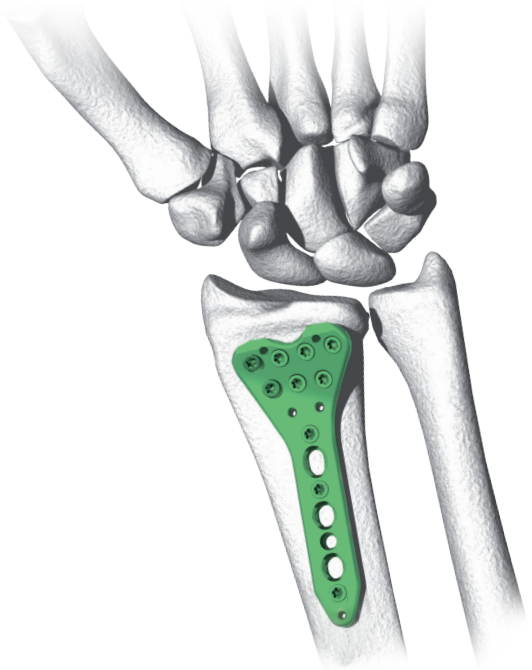
ST/32F

ChM®

4,0 ChM Locked Plating ChLPsystem

4.0ChLP DISTAL RADIUS PLATES

- *IMPLANTS*
- *INSTRUMENT SET 40.5711.200*
- *SURGICAL TECHNIQUE*



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SYMBOLS DESCRIPTIONS

	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.

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I. INTRODUCTION

This instruction refers to a set of 4.0ChLP locking plates intended for the treatment of fractures of distal radius. The plates discussed are a part of the ChLP locking plates system developed by **ChM** sp. z o.o. The implants presented herein are made of titanium, titanium alloys and cobalt alloy with ISO 5832. These are Quality Management Systems, ISO 9001, ISO 13485 and Directive 93/42/EEC that guarantee high quality of implants.

The system for distal radial fractures treatment consists of:
- Implants *(locking plates, locking screws and standard cortical screws)*,
- Instrument set,
- Surgical technique.

I.1. INDICATIONS

The main purpose of surgical treatment of radial bone fractures with 4.0ChLP locking plates is its anatomical reconstruction, and faster recovery to public and professional life. The stabilization with this method provides the possibility of: precise fracture reduction, stable angular immobilization of bone fragments while preserving the blood supply.

Plates are intended for treatment of:
- fractures in distal part of radial bone and fractures extending to radial bone shaft,
- compound exta-articular and intra-articular fractures,
- osteotomies,
- possibility of using them in treatment of other small bones fractures.

I.2. CONTRAINDICATIONS

- infections,
- physical maturation.

I.3. PLATE SELECTION AND CONTOURING

Wide size range of locking plates enables proper plate selection.
Locking plate contouring is not recommended due to possiblity of threaded holes damaging.
Bottom surface of the plate does not have to contact the bone if locking screws are used. There is no necessity of accurate plates contouring, then. Pre-shaped plates do not require additional bending in most cases.

If the plate bending is necessary, remember not to deform threaded holes excessively. It is essential to ensure that the desired shape of the implant is reached in as few bends as possible because titanium hardness increases and ductility *(bendability)* decreases. Excessive bending can lead to postoperative fracture of the plate. Due to potential risk of postoperative implant breakage, extremely acute angles together with small bending radius must be avoided. If implant damage *(indentations, elongated screw holes, etc.)* occurs, plate is to be exchanged for a new, more carefully bent one.

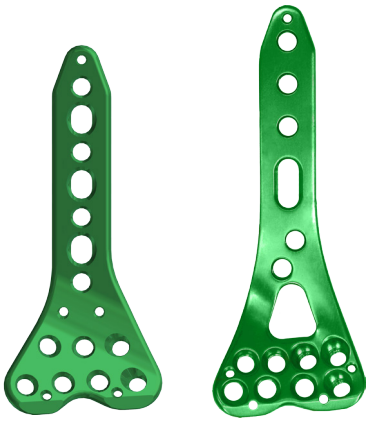
If the plate bending is required:
- perform it between locking holes;
- do not bend the plate more than 20° – 25°;
- do not bend the plate back and forth;
- before bending, insert the locking screws in the bending area, that decreases the threaded holes deformation degree.

Prior to using the product, read the Instructions For Use carefully. The IFU is supplied with the product and attached at the end of this document. It includes, among others: the indications, contraindications, adverse effects, warnings and recommendations associated with product usage.

II. IMPLANTS

System consists of plates and corresponding screws. For more comfortable use, plates and titanium locking screws are in the same green color.

II.1. VOLAR PLATES

Left anatomical plates	Right anatomical plates
	
wide	wide
narrow	narrow

Features of volar plates:

- new, more anatomical shape of the plates,
- determined screws direction provides optimal support of articular surface, stable fixation of radial styloid with two lateral screws,
- holes for temporary plate positioning with K-wires,
- elongated hole for plate positioning,
- undercuts of bottom plate side to obtain limited contact with bone and better blood supply of surrounding tissues,
- holes in shaft part allow for placing conventional cortical screws, with or without compression, and locking screws.

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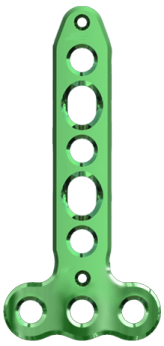
II.2. DORSAL PLATES

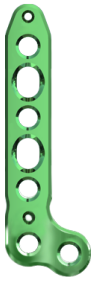
straight



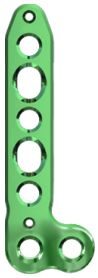
T 3 holes

Left-side directed

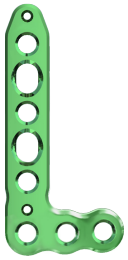
Right-side directed



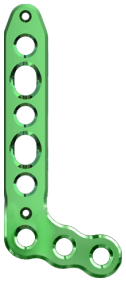
L 2 holes oblique



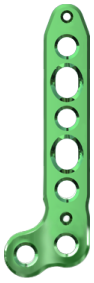
L 2 holes



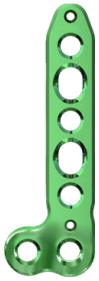
L 3 holes



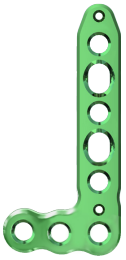
L 3 holes oblique



L 2 holes oblique



L 2 holes



L 3 holes

L 3 holes oblique

Above plates are generally intended for stabilization of distal radius in 2 plates system technique. This ensures stable construction for complex fractures. There is no need to remove a dorsal tubercle of radius and the tendon and soft tissue irritation is decreased.

Left anatomical plates

Right anatomical plates

Delta plate

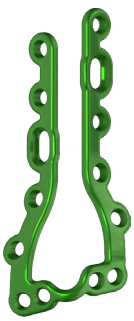
Y plate

Delta plate

Y plate

H plate narrow

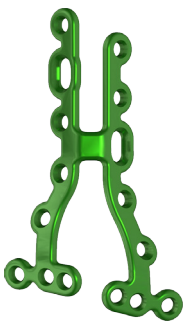
H plate wide



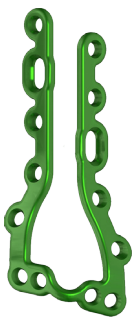
Pi plate narrow

Pi plate wide

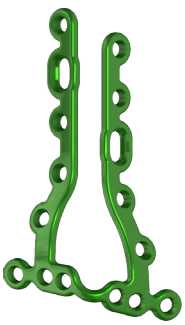
H plate narrow



H plate wide



Pi plate narrow



Pi plate wide

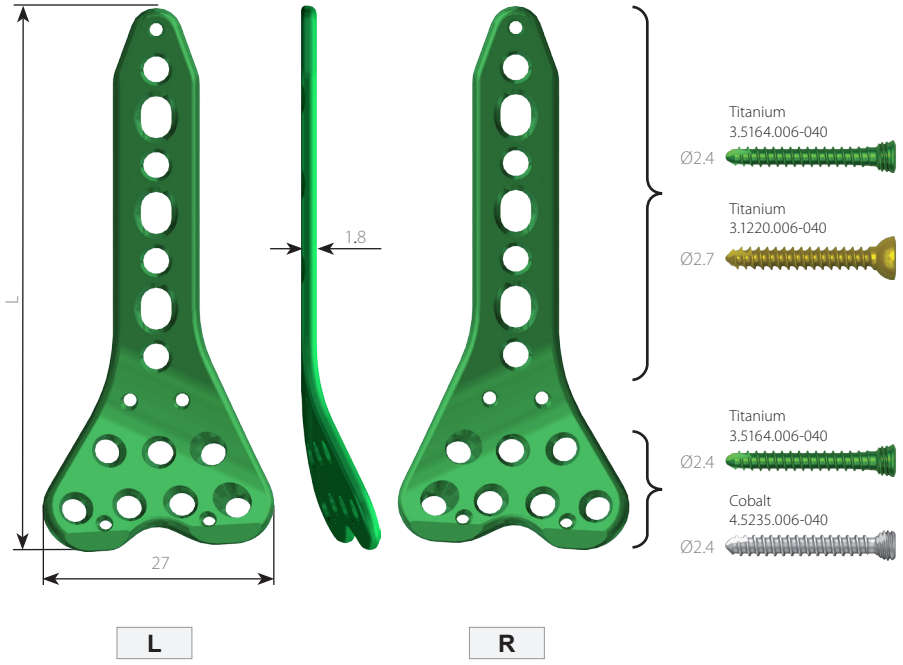
4.0 ChM Locked Plating ChLPsystem

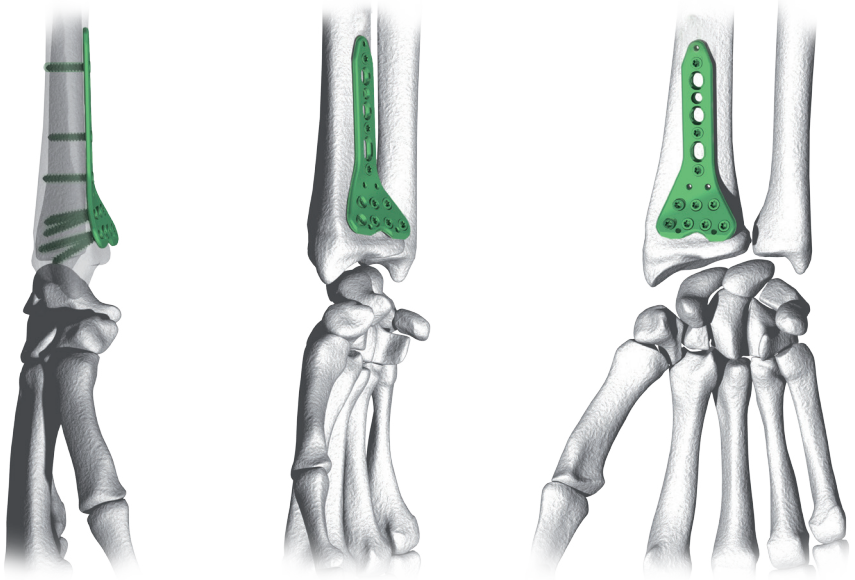
TITANIUM

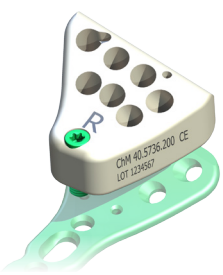
4.0ChLP Wide radius volar plate

		Catalogue no.	
O	L [mm]	Left	Right
3	53	3.4049.603	3.4050.603
4	64	3.4049.604	3.4050.604
5	75	3.4049.605	3.4050.605

O - threaded holes number in shaft part of the plate





No.		Name	Catalogue No.	Pcs
1		Aiming block L (3.4049)	**40.5736.100**	1
2		Aiming block R (3.4050)	**40.5736.200**	1

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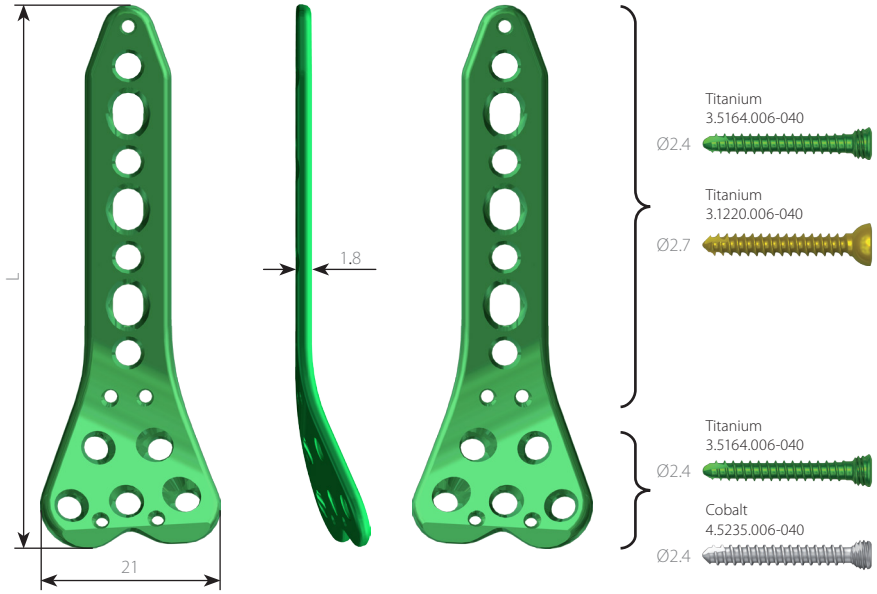
4.0 ChM Locked Plating ChLPsystem

TITANIUM Ti

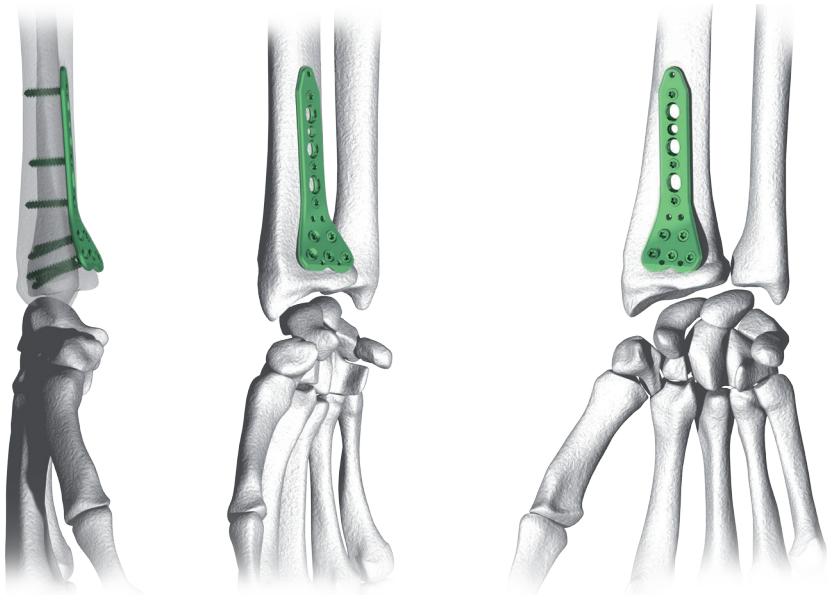
4.0ChLP Narrow radius volar plate

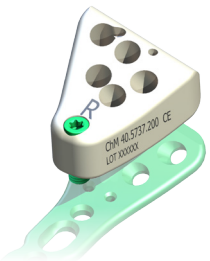
		Catalogue no.	
O	L [mm]	Left	Right
3	53	3.4053.603	3.4054.603
4	64	3.4053.604	3.4054.604
5	75	3.4053.605	3.4054.605

O - threaded holes number in shaft part of the plate



L R



No.		Name	Catalogue No.	Pcs
1		Aiming block L [3.4053]	**40.5737.100**	1
2		Aiming block R [3.4054]	**40.5737.200**	1

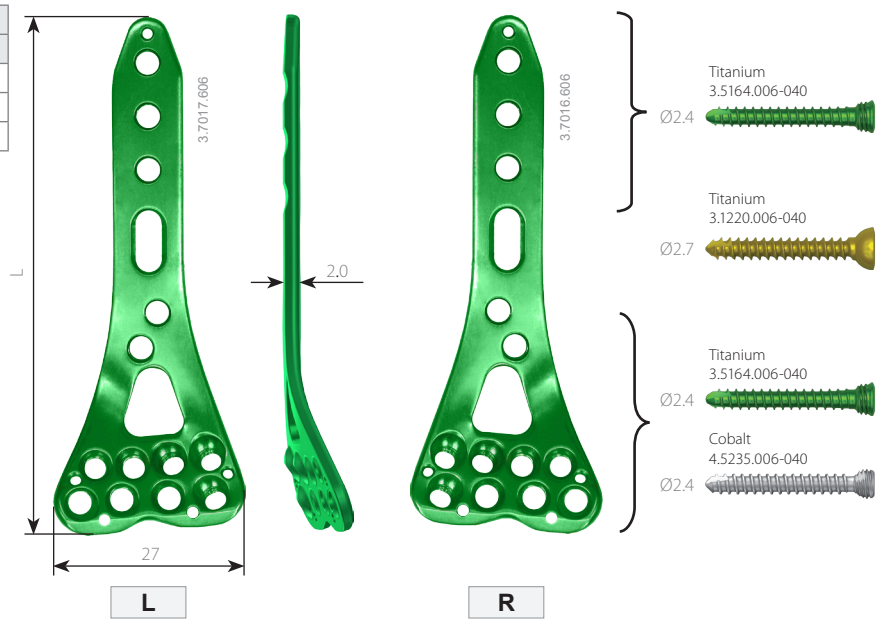
4.0 ChM Locked Plating ChLP system

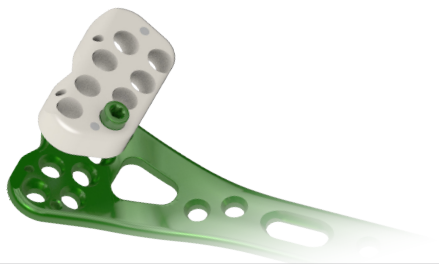
TITANIUM

4.0ChLP distal volar radius plate

O	L [mm]	Catalogue no. Left	Catalogue no. Right
4	59	3.7017.604	3.7016.604
5	67	3.7017.605	3.7016.605
6	75	3.7017.606	3.7016.606

O - threaded holes number in shaft part of the plate



No.		Name	Catalogue No.	Pcs
1		Aiming block L [3.7017]	40.5727.100	1
2		Aiming block R [3.7016]	40.5727.200	1

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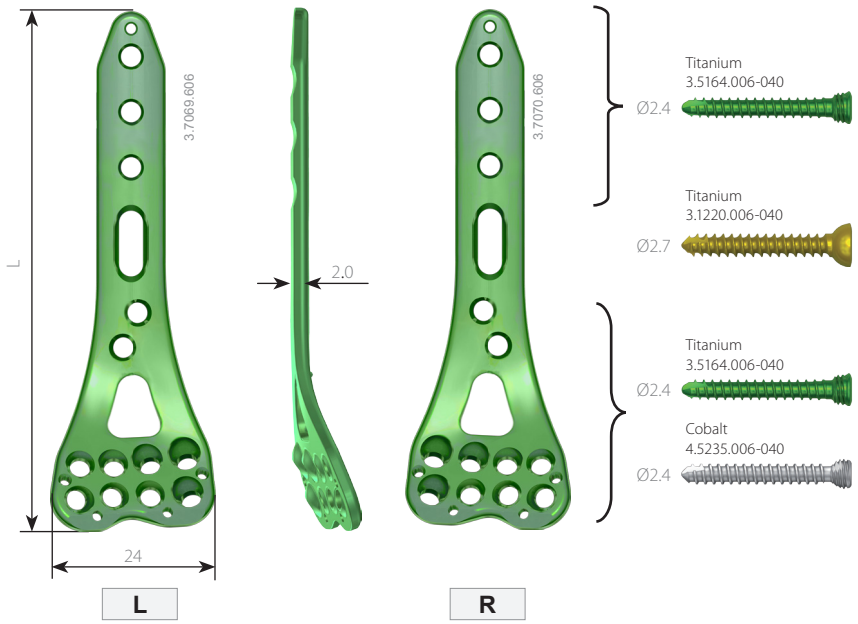
4.0 ChM Locked Plating ChLP system

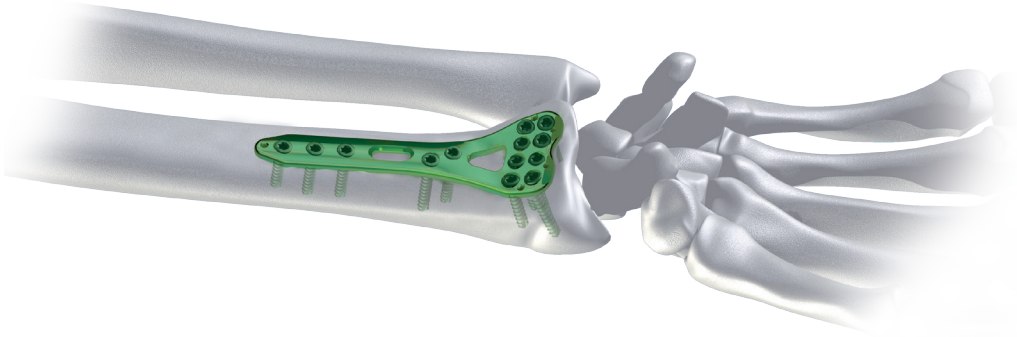
TITANIUM

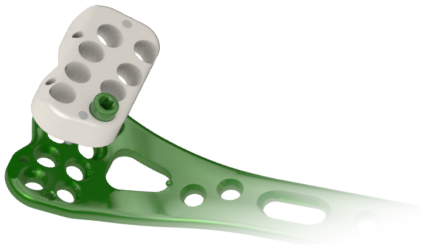
4.0ChLP distal radius volar narrow plate

		Catalogue no.	
O	**L** [mm]	**Left**	**Right**
4	59	3.7069.604	3.7070.604
5	67	3.7069.605	3.7070.605
6	75	3.7069.606	3.7070.606

O - threaded holes number in shaft part of the plate



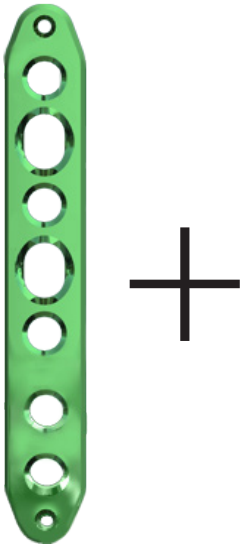


No.		Name	Catalogue No.	Pcs
1		Aiming block L [3.7069]	40.5743.100	1
2		Aiming block R [3.7070]	40.5743.200	1

4,0 ChM Locked Plating ChLP system

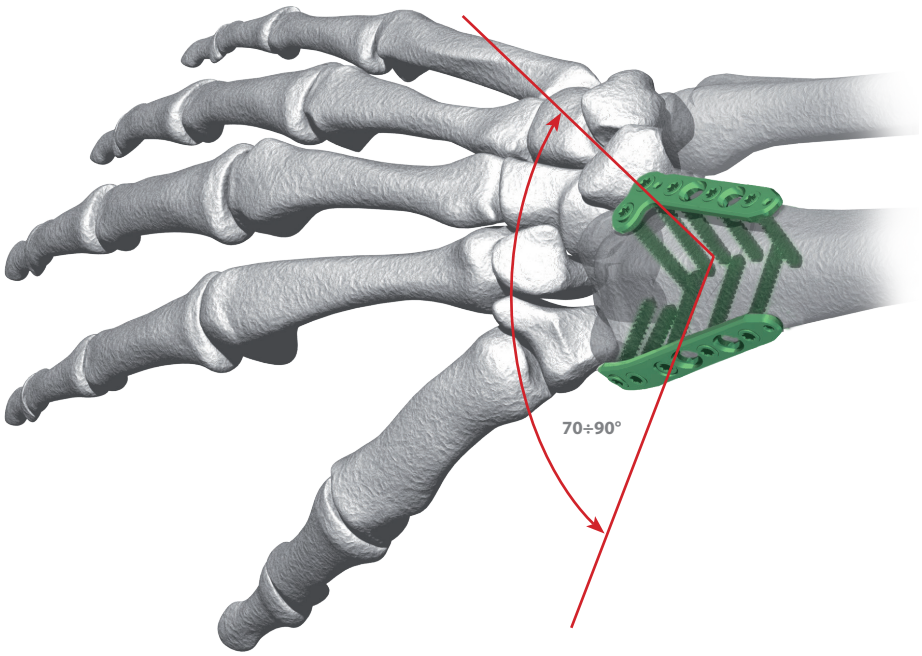
TITANIUM Ti

Plates for distal radius – dorsal side



Interchangeable plates used with straight plate in 2-plates technique

3.4047.6xx	Left	3.4041.6xx	3.4043.6xx	3.4037.6xx	3.4045.6xx	3.4048.6xx
	Right	3.4042.6xx	3.4044.6xx	3.4038.6xx	3.4046.6xx	



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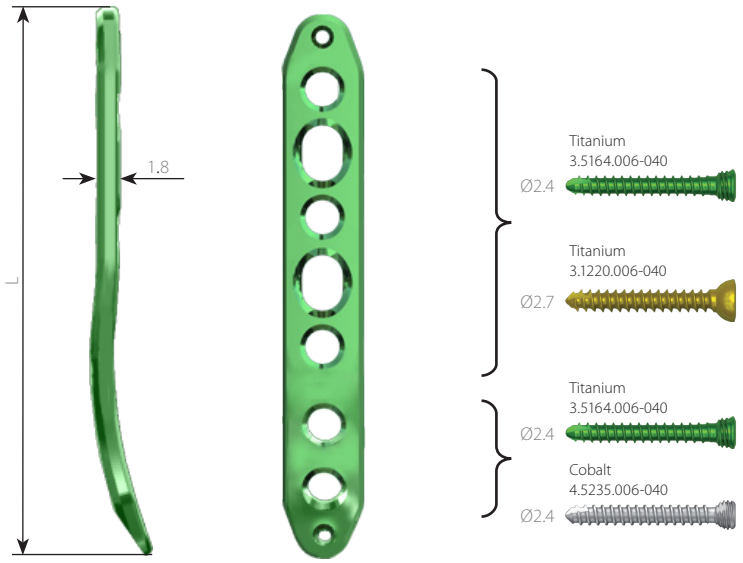
4.0 ChM Locked Plating ChLP system

TITANIUM

4.0ChLP Straight plate

O	L [mm]	Catalogue no.
3	47	3.4047.603
4	58	3.4047.604

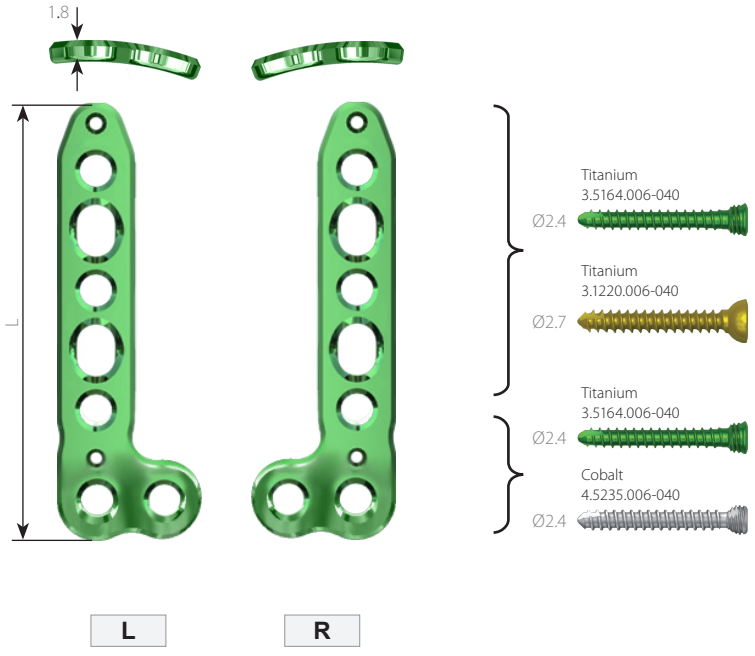
O - threaded holes number in shaft part of the plate



4.0ChLP L plate

		Catalogue no.	
O	L [mm]	Left	Right
2	29	3.4041.602	3.4042.602
3	40	3.4041.603	3.4042.603
4	51	3.4041.604	3.4042.604

O - threaded holes number in shaft part of the plate



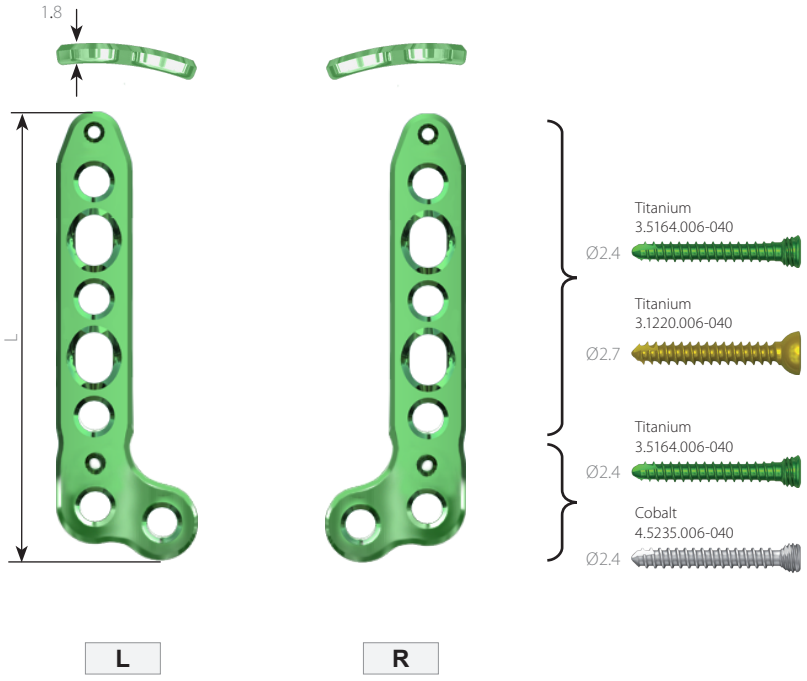
4.0 ChM Locked Plating ChLP system

TITANIUM

4.0ChLP Oblique L plate

		Catalogue no.	
O	L [mm]	Left	Right
2	30	3.4037.602	3.4038.602
3	41	3.4037.603	3.4038.603
4	52	3.4037.604	3.4038.604

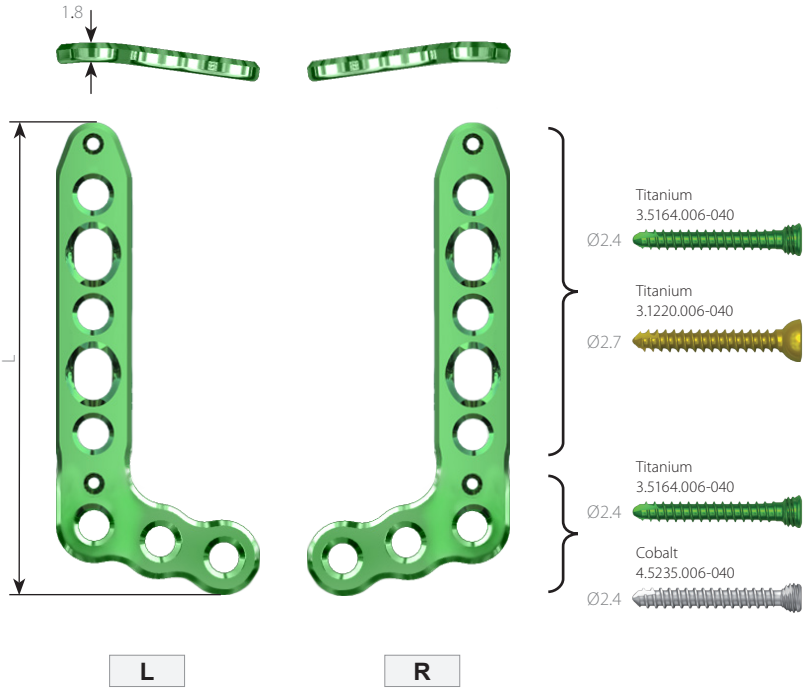
O - threaded holes number in shaft part of the plate



4.0ChLP oblique L plate

		Catalogue no.	
O	L [mm]	Left	Right
2	32	3.4045.602	3.4046.602
3	43	3.4045.603	3.4046.603
4	54	3.4045.604	3.4046.604

O - threaded holes number in shaft part of the plate



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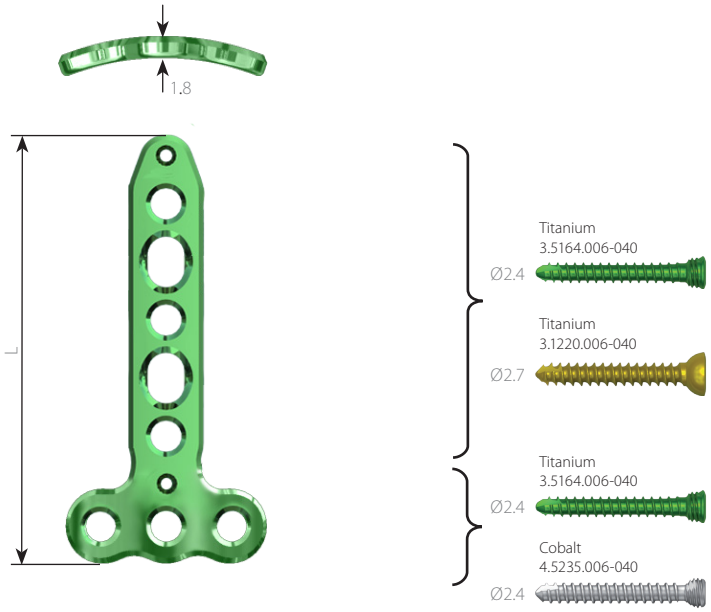
4.0 ChM Locked Plating ChLP system

TITANIUM

4.0ChLP T-plate

O	L [mm]	Catalogue no.
3	40	3.4048.603
4	51	3.4048.604

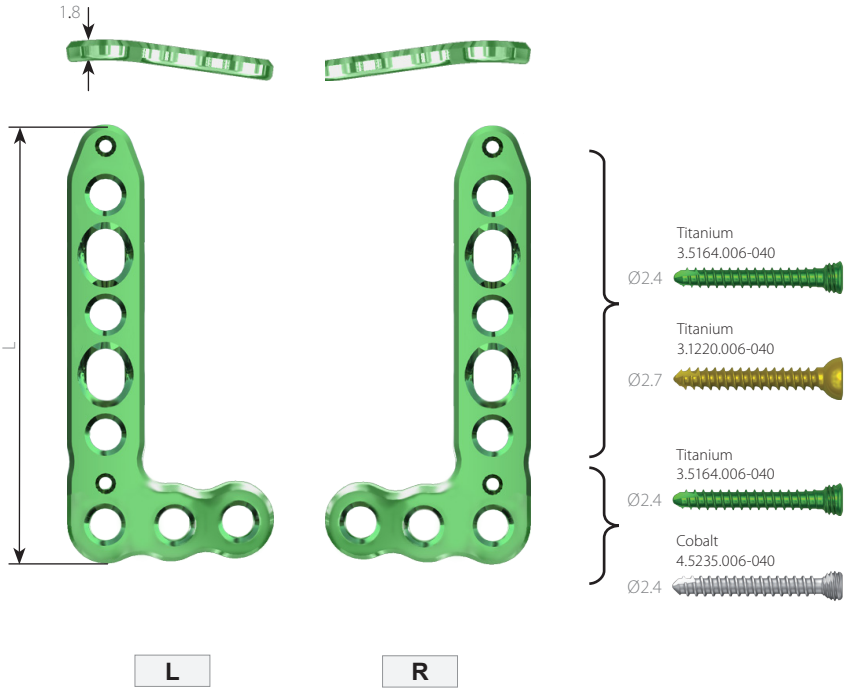
O - threaded holes number in shaft part of the plate



4.0ChLP L plate

		Catalogue no.	
O	L [mm]	Left	Right
2	29	3.4043.602	3.4044.602
3	40	3.4043.503	3.4044.603
4	51	3.4043.604	3.4044.604

O - threaded holes number in shaft part of the plate



4.0 ChM Locked Plating ChLP system

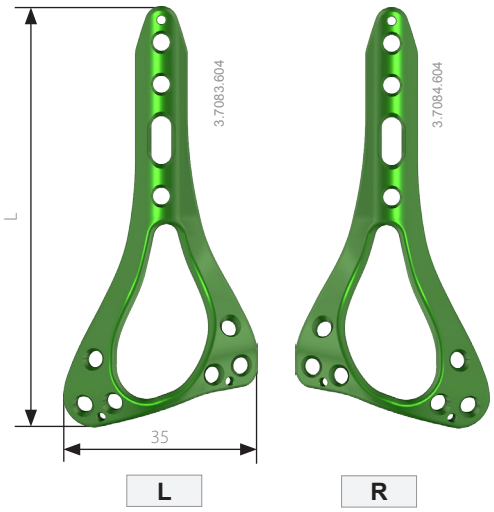
TITANIUM Ti

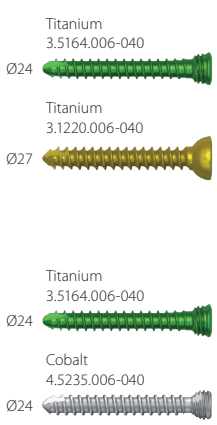
4.0ChLP dorsal-radial Delta plate

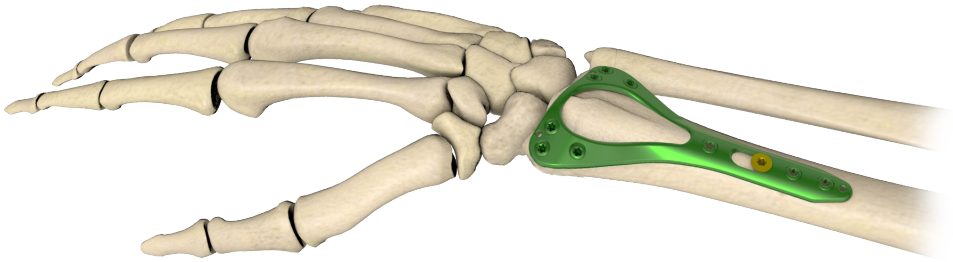
O	L [mm]	Catalogue no. Left	Right
4	75	3.7083.604	3.7084.604
5	82	3.7083.605	3.7084.605
6	90	3.7083.606	3.7084.606

O - holes number in shaft part of the plate

2,0 [mm] - thickness



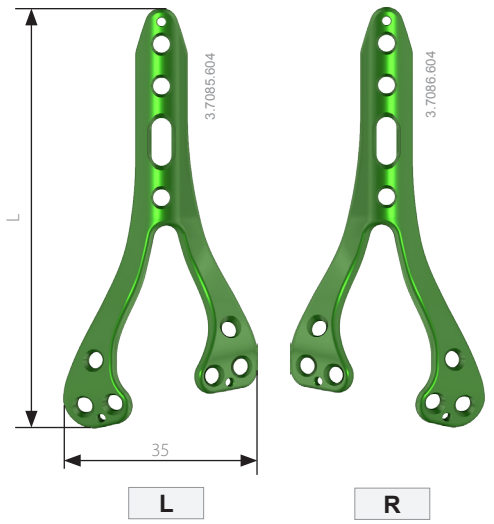


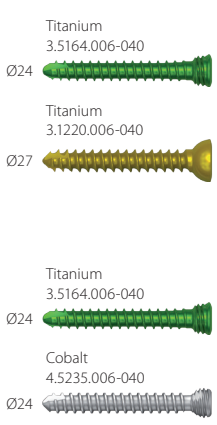


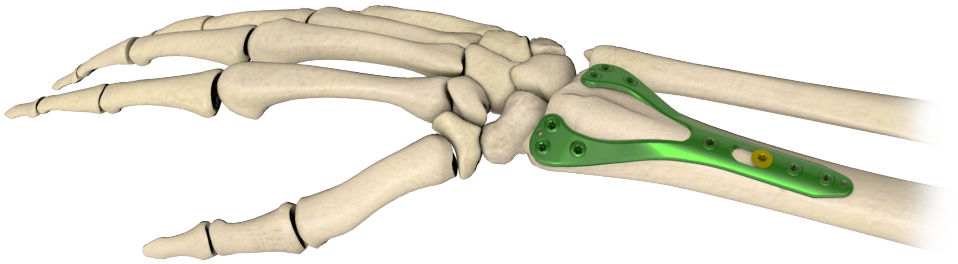
4.0ChLP dorsal-radial Y plate

O	L [mm]	Catalogue no. Left	Right
4	75	3.7085.604	3.7086.604
5	82	3.7085.605	3.7086.605
6	90	3.7085.606	3.7086.606

O - holes number in shaft part of the plate
2,0 [mm] - thickness







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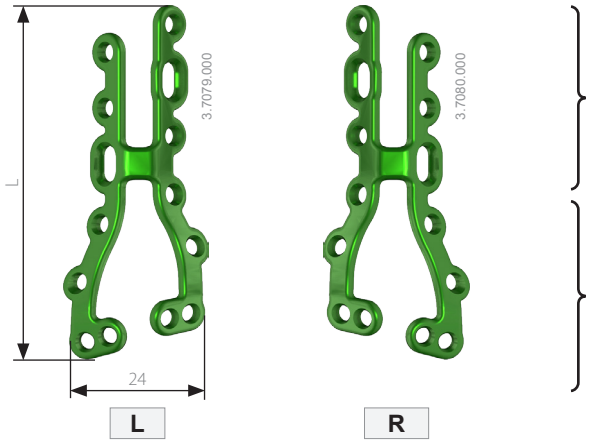
4,0 ChM Locked Plating ChLPsystem

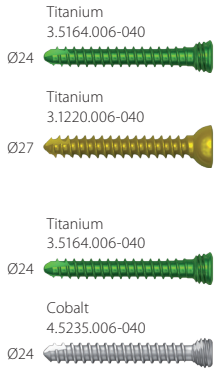
TITANIUM Ti

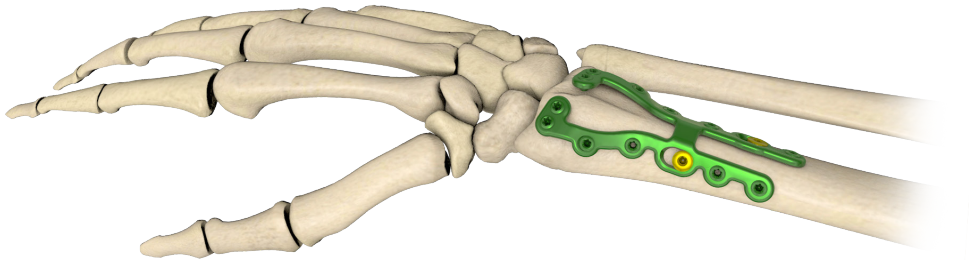
4.0ChLP dorsal-radial H plate narrow

	Catalogue no.	
L [mm]	Left	Right
63	3.7079.000	3.7080.000

2,0 [mm] - thickness



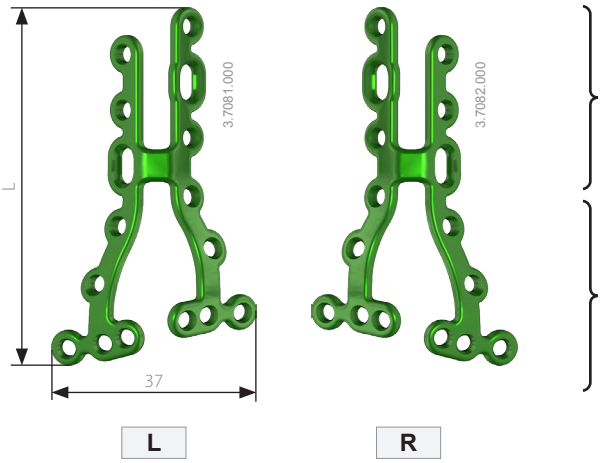


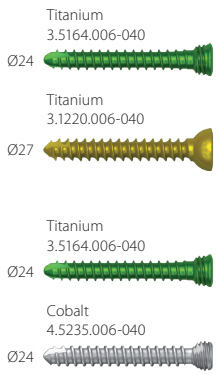


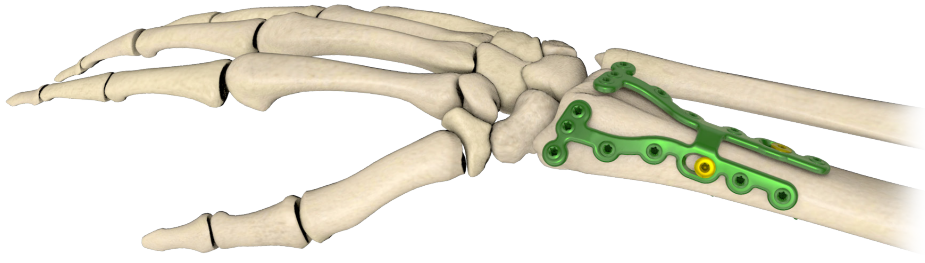
4.0ChLP dorsal-radial H plate wide

	Catalogue no.	
L [mm]	Left	Right
64	3.7081.000	3.7082.000

2,0 [mm] - thickness







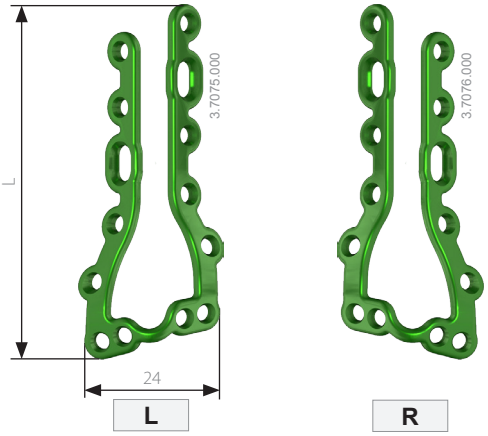
4.0 ChM Locked Plating ChLP system

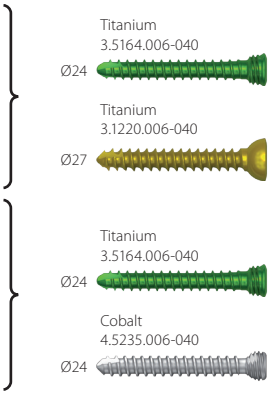
TITANIUM

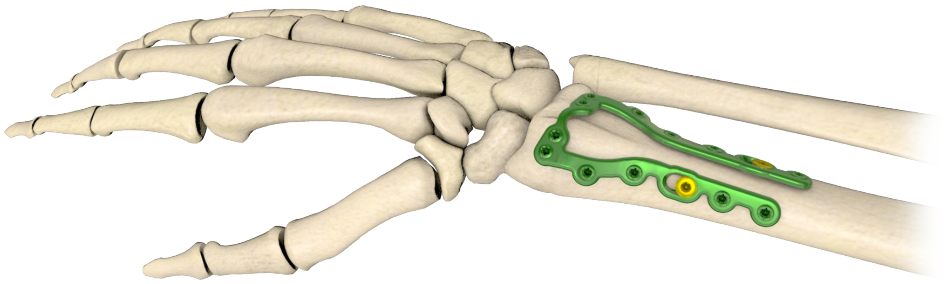
4.0ChLP dorsal-radial Pi plate narrow

	Catalogue no.	
L [mm]	Left	Right
63	3.7075.000	3.7076.000

2,0 [mm] - thickness



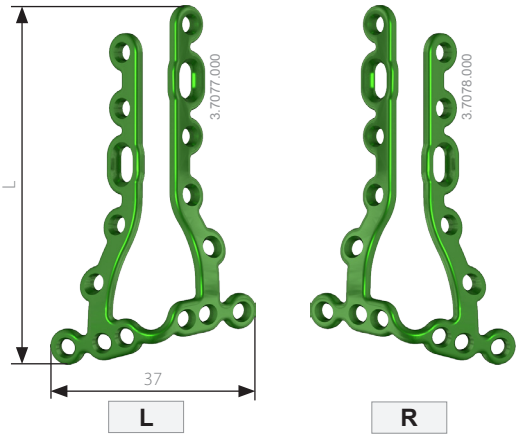


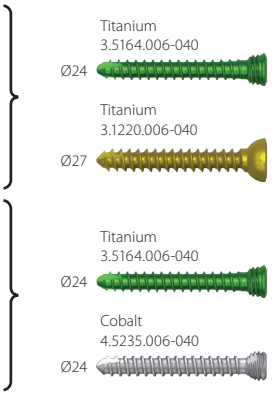


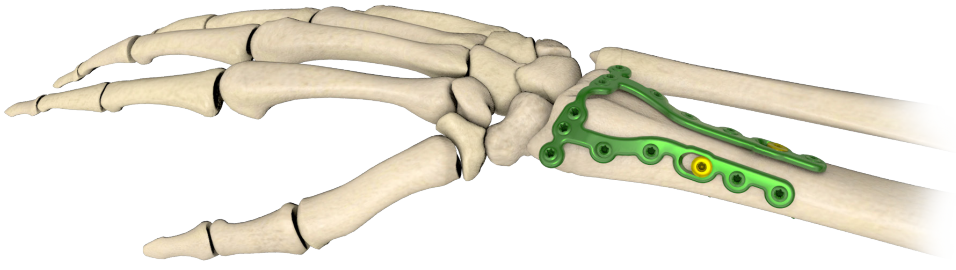
4.0ChLP dorsal-radial Pi plate wide

	Catalogue no.	
L [mm]	Left	Right
64	3.7077.000	3.7078.000

2,0 [mm] - thickness







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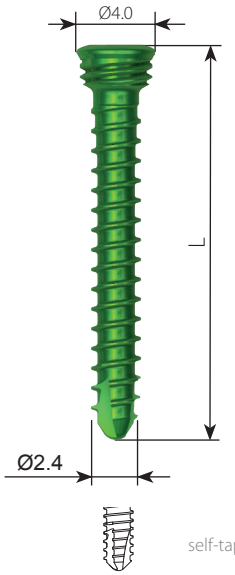
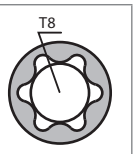
II.3. SCREWS

4.0ChLP screw Ø2.4



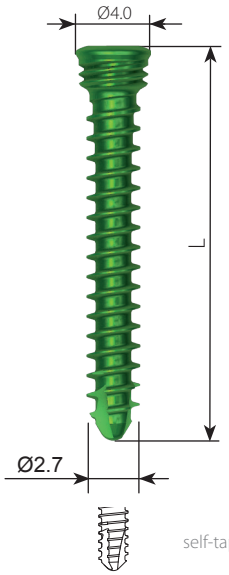
self-tapping



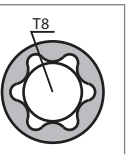
L [mm]	Catalogue no. Titanium
6	3.5164.006
8	3.5164.008
10	3.5164.010
12	3.5164.012
14	3.5164.014
16	3.5164.016
18	3.5164.018
20	3.5164.020
22	3.5164.022
24	3.5164.024
26	3.5164.026
28	3.5164.028
30	3.5164.030
32	3.5164.032
34	3.5164.034
36	3.5164.036
38	3.5164.038
40	3.5164.040

Ø core		1.8
Ø drill bit for thread hole	40.2063.181	1.8
threaded guide	40.4896.018	M3.5/1.8
screwdriver tip	40.5682.000	T8

4.0ChLP screw Ø2.7



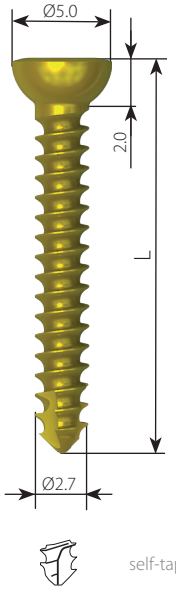
self-tapping



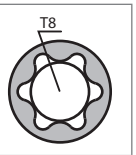
L [mm]	Catalogue no. Titanium
6	3.5165.006
8	3.5165.008
10	3.5165.010
12	3.5165.012
14	3.5165.014
16	3.5165.016
18	3.5165.018
20	3.5165.020
22	3.5165.022
24	3.5165.024
26	3.5165.026
28	3.5165.028
30	3.5165.030
32	3.5165.032
34	3.5165.034
36	3.5165.036
38	3.5165.038
40	3.5165.040

Ø core		1.8
Ø drill bit for thread hole	40.2063.181	1.8
threaded guide	40.4896.018	M3.5/1.8
screwdriver tip	40.5682.000	T8

Cortical screw Ø2.7



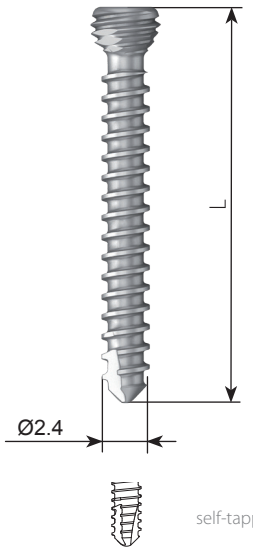
self-tapping



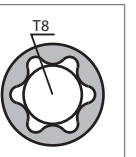
L [mm]	Catalogue no. Titanium
6	3.1220.006
8	3.1220.008
10	3.1220.010
12	3.1220.012
14	3.1220.014
16	3.1220.016
18	3.1220.018
20	3.1220.020
22	3.1220.022
24	3.1220.024
26	3.1220.026
28	3.1220.028
30	3.1220.030
32	3.1220.032
34	3.1220.034
36	3.1220.036
38	3.1220.038
40	3.1220.040

Ø core		1.8
Ø drill bit for thread hole	40.2063.181	1.8
compression guide	40.4897.018	1.8
screwdriver	40.0669.100	T8

4.0ChLP Screw VA 2.4



self-tapping



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

Ø	core		1.8
Ø	drill bit for thread hole	40.2063.181	1.8
	Guide sleeve VA	40.5928.018	1.8
	screwdriver tip	40.5682.000	T8

III. INSTRUMENTS

Set for 4.0ChLP - distal radius **40.5710.141**

No.		Name	Catalogue No.	Pcs
1		Instrument set for 4.0 ChLP	**40.5711.200**	1
2		Palette for 4.0ChLP implants - distal radial *(with instruments)*	**40.5713.040**	1
3		Perforated aluminum lid 1/2 306x272x15mm gray	**12.0751.200**	1
4		Container with solid bottom 1/2 306x272x85mm	**12.0751.100**	1

Palette for 4.0ChLP implants - distal radius **40.5713.050**

No.		Name	Catalogue No.	Pcs
1		Palette for 4.0ChLP implants - distal radial	**40.5713.150**	1
2		Perforated aluminum lid 1/2 306x272x15mm gray	**12.0751.200**	1
3		Container with solid bottom 1/2 306x272x85mm	**12.0751.100**	1

PALETTE FOR DISTAL RADIUS PLATES: 3.7075÷3.7086

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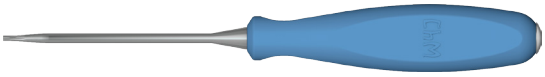
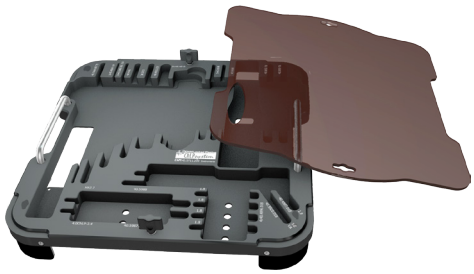
Instrument set for 4.0ChLP **40.5711.200**

No.		Name	Catalogue No.	Pcs
1		Threaded guide M3.5/1.8 -4,0	**40.4896.018**	4
2		Compression guide 1.8	**40.4897.018**	1
3		Guide VA 1.8	**40.5928.018**	1
4		Kirschner wire 1.0/180	**40.4814.000**	5
5		Drill 1.8/180	**40.2063.181**	2
6		Length measure of locking screw	**40.4818.100**	1
7		Depth measure	**40.4640.000**	1
8		Screwdriver tip T8.0	**40.5682.000**	1
9		T8 screwdriver tip with holder	**40.5989.000**	1
10		Cortical tap HA 2.7	**40.5988.000**	1
11		Tap 4.0ChLP -2.4	**40.5987.024**	1
12		Setting-compressing screw 1.8/120	**40.5678.000**	2
13		Torque limiting ratchet handle1.0Nm	**40.6650.000**	1
14		Star screwdriver T8	**40.0669.100**	1
15		Plates bender 4,0	**40.4643.000**	2
16		Dissecting forceps Standard 14.5cm	**30.3303.000**	1
17		Palette for instruments 4.0ChLP	**40.5712.100**	1

Instrument set for 4.0ChLP **40.5711.300**

No.		Name	Catalogue No.	Pcs
1		INSTRUMENT SET FOR 4.0ChLP	**40.5711.200**	1
2		Perforated aluminum cover 1/2 306x272x15 mm gray	**12.0751.200**	1
3		Container with solid bottom 1/2 306x272x85 mm	**12.0751.100**	1

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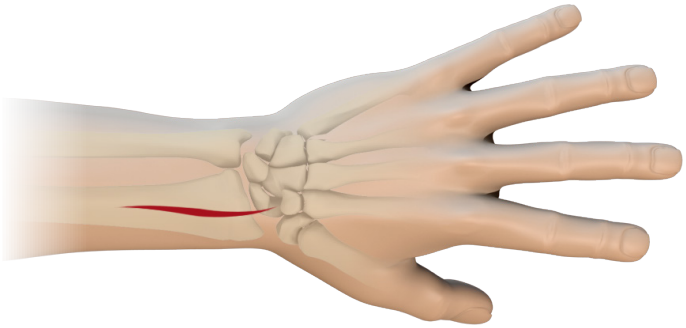
IV. SURGICAL TECHNIQUE

IV.1. PATIENT POSITION

Supine position of the patient is recommended. Hand and arm placed on the hand table, preferably radiolucent for fluoroscopic imaging.

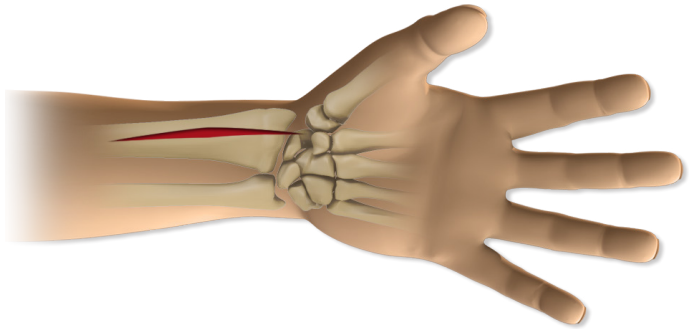
IV.2. DORSAL APPROACH

Make a longitudinal straight incision:
- from medial of the wrist *(2 cm proximally from the base of the second metacarpal)*,
- over the dorsal tubercle of radius,
- incision up to the 9 cm in length.



IV.3. VOLAR APPROACH.

For volar approach make a longitudinal incision between tendon sheath of flexor carpi radialis and radial artery.

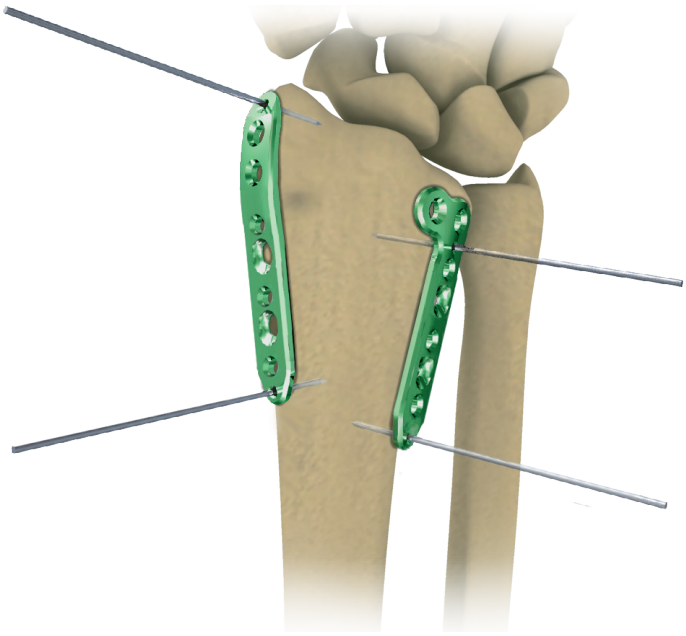


IV.4. TEMPORARY PLATE STABILIZATION

IV.4.1. Kirschner 1.0 Wire Usage

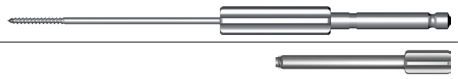
Use Kirschner wire 1.0/180 **[40.4814.000]** through dedicated holes in the plates for temporary stabilization on the bone.

Confirm the correct positioning using X-Ray.



EXAMPLE of K-wires usage

IV.4.2. Use of setting-compressing screw 1.8/120



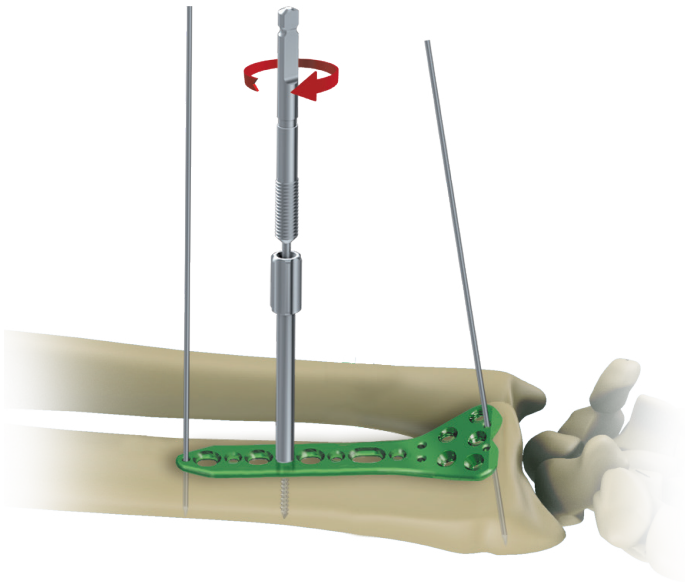
40.5678.000

40.4896.018

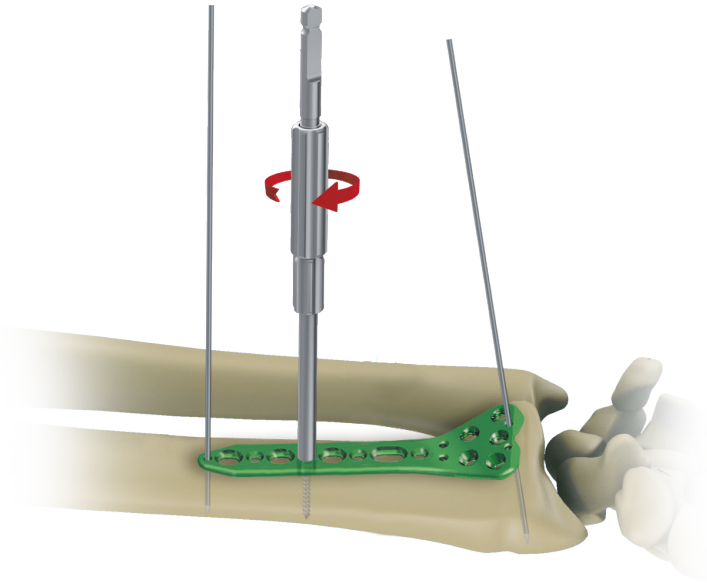
NOTE:
For temporary stabilization and moving the plate to the bone you may use the Setting-compressing screw 1.8/120 **[40.5678.000]**. Insert the screw through the Threaded guide M3.5/1.8 - 4.0 **[40.4896.018]**.

Insert the locking screw into the hole created by the removed Setting-compressing screw 1.8/120.

Insert the self-drilling tip of the setting-compressing screw.



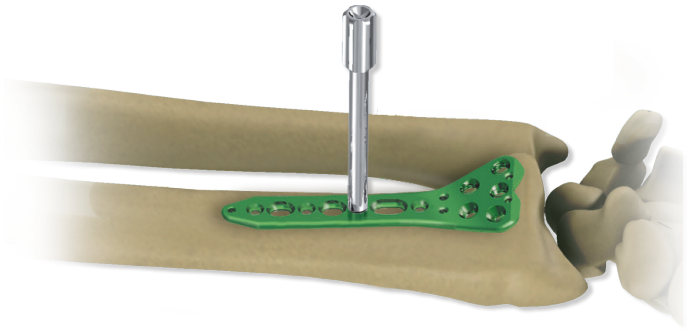
Tighten the plate to the bone by screwing in the sleeve.



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

IV.5. LOCKING SCREW INSERTION

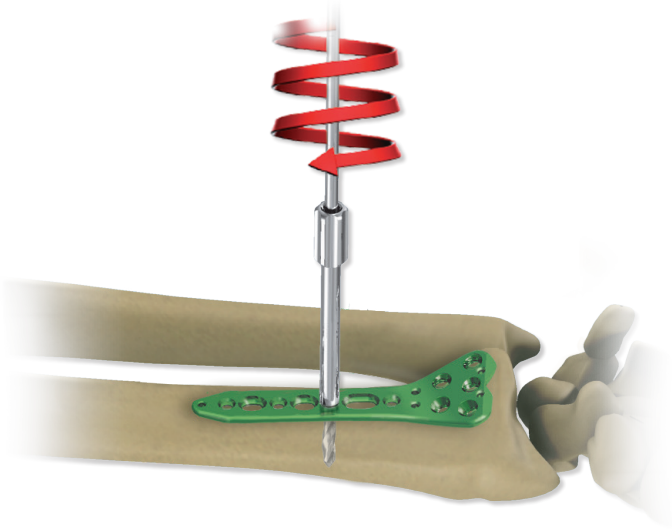
It is important to drill exactly in the axis of a locking hole. Always use the appropriate guide sleeve when drilling. The guide sleeve will ensure that the locking screw take an axial position towards the hole of the plate and be correctly locked in the plate. Free hand drilling of a hole can lead to: thread skewing and jamming the screw, incorrect screw locking and problems when removing the screws *(thread seizure)*.



IV.5.1. Insertion of the guide sleeve

40.4896.018

Insert the Threaded Guide M3.5/1.8 - 4.0 **[40.4896.018]** into the plate.



IV.5.2. Hole Drilling

40.2063.181

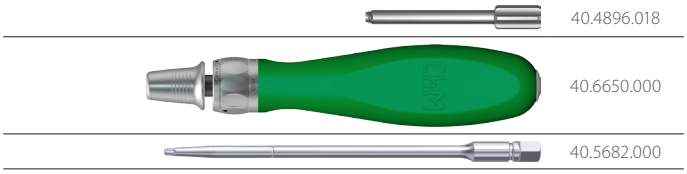
Drill on the advisable depth using the Drill 1.8/180 **[40.2063.181]**.

IV.5.3. Hole Depth Measurement

40.4818.100

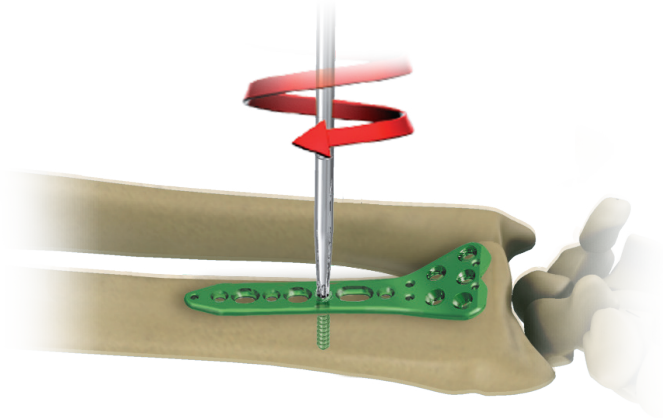
Measure the hole depth using the Locking screw length measure **[40.4818.100]** and select the proper screw length.

IV.5.4. Screw Insertion



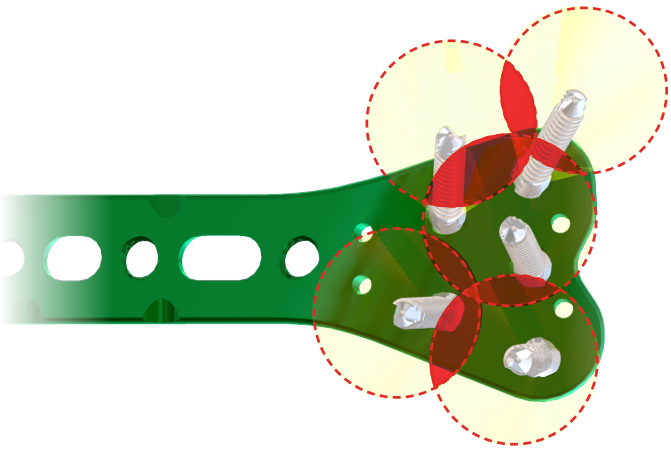
Remove the Threaded Guide M3.5/1.8-4.0 **[40.4896.018]**.
Insert locking screw using the Screwdriver Tip T8 **[40.5682.000]** with Torque Limiting Handle **[40.6650.000]**.

CAUTION:
The final tightening of the locking screw, especially when mechanical motor is used, should always be performed with the use of torque limiting handle. Failure to use the torque limiting handle may lead to intraoperative and postoperative complications *(during later removal of the plate and locking screws)*.



IV.6. INSERTION OF VARIABLE ANGLE SCREWS *(VA)*

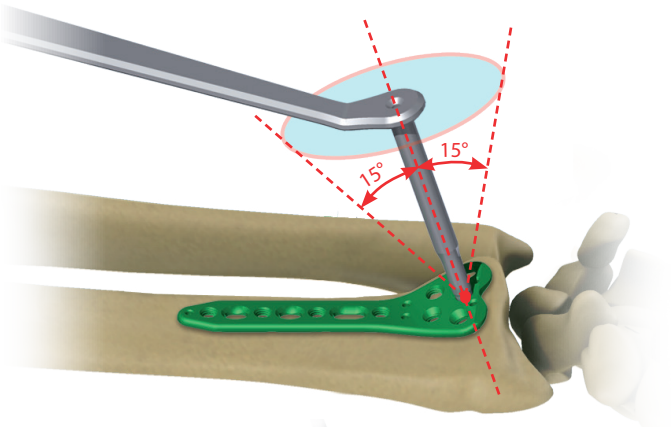
CAUTION:
When using the VA screws there is a risk of a collision between the screws or drill and the already inserted screws. Proper planning of trajectory of inserted screws and intraoperative X-Ray control while drilling reduces the risk of collision.



IV.6.1. Positioning of Guide VA

Insert the Guide VA 1.8 **[40.5928.018]** completely in the axis of the locking hole. Set the desired deviation from the locking hole. The guide allows the deviation of 15° in all directions in relation to the locking hole axis.

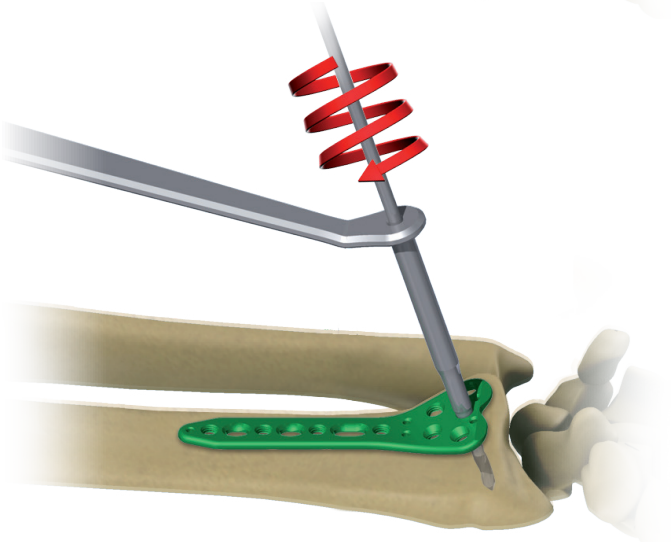
IMPORTANT:
The deviation above the 15° may make it impossible to properly lock the VA screw in the plate hole.



IV.6.2. Drilling

Drill on the advisable depth using the Drill 1.8/180 **[40.2063.181]**.

CAUTION:
Confirm the correct positioning using X-Ray to avoid collision of the drill with the already inserted screws.



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

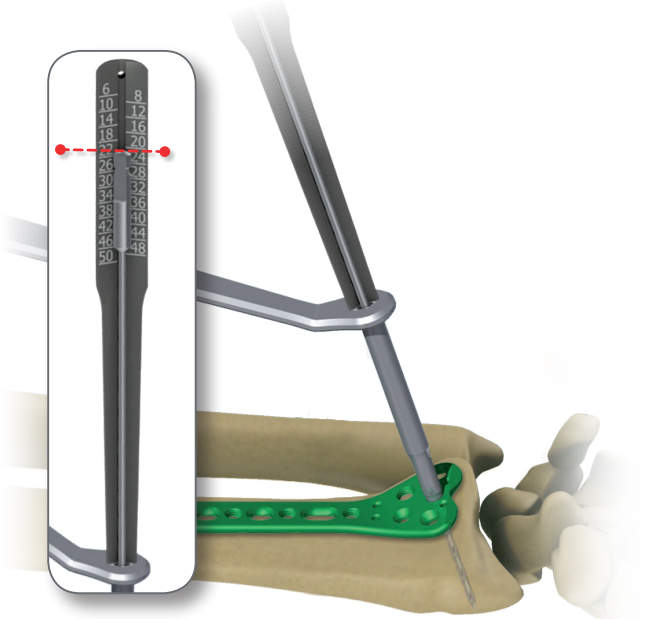
IV.6.3. Hole depth measurement

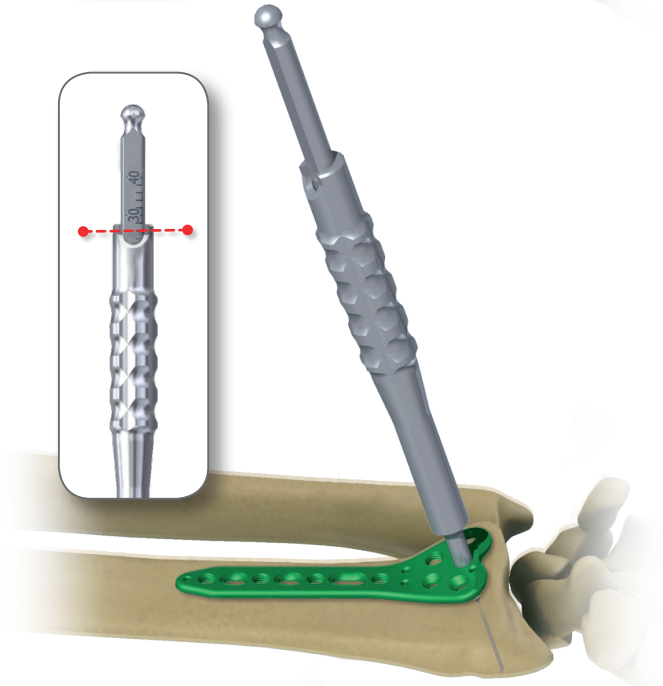
40.4818.100

OPTION I: Measure the hole depth using the Locking screw length measure **[40.4818.100]**.

40.4640.000

OPTION II: After removal of guide VA use the Depth measure **[40.4640.000]** to establish the screw length.





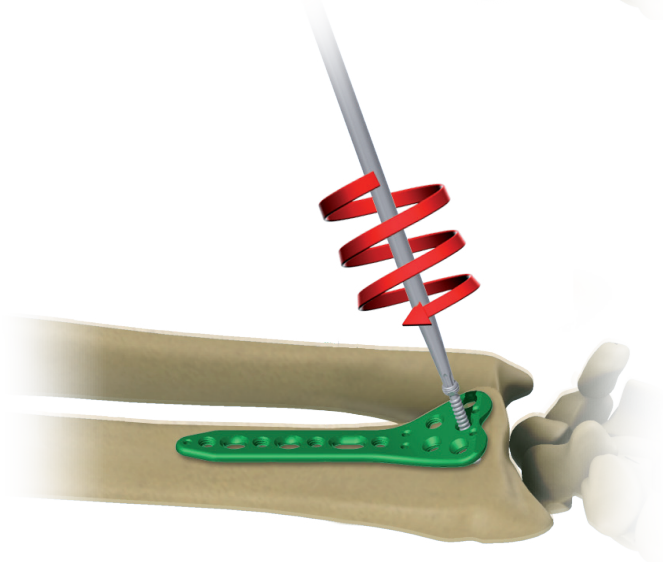
IV.6.4. Insertion of the VA screw

40.6650.000

40.5682.000

Insert the VA screw using the Screwdriver Tip T8 **[40.5682.000]** with Torque Handle **[40.6650.000]**.

CAUTION:
When VA screw is considerably deviated in relation to the locking hole, the screw may not flush with the plate after use of the torque handle. In such case it may be necessary to use the Star screwdriver T8 **[40.0669.100]**. Screw in the VA screw with care, making sure not to damage the screw socket or the screwdriver tip, and to not screw the screw too deep into the plate.



Do not change the angle of insertion after locking the VA screw in the plate hole. Repeated locking of the screw in different setting may reduce the effectiveness of screw-plate connection. Proper screw setting should be verified during hole drilling or before locking the screw in the plate hole. The hole in which the VA screw was locked and removed cannot be reused for insertion of other locking screws.

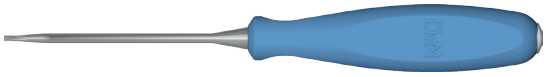
IV.7. THE USE OF AIMING BLOCK

NOTE:
Use of aiming block allows for insertion of VA screws in specific direction, not allowing the change in the angle.

Most locking plates ChLP are available with aiming blocks, as additional complementary instruments. Using aiming blocks ensures proper fastening of guide sleeves in the locking holes, in the epiphyseal part of the plate. It facilitates also the smooth conduct of the procedure, reduces its duration, and ensures that drilling is performed in the axis of the locking hole *(note from point IV.5)*.

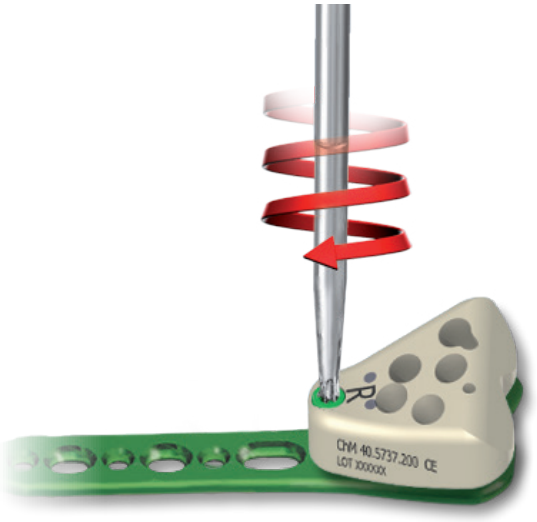
When aiming blocks are not used, the implantation can be incorrect, and in particular can cause:
- improper locking of the screws and their migration,
- decrease of the fixation stability,
- complications while implants removing.

Position the aiming block on the plate.



40.0669.100

Tighten up with Star screwdriver T8 **[40.0669.100]**.



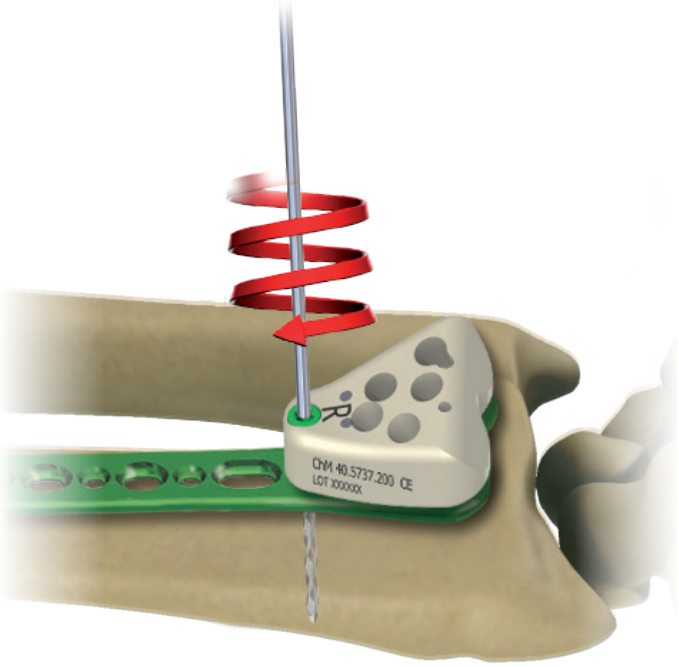
40.4896.018

Screw the Threaded Guide M3.5/1.8-4.0 **[40.4896.018]** into the plate.

NOTE:
Further proceedings in accordance with the steps described in the point IV.5 on page 25

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

Cannulated mounting screw of the aiming block allows for drilling a hole for locking screw in the first hole of the plate shaft.



IV.8. CORTICAL SCREW 2.7 INSERTION

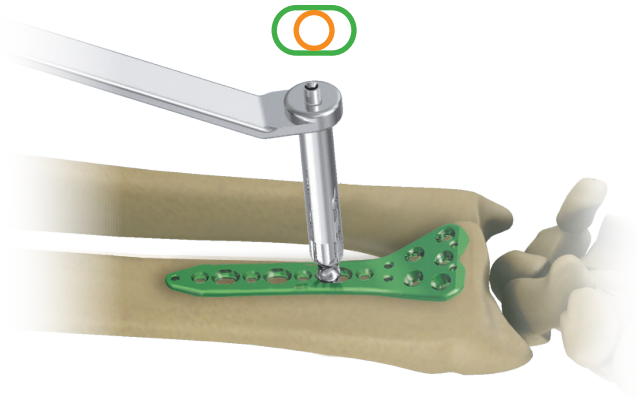
IV.8.1. Compression guide setting

40.4897.018

Set the Compression Guide 1.8 **[40.4897.018]** in the advisable position:

IV.1.0.A. ***Neutral Position***

Press down the guide to the plate. Guide will set in position that allows neutral insertion of the screw.



IV.1.0.B. ***Compression Position***

Move the guide without pressure to the edge of compression hole. Hole drilled in this position allows for screw insertion in compression position.

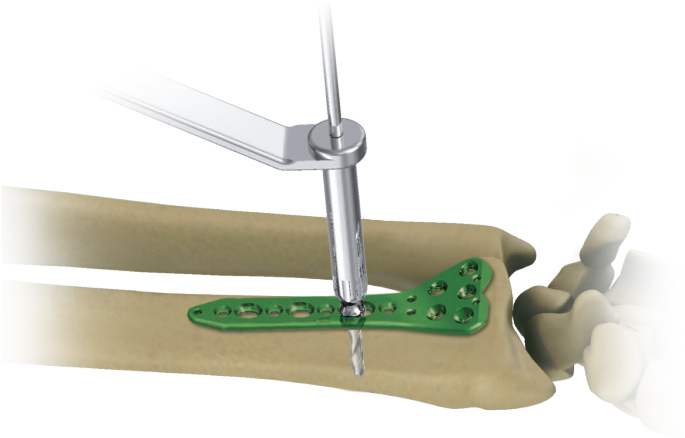
IV.1.0.C. ***Angular Position***

Angular positioning of the guide is also possible.

IV.8.2. Drilling

40.2063.181

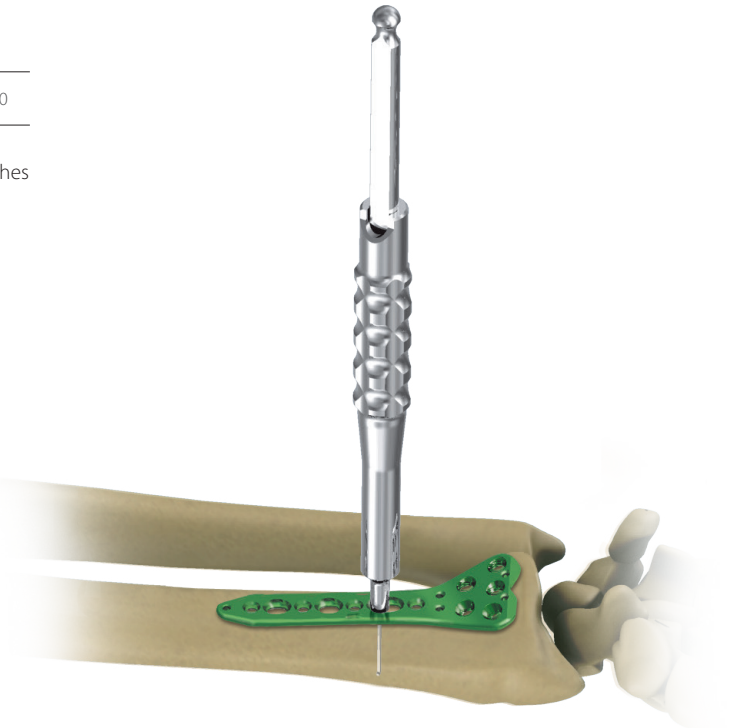
In the desired position make a hole for cortical screw 2.7 through both cortices using the Drill 1.8/180 **[40.2063.181]**.



IV.8.3. Hole Depth Measurement

40.4640.000

Insert the Depth Measure **[40.4640.000]**, into drilled hole, until its hook reaches the outer surface of opposite cortex bone.

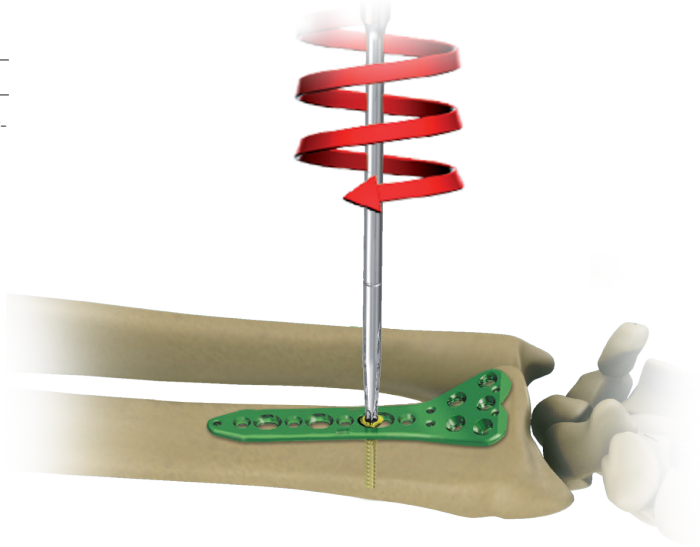


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.8.4. Screw Insertion

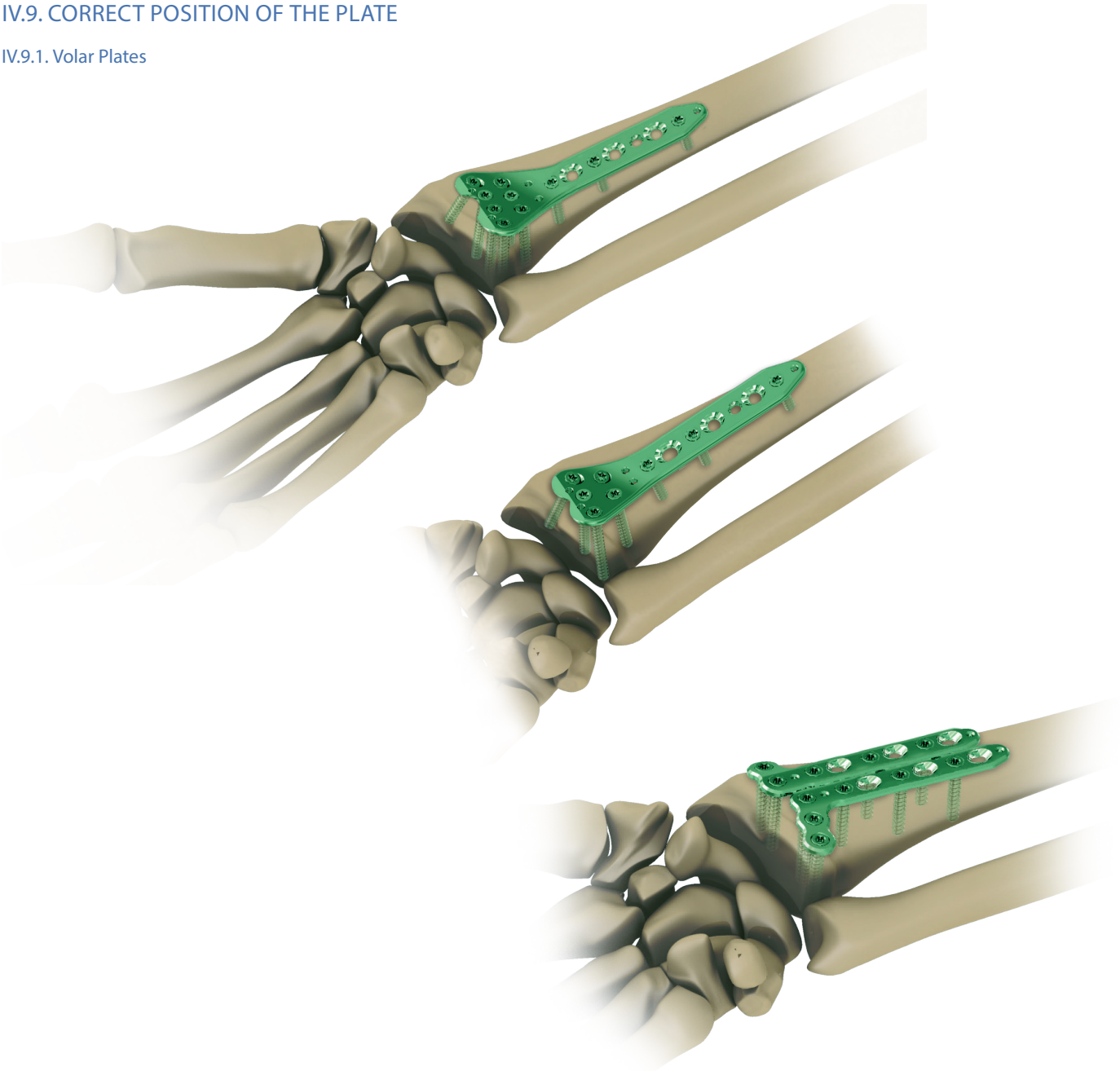
40.5682.000

Insert the Cortical self-tapping screw 2.7 **[3.1220.006÷040]** using the Screwdriver Tip T8 **[40.5682.000]**.

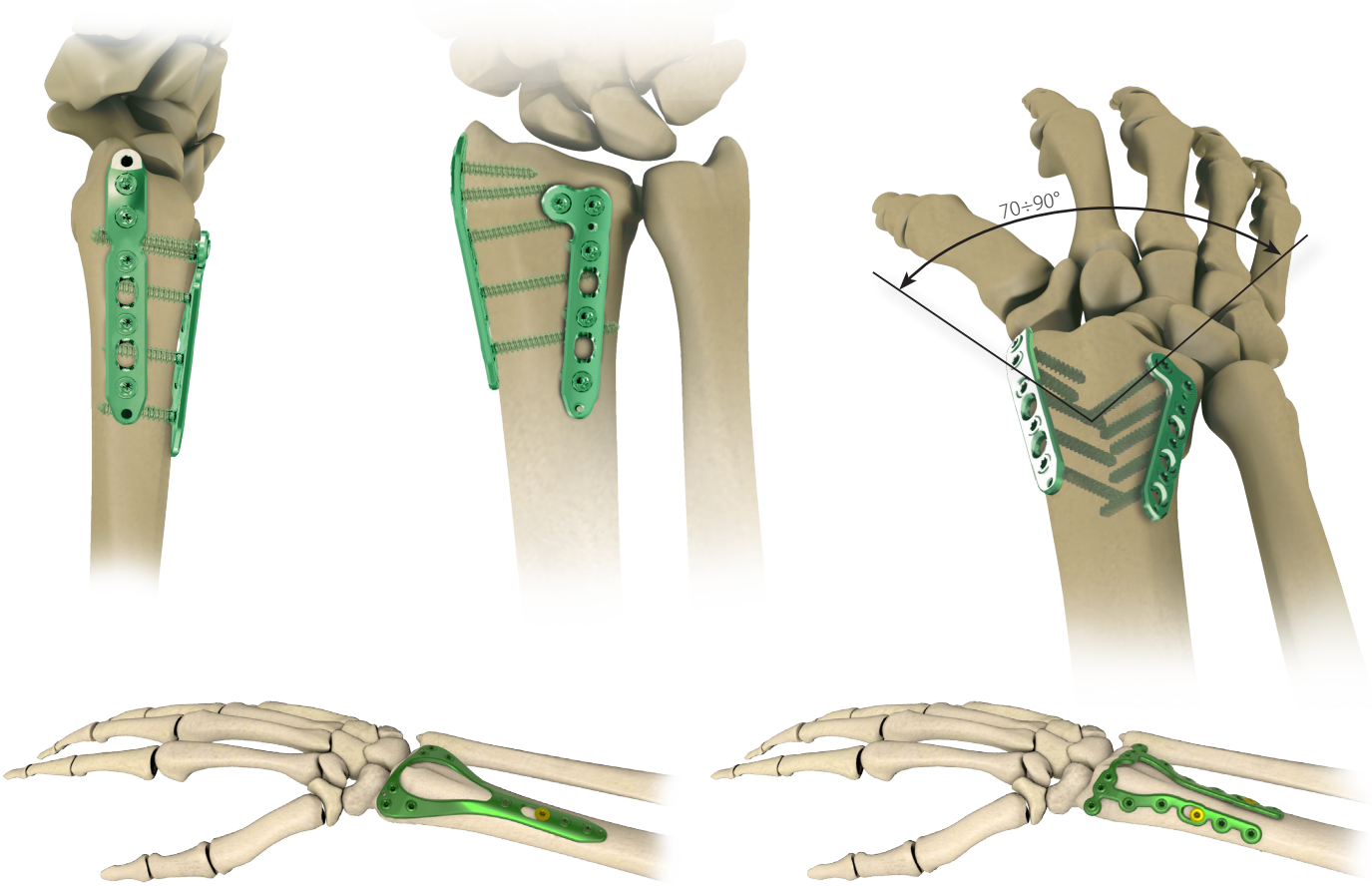


IV.9. CORRECT POSITION OF THE PLATE

IV.9.1. Volar Plates



IV.9.2. Dorsal Plates



IV.10. 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

Follow the standard operative procedure for internal stabilization. To prevent restrictions in movement the patient shall exercise after surgery as soon as possible. However, it is important to take heed not to load the limb with full load before complete union of the fractured bone occurs.

VI. IMPLANT REMOVAL

For implant removal, first it is necessary to unlock all locking screws from the plate. Next, remove screws from bone. It will allow to avoid plate rotation while the last locking screw unlocking.

NOTE:
After cleaning the external surface of the plate and screws sockets from the tissue, it is advisable to mount the aiming block on the plate *(see IV.7)*. Insertion of the screwdriver through the protective guide ensures its positioning in the screw axis and proper entrance into the socket, and reduces the risk of twisting the socket while unscrewing.

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

VII. INSTRUCTIONS FOR USE

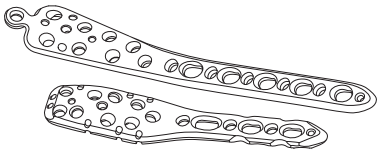
GB

ISO 9001/ ISO 13485

CE 0197

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 713-13-20 fax: +48 85 713-13-19
e-mail: chm@chm.eu www.chm.eu

IFU-010/16



GB

INSTRUCTIONS FOR USE

Important product information for

BONE PLATES, SCREWS AND WASHERS

ChM Locked Plates ChLP system | ChM Micro Plates ChMP system | ChM Pelvic System ChARPEL system

1 PURPOSE AND INDICATIONS

1. Bone plates, screws and washers are intended for stabilization and support of bone structure treatment. They are used for treatment of: bone fractures, non-unions, delayed unions, osteotomies and arthrodeses.
   1) Bone plates are fixed to the bone with the use of bone screws.
   2) Bone screws may be used independently, with bone washers or plates.
   3) Bone washers are used in conjunction with bone screws.
2. Compatible implants are presented on respective pages in a **ChM** sp. z o.o. catalogue.
3. **ChM** sp. z o.o. does not recommend any specific treatment method for a particular patient.

2 CONTRAINDICATIONS

1. Contraindications may be relative or absolute. The choice of particular device must be carefully weighed against patient's overall condition. Conditions listed below may preclude or reduce the chance of successful outcome:
   1) Infection local to the operative site.
   2) Signs of local inflammation.
   3) Fever or leukocytosis.
   4) Pregnancy.
   5) Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care.
   6) Any other condition which would preclude the potential benefit of implant insertion surgery and disturb the normal process of bone remodeling, e.g. the presence of tumours or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cells *(WBC)* count, or a marked left shift in the WBC differential count.
   7) Suspected or documented allergy or intolerance to implant materials. Surgeon shall find out if the patient develops allergic reaction to the material of the implant *(content of the implant material is presented in IMPLANT MATERIAL)*.
   8) Any case not needing a surgical intervention.
   9) Any case not described in the indications.
   10) Any patient unwilling to cooperate with postoperative instructions; mental illness, a condition of senility or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the implant usage.
   11) Any case where the implant components selected for use would be too large or too small to achieve a successful result.
   12) Any case that requires the simultaneous use of elements from different systems that are made of different metals.
   13) Any case in which implant utilization would disturb physiological processes.
   14) Blood supply limitation in the operative site.
   15) Morbid obesity *(defined according to the WHO standards)*.
   16) Any case in which there is inadequate tissue coverage of the operative site.
   17) Inadequate bone quality for stable implant fixation *(bone resorption, osteopenia, and/or osteoporosis)*. This surgical treatment should not be used in patients with a known hereditary or acquired osteogenesis imperfecta or calcification problems.
2. The above-mentioned list does not exhaust the topic of contraindications.

3 ADVERSE EFFECTS

1. The adverse effects may necessitate reoperation or revision. The surgeon should warn the patient about the possibility of adverse effects occurrence.
2. The undermentioned list does not exhaust the topic of adverse events. There is a risk of occurrence of adverse events with unknown aetiology which may be caused by many unpredictable factors.
3. Potential adverse events include but are not limited to:
   1) Implant damage *(fracture, deformation or detachment)*.
   2) Early or late loosening, or displacement of the implant from the initial place of insertion.
   3) Possibility of corrosion as a result of contact with other materials.
   4) Body reaction to implants as foreign bodies e.g. possibility of tumour metaplasia, autoimmune disease and/or scarring.
   5) Compression on the surrounding tissue or organs.
   6) Infection.
   7) Bone fractures or *"stress shielding"* phenomenon causing loss of bone above, below or at the operative site.
   8) Haemorrhage of blood vessels and /or hematomas.
   9) Pain.
   10) Inability to perform everyday activities.
   11) Mental condition changes.
   12) Death.
   13) Deep vein thrombosis, thrombophlebitis.
   14) Occurrence of respiratory complications, e.g.: pulmonary embolism, atelectasis, bronchitis, pneumonia, pulmonary infection, disturbed lung growth, respiratory acidosis, etc.
   15) Scar formation that could cause neurological impairment, or nerves compression and /or pain.
   16) Late bone fusion or no visible fusion mass and pseudoarthrosis.
   17) Loss of proper curvature and/or length of bone.
   18) Bone graft donor site complication.

4 WARNINGS

1. The important medical information given in this document should be conveyed to the patient.
2. The selection of proper shape and size of the implant appropriate for a specific patient is crucial to achieving success of the surgery. The surgeon is responsible for this choice.
3. Preoperative and operating procedures, including knowledge of surgical techniques, and correct placement of implants are important and shall be considered by the surgeon in order to achieve success during operation.
4. No implant can withstand body loads without the biomechanical continuity of the bone.
5. During normal use all surgical implants are subjected to repeated stresses which can result in material fatigue and failure of the implant.
6. To avoid excessive stress on the implant which could lead to non-union or implant failure and associated clinical problems, the surgeon must inform the patient about the physical activity limitations during the treatment period.
7. If the patient is involved in an occupation or activity *(e.g.: substantial walking, running, lifting weights, muscles strain)* which may apply excessive stress on the implant, the surgeon must inform the patient that resultant forces can cause implant failure.
8. A successful result is not always achieved in every surgical case. This fact is especially true in the case where other patient's conditions may compromise the results.
9. The proper selection, compliance of the patient and observance of post-operative recommendations will greatly affect the results. The bone union is less likely to occur among patients who smoke. These patients should be informed about this fact and warned of this consequence.
10. Overweight may cause additional stresses and strains within implant which can lead to fatigue and deformation of the implant.
11. Patients who are overweight, malnourished and/or abusing alcohol or drugs, with weak muscles and low quality bones and/or with nerve palsy are not the best candidates for the procedure of surgical stabilization. These patients are not able or not ready to observe the post-operative recommendations and limitations.
12. The implants are intended as an aid to the healing process and are **NOT** intended to replace body structures or bear the body weight when the treatment process has not yet finished.
13. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
14. The surgeon must warn the patient that the device cannot and does not restore the function and efficiency of a healthy bone.
15. In the case of delayed union or non-union, the load or weight bearing may eventually cause the implant bending, loosening, disassembling or fatigue breakage.

5 PACKAGING AND STORAGE

1. Implants are single-use devices, provided sterile or non-sterile.
2. Implants not labeled as sterile are non-sterile.
3. Implant packaging must be intact at the time of receipt.
4. The unit package contains:
   1) sterile version - one piece of the product in a sterile condition. A double package made of Tyvek-foil or a single blister are typical packaging material.
   2) non-sterile version - one piece of the product. Clear plastic bags are a typical packaging material.
5. A sterility indicator is placed on the sterile package.
6. The packaging is equipped with the product label. The label *(as a primary label)* contains e.g.:
   1) Sterile product
      a) Logo **ChM** and the address of the manufacturer.
      b) Name and size of the device and its catalogue number *(REF)*, e.g.: 3.XXXX.XXX.
      c) Production batch number *(LOT)*, e.g. XXXXXXX.
      d) Material of the implant *(see IMPLANT MATERIAL)*.
      e) STERILE sign - indicating a sterile device and the sterilization method used, e.g.: R or VH202 *(symbols are described in the footer of this Instructions For Use)*.
      f) Sterilization batch number, e.g.: S-XXXXXXX.
      g) Device pictogram and information symbols *(described in the footer of this Instructions For Use)*.
      h) Expiration date and sterilization method.
   2) Non-sterile product
      a) Logo **ChM** and the address of the manufacturer.
      b) Name and size of the device and its catalogue number *(REF)*, e.g.: 3.XXXX.XXX.
      c) Production batch number *(LOT)*, e.g. XXXXXXX.
      d) Material of the implant *(see IMPLANT MATERIAL)*.
      e) NON-STERILE sign - indicates non-sterile product.
      f) Device pictogram and information symbols *(described in the footer of this Instructions For Use)*.
7. In addition to the device primary label, an auxiliary label with specific market requirements of a given area may be placed on the unit package *(e.g. legal requirements of the country in which the device will be distributed)*.
8. The package may contain: Instructions For Use and labels to be placed in a patient's medical record.
9. Depending on the size or type of the product, the following information may be marked on its surface: manufacturer's logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.
   1) Additional identification system for the ChLP locking plates has been introduced. On the surfaces of locking plates an additional feature *"System e.g. 4.0, 4.5, 5.0, 7.0."* has been placed. It informs that particular screws with head diameters of 4.0, 4.5, 5.0, 7.0. cooperate with particular plates. Additionally, plates and screws included in the system, made of titanium, are coloured: system 4.0 - green, system 4.5 - gold, system 5.0 – brown, system 7.0 - blue.
   2) Additional identification system for the ChMP microplates has been introduced. Plates and basic screws included in the system, made of titanium, are coloured: system 1.2 - blue, system 1.5 - gold, system 2.0 - green, system 2.7 - turquoise.
10. Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.

6 IMPLANT MATERIAL

1. Identification of the materials
   1) Depending on the material used, the following symbols may be marked on the device surface:
      a) Titanium and titanium alloys: symbol *(T)*.
      b) Cobalt alloy: symbol *(Co)*.
      c) Steel: symbol *(S)*.
   2) The plates are made of:
      a) Implantable stainless steel.
      b) Implantable titanium or titanium alloy.
      c) Implantable cobalt alloy.
   3) The screws are made of:
      a) Implantable stainless steel.
      b) Implantable titanium alloy.
      c) Implantable cobalt alloy.
   4) The bone washers are made of:
      a) Implantable stainless steel.
      b) Implantable titanium alloy.
   5) Percent composition of elements in the implantable materials *(max. values)*:
      a) Steel according to ISO 5832-1/ASTM F138: | C:0.03 | Si:1.0 | Mn:2.0 | P:0.025 | S:0.01 | N:0.1 | Cr:19.0 | Mo:3.0 | Ni: 15.0 | Cu:0.5 | Fe:rest.
      b) Steel according to ISO 5832-9/ASTM F1586: | C:0.08 | Si:0.75 | Mn:4.25 | P:0.025 | S:0.01 | N:0.5 | Cr:22.0 | Mo:3.0 | Nb:0.8 | Ni: 11.0 | Cu:0.25 | Fe:rest.
      c) Titanium according to ISO 5832-2/ASTM F67: | Fe:0.5 | O:0.4 | C:0.1 | N:0.05 | H:0.0125 | Ti:rest.
      d) Titanium alloy according to ISO 5832-3/ASTM F136: | Al:6.75 | V:4.5 | Fe:0.3 | O:0.2 | C:0.08 | N:0.05 | H:0.015 | Ti:rest.
      e) Titanium alloy according to ISO 5832-11/ASTM F1295: | Al:6.5 | Nb:7.5 | Ta:0.5 | Fe:0.25 | O:0.2 | C:0.08 | N:0.05 | H:0.009 | Ti:rest.
      f) Cobalt alloy according to ISO 5832-12/ASTM F1537: | Cr:30 | Mo:7 | Fe:0.75 | Mn:1 | Si:1 | C:0.14 | Ni:1 | N:0.25 | Co:rest.
   6) ATTENTION: Implantable titanium, titanium alloy and/or implantable cobalt alloy may be used together in the same construct. Never use titanium, titanium alloy and/or cobalt alloy with implantable stainless steel components in the same construct as it may lead to corrosion and reduction of mechanical strength of implants.
2. Magnetic Resonance compatibility
   1) **ChM**'s implants made completely from or containing elements made of implantable steel were not assessed for their safety and compatibility with magnetic resonance imaging procedures. The performance of MRI on these implants *(especially in the magnetic field with a significant induction)* may pose a potential risk of, i.a.:
      a) implant displacement or heating up,
      b) artifacts on MR images.
   2) Implants made of titanium, titanium alloys and cobalt alloys are conditionally compatible with magnetic resonance imaging.
   3) The patient can be scanned safely under the following conditions:
      a) static magnetic field of ≤ 3 Tesla,
      b) maximum magnetic field spatial gradient of ≤ 720 Gauss/cm,
      c) maximum MR system reported whole-body-averaged specific absorption rate *(SAR)* of 3W/kg for 15 minutes of scanning.
   4) CAUTION: the user should be absolutely familiar with the contraindications and warnings established by the manufacturer of the MRI scanner to be used for imaging procedure.
   5) MR imaging may be interfered with if the area of interest is in the exact same area or relatively close to the position of the implant.
   6) Do not perform MRI if there are doubts about the tissue integrity and the implant fixation or if the proper location of the implant is impossible to be established.

7 PRE-OPERATIVE RECOMMENDATIONS

1. Only patients that meet the criteria described in the PURPOSE AND INDICATIONS should be selected.
2. Patients' conditions and/or predispositions such as those addressed in the above-mentioned CONTRAINDICATIONS should be avoided.
3. Before deciding about implantation, the surgeon shall inform the patient about indications and contraindications of such procedure and possibility of complications occurrence after the operation. Patient shall be introduced to the purpose and manner of the procedure, and to functional and aesthetic effects of such treatment. Proper clinical diagnosis and accurate operation planning and performance are needed to achieve good final result of treatment.
4. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation *(alloying elements of implant material are presented in IMPLANT MATERIAL)*.
5. The implantation shall be carried out by the surgeon familiar with adequate rules and operating techniques, and who has acquired practical skills of using **ChM** instrument set. The selection of surgical technique adequate for a specific patient remains surgeon's responsibility.
6. The operation procedure shall be carefully planned. The size of implant should be determined prior to the beginning of the surgery. An adequate inventory of implants with required sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. The surgeon should be familiar with all components of the implant system before use and should personally verify if all components and instruments are present before the surgery begins.
8. Do not use the implant if the original, sterile packaging is damaged. Sterility cannot be guaranteed if the packaging is not intact. The packaging shall be carefully checked prior to use.
9. Implants are delivered in protective packages. The package should be intact at the time of receipt.
10. Unless supplied sterile, all implants and instruments should be washed, disinfected and sterilized before use. Additional sterile components should be available in case of any unexpected need.
11. Before procedure begins, all implants should be carefully checked to ensure that there is no damage *(surface scratching, dents, signs of corrosion and shape deformations)*. Damaged implant cannot be inserted into the body.

8 RECOMMENDATIONS FOR IMPLANTS PROVIDED STERILE

1. Sterile implant - is delivered in sterile package, with the inscription: *"STERILE"*. Such product is sterile and the manufacturer is responsible for the process of sterilization. The sterilization is performed with the use of one of the following methods:
   1) gamma radiation, with a minimum dose of **25 kGy**,
   2) hydrogen peroxide vapour.
2. The symbol designating the sterilization method used is visible on the device label *(symbols are described in the footer of this Instructions For Use)*.
3. Prior to use of a sterile device the following rules apply:
   1) Check out the expiration date of sterilization. Do not use the device with an overstepped sterility date!
   2) Check out if the sterile package is not damaged. Do not use the device if the sterile package is damaged.
   3) Check out the colour of the sterility indicator on the sterile packaging which indicates that sterilization of the device was performed. Do not use the device if the sterility indicator colour is different than:
      a) red - for devices sterilized with gamma radiation,
      b) blue - for devices sterilized with hydrogen peroxide vapour.
4. CAUTION: products should be removed from their packages in accordance with aseptic rules.

9 RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE

1. Prior to use of a non-sterile device the following rules apply:
   1) The device must undergo washing, disinfection and sterilization procedures. It is recommended to use automated procedures for washing and disinfecting in the washer-disinfector.
   2) Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of cleaning *(manual, ultrasound, with the use of washing/disinfecting machine)*, the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process.
   3) Labels to be placed in patient's medical records *(delivered together with the implant)* must be protected against loss or damage during the implant washing and sterilization.
2. Preparation for washing
   1) After taking the device out from the original package, remove possible surface contamination *(resulting from e.g.: damage to unit package)* using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*. Do not use brushes made of metal, bristles or materials which could damage the implant.
3. Cleaning and disinfection process
   1) The chosen washing and disinfecting detergents must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of those detergents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 7 and 10.8.
4. Manual cleaning

1) Apply washing detergent *(e.g. MEDICLEAN)* to implant surface and brush carefully. Suitable brushes must be used for holes cleaning.
2) If applicable, ultrasonic cleaning may be performed. The ultrasonic bath must be prepared according to the manufacturer's instructions.
3) Rinse thoroughly under running water. It is recommended to rinse with demineralized water.
4) Visually inspect the entire surface of the device for damage and contaminants. Damaged implants must be removed.
5) For contaminated implants, the cleaning process should be repeated.

5. Cleaning in the washer-disinfector
1) The device should undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for medical devices)*. CAUTION: The equipment used for washing/disinfection should meet the requirements of ISO 15883.
2) 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 agent manufacturer. Disinfection should be carried out at temperature of 90°C *(soak in demineralized water)* for at least 10 minutes without the use of detergents.

6. Drying
1) Drying of the device must be performed as a part of the washing/disinfection process.

7. Packaging
1) The device supplied non-sterile must be repacked in a packaging intended for a specific sterilization method that meets the requirements of ISO 11607-1. The packaging procedure must be performed in controlled purity conditions. The device must be packed in such a way that during removal from the package, when 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.

8. Sterilization
1) Washed, disinfected, and dried device shall undergo the sterilization process. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:
a) temperature: 134°C,
b) minimum exposure time: 7 min,
c) minimum drying time: 20 min.

9. CAUTION:
1) Sterilization must be effective and in accordance with requirements of the EN 556 standard to ensure the required level of guaranteed sterility SAL 10^{-6} *(where SAL stands for Sterility Assurance Level)*.
2) Implant must not be sterilized in the package in which it was delivered.
3) Validated sterilization methods used by sterilization facilities are allowed.
4) The above-mentioned rules of cleaning and sterilization must be followed when dealing with any device intended for implantation.
5) Surgical instrument set, which is used for device implantation, shall also be included into the cleaning and sterilization procedure.

10 RE-STERILIZATION

1. It is permitted to re-sterilize devices by end-user.
1) ATTENTION: The user of the product bears all responsibility for re-sterilization. In such case the device shall be washed and sterilized in a way described in RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE.

11 PRECAUTIONS

1. Implant is intended for single use only. After removing the implant from the patient's body, it must be secured against re-use, and then finally disposed of in accordance with current hospital procedures.
2. Under no circumstances is it allowed to reuse or reimplant once used device. Even if the removed implant appears to be undamaged, it may have small latent defects or internal stresses, which could lead to early failure, fatigue wear, and as a result to e.g.: an implant breakage.
3. Implant which had contact with tissues or body fluids of another patient cannot be re-implanted due to a potential risk of cross-infection caused by viruses, bacteria and prions.
4. Misuse of instruments or implants may cause injury to the patient or operative personnel.
5. Avoid damaging implant surface and deforming its shape during the implantation; the damaged implant cannot be implanted or left in the patient's body.
6. Insertion, removal and adjustment of implants must only be done with instruments specially designated for those implants, and manufactured by **ChM** sp. z o.o.
7. Use of **ChM**'s implants and instruments in combination with implants and instruments from other manufacturers may cause damage or failure of those implants or instruments and may lead to improper course of surgery and healing process.
8. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive force are more susceptible to fractures, depending on care taken during surgery, number of procedures performed and attention paid. Instruments should be examined for wear or damage prior to surgery.
9. The plates structure allows for an intraoperative bending, though it should be done carefully. Limitations and instructions issued by the manufacturer should be obeyed due to the fact that implant bending influences its strength parameters, causes surface defects and internal stresses that reduce its fatigue strength. Disobeying the above-mentioned may result in postoperative complications like implant fracture or breakage.
10. If there is a necessity to bend the implant, please, remember that:
1) it is forbidden to bend an implant which was already bent,
2) it is forbidden to bend a short fragment of the implant or to bend with a small bending radius,
3) the bending should occur between plates holes,
4) before bending the locking plates it is advisable to insert the locking screws near the bending area, as deformed holes may not provide appropriate plate-screw cooperation,
5) in locking shape plates only the shaft part may be shaped,
6) it is forbidden to bend a plate back and forth,
7) the plate should not be bent more than 20°÷25°,
8) the bending should be performed only with the use of instruments intended for bending.
11. If the operator decides to cut the bone plate, he must remember that:
1) cutting the plate may influence the strength characteristics of the implant and of the whole bone fixation,
2) the plate length and the number of holes for bone screws must be appropriate for a fixation conducted, allow for sufficient support and stable immobilization of the fixation,
3) it is recommended to cut the plate between the holes for bone screws,
4) during plate cutting special attention must be paid to not direct the cut-off fragment in the direction of the user, patient or third parties,
5) all sharp edges created by cutting on the external surfaces are to be eliminated,
6) it is important to ensure an unambiguous identification of the implant.
12. While inserting the screw, it is essential to correctly set the screwdriver in relation to the screw. Following the instructions given allows for reduction of the risk of mechanical damage to the screw, screwdriver, or bony hole:
1) screwdriver should be set in the screw axis,
2) apply proper axial pressure to ensure that the screwdriver goes as deep in the head of the bone screw as possible,
3) the final phase of tightening shall be performed carefully.

12 POST-OPERATIVE RECOMMENDATIONS

1. It is essential to follow all of physician's postoperative directions and warnings.
2. It is essential to confirm proper position of the implant by roentgenographic examination.
3. In postoperative period, in treatment, the correctness of implant positioning and immobilization of union should be confirmed by roentgenographic examination.
4. The patient should be warned about the risk should he fail to follow the above-mentioned rules, or should he be unavailable for follow-up clinical examination.
5. The surgeon must instruct the patient to report any unusual changes of the operative site to his/her physician. If any change at the site has been detected, the patient should be closely monitored.
6. The patient should be informed about the type of implant material.
7. The patient should be warned to inform the medical staff about the inserted implants prior to any MRI procedure.
8. The patient should be advised not to smoke or consume alcohol excessively during the period of treatment.
9. If the patient is involved in an occupation or activity which may apply excessive stress on the implant *(e.g. substantial walking, running, lifting, or muscle strain)* the surgeon must advise the patient that resultant forces can cause implant failure.
10. The surgeon must instruct the patient regarding appropriate and restricted activities during consolidation and maturation of the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and further clinical problems. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
11. Failure to perform appropriate immobilization of bone when delayed or non-union occurs may lead to excessive fatigue stresses in the implant. Fatigue stresses may be a potential cause of implant becoming bent, loosened or fractured. If non-union of fracture or implant bending, loosening or fracture occurs, the patient should be immediately revised, and the implants should be removed before any serious injuries occur. The patient must be appropriately warned about these risks and closely monitored to ensure compliance during the treatment until the bone union is confirmed.

13 CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER TREATMENT

1. When bone union is achieved, the implants serve no functional purpose and their removal is recommended. The possibility of another surgical procedure and associated risks must be analysed and discussed with the patient. The final decision on implant removal is up to the surgeon. In most patients, removal is indicated because the implants are not intended to transfer forces developed during normal activities.
2. If the device is not removed following completion of its intended use, one or more complications may occur, in particular:
1) Corrosion, with localized tissue reaction or pain.
2) Migration of the implant, possibly resulting in injury.
3) Risk of additional injury from postoperative trauma.
4) Bending, loosening, or breakage, which could make implant removal difficult or impossible.
5) Pain, discomfort, or abnormal sensation due to the presence of the implant.
6) Increased risk of infection.
7) Bone loss due to the stress shielding.
8) Potentially unknown and/or unexpected long term effects.
3. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
4. Implantable stainless steel implant shall be removed after period of not more than two years after its implantation.

If these instructions appear unclear, please contact the manufacturer, who shall provide all required explanations.

Updated INSTRUCTIONS FOR USE are available at the following website: **www.chm.eu**

IFU-010/16; Date of verification: March 2016

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
	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 è 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 • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Avvertenza
STERILE R	Sterilized using irradiation • Sterylizowany przez napromieniowanie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione
STERILE VH202	Sterilized using hydrogen peroxide • Sterylizowany nadtlenkiem wodoru • Стерилизован перекисью водорода • Esterilizado con peróxido de hidrógeno • Sterilisiert mit Wasserstoffperoxid • Sterilizováno s peroxidem vodíku • Sterilizzato mediante perossido di idrogeno
REF	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo
LOT	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto
Mat:	Material • Materiał • Материал • Material • Materiál • Materiál • Materiale
Qty:	Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita'
	Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 713-13-20 fax: +48 85 713-13-19
e-mail: chm@chm.eu www.chm.eu

GB

ISO 9001/ ISO 13485

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
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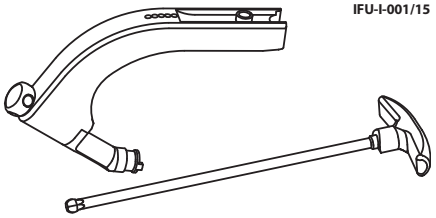
e-mail: chm@chm.eu www.chm.eu

IFU-I-001/15



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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
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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