ST/65B

ChM®

4,0 ChM Locked Plating ChLP system

4.0ChLP ENDOSTEAL PLATE

- IMPLANTS
- INSTRUMENT SET 15.0204.002
- SURGICAL TECHNIQUE

www.chm.eu

SYMBOLS DESCRIPTIONS

Ti	Titanium or titanium alloy
Co	Cobalt
L	Left
R	Right
L R	Available versions: left/right
Len	Length
	Torx drive
	Torx drive cannulated
	Hexagonal drive
	Hexagonal drive cannulated
	Cannulated
	Locking
	Diameter [mm]
H	H length [mm]
	Angle
88 - 340	available lengths
4-22	Available number of holes
1.8	Thickness [mm]
1:1	Scale 1:1
	Number of threaded holes in the shaft part of the plate
	Number of locking holes in the plate
VA	Variable angle
	Cortical
	Cancellous
Ster Non Ster	Available in sterile/ non- sterile condition
	See surgery technique

	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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The manufacturer reserves the right to introduce design changes.

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 ISO 9001, EN ISO 13485 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

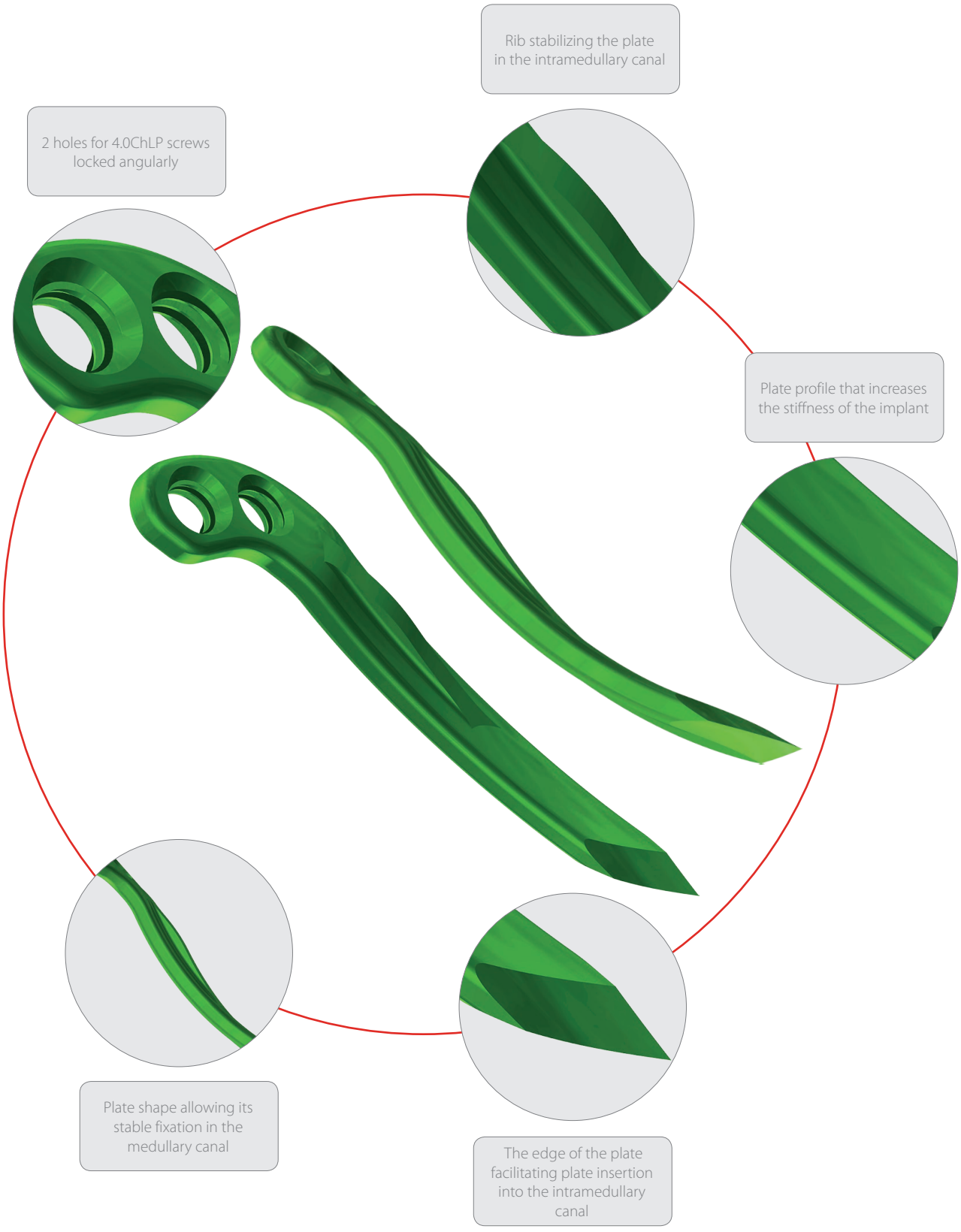
The plates are available in various lengths, two blade deflection variants, and left and right variant. This allows for optimal selection of the implant to the developed deformation.
Shaping of the plates is not allowed.

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.

II.1. PLATE PROPERTIES



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4.0ChLP ENDOSTEAL PLATE

Ti | Ster / Non Ster

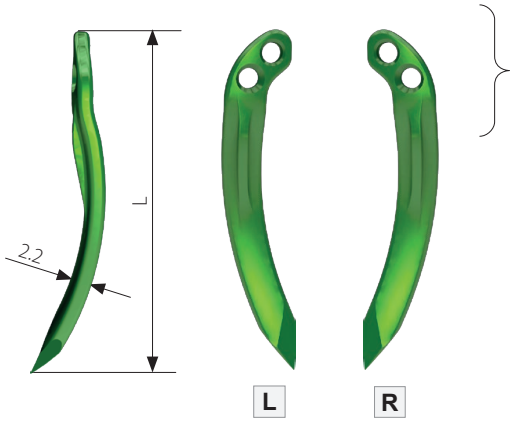
4.0 ChM Locked Plating ChLP system

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
2.4

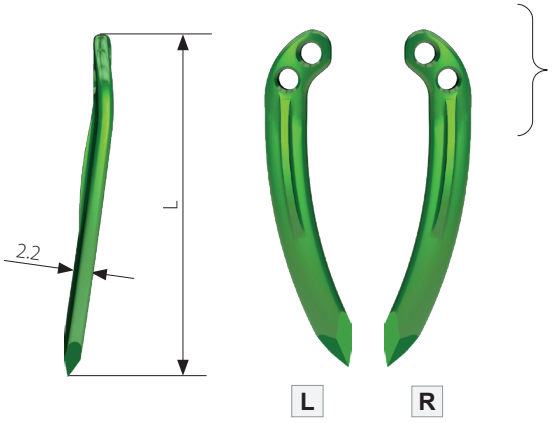
Cobalt
4.5235.006-040
2.4

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
2.4

Cobalt
4.5235.006-040
2.4

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

LOCKING ELEMENTS

Ster
Non Ster

4.0 ChM Locked Plating ChLP system

4.0ChLP SCREW 2.4

Ti

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

Co

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

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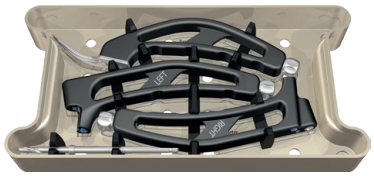
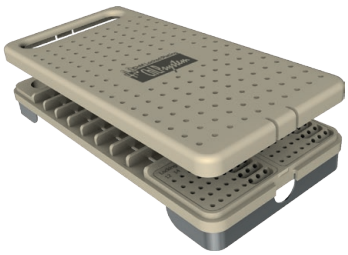
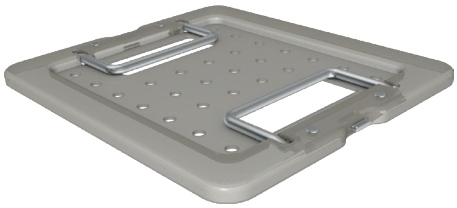
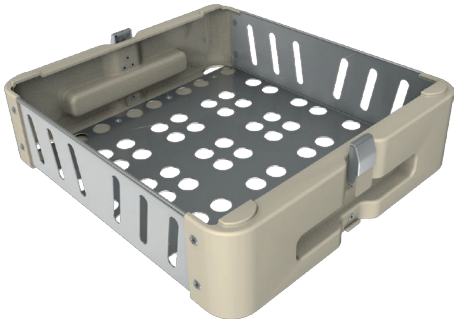
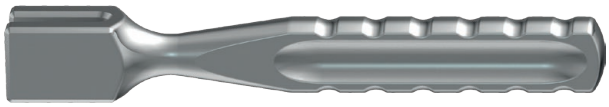
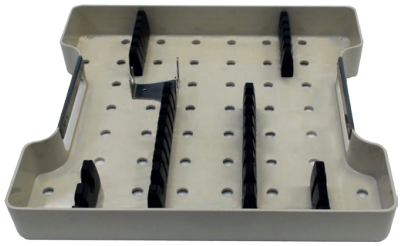
III. INSTRUMENT SET

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 handle1Nm	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

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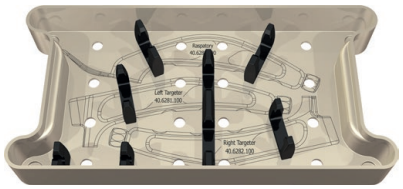
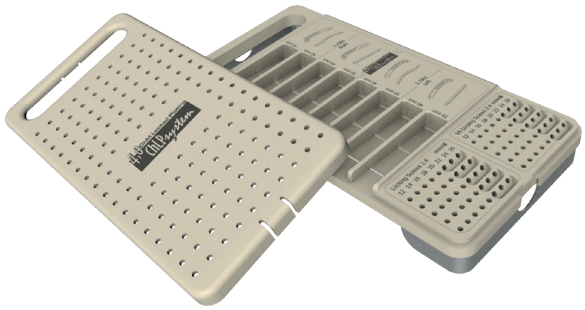
Instrument set for 4.0ChLP 3.7060/3.7061 4x2 1/2H

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

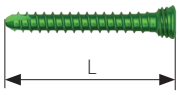
Stand for 4.0ChLP implants 3.7060/3.7061 4x2 1/2H

14.0204.601***



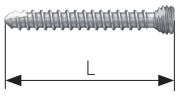
4.0ChLP endosteal plate

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.

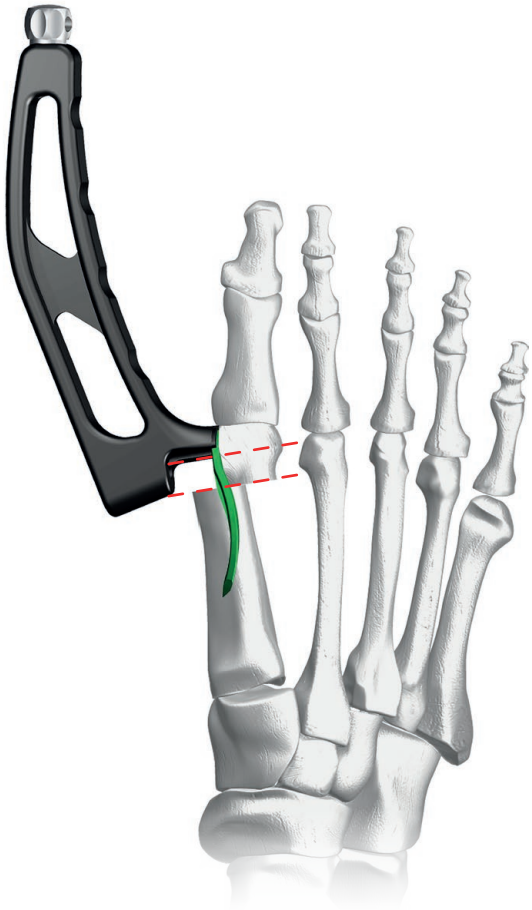
V. SURGICAL APPROACH

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

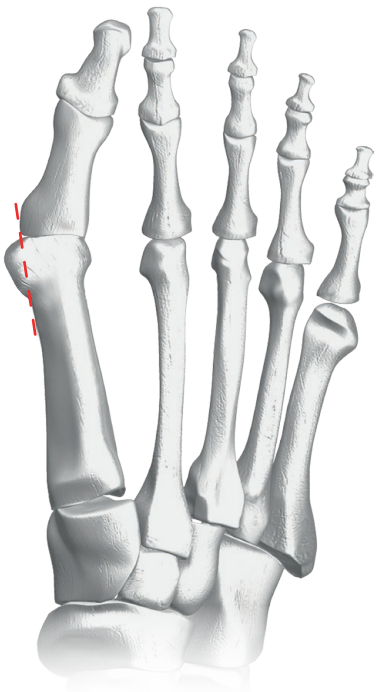
VI.A.1. Plate and targeter assembly

	40.6281.100
	40.6282.100
	40.5682
	40.4896.018

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]**.

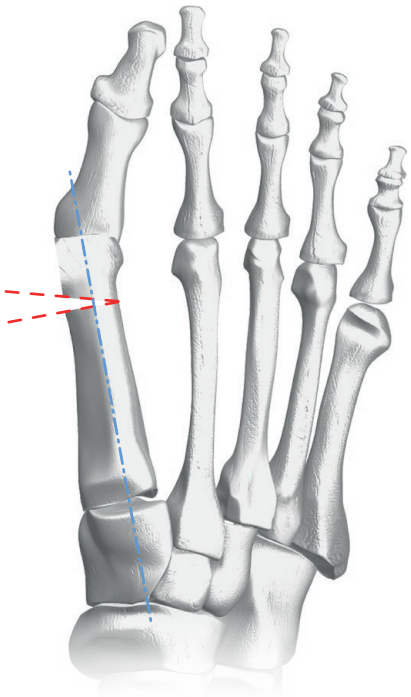
VI.A.2. Bone correction

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

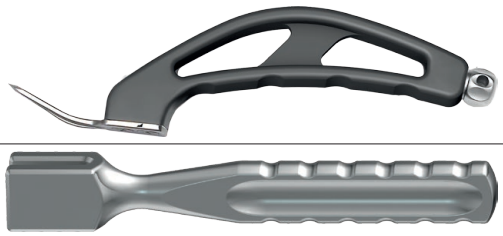


VI.A.3. Bone cutting

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



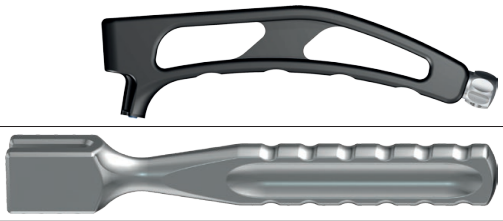
40.6285

40.6284

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

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

VI.A.5. Plate insertion



40.6281.100

40.6282.100

40.6284

Insert the plate into the prepared canal.

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

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

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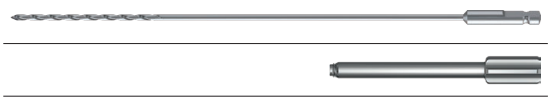
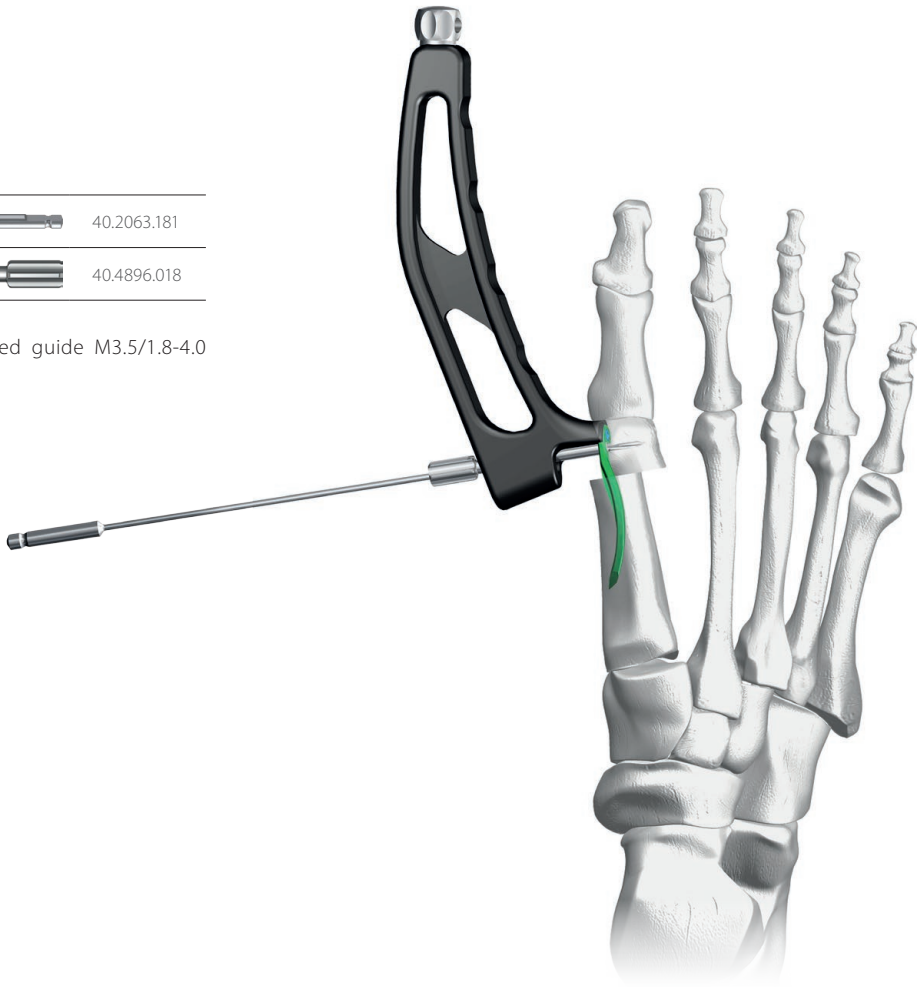
VI.A.6.1 Drilling



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.

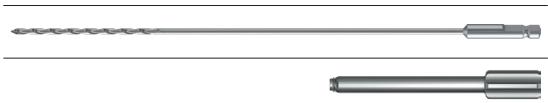


VI.A.6.2 Depth measurement

40.4818.100

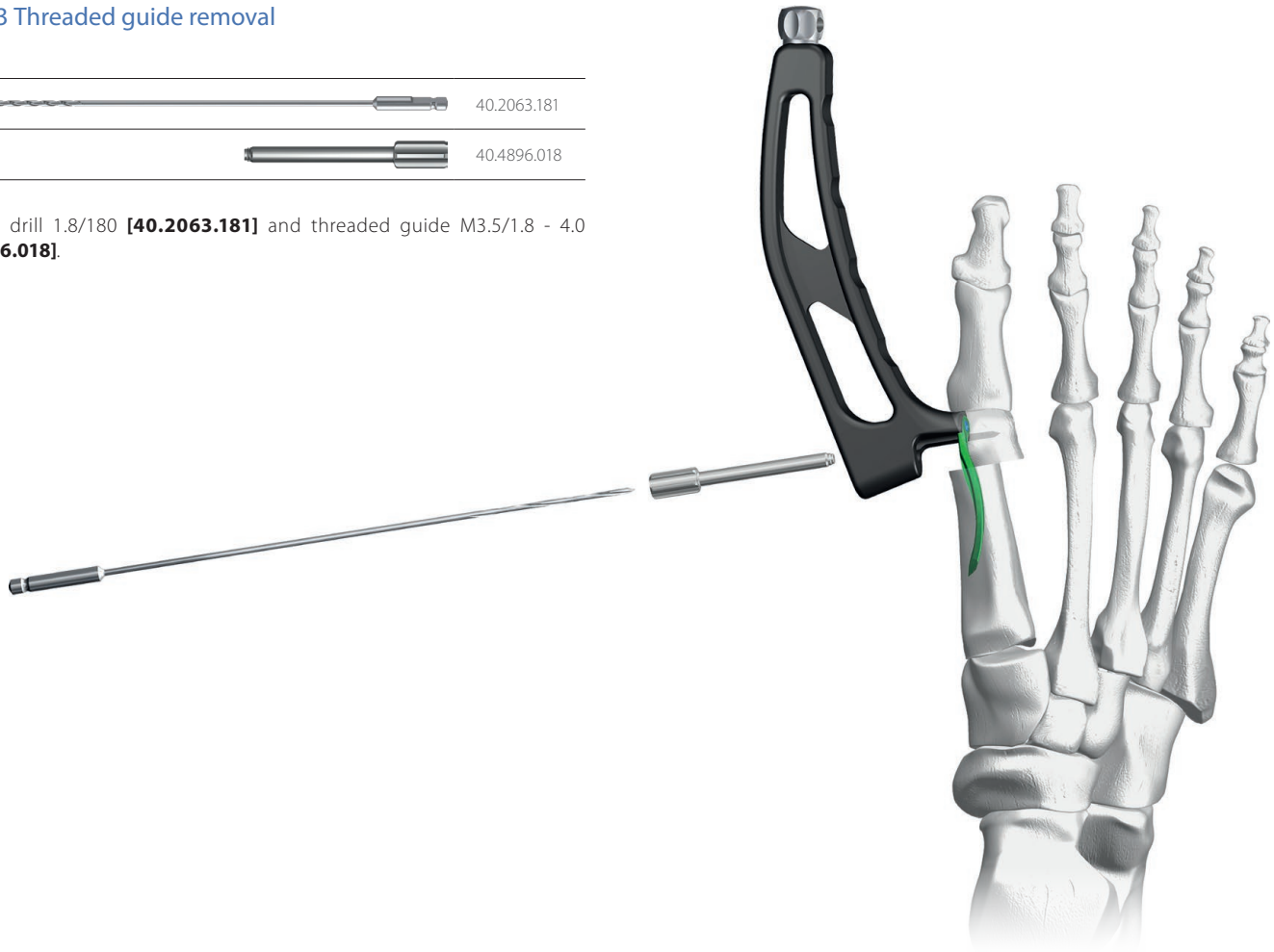
Use locking screw length measure **[40.4818.100]** to measure the hole depth.

VI.A.6.3 Threaded guide removal


40.2063.181

40.4896.018

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

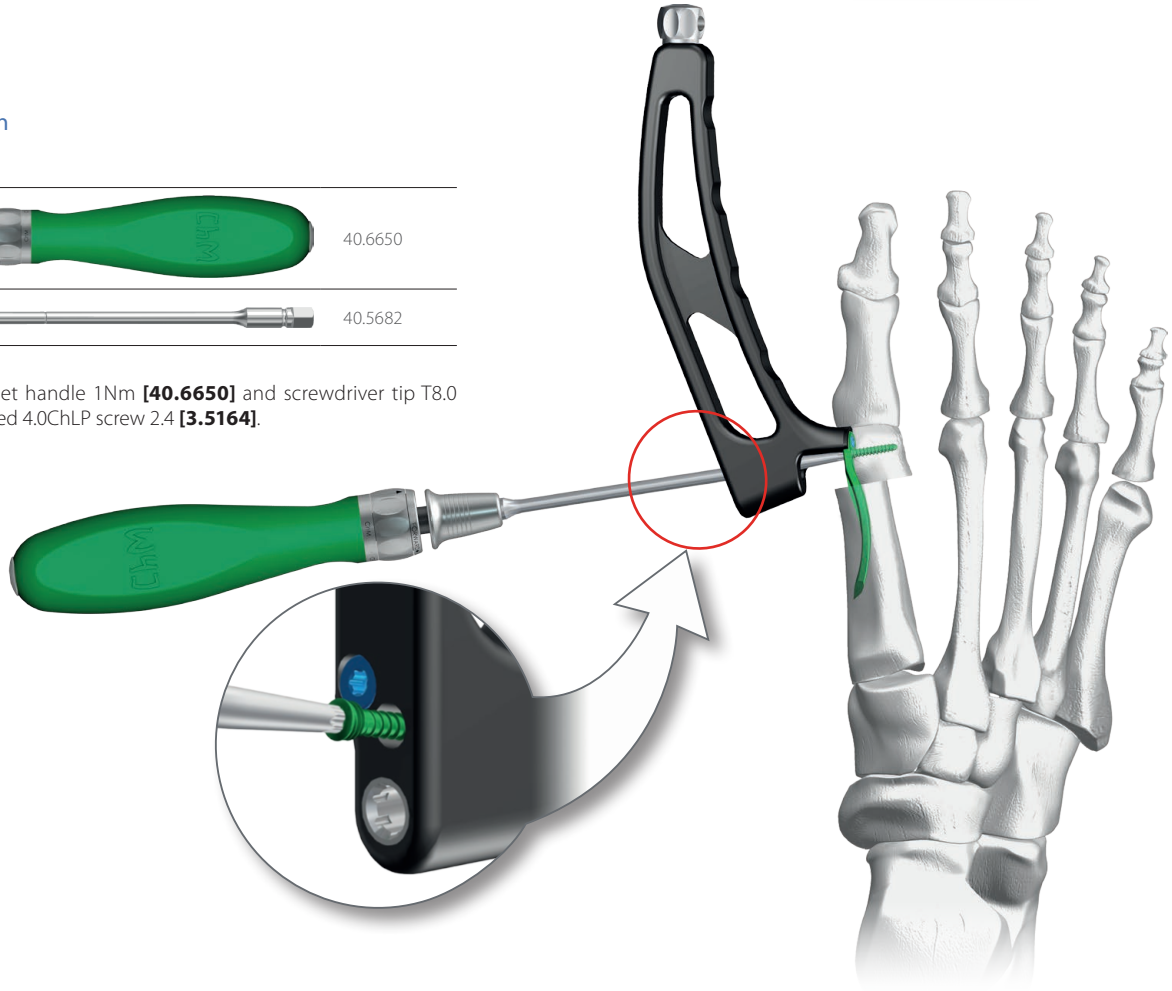


VI.A.6.4 Screw insertion


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 2.4 **[3.5164]**.

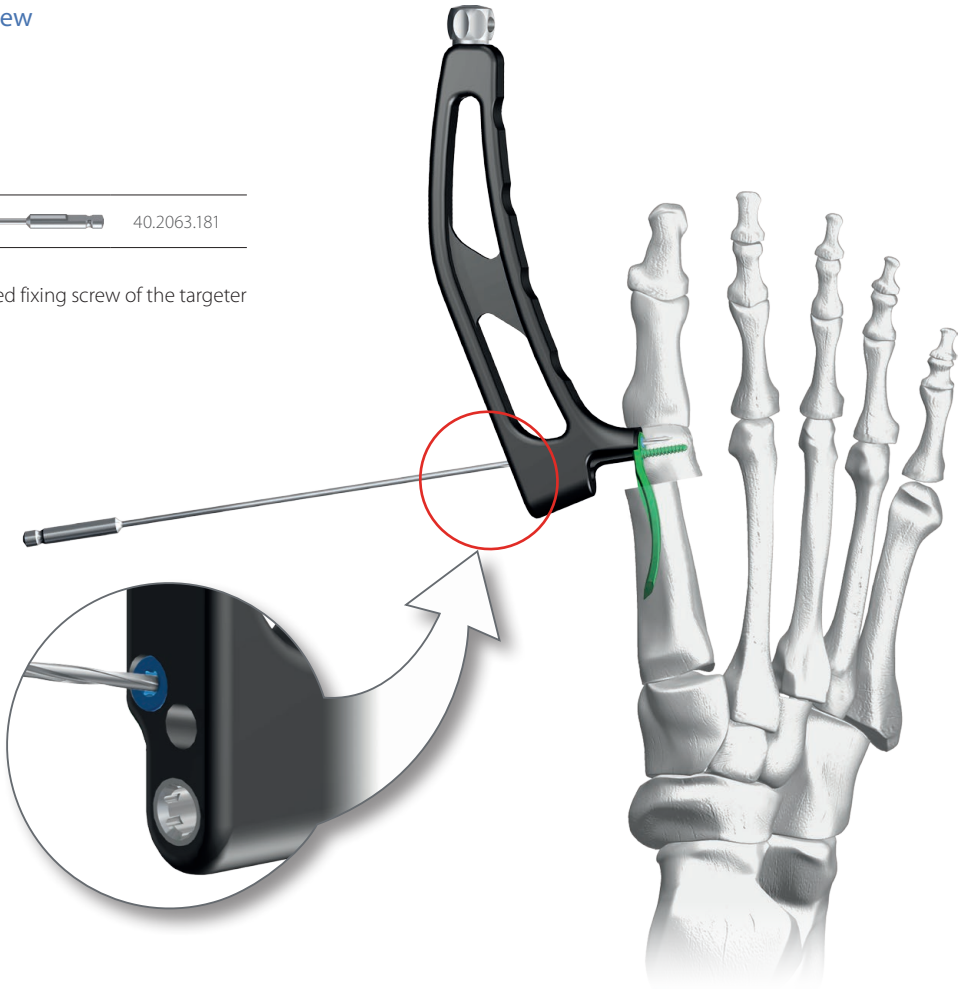


VI.A.7. Insertion of the other locking screw

VI.A.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.A.7.2 Targeter removal

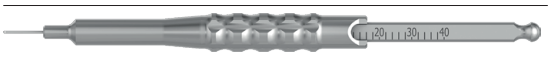
40.5682

40.6281.100

40.6282.100

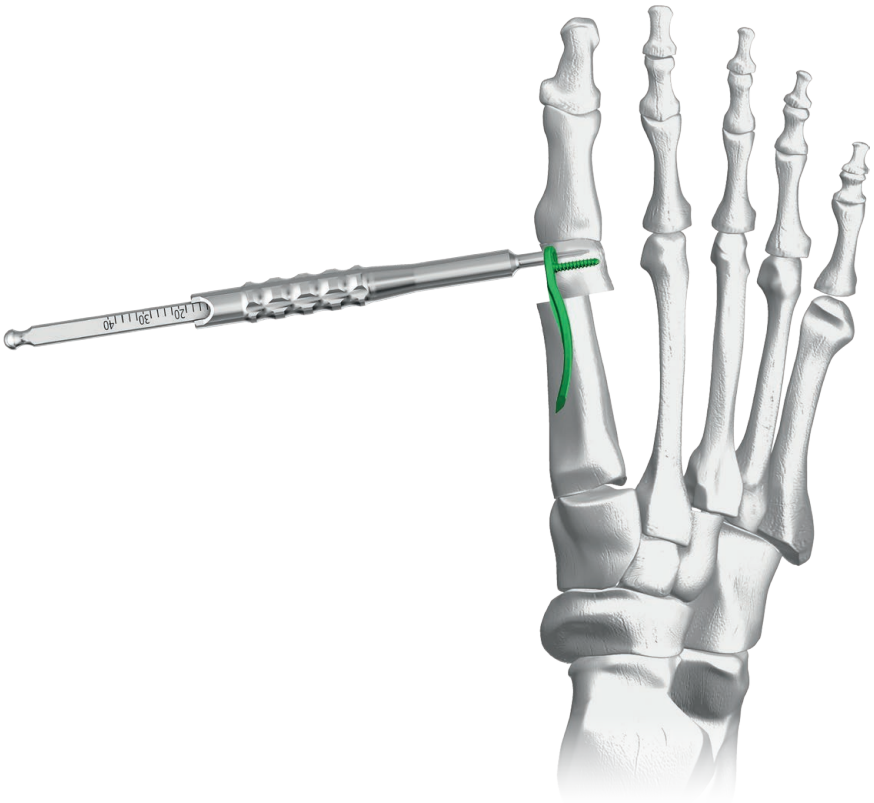
Loosen the fixing screw using screwdriver tip T8.0 **[40.5682]** and remove the targeter **[40.6281.100]**/**[40.6282.100]**.

VI.A.7.3 Depth measurement



40.4640

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

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 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

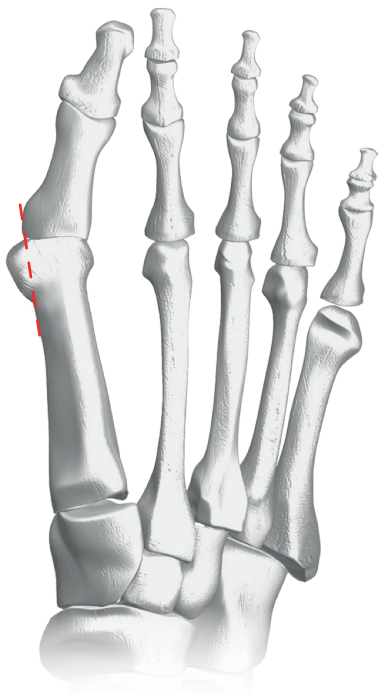
VI.B.1. Plate and targeter assembly

	40.6281.100
	40.6282.100
	40.5682
	40.4896.018

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]**.

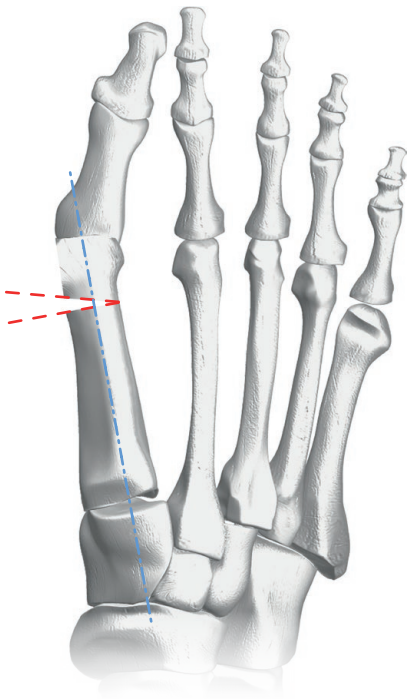
VI.B.2. Bone correction

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

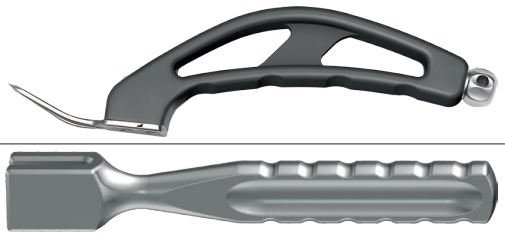


VI.B.3. Bone cutting

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


40.6278

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


40.4896.018

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.

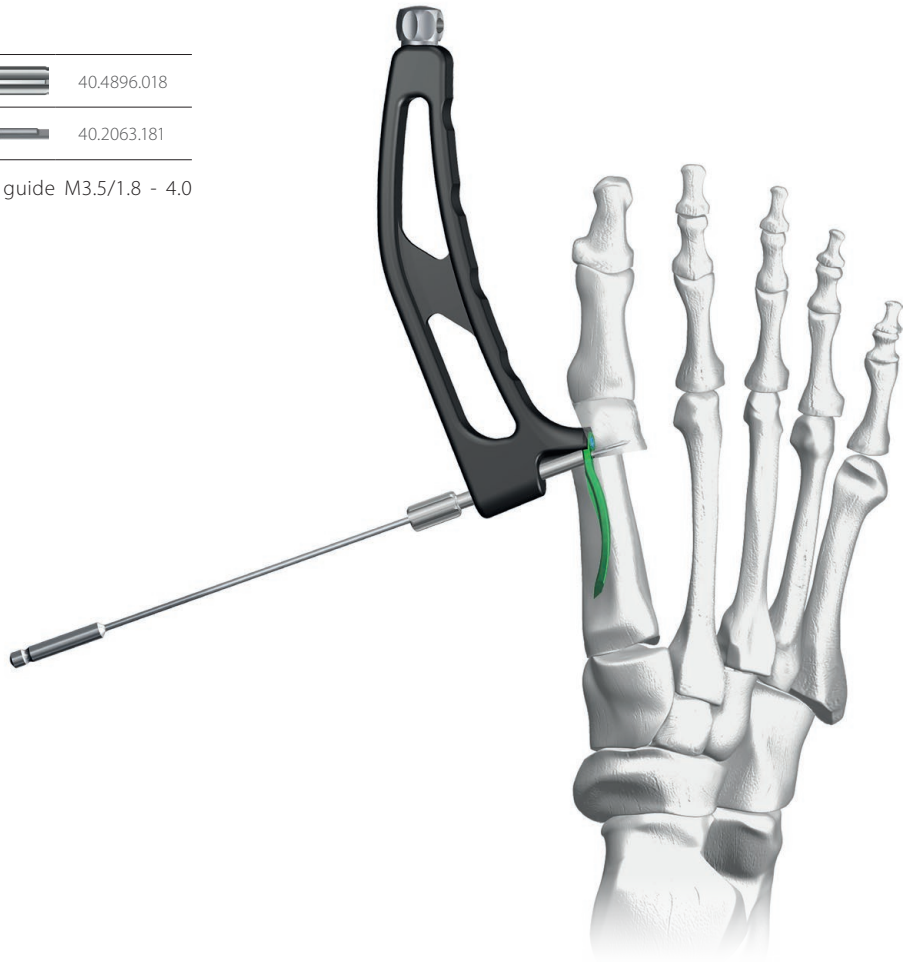
NOTE! Do not screw in the guide. The holes in the guide and in the implant do not correspond with each other in this position. There is a risk of threads damage.

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

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]**.

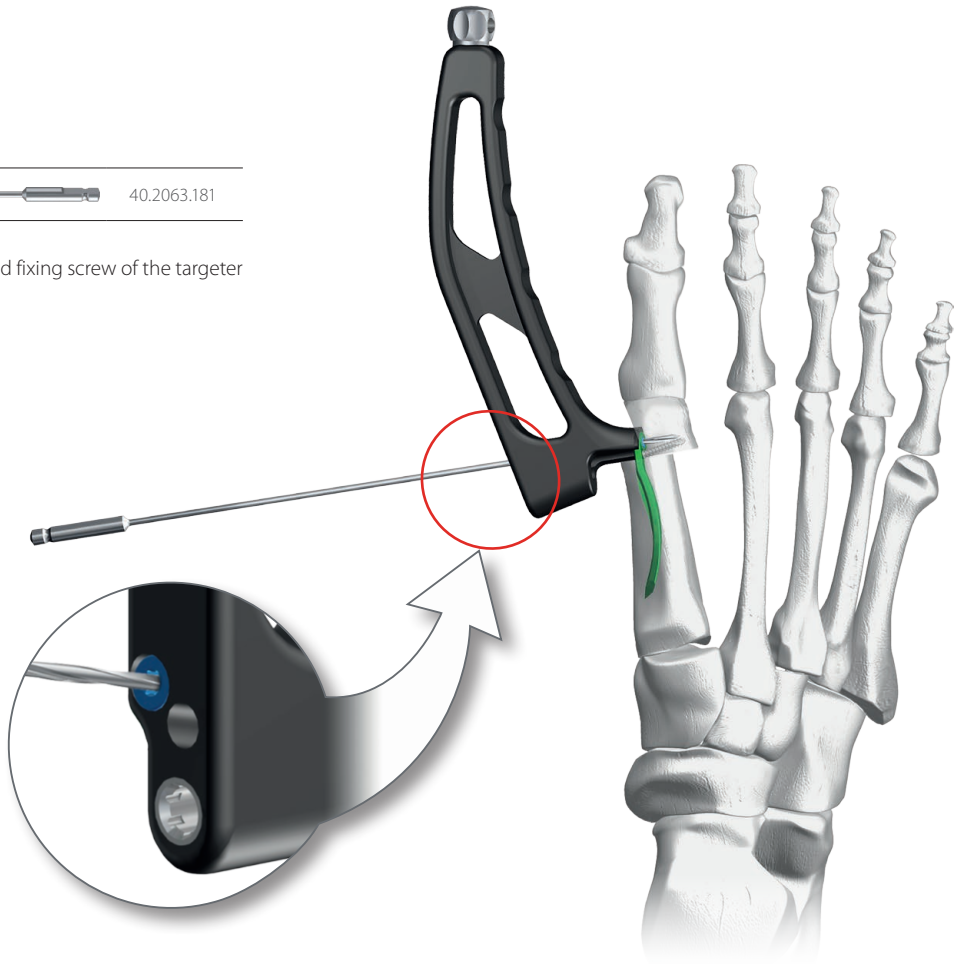
After locking of the variable angle *(VA)* screw in the plate hole, do not change the angle of screw insertion. Re-locking of the screw in another position decreases efficiency of the screw-plate connection. Appropriate angle of screw insertion should be verified either at the drilling stage or before 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.



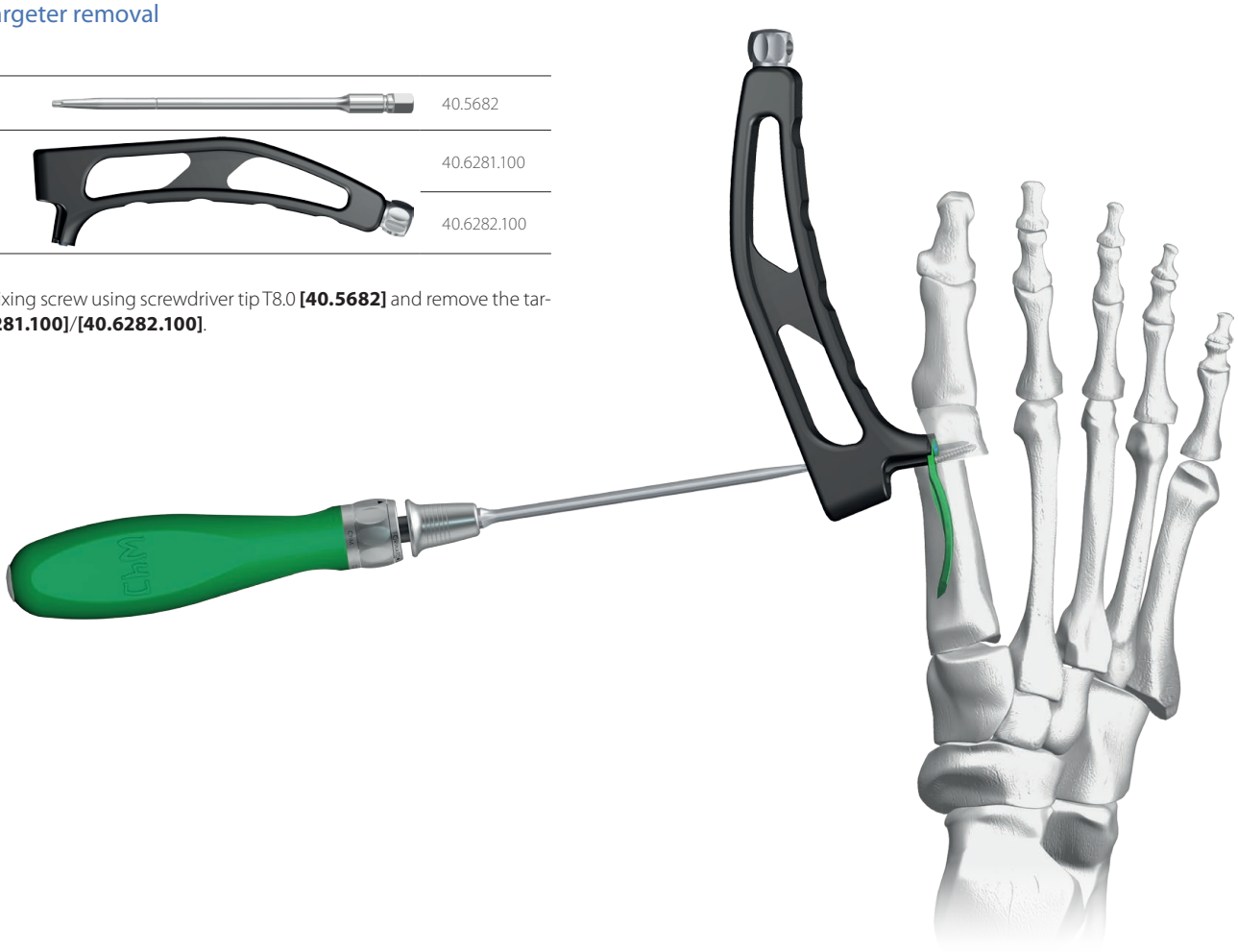
VI.B.7.2 Targeter removal

40.5682

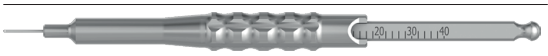
40.6281.100

40.6282.100

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

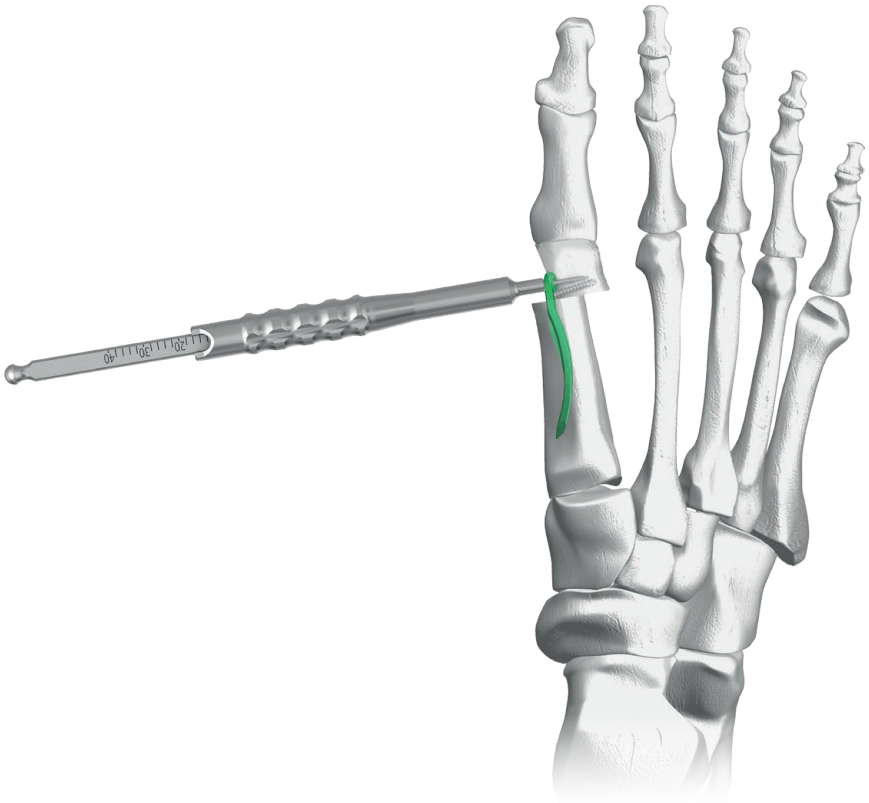


VI.B.7.3 Depth measure



40.4640

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



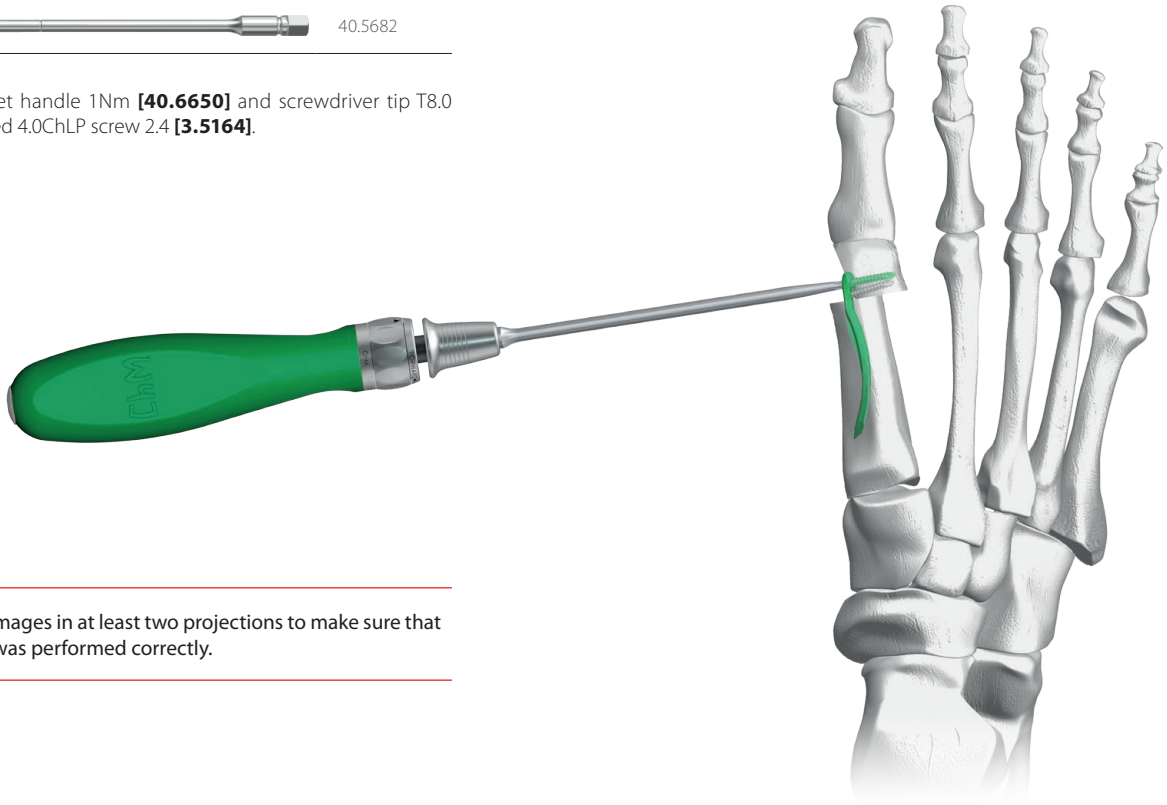
NOTE! Do not measure the other hole depth using locking screw length measure **[40.4818.100]** via the cannulated screw that secures the targeter **[40.6281.100]**/**[40.6282.100]**. Measurement with the use of locking screw length measure **[40.4818.100]** is possible only via threaded guide M3.5/1.8-4.0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

VI.B.7.4 Screw insertion

40.6650

40.5682

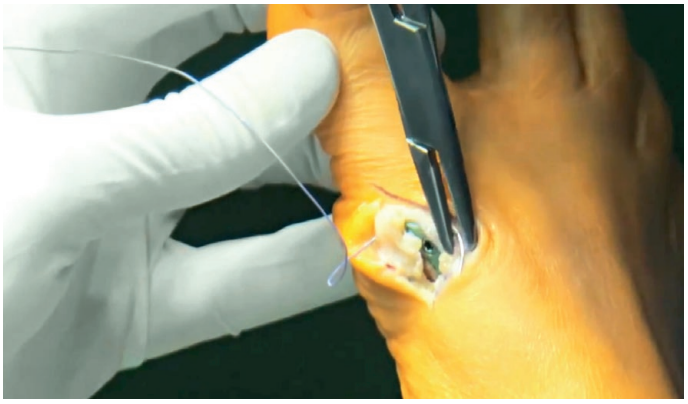
Use torque limiting ratchet handle 1Nm **[40.6650]** and screwdriver tip T8.0 **[40.5682]** to insert selected 4.0ChLP screw 2.4 **[3.5164]**.



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

VII. WOUND CLOSURE

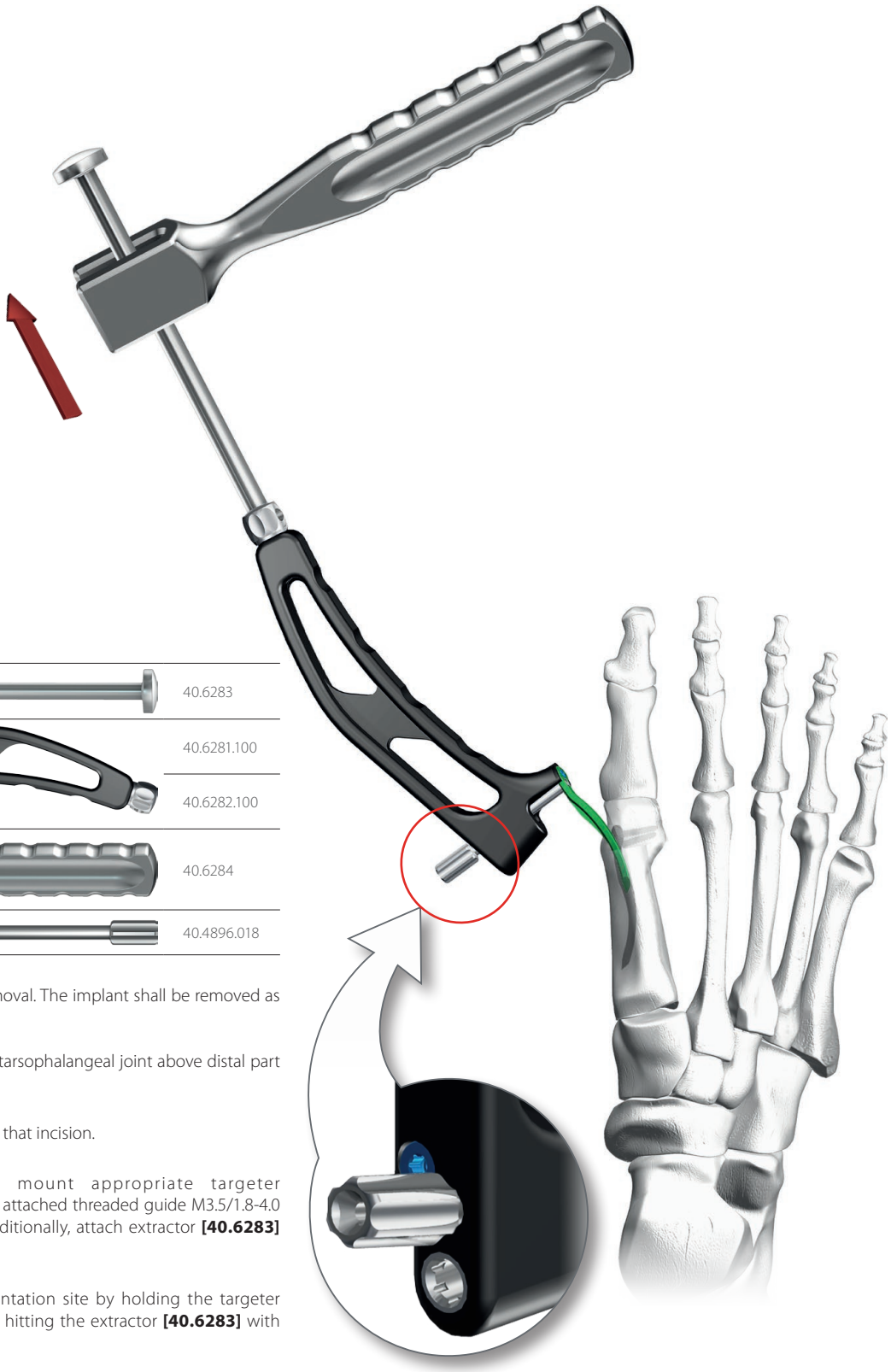
Use appropriate surgical technique to close the wound. Prior to wound closure, make sure that all screws are properly tightened.

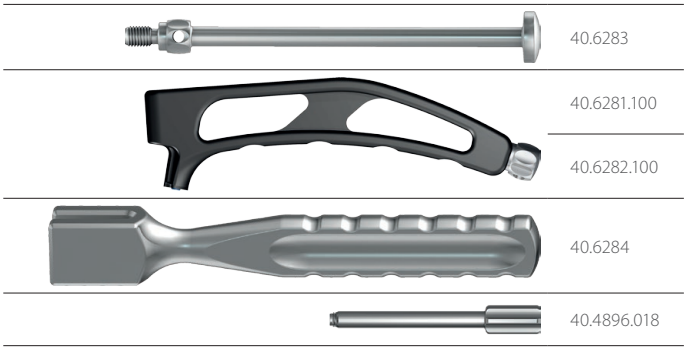


VIII. POSTOPERATIVE PROCEDURE

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:

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 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.

d) 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

GB

ISO 9001/ ISO 13485

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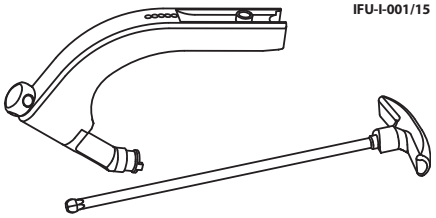
IFU-I-001/15



GB

INSTRUCTIONS FOR USE REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

DESCRIPTION AND INDICATIONS

Instruments manufactured by **ChM** sp. z o.o. are mainly made of steel, aluminium alloys and plastics used in medicine and in accordance with the applicable procedures.

Each medical instrument is exposed tooccurrence of corrosion, stains and damage if not treated with special care and according to recommendations provided below.

The use of instruments in accordance with their intended purpose prolongs their usability.

Instrument's durability is limited and highly related to the manner and frequency of its usage.

The unit package contains one piece of the product in non-sterile condition. The welded clear foil sleeve is typical packaging material. The products may also be supplied as complete sets *(arranged on trays and placed into specially designed sterilization containers)*.

This Instructions For Use is attached both to the unit package and to the instrument set as well.

The packaging is equipped with the product label. The label contains:
- **ChM** logo and the manufacturer's address,
- name, size and catalogue number of the device *(REF)*, e.g.: 40.XXXX.XXX,
- production batch number *(LOT)*, e.g.: XXXXXXX,
- NON-STERILE sign: indicates non-sterile product,
- information symbols *(described in the footer of this Instructions For Use)*.

Depending on the size or type of the product, the following information may be marked on its surface: **ChM** logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.

MATERIALS

Devices are produced of corrosion-resistant steel. The protective layer *(passive layer)* against corrosion is formed on the surface of the steel due to high content of chromium.

Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as handles of screwdrivers, awls or wrenches, etc. The protective oxide layer, which may be dyed or stays in natural colour *(silvery-grey)*, is formed on the aluminium as an effect of electrochemical treatment on its surface.

Devices made of aluminium with processed layer have a good corrosion resistance.

The contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference with the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: PPSU *(Polyphenylsulfone)*, PEEK *(Polyetheretherketone)* and teflon *(PTFE - Polytetrafluoroethylene)*.

The above mentioned materials can be processed *(washed, cleaned, sterilized)* at temperatures not higher than 140°C, they are stable in aqueous solution of washing-disinfecting agents with pH values from 4 to 10.8.

If the material of the device cannot be specified, please contact ChM sp. z o.o. representative.

WARNINGS AND PRECAUTIONS

1. Reusable orthopaedic and surgical instruments are intended for use in operating room conditions only by skilled and trained medical professionals, specialists in surgery, who are familiar with their use and application.
2. The surgeon should be familiar with all components of the device before use and should personally verify if all components and devices are present before the surgery begins.
3. Prior to the device usage and before procedure begins, all components of instruments should be carefully inspected for proper functioning and condition.Blades of all cutting edges should be sharp and undamaged. Replace any damaged accessory immediately. Employing bent or damaged surgical instruments in surgery is not allowed.
4. Tissue structures close tooperative site must be protected.
5. Contact of the instrument with metal operating equipment, retractors or other devices may cause damage that necessitates intraoperative replacement of that instrument.
6. Do not apply excessive force when using the instrument – it may lead to its faulty operation and, in consequences, to permanent damage.
7. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to extensive use or extensive force are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed.
8. In the case of breakage and presence of instrument fragments in the patients' body, remove and dispose of them following the appropriate protocol of the unit.
9. 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.
10. Improper or careless handling of the instruments and related chemical, electrochemical and physical damage may adversely affect the corrosion resistance and shorten the life of the instruments.
11. Reusable orthopaedic and surgical 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 of the instrument.
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.

CLEANING, DISINFECTION AND STERILIZATION

Prior to use of a non-sterile device the following rules apply:

- Before use, the device must undergo cleaning, disinfection and sterilization procedures. It is recommended to use an automated procedure *(washer-disinfector)* for cleaning and disinfecting.
- Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the techniques of cleaning *(manual, ultrasound, with the use of washing/disinfecting machine)*, the proper rinsing and drying, the proper preparation of the instrument, the time, the temperature and carefulness of the person conducting this process.

Preparation for cleaning

After removing the product from its original packaging and before each cleaning, remove possible surface contamination using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*.

It is not permitted to use brushes made of metal, bristles or materials which can cause damage to the device.

Cleaning and disinfection process

Chosen detergents and disinfectants must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of these detergents.

CAUTION:

To avoid product damage (pitting, rust), **DO NOT** *use highly aggressive agents (NaOH, NaOCl), salt solutions and other unsuitable cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 7 and 10.8.*

Manual cleaning

- Apply cleaning agent solution to the product surfaces with careful brushing. A suitable brush must be used for cleaning holes.
- If applicable, ultrasonic cleaning may be used. The ultrasonic bath must be prepared according to the manufacturer's instructions.
- Next rinse thoroughly under running water. It is recommended to use demineralized water.
- Visually inspect the entire surface of the device for damage and contaminants. Damaged products must be removed. For contaminated products, the cleaning process should be repeated.

CAUTION:

- *Never use metal brushes, files or sponges for contaminants removal.*
- *Rinse thoroughly and carefully. Sterile demineralized water facilitates water spots removal from the instrument's surface.*
- *Instruments with cannula should be blown through using compressed air gun, or air supplied from a syringe.*
- *If the accumulated in the cannula material cannot be removed in accordance with the instructions, the device should be considered at the end of its useful life and should be disposed of in accordance with the facility procedures and guidelines.*

Cleaning with washer-disinfector

The device should undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for medical devices)*.

CAUTION: The cleaning/disinfecting appliances should be compliant with requirements specified in ISO 15883.

Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and instructions for use prepared by the washing-disinfecting agents manufacturer.

Disinfection should be carried out at 90° *(soak for at least 10 minutes in demineralized water)* without the use of detergents.

Drying

Drying of the device must be performed as a part of the cleaning/ disinfection process.

Inspection

Before preparing for sterilization, all medical devices should be inspected.

Generally, visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion. Particular attention should be paid to:

- soil traps such as mating surfaces, hinges, recesses, instruments shafts,
- holes, cannulations,
- places where soil may be pressed during use,
- cutting edges should be checked for sharpness and damage,
- special care should be taken to inspect the instruments for complete dryness prior to their storage.

Functional checks should be performed where possible:

- mating devices should be checked for proper assembly,
- all reusable orthopaedic and surgical instruments should be checked for straightness.

CAUTION:

The **ChM** *sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The life of these devices depends on many factors including the method, way and duration of each use, and the handling between uses.*

Inspection and functional testing of the device must be carried out before each use. In the case of identified damage, the instrument must not be used again.

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

Packaging

The product supplied non-sterile must be repacked in a packaging intended for a specific sterilization method that meets the requirements of ISO 11607-1 and is marked with CE sign. The packaging procedure must be performed in controlled purity conditions. The product must be packed in such a way that during removal from the package to be used, there is no risk for its contamination. Sterilization package is designed to maintain the sterility of medical devices after the sterilization process and during their storage prior to use.

Sterilization

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds like residues after disinfection and sterilization processes and without structure damage *(cracks, fractures, bending, peeling)*. Remember that sterilization is not a substitute for cleaning process!

Disinfected, washed, and dried device shall undergo the sterilization process in accordance with the client procedures. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:

- temperature: 134°C,
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

CAUTION:

- *Sterilization must be effective and in accordance with requirements of the EN 556 standard which means that theoretical probability of presence of a living microorganism is less than 1/10⁶ (SAL=10⁻⁶, where SAL stands for Sterility Assurance Level).*
- *Device must not be sterilized in the package in which it was delivered, except specially designed sterilization containers.*
- *Validated sterilization methods are allowed.*
- *Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards.*
- *Devices manufactured out of plastics (PPSU, PEEK, PTFE) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.*

Durability and strength of instruments to a considerable degree depend on how they are used. Careful usage consistent with intended use of the product protects it against damage and prolongs its life.

STORAGE

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 dark, dry room, if possible – in suitable storage racks and placed into specially designed sterilization containers.

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. The calibration is conducted by the manufacturer – **ChM** sp. z o.o. Any unauthorized modifications of the structure or default, factory settings may lead to potential injury or device damage and are forbidden.

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-001/15; Date of verification: December 2015

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
STERILIZE	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 envase 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 • Attenzione leggere il foglietto illustrativo
STERILE R	Sterilized using irradiation • Sterylizowany przez napromieniowanie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione
STERILE VH2O2	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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CE 0197
ISO 9001
ISO 13485