX system 2





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	360	3.6323.360
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	400	3.6323.400
	420	3.6323.420
	440	3.6323.440
	460	3.6323.460
	480	3.6323.480

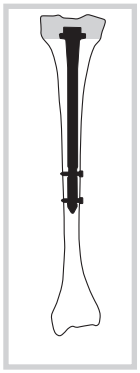
L	
10	
11	
12	

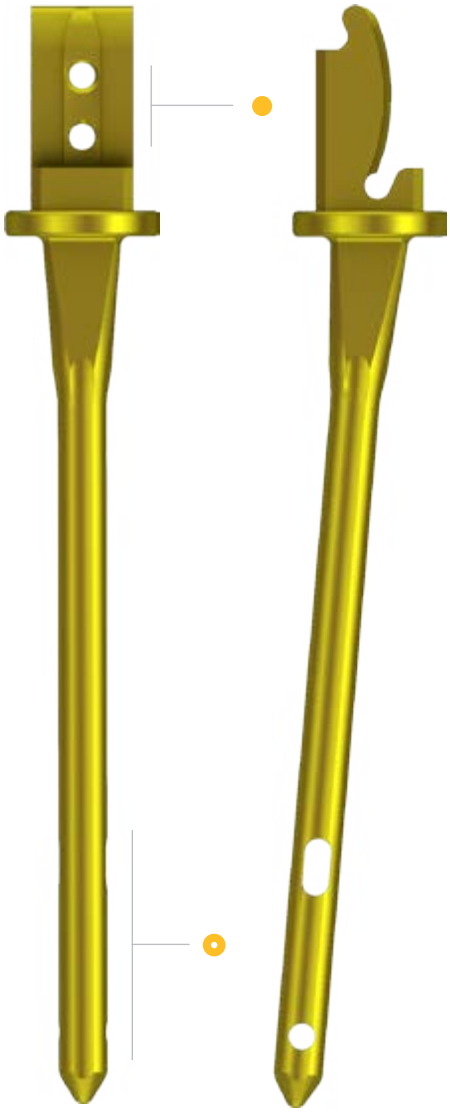
	Ti				
	3.5159.xxx	✓		5.0	26÷100
	3.6300.000	✓			

available		Ø	8 mm ÷ 19 mm	pitch	1 mm
		L	180 mm ÷ 480 mm		20 mm

CHARFIX2 FN NAIL - TIBIA

CHARFIX system 2





Ster
Non Ster

	Len	Ti
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	280	3.6343.280
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	400	3.6345.400
	420	3.6345.420
	440	3.6345.440
	460	3.6345.460
	480	3.6345.480

10	
11	
12	

	Ti				
	3.5159.xxx	✓		5.0	26÷100
	3.6300.000	✓			

available		Ø	8 mm ÷ 19 mm	pitch	1 mm
		L	180 mm ÷ 480 mm		20 mm

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LOCKING ELEMENTS

CHARFIX system 2

Ti | Ster Non Ster

CHARFIX2 FN SCREW T

	Ti
	3.6300.000

CHARFIX2 DISTAL SCREW 5.0

	Ti
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

26 ÷ 100

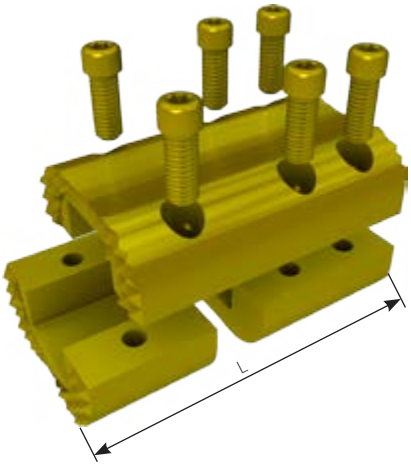
Stand for **CHARFIX2** nail locking elements
(set with box without implants)

40.5058.200

CHARFIX2 FN Spacer (non-sterile)

CHARFIX system 2

Ti | Ster Non Ster



↔	Ti
60	3.6367.060
70	3.6367.070
80	3.6367.080
90	3.6367.090
100	3.6367.100

60 ÷ 100

CHARFIX2 FN Spacer (sterile)

CHARFIX system 2

CHARFIX2 FN SPACER – LOWER FEMORAL

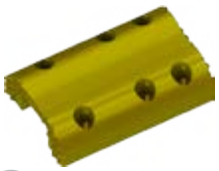
↔	Ti
30	3.6368.030

CHARFIX2 FN SPACER – LOWER TIBIAL

↔	Ti
30	3.6369.060
40	3.6369.070
50	3.6369.080
60	3.6369.090
70	3.6369.100

30 ÷ 70

CHARFIX2 FN SPACER – UPPER



↔	Ti
60	3.6370.060
70	3.6370.070
80	3.6370.080
90	3.6370.090
100	3.6370.100

60 ÷ 100

CHARFIX2 FN SCREW T

	Ti
	3.6300.000

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III. INSTRUMENT SET

INSTRUMENT SET FOR CHARFIX2 FN NAILS

The instrumentarium set **[15.0427.100]** is used to join the femur and tibia in the place of knee resection or partially removed joint surfaces. Instruments included in the instrument set are placed on the stands and covered with a cover to facilitate their storage and transportation to the operating theater.

15.0427.100	Name	Pcs	Catalogue No.
	Countersink	1	40.6631.000
	Handle	1	40.6632.000
	Handle	1	40.6633.000
	Targeter arm	1	40.6634.000
	Distal tibial targeter	1	40.6635.000
	Targeter arm	1	40.6636.000
	Distal targeter	1	40.6637.000
	Trial 10	3	40.6638.000
	Trial 20	2	40.6639.000
	Trial 30	2	40.6640.000
	Guide rod handle	1	40.1351.100
	Trocar short 7	1	40.1354.200
	Hole depth measure	1	40.2665.100

INSTRUMENT SET FOR CHARFIX2 FN NAILS

CHARFIX system 2

15.0427.100	Name	Pcs	Catalogue No.
	Mallet	1	40.3667.000
	Guide rod 3.0/580	1	40.3925.580
	Nail length measure	1	40.6641.000
	Aiming insert 9.0	2	40.5065.009
	Wrench S8	1	40.5304.100
	Impactor-extractor	1	40.5308.100
	Cannulated drill 12/3.0	1	40.5314.000
	Protective guide	1	40.5315.100
	Drill with scale 3.5/350	2	40.5339.002
	Drill with scale 3.5/150	1	40.5343.002
	Set block 9/5.0	2	40.5509.200
	Protective guide 9/7	2	40.5510.300
	Drill guide 7/3.5	2	40.5511.300
	Curved awl 8.0	1	40.5523.100
	Screw length measure	1	40.5530.400
	Trocar 6.5	1	40.5534.200
	Screwdriver T25	1	40.5575.300
	Protective guide short	1	40.5871.100
	Drill guide short	1	40.5872.100

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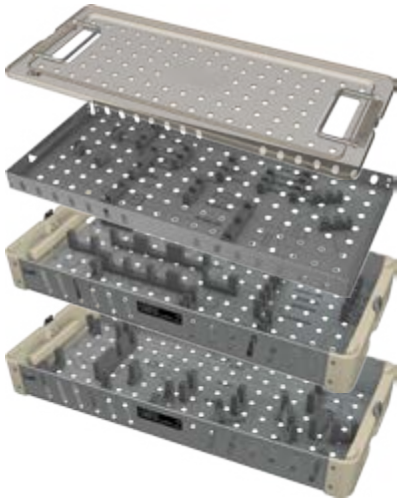
INSTRUMENT SET FOR CHARFIX2 FN NAILS

CHARFIX system 2

15.0427.100	Name	Pcs	Catalogue No.
	Perforated aluminum lid 1/1 595x275x15mm Gray	1	12.0750.200
	Stand	1	14.0427.100
	Container with solid bottom 1/1 595x275x185mm	1	12.0750.103

Additionally, to carry out the procedure, the basic equipment for orthopedic procedures is required, such as:

- bone saws
- drive,
- set of flexible intramedullary reamers 8.0÷13.0 mm with guide and handle,
- set of awls, bone curettes,
- set of drill bits,
- Kirschner wires,
- mallets.

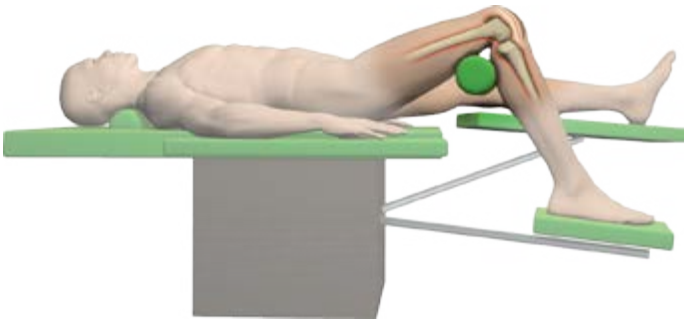
IV. SURGICAL TECHNIQUE

Each surgical treatment must be planned carefully. Prior to surgery, appropriate X-Ray images of the affected limb should be taken to determine the pathological changes within the knee joint and the size of the nail to be implanted. AP, PA and lateral X-Ray images are recommended.
The implantation procedure should be performed on an operating table equipped with an X-Ray camera.

IV.A. WITHOUT KNEE RESECTION

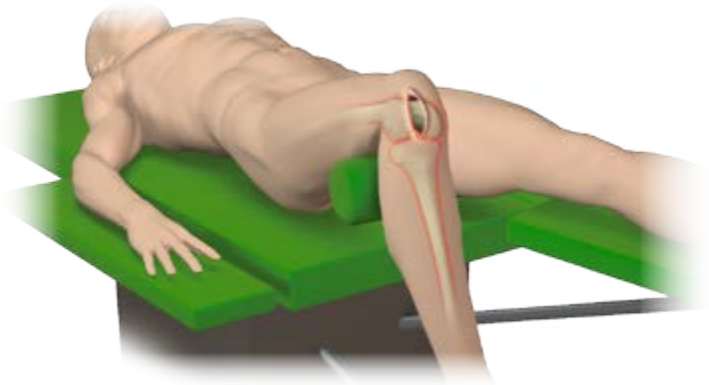
IV.A.1. PATIENT POSITIONING

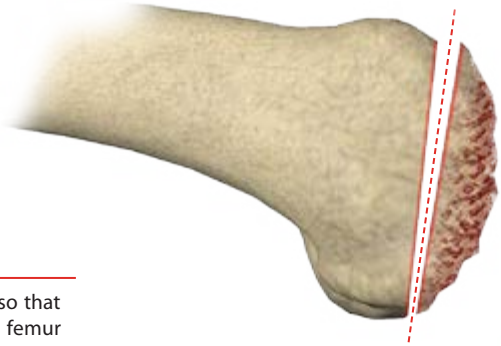
The limb should be flexed at 90°.

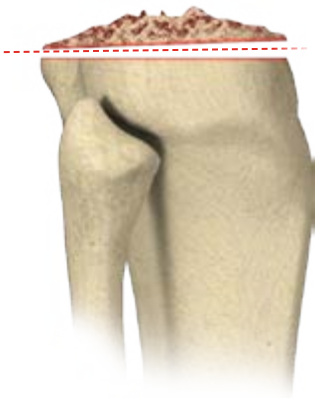


IV.A.2. SURGICAL APPROACH

Make a vertical incision of tissues extending from the region of the femoral condyle to the tibial tuberosity allowing free access to the affected joint.







Femorotibial joint surfaces are resected plane-parallel so that sufficient surface contact of vital bone tissue between femur and tibia is achieved.

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

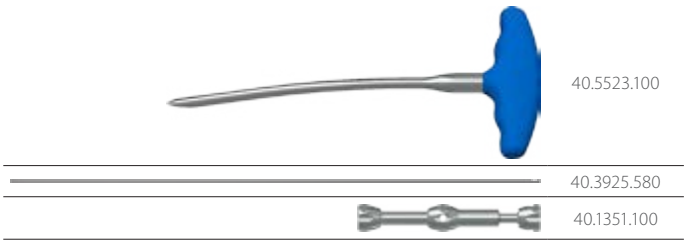
IV.A.3. INSERTION OF CHARFIX2 FN NAIL - TIBIA

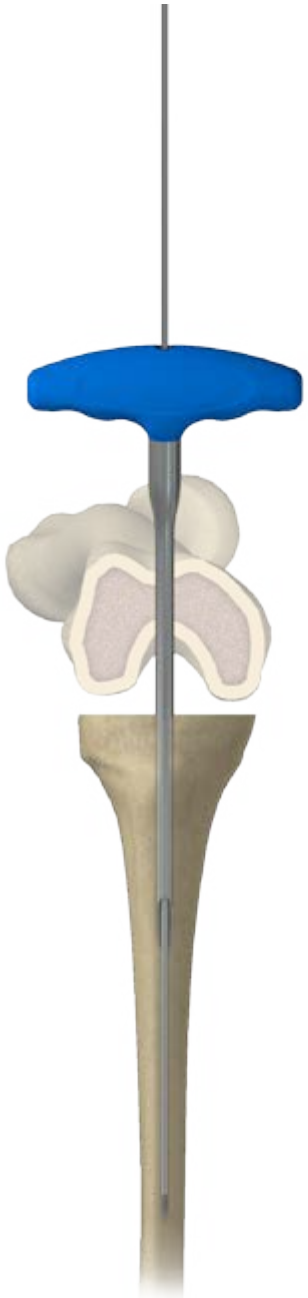
IV.A.3.1. Opening of the medullary canal of the tibia

Use the curved awl 8.0 **[40.5523.100]** to open the medullary canal.

Attach the guide rod 3.0/580 **[40.3925.580]** to the guide rod handle **[40.1351.100]** and using the curved awl, insert into the medullary canal.

Remove the handle and curved awl..





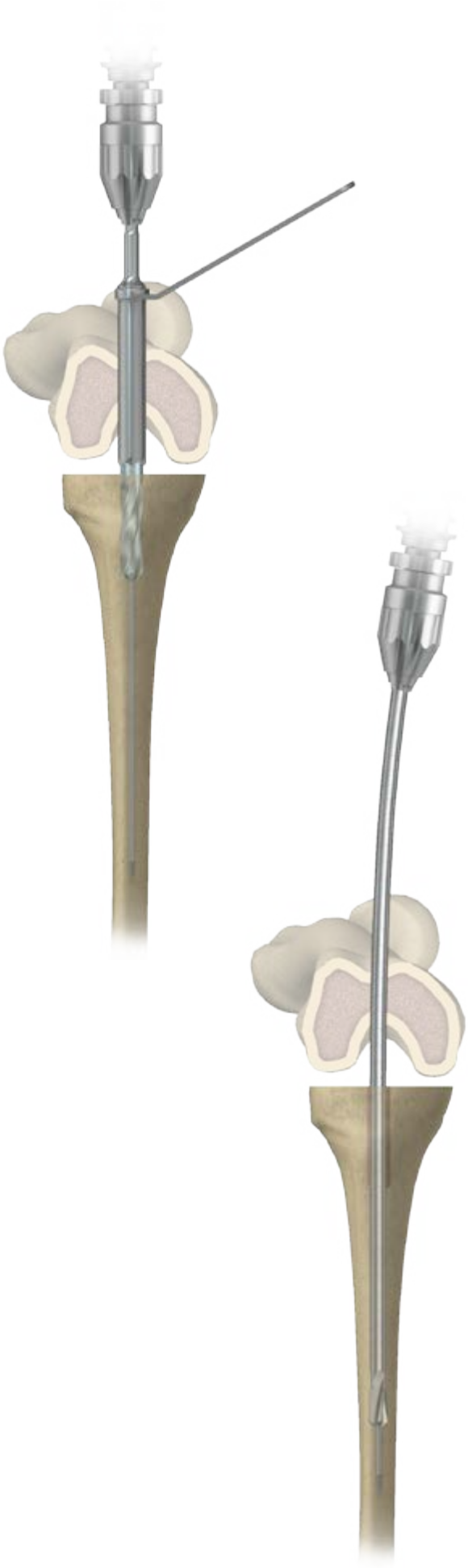
Attach cannulated drill 12/3.0 **[40.5314]** to a drive and using the protective guide **[40.5315.100]**, deepen the entry point in the medullary canal.

Remove the drill and protective guide.


40.5314.000


40.5315.000

Afterwards, attach a flexible reamer to the drive. Widen the tibial medullary canal gradually until the canal diameter is 1.0 ÷ 1.5mm larger than the diameter of the selected nail.

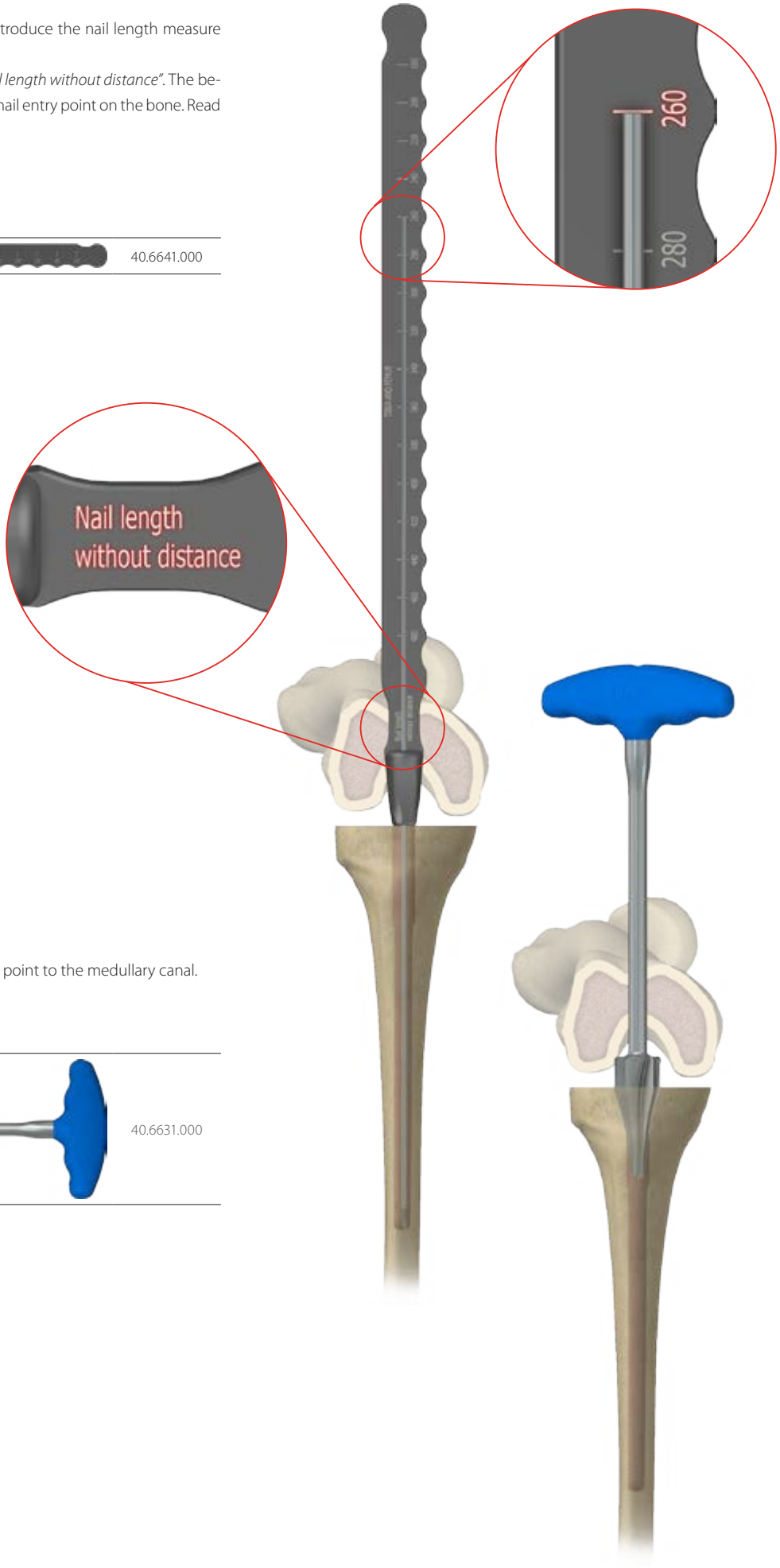


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

Use the guide rod 3.0/580 **[40.3925.580]** to introduce the nail length measure **[40.6641.000]**.
Use the scale on the measure described as *"Nail length without distance"*. The beginning of the measure should be placed in the nail entry point on the bone. Read the length of the nail on the scale provided.

Remove the measure and guide rod

40.6641.000



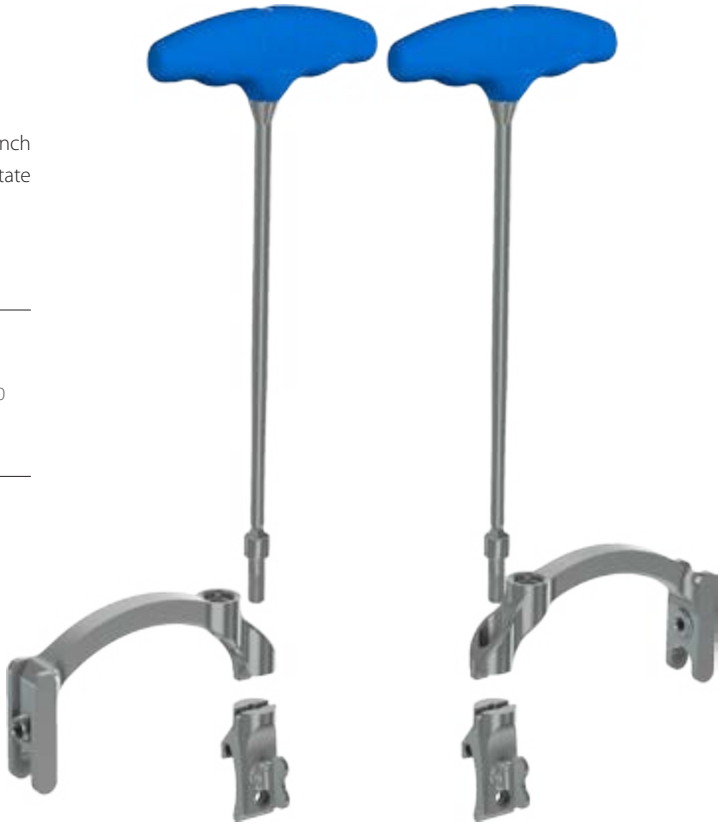
Use countersink **[40.6631]** to deepen the entry point to the medullary canal.

40.6631.000

IV.A.3.2. Targeters assembly

The targeter arm **[40.6634]** can be used with both right and left limb. Use wrench S8 **[40.5304.100]** to loosen the connecting screw of the targeter arm and rotate the targeter arm connector by 180°.

405304.100



IV.A.3.3. Nail insertion

Prior to nail insertion, determine the position of the distal tibial targeter **[40.6635]** in relation to the nail holes. For this purpose, attach **CHARFIX2** FN Nail - tibia to the targeter arm **[40.6634]** with a wing screw. Afterwards, attach the distal tibial targeter to the targeter arm. Using screwdriver T25 **[40.5575.300]**, loosen the locking screws of a slider *(allowing the slider to move)* and move it near the holes in the distal part of the nail.

Determine the correct position of the targeter slider in relation to the nail holes in the distal part using two set blocks 9/5,0 **[40.5509.200]**.
Lock the targeter slider with the screws using screwdriver T25.

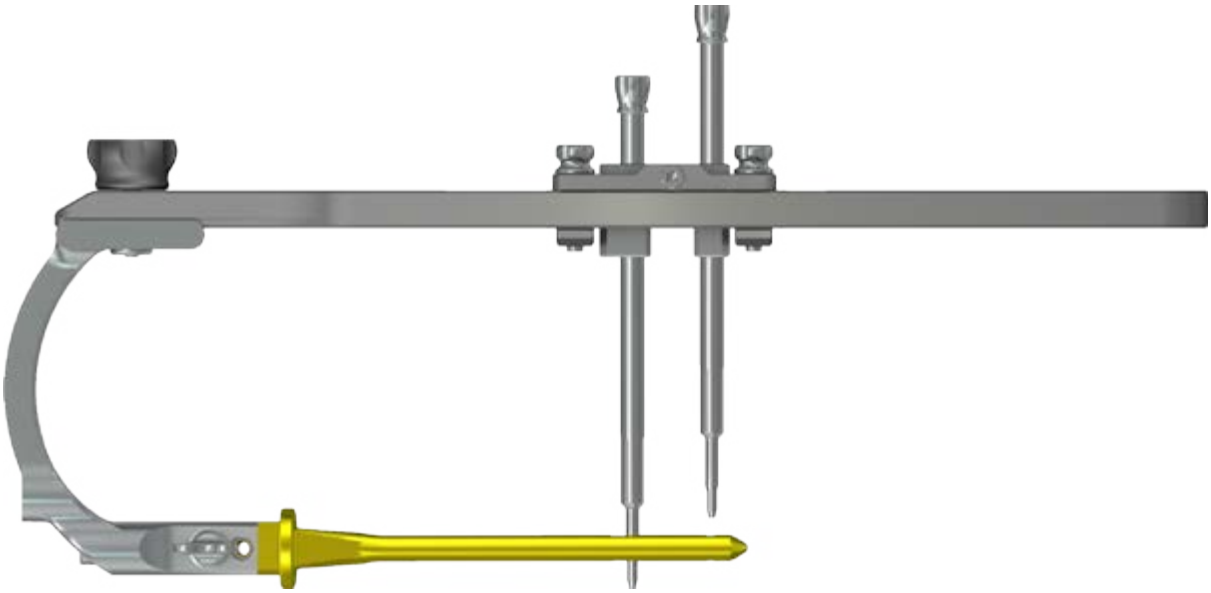
Remove set blocks.

VERIFY: if the targeter slider is properly set and locked, the set blocks should pass through nail holes.

40.6635.000

40.6634.000

40.5509.200



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

Remove distal tibial trageter **[40.6635]** from the targeter arm **[40.6634]**. Attach impactor-extractor **[40.5308.100]** to the targeter arm. Use the mallet **[40.3667]** to insert the nail into the tibial medullary canal.

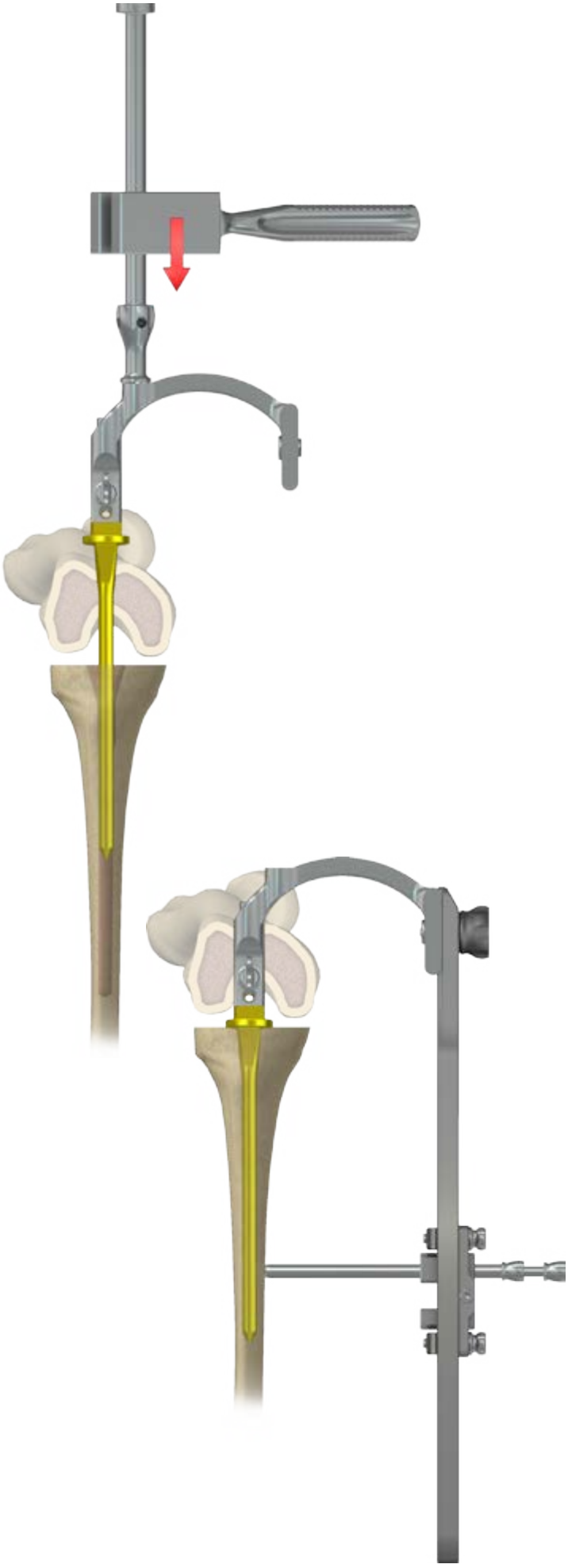
Attach the distal tibial targeter to the targeter arm.


40.6635.000


40.6634.000


40.5308.100


40.3667.000



Insert the protective guide 9/7 **[40.5510.300]** and trocar 6.5 **[40.5534.200]** into the proximal hole of the distal tibial targeter **[40.6635]** slider. Mark the entry point for a locking screw on the skin and make an incision of soft tissues.

Push the protective guide and trocar to the bone and mark the entry point for a drill.

Remove the trocar.


40.5510.300

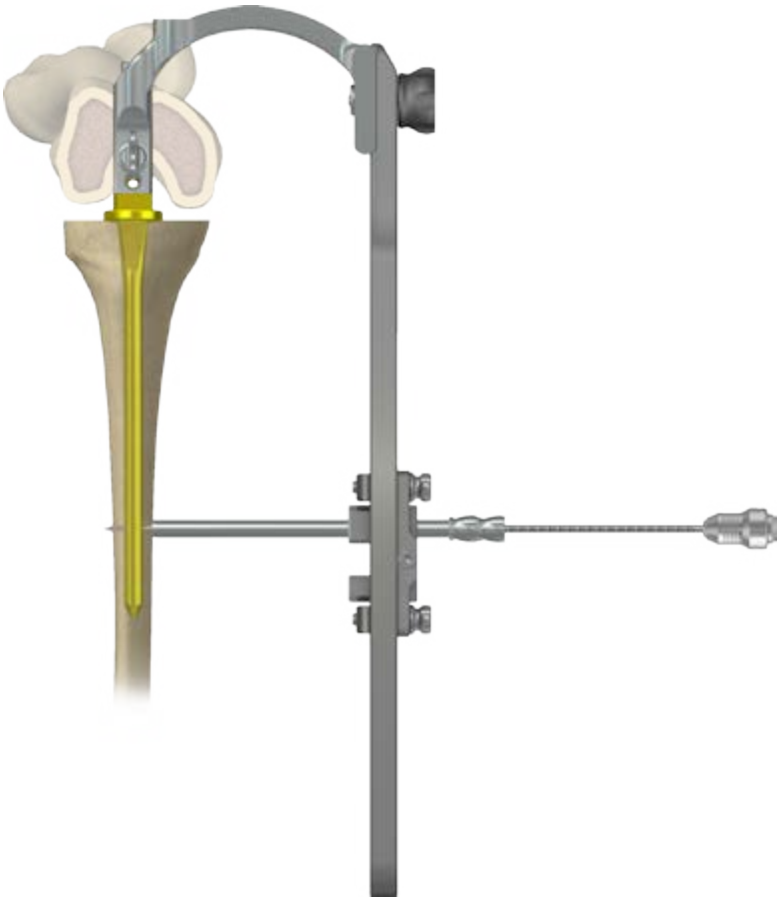

40.5534.200

Insert the drill guide 7/3.5 **[40.5511.300]** into the protective guide. Use a drive and the drill with scale 3.5/350 **[40.5339.002]**, guided in the drill guide, to drill a hole in the tibia through both cortical layers and the hole in the nail. The scale on the drill indicates the length of the locking element.

Remove the drive, leave the drill with guides in place.


40.5511.300

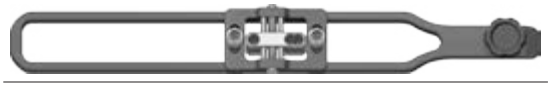

40.5339.002



Insert the protective guide 9/7 **[40.5510.300]** and trocar 6.5 **[40.5534.200]** into the other hole of the distal tibial targeter **[40.6635]** slider. Mark the entry point for the locking screw on the skin and make the incision of soft tissues.

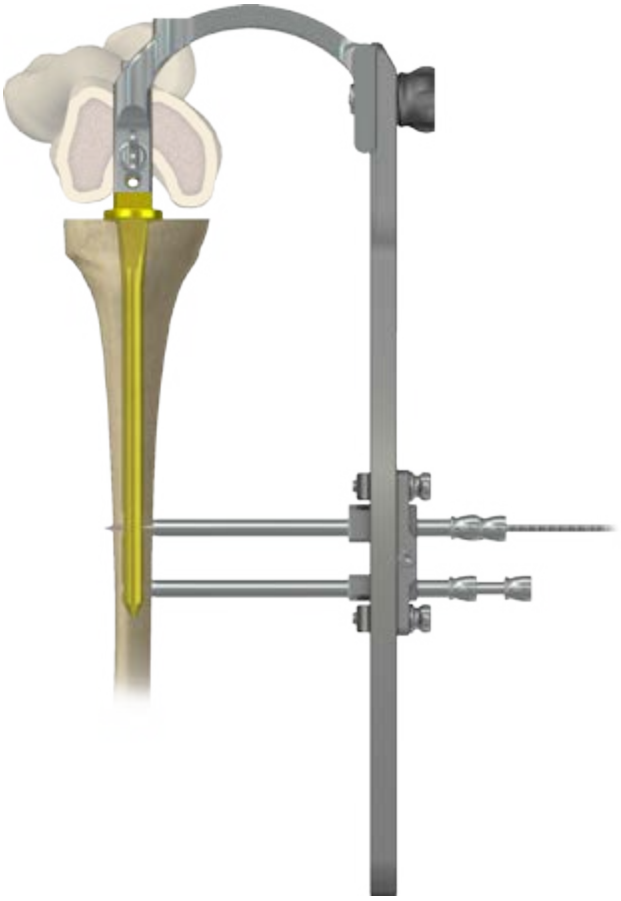
Push the protective guide and trocar to the bone and mark the entry point for the drill.

Remove the trocar.


40.6635.000


40.5510.300

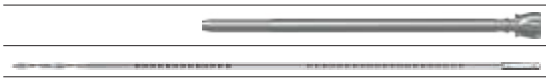

40.5534.200

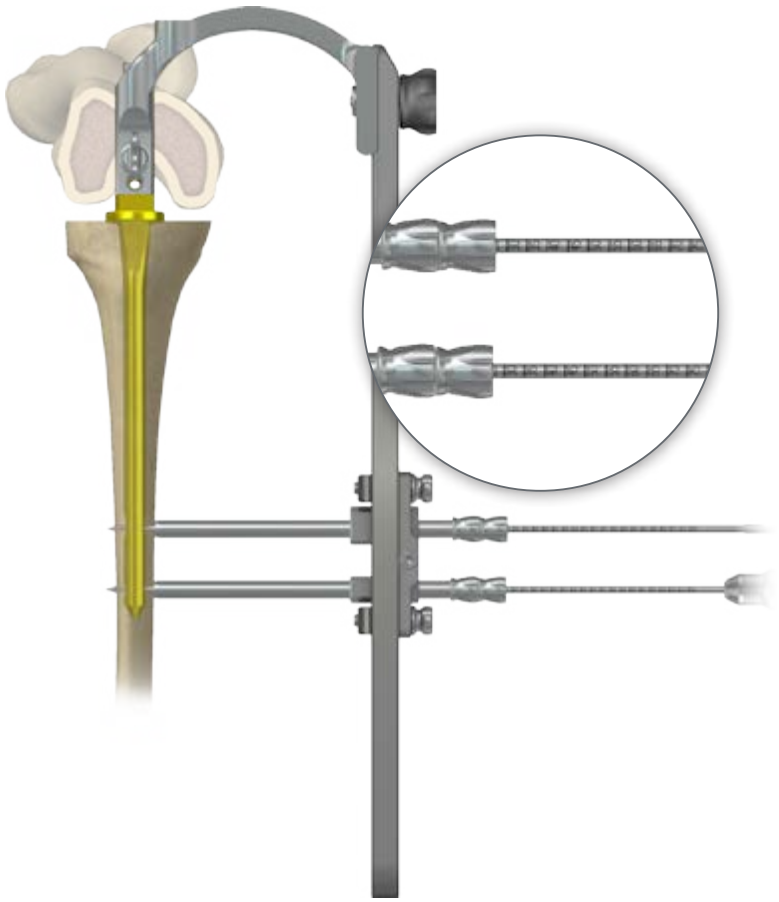


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

Insert the drill guide 7/3.5 **[40.5511.300]** into the protective guide. Use the drive and the drill with scale 3.5/350 **[40.5339.002]**, guided in the drill guide, to drill a hole in the tibia through both cortical layers and the hole in the nail. The scale on the drill indicates the length of the locking element.

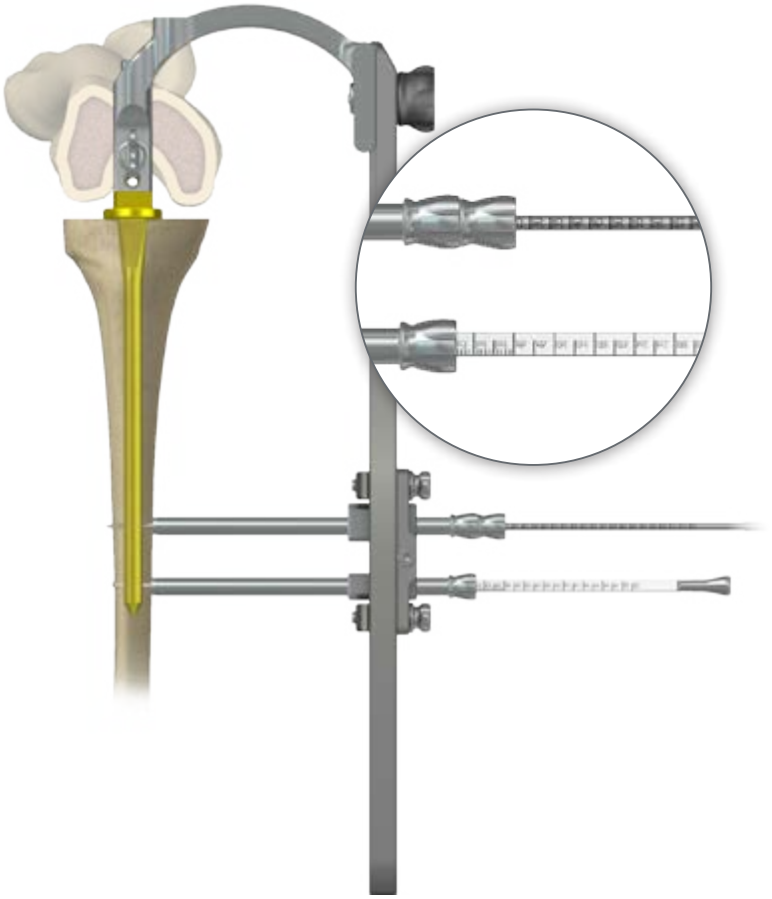
Remove the drill and the drill guide.





Using the protective guide 9/7 **[40.5510.300]**, insert the screw length measure **[40.5530.400]** into the drilled hole until its hook reaches the *"exit"* plane of the hole. Read the length of the locking screw on the scale. During measurement, the protective guide should be pressed against the bone.

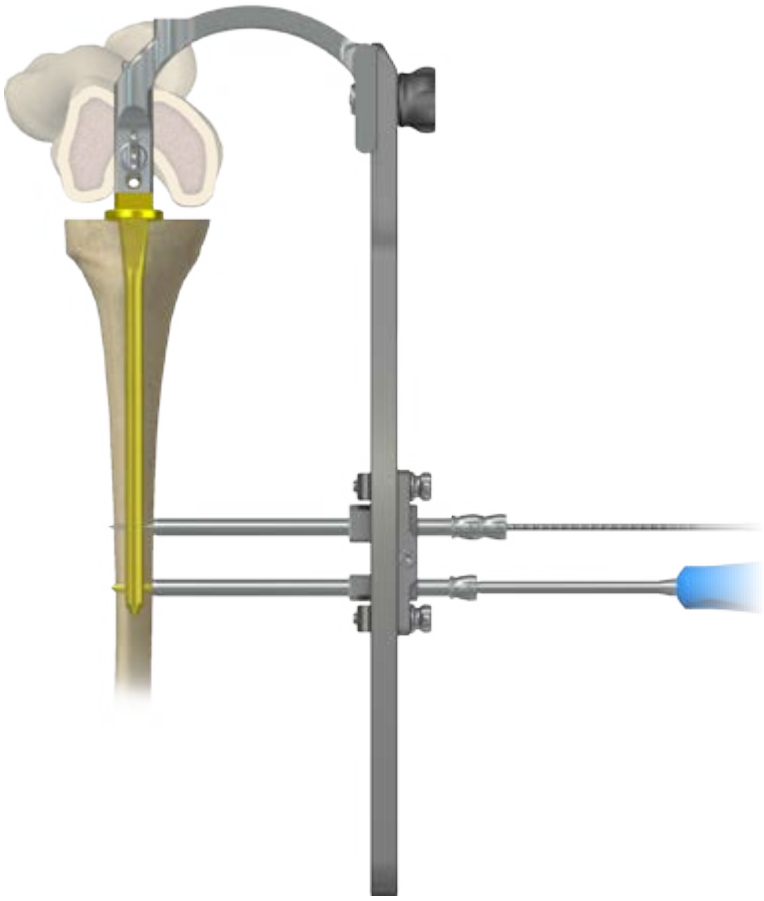
Remove the screw length measure.
Leave the protective guide in place.



Insert the tip of the screwdriver T25 **[40.5575.300]** into the socket of the determined locking screw and then, through the protective guide, into the drilled hole, until the head of the screw reaches the bone *(the mark on the screwdriver shaft shall match the edge of protective guide)*.


40.5575.300


40.5510.300



Remove drill with scale 3.5/350 **[40.5339.002]** and drill guide 7/3.5 **[40.5511.300]** from the other hole of distal tibial targeter **[40.6635]** slider. Leave protective guide 9/7 **[40.5510.300]** in the slider. Insert screw length measure **[40.5530.400]**, through the protective guide, into the drilled hole, until the hook of the measure reaches the *"exit"* plane of the hole.
Read the length of the locking screw on the scale. During measurement, the protective guide should be pressed against the bone.

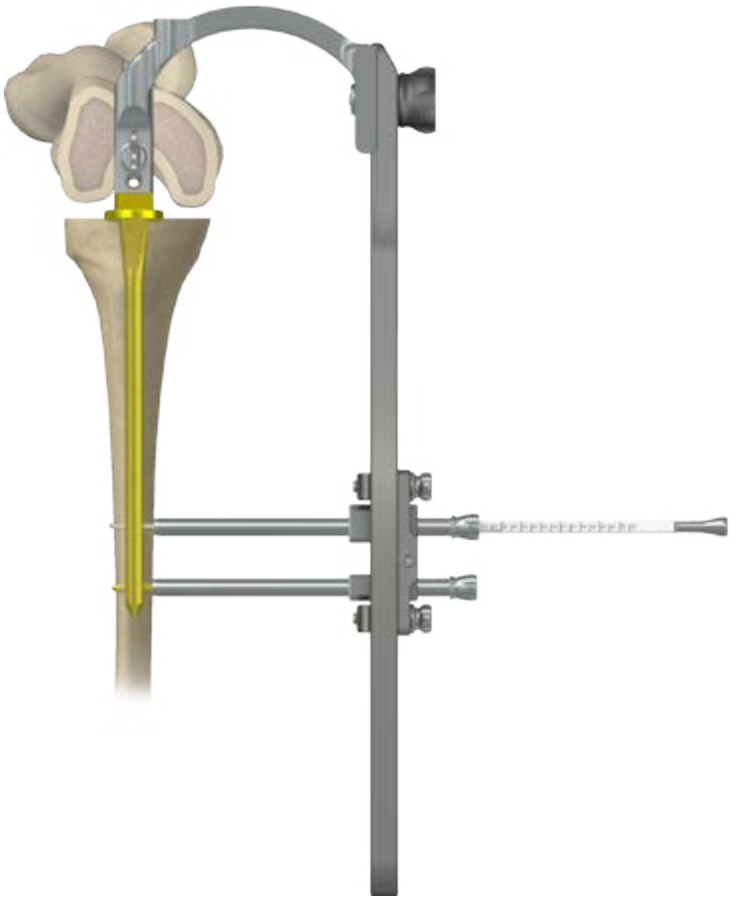
Remove the screw length measure.
Leave the protective guide in place.


40.5339.002

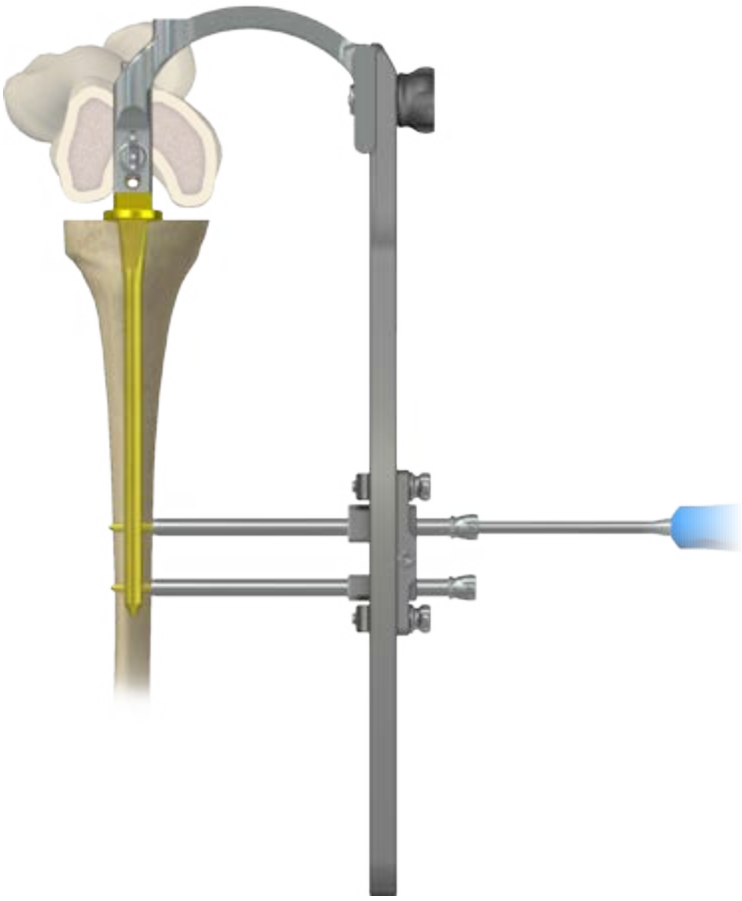

40.5511.300


40.5510.300


40.5530.400

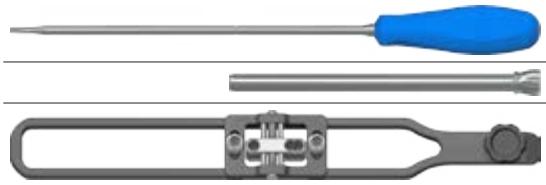


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



Insert the tip of the screwdriver T25 **[40.5575.300]** into the socket of the determined locking screw and then, through the protective guide, into the drilled hole, until the head of the screw reaches the bone *(the mark on the screwdriver shaft shall match the edge of protective guide)*.

Remove the screwdriver and protective guides.
Remove distal tibial targeter **[40.6635]**.



40.5575.300

40.5510.300

40.6635.000

IV.A.3.4. NAIL LOCKING USING "FREE-HAND TECHNIQUE"

The radiological control is necessary to determine the drilling location of the holes and drilling procedure itself.

It is recommended to use an angular drill attachment for drilling holes, so that the operator's hands are outside the direct X-Ray exposure. Mark on the skin the points for drill insertion and perform incisions of soft tissues passing through these points of about 1.5 cm. Use the X-Ray device to position the protective guide short **[40.5871.100]** in relation to the hole in the nail.

The holes in the nail and the protective guide short [40.5871.100] must overlap.

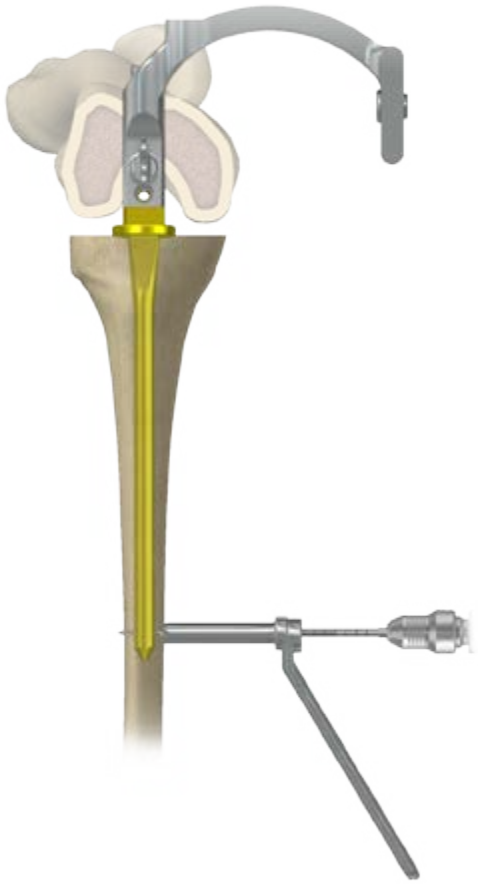
Insert trocar short 7 **[40.1354.200]** into the protective guide short and mark the entry point for the drill.

Remove the trocar short.
The sharp end of the protective guide short should be immersed in the bone.


40.5871.100


40.1354.200

Insert drill guide short **[40.5872.100]** into the protective guide short **[40.5871.100]**. Drill, using drill with the scale 3.5/150 **[40.5343.002]**, a hole that passes through the nail and both cortical layers of the bone. The scale on the drill indicates the length of the locking element.



Remove the drill and drill guide.

The hole drilling should be performed under X-Ray control.


40.5871.100


40.5872.100

40.5343.002

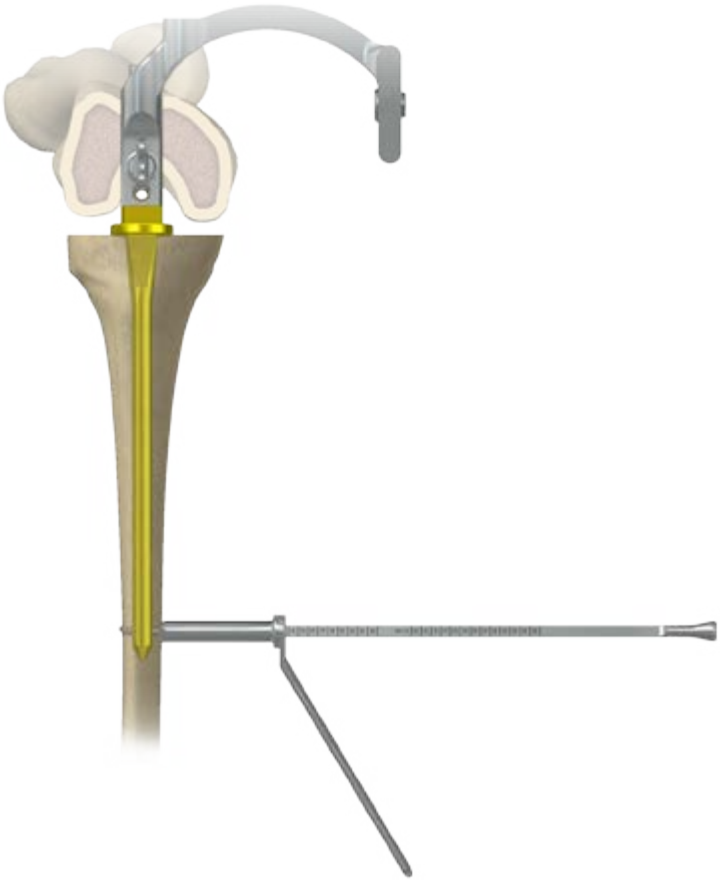
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

Insert, through the protective guide short **[40.5871.100]** and into the drilled hole, the screw length measure **[40.5530.400]**, until the tip of the measure leans against the outer surface of the second cortical layer. Read the length of the locking screw on the scale.

Remove the screw length measure.
Leave the protective guide in place.

40.5871.100

40.5530.400



Insert the tip of the screwdriver T25 **[40.5575.300]** into the socket of the determined locking screw and then, through the protective guide short, into the drilled hole, until the head of the screw reaches the bone.

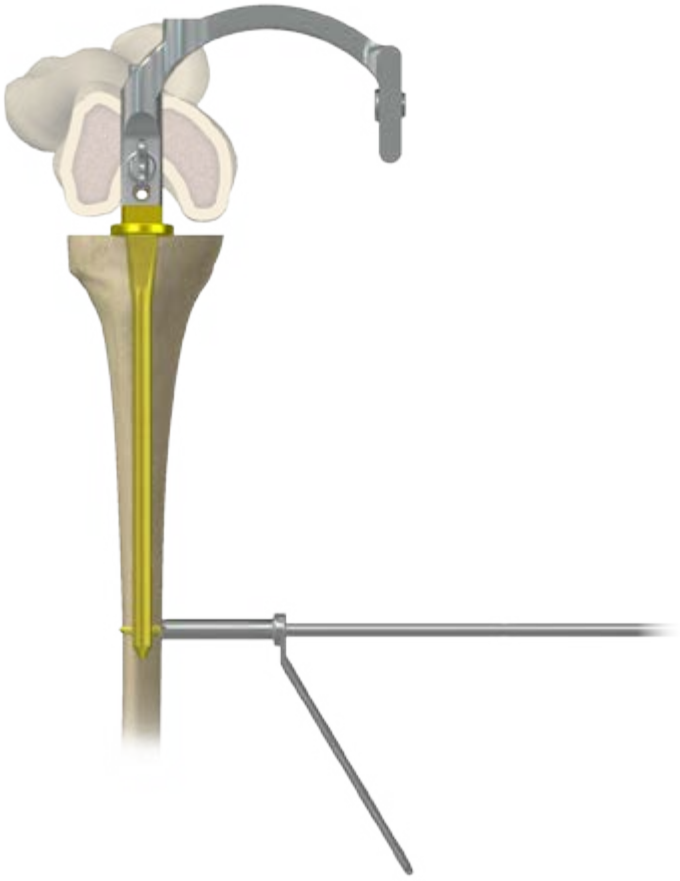
Remove the screwdriver and protective guide.

When locking the other hole, follow the steps of point IV.A.3.4.

Verify, using X-Ray machine, the performed locking in at least two projections.

40.5575.300

40.5871.100



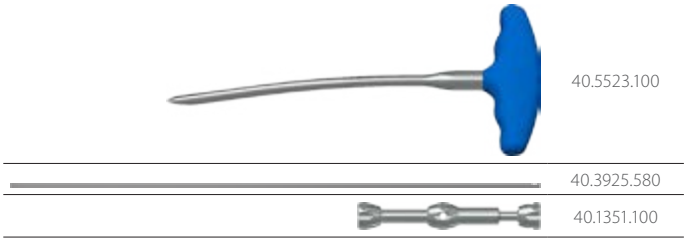
IV.A.4. INSERTION OF CHARFIX2 FN NAIL - FEMUR

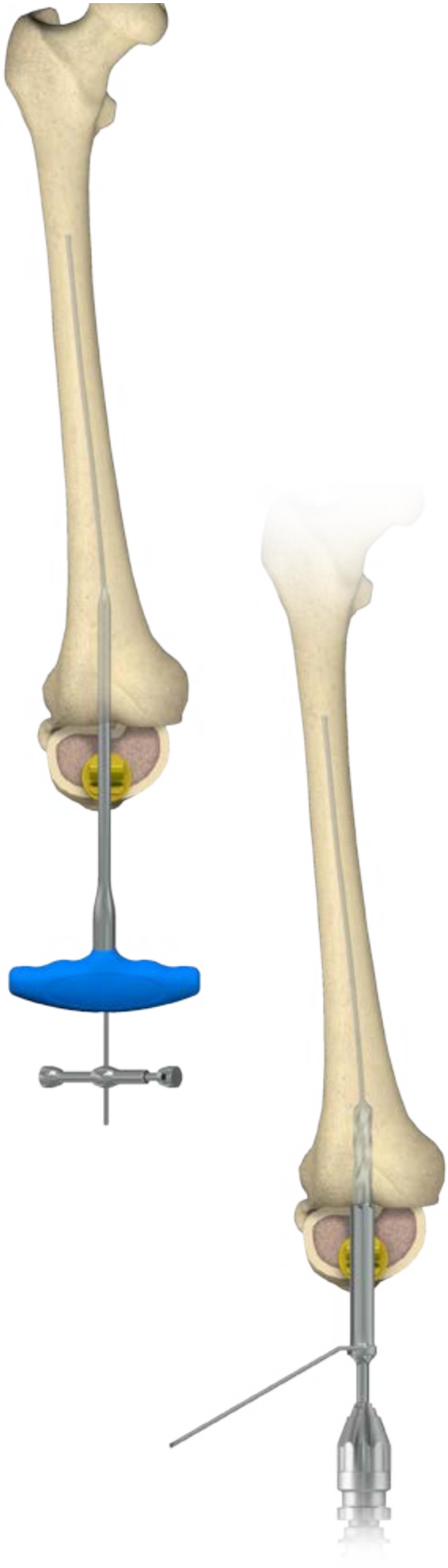
IV.A.4.1. Opening of the medullary canal of the femur

Use the curved awl 8.0 **[40.5523.100]** to open the medullary canal.

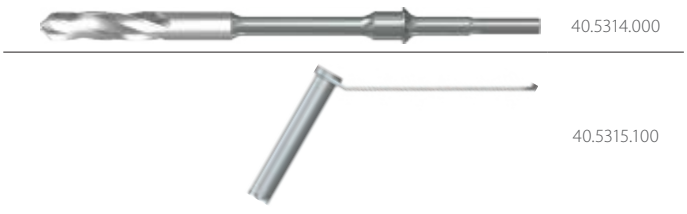
Attach the guide rod 3.0/580 **[40.3925.580]** to the guide rod handle **[40.1351.100]** and using the curved awl, insert into the medullary canal.

Remove the handle and curved awl.



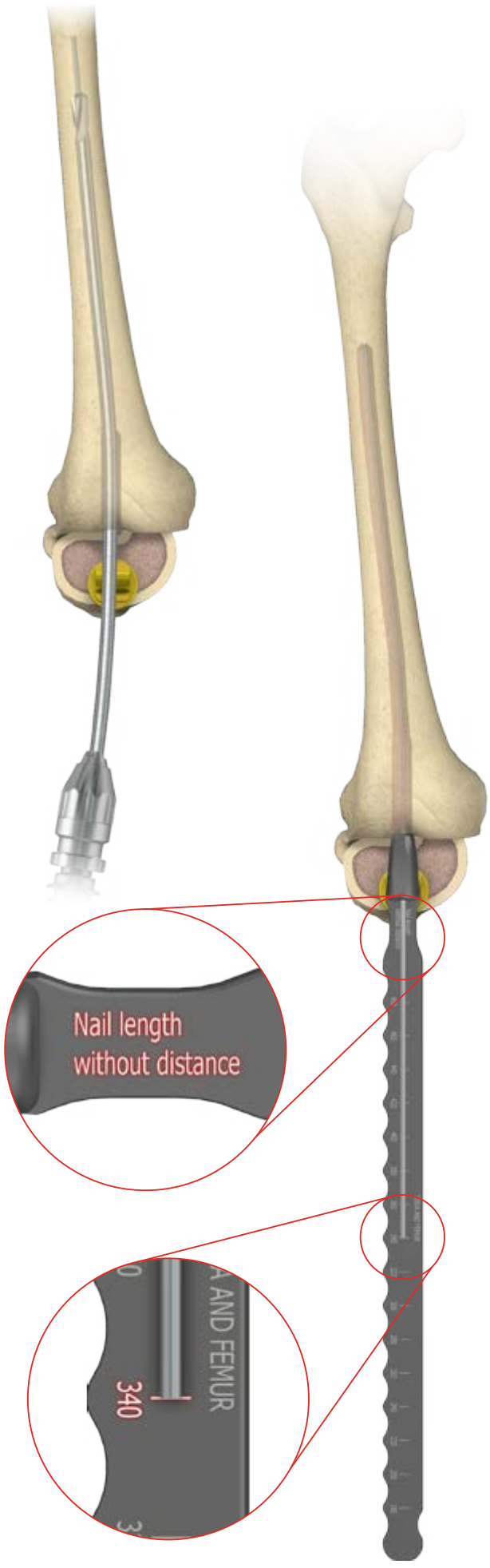


Attach cannulated drill 12/3.0 **[40.5314]** to a drive and using the protective guide **[40.5315.100]**, deepen the entry point in the medullary canal.



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

Afterwards, attach a flexible reamer to the drive. Widen the femoral medullary canal gradually until the canal diameter is 1.0 ÷ 1.5mm larger than the diameter of the selected nail.



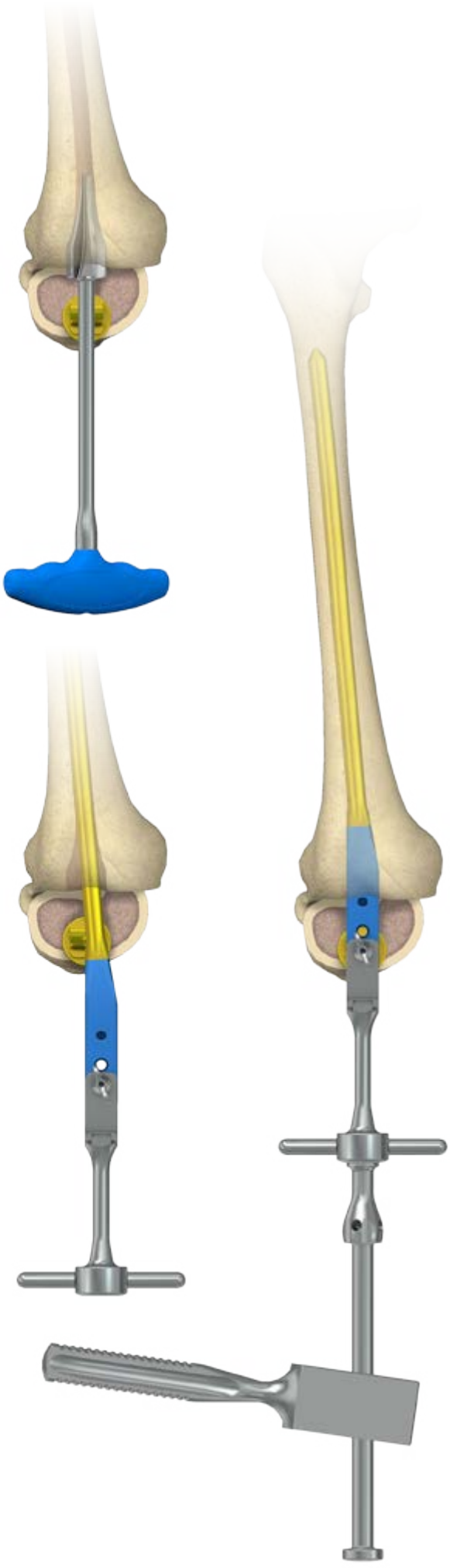
Use the guide rod 3.0/580 **[40.3925.580]** to introduce the nail length measure **[40.6641.000]**.
Use the scale on the measure described as *"Nail length without distance"*. The beginning of the measure should be placed in the nail entry point on the bone. Read the length of the nail on the scale provided.

Remove the measure and guide rod


40.6641.000

Use countersink **[40.6631]** to deepen the entry point to the medullary canal.

40.6631.000



IV.A.4.2. Nail insertion

Attach **CHARFIX2** FN Nail - femur to the handle **[40.6632]** and insert into the medullary canal of the femur.

Should significant resistance be felt, attach the impactor-exctractor **[40.5308.100]** and using the mallet **[40.3667]**, insert the implant into the medullary canal.

40.6632.000

40.5308.100

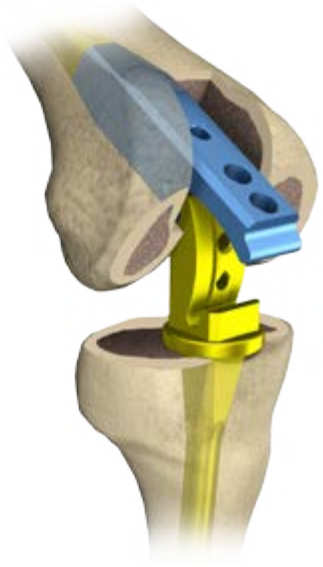
40.3667.000

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

IV.A.5. JOINING CHARFIX2 FN NAIL - FEMUR AND CHARFIX2 FN NAIL - TIBIA

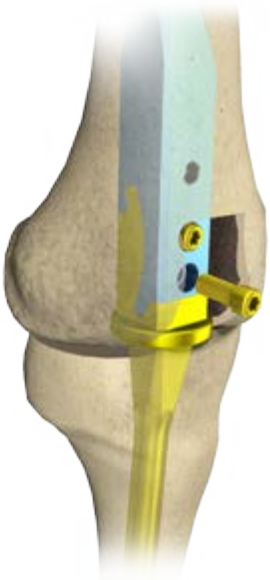
Having inserted both implants, join them the way presented, connecting the tibial with femoral part.

Should there be no access to the holes in the implants, use an oscillating saw to prepare the access *(a "*window") allowing the screws to be inserted to connect the two implants.



Next, lift the tibial part of the limb until both implants are completely joined.

Use **CHARFIX2** FN Screws T **[3.6300]** and screwdriver T25 **[40.5575.300]** to joint the both implants.



After joining the implants, determine the correct length of the operated limb by adjusting the position of the tibial part in relation to the femoral part.

40.5575.300

IV.A.6. CHARFIX2 FN NAIL - FEMUR - DISTAL LOCKING

The radiological inspection is necessary to determine the drilling location and procedure.

For holes drilling, it is recommended to use an angular drill adapter, so that the operator's hands are outside the X-Rays radiation.
Mark on the skin an entry point for the drill and perform soft tissues incision for about 1.5 cm.

Use the X-Ray device to position the protective guide short **[40.5871.100]** in relation to the hole in the nail.

The holes in the nail and the protective guide short [40.5871.100] must overlap.

The protective guide end must be immersed in the bone.
Insert the short trocar 7 **[40.1354.200]** into the protective guide short and mark on the bone the entry point for the drill.

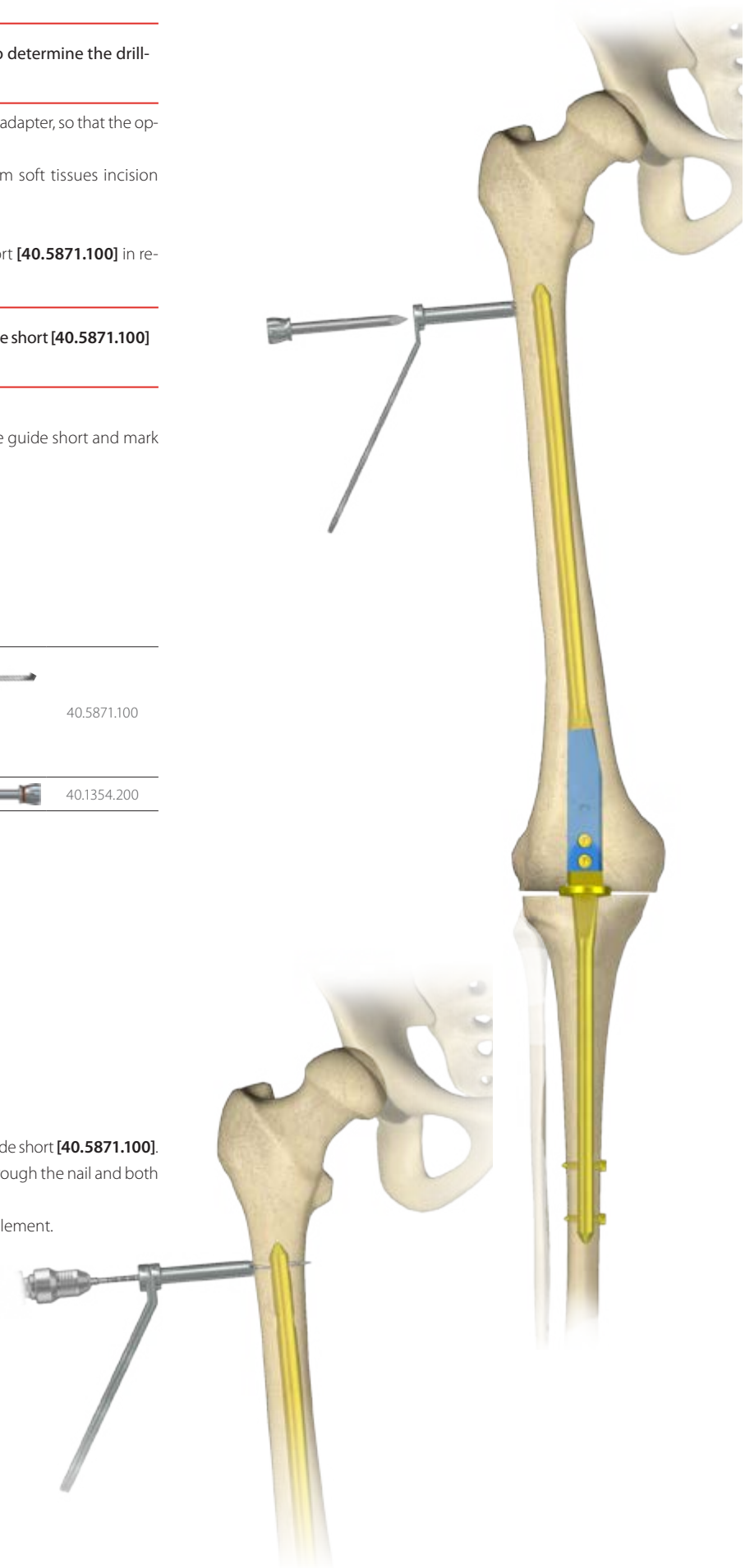
Remove the short trocar.

40.5871.100

40.1354.200

Insert drill guide short **[40.5872.100]** into the protective guide short **[40.5871.100]**.
Use drill with scale 3.5/150 **[40.5343.002]** to drill a hole through the nail and both cortical layers of the bone.
The scale on the drill indicates the length of the locking element.

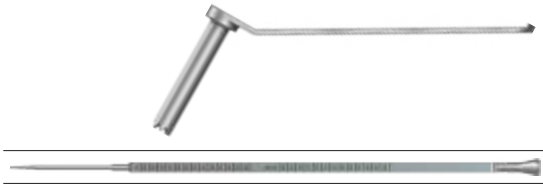
Remove the drill and drill guide.

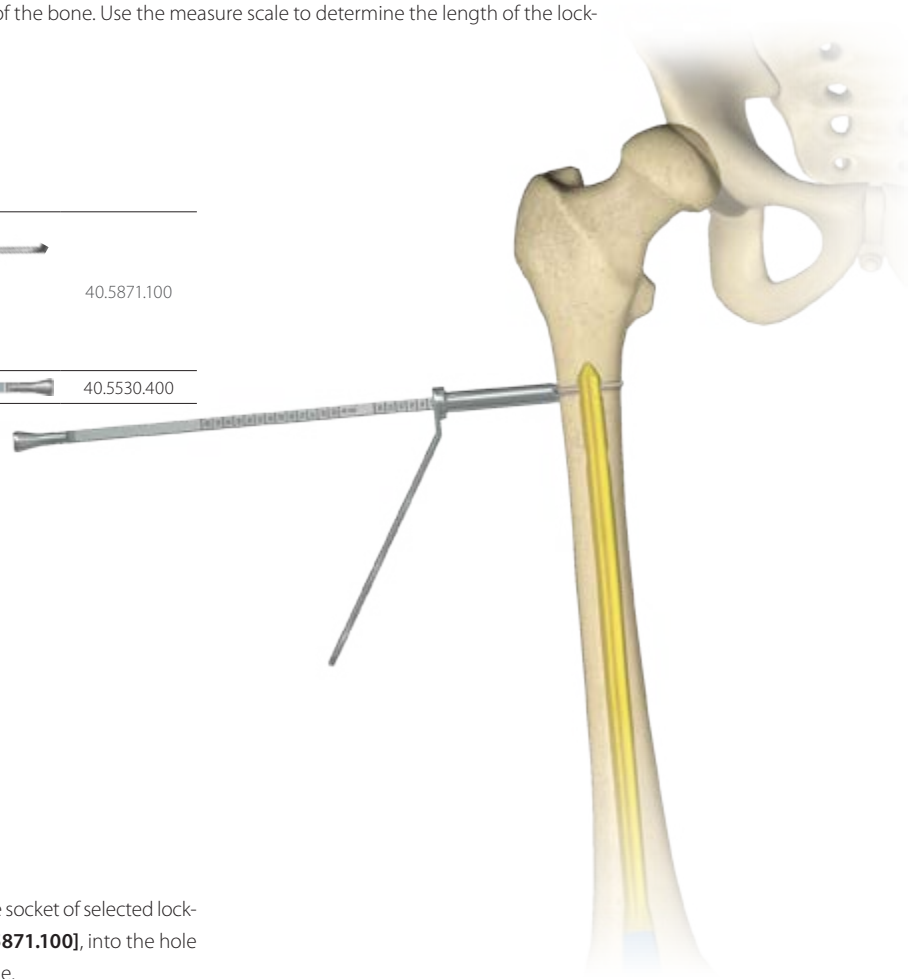


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

Insert the screw length measure **[40.5530.400]**, through the protective guide short **[40.5871.100]**, into the drilled hole, until the hook of the measure leans against the outer surface of the bone. Use the measure scale to determine the length of the locking screw.

Remove the screw length measure.
Leave the protective guide in the place.

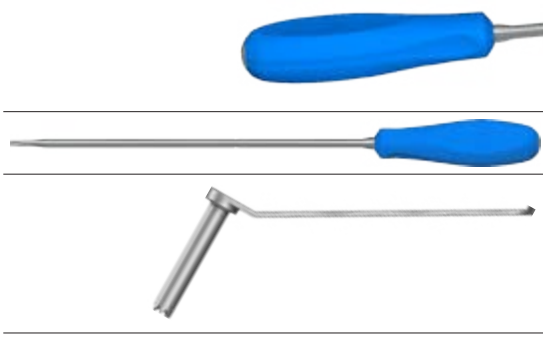


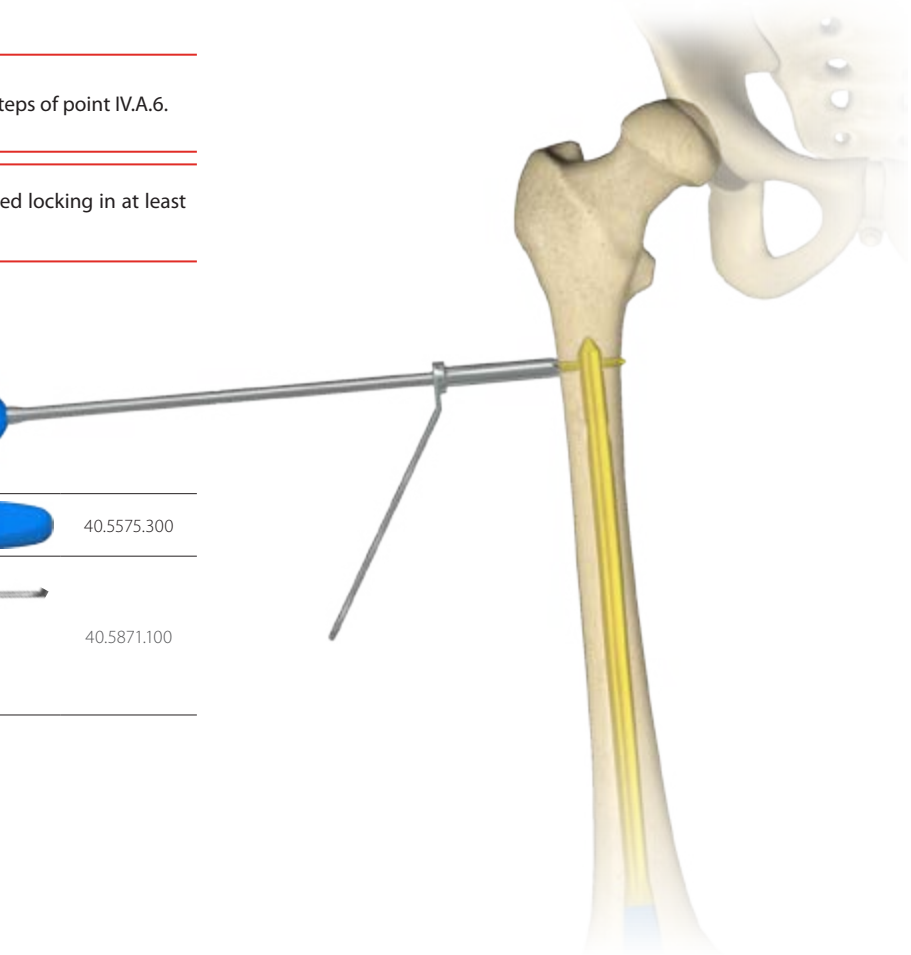


Insert the tip of the screwdriver T25 **[40.5575.300]** into the socket of selected locking screw and then, through protective guide short **[40.5871.100]**, into the hole until the head of the screw reaches the cortex of the bone.
Remove the screwdriver and the protective guide.

When locking the other hole, follow the steps of point IV.A.6.

Verify, using X-Ray machine, the performed locking in at least two projections.





IV.A.7. IMPLANT REMOVAL

Use screwdriver T25 **[40.5575.300]** to remove the screws that lock the two implants.

Use screwdriver T25 **[40.5575.300]** to remove the **CHARFIX2** FN Screws T **[3.6300]** that join the femoral and tibial nail. Disconnect **CHARFIX2** FN Nail - femur and **CHARFIX2** FN Nail - tibia.

Attach the handle **[40.6632]** to **CHARFIX2** FN Nail - femur and then impactor-extractor **[40.5308.100]** to the handle. Use mallet **[40.3667]** to remove the implant from the bone.

Attach the handle **[40.6633]** to **CHARFIX2** FN Nail - tibia and then impactor-extractor **[40.5308.100]** to the handle. Use mallet **[40.3667]** to remove the implant from the bone.

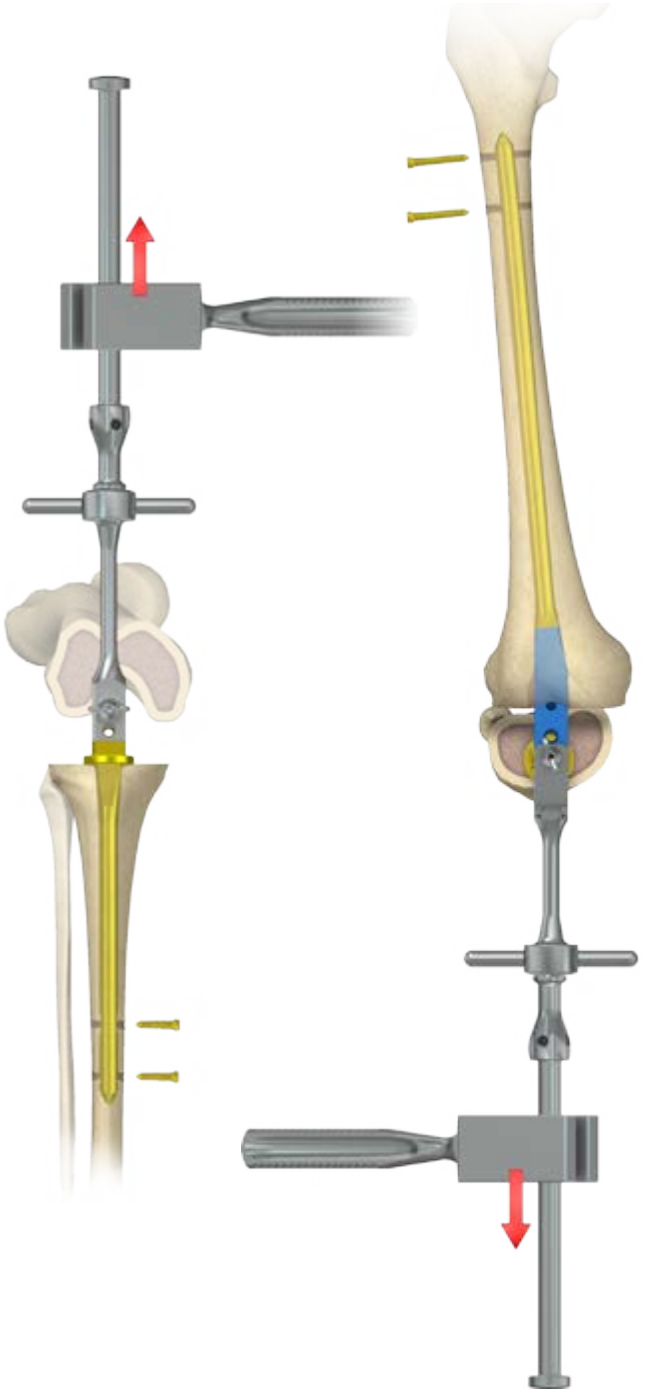

40.5575.300


40.6632.000


40.5308.100


40.3667.000


40.6633.000



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

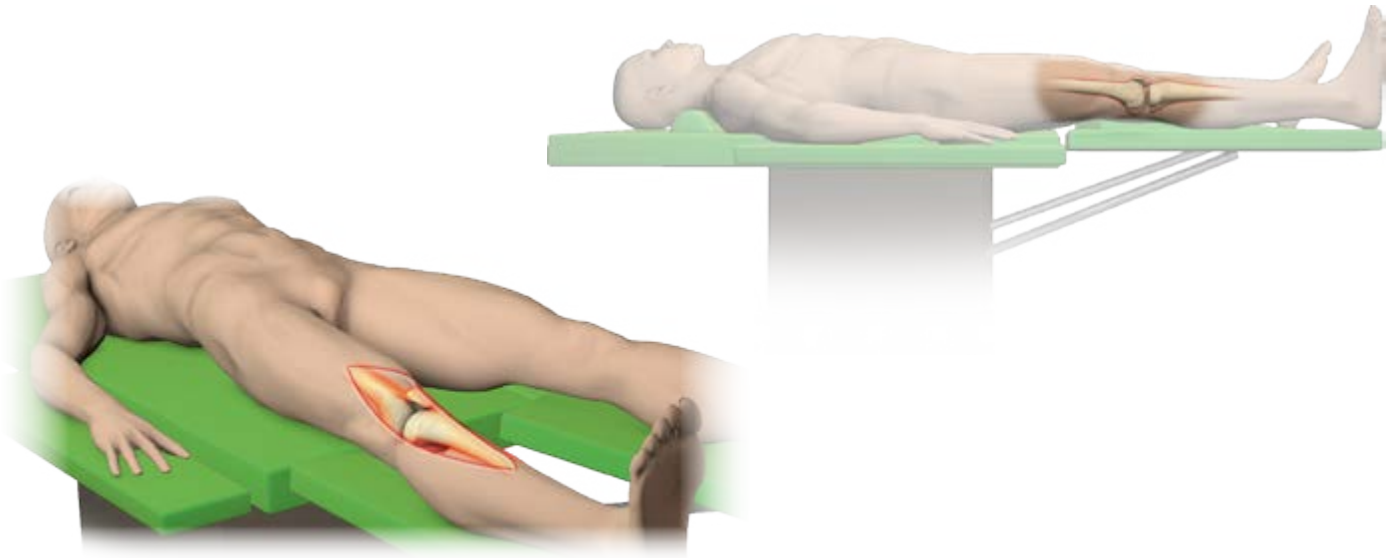
IV.B. WITH KNEE RESECTION

IV.B.1. PATIENT POSITIONING

Place the patient supine with their limb straight.
The surgery must be properly planned.
It is necessary to take X-Ray pictures.

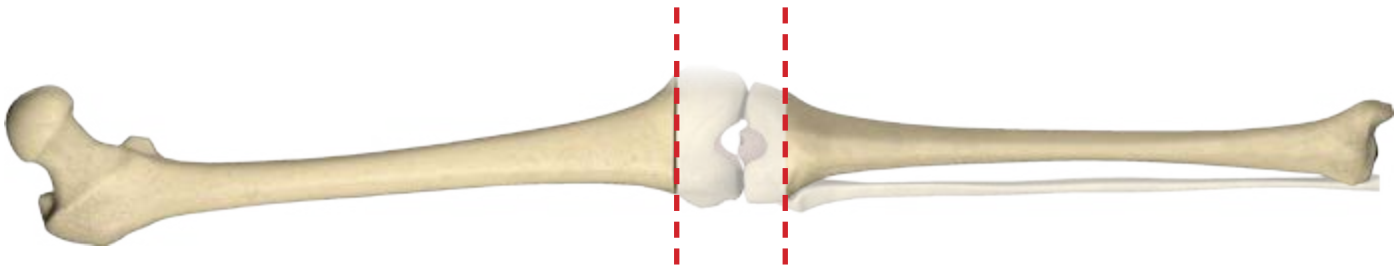
IV.B.2. SURGICAL APPROACH

Make a vertical incision of tissues extending from the region of the femoral condyle to the tibial tuberosity allowing free access to the affected joint.



IV.B.3. KNEE RESECTION

The prosthesis, if has been used, must be removed.
Use a bone saw to cut off the diseased ends of the joint on both the femoral and tibial sides. The saw blade should be led perpendicular to the axis of the bone. Do not lean the saw blade.



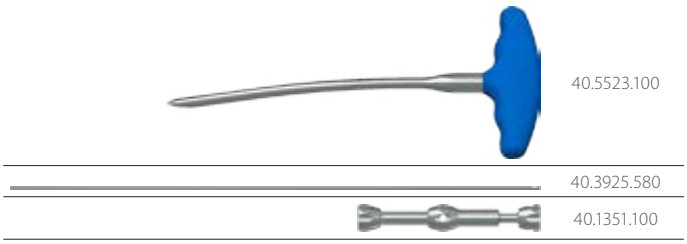
IV.B.4. INSERTION OF CHARFIX2 FN NAIL - TIBIA

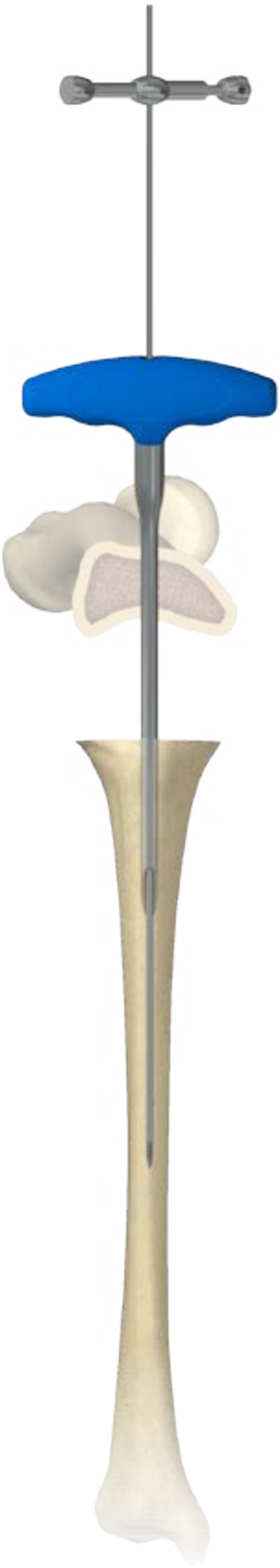
IV.B.4.1. Opening of the medullary canal of the tibia

Use the curved awl 8.0 **[40.5523.100]** to open the medullary canal.

Attach the guide rod 3.0/580 **[40.3925.580]** to the guide rod handle **[40.1351.100]** and using the curved awl, insert into the medullary canal.

Remove the handle and curved awl.



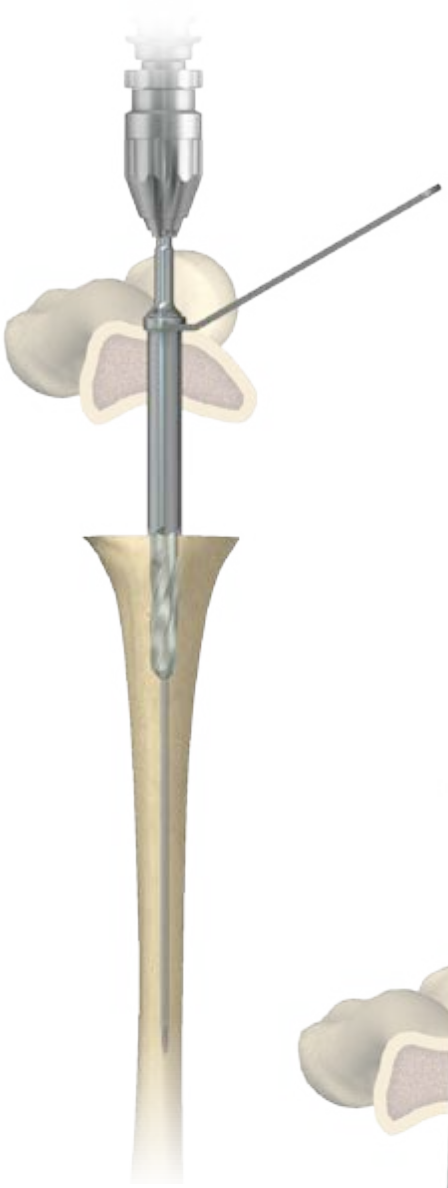


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

Attach cannulated drill 12/3.0 **[40.5314]** to a drive and using the protective guide **[40.5315.100]**, deepen the entry point in the medullary canal.


40.5314.000

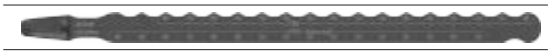

40.5315.000

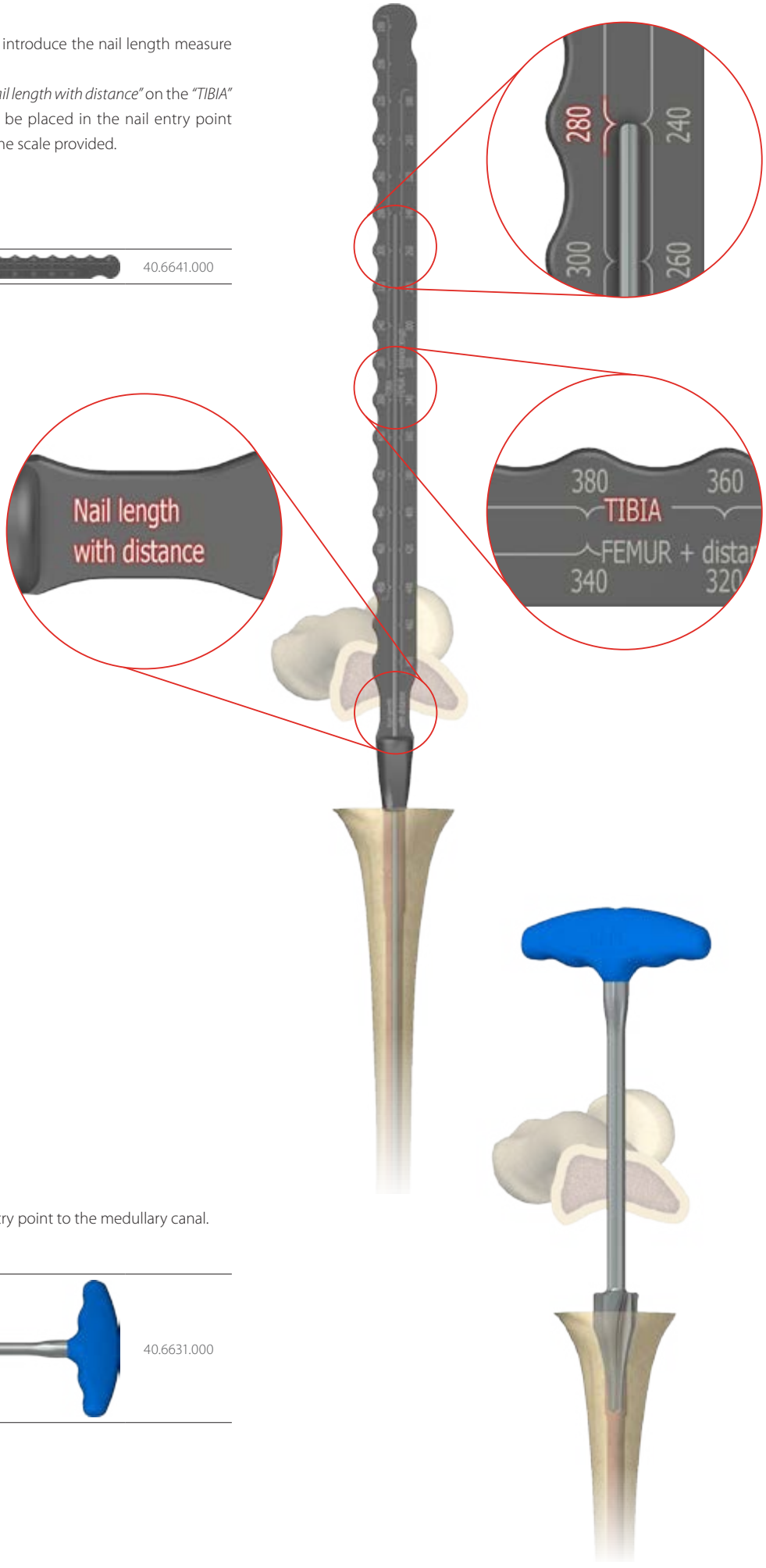


Afterwards, attach a flexible reamer to the drive. Widen the tibial medullary canal gradually until the canal diameter is 1.0 ÷ 1.5mm larger than the diameter of the selected nail.

Use the guide rod 3.0/580 **[40.3925.580]** to introduce the nail length measure **[40.6641]**.
Use the scale on the measure described as *"Nail length with distance"* on the *"TIBIA"* side. The beginning of the measure should be placed in the nail entry point on the bone. Read the length of the nail on the scale provided.

Remove the measure and guide rod


40.6641.000



Use countersink **[40.6631]** to deepen the entry point to the medullary canal.


40.6631.000

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

IV.B.4.2. Targeters assembly

The targeter arm **[40.6634]** can be used with both right and left limb. Use wrench S8 **[40.5304.100]** to loosen the connecting screw of the targeter arm and rotate the targeter arm connector by 180°.

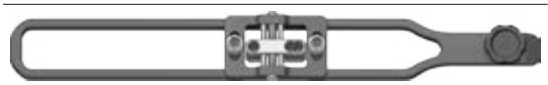
405304.100

IV.B.4.3. Nail insertion

Prior to nail insertion, determine the position of the distal tibial targeter **[40.6635]** in relation to the nail holes. For this purpose, attach **CHARFIX2** FN Nail - tibia to the targeter arm **[40.6634]**. Afterwards, attach the distal tibial targeter to the targeter arm. Using screwdriver T25 **[40.5575.300]**, loosen the locking screws of a slider *(allowing the slider to move)* and move it near the holes in the distal part of the nail.

Determine the correct position of the targeter slider in relation to the nail holes in the distal part using two set blocks 9/5,0 **[40.5509.200]**.
Lock the targeter slider with the screws using screwdriver T25.

Remove set blocks.

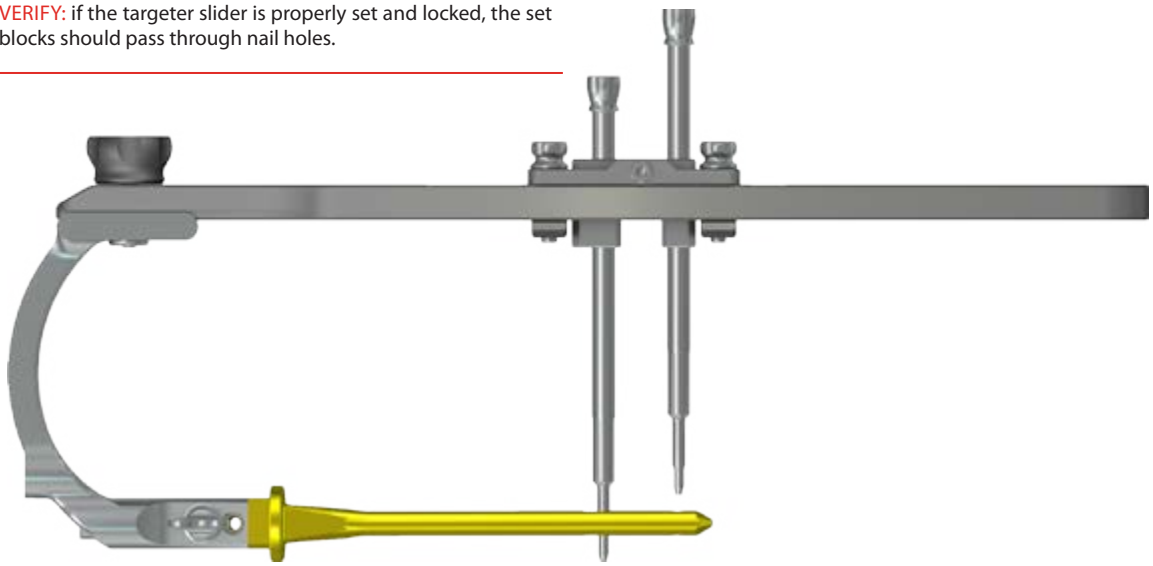


40.6635.000

40.6634.000

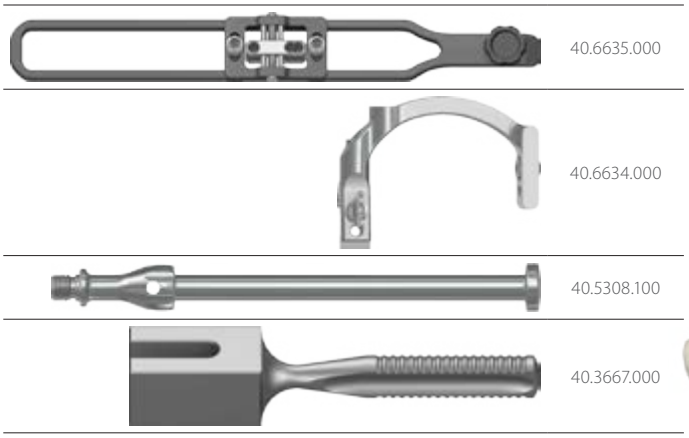
40.5509.200

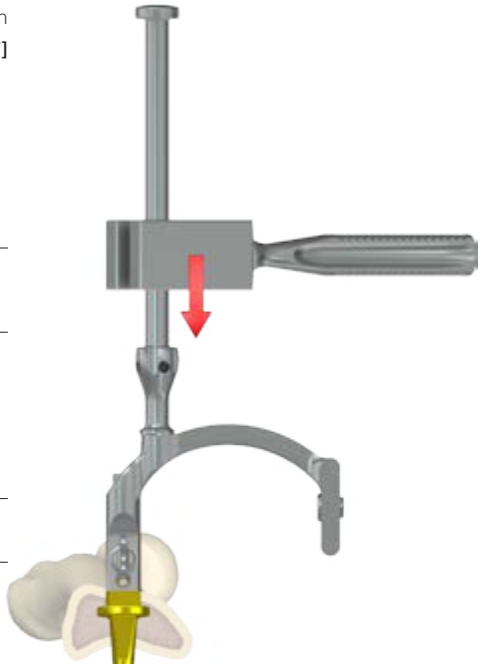
VERIFY: if the targeter slider is properly set and locked, the set blocks should pass through nail holes.



Remove distal tibial trageter **[40.6635]** from the targeter arm **[40.6634]**. Attach impactor-extractor **[40.5308.100]** to the targeter arm. Use the mallet **[40.3667]** to insert the nail into the tibia medullary canal.

Remove impactor-extractor.



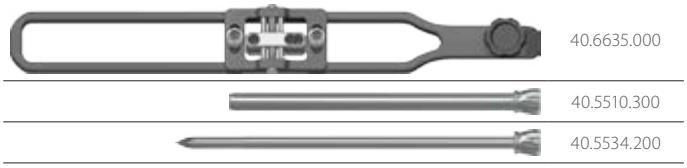


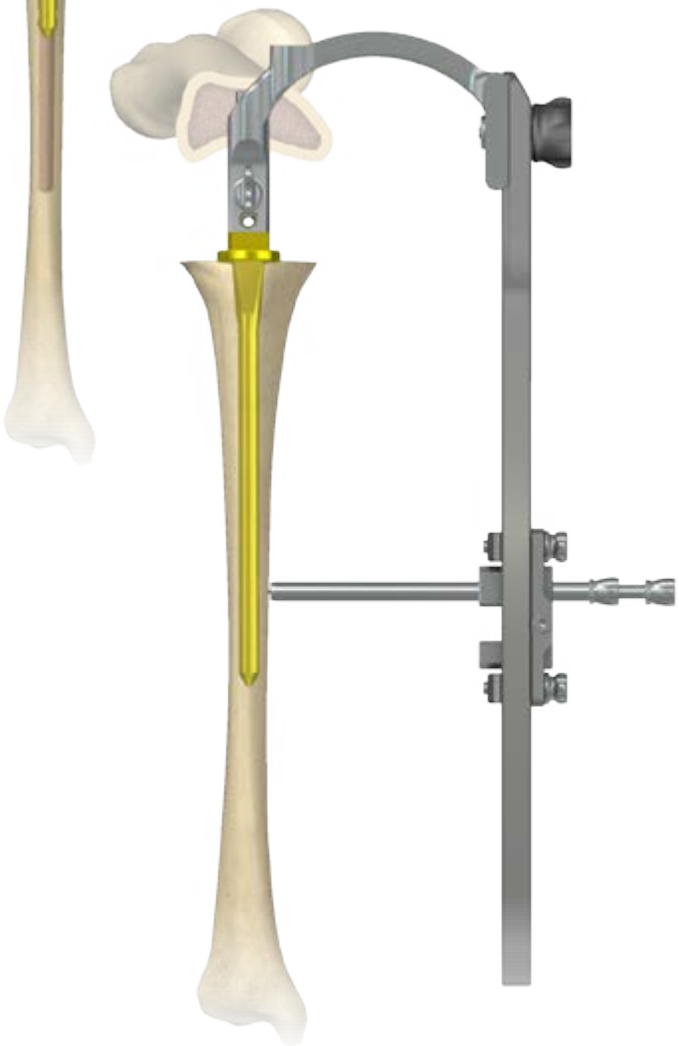
Attach the distal tibial targeter **[40.6635]** to the targeter arm **[40.6634]**.

Insert the protective guide 9/7 **[40.5510.300]** and trocar 6.5 **[40.5534.200]** into the proximal hole of the distal tibial targeter **[40.6635]** slider. Mark the entry point for a locking screw on the skin and make an incision of soft tissues.

Push the protective guide and trocar to the bone and mark the entry point for a drill.

Remove the trocar.





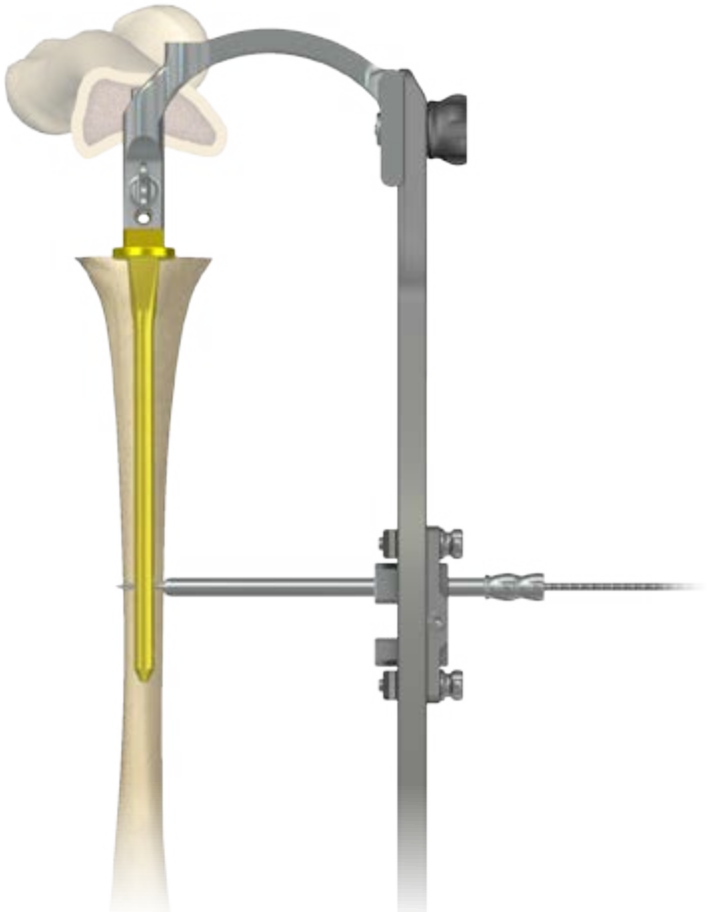
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

Insert the drill guide 7/3.5 **[40.5511.300]** into the protective guide. Use a drive and the drill with scale 3.5/350 **[40.5339.002]**, guided in the drill guide, to drill a hole in the tibia through both cortical layers and the hole in the nail. The scale on the drill indicates the length of the locking element.

Remove the drive, leave the drill with guides in place.


40.5511.300

40.5339.002



Insert the protective guide 9/7 **[40.5510.300]** and trocar 6.5 **[40.5534.200]** into the other hole of the distal tibial targeter **[40.6635]** slider. Mark the entry point for the locking screw on the skin and make the incision of soft tissues.

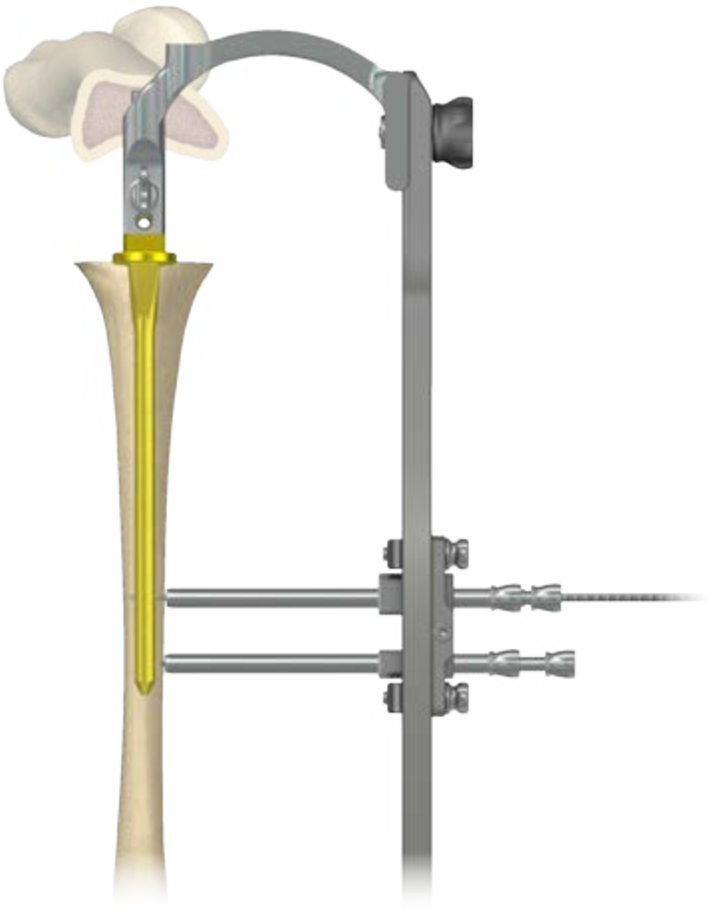
Push the protective guide and trocar to the bone and mark the entry point for the drill.

Remove the trocar.


40.6635.000


40.5510.300


40.5534.200

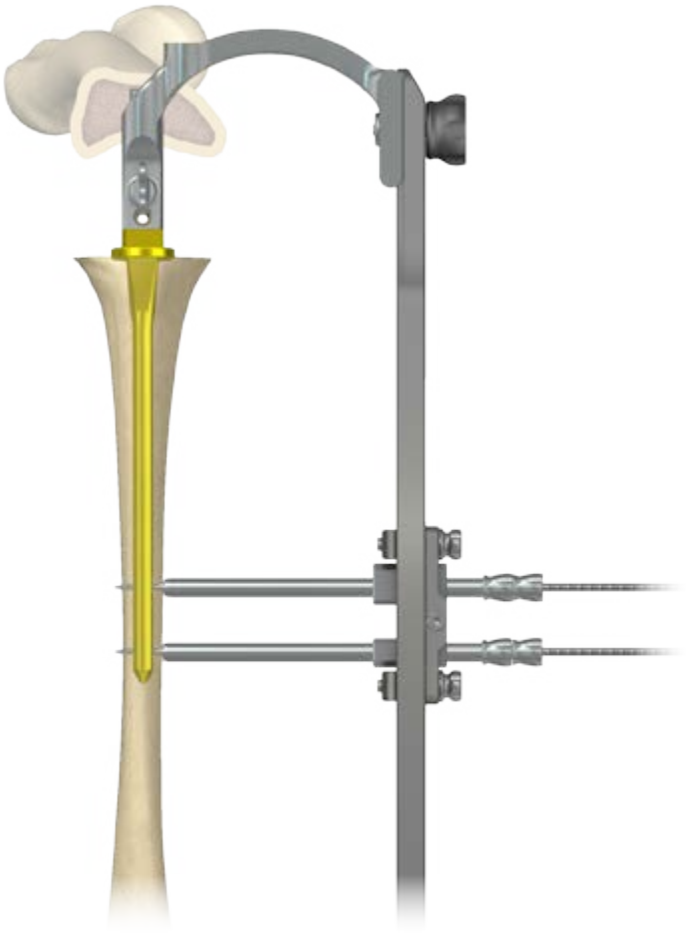


Insert the drill guide 7/3.5 **[40.5511.300]** into the protective guide. Use the drive and the drill with scale 3.5/350 **[40.5339.002]**, guided in the drill guide, to drill a hole in the tibia through both cortical layers and the hole in the nail. The scale on the drill indicates the length of the locking element.

Remove the drill and the drill guide.


40.5511.300


40.5339.002

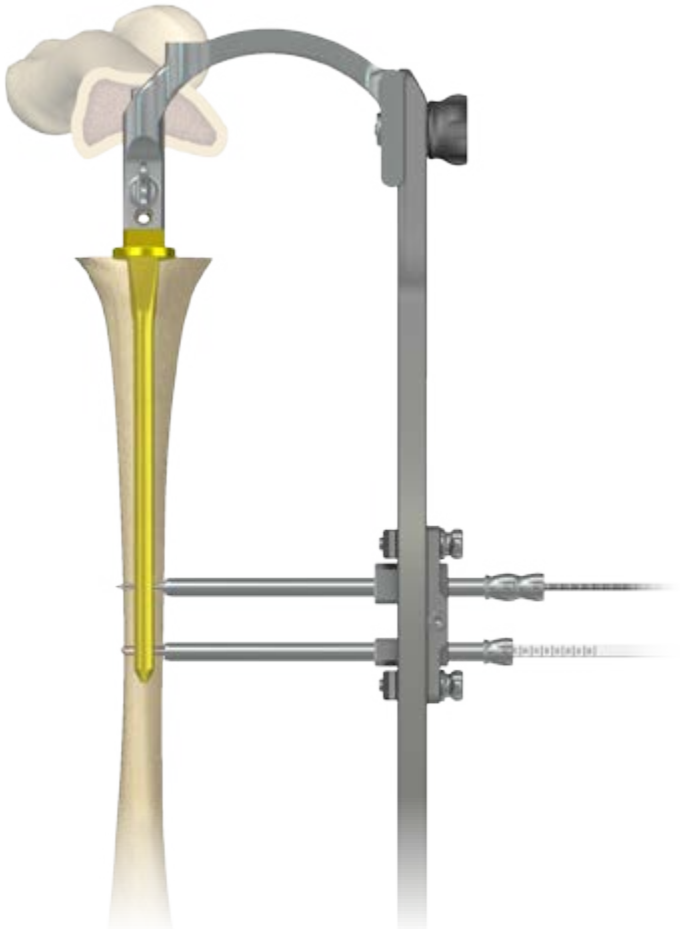


Using the protective guide 9/7 **[40.5510.300]**, insert the screw length measure **[40.5530.400]** into the drilled hole until its hook reaches the *"exit"* plane of the hole. Read the length of the locking screw on the screw. During measurement, the protective guide should be pressed against the bone.

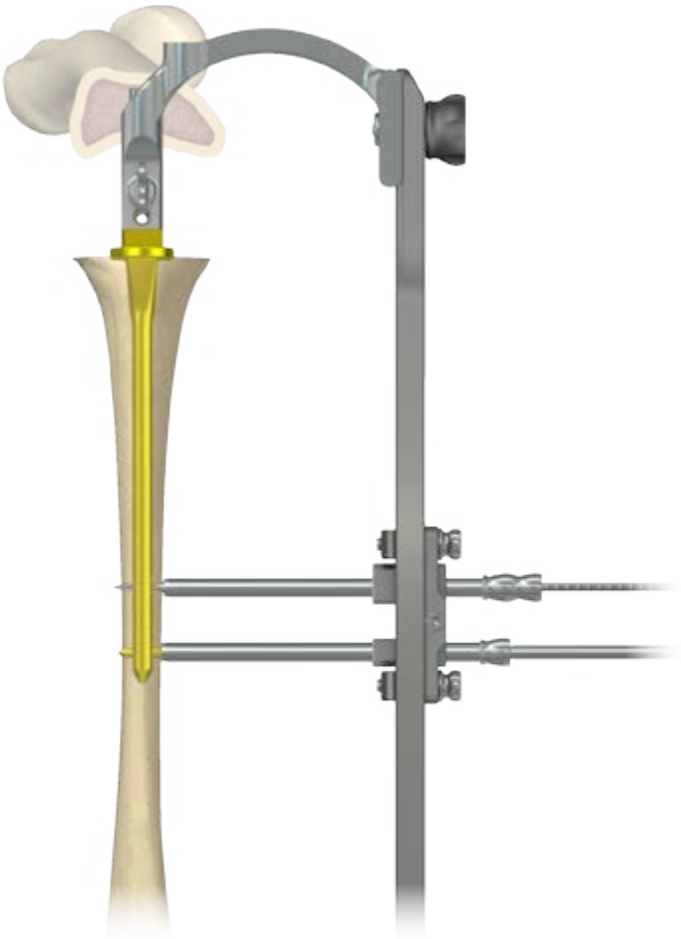
Remove the screw length measure.
Leave the protective guide in place.


40.5510.300

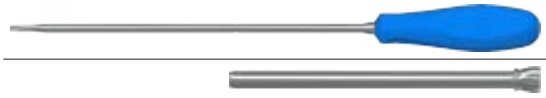

40.5530.400



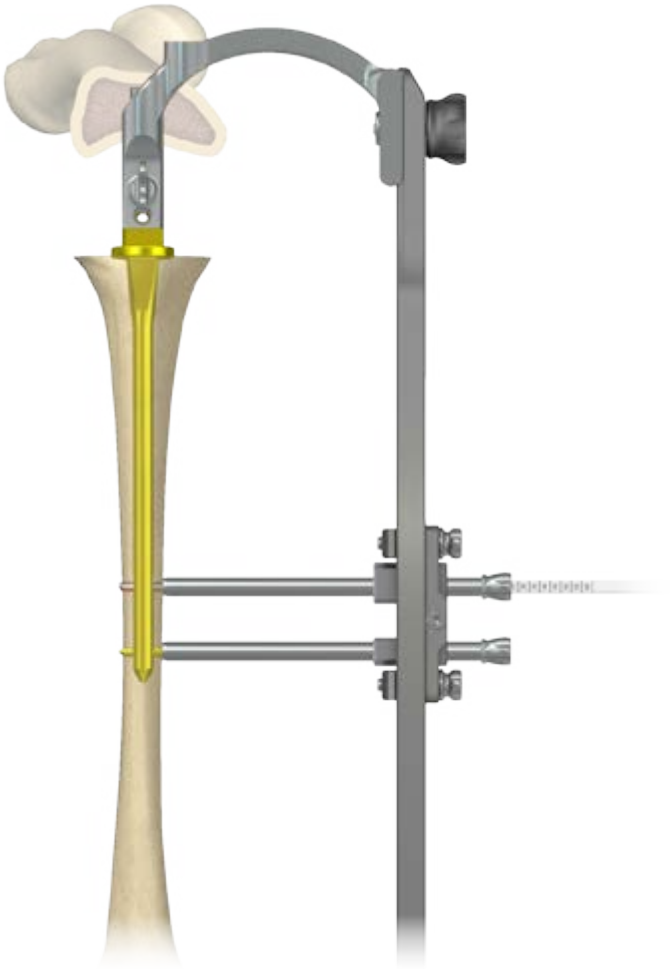
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



Insert the tip of the screwdriver T25 **[40.5575.300]** into the socket of the determined locking screw and then, through the protective guide, into the drilled hole, until the head of the screw reaches the bone *(the mark on the screwdriver shaft shall match the edge of protective guide)*.

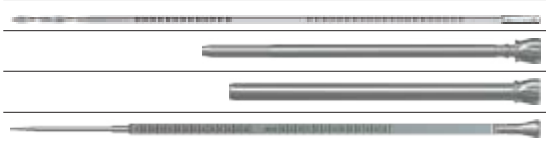


40.5575.300
40.5510.300

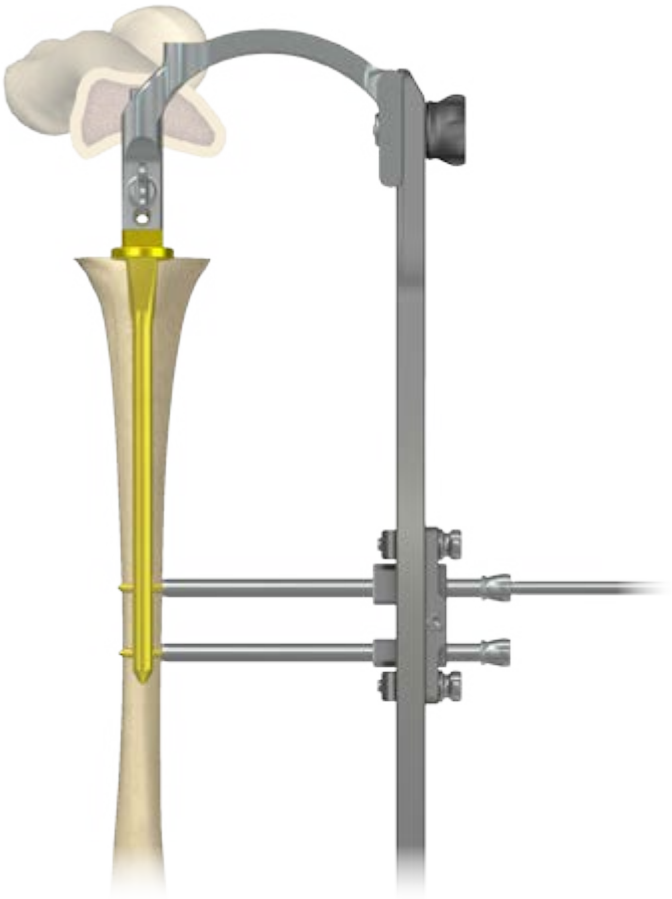


Remove drill with scale 3.5/350 **[40.5339.002]** and drill guide 7/3.5 **[40.5511.300]** from the proximal hole of distal tibial targeter **[40.6635]** slider. Leave protective guide 9/7 **[40.5510.300]** in the slider. Insert screw length measure **[40.5530.400]**, through the protective guide, into the drilled hole, until the hook of the measure reaches the *"exit"* plane of the hole.
Read the length of the locking screw on the scale. During measurement, the protective guide should be pressed against the bone.

Remove the screw length measure.
Leave the protective guide in place.

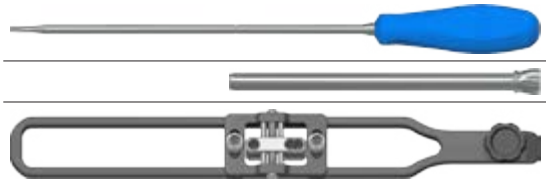


40.5339.002
40.5511.300
40.5510.300
40.5530.400



Insert the tip of the screwdriver T25 **[40.5575.300]** into the socket of the determined locking screw and then, through the protective guide, into the drilled hole, until the head of the screw reaches the bone *(the mark on the screwdriver shaft shall match the edge of protective guide)*.

Remove the screwdriver and protective guides.
Remove distal tibial targeter **[40.6635]**.



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

IV.B.4.4. NAIL LOCKING USING "FREE-HAND TECHNIQUE"

The radiological control is necessary to determine the drilling location of the holes and drilling procedure itself.

It is recommended to use an angular drill attachment for drilling holes, so that the operator's hands are outside the direct X-Ray exposure. Mark on the skin the points for drill insertion and perform incisions of soft tissues passing through these points of about 1.5 cm. Use the X-Ray device to position the protective guide short **[40.5871.100]** in relation to the hole in the nail.

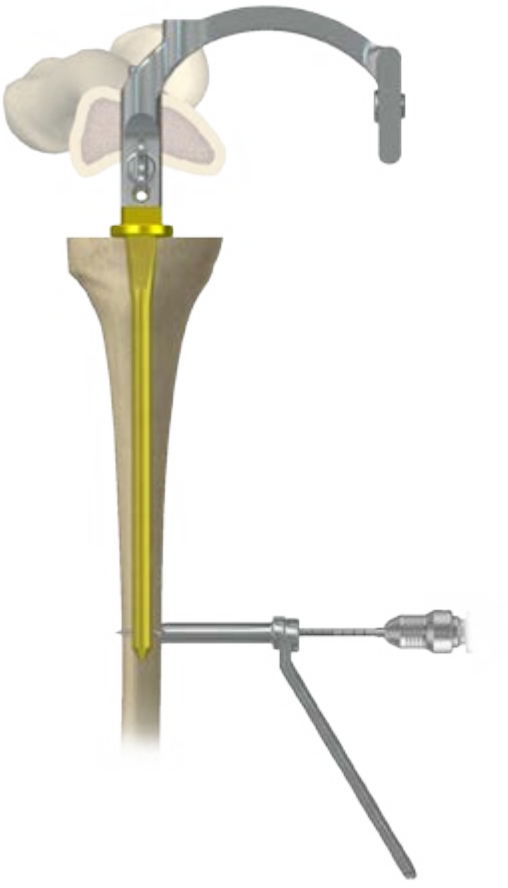
The holes in the nail and the protective guide short **[40.5871.100]** must overlap.

The sharp end of the protective guide short should be immersed in the bone. Insert trocar short 7 **[40.1354.200]** into the protective guide short and mark the entry point for the drill.

Remove the trocar short.

40.5871.100

40.1354.200



Insert drill guide short **[40.5872.100]** into the protective guide short **[40.5871.100]**. Drill, using drill with the scale 3.5/150 **[40.5343.002]**, a hole that passes through the nail and both cortical layers of the bone. The scale on the drill indicates the length of the locking element.

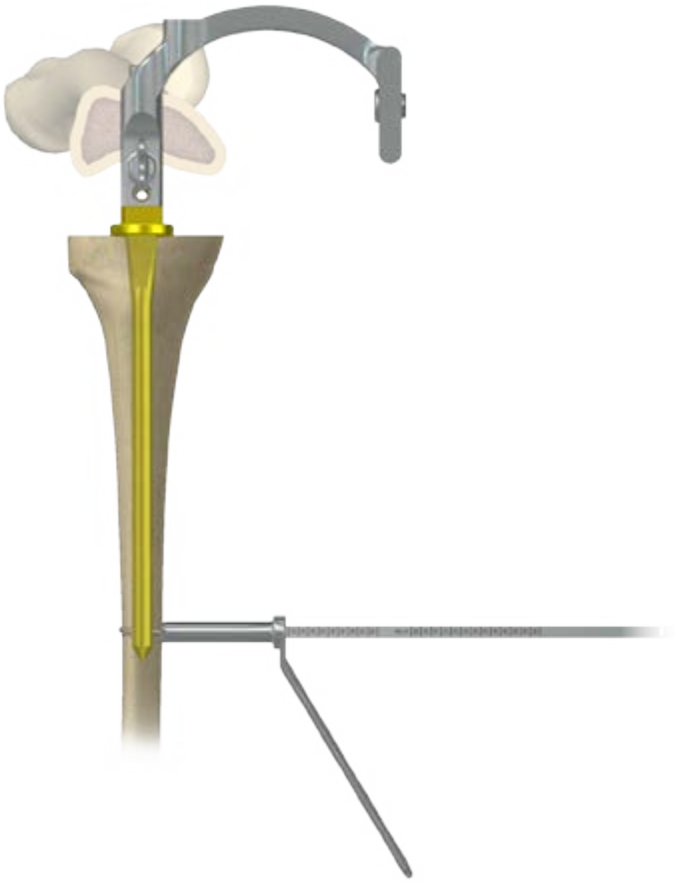
Remove the drill and drill guide.

The hole drilling should be performed under X-Ray control.

40.5871.100

40.5872.100

40.5343.002

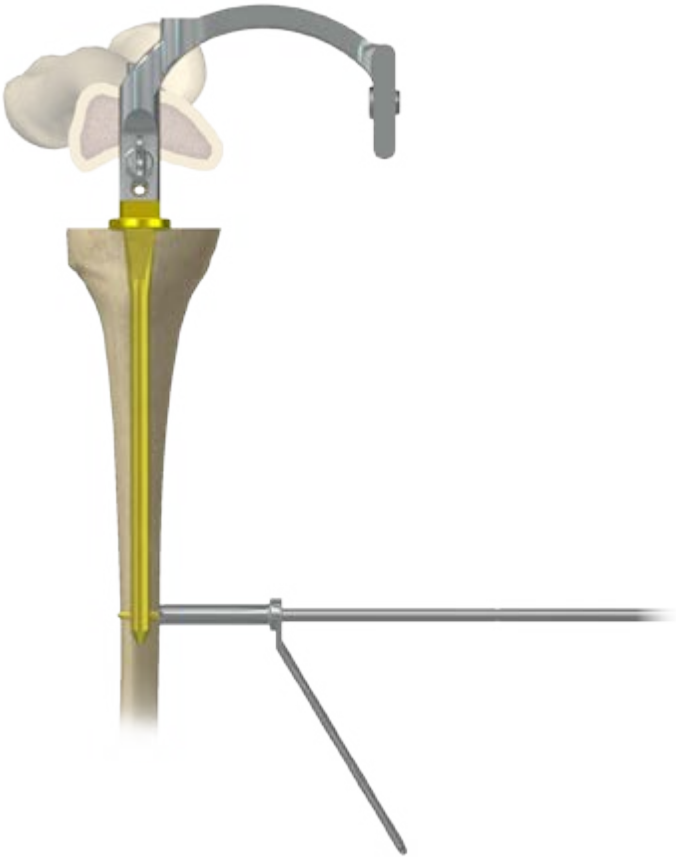


Insert, through the protective guide short **[40.5871.100]** and into the drilled hole, the screw length measure **[40.5530.400]**, until the hook of the measure reaches the *"exit"* plane of the hole. Read the length of the locking screw on the scale.

Remove the screw length measure.
Leave the protective guide in place.

40.5871.100

40.5530.400



Insert the tip of the screwdriver T25 **[40.5575.300]** into the socket of the determined locking screw and then, through the protective guide short, into the drilled hole, until the head of the screw reaches the bone.

Remove the screwdriver and protective guide.

When locking the other hole, follow the steps of point IV.B.4.4.

Verify, using X-Ray machine, the performed locking in at least two projections.

40.5575.300

40.5871.100

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

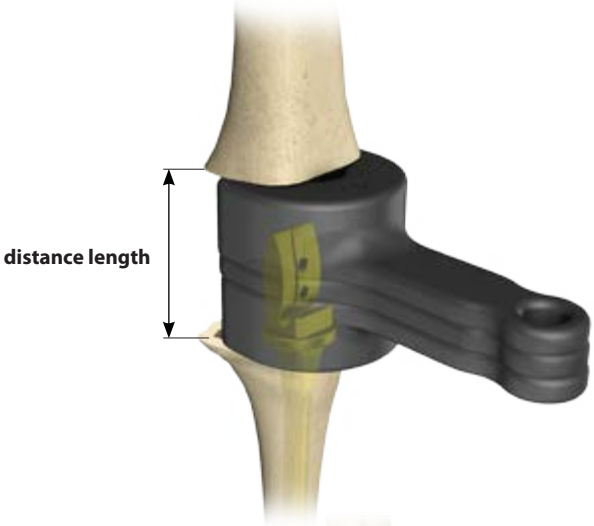
IV.B.5. INSERTION OF CHARFIX2 FN NAIL - FEMUR

IV.B.5.1. Initial CHARFIX2 FN Spacer selection

Before opening the medullary canal of the femur, the length of the spacer should be pre-selected.

Insert trials 10; 20; 30 **[40.6638÷40.6640]** to determine the distance between the femur and the tibia and correct length of the limb.

Remove trials.

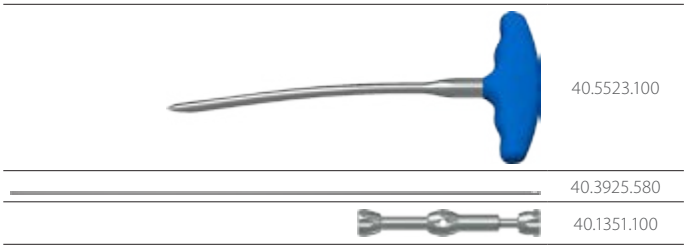


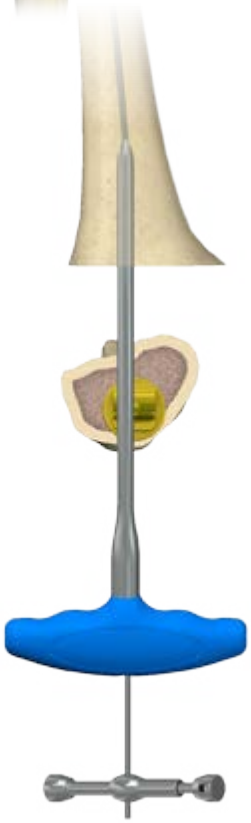
IV.B.5.2. Opening of the medullary canal of the femur

Use the curved awl 8.0 **[40.5523.100]** to open the medullary canal.

Attach the guide rod 3.0/580 **[40.3925.580]** to the guide rod handle **[40.1351.100]** and using the curved awl, insert into the medullary canal.

Remove the handle and curved awl.





Attach cannulated drill 12/3.0 **[40.5314]** to the drive and using the protective guide **[40.5315.100]**, deepen the entry point in the medullary canal.


40.5314.000


40.5315.100

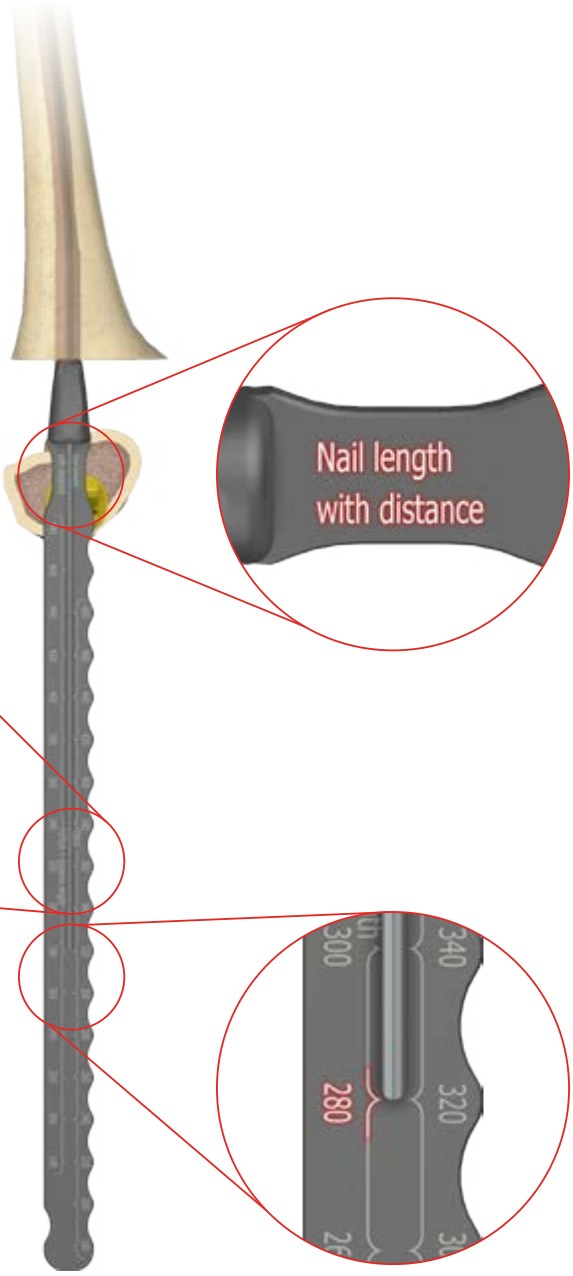
Afterwards, attach the flexible reamer to the drive. Widen the femoral medullary canal gradually until the canal diameter is 1.0 ÷ 1.5mm larger than the diameter of the selected nail.

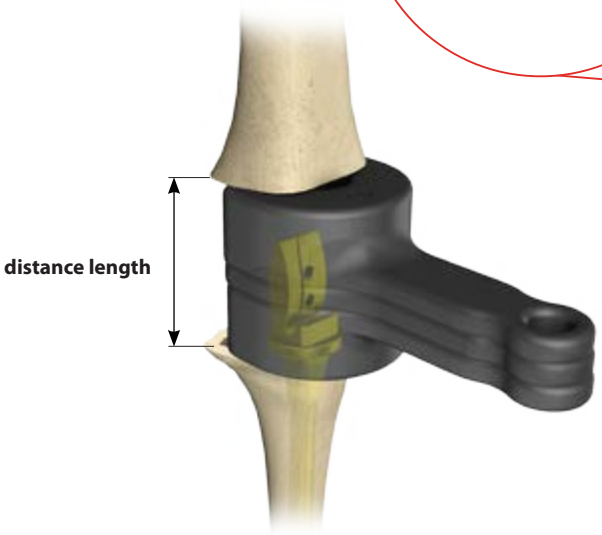
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

Use the guide rod 3.0/580 **[40.3925.580]** to introduce the nail length measure [40.6641,000].
Use the scale on the measure described as *"Nail length with distance"* at *"FEMUR+distance length"* side of the measure. The beginning of the measure should be placed in the nail entry point on the bone. Read the length of the nail on the scale provided.
To determine the length of **CHARFIX2** FN Nail - femur, add the length of the pre-selected **CHARFIX2** FN Spacer to the indicated by the guide rod value on the scale *(step IV.B.5.1)*.

Remove the measure and guide rod.

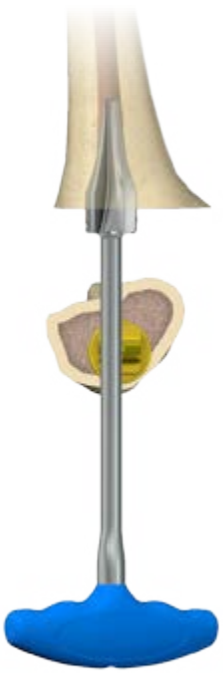

40.6641.000





Use countersink **[40.6631]** to deepen the entry point to the medullary canal.


40.6631.000

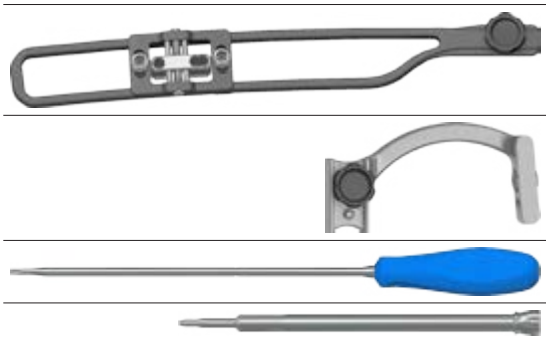


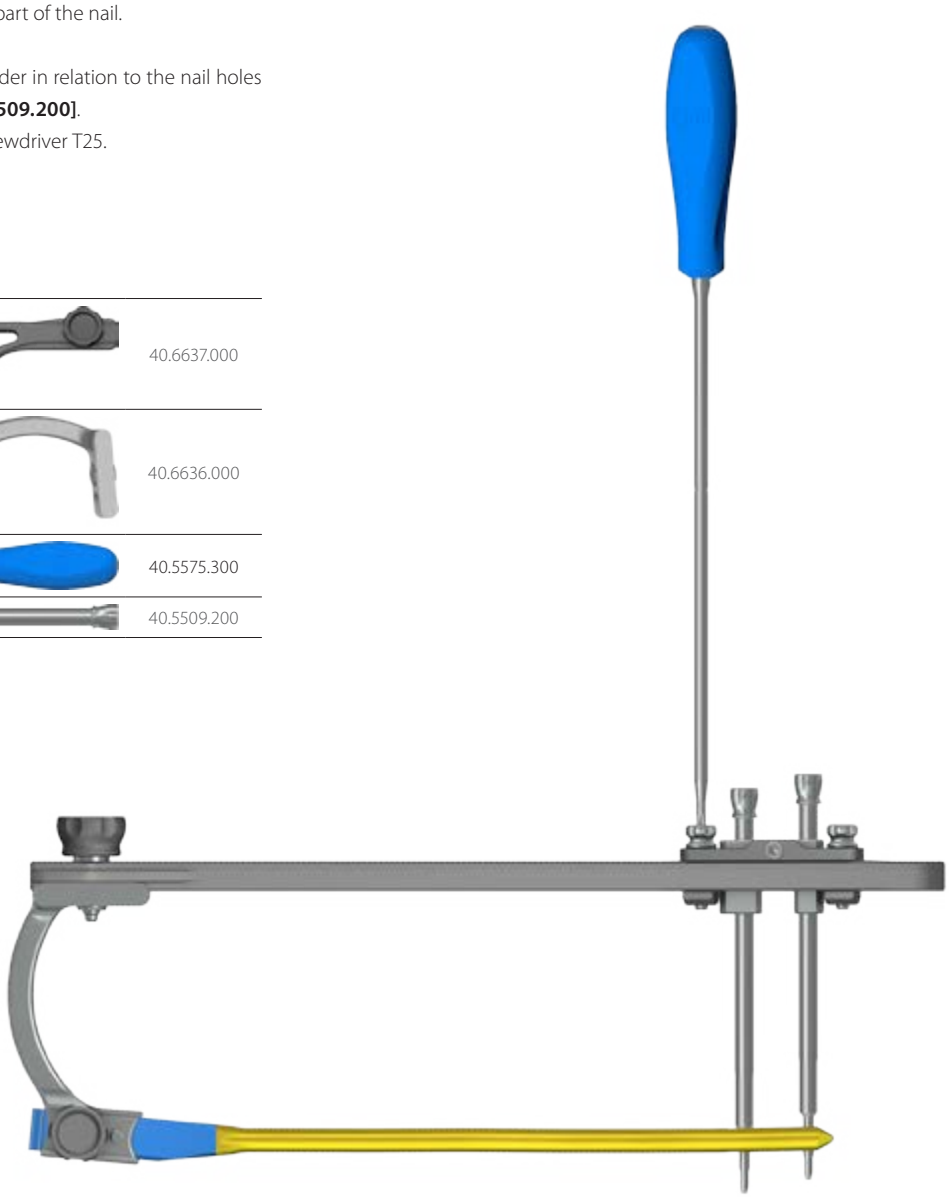
IV.B.5.3. Nail insertion

Prior to nail insertion, determine the position of the slider of the distal targeter **[40.6637]** in relation to the nail holes.
Attach **CHARFIX2** FN Nail - femur to the targeter arm **[40.6636]**. Using screwdriver T25 **[40.5575.300]**, loosen the locking screws of the slider *(allowing the slider to move)* and move it near the holes in the distal part of the nail.

Determine the correct position of the targeter slider in relation to the nail holes in the distal part using two set blocks 9/5,0 **[40.5509.200]**.
Lock the targeter slider with the screws using screwdriver T25.

Remove set blocks.





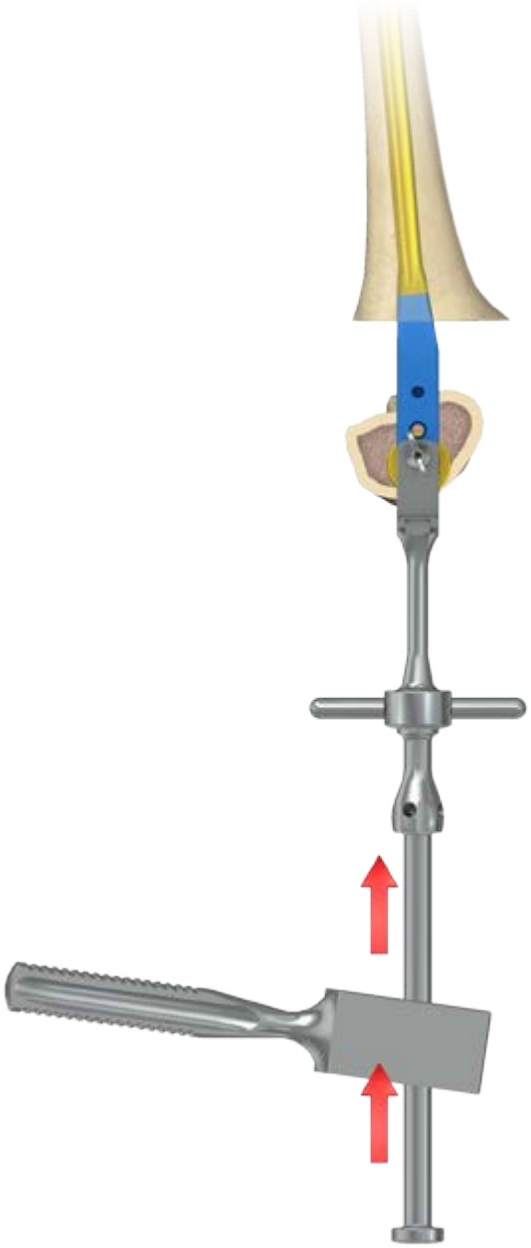
VERIFY: if the targeter slider is properly set and locked, the set blocks should pass through nail holes.

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

Remove distal trageter **[40.6637]** from the targeter arm **[40.6634]**.

Attach the handle **[40.6632]** to **CHARFIX2** FN Nail - femur.

	40.6637.000
	40.6636.000
	40.6632.000

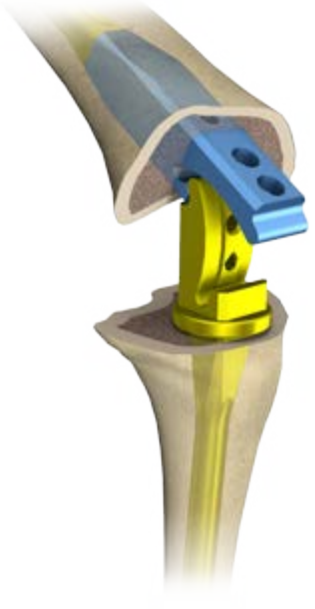


Attach impactor-extractor **[40.5308.100]** to the handle. Use mallet **[40.3667]** to insert the implant into the bone.

Remove the handle and impactor-extractor from the nail.

	40.6632.000
	40.5308.100
	40.3667.000

IV.B.6. JOINING CHARFIX2 FN NAIL - FEMUR AND CHARFIX2 FN NAIL - TIBIA



Having inserted both implants, join them the way presented, connecting the tibial with femoral part.

If the both implant cannot be joined due to the lack of a proper distance between them, this distance should be adjusted by maneuvering **CHARFIX2** FN Nail - femur. Attache the handle **[40.6632]** to the implant and move it back or forth.

When both implants are connected, insert **CHARFIX2** FN Screws T **[3.6300]**. Use the screwdriver T25 **[40.5575.300]** and insert the screw into the first hole from the tibia. The other hole will be used by the targeter - leave it empty.

If locking of the nail is performed using *"free hand"* technique, two **CHARFIX2** FN Screws T **[3.6300]** should be inserted.

40.6632.000

40.5575.300

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

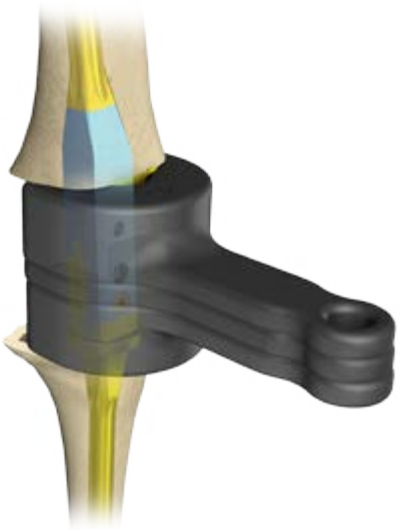
IV.B.7. CHARFIX2 FN SPACER INSERTION AND CHARFIX2 FN NAIL - FEMUR LOCKING

Use trials 10, 20 and 30 **[40.6638÷40.6640]** to determine the distance between the femoral and tibial bones. Determine the correct length of the limb.

40.6638.000

40.6639.000

40.6640.000

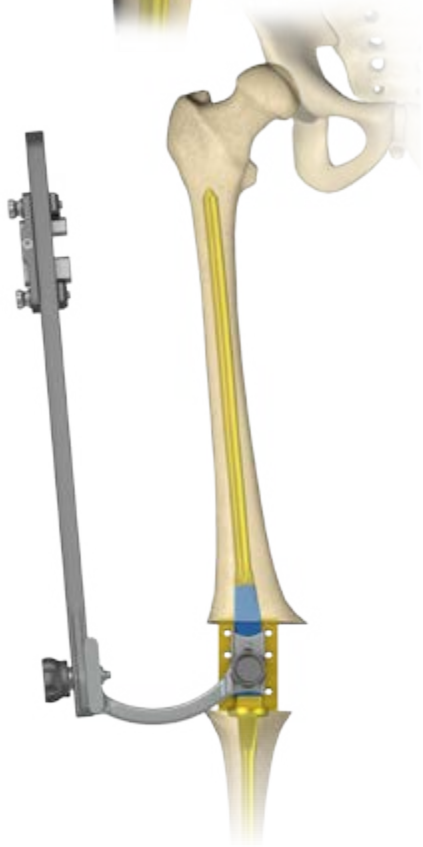


On the basis of the measured distance, place the spacer elements **[3.6367.060÷3.6367.120]** posterior. Push the femoral and tibial part of the limb to the spacer.

Attach the targeter arm **[40.6636]** with distal targeter **[40.6637]** to the free hole in the **CHARFIX2** FN Nail - femur.

40.6636.000

40.6637.000



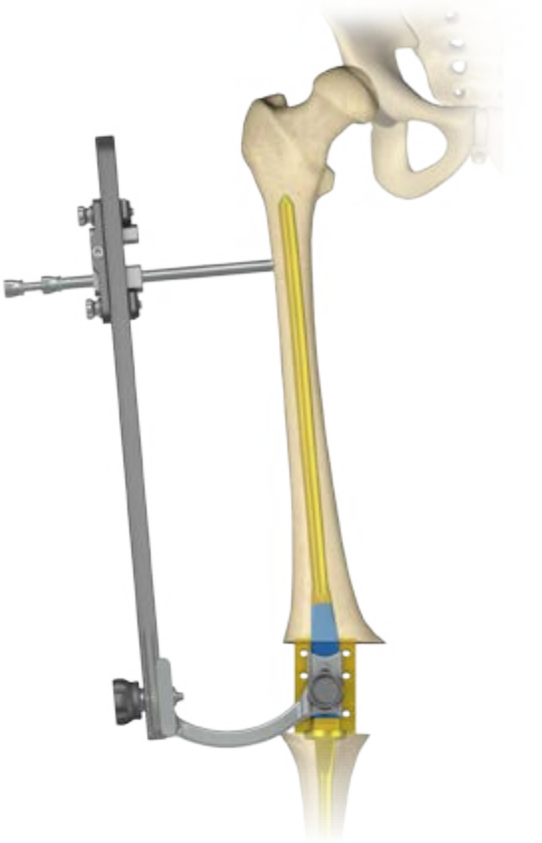
Insert the protective guide 9/7 **[40.5510.300]** and trocar 6.5 **[40.5534.200]** into the distal hole of the distal targeter slider. Mark the entry point for a locking screw on the skin and make an incision of soft tissues.

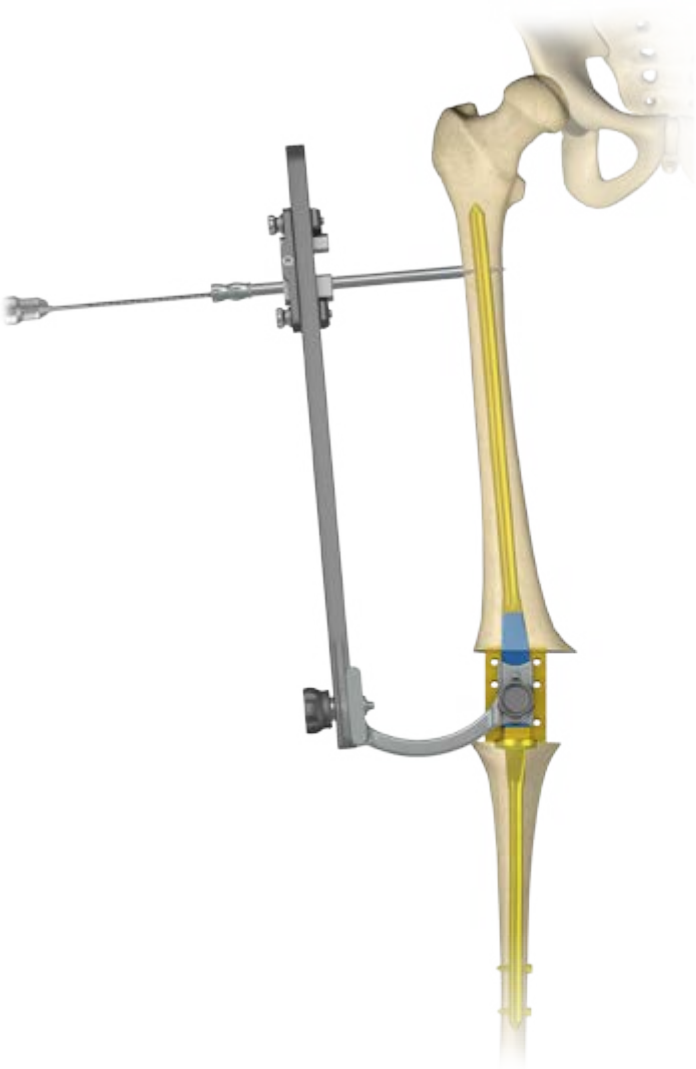
Push the protective guide and trocar to the bone and mark the entry point for a drill.

Remove the trocar.


40.5510.300


40.5534.200





Insert the drill guide 7/3.5 **[40.5511.300]** into the protective guide. Use a drive and the drill with scale 3.5/350 **[40.5339.002]**, guided in the drill guide, to drill a hole in the femur through both cortical layers and the hole in the nail. The scale on the drill indicates the length of the locking element.

Remove the drive, leave the drill with guides in place.


40.5511.300


40.5339.002

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

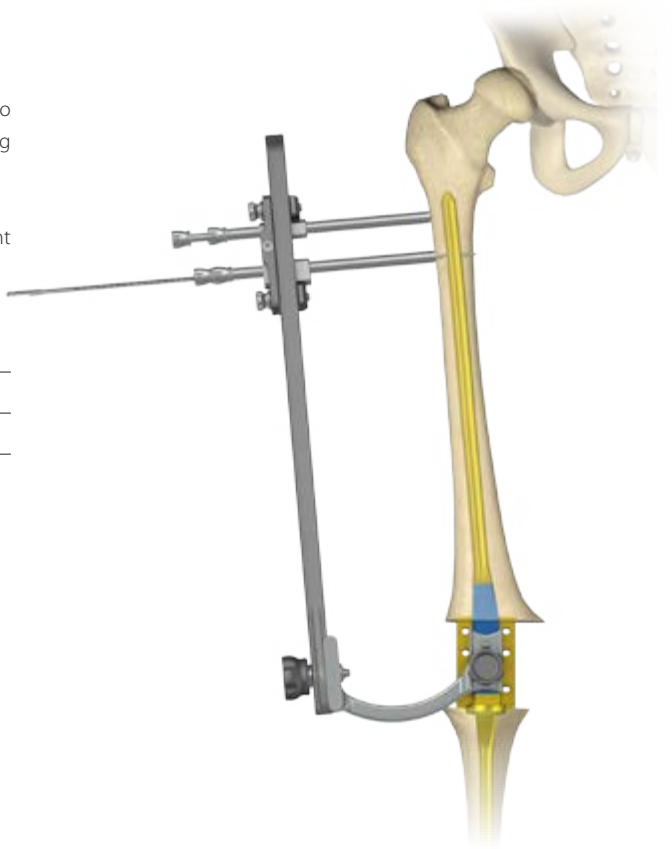
Insert the protective guide 9/7 **[40.5510.300]** and trocar 6.5 **[40.5534.200]** into the other hole of the distal targeter slider. Mark the entry point for the locking screw on the skin and make the incision of soft tissues.

Push the protective guide and trocar to the bone and mark the entry point for the drill.

Remove the trocar.


40.5510.300


40.5534.200

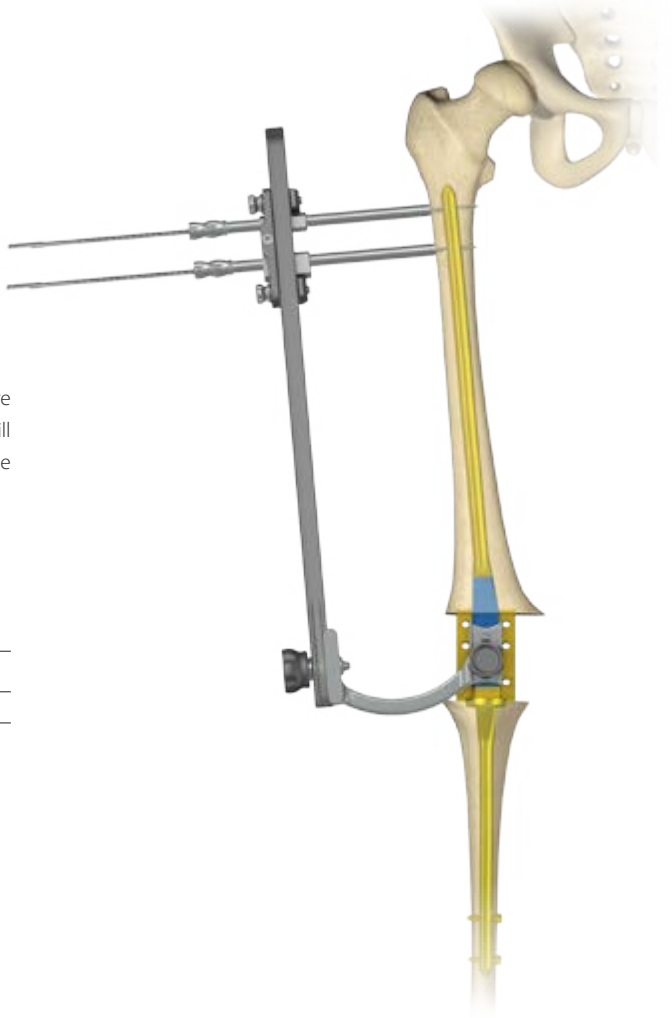


Insert the drill guide 7/3.5 **[40.5511.300]** into the protective guide. Use the drive and the drill with scale 3.5/350 **[40.5339.002]**, guided in the drill guide, to drill a hole in the femur through both cortical layers and the hole in the nail. The scale on the drill indicates the length of the locking element.

Remove the drill and the drill guide.


40.5511.300

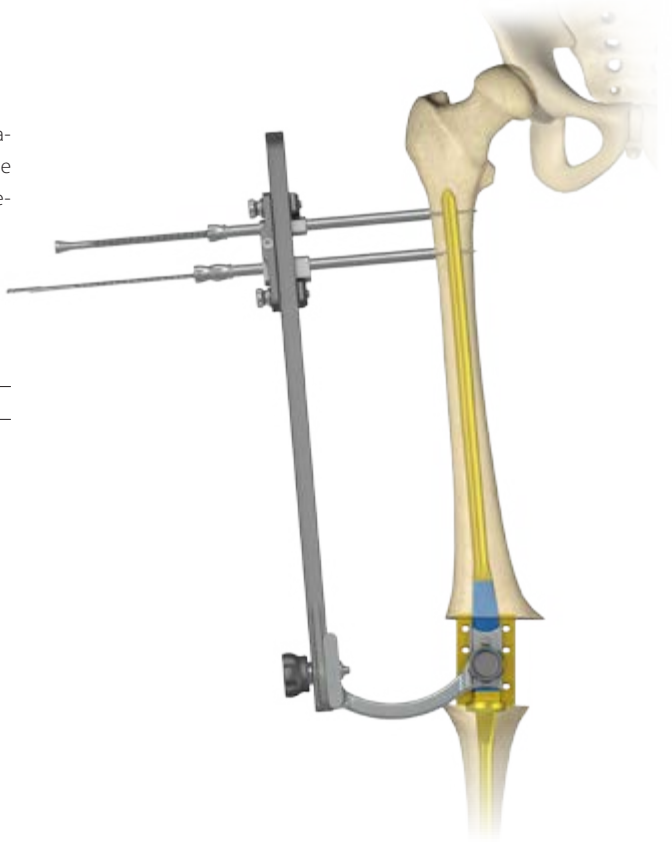

40.5339.002



Using the protective guide 9/7 **[40.5510.300]**, insert the screw length measure **[40.5530.400]** into the drilled hole until its hook reaches the *"exit"* plane of the hole. Read the length of the locking screw on the scale. During measurement, the protective guide should be pressed against the bone.

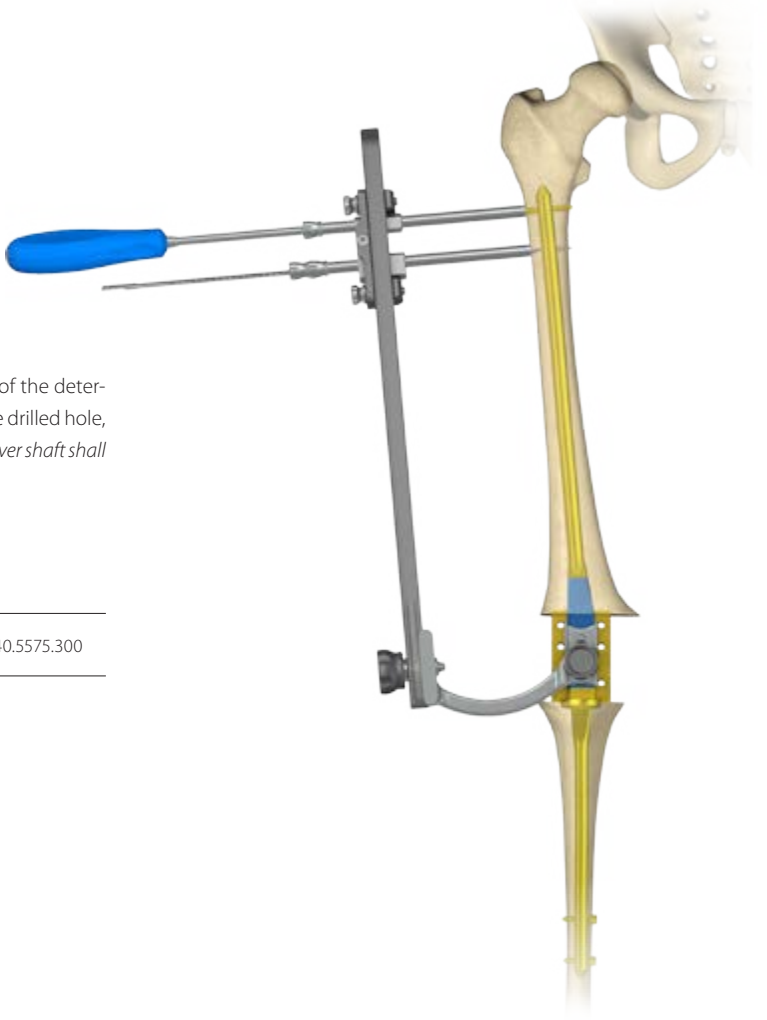
Remove the screw length measure.
Leave the protective guide in place.


40.5530.400



Insert the tip of the screwdriver T25 **[40.5575.300]** into the socket of the determined locking screw and then, through the protective guide, into the drilled hole, until the head of the screw reaches the bone *(the mark on the screwdriver shaft shall match the edge of protective guide)*.


40.5575.300

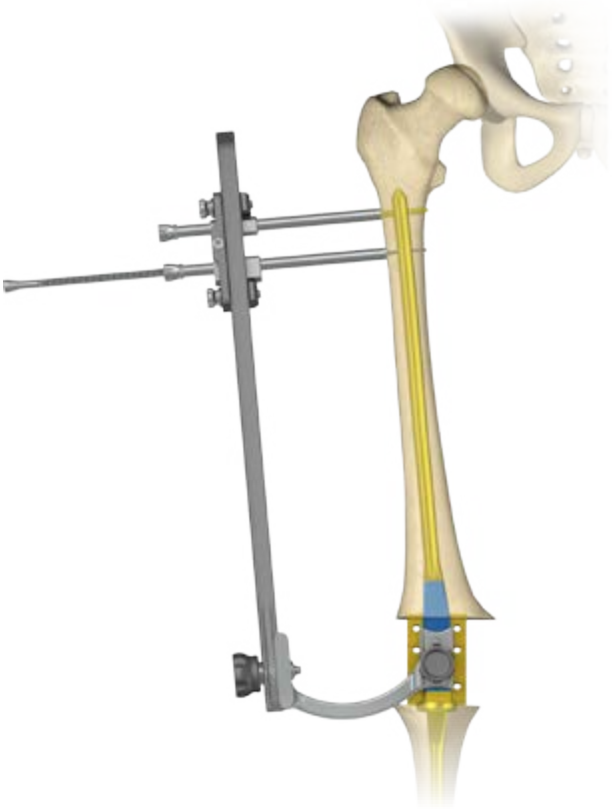


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

Remove drill with scale 3.5/350 **[40.5339.002]** and drill guide 7/3.5 **[40.5511.300]** from the distal hole of distal targeter slider. Leave protective guide 9/7 **[40.5510.300]** in the slider. Insert screw length measure **[40.5530.400]**, through the protective guide, into the drilled hole, until the hook of the measure reaches the *"exit"* plane of the hole.
Read the length of the locking screw on the scale. During measurement, the protective guide should be pressed against the bone.

Remove the screw length measure.
Leave the protective guide in place.

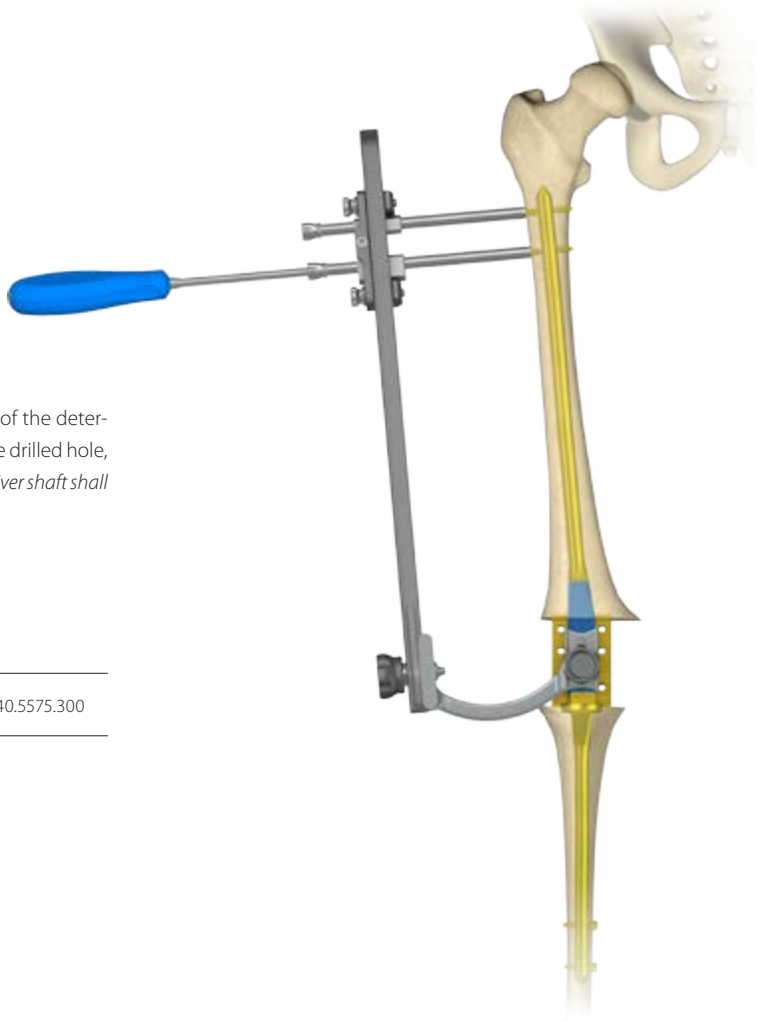

40.5530.400

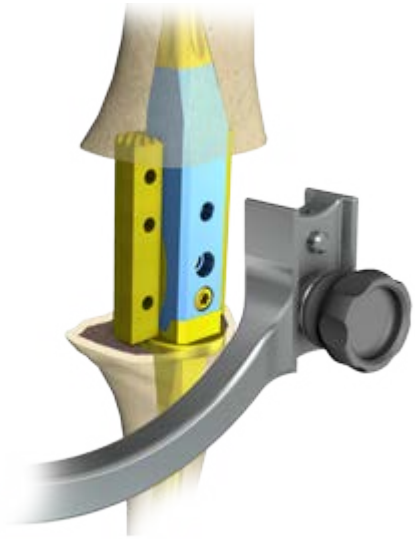


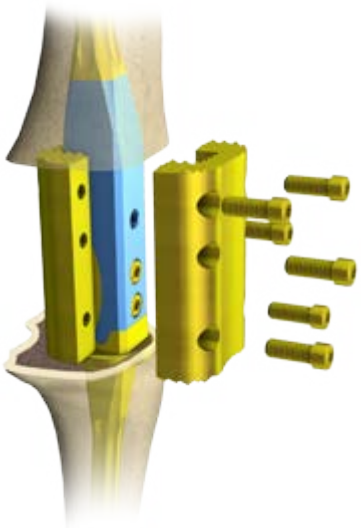
Insert the tip of the screwdriver T25 **[40.5575.300]** into the socket of the determined locking screw and then, through the protective guide, into the drilled hole, until the head of the screw reaches the bone *(the mark on the screwdriver shaft shall match the edge of protective guide)*.

Remove the screwdriver and protective guides.


40.5575.300







Having locked the **CHARFIX2** FN Nail - femur, remove the distal targeter with targeter arm, insert the other screw that joins two implants and then, place the anterior part of the spacer to the posterior part and connect the two parts using **CHARFIX2** FN Screws T **[3.6300]** and screwdriver T25 **[40.5575.300]**.

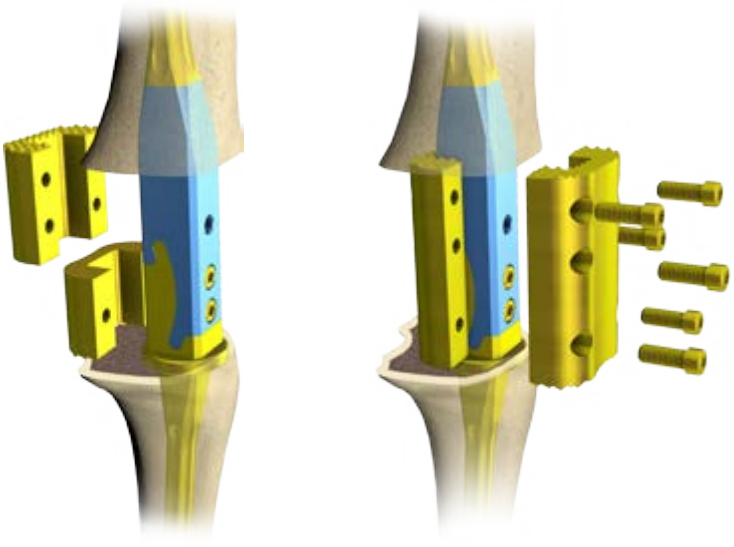
40.5575.300

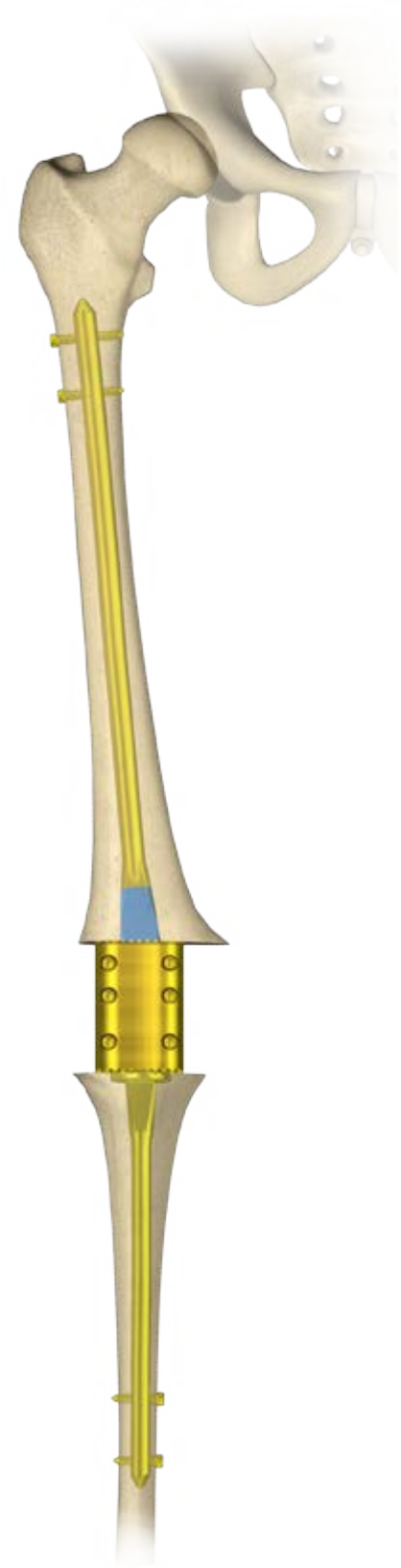
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.B.8. NAIL LOCKING USING "FREE-HAND TECHNIQUE"

Use two **CHARFIX2** FN Screws T **[3.6300]** and screwdriver T25**[40.5575.300]** to connect **CHARFIX2** FN Nail - femur and **CHARFIX2** FN Nail - tibia.

On the basis of the measured distance, place the spacer elements **[3.6367.060÷3.6367.120]** posterior. Push the femoral and tibial part of the limb to the spacer. Place the anterior part of the spacer and connect the two parts using **CHARFIX2** FN Screws T **[3.6300]** and screwdriver T25 **[40.5575.300]**.





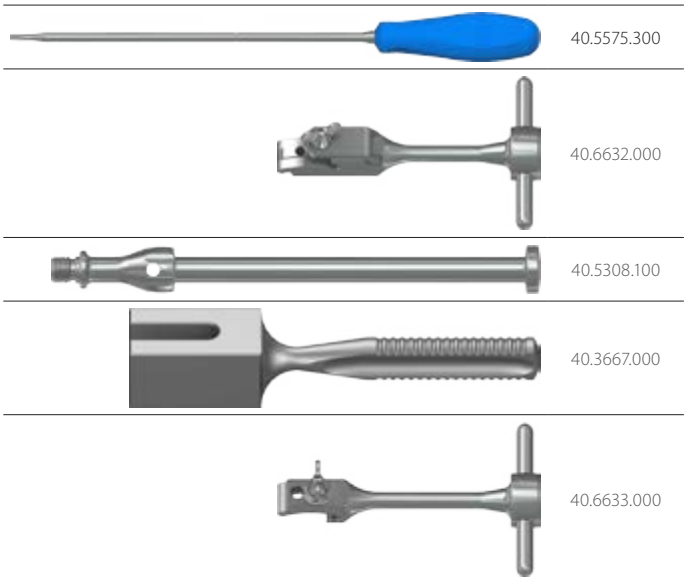
The radiological control is necessary to determine the drilling location of the holes and drilling procedure itself.

It is recommended to use an angular drill attachment for drilling holes, so that the operator's hands are outside the direct X-Ray exposure. Mark on the skin the points for drill insertion and perform incisions of soft tissues passing through these points for about 1.5 cm. Use the X-Ray device to position the protective guide short **[40.5871.100]** in relation to the hole in the nail.

The locking of **CHARFIX2** FN Nail - femur should be performed in accordance with chapter IV.A.6 (**CHARFIX2** *FN NAIL - FEMUR - DISTAL LOCKING*)**.**

40.5871.100

IV.B.9. IMPLANT REMOVAL



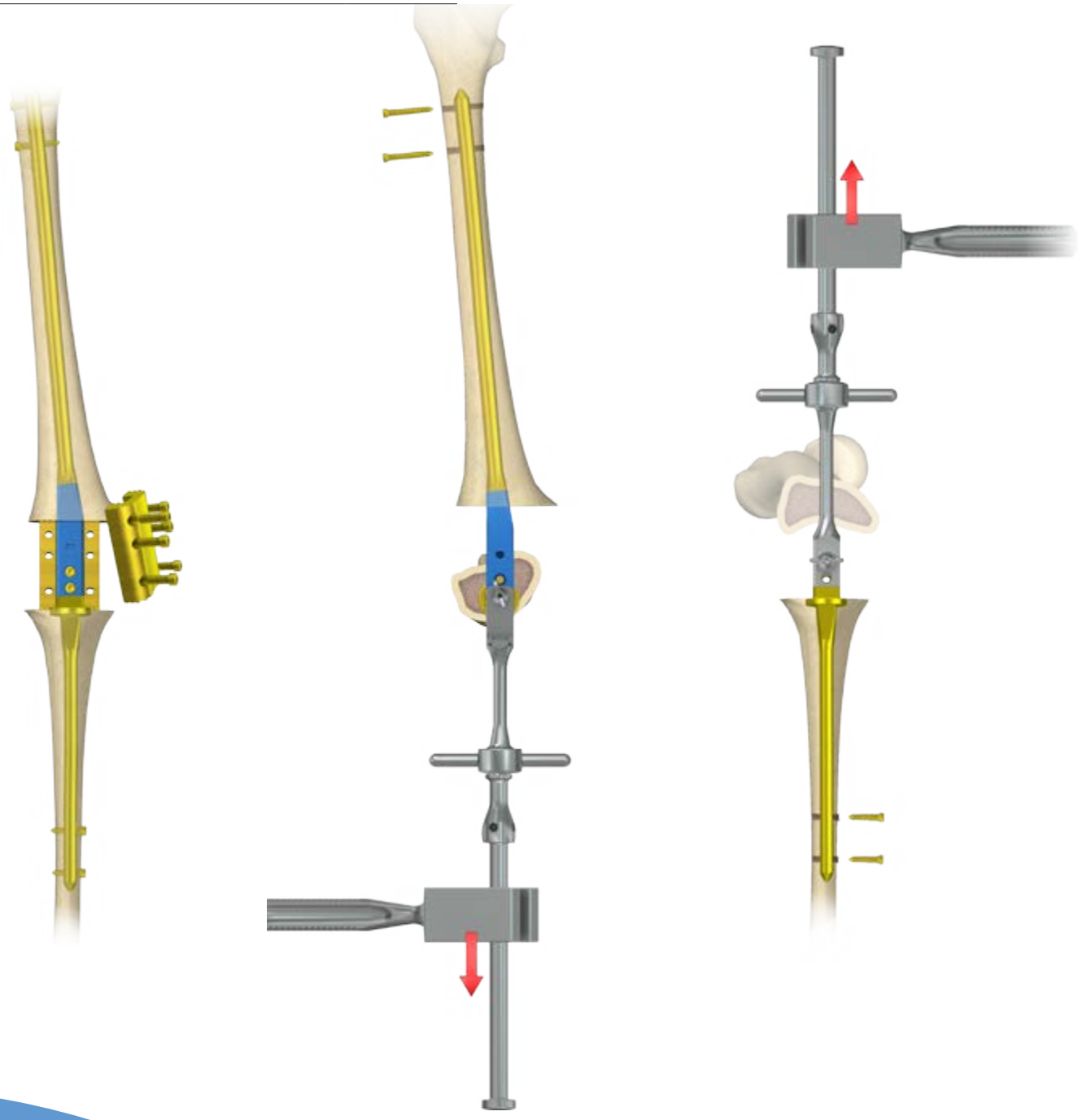
Use screwdriver T25 **[40.5575.300]** to remove screws locking the **CHARFIX2** FN Nail - femur and **CHARFIX2** FN Nail - tibia.

Use screwdriver T25 **[40.5575.300]** to remove **CHARFIX2** FN Screws T **[3.6300]** that connect the posterior and anterior parts of the spacer. Remove the **CHARFIX2** Spacer **[3.6367.060÷3.6367.120]**.

Use screwdriver T25 **[40.5575.300]** to remove **CHARFIX2** FN Screws T **[3.6300]** that join the **CHARFIX2** FN Nail - femur and **CHARFIX2** FN Nail - tibia. Detach the two nails.

Attach the handle **[40.6632]** to the **CHARFIX2** FN Nail - femur. Attach the impactor-extractor **[40.5308.100]** to the handle and using the mallet **[40.3667]**, remove the implant from the bone.

Attach the handle **[40.6633]** to the **CHARFIX2** FN Nail - tibia. Attach the impactor-extractor **[40.5308.100]** to the handle and using the mallet **[40.3667]**, remove the implant from the bone.



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

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ISO 9001/ ISO 13485

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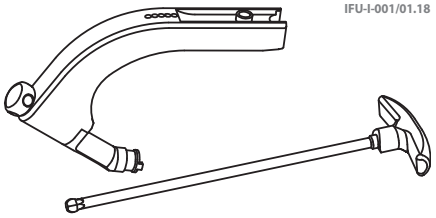

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INSTRUCTIONS FOR USE

REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

1 INDICATIONS

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

2 DESCRIPTION

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

3 MATERIALS

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

4 WARNINGS AND PRECAUTIONS

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

5 CLEANING, DISINFECTION, STERILIZATION

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

6 STORAGE

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

7 CALIBRATION

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

8 COMPATIBILITY

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

If this instructions appears unclear, please contact the manufacturer, who shall provide all required explanations.
Updated INSTRUCTIONS FOR USE are available on the following website: **www.chm.eu**
IFU-I-001/01.18; Date of verification: January 2018

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

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

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