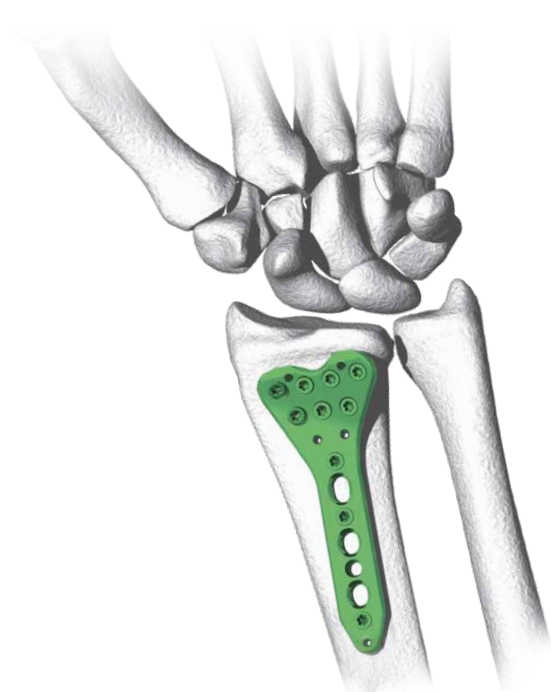


ChM[®]








4.0 ChM Locked Plating
ChLP system

4.0ChLP DISTAL RADIUS PLATES

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



SYMBOLS DESCRIPTION

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

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

1. INTRODUCTION	5
1.1. INDICATIONS	5
1.2. CONTRAINDICATIONS	5
1.3. PLATE SELECTION AND CONTOURING	5

2. IMPLANTS	6
2.1. VOLAR PLATES	6
2.2. DORSAL PLATES	7
2.3. SCREWS	19

3. INSTRUMENTS	20
----------------	----

4. SURGICAL TECHNIQUE	23
4.1. PATIENT POSITION	23
4.2. DORSAL APPROACH	23
4.3. VOLAR APPROACH.	23
4.4. TEMPORARY PLATE STABILIZATION	23
4.5. LOCKING SCREW INSERTION	25
4.6. INSERTION OF VARIABLE ANGLE SCREWS (VA)	26
4.7. THE USE OF AIMING BLOCK	28
4.8. CORTICAL SCREW 2.7 INSERTION	29
4.9. CORRECT POSITION OF THE PLATE	31
4.10. WOUND CLOSURE	32

5. POSTOPERATIVE PROCEDURE	32
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6. IMPLANT REMOVAL	32
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1. 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 presented range of implants is made of titanium, titanium alloys and cobalt alloy in accordance with ISO 5832 standard. Compliance with the requirements of quality management systems and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered implants.

The system for distal radial fractures treatment consists of:

- Implants (*locking plates, locking screws and standard cortical screws*),
- Instrument set,
- Surgical technique.

1.1. 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 extra-articular and intra-articular fractures,
- osteotomies,
- possibility of using them in treatment of other small bones fractures.

1.2. CONTRAINDICATIONS

- infections,
- physical maturation.

1.3. PLATE SELECTION AND CONTOURING

Wide size range of locking plates enables proper plate selection.

Locking plate contouring is not recommended due to possibility 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.

2. IMPLANTS

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



2.1. VOLAR PLATES

Left anatomical plates



wide

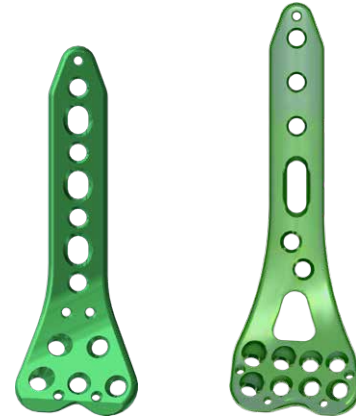
Right anatomical plates



wide



narrow

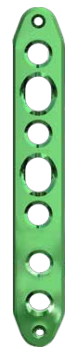


narrow

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.

2.2. DORSAL PLATES



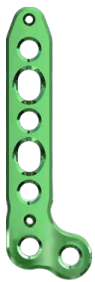
straight



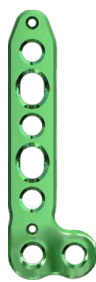
T 3 holes

Left-side directed

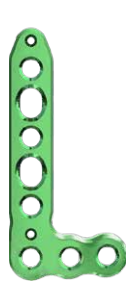
Right-side directed



L 2 holes oblique



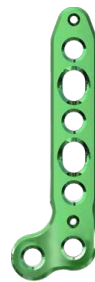
L 2 holes



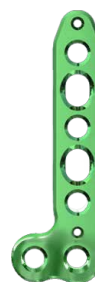
L 3 holes



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

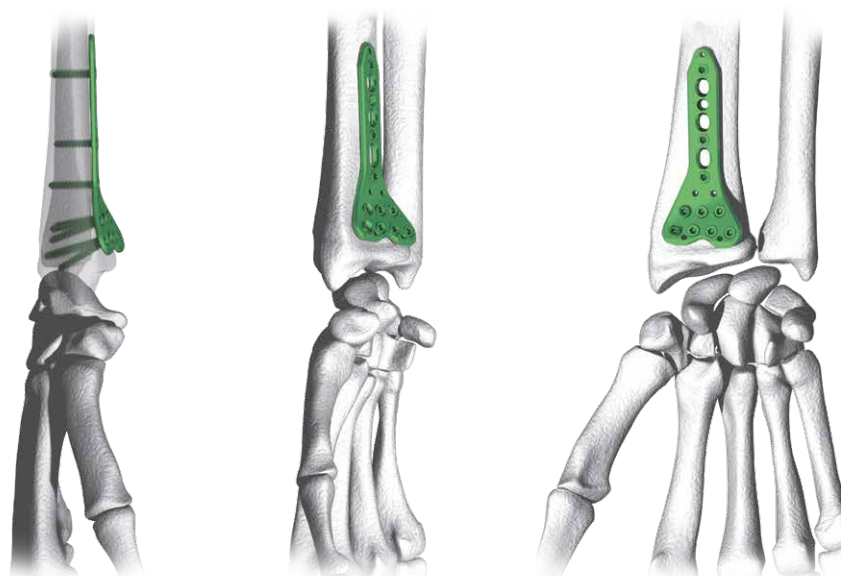
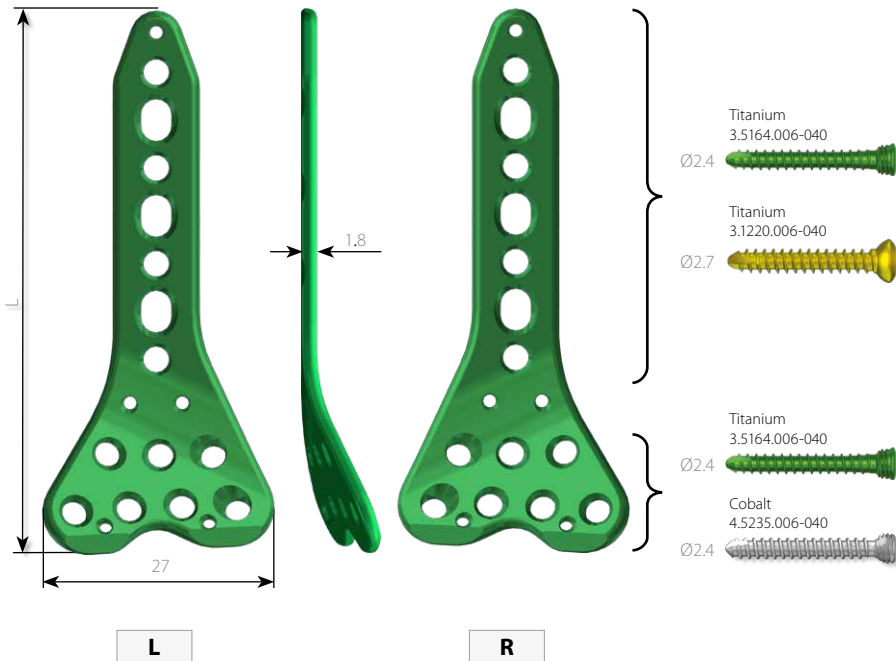


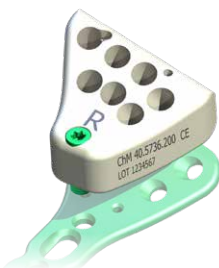
Pi plate wide

4.0ChLP Wide radius volar plate

O	L [mm]	Catalogue no.	
		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

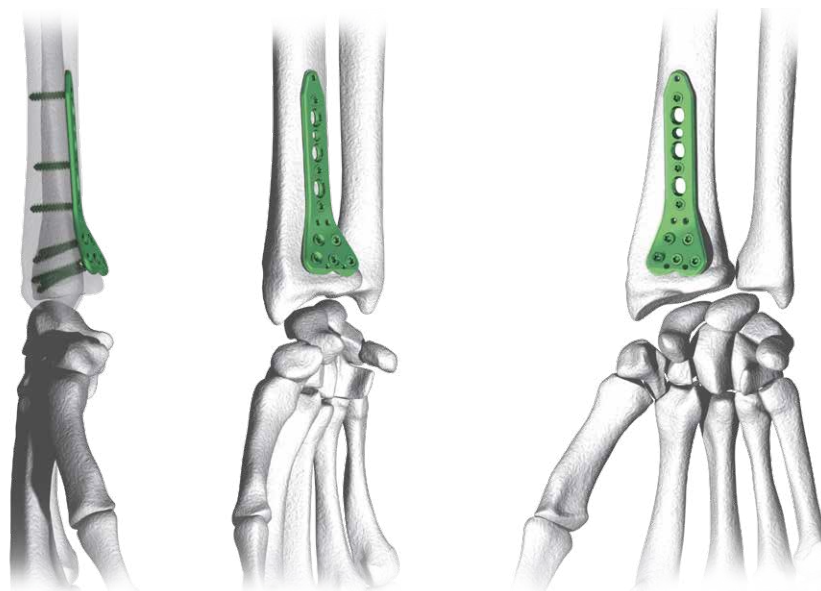
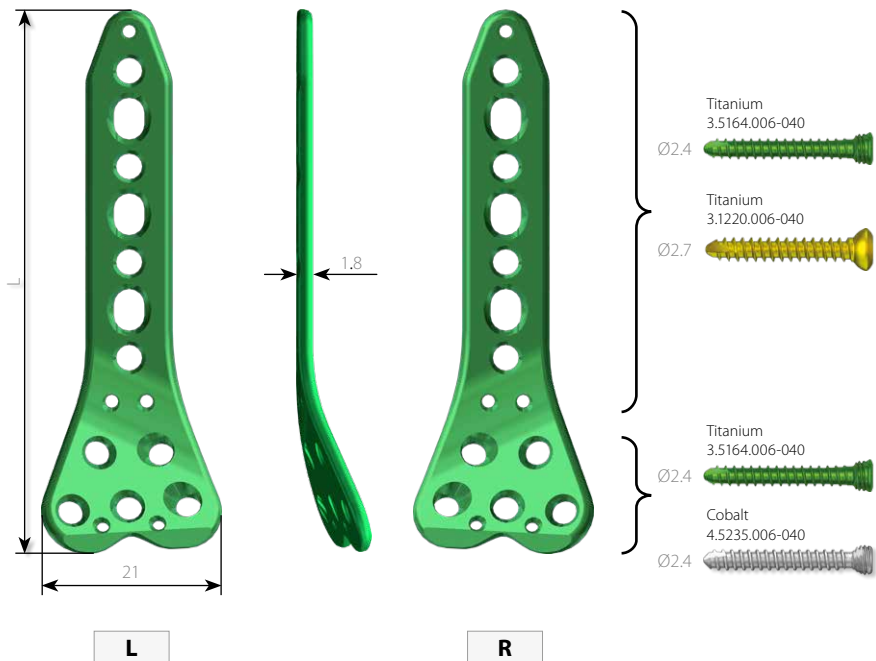


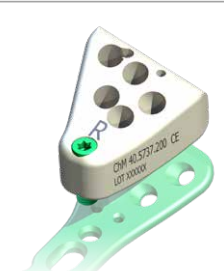
No.		Name	Catalogue No.	Pcs
1		Aiming block L (3.4049)	40.5736.100	1
2		Aiming block R (3.4050)	40.5736.200	1

4.0ChLP Narrow radius volar plate

O	L [mm]	Catalogue no.	
		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

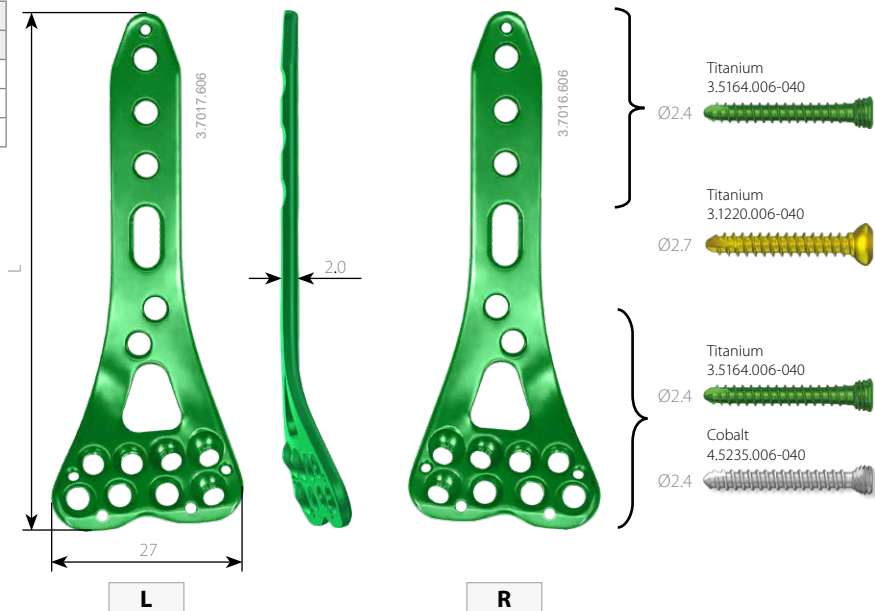



No.		Name	Catalogue No.	Pcs
1		Aiming block L [3.4053]	40.5737.100	1
2		Aiming block R [3.4054]	40.5737.200	1

4.0ChLP distal volar radius plate

O	L [mm]	Catalogue no.	
		Left	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

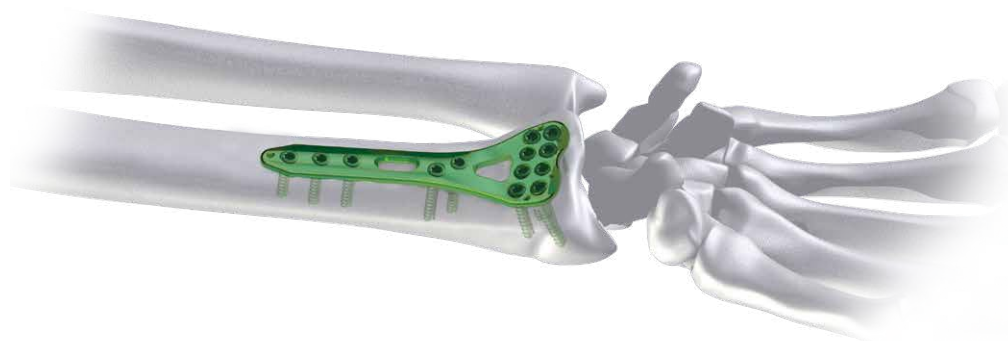
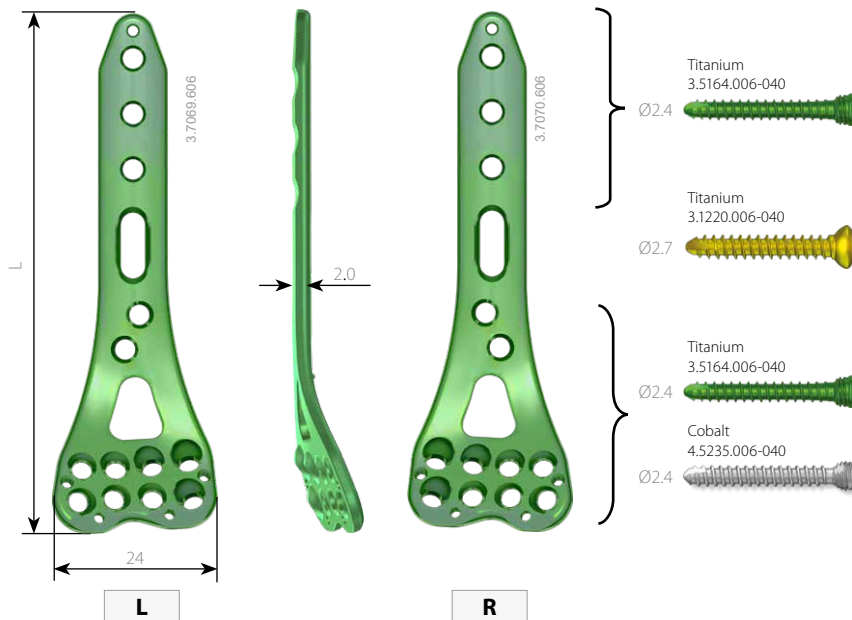



No.		Name	Catalogue No.	Pcs
1		Aiming block L [3.7017]	40.5727.100	1
2		Aiming block R [3.7016]	40.5727.200	1

4.0ChLP distal radius volar narrow plate

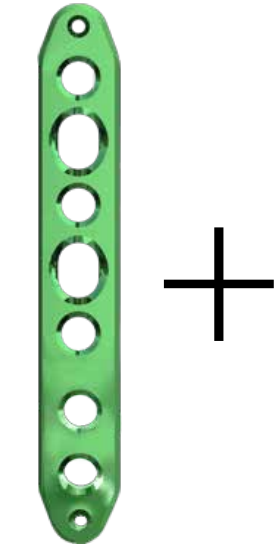
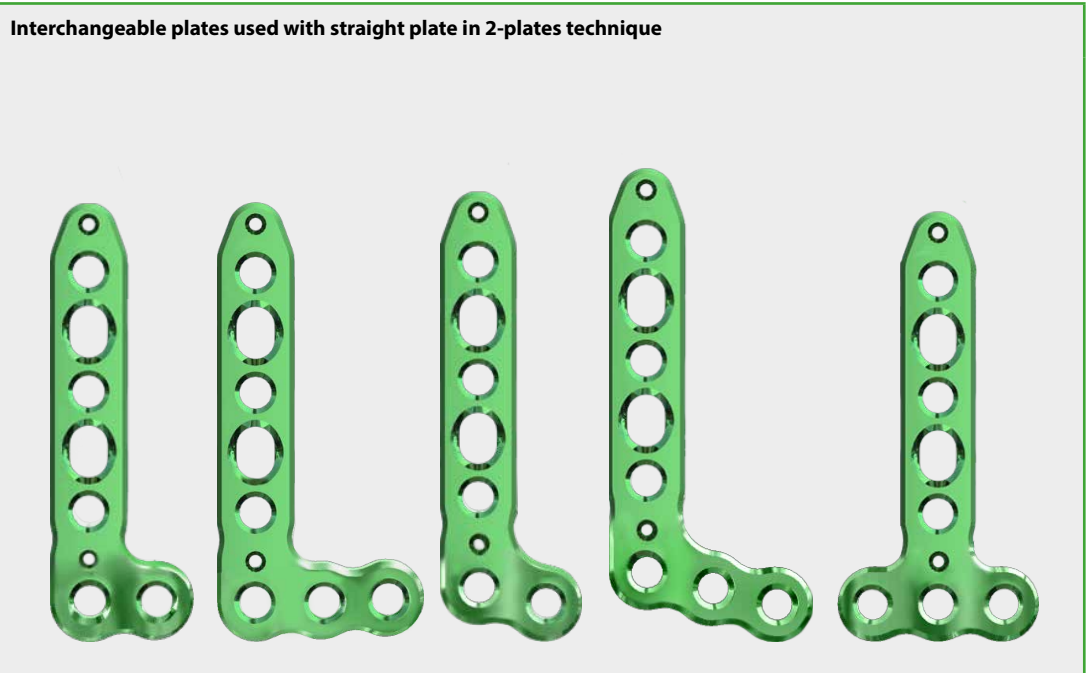
O	L [mm]	Catalogue no.	
		Left	Right
4	59	3.7069.604	3.7070.604
5	67	3.7069.605	3.7070.605
6	75	3.7069.606	3.7070.606

O - threaded holes number in shaft part of the plate



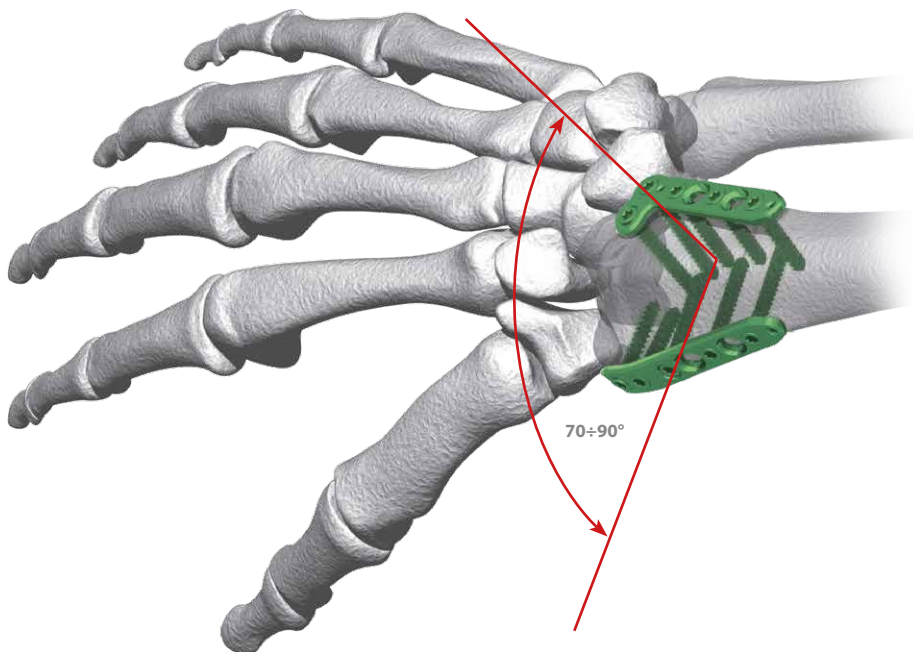
No.		Name	Catalogue No.	Pcs
1		Aiming block L [3.7069]	40.5743.100	1
2		Aiming block R [3.7070]	40.5743.200	1

Plates for distal radius – dorsal side



3.4047.6xx

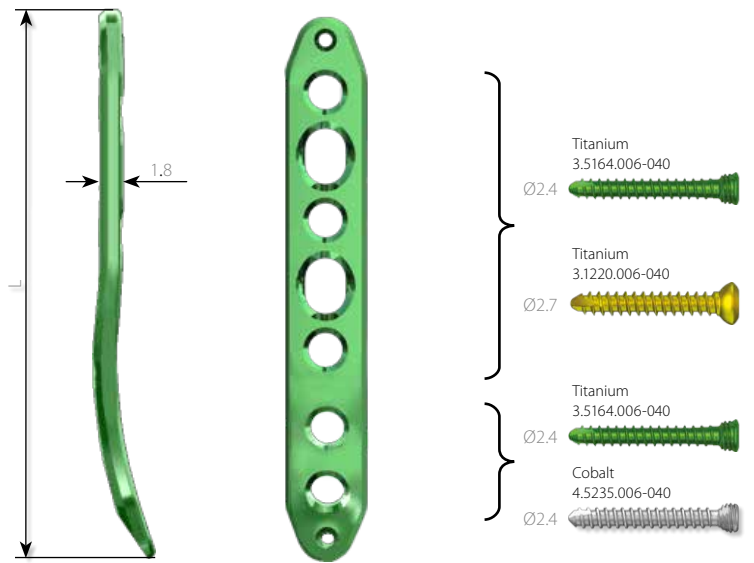
Left	3.4041.6xx	3.4043.6xx	3.4037.6xx	3.4045.6xx	3.4048.6xx
Right	3.4042.6xx	3.4044.6xx	3.4038.6xx	3.4046.6xx	



4.0ChLP Straight plate

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

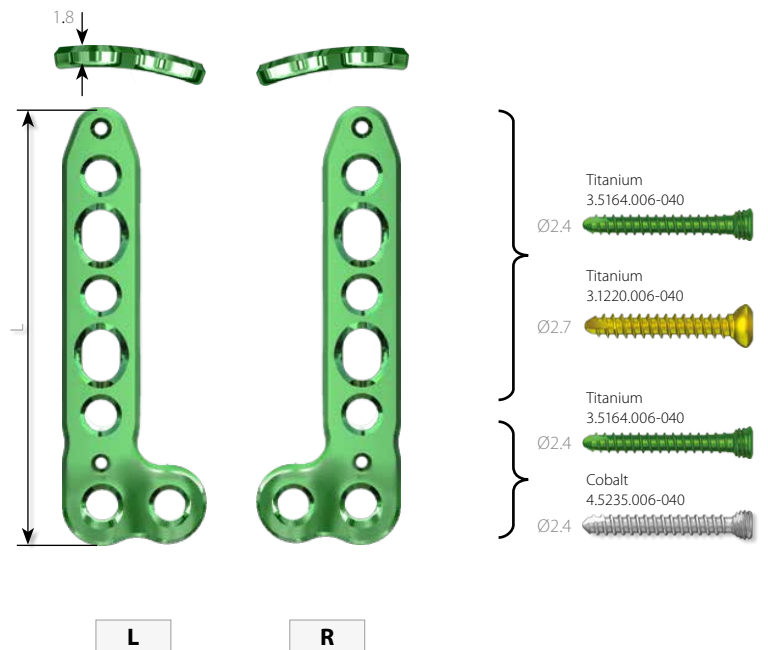
O - threaded holes number in shaft part of the plate



4.0ChLP L plate

O	L [mm]	Catalogue no.	
		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

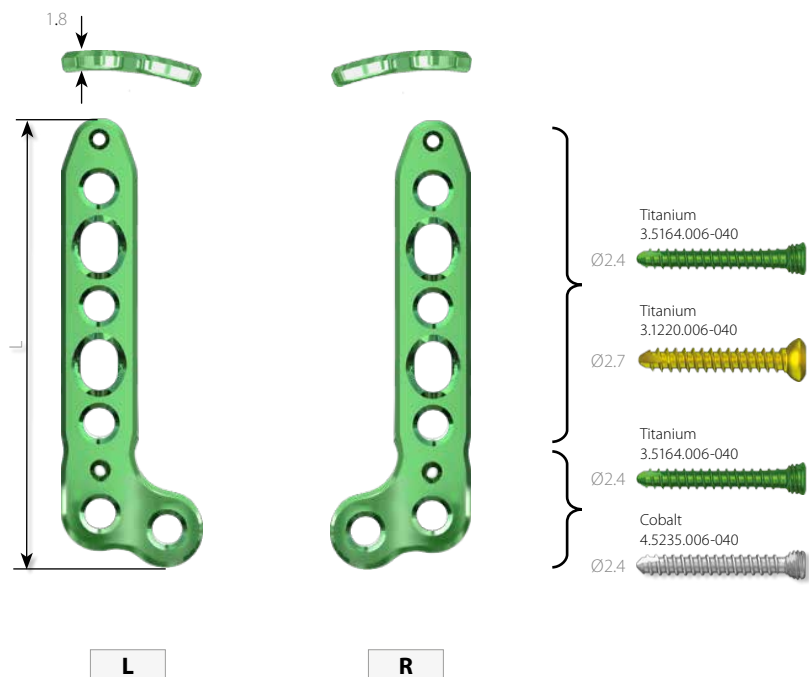
O - threaded holes number in shaft part of the plate



4.0ChLP Oblique L plate

O	L [mm]	Catalogue no.	
		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

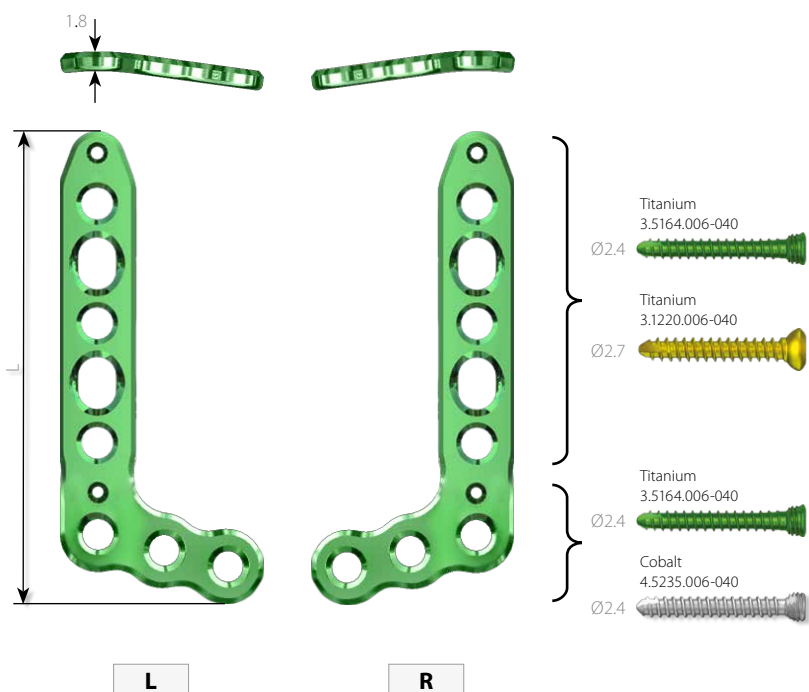
O - threaded holes number in shaft part of the plate



4.0ChLP oblique L plate

O	L [mm]	Catalogue no.	
		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

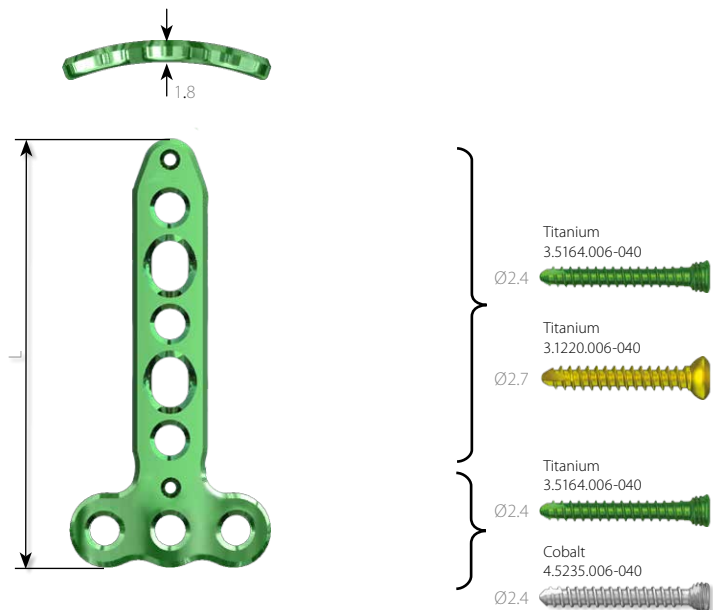
O - threaded holes number in shaft part of the plate



4.0ChLP T-plate

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

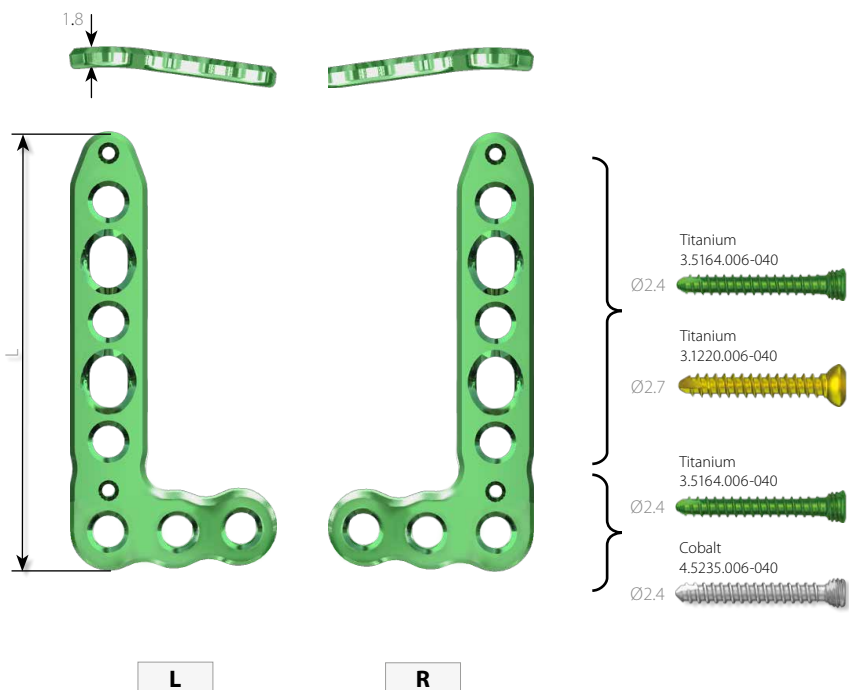
O - threaded holes number in shaft part of the plate



4.0ChLP L plate

O	L [mm]	Catalogue no.	
		Left	Right
2	29	3.4043.602	3.4044.602
3	40	3.4043.603	3.4044.603
4	51	3.4043.604	3.4044.604

O - threaded holes number in shaft part of the plate

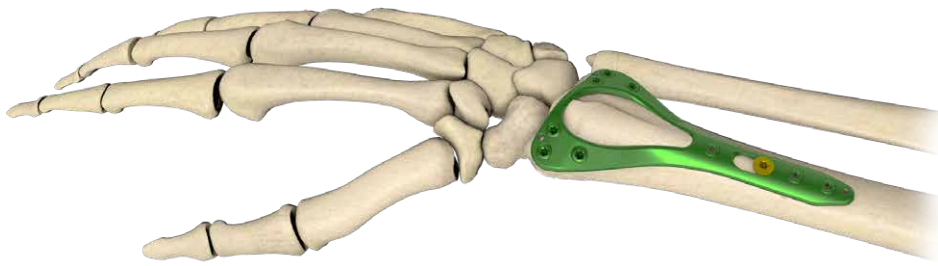
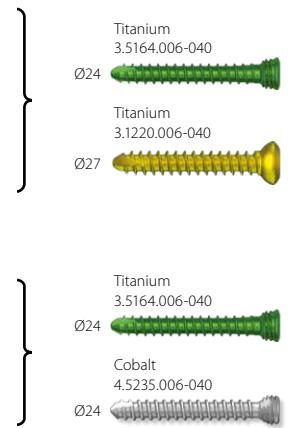
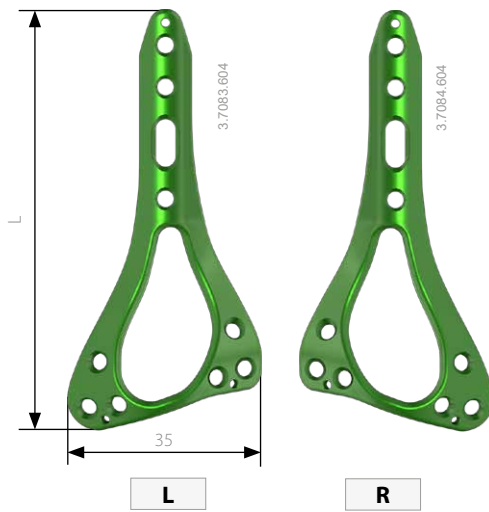


4.0ChLP dorsal-radial Delta plate

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

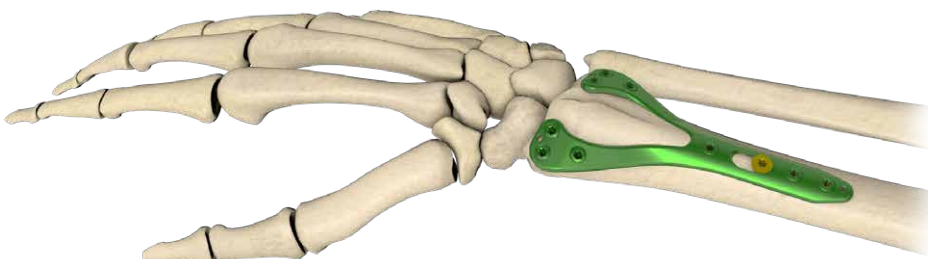
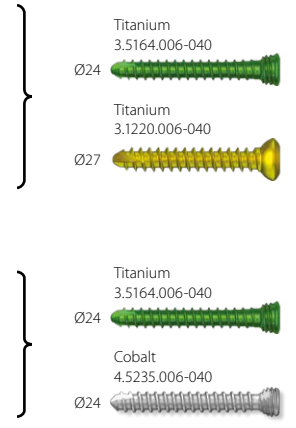
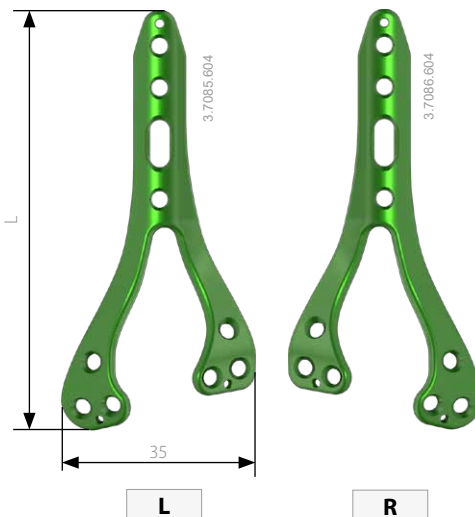
2,0 [mm] - thickness



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

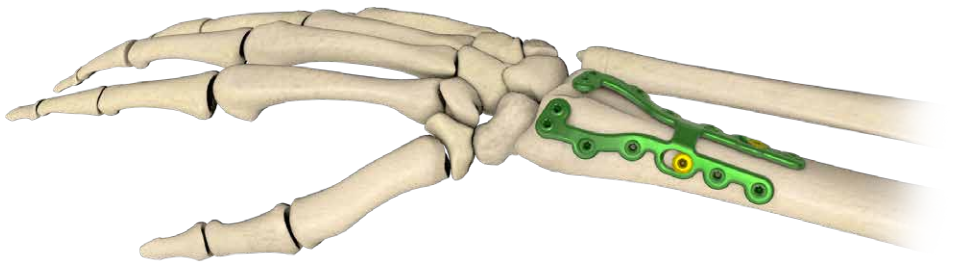
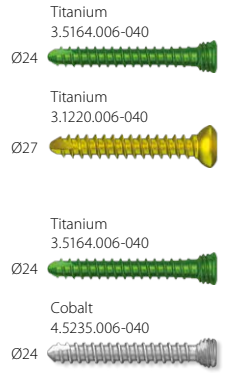
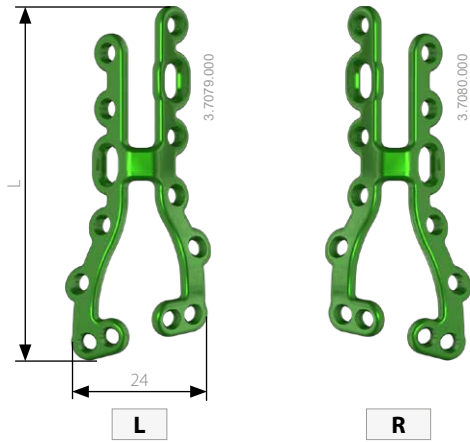
O - holes number in shaft part of the plate
2,0 [mm] - thickness



4.0ChLP dorsal-radial H plate narrow

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

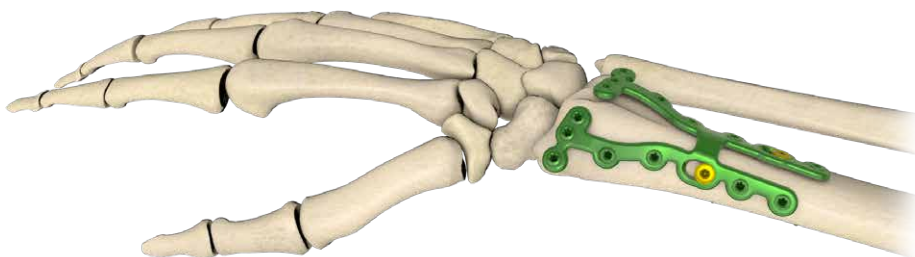
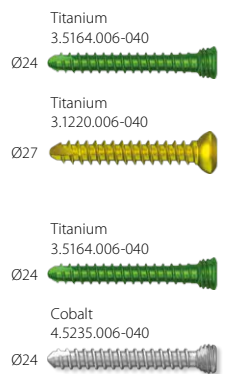
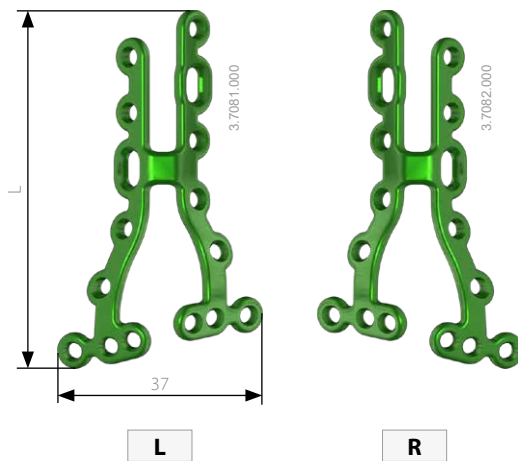
2,0 [mm] - thickness



4.0ChLP dorsal-radial H plate wide

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

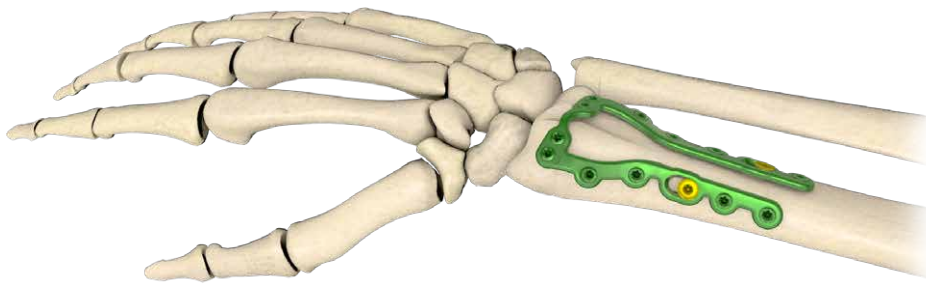
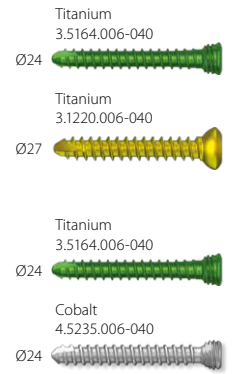
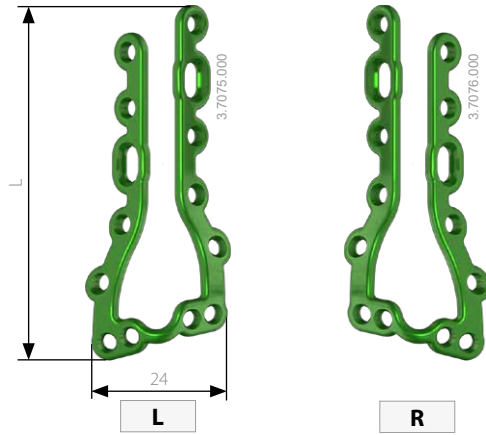
2,0 [mm] - thickness



4.0ChLP dorsal-radial Pi plate narrow

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

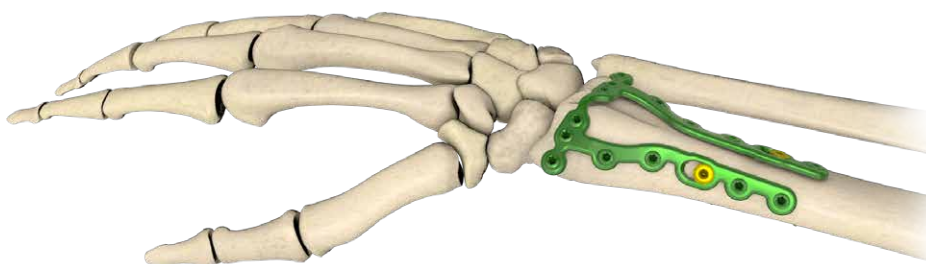
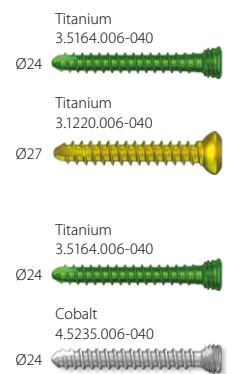
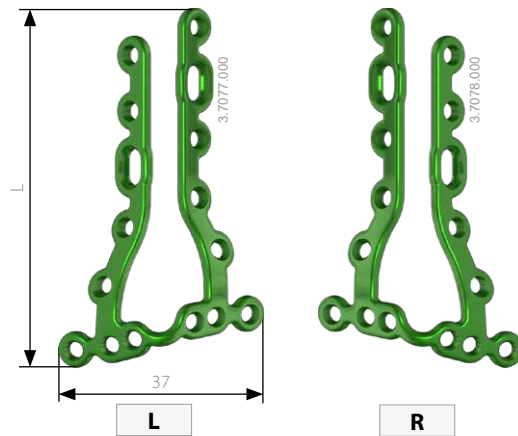
2,0 [mm] - thickness



4.0ChLP dorsal-radial Pi plate wide

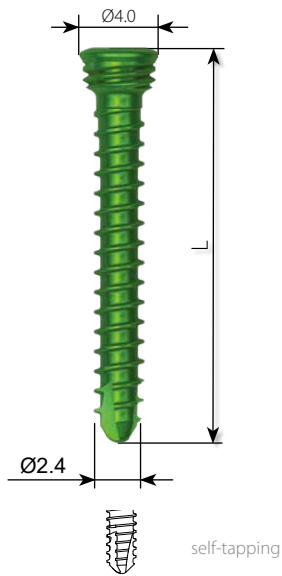
L [mm]	Catalogue no.	
	Left	Right
64	3.7077.000	3.7078.000

2,0 [mm] - thickness



2.3. SCREWS

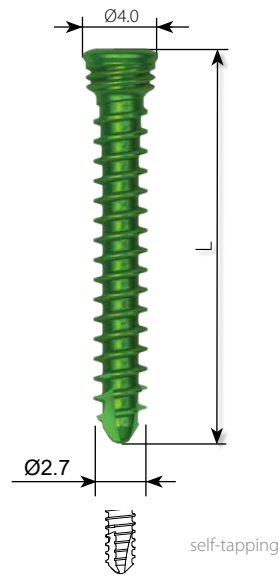
4.0ChLP screw Ø2.4



T8	
Catalogue no.	
L [mm]	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

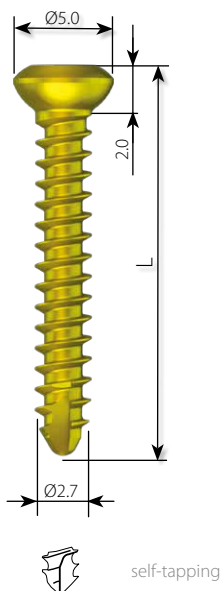
4.0ChLP screw Ø2.7



T8	
Catalogue no.	
L [mm]	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

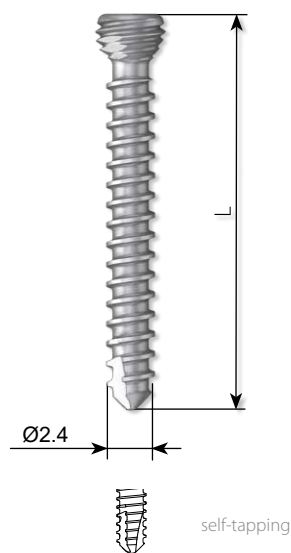
Cortical screw Ø2.7



T8	
Catalogue no.	
L [mm]	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



T8	
Catalogue no.	
L [mm]	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

3. 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

Instrument set for 4.0ChLP

40.5711.200

	Name	Catalogue No.	Pcs
	Threaded guide M3.5/1.8 -4,0	40.4896.018	4
	Compression guide 1.8	40.4897.018	1
	Guide VA 1.8	40.5928.018	1
	Kirschner wire 1.0/180	40.4814.000	5
	Drill 1.8/180	40.2063.181	2
	Length measure of locking screw	40.4818.100	1
	Depth measure	40.4640.000	1
	Screwdriver tip T8.0	40.5682.000	1
	T8 screwdriver tip with holder	40.5989.000	1
	Cortical tap HA 2.7	40.5988.000	1
	Tap 4.0ChLP -2.4	40.5987.024	1
	Setting-compressing screw 1.8/120	40.5678.000	2
	Torque limiting ratchet handle 1.0Nm	40.6650.000	1
	Star screwdriver T8	40.0669.100	1
	Plates bender 4.0	40.4643.000	2
	Dissecting forceps Standard 14.5cm	30.3303.000	1
	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

4. SURGICAL TECHNIQUE

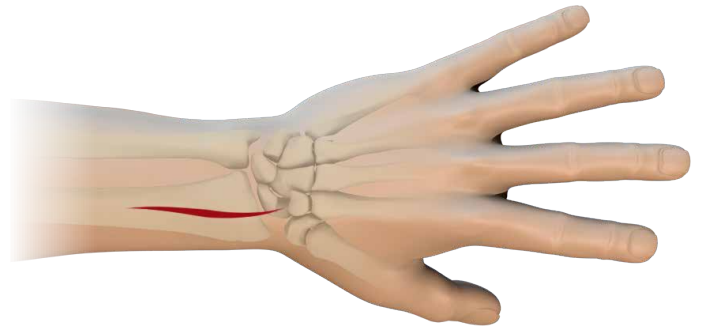
4.1. PATIENT POSITION

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

4.2. DORSAL APPROACH

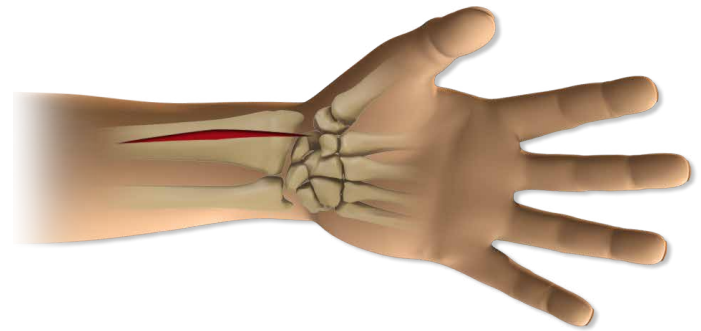
Make a longitudinal straight incision:

- 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.



4.3. VOLAR APPROACH.

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



4.4. TEMPORARY PLATE STABILIZATION

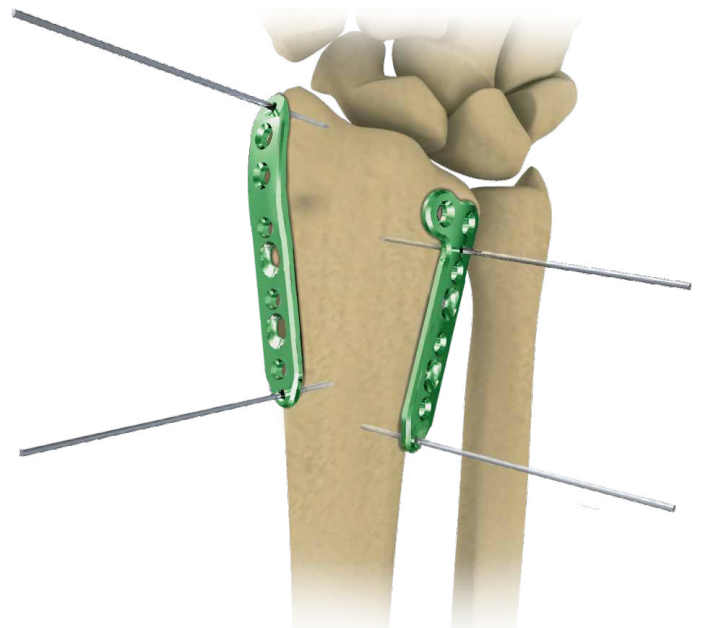
4.4.1. Kirschner 1.0 Wire Usage



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

4.4.2. Use of setting-compressing screw 1.8/120

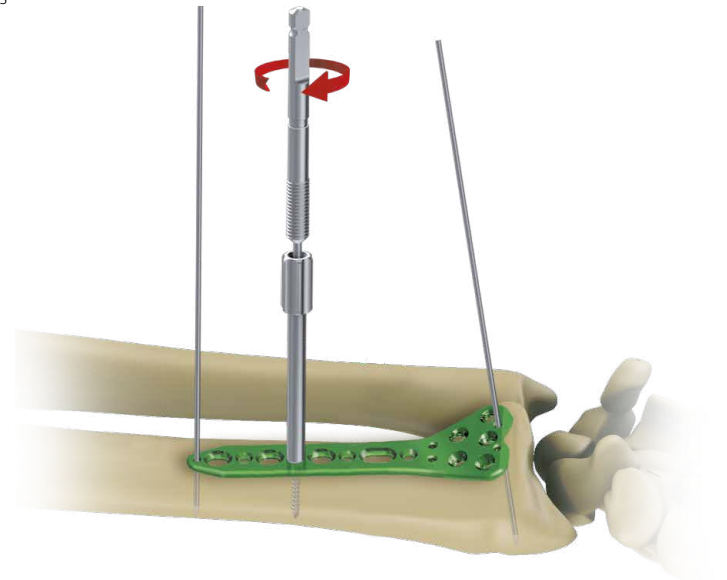
	40.5678.000
	40.4896.018

**NOTE:**

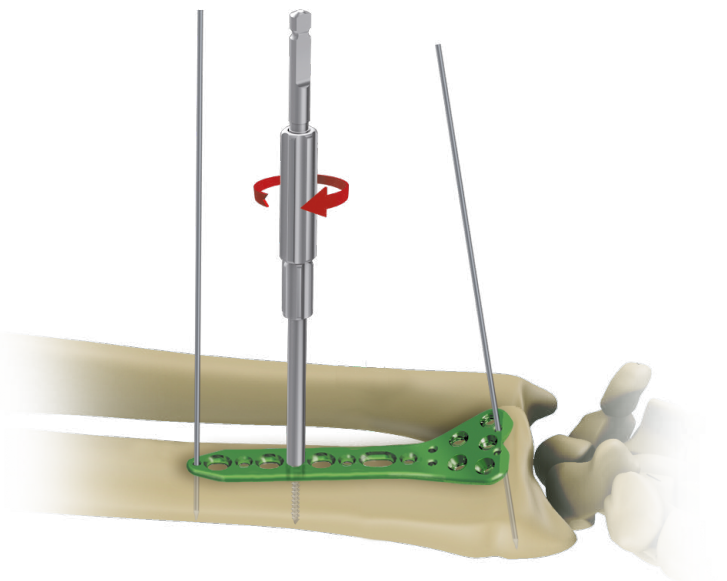
For temporary stabilization and moving the plate to the bone you may use the Setting-compressing screw 1.8/120 **[40.5678.000]**. Insert the screw through the Threaded guide M3.5/1.8 - 4.0 **[40.4896.018]**.

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.



4.5. 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*).

4.5.1. Insertion of the guide sleeve



40.4896.018

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

4.5.2. Hole Drilling



40.2063.181

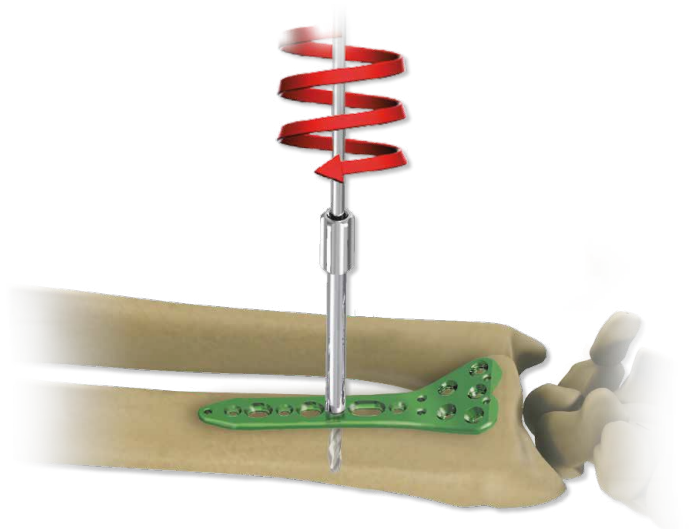
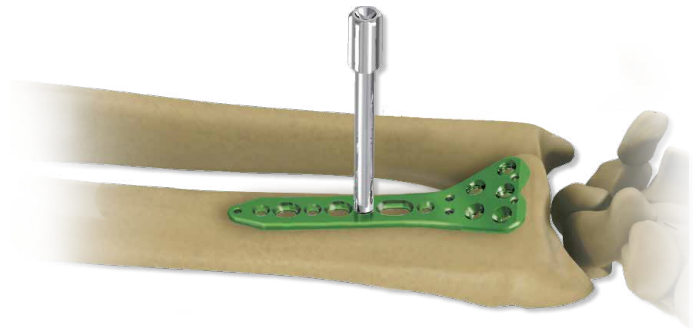
Drill on the advisable depth using the Drill 1.8/180 **[40.2063.181]**.

4.5.3. 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.



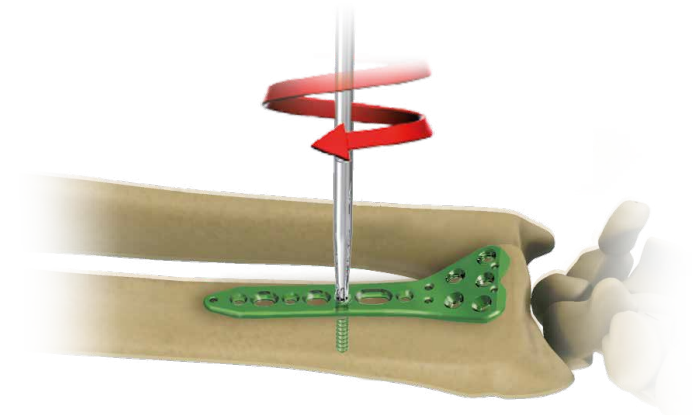
4.5.4. Screw Insertion



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].



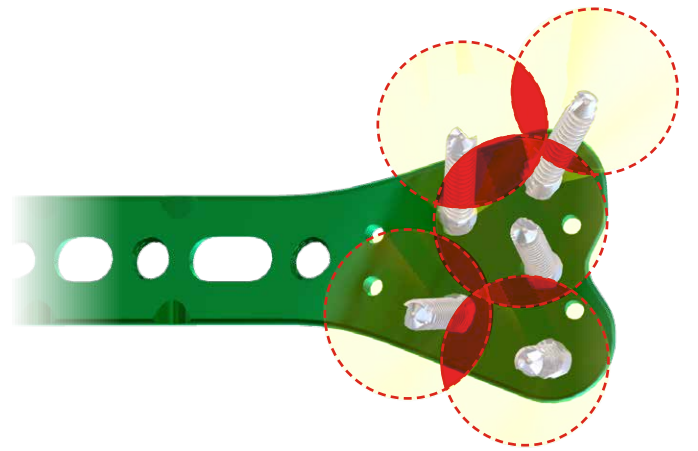
CAUTION:
 The final tightening of the locking screw, especially when mechanical motor is used, should always be performed with the use of torque limiting handle. Failure to use the torque limiting handle may lead to intraoperative and postoperative complications (during later removal of the plate and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



4.6. 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.



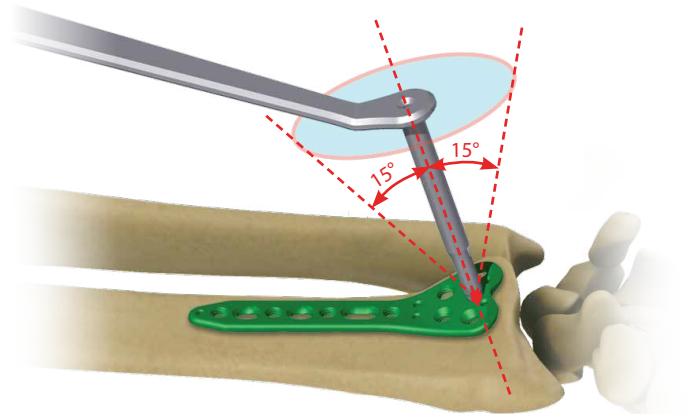
4.6.1. Positioning of Guide VA



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.



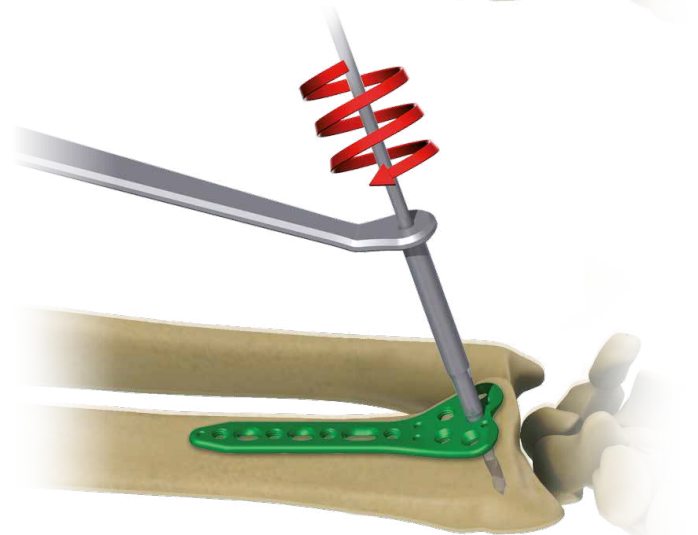
4.6.2. Drilling



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



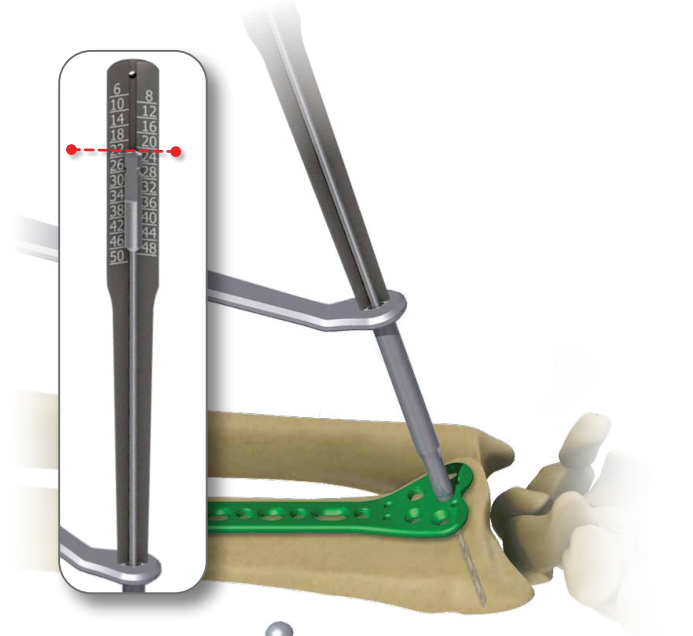
CAUTION:
 Confirm the correct positioning using X-Ray to avoid collision of the drill with the already inserted screws.



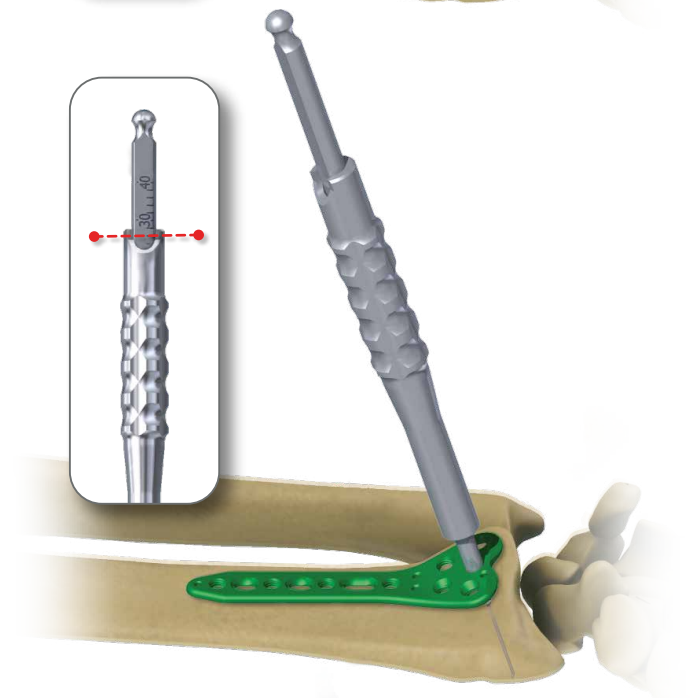
4.6.3. Hole depth measurement



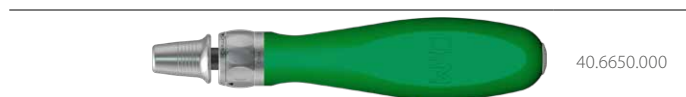
OPTION I: Measure the hole depth using the Locking screw length measure **[40.4818.100]**.



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



4.6.4. Insertion of the VA screw



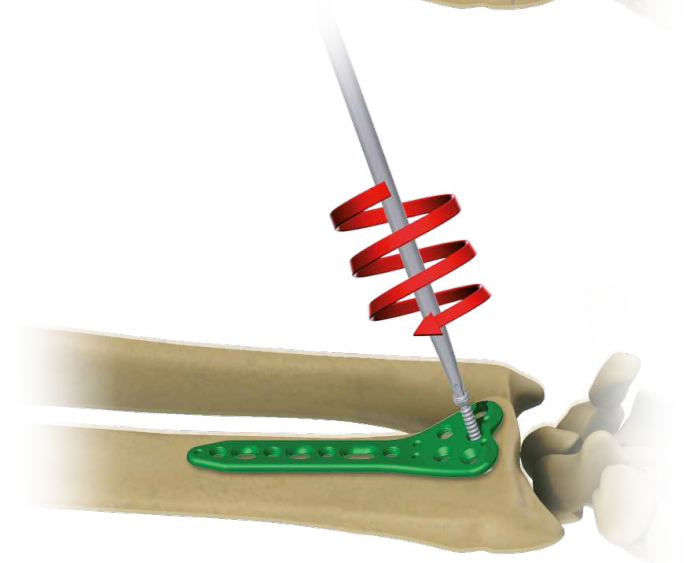
Insert the VA screw using the Screwdriver Tip T8 **[40.5682.000]** with Torque Handle **[40.6650.000]**.

**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.



It is possible to lock the VA screw three times in the threaded hole of the plate. The hole in the plate in which the VA screw was locked cannot be used to insert a standard locking screw.



4.7. 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.



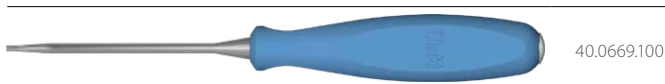
Most locking plates ChLP are available with aiming blocks, as additional complementary instruments. Using aiming blocks ensures proper fastening of guide sleeves in the locking holes, in the epiphyseal part of the plate. It facilitates also the smooth conduct of the procedure, reduces its duration, and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



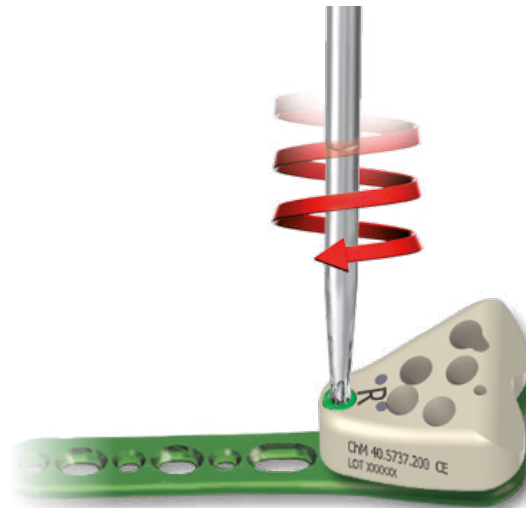
When aiming blocks are not used, the implantation can be incorrect, and in particular can cause:

- improper locking of the screws and their migration,
- decrease of the fixation stability,
- complications while implants removing.

Position the aiming block on the plate.



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



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

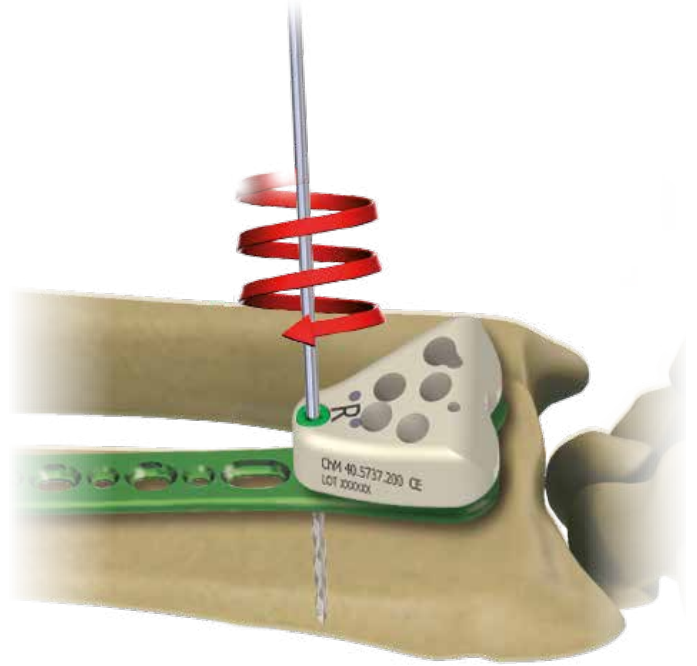
**NOTE:**

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





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



4.8. CORTICAL SCREW 2.7 INSERTION

4.8.1. Compression guide setting

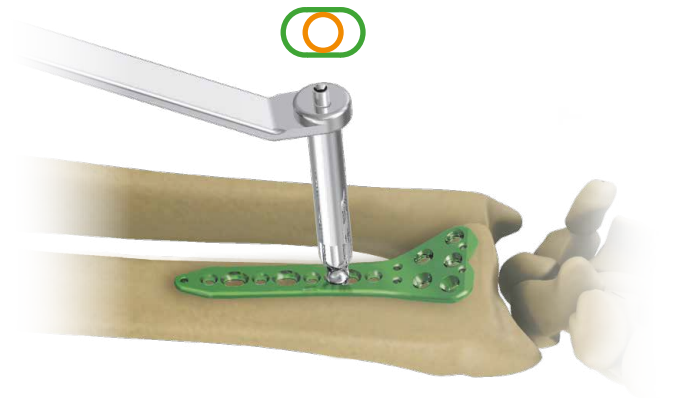


40.4897.018

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

4.8.1.A. Neutral Position

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



4.8.1.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.

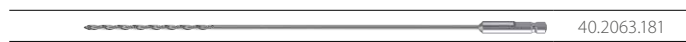


4.8.1.C. Angular Position

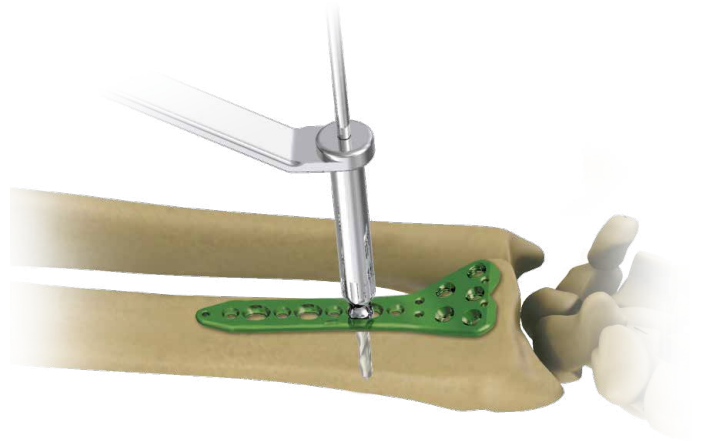
Angular positioning of the guide is also possible.



4.8.2. Drilling



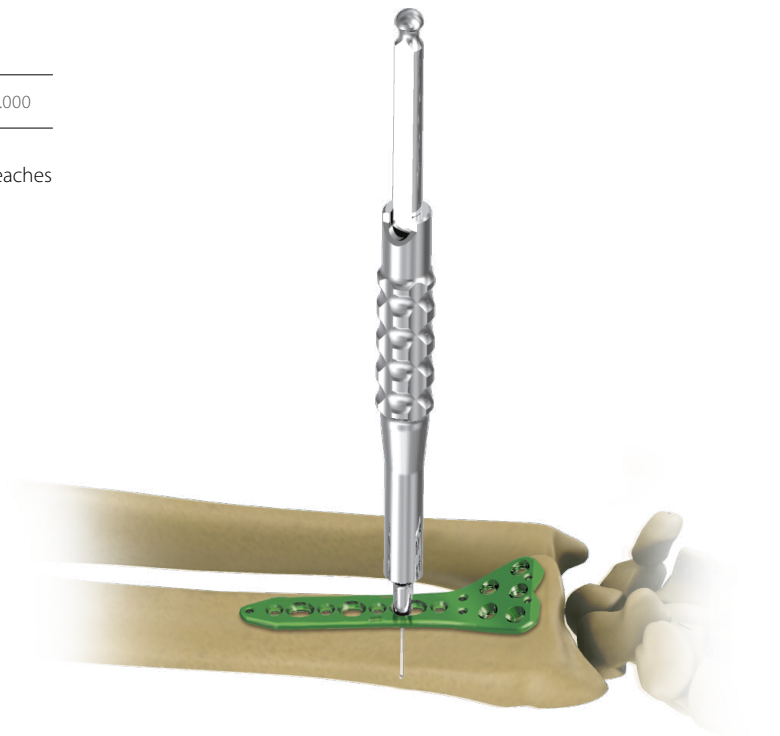
In the desired position make a hole for cortical screw 2.7 through both cortices using the Drill 1.8/180 **[40.2063.181]**.



4.8.3. Hole Depth Measurement



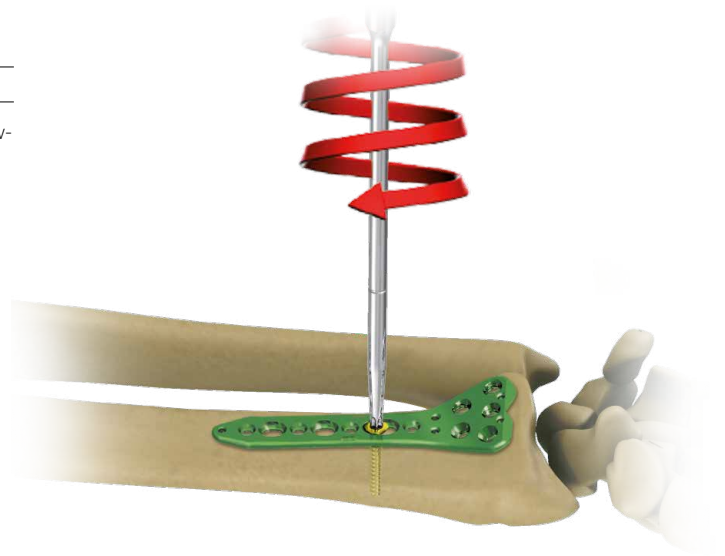
Insert the Depth Measure **[40.4640.000]**, into drilled hole, until its hook reaches the outer surface of opposite cortex bone.



4.8.4. Screw Insertion

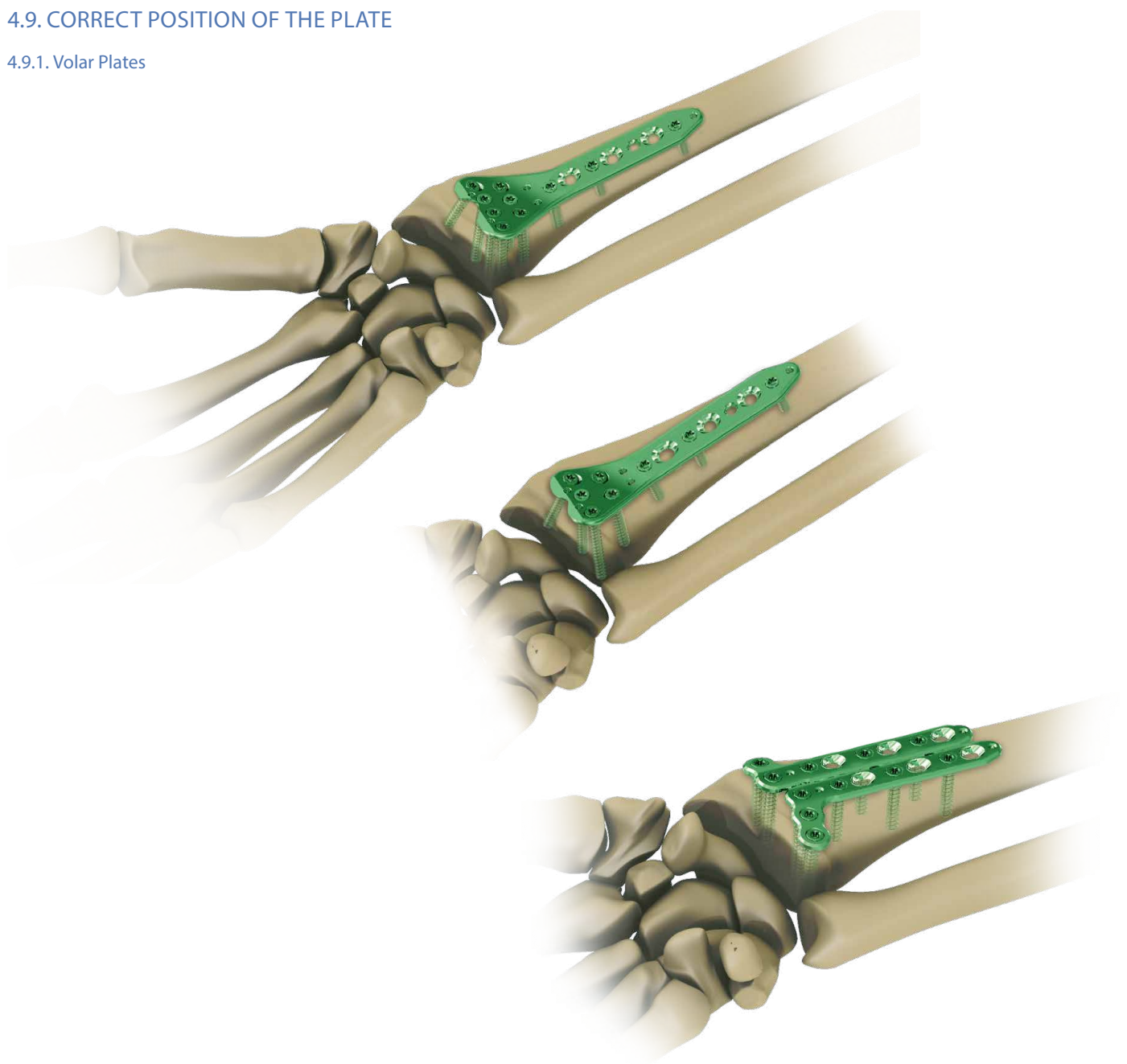


Insert the Cortical self-tapping screw 2.7 [3.1220.006+040] using the Screwdriver Tip T8 [40.5682.000].

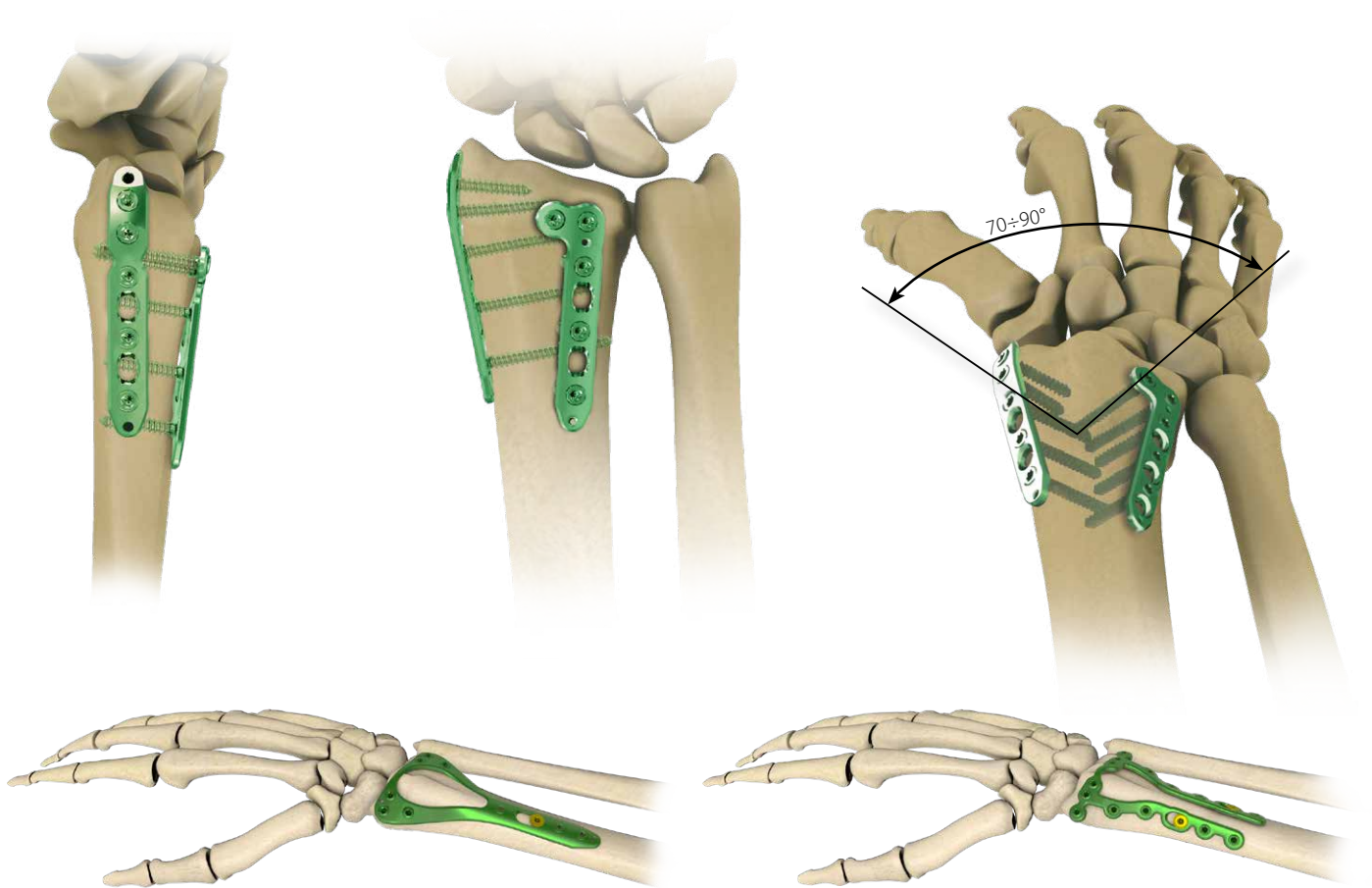


4.9. CORRECT POSITION OF THE PLATE

4.9.1. Volar Plates



4.9.2. Dorsal Plates



4.10. WOUND CLOSURE

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

5. 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.

6. 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.

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