ST/65A

ChM®

4,0 ChM Locked Plating ChLP system

4.0ChLP ENDOSTEAL PLATE

- IMPLANTS
- INSTRUMENT SET 15.0204.001
- SURGICAL TECHNIQUE

www.chm.eu

SYMBOLS DESCRIPTION

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

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Document No	ST/65A
Date of issue	25.02.2016
Review date	P-006-10.12.2020

I. INTRODUCTION

Endosteal plates are used for the first metatarsal bone correction. The plates are a part of the ChLP 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 plate, locking screws)*,
- instrument set used for plates implantation/ removal,
- surgical technique.

The plate is used to treat:
- metatarsus primus varus *(hallux valgus)*

Contraindications:
- infections,
- growing children.

Plate selection
The plates are available in various length sizes and two blade deflection variants. This allows for optimal selection of the implant to the occurring deformation.

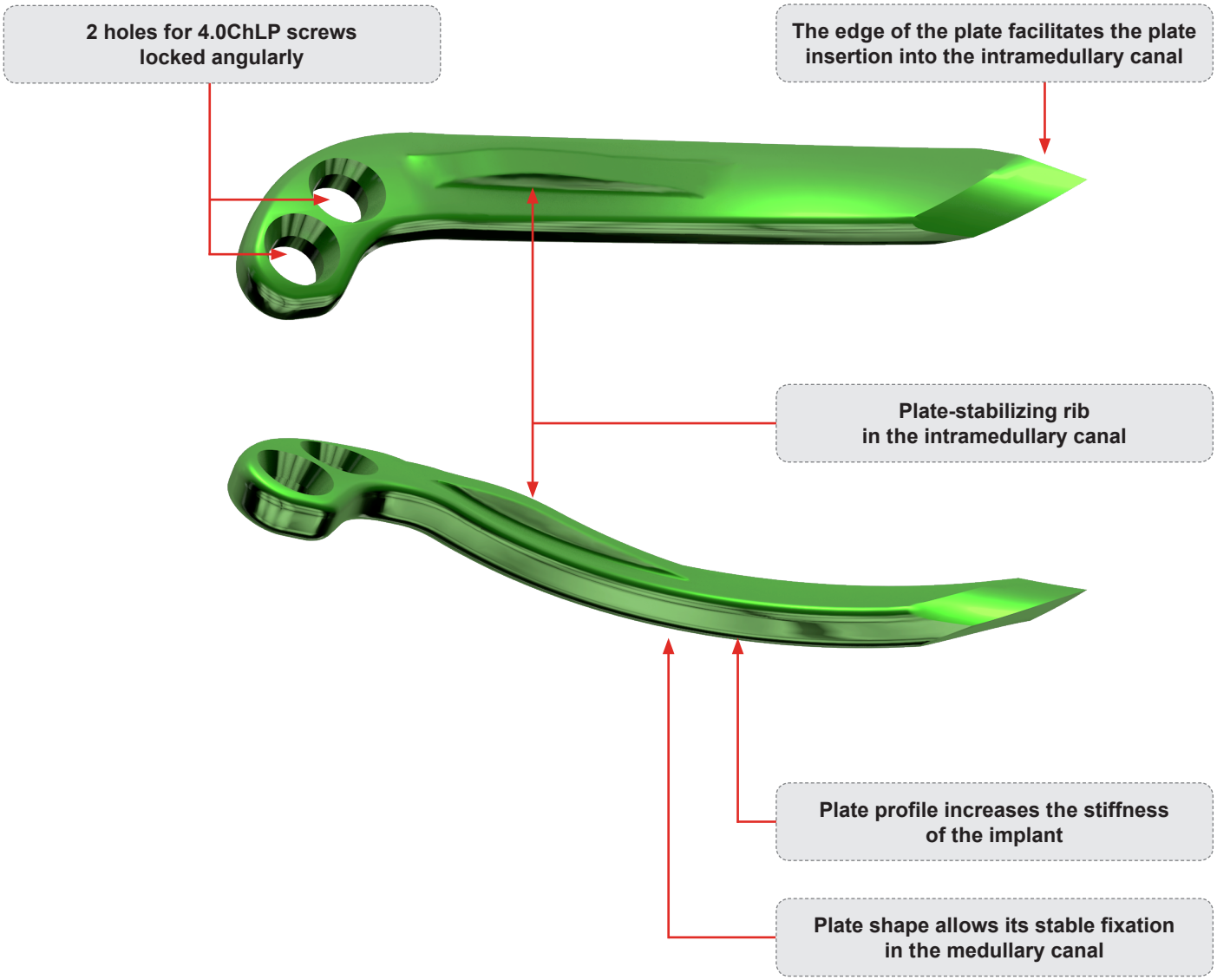
Plate shaping
Shaping of the plates is not allowed.

Prior to use, carefully read the instructions for use supplied with the device and attached at the end of this document. It includes, e.g.: indications, contraindications, adverse effects, recommendations and warnings related to the device use.

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.

Plate properties



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4.0ChLP endosteal plate

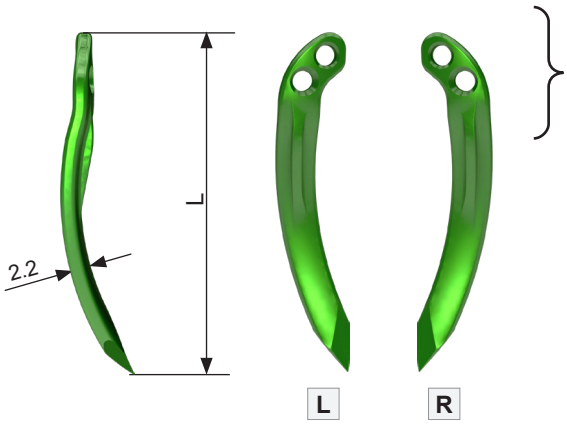
TITANIUM

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



Titanium
3.5164.006-040
Ø2.4

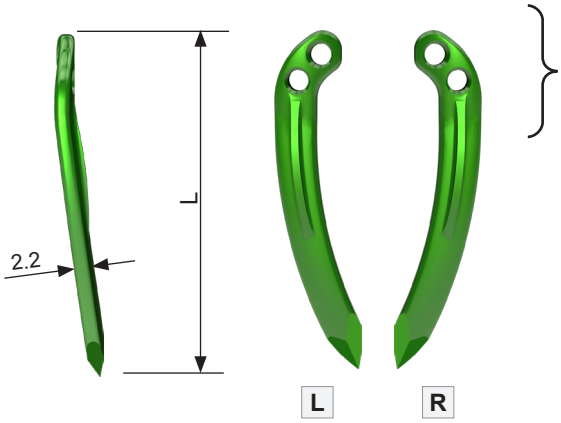
Cobalt
4.5235.006-040
Ø2.4

Left

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

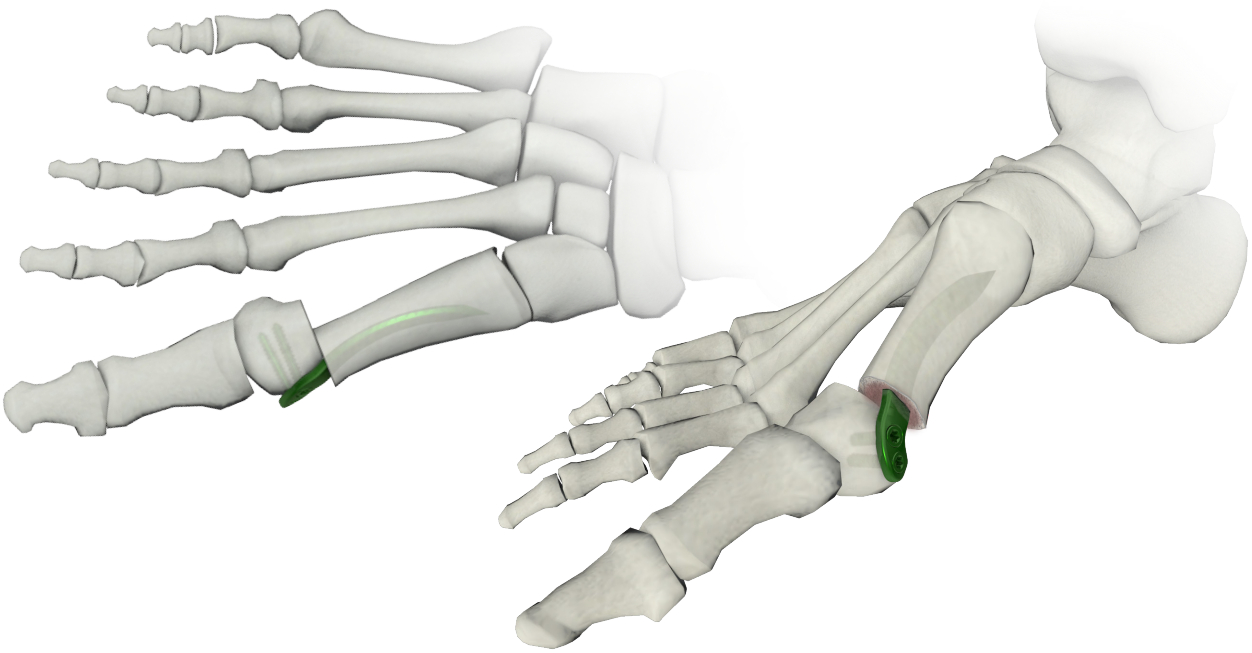
Right

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



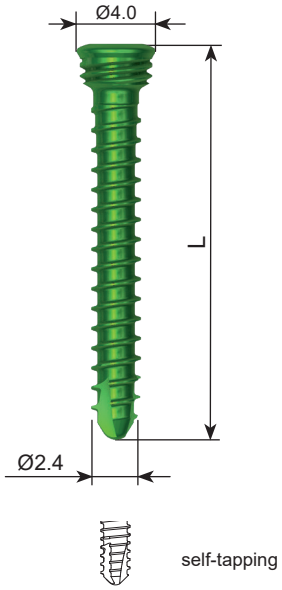
Titanium
3.5164.006-040
Ø2.4

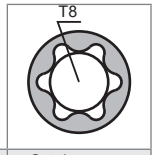
Cobalt
4.5235.006-040
Ø2.4



TITANIUM ALLOY

4.0ChLP screw 2.4

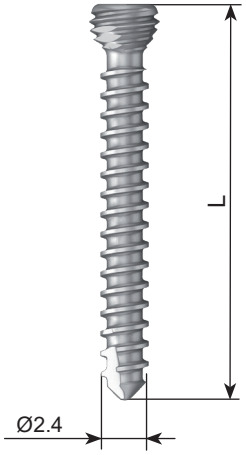


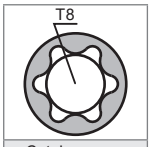


L [mm]	Catalogue no.
6	3.5164.006
8	3.5164.008
10	3.5164.010
12	3.5164.012
14	3.5164.014
16	3.5164.016
18	3.5164.018
20	3.5164.020
22	3.5164.022
24	3.5164.024
26	3.5164.026
28	3.5164.028
30	3.5164.030
32	3.5164.032
34	3.5164.034
36	3.5164.036
38	3.5164.038
40	3.5164.040

COBALT ALLOY

4.0ChLP Screw VA 2.4





L [mm]	Catalogue no. Cobalt
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

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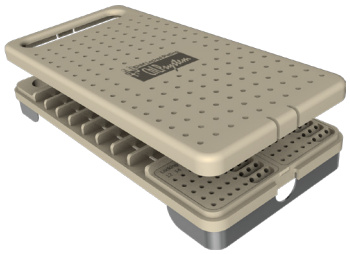
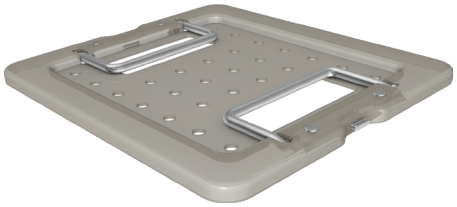
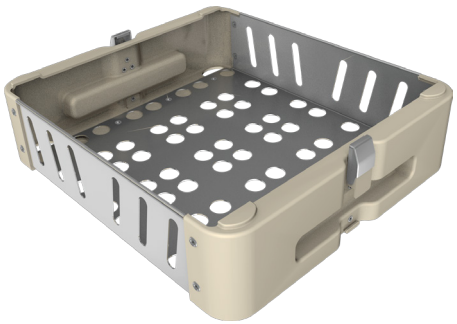
III. INSTRUMENT SET

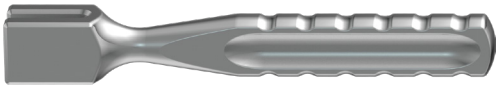
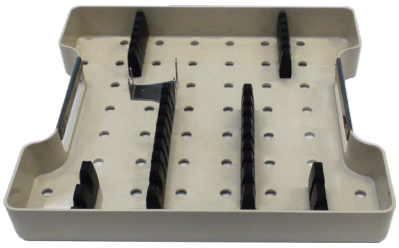
Set for 4.0ChLP 3.7060/3.7061 4x4 H

15.0204.001

No.		Name	Catalogue No.	Pcs
1		Instrument set for 4.0ChLP 3.7060/3.7061 4x4 1/2H	**15.0204.201**	1
2		Instrument set for 4.0ChLP 3.7060/3.7061 4x2 1/2H	**15.0204.202**	1
3		Stand for 4.0ChLP implants 3.7060/3.7061 4x2 1/2H	**14.0204.601**	1
4		4.0ChLP container lid 3.7060/3.7061 4x4	**14.0204.104**	1
5		4.0ChLP container 3.7060/3.7061 4x4	**14.0204.103**	1

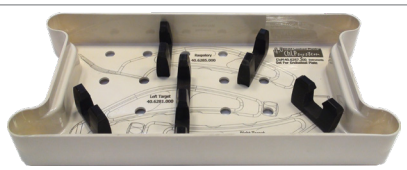
Instrument set for 4.0ChLP 3.7060/3.7061 4x4 1/2H

15.0204.201

No.		Name	Catalogue No.	Pcs
1		Threaded guide M3.5/1.8 -4.0	**40.4896.018**	2
2		Drill 1.8/180	**40.2063.181**	1
3		Screwdriver tip T8.0	**40.5682.000**	1
4		Screwdriver tip T8 with holder	**40.5989.000**	1
5		Depth measure	**40.4640.000**	1
6		Locking screw length measure	**40.4818.100**	1
7		BUCK-GRAMCKO elevator 7.5	**40.2185.000**	2
8		Mallet	**40.6284.000**	1
9		Extractor	**40.6283.000**	1
10		Torque limiting ratchet handle1Nm	**40.6650.000**	1
11		Guide VA 1.8	**40.5928.018**	1
12		Tray for 4.0ChLP instrument set 3.7060/3.7061 4x4 1/2H	**14.0204.201**	1

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

15.0204.202

No.		Name	Catalogue No.	Pcs
1		Raspatory	**40.6285.000**	1
2		Targeter for endosteal plate - left	**40.6281.000 ***	1
3		Targeter for endosteal plate - right	**40.6282.000 ****	1
4		Tray for 4.0ChLP instrument set 3.7060/3.7061 4x2 1/2H	**14.0204.202**	1

* use with plates 3.7061.1xx; 3.7061.2xx
** use with plates 3.7060.1xx; 3.7060.2xx

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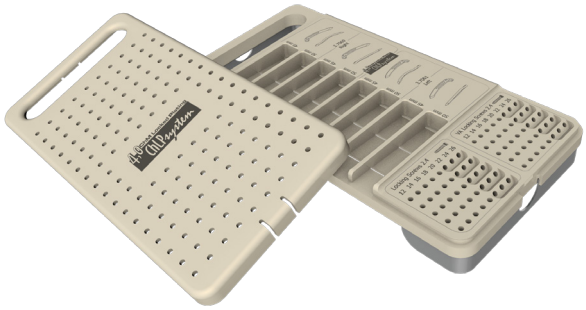
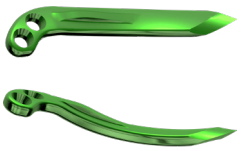
Stand for 4.0ChLP implants 3.7060/3.7061 4x2 1/2H

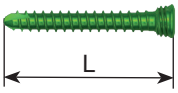
14.0204.601



4.0ChLP endosteal plate

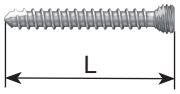


4.0ChLP Screw 2.4



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

* Tray does not include implants

IV. SURGICAL TECHNIQUE

IV.1. PATIENT'S POSITIONING

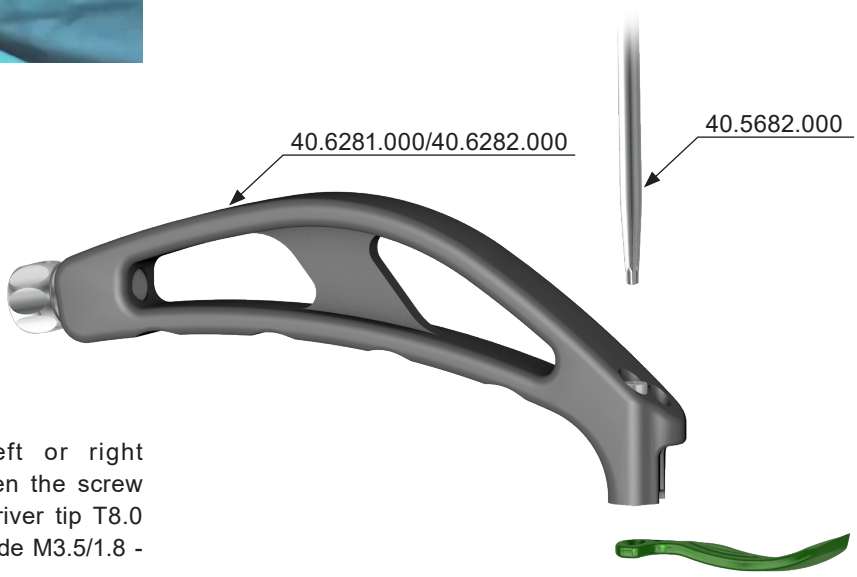
It is recommended to position the patient on his back with a roller under his calf to lift the foot.

IV.2. SURGICAL APPROACH

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

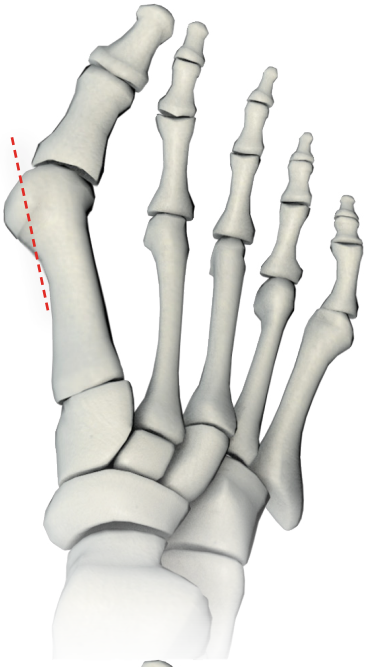
IV.3. TARGETER AND PLATE ASSEMBLY

Attach targeter for endosteal plate – left or right **[40.6281.000/40.6282.000]** to the plate. Tighten the screw that fixes the targeter with plate using screwdriver tip T8.0 **[40.5682.000]**. Additionally, lock the threaded guide M3.5/1.8 - 4.0 **[40.4896.018]**.



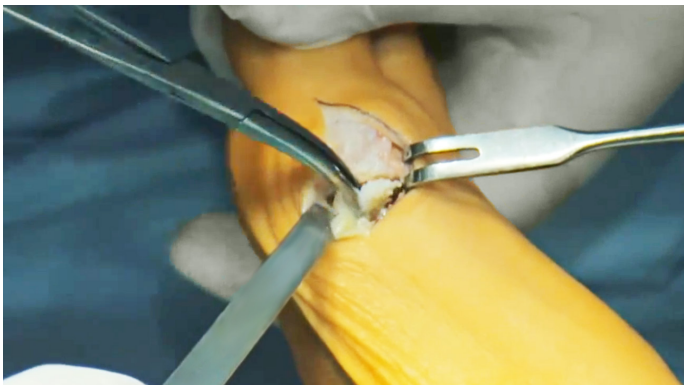
IV.4. BONE CORRECTION

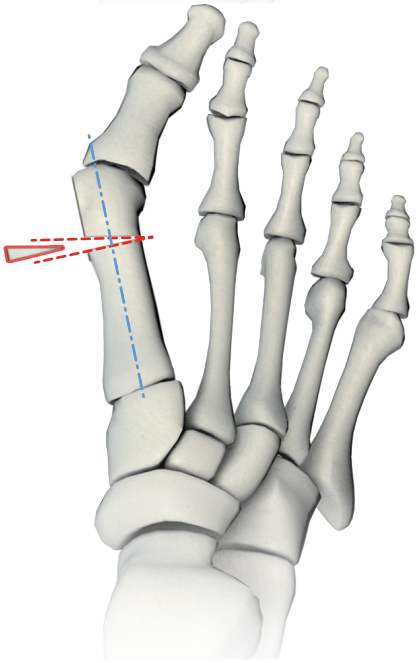
If need be, prior to osteotomy, remove a part of the first metatarsal bone.



IV.5. BONE CUTTING

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

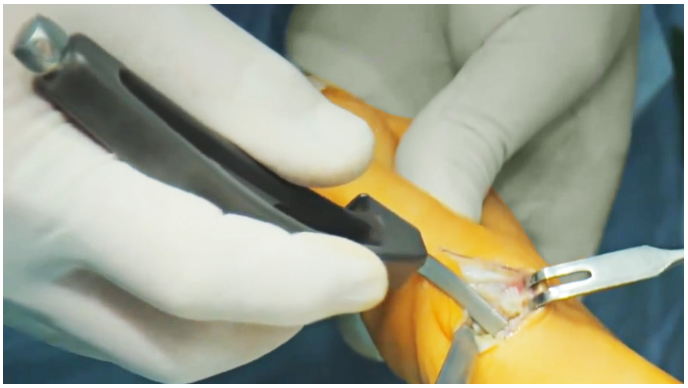


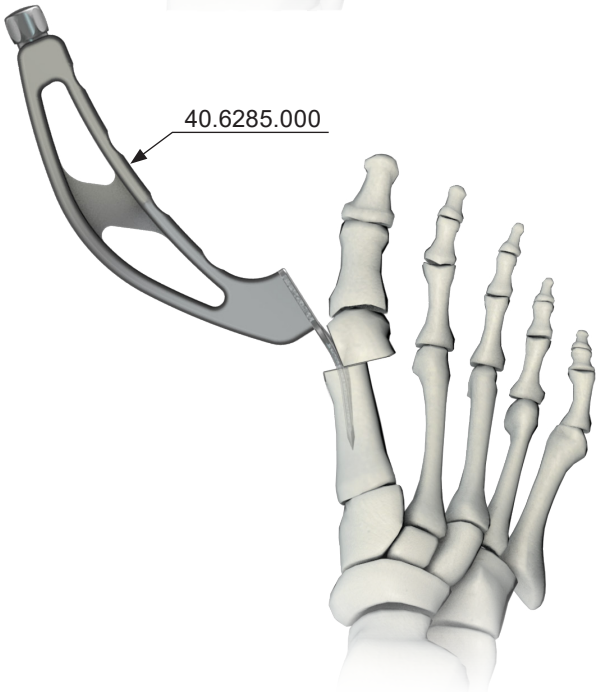


IV.6. MEDULLARY CANAL PREPARATION

Prepare the medullary canal for plate insertion using raspatory **[40.6285.000]**.

Note:
Use mallet [40.6284.000] if required.

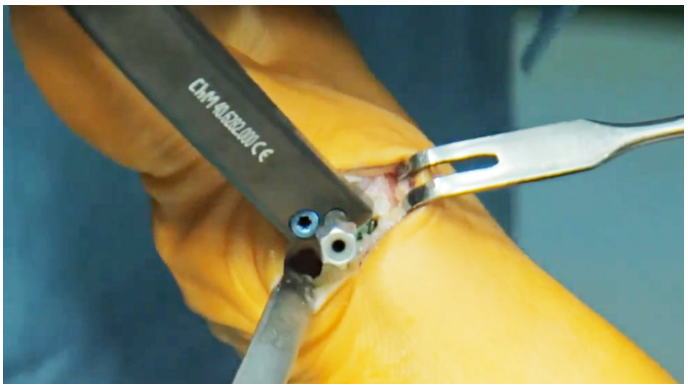




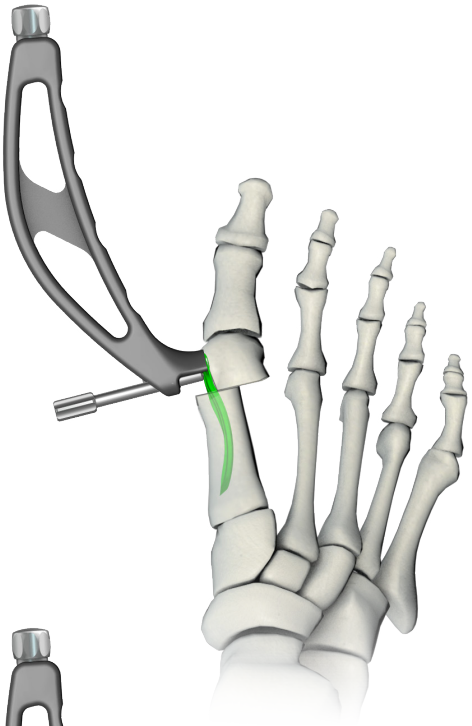
IV.7. PLATE INSERTION

Insert the plate into the prepared canal.

Note:
Use mallet [40.6284.000] if required.



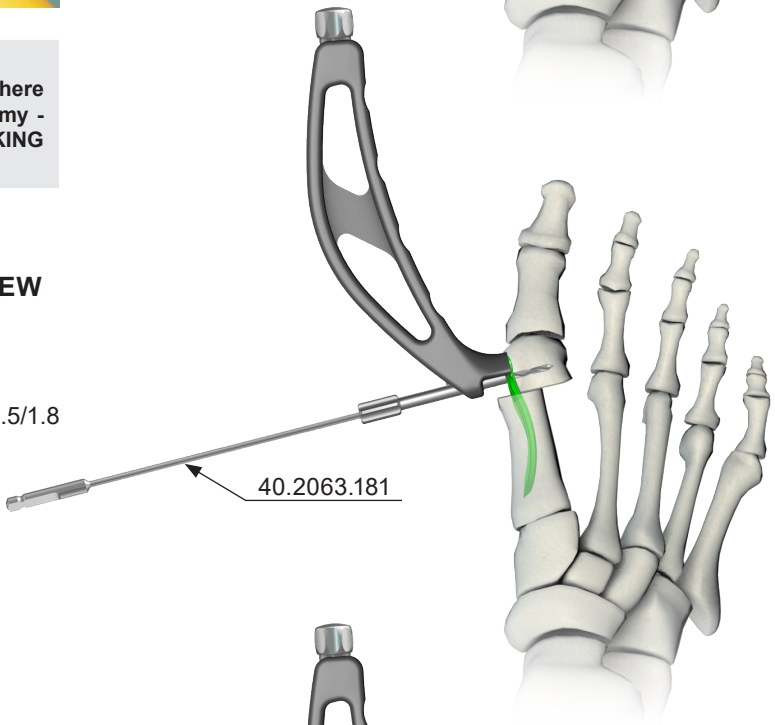
NOTE:
If there is a need for a deeper plate introduction, where the screw is too close to the edge of the osteotomy - see point IV.10 TECHNIQUE WITH USE OF VA LOCKING SCREW.



IV.8. INSERTION OF THE FIRST LOCKING SCREW

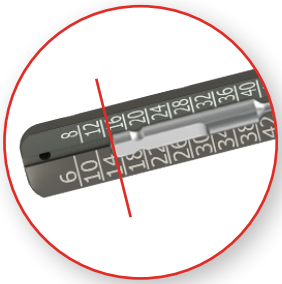
IV.8.1. DRILLING

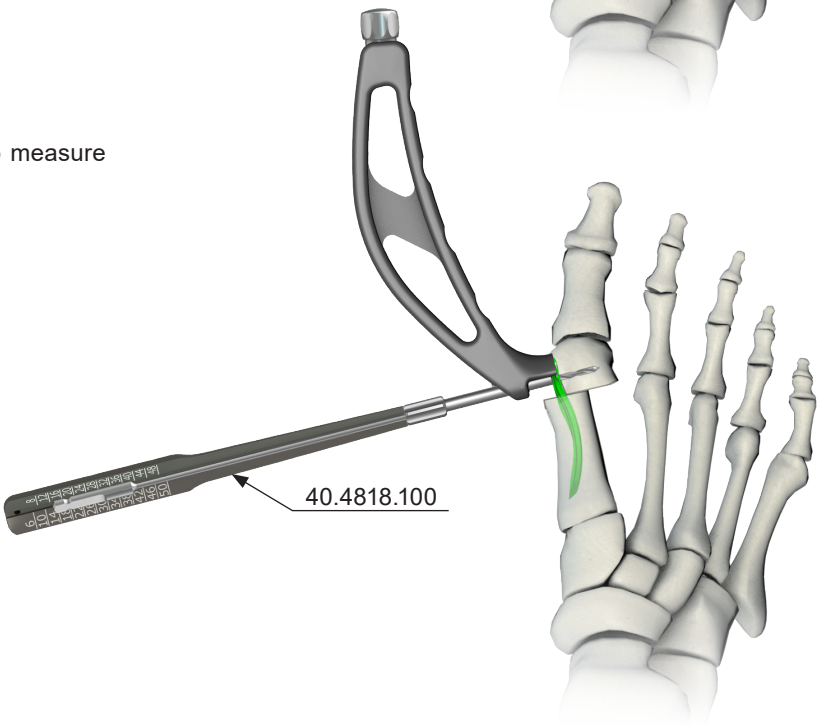
Drill using drill 1.8/180 **[40.2063.181]** via threaded guide M3.5/1.8 - 4.0 **[40.4896.018]** until the desired depth is reached.



IV.8.2. HOLE DEPTH MEASUREMENT

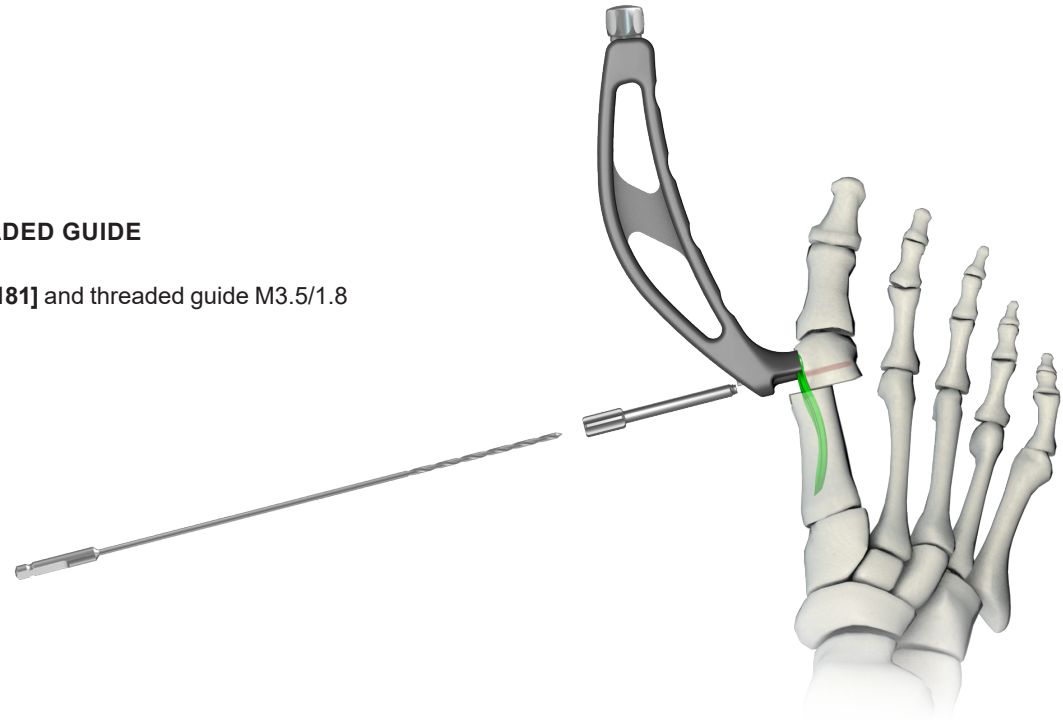
Use locking screw length measure **[40.4818.100]** to measure the hole depth.





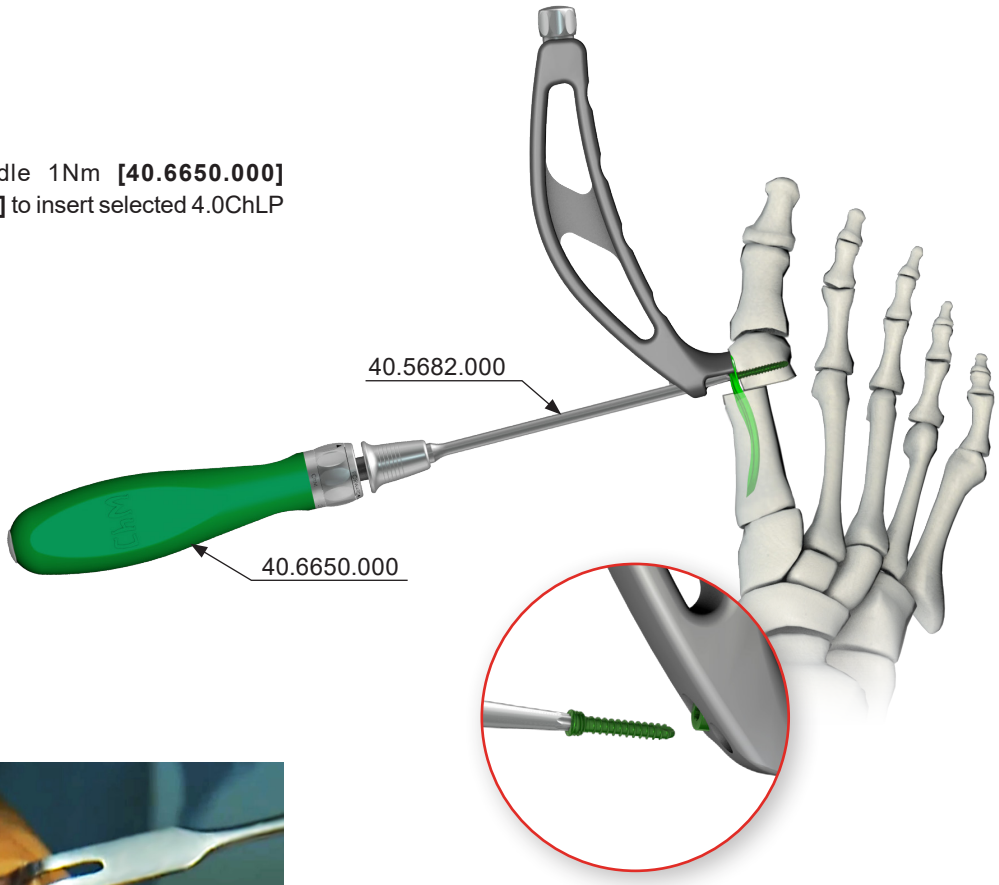
IV.8.3. REMOVAL OF THREADED GUIDE

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



IV.8.4. SCREW INSERTION

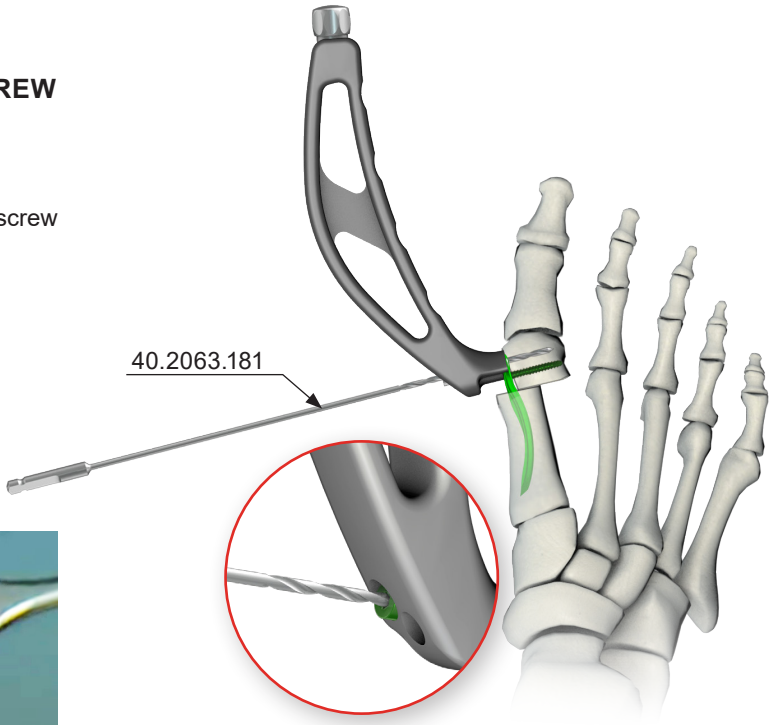
Use torque limiting ratchet handle 1Nm **[40.6650.000]** and screwdriver tip T8.0 **[40.5682.000]** to insert selected 4.0ChLP screw 2.4 **[3.5164]**

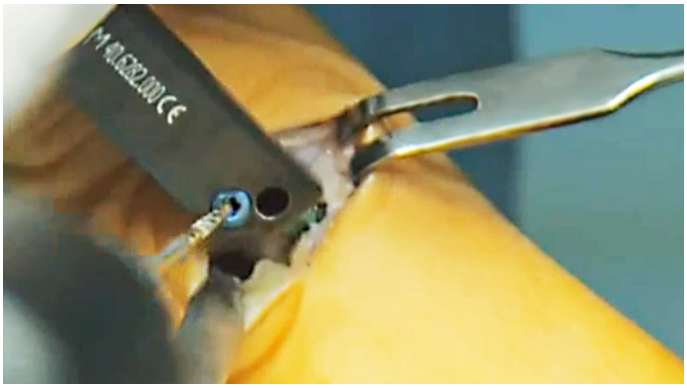


IV.9. INSERTION OF THE OTHER LOCKING SCREW

IV.9.1. DRILLING

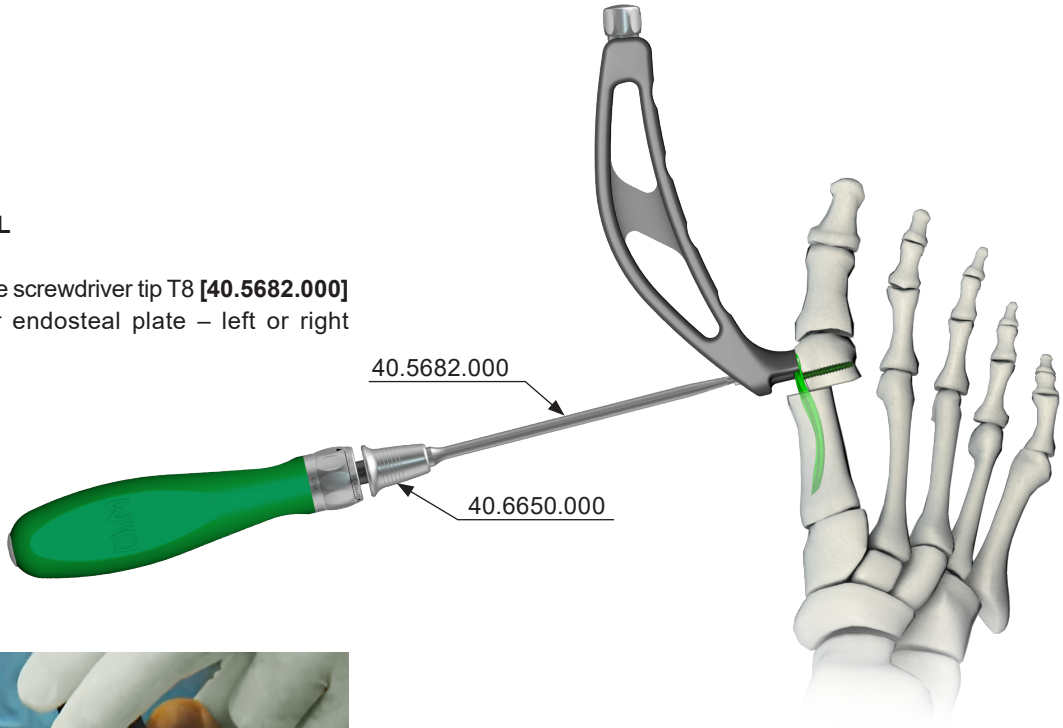
Drill using drill 1.8/180 **[40.2063.181]** via cannulated fixing screw until the desired depth is reached.

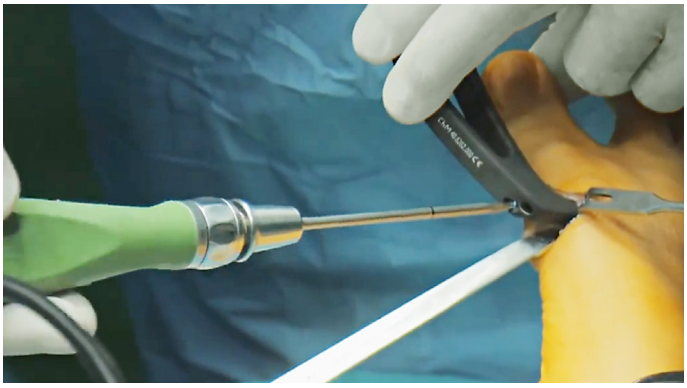




IV.9.2. TARGETER REMOVAL

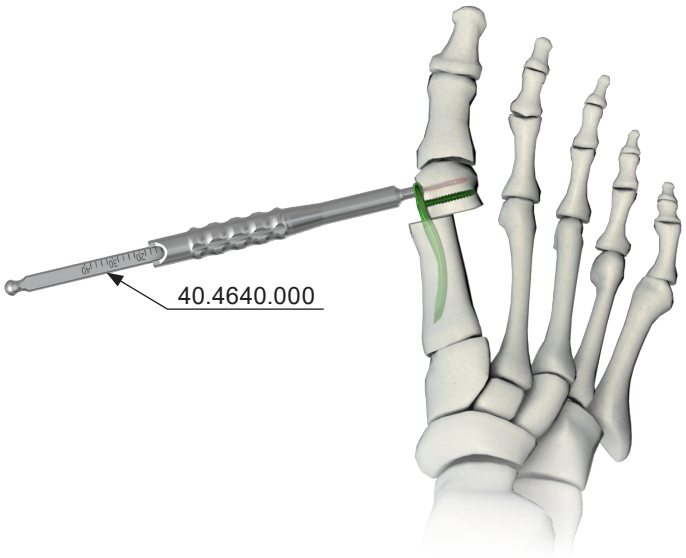
Loosen the fixing screw using the screwdriver tip T8 **[40.5682.000]** and then remove targeter for endosteal plate – left or right **[40.6281.000/40.6282.000]**.





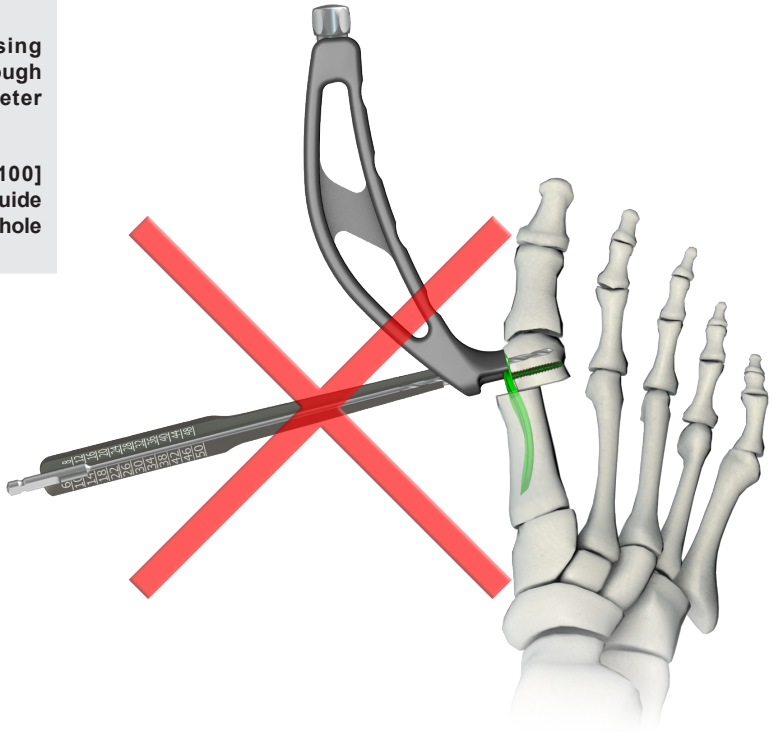
IV.9.3. HOLE DEPTH MEASUREMENT

Use depth measure **[40.4640.000]** to measure the depth.



Note:
Do not measure the second hole depth using locking screw length measure [40.4818.100] through the cannulated screw that secures the targeter [40.6281.000/ 40.6282.000].

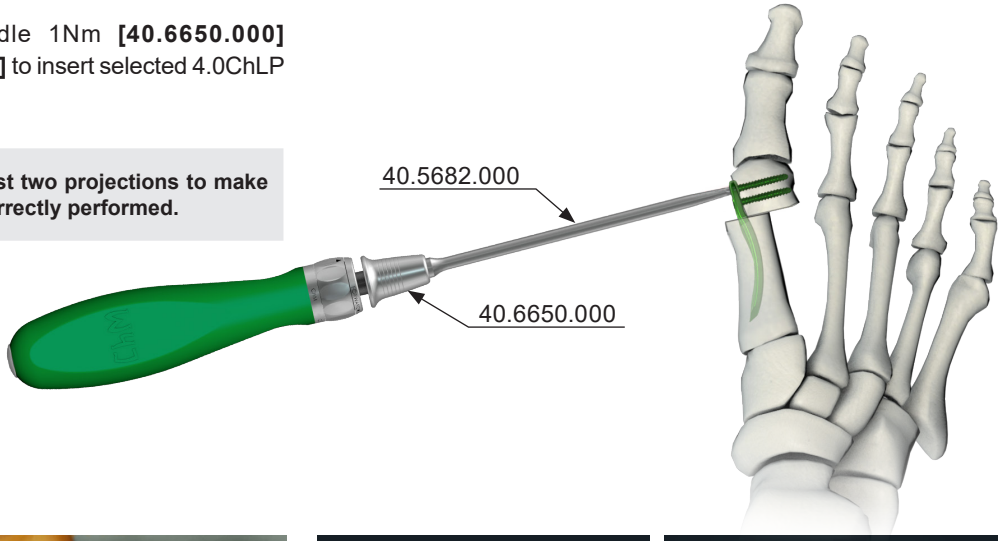
Use locking screw length measure [40.4818.100] to measure the hole depth only when the threaded guide M3.5/1.8 - 4.0 [40.4896.018] is attached to the locking hole of the plate - p. IV.8.2 of this surgical technique

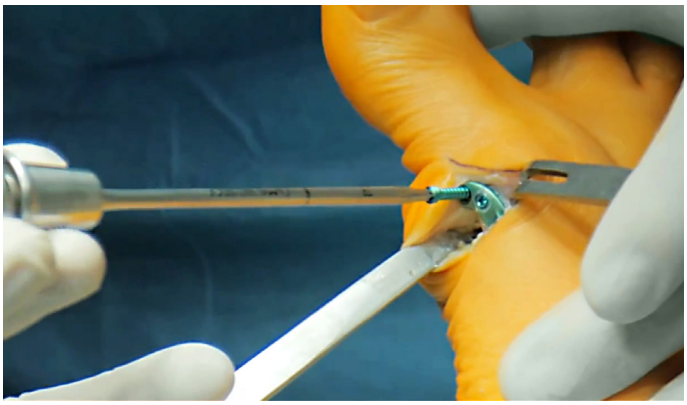


IV.9.4. SCREW INSERTION

Use torque limiting ratchet handle 1Nm **[40.6650.000]** and screwdriver tip T8.0 **[40.5682.000]** to insert selected 4.0ChLP screw 2.4 **[3.5164]**

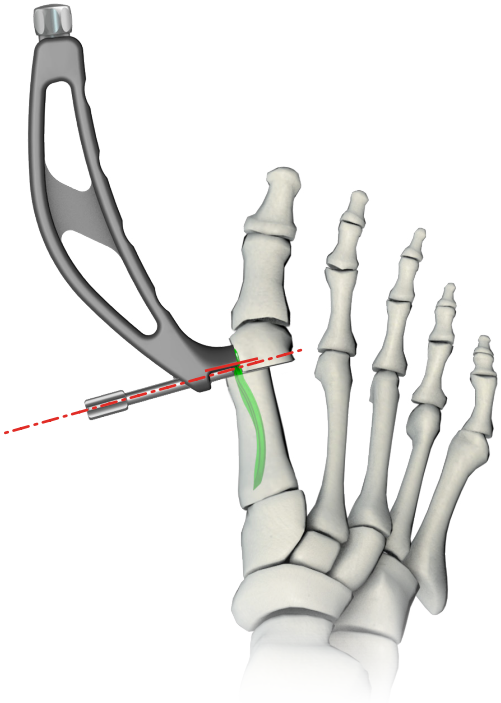
Take X-Ray images in at least two projections to make sure that the locking was correctly performed.





IV.10. TECHNIQUE WITH USE OF VA LOCKING SCREW

Use the technique if there is a need for a deeper plate introduction, where the screw is too close to the edge of the osteotomy Firstly, insert 4.0ChLP screw 2.4 **[3.5164]** into the distal hole of the plate *(p. IV.10.1)* and then 4.0ChLP screw VA 2.4 **[4.5235]** into the proximal hole of the plate *(p. IV.10.2)*.

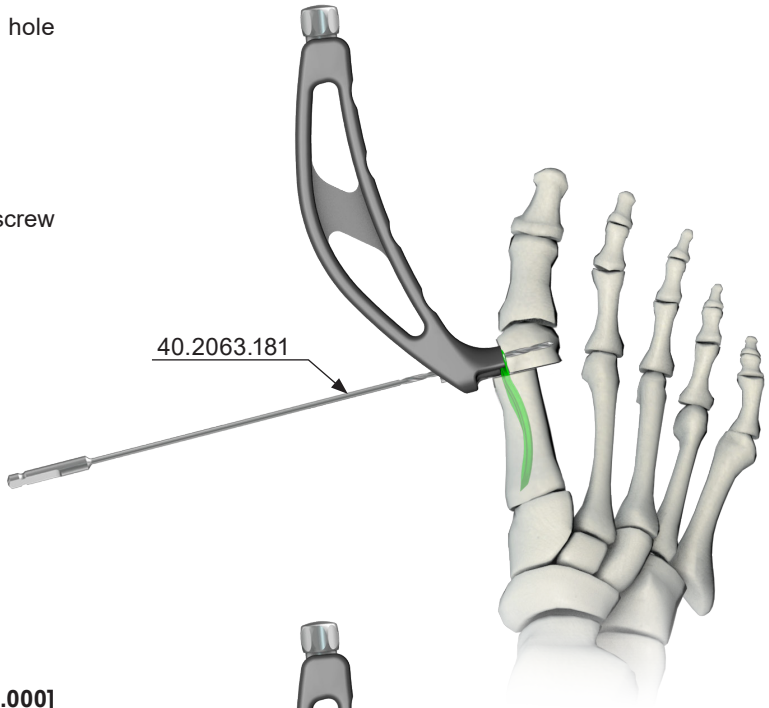


IV.10.1. FIRST LOCKING SCREW INSERTION

Firstly, insert 4.0ChLP screw 2.4 **[3.5164]** into the distal hole of the plate.

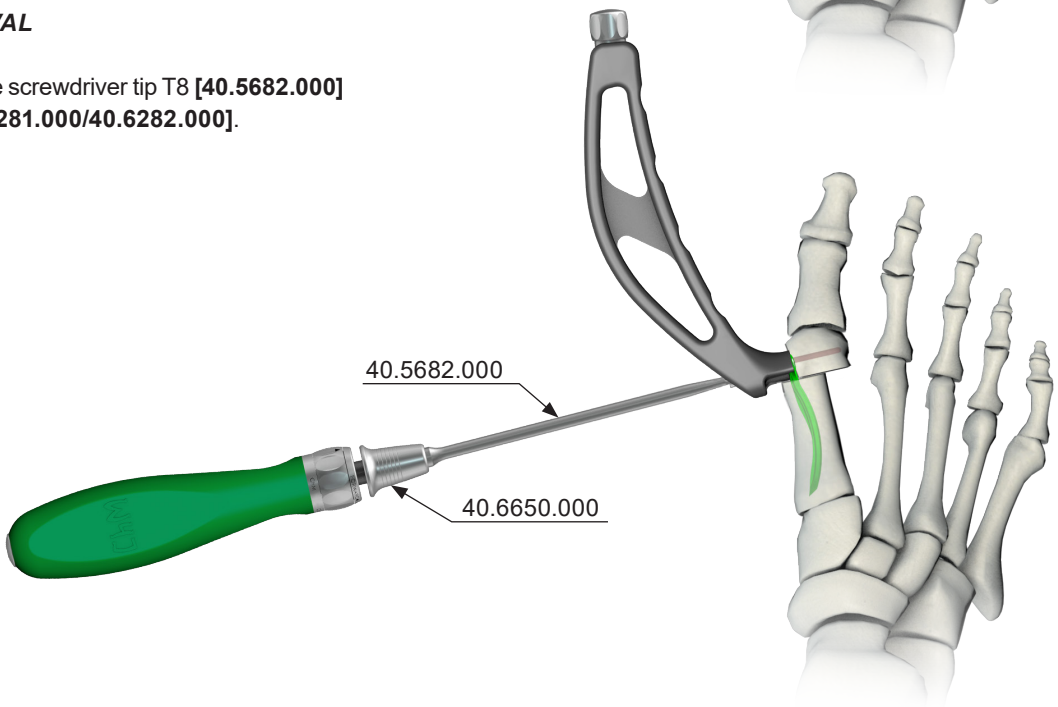
IV.10.1.1 DRILLING

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



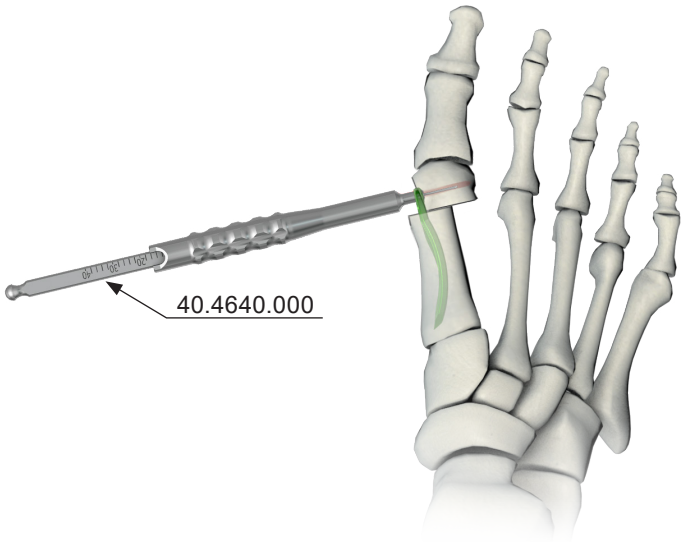
IV.10.1.2 TARGETER REMOVAL

Loosen the fixing screw using the screwdriver tip T8 **[40.5682.000]** and then remove targeter **[40.6281.000/40.6282.000]**.



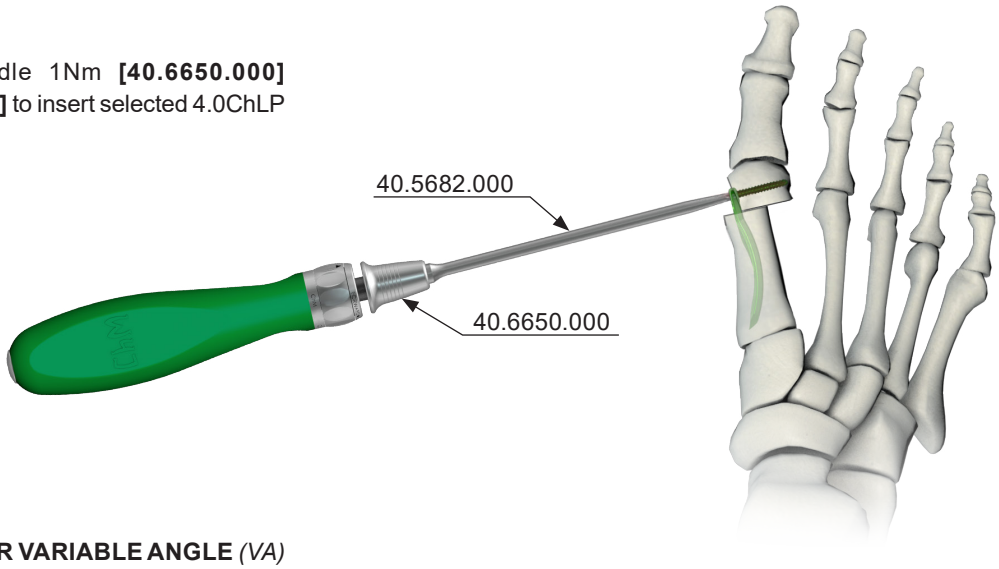
IV.10.1.3 HOLE DEPTH MEASUREMENT

Use depth measure **[40.4640.000]** to measure the hole depth.



IV.10.1.4 SCREW INSERTION

Use torque limiting ratchet handle 1Nm **[40.6650.000]** and screwdriver tip T8.0 **[40.5682.000]** to insert selected 4.0ChLP screw 2.4 **[3.5164]**



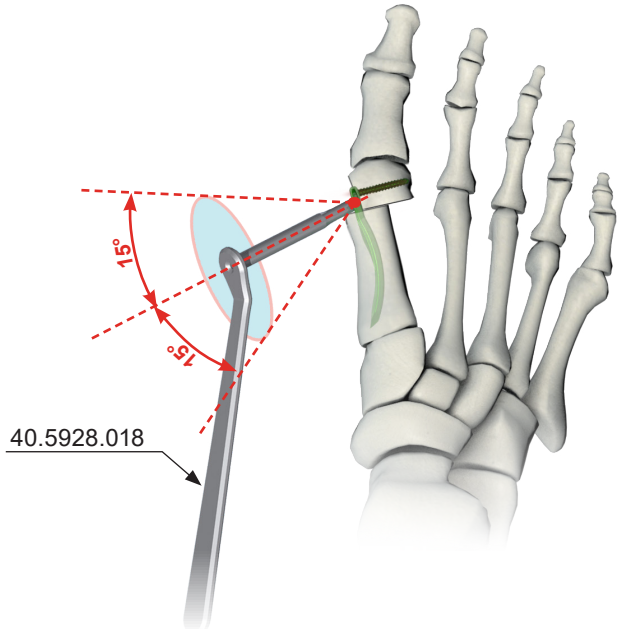
IV.10.2. INSERTION OF THE OTHER VARIABLE ANGLE *(VA)* LOCKING SCREW

Secondly, insert 4.0ChLP screw VA 2.4 **[4.5235]** into the proximal hole of the plate.

NOTE:
When using variable axle *(VA)* screws, there is a risk screws or drill will collide with already inserted screws. Careful planning of the screw trajectory and intraoperative X-Ray control during the drilling reduce the risk of collision.

IV.10.2.1 VA GUIDE POSITIONING

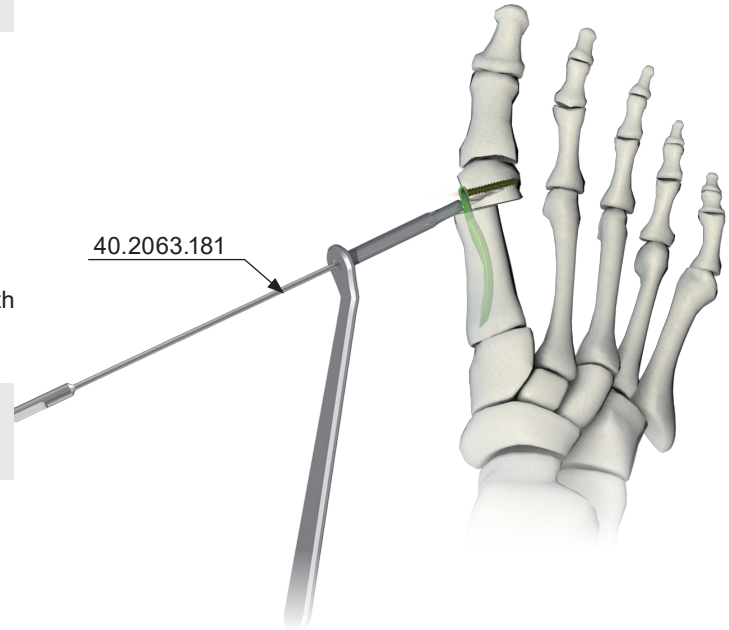
Insert fully the guide VA 1.8 **[40.5928.018]** into the locking hole axially. Then, set the desired deflection from the axis of the locking hole. The guide allows 15° tilting in any direction in relation to the locking hole axis.



Important:
Exceeding the tilt angle of more than 15° may prevent proper locking of the VA screw in the plate hole.

IV.10.2.2 DRILLING

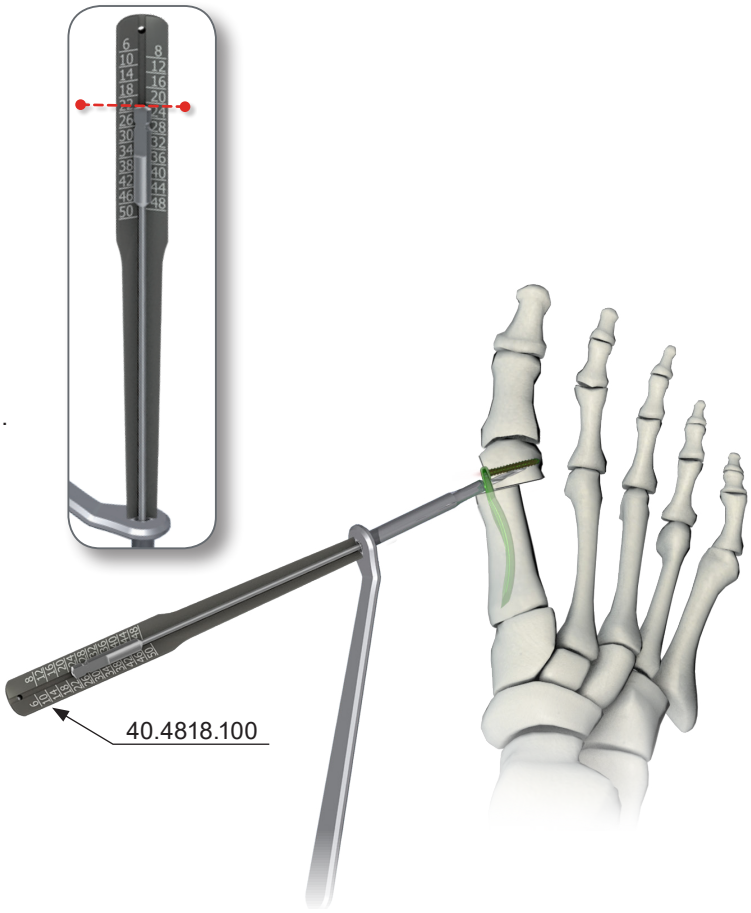
Drill using drill 1.8/180 **[40.2063.181]** until the desired depth is reached.



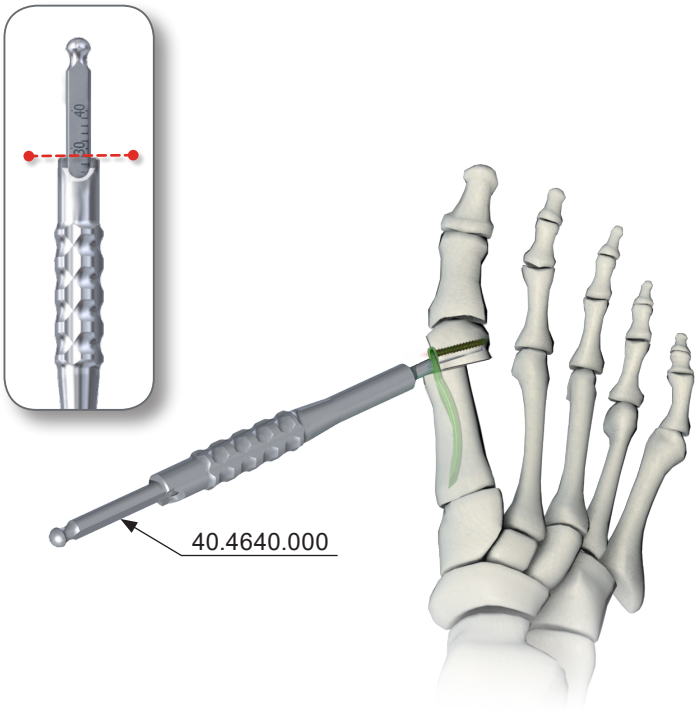
NOTE:
Drill under the X-Ray control in order to avoid the collision of the drill with already inserted screws.

IV.10.2.3 HOLE DEPTH MEASUREMENT

OPTION I: Use locking screw length measure **[40.4818.100]**.



OPTION II: Remove VA guide and use the depth measure **[40.4640.000]** to determine the length of the locking screw.



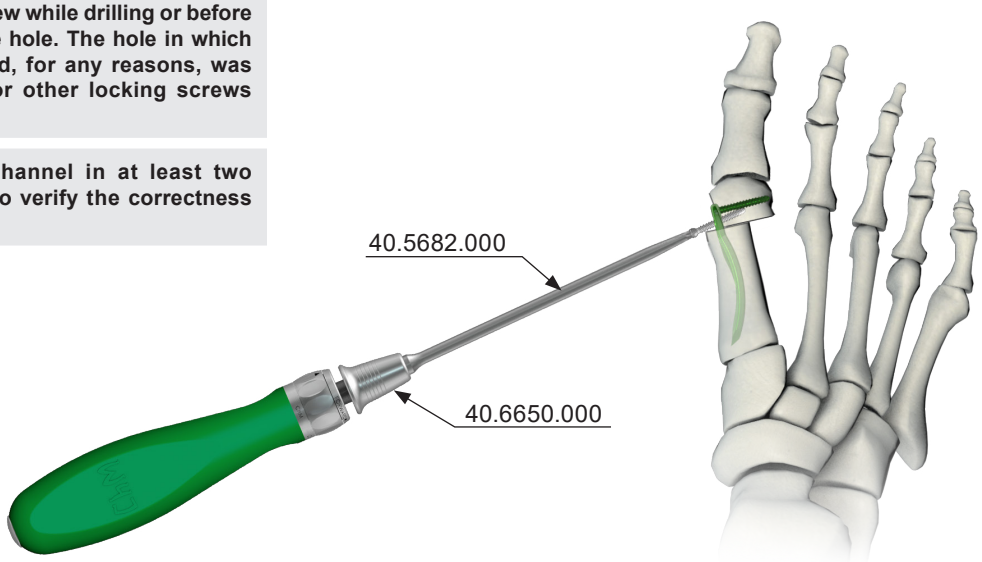
VA SCREW INSERTION

Use torque limiting ratchet handle 1Nm **[40.6650.000]** and screwdriver tip T8.0 **[40.5682.000]** to insert selected 4.0ChLP screw VA 2.4 **[4.5235]**

NOTE:
For large tilt angles of VA screws in relations to the locking hole axis, after tightening using torque limiting ratchet handle, the screw head may protrude from the plate. In such case, the use of star screwdriver T8 [40.0669.100] may be needed. Gently tighten the VA screw, paying attention to not damage the screw socket or screwdriver tip, and to not insert the screw too deep into the plate.

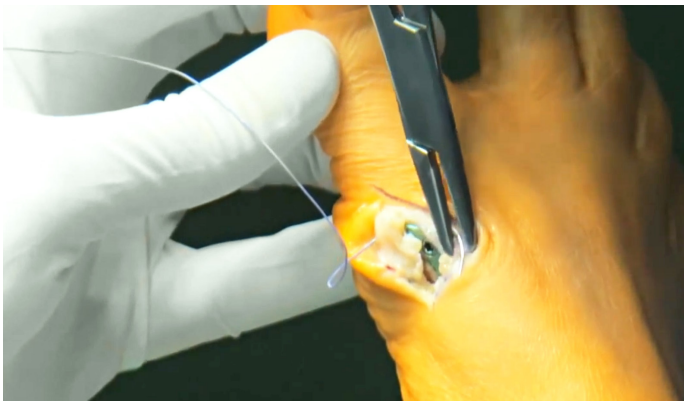
After locking the variable angle *(VA)* screw in the plate hole, do not change the angle of its introduction. Re-locking of the screw in another position reduces the efficiency of the screw-plate connection. Verify the correct position of the screw while drilling or before locking the screw in the plate hole. The hole in which the VA screw was locked and, for any reasons, was removed, cannot be used for other locking screws insertion.

X-Ray camera with video channel in at least two projections should be used to verify the correctness of the locking performed.



IV.11. WOUND CLOSURE

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



V. POSTOPERATIVE PROCEDURE

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

VI. IMPLANT REMOVAL

The physician decides about implant removal.

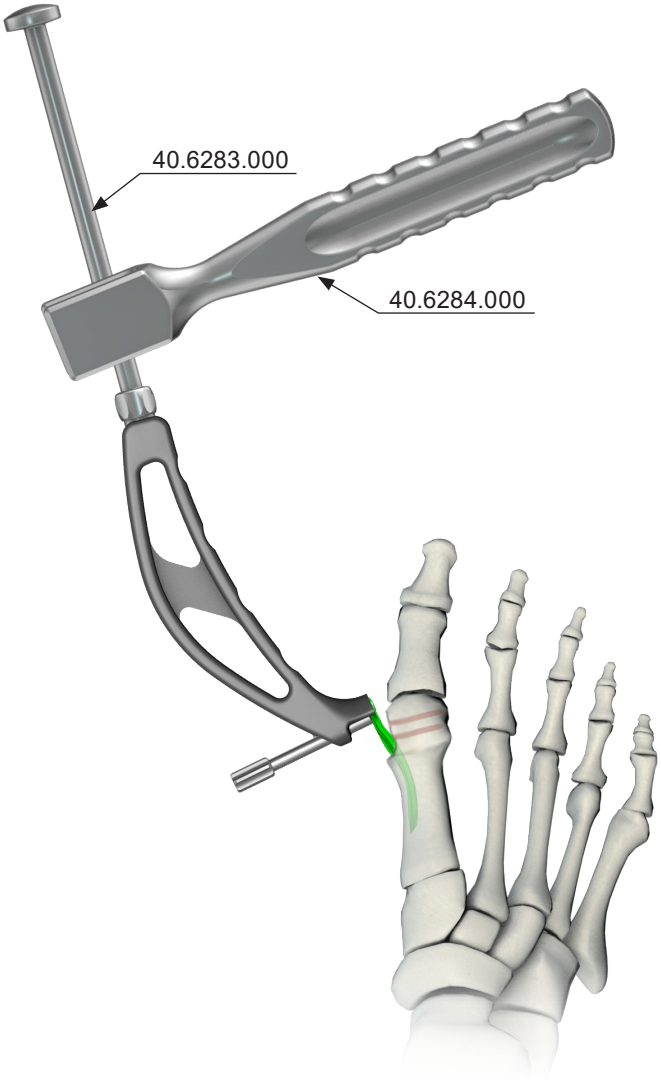
The implant shall be removed as specified below:

a) Perform an incision above the metatarsophalangeal joint above distal part of the plate.

b) Remove the locking screws through that incision.

c) To facilitate plate removal, mount *(acc. point IV.3)* appropriate targeter **[40.6281.000 /40.6282.000]** with attached extractor **[40.6283.000]**.

d) Remove the plate by holding the targeter **[40.6281.000 /40.6282.000]** and hitting the extractor **[40.6283.000]** with mallet **[40.6284.000]**.



ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Kościelny
Poland
tel. +48 85 86 86 100
fax +48 85 86 86 101
chm@chm.eu
www.chm.eu

CE 0197