

ChM[®]

4.0 ChM Locked Plating
ChLPsystem

4.0ChLP ENDOSTEAL PLATE

- IMPLANTS
- INSTRUMENT SET 15.0204.002
- SURGICAL TECHNIQUE



SYMBOLS DESCRIPTION

	Titanium or titanium alloy		H length [mm]
	Cobalt		Angle
	Left		available lengths
	Right		Available number of holes
	Available versions: left/right		Thickness [mm]
	Length		Scale 1:1
	Torx drive		Number of threaded holes in the shaft part of the plate
	Torx drive cannulated		Number of locking holes in the plate
	Hexagonal drive		Variable angle
	Hexagonal drive cannulated		Cortical
	Cannulated		Cancellous
	Locking		Available in sterile/ non- sterile condition
	Diameter [mm]		Refer to surgical technique
	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.		

www.chm.eu

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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

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I. INTRODUCTION

Endosteal plates are used for the first metatarsal bone correction. The plates are a part of the 4.0ChLP locking plates system developed by **ChM**. The presented range of implants is made of titanium, titanium alloys and cobalt alloy 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.

The system for the first metatarsal bone treatment includes:

- implants (*left and right endosteal plates, locking screws*),
- instrument set used for plates implantation/removal,
- surgical technique.

I.1. INDICATIONS

The plates are used to treat:

- metatarsus primus varus (*hallux valgus*)

I.2. CONTRAINDICATIONS

- infections,
- growing children.

I.3. PLATE SELECTION AND SHAPING

The plates are available in various lengths, two blade deflection variants, and left and right variant. This allows for optimal selection of the implant to the developed deformation.

Shaping of the plates is not allowed.



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.

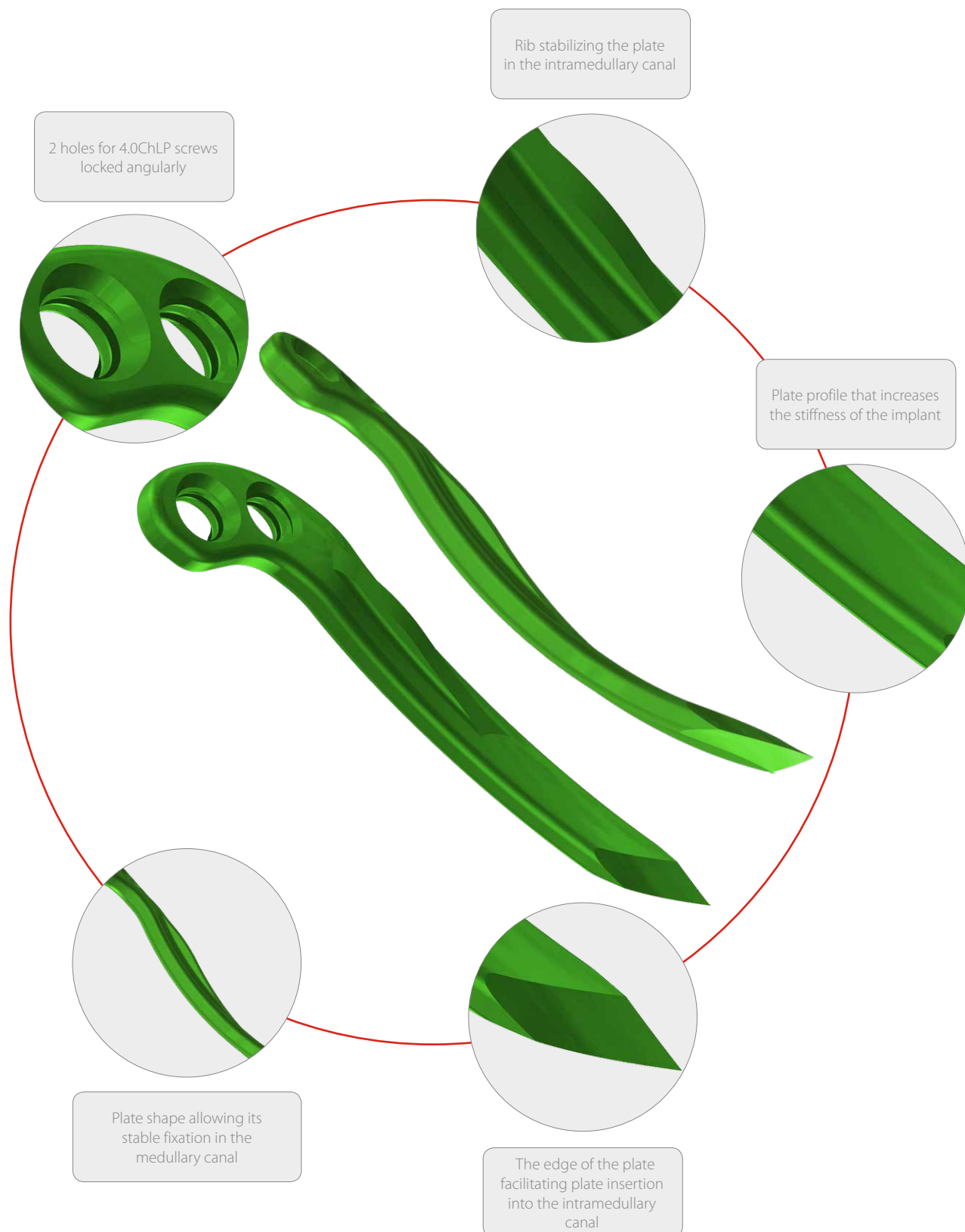


The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

II. IMPLANTS

Endosteal plates are a part of 4.0ChLP system. This system includes also compatible locking screws. To facilitate the identification, both the plate and the screws are colored green.

II.1. PLATE PROPERTIES

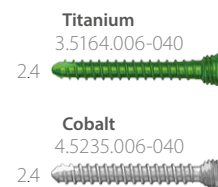
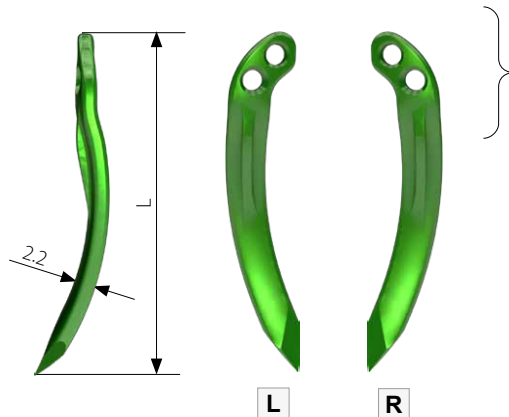


4.0ChLP ENDOSTEAL PLATE 4,0ChLP ПЛАСТИНА ВНУТРИКОСТНАЯ



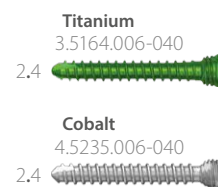
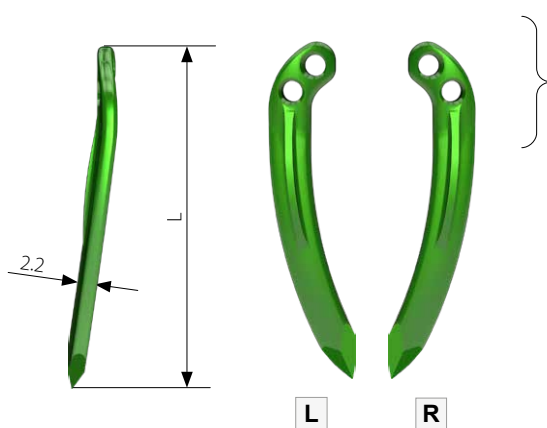
Left	
L [mm]	Catalogue no.
40	3.7061.140
45	3.7061.145
50	3.7061.150

Right	
L [mm]	Catalogue no.
40	3.7060.140
45	3.7060.145
50	3.7060.150



Left	
L [mm]	Catalogue no.
40	3.7061.240
45	3.7061.245
50	3.7061.250

Right	
L [mm]	Catalogue no.
40	3.7060.240
45	3.7060.245
50	3.7060.250



		Ti	Co			VA		
	3.5164.xxx	✓		✓	✓		✓	2.4
	4.5235.xxx		✓	✓	✓	✓	✓	2.4



4.0ChLP SCREW 2.4



6	3.5164.006
8	3.5164.008
10	3.5164.010
12	3.5164.012
14	3.5164.014
16	3.5164.016
18	3.5164.018
20	3.5164.020
22	3.5164.022
24	3.5164.024
26	3.5164.026
28	3.5164.028
30	3.5164.030
32	3.5164.032
34	3.5164.034
36	3.5164.036
38	3.5164.038
40	3.5164.040

diameter of the core	1.8	
drill	1.8	40.2063.181
threaded guide	M3.5/1.8	40.4896.018
screwdriver tip	T8	40.5682.000

4.0ChLP SCREW VA 2.4



6	4.5235.006
8	4.5235.008
10	4.5235.010
12	4.5235.012
14	4.5235.014
16	4.5235.016
18	4.5235.018
20	4.5235.020
22	4.5235.022
24	4.5235.024
26	4.5235.026
28	4.5235.028
30	4.5235.030
32	4.5235.032
34	4.5235.034
36	4.5235.036
38	4.5235.038
40	4.5235.040

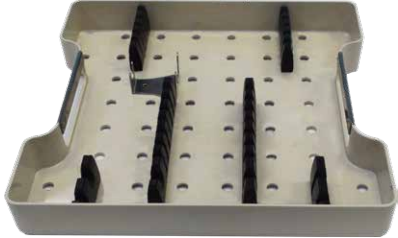
diameter of the core	1.8	
drill	1.8	40.2063.181
guide VA	1.8	40.5928.018
screwdriver tip	T8	40.5682.000

III. INSTRUMENT SET

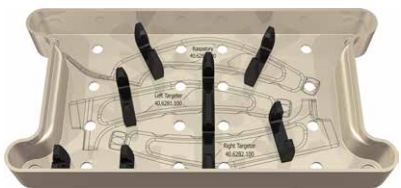
Set for 4.0ChLP 3.7060/3.7061 4x4 H

15.0204.002	Name	Pcs	Catalogue No.
	Instrument set for 4.0ChLP 3.7060/3.7061 4x4 1/2H	1	15.0204.201
	Instrument set for 4.0ChLP 3.7060/3.7061 4x2 1/2H	1	15.0204.203
	Stand for 4.0ChLP implants 3.7060/3.7061 4x2 1/2H	1	14.0204.601
	4.0ChLP container lid 3.7060/3.7061 4x4	1	14.0204.104
	4.0ChLP container 3.7060/3.7061 4x4	1	14.0204.103

Instrument set for 4.0ChLP 3.7060/3.7061 4x4 1/2H

15.0204.201	Name	Pcs	Catalogue No.
	Threaded guide M3.5/1.8 - 4.0	2	40.4896.018
	Drill 1.8/180	1	40.2063.181
	Screwdriver tip T8.0	1	40.5682.000
	Screwdriver tip T8 with holder	1	40.5989.000
	Depth measure	1	40.4640.000
	Locking screw length measure	1	40.4818.100
	BUCK-GRAMCKO elevator 7.5	2	40.2185.000
	Mallet	1	40.6284.000
	Extractor	1	40.6283.000
	Torque limiting ratchet handle 1Nm	1	40.6650.000
	Guide VA 1.8	1	40.5928.018
	Tray for 4.0ChLP instrument set 3.7060/3.7061 4x4 1/2H	1	14.0204.201

Instrument set for 4.0ChLP 3.7060/3.7061 4x2 1/2H

15.0204.203	Name	Pcs	Catalogue No.
	Raspatory	1	40.6285.000
	Targeter for endosteal plate - left	1	40.6281.100 *
	Targeter for endosteal plate - right	1	40.6282.100 **
	Drill 4.0	1	40.6278.000
	Tray for 4.0ChLP instrument set 3.7060/3.7061 4x2 1/2H	1	14.0204.203
* compatible with plates 3.7061.1xx; 3.7061.2xx			
** compatible with plates 3.7060.1xx; 3.7060.2xx			

Stand for 4.0ChLP implants 3.7060/3.7061 4x2 1/2H

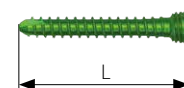
14.0204.601***



4.0ChLP endosteal plate

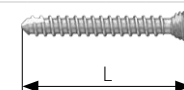


4.0ChLP screw 2.4



L [mm]	12	14	16	18	20	22	24	26
Pcs	5	5	5	5	5	5	5	5

4.0ChLP screw VA 2.4



L [mm]	12	14	16	18	20	22	24	26
Pcs	5	5	5	5	5	5	5	5

*** Implants are not included in the stand

IV. PATIENT'S POSITIONING

It is recommended to position the patient on his back with a roller under his calf to lift the foot.



V. SURGICAL APPROACH

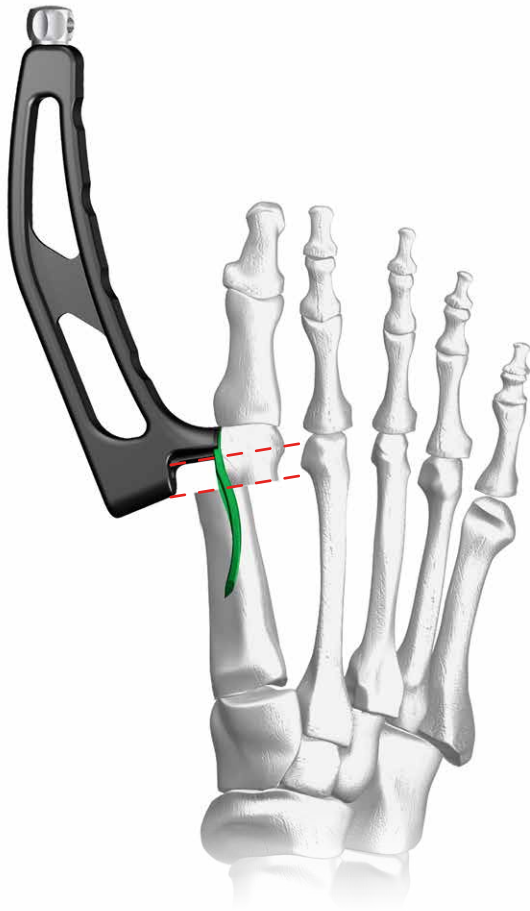
Medial approach is recommended. Perform a short arched incision above the metatarsophalangeal joint. The cutting shall be slightly dorsal.



VI. SURGICAL TECHNIQUE

VI.A. STANDARD TECHNIQUE

Technique using 2 screws of determined direction corresponding with direction of the locking holes. Use the technique if direction of the screws allows for their stable fixation in the distal part of the bone.

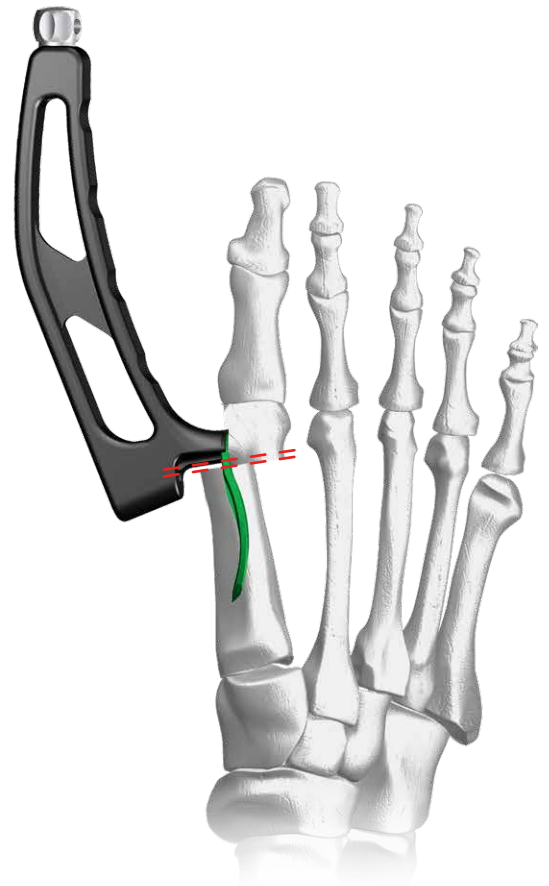


VI.B. TECHNIQUE WITH USE OF VA LOCKING SCREW

Technique with use of VA locking screw inserted in the direction predefined by a targeter.

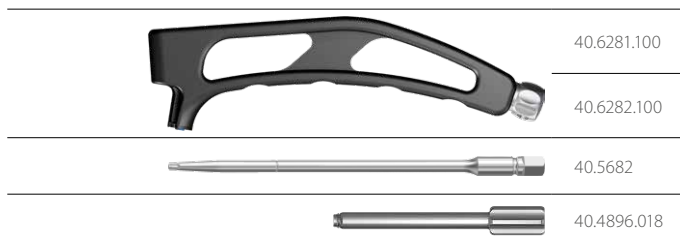
Use the technique when:

- there is deep plate introduction into the medullary canal,
- the distal part of the bone is not big enough for proximal screw's introduction using the standard technique.



VI.A. STANDARD TECHNIQUE

VI.A.1. Plate and targeter assembly

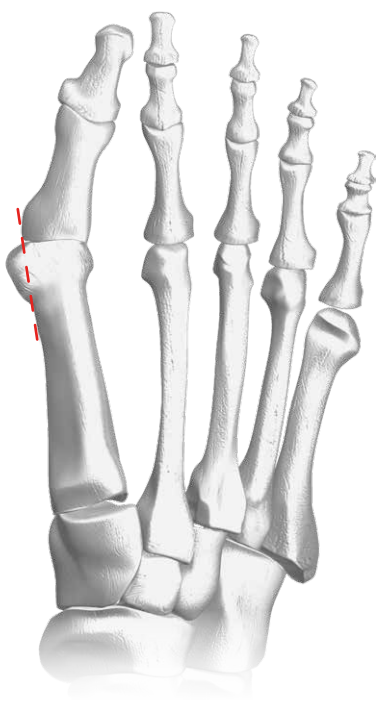


Attach suitable targeter - left or right **[40.6281.100]/[40.6282.100]** - to the plate. Tighten the screw that secures the targeter to plate using screwdriver tip T8.0 **[40.5682]**. Additionally, lock the threaded guide M3.5/1.8 - 4.0 **[40.4896.018]**.



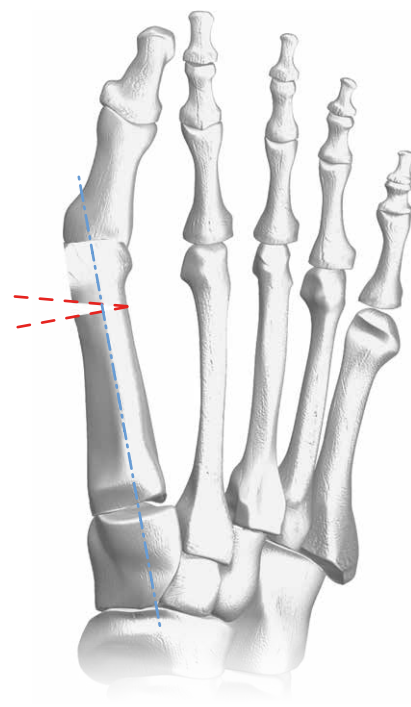
VI.A.2. Bone correction

If need be, prior to osteotomy, remove a part of the head of the first metatarsal bone.



VI.A.3. Bone cutting

Perform osteotomy at the site of endosteal plate implantation. The cutting should be performed at the base of the metatarsal head.



VI.A.4. Medullary canal preparation



Prepare the medullary canal for plate insertion using raspatory **[40.6285]**.



NOTE! Use mallet **[40.6284]** if required.



VI.A.5. Plate insertion



40.6282.100



Insert the plate into the prepared canal.



NOTE! Use mallet **[40.6284]** if required.

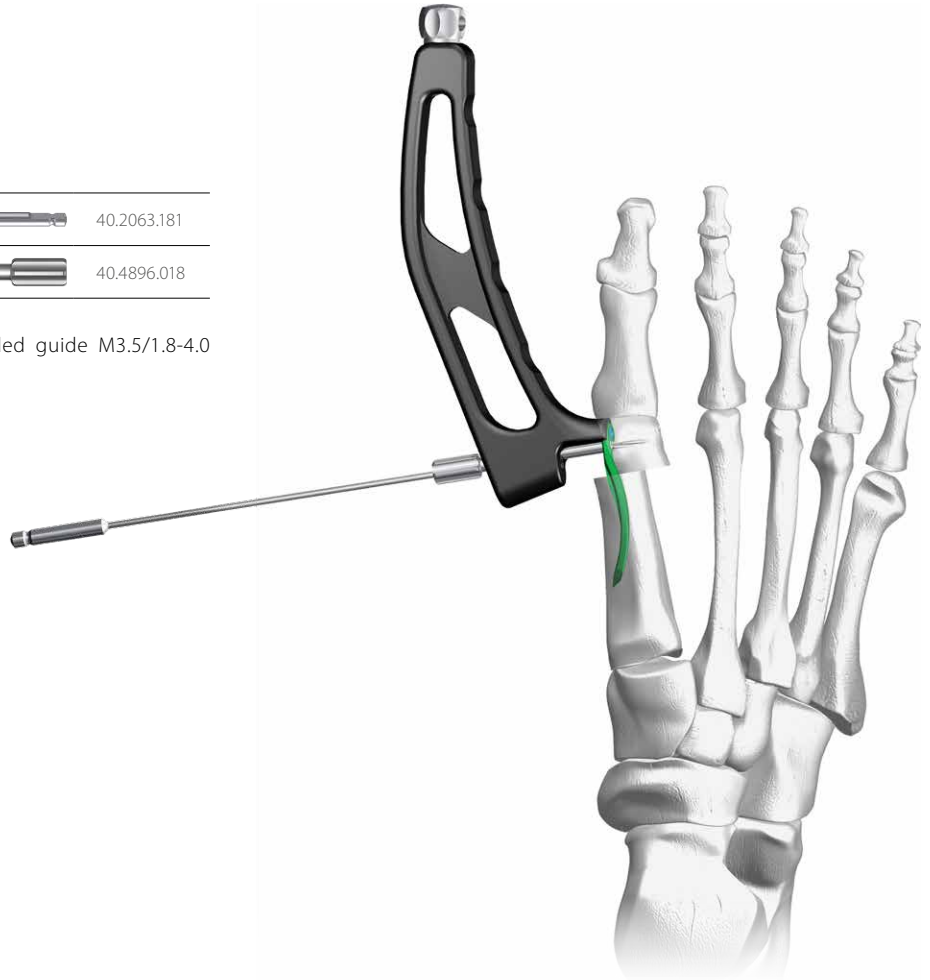


VI.A.6. Insertion of the first locking screw

VI.A.6.1 Drilling

	40.2063.181
	40.4896.018

Drill using drill 1.8/180 **[40.2063.181]** via threaded guide M3.5/1.8-4.0 **[40.4896.018]** until the desired depth is reached.



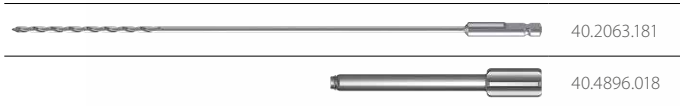
VI.A.6.2 Depth measurement

	40.4818.100
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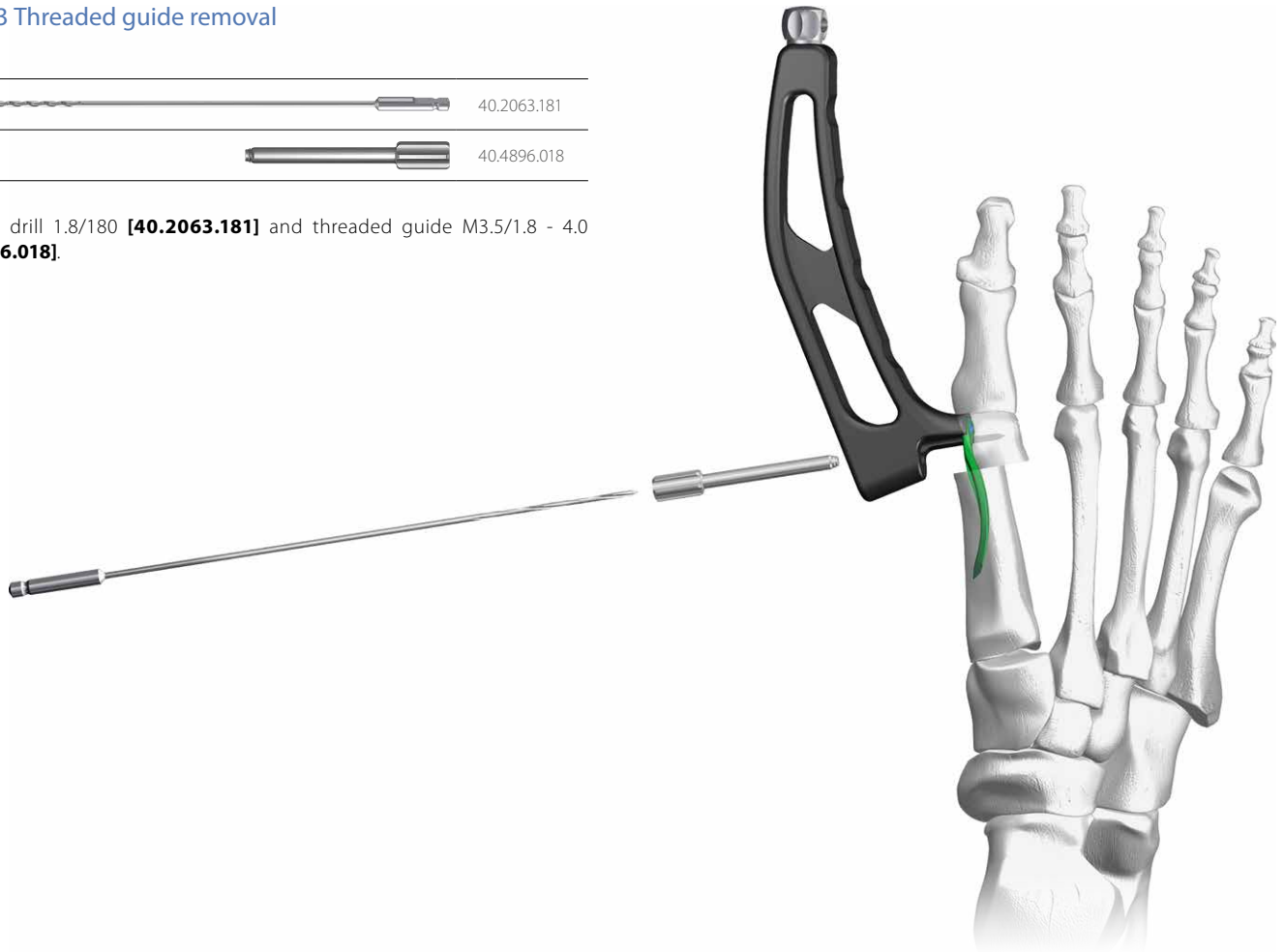
Use locking screw length measure **[40.4818.100]** to measure the hole depth.



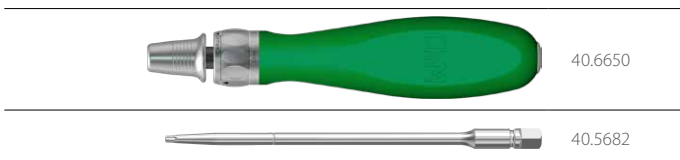
VI.A.6.3 Threaded guide removal



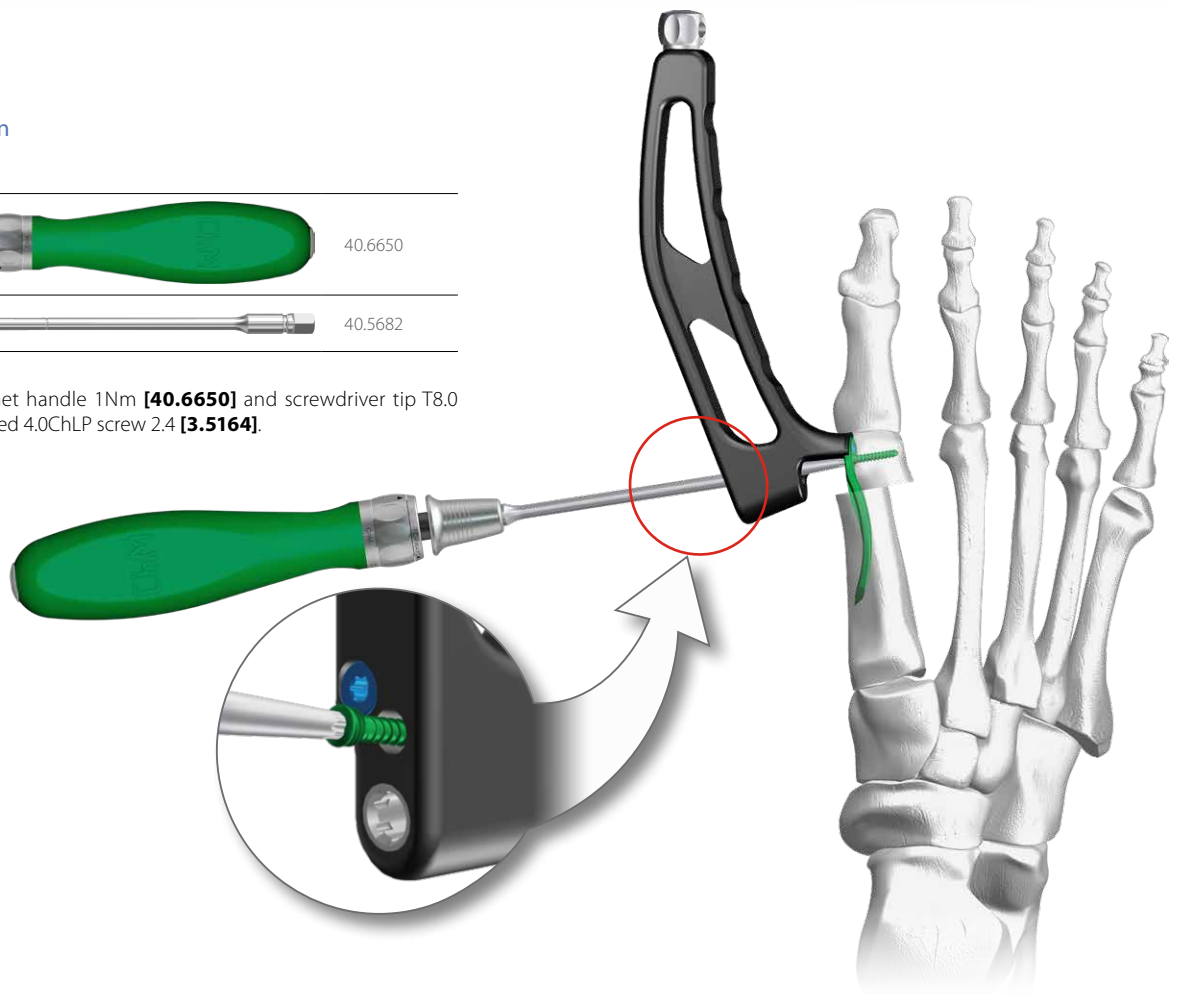
Remove drill 1.8/180 **[40.2063.181]** and threaded guide M3.5/1.8 - 4.0 **[40.4896.018]**.



VI.A.6.4 Screw insertion



Use torque limiting ratchet handle 1Nm **[40.6650]** and screwdriver tip T8.0 **[40.5682]** to insert selected 4.0ChLP screw 2.4 **[3.5164]**.

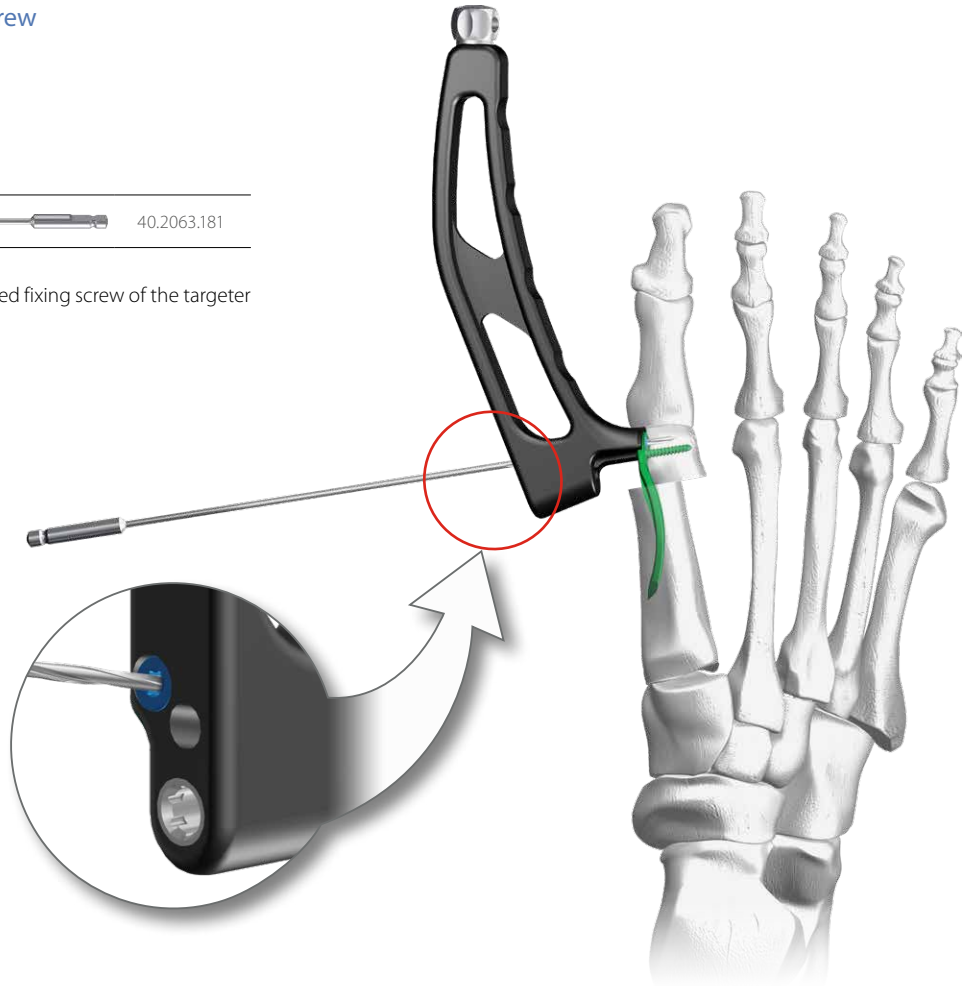


VI.A.7. Insertion of the other locking screw

VI.A.7.1 Drilling



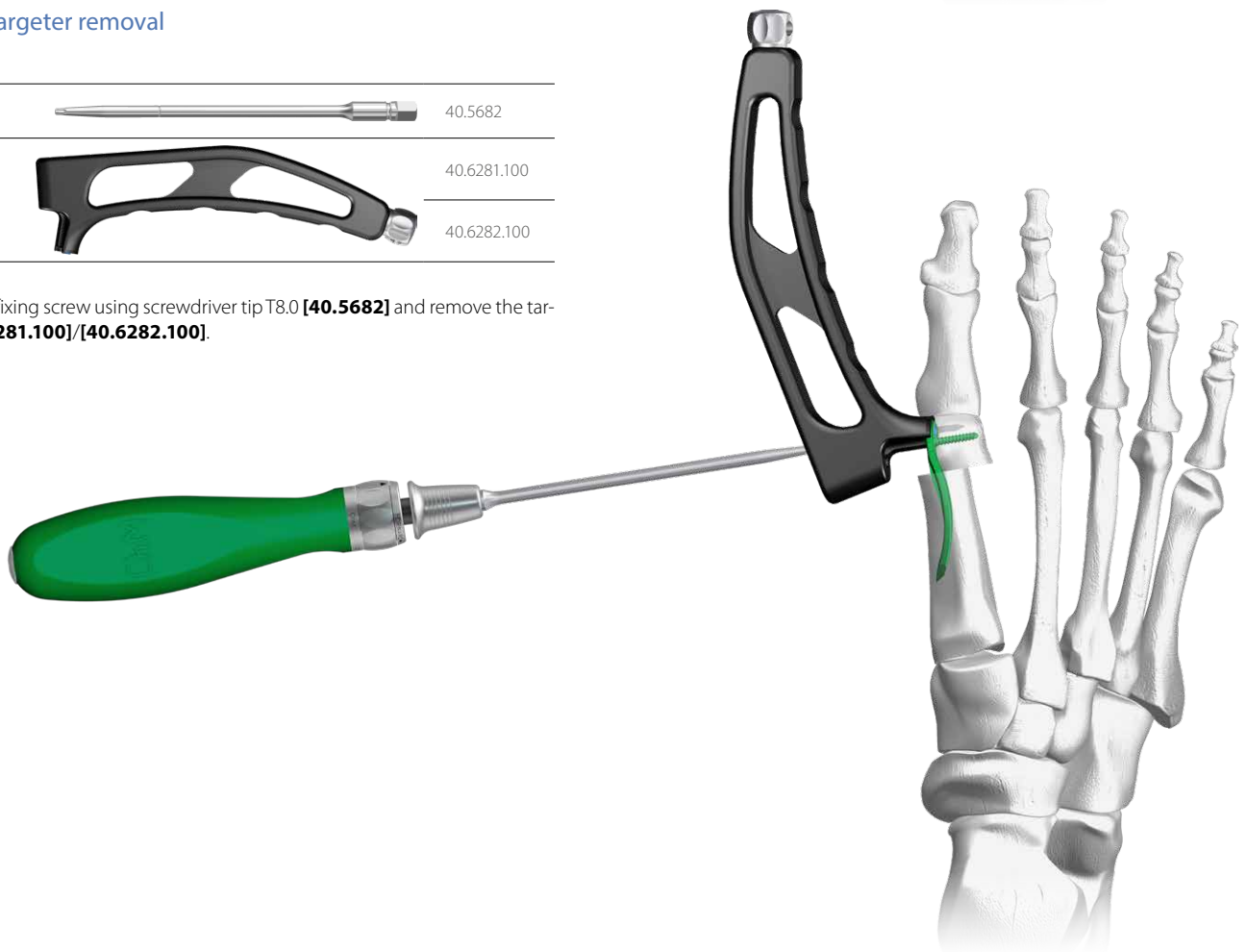
Drill using drill 1.8/180 **[40.2063.181]** via cannulated fixing screw of the targeter until the desired depth is reached.



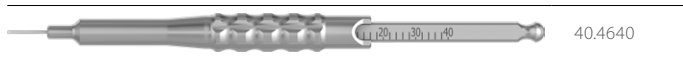
VI.A.7.2 Targeter removal



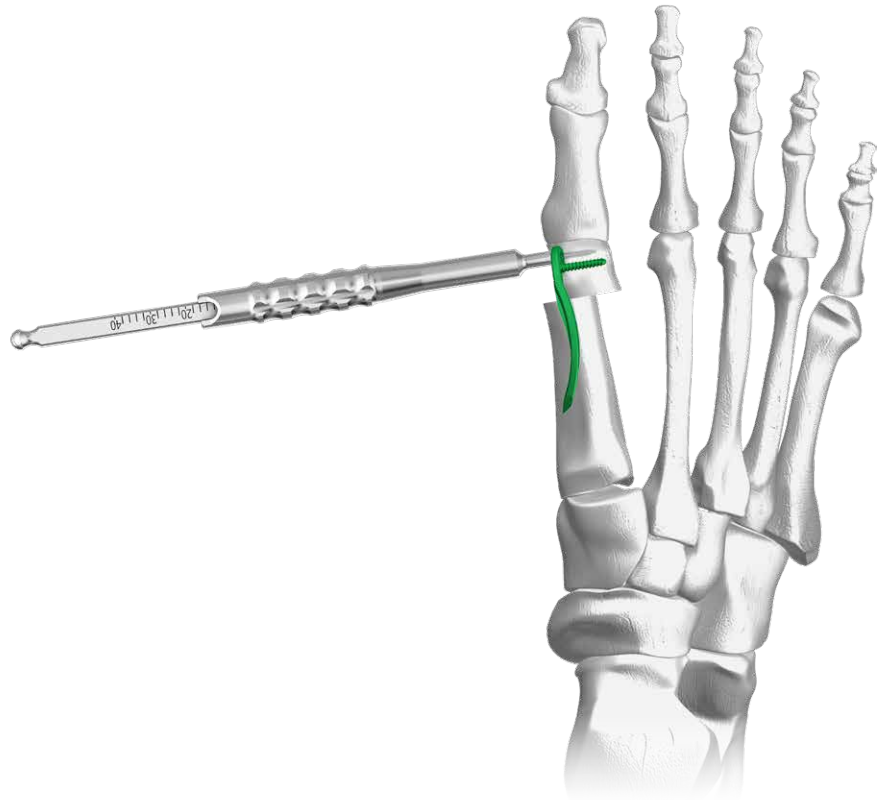
Loosen the fixing screw using screwdriver tip T8.0 **[40.5682]** and remove the targeter **[40.6281.100]/[40.6282.100]**.



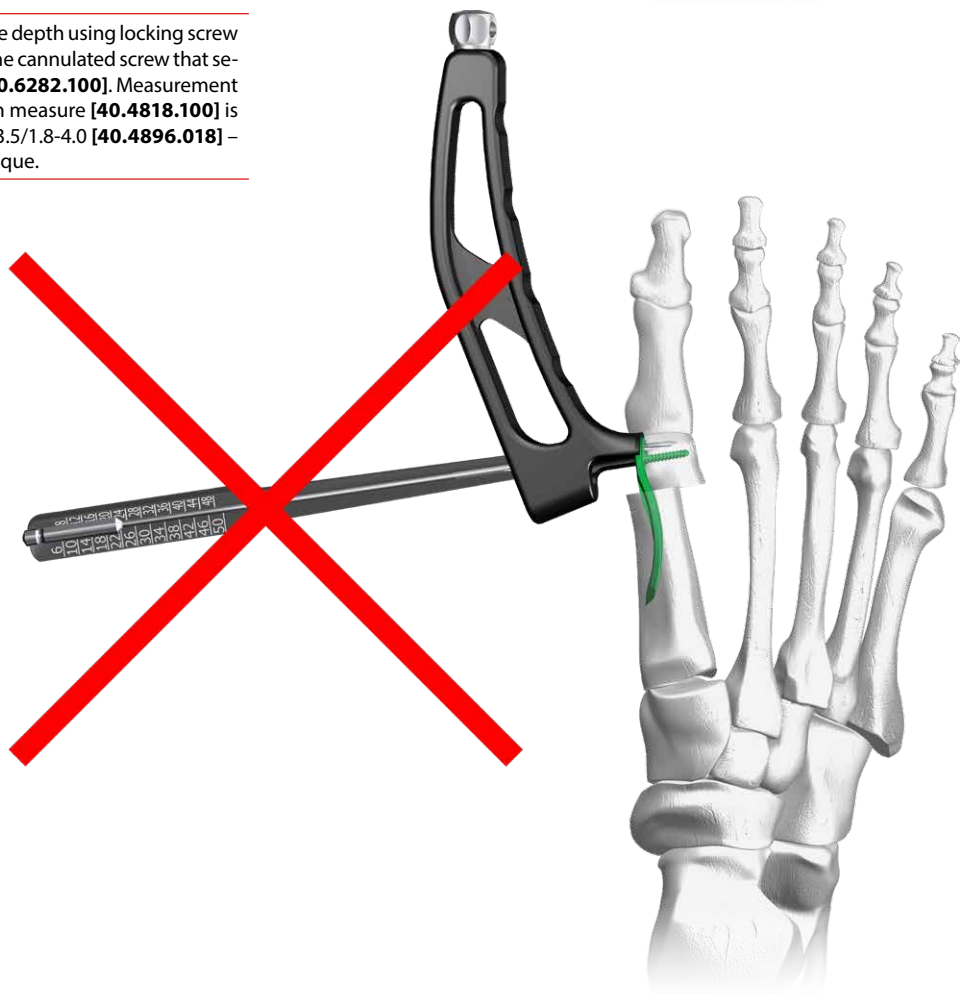
VI.A.7.3 Depth measurement



Use depth measure **[40.4640]** to measure the hole depth.



NOTE! Do not measure the other hole depth using locking screw length measure **[40.4818.100]** via the cannulated screw that secures the targeter **[40.6281.100]/[40.6282.100]**. Measurement with the use of locking screw length measure **[40.4818.100]** is possible only via threaded guide M3.5/1.8-4.0 **[40.4896.018]** – point VI.A.6.2. of this surgical technique.



VI.A.7.4 Screw insertion



Use torque limiting ratchet handle 1Nm **[40.6650]** and screwdriver tip T8.0 **[40.5682]** to insert selected 4.0ChLP screw 2.4 **[3.5164]**.

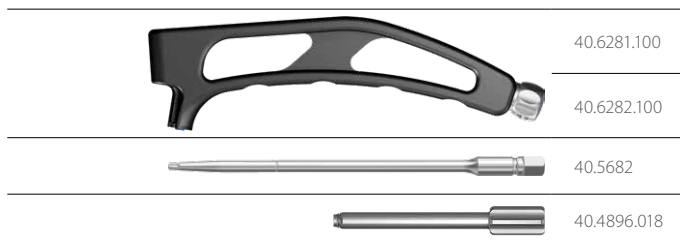


Take X-Ray images in at least two projections to make sure that the locking was performed correctly.



VI.B. TECHNIQUE WITH USE OF VA LOCKING SCREW

VI.B.1. Plate and targeter assembly

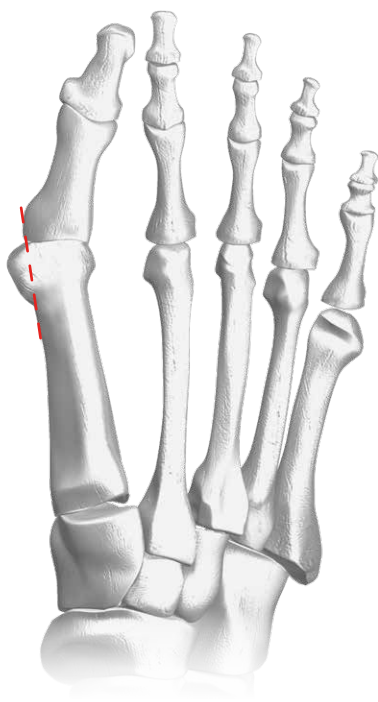


Attach suitable targeter - left or right **[40.6281.100]/[40.6282.100]** - to the plate. Tighten the screw that secures the targeter to the plate using screwdriver tip T8.0 **[40.5682]**. Additionally, lock the threaded guide M3.5/1.8 - 4.0 **[40.4896.018]**.



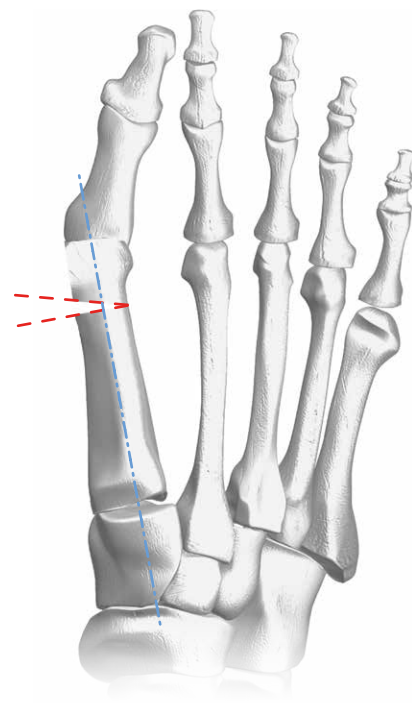
VI.B.2. Bone correction

If need be, prior to osteotomy, remove a part of the head of the first metatarsal bone.



VI.B.3. Bone cutting

Perform osteotomy at the site of endosteal plate implantation. The cutting should be performed at the base of the metatarsal head.



VI.B.4. Medullary canal preparation



40.6285



40.6284

Prepare the medullary canal for plate insertion using raspatory **[40.6285]**.



NOTE! Use mallet **[40.6284]** if required.



VI.B.5. Plate insertion



40.6281.100



40.6282.100



40.6284



40.4896.018

Insert the plate into the prepared canal.

In order to facilitate deeper plate insertion, remove threaded guide M3.5/1.8 - 4.0 **[40.4896.018]** at the final stage of the insertion.



NOTE! Use mallet **[40.6284]** if required.



VI.B.6. Insertion of the first VA locking screw

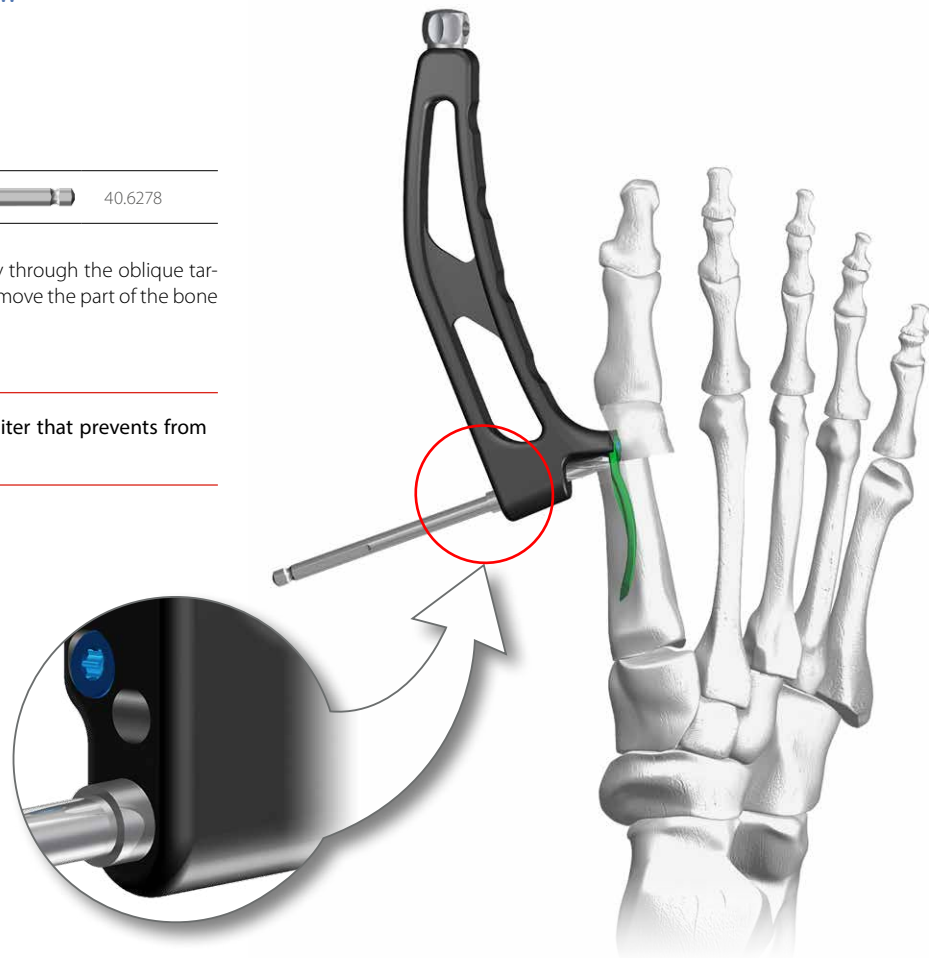
VI.B.6.1 Approach preparation



Drill using drill 4.0 **[40.6278]** to the full depth, directly through the oblique targeter hole **[40.6281.100]/[40.6282.100]** and thus remove the part of the bone that covers proximal locking hole.



NOTE! The drill is equipped with a limiter that prevents from instrument-implant collision.



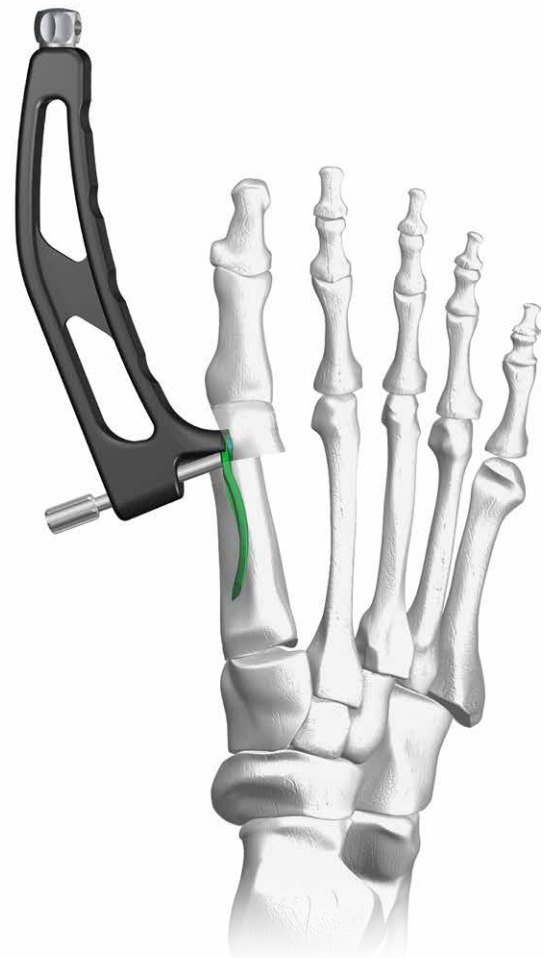
VI.B.6.2 Guide insertion



Insert the threaded guide M3.5/1.8 - 4.0 **[40.4896.018]** into the oblique hole of the targeter until it reaches the plate.



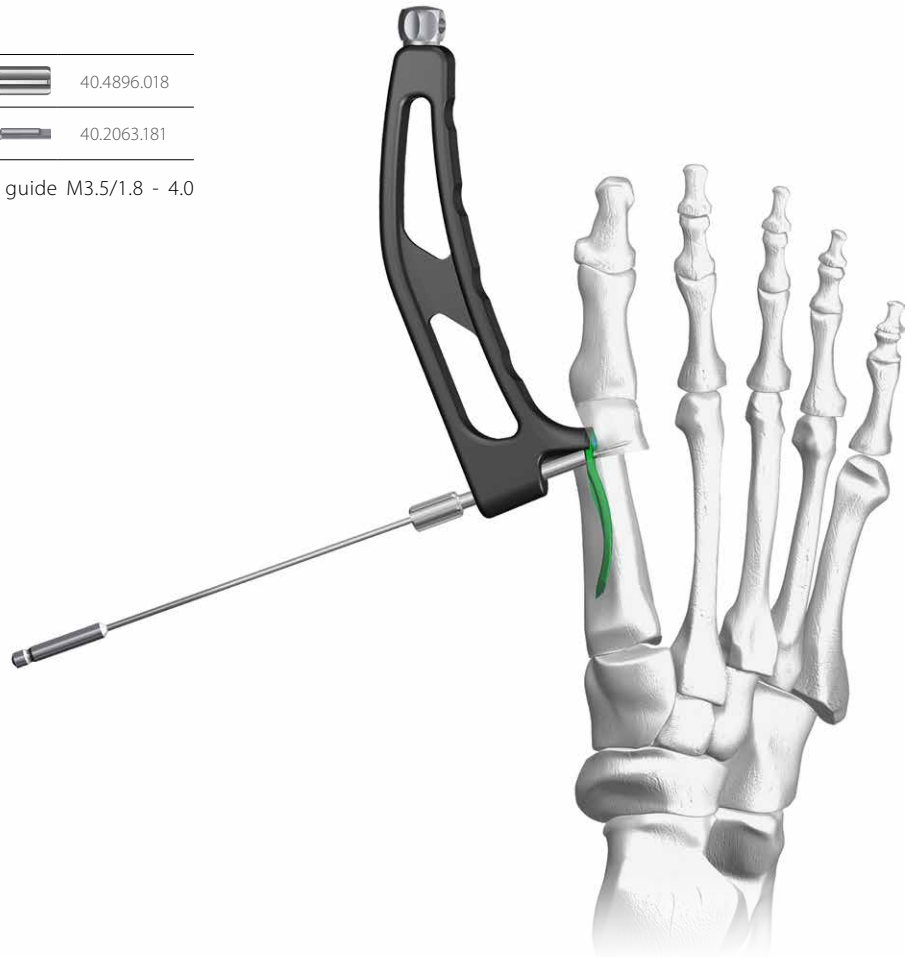
NOTE! Do not screw in the guide. The holes in the guide and in the implant do not correspond with each other in this position. There is a risk of threads damage.



VI.B.6.3 Drilling

	40.4896.018
	40.2063.181

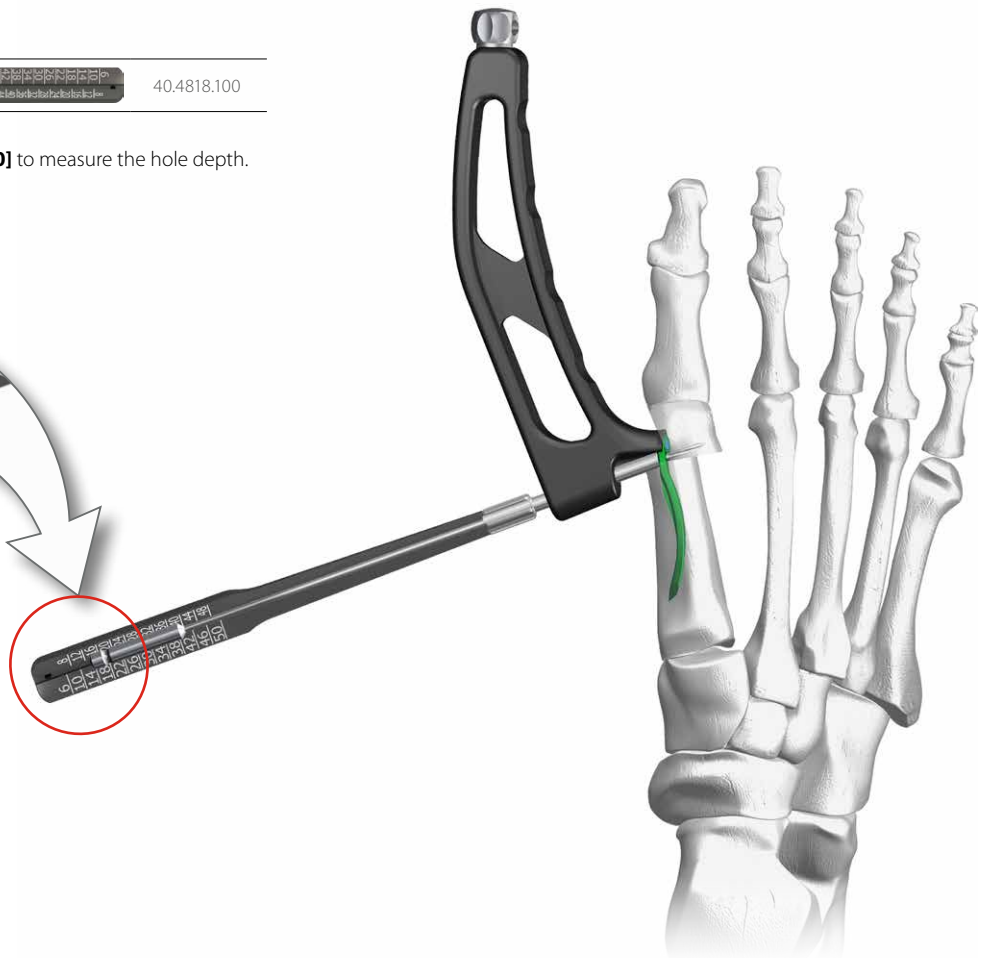
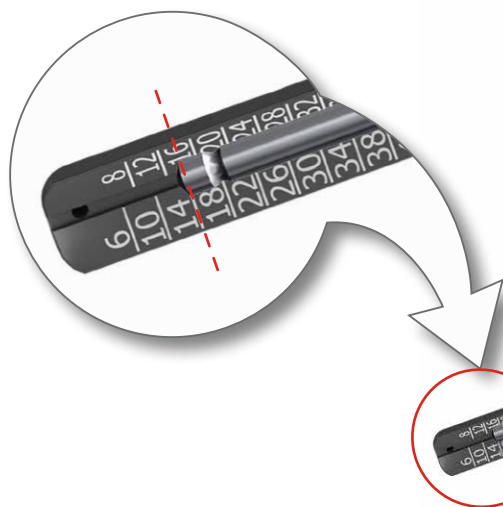
Drill using drill 1.8/180 **[40.2063.181]** via threaded guide M3.5/1.8 - 4.0 **[40.4896.018]** until desired depth is reached.



VI.B.6.4 Depth measure

	40.4818.100
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Use locking screw length measure **[40.4818.100]** to measure the hole depth.



VI.B.6.5 Threaded guide removal

	40.4896.018
	40.2063.181

Remove drill 1.8/180 **[40.2063.181]** and threaded guide M3.5/1.8 - 4.0 **[40.4896.018]**.



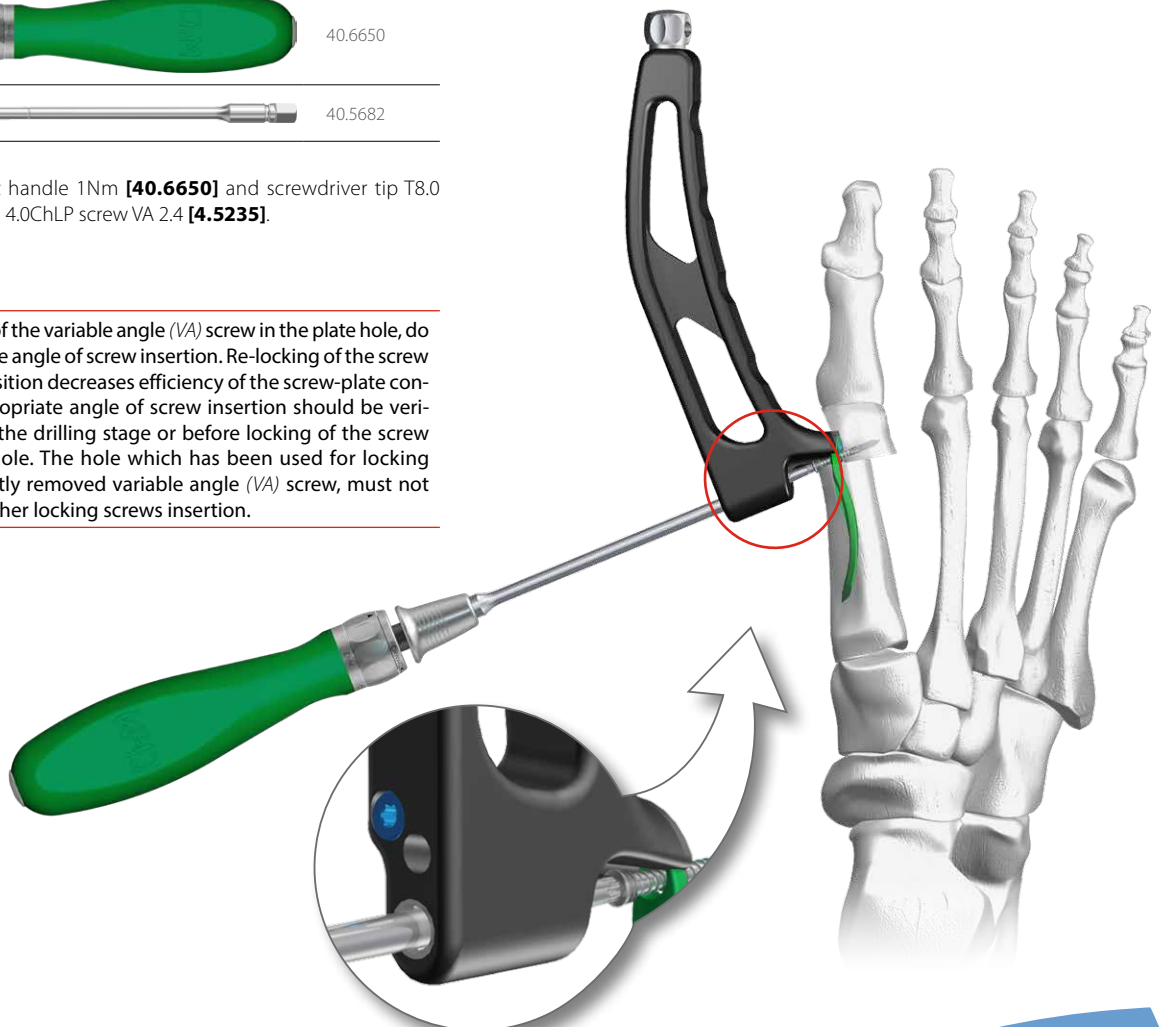
VI.B.6.6 VA screw insertion

	40.6650
	40.5682

Use torque limiting ratchet handle 1Nm **[40.6650]** and screwdriver tip T8.0 **[40.5682]** to insert selected 4.0ChLP screw VA 2.4 **[4.5235]**.



After locking of the variable angle (VA) screw in the plate hole, do not change the angle of screw insertion. Re-locking of the screw in another position decreases efficiency of the screw-plate connection. Appropriate angle of screw insertion should be verified either at the drilling stage or before locking of the screw in the plate hole. The hole which has been used for locking of subsequently removed variable angle (VA) screw, must not be used for other locking screws insertion.



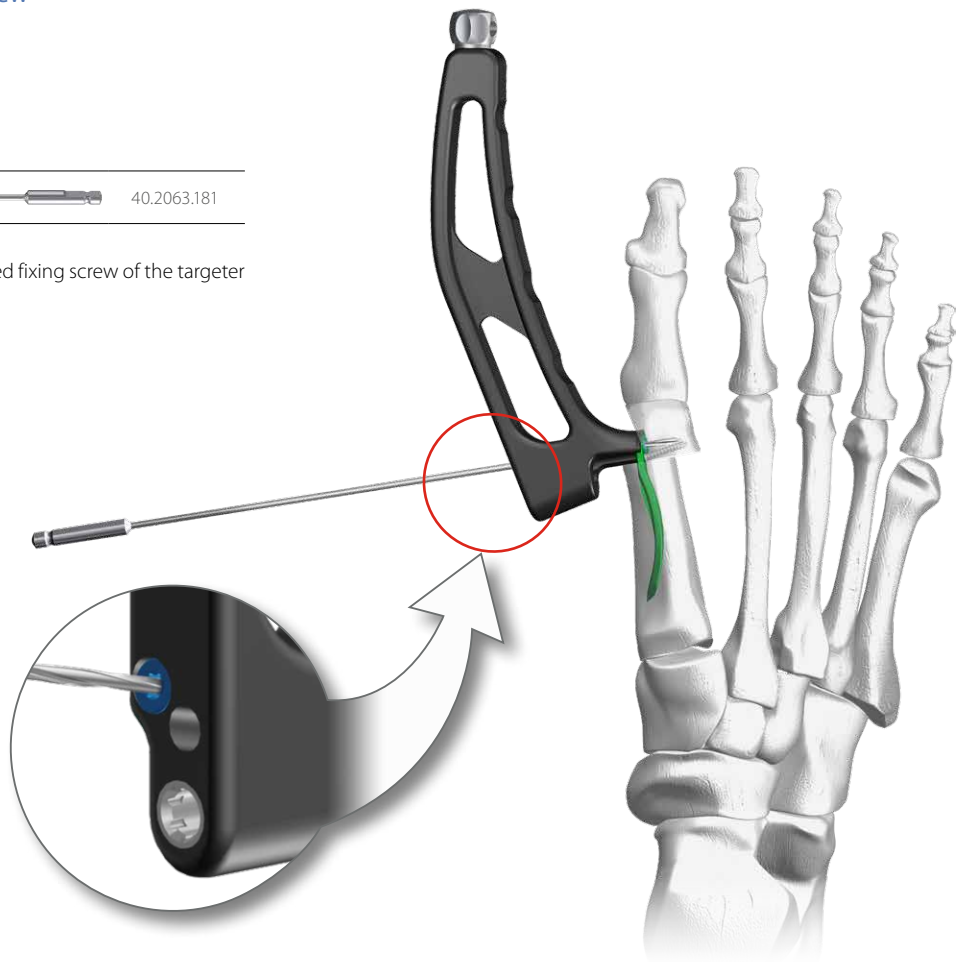
VI.B.7. Insertion of the other locking screw

VI.B.7.1 Drilling



40.2063.181

Drill using drill 1.8/180 **[40.2063.181]** via cannulated fixing screw of the targeter until the desired depth is reached.



VI.B.7.2 Targeter removal



40.5682



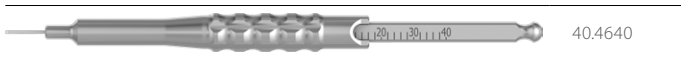
40.6281.100

40.6282.100

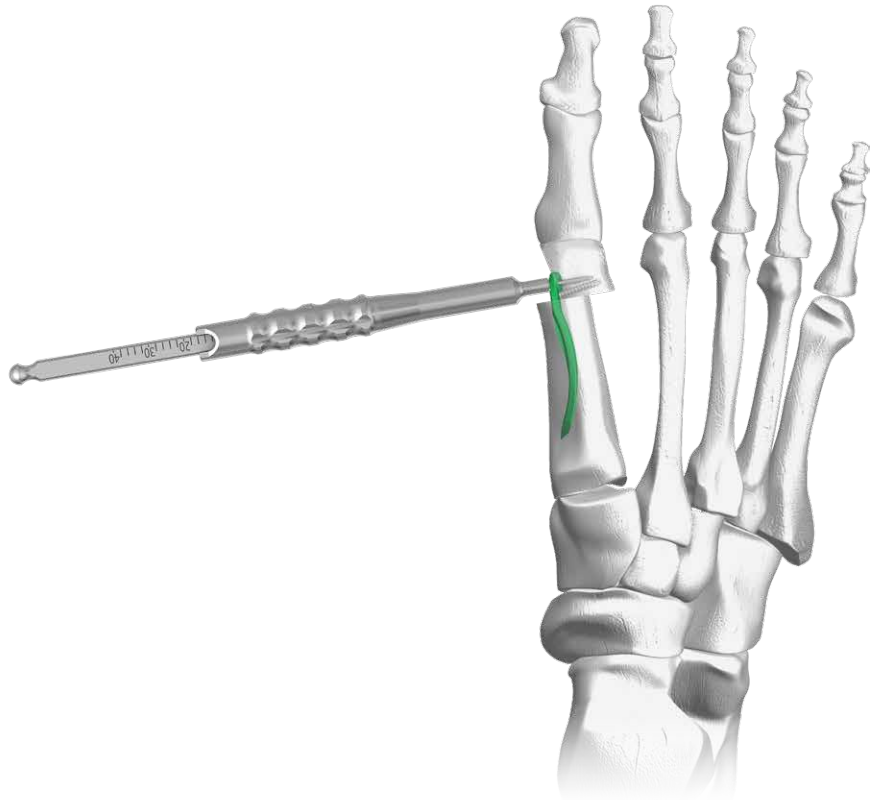
Loosen the fixing screw using screwdriver tip T8.0 **[40.5682]** and remove the targeter **[40.6281.100]/[40.6282.100]**.



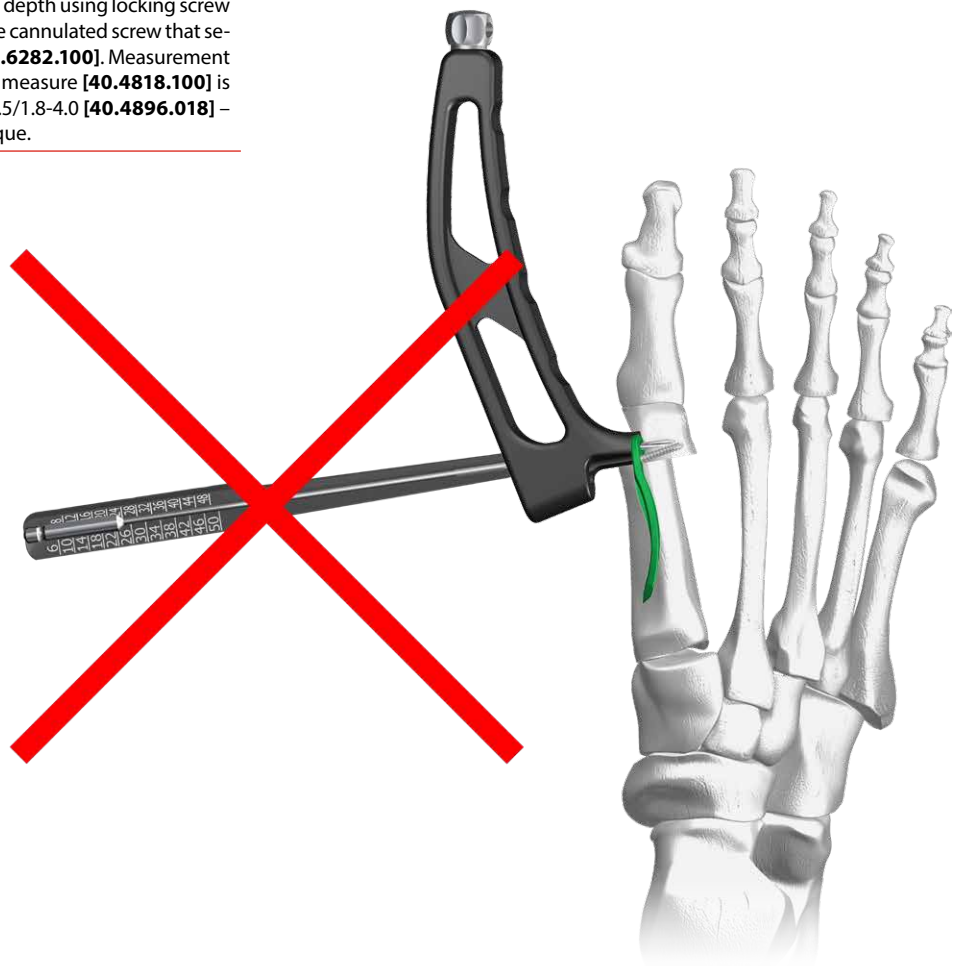
VI.B.7.3 Depth measure



Use depth measure **[40.4640]** to measure the hole depth.



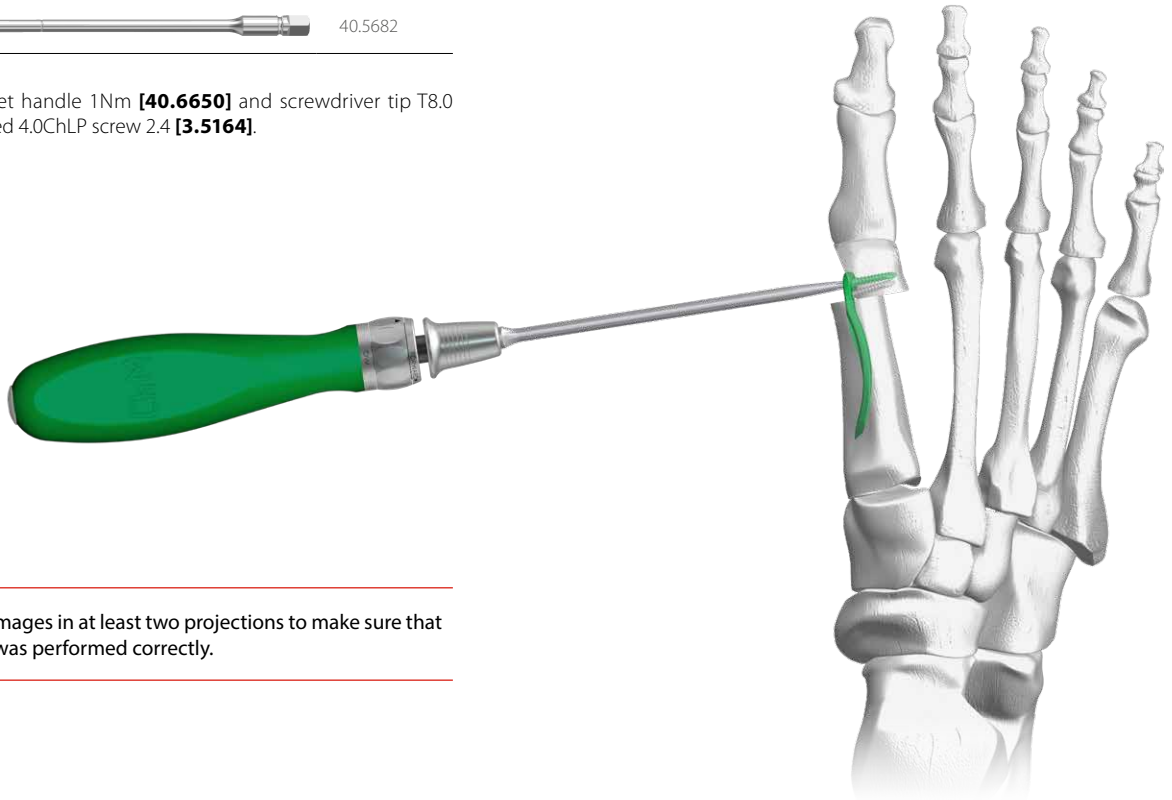
NOTE! Do not measure the other hole depth using locking screw length measure **[40.4818.100]** via the cannulated screw that secures the targeter **[40.6281.100]/[40.6282.100]**. Measurement with the use of locking screw length measure **[40.4818.100]** is possible only via threaded guide M3.5/1.8-4.0 **[40.4896.018]** – point VI.A.6.2. of this surgical technique.



VI.B.7.4 Screw insertion



Use torque limiting ratchet handle 1Nm **[40.6650]** and screwdriver tip T8.0 **[40.5682]** to insert selected 4.0ChLP screw 2.4 **[3.5164]**.



Take X-Ray images in at least two projections to make sure that the locking was performed correctly.

VII. WOUND CLOSURE

Use appropriate surgical technique to close the wound. Prior to wound closure, make sure that all screws are properly tightened.

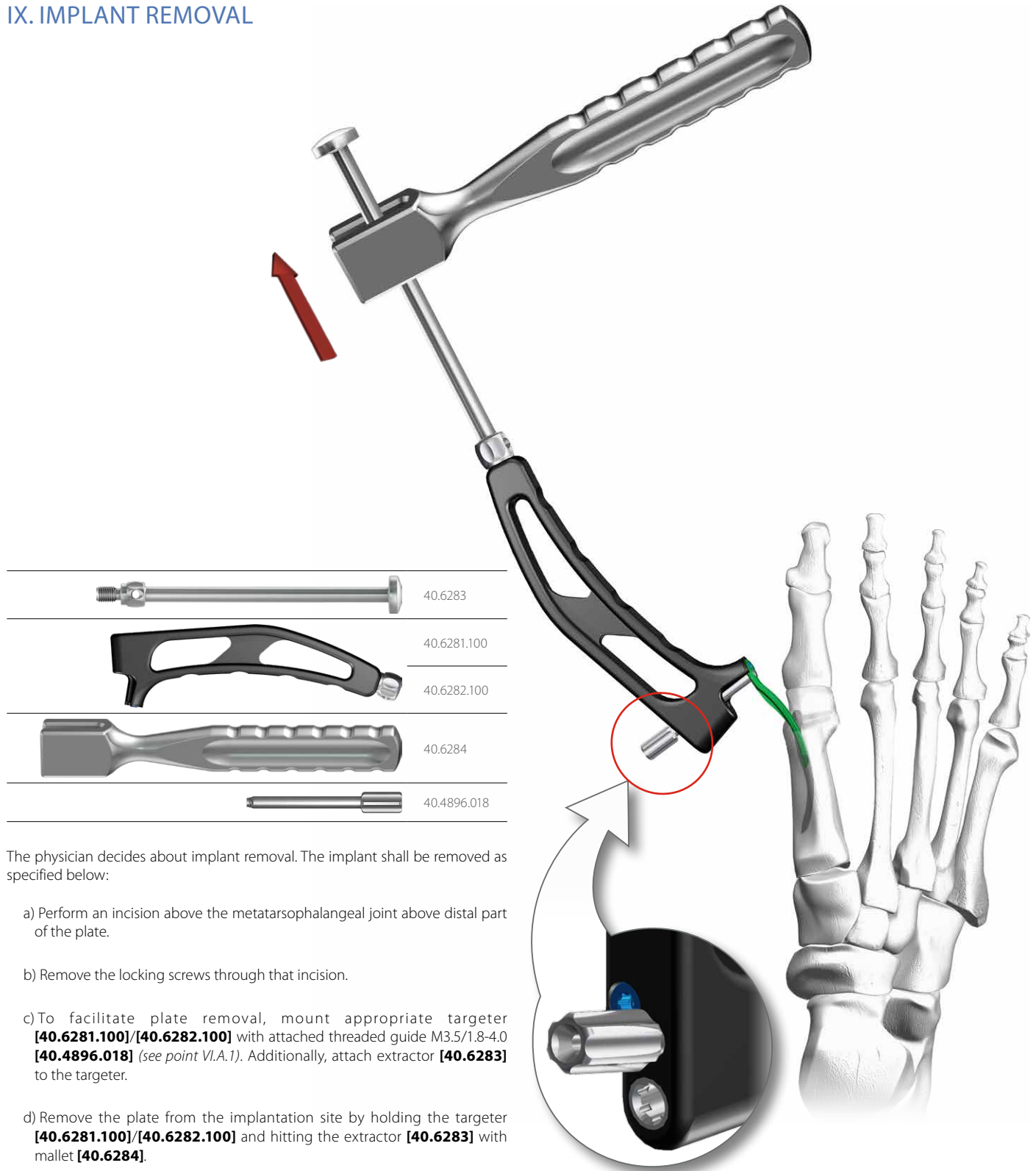


VIII. POSTOPERATIVE PROCEDURE

Introduce appropriate postoperative treatment. The physician decides on the post-operative treatment and its conduct. In order to avoid patient's movement limitations, introduce exercises as soon after surgery as possible. However, make sure that the limb is not fully loaded before fragments osteosynthesis is complete.



IX. IMPLANT REMOVAL



The physician decides about implant removal. The implant shall be removed as specified below:

- Perform an incision above the metatarsophalangeal joint above distal part of the plate.
- Remove the locking screws through that incision.
- To facilitate plate removal, mount appropriate targeter **[40.6281.100]/[40.6282.100]** with attached threaded guide M3.5/1.8-4.0 **[40.4896.018]** (see point VI.A.1). Additionally, attach extractor **[40.6283]** to the targeter.
- Remove the plate from the implantation site by holding the targeter **[40.6281.100]/[40.6282.100]** and hitting the extractor **[40.6283]** with mallet **[40.6284]**.

X. CASES OF CLINICAL USE



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