ST/80-401

ChM®

4,0 ChM Locked Plating ChLP system

4.0ChLP wedge plates for osteotomy

3.7056
3.7057

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

www.chm.eu

SYMBOLS DESCRIPTION

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
	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

Document No	ST/80-401
Date of issue	09.11.2017
Review date	P-001-02.12.2020

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

1. INTRODUCTION

This surgical technique applies to 4.0ChLP locked plating system used for opening wedge osteotomy of the first metatarsal bone. The plates are a part of the ChLP locked plating system developed by **ChM**. The presented range of implants is made of materials in accordance with ISO 5832 standards. 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 *(plates and screws)*,
- instrument set used for conducting the surgical procedure,
- surgical technique.

Indications

The plates are used to treat:
- metatarsus primus varus *(hallux valgus)*.

Contraindications

- local infections,
- growing children.

Plate selection and shaping

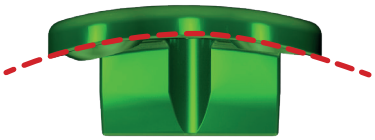
The plates are available in T and X shape and various wedge height variants. This allows for optimal selection of the implant to the developed deformity. Shaping of plates is not allowed.

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.

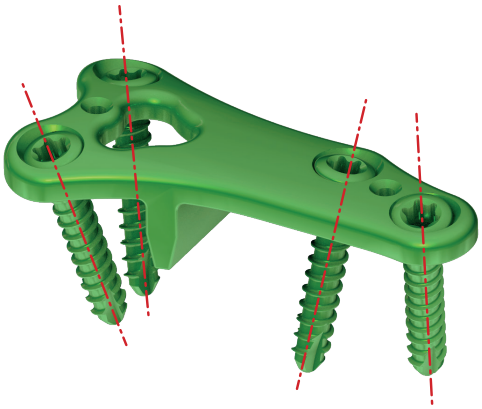
2. IMPLANT FEATURES

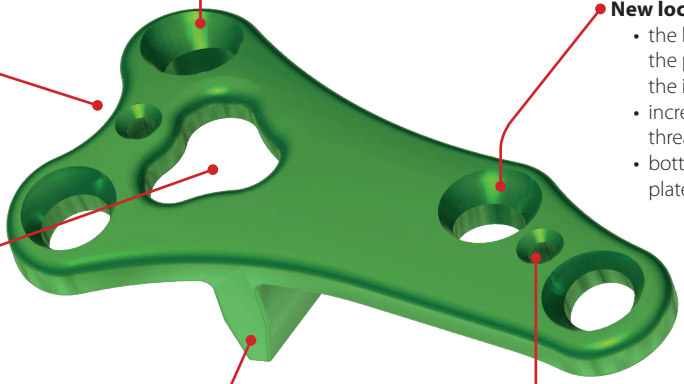
Wedge osteotomy plates are a part of 4.0ChLP system. This system includes also compatible locking screws. To facilitate their identification, both titanium plate and screws are green anodized.



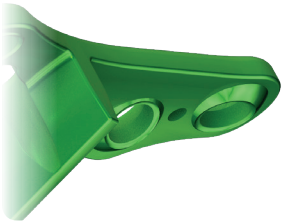
Anatomical profile of the plate:
- better anatomical fit to the bone shape,
- rounded edges limiting soft tissue irritation.

Locking screws:
- screws positioning fits anatomical shape of the bone,
- angular setting provides optimal biomechanical stability of bone fragments.





New locking hole design:
- the heads of the screws do not protrude above the plate surface what significantly reduces the irritation of the periimplant tissues,
- increased strength of screw-to-plate threaded connection,
- bottom extrusion reduces the area of plate-to-bone contact.



Hole in the proximal part:
- limited implant-to-bone contact,
- better visibility of bone fragments.

Wide wedge size range:
- heights of the wedge: 2, 3, 4, 5, 6 and 7mm.

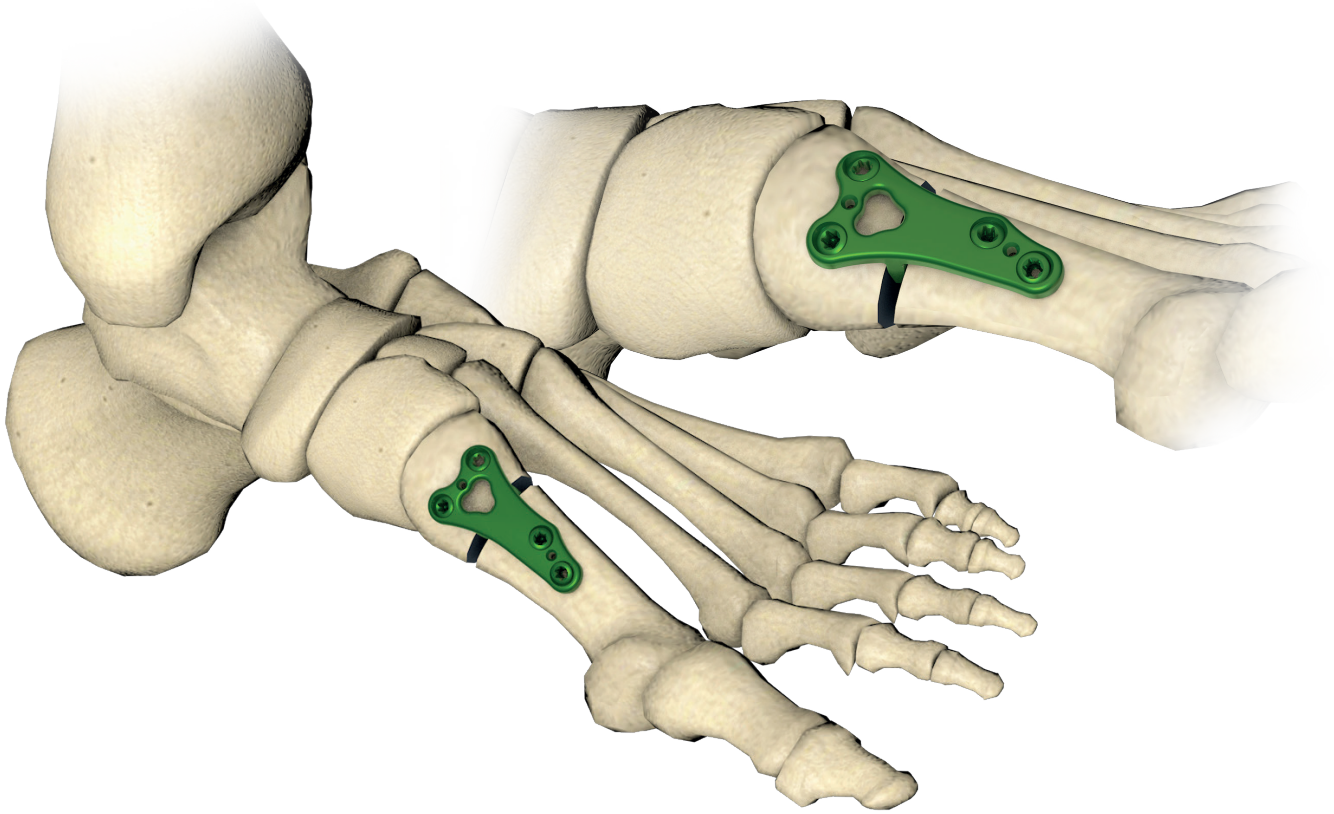
Holes for Kirschner wires in epiphyseal and shaft parts of the plate:
- easier plate positioning,
- temporary plate stabilization.

Two plate shapes available:

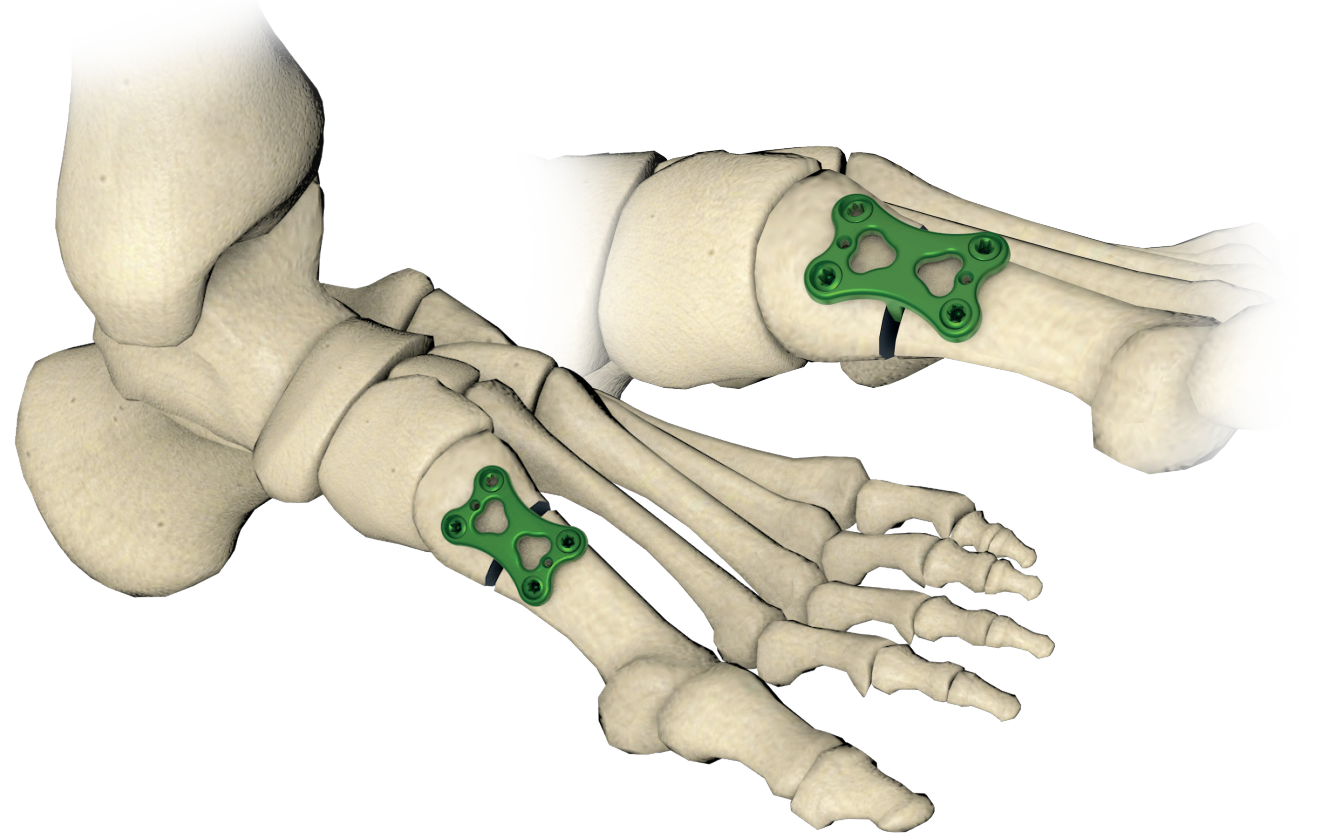
T-shape plate

X-shape plate

4.0ChLP wedge T plate



4.0ChLP wedge X plate



3. SURGICAL TECHNIQUE

3.1. PATIENT POSITIONING

It is recommended to position the patient supine, with the surgical cushion under their calf to elevate the foot.

3.2. SURGICAL APPROACH

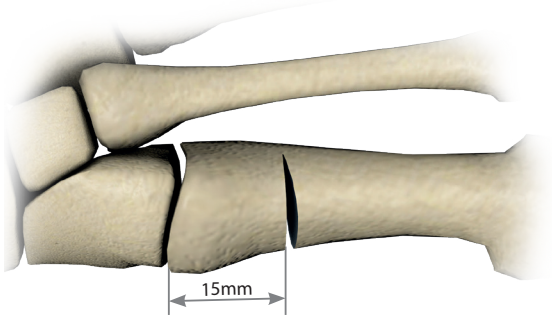
Medial approach is recommended. Perform a skin incision over the first tarsal metatarsal *(TMT)* joint and dorsally over the first metatarsal bone.

NOTE:
Isolate the medial branch of the superficial fibular nerve.

3.3. OSTEOTOMY

Create a bone osteotomy perpendicular to its axis at the planned implantation site. The incision should be located approximately 15 mm distally to the TMT joint.

NOTE:
Leave the lateral cortex intact *(the depth of the cut - about 2/3 of the bone width)*.



3.4. IMPLANT SELECTION

Choose the right size of the implant for the planned correction.

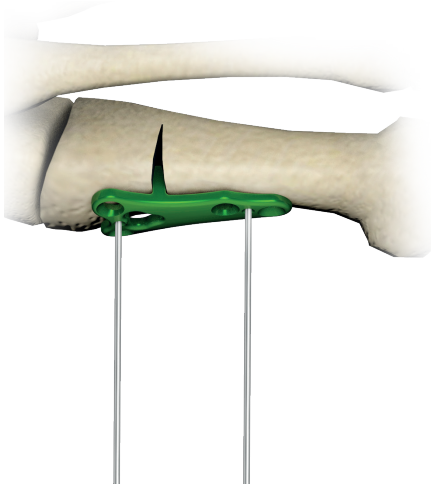
3.5. PLATE INSERTION

Insert the wedge of the plate in the incision performed.

3.6. TEMPORARY PLATE STABILIZATION

Stabilize the position of the implant inserting Kirschner wires into appropriate holes *(acc. to procedure 4a)*.

NOTE:
Confirm the correct position of the implant by taking X-Ray image.



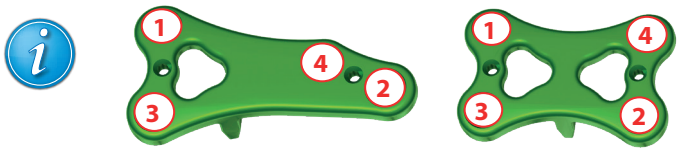
3.7. INSERTION OF LOCKING SCREW

Insert locking screws of a proper length in the locking holes of the plate.

- Insert 4.0ChLP screw 2.7 **[3.5165]** acc. to 4b procedure,
- Insert 4.0ChLP screw VA 2.4 **[4.5235]** acc. to 4c procedure.

Remove Kirschner wires

INFO: Recommended screws insertion order.



3.8. WOUND CLOSURE

Before closing the wound, take an X-Ray image in at least two projections to confirm implant position and correction achieved. Make sure all the screws are properly tightened.

Use appropriate surgical technique to close the wound.

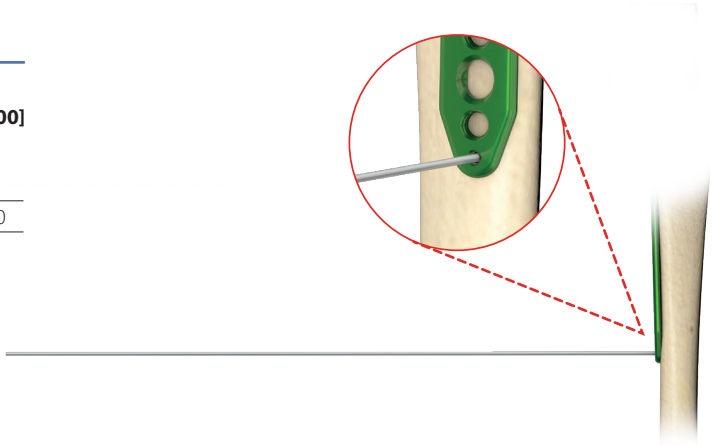
4. SURGICAL PROCEDURES

4a. PROCEDURE OF TEMPORARY IMPLANT STABILIZATION

Stabilization using Kirschner wire

- Stabilize temporary the implant inserting Kirschner wire 1.0/180 **[40.4814.000]** into dedicated hole in the plate.

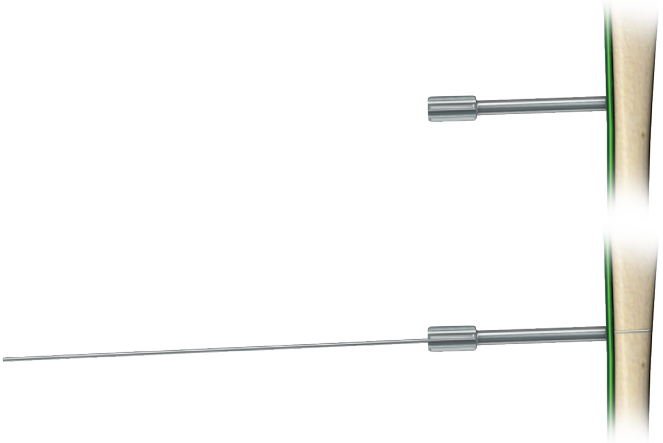
	40.4814.000



Stabilization in locking holes using Kirschner wires

- Insert threaded guide M3.5/1.8-4.0 **[40.4896.018]** into locking hole of the plate.
- Insert Kirschner wire 1.0/180**[40.4814.000]** through the threaded guide M3.5/1.8-4.0 **[40.4896.018]**.

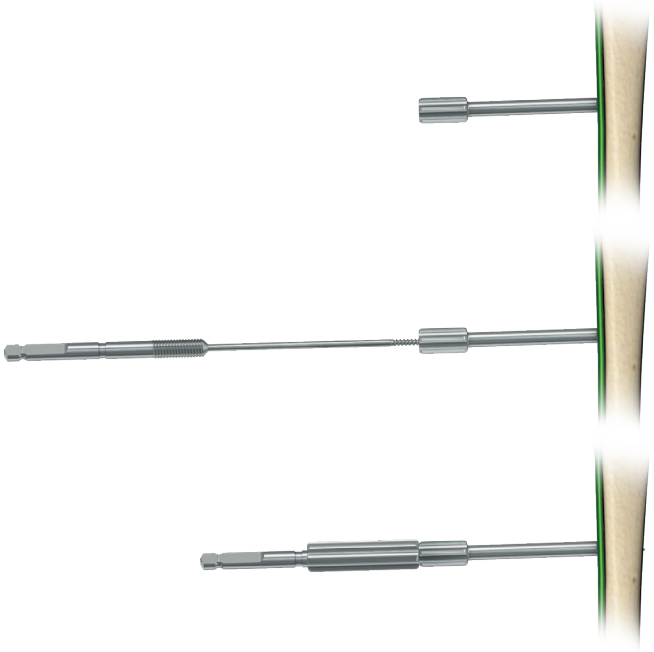
	40.4896.018
	40.4814.000



Stabilization using setting-compressing screw

- Insert threaded guide M3.5/1.8-4.0 **[40.4896.018]** into the locking hole of the plate.
- Insert setting-compressing screw 1.8/120 **[40.5678.000]** through the threaded guide **[40.4896.018]**.
- Tighten the nut of the setting-compressing screw **[40.5678.000]** and push the plate to the bone.

	40.4896.018
	40.5678.000

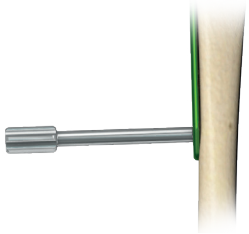


4b. PROCEDURE OF 4.0ChLP SCREW 2.7 [3.5165] INSERTION

Threaded guide insertion

Insert threaded guide M3.5/1.8-4.0 **[40.4896.018]** into the threaded hole of the plate.

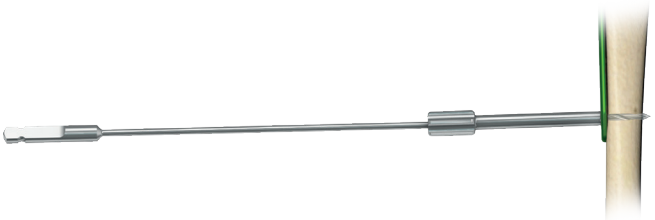
40.4896.018



Hole drilling

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

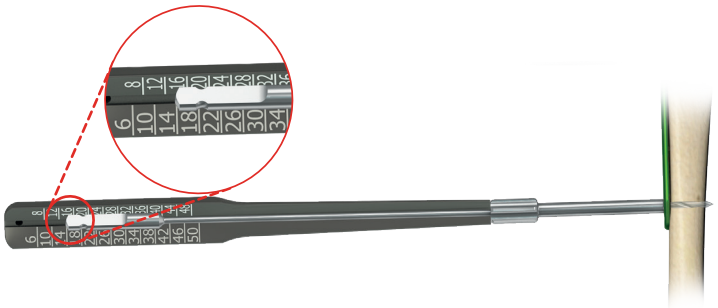
40.2063.181



Measurement of hole depth

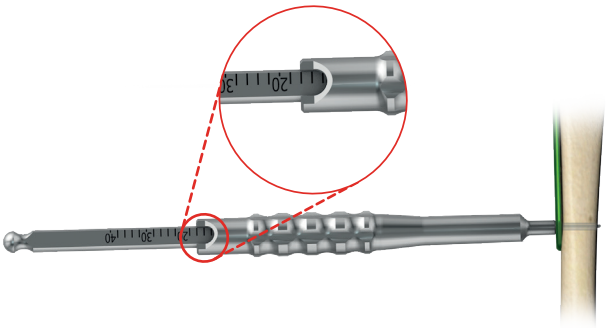
OPTION I: Determine the length of the screw to be used using locking screw length measure **[40.4818.100]**.

40.4818.100



OPTION II: or having removed the threaded guide M3.5/1.8-4.0 **[40.4896.018]**, use depth measure **[40.4640.000]** to determine the length of the screw.

40.4640.000

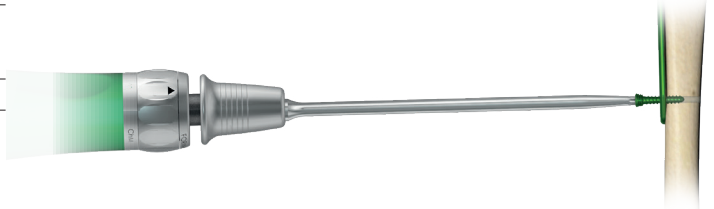


Screw insertion

Remove threaded guide M3.5/1.8-4.0 **[40.4896.018]**. Insert locking screw using torque limiting ratchet handle 1Nm **[40.6650.000]** and screwdriver tip T8 **[40.5682.000]**.

40.6650.000

40.5682.000



4c. PROCEDURE OF 4.0ChLP SCREW VA 2.4 [4.5235] INSERTION

Guide VA positioning

- Insert the guide VA 1.8 **[40.5928.018]** into the locking hole co-axially.
- Set the desired inclination of the guide in relation to the locking hole axis. The guide enables the inclination of 15° in each direction with respect to the axis of the locking hole..

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

40.5928.018

Hole drilling

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

NOTE: Drill under X-Ray control to avoid a drill collision with already implanted screws.

40.2063.181

Measurement of hole depth

OPTION I: Determine the length of the screw to be used using locking screw length measure **[40.4818.100]**.

40.4818.100

OPTION II: or having removed the guide VA, use depth measure **[40.4640.000]** to determine the length of the screw.

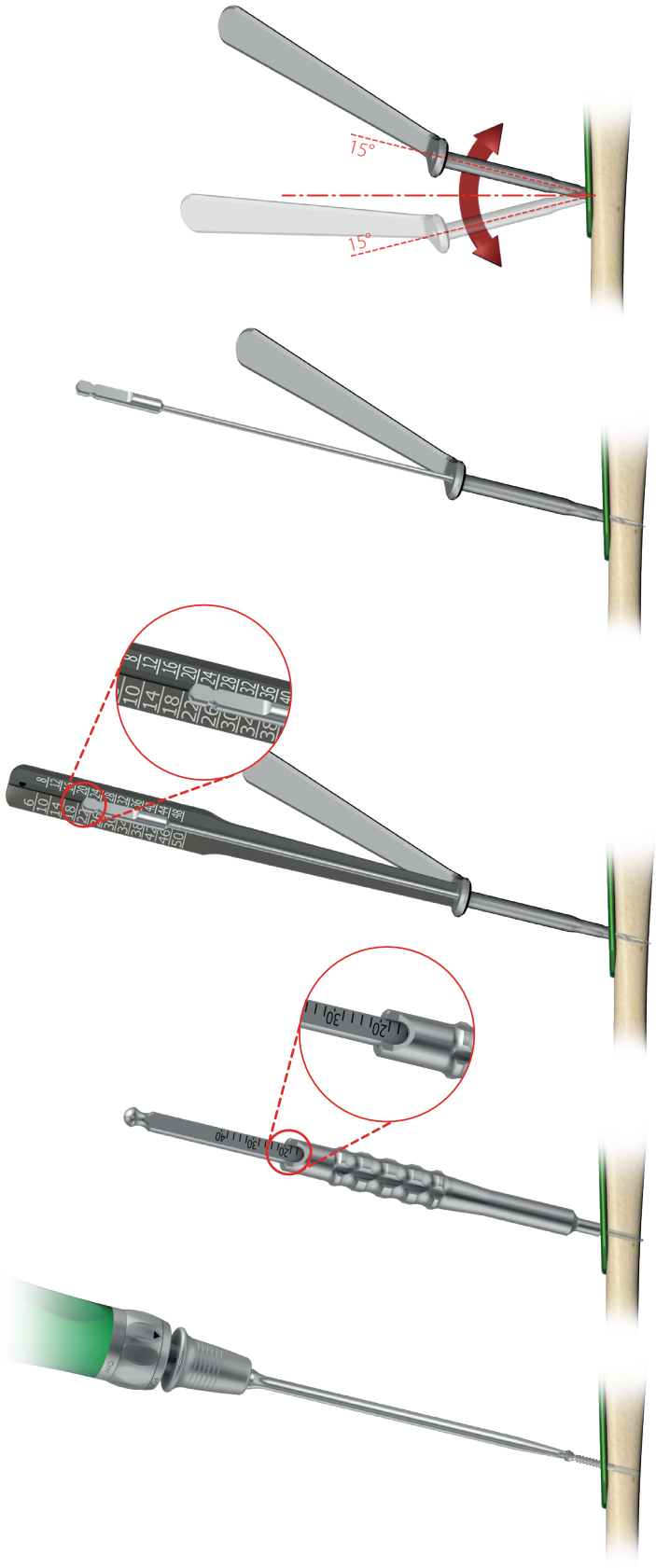
40.4640.000

Screw insertion

Insert VA screw using torque limiting ratchet handle 1Nm **[40.6650.000]** and screwdriver tip T8 **[40.5682.000]**.

40.6650.000

40.5682.000



5. POSTOPERATIVE PROCEDURE

Introduce appropriate postoperative treatment that is determined by the physician. 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.

6. IMPLANT REMOVAL

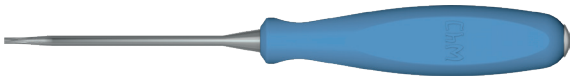
The physician decides about implant removal. In order to remove the implants from the body, unlock all the locking screws first and then remove them from the bone. This will prevent any rotation of the plate when removing the last locking screw.

7. CATALOGUE PAGES

7a. INSTRUMENT SET

Set 4.0ChLP – wedge osteotomy

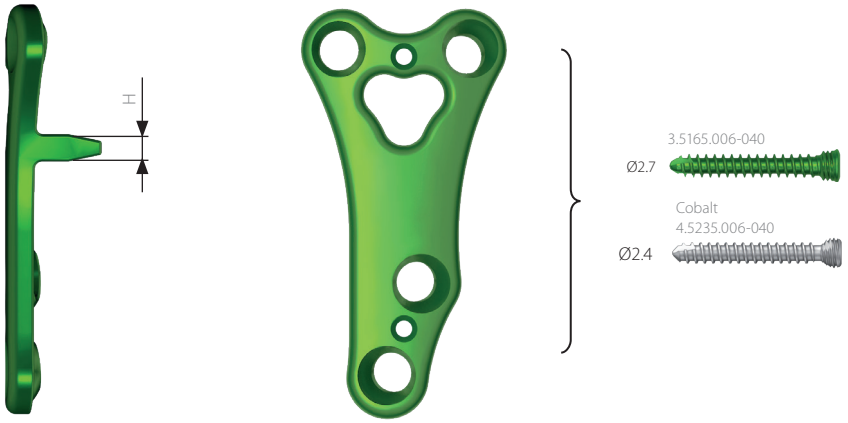
40.6297.000

	Name	Catalogue no.	Pcs
	Threaded guide M3.5/1.8 - 4.0	40.4896.018	4
	Guide VA 1.8	40.5928.018	1
	Kirschner wire 1.0/180	40.4814.000	5
	Drill 1.8/180	40.2063.181	2
	Depth measure	40.4640.000	1
	Screwdriver tip T8-3/16	40.5682.000	1
	Torque limiting ratchet handle1.0Nm	40.6650.000	1
	Star screwdriver T8	40.0669.100	1
	Dissecting forceps Standard 14.5cm	30.3303.000	1
	Scarf bone holding forceps 175 mm	40.4146.000	1
	Pallete for 4.0ChLP implants and instruments- opening wedge osteotomy	40.6298.000	1
	Container solid bottom 1/2 306x272x85mm	12.0751.100	1
	Perforated aluminum lid 1/2 306x272x15mm Gray	12.0751.200	1

4.0ChLP osteotomy plate T

Ti | Ster Non Ster

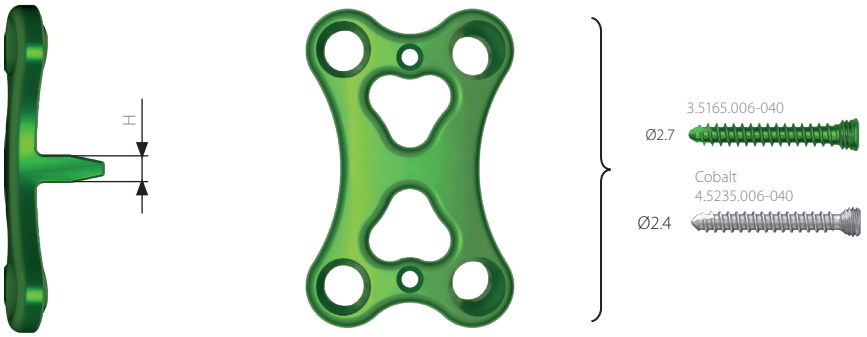
H	Len	L R
2	30	3.7056.002
3	30	3.7056.003
4	30	3.7056.004
5	30	3.7056.005
6	30	3.7056.006
7	30	3.7056.007



4.0ChLP osteotomy plate X

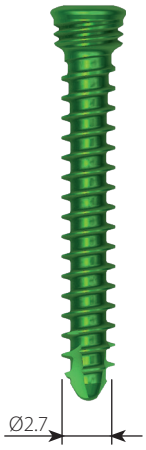
Ti | Ster Non Ster

H	Len	L R
2	23	3.7057.002
3	23	3.7057.003
4	23	3.7057.004
5	23	3.7057.005
6	23	3.7057.006
7	23	3.7057.007



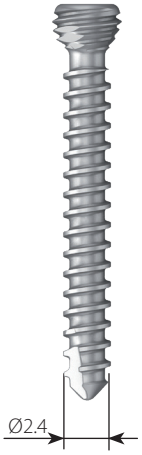
Ster
Non
Ster

4.0ChLP screw 2.7



Len	Ti
6	3.5165.006
8	3.5165.008
10	3.5165.010
12	3.5165.012
14	3.5165.014
16	3.5165.016
18	3.5165.018
20	3.5165.020
22	3.5165.022
24	3.5165.024
26	3.5165.026
28	3.5165.028
30	3.5165.030
32	3.5165.032
34	3.5165.034
36	3.5165.036
38	3.5165.038
40	3.5165.040

4.0ChLP screw VA 2.4



Len	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

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