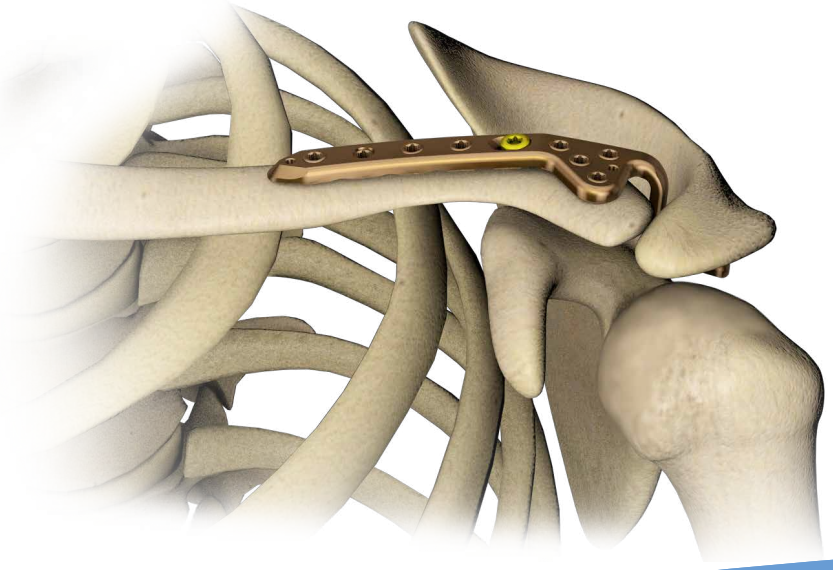
ST/80-502

ChM®

5,0 ChM Locked Plating ChLP system

5.0ChLP clavicular hook plate
3.4025; 3.4026
3.4027; 3.4028
3.4029; 3.4030

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



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SYMBOLS DESCRIPTION

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

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

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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

This surgical technique applies to 5.0ChLP locked plating system used for distal clavicular bone osteosynthesis. The plates are a part of the ChLP locked plating system developed by **ChM**. The presented range of implants is made of materials in accordance with ISO 5832 standards.

The system for the distal clavicular bone treatment includes:
- implants *(plates and screws)*,
- instrument set used for conducting a surgical procedure,
- surgical technique.

Indications

The plates are used to treat:
- Fractures of the acromial end of clavicle,
- Acute and inveterate acromioclavicular joint dislocations.

Contraindications

Absolute:
- Health condition precluding surgery.
- Allergic reactions to the metal from which the implant is made.
- Active infection.

Relative:
- Stable lateral clavicular fractures.
- Weakened bone making it impossible to install/stabilize the implant properly.
- Abnormal perfusion of fracture area or surgical site.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create a risk of fusion failure or complications in the postoperative period.
- Other medical conditions that exclude the potential benefits of the treatment.

Plate selection and shaping

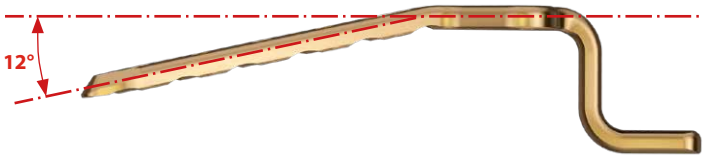
The plates are available in various hook height and length. This allows for optimal selection of the implant to the fracture type.
Shaping of the plates in its epiphysial part is not allowed.

Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.

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

2. IMPLANT DESCRIPTION

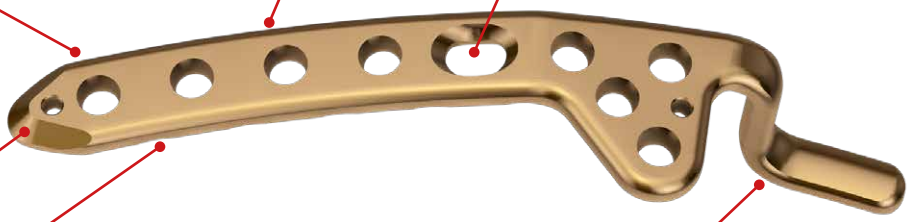
Clavicular hook plates are a part of 5.0ChLP system. This system includes also compatible locking screws. To facilitate the identification, both titanium plate and screws are brown anodized.



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

Plate profile:
- slightly bent *(12°)* shaft part of the plate facilitates insertion.

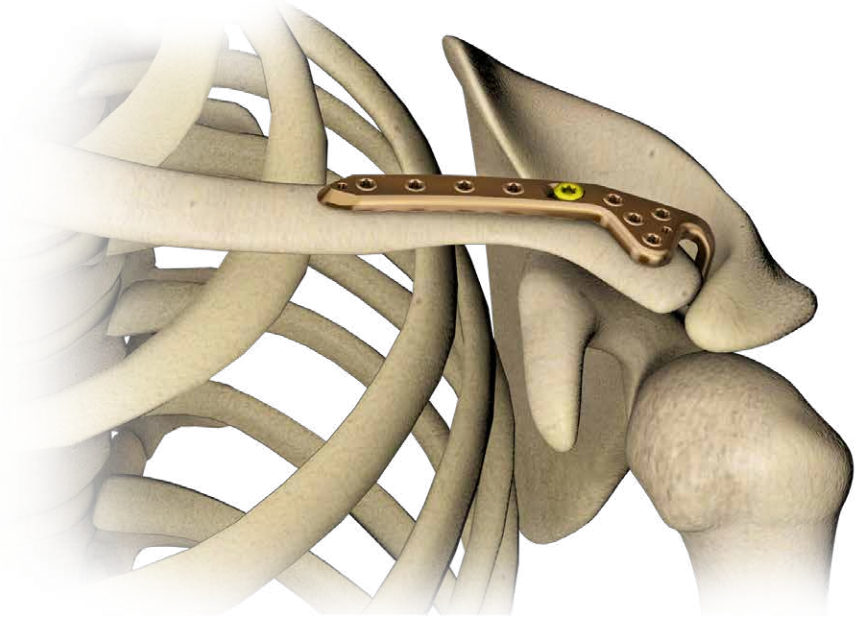
Oval-shaped compression hole:
- convenient plate positioning,
- bidirectional compression possibility.

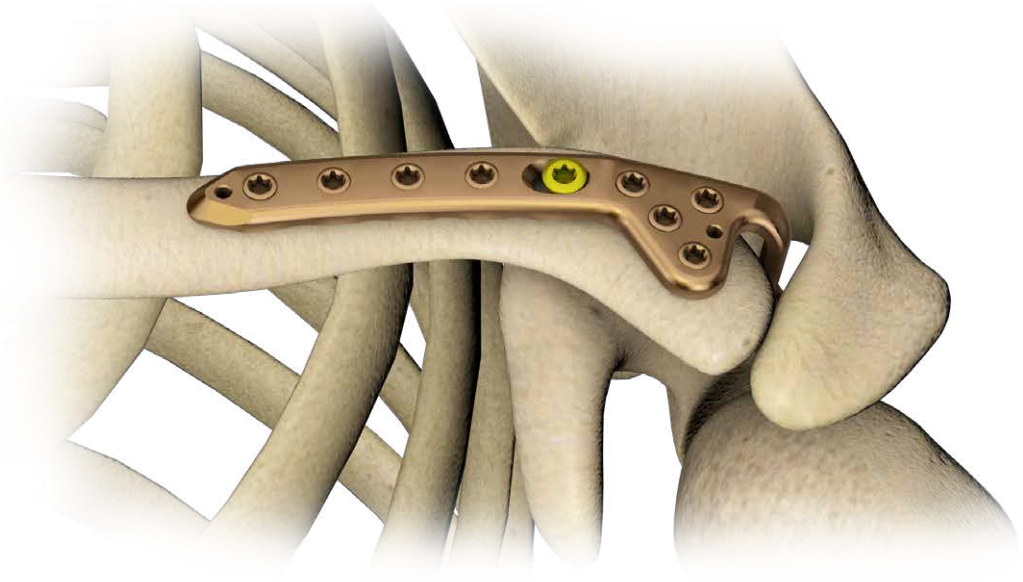


Bottom undercuts of the shaft part:
- limited bone-to-plate contact,
- better blood circulation of periimplant tissues.

Acromioclavicular hook:
- hook depth - 12, 15 or 18mm,
- useful in acromioclavicular joint injury.

Plate cutting:
- allows for use a minimally invasive technique.



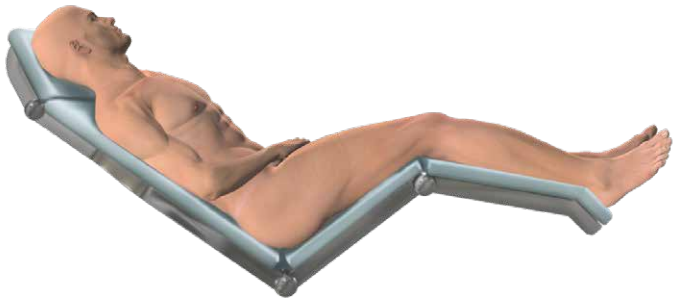


3. SURGICAL TECHNIQUE

This surgical technique defines steps when a fracture of the acromial end of clavicle or acromioclavicular joint dislocation appears.

3.1. PATIENT'S POSITIONING

It is recommended to position a patient in a beach-chair position. Make sure the position allows taking adequate X-Ray image.



3.2. SURGICAL APPROACH

a. Fracture: Expose the fracture site.

b. Dislocation: Expose and *"clean"* the joint.

Dostęp przednio-górny typu *„cięcie szablą" (ang. sabre cut).*

3.3. INITIAL FRACTURE REDUCTION

a. Fracture: Reduce initially the fracture. If need be, temporarily stabilize the bone fragments with Kirschner wires and/or reduction pliers.
Fracture reduction 'to the plate' possible.

b. Dislocation: Reduce initially the dislocation. If need be, temporarily stabilize the acromioclavicular joint with Kirschner wire.
Capsular and ligament reconstruction recommended.

3.4. IMPLANT SELECTION

Select the right height of the hook using plate trial.

H [mm]	Left	Right
12	43.4025.505	43.4026.505
15	43.4027.505	43.4028.505
18	43.4029.505	43.4030.505

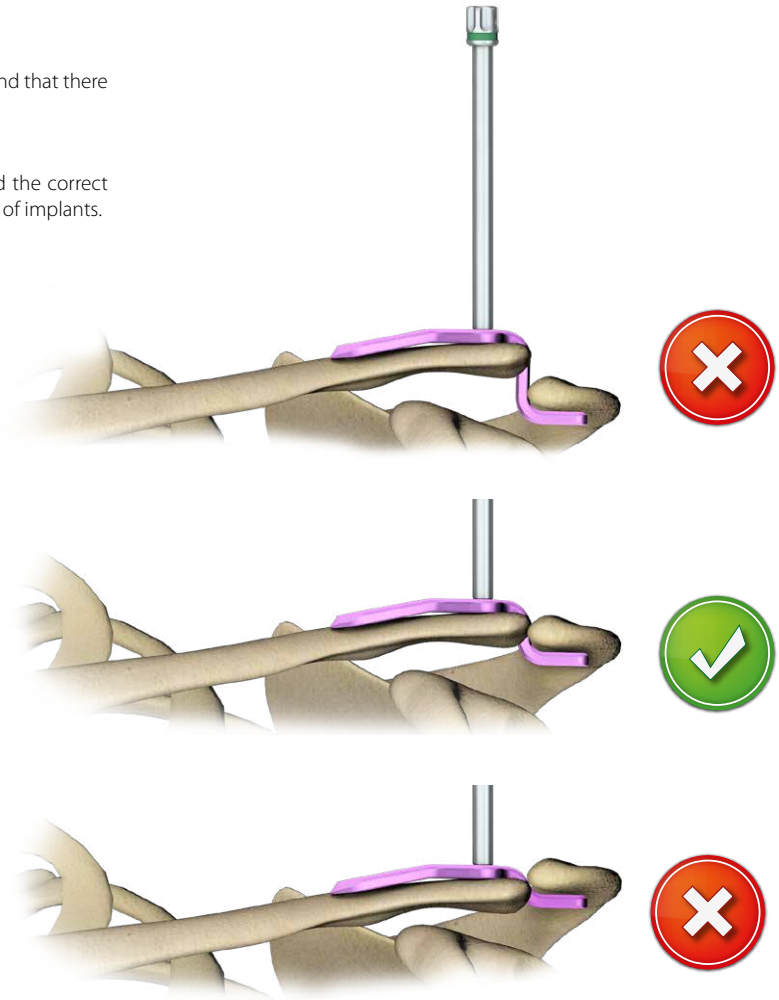
Attach two guide sleeves 5.0/2.8 **[40.5673.728]** into the threaded holes of the plate trial to facilitate handling.

40.5673.728

Determine the right height of the hook. The end of the hook should rest on the bottom surface of the acromion.

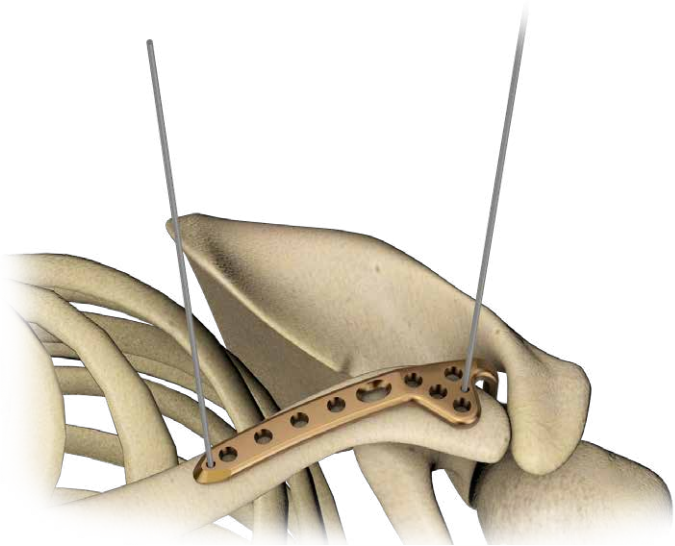
Confirm the anatomical position of the clavicle and the acromion and that there is no collision of the hook with the head of the humerus.

Remove the plate trial from the operating site. Having determined the correct hook height, select the length of the plate from the available range of implants.



3.5. PLATE INSERTION

Position the implant correctly on the bone.



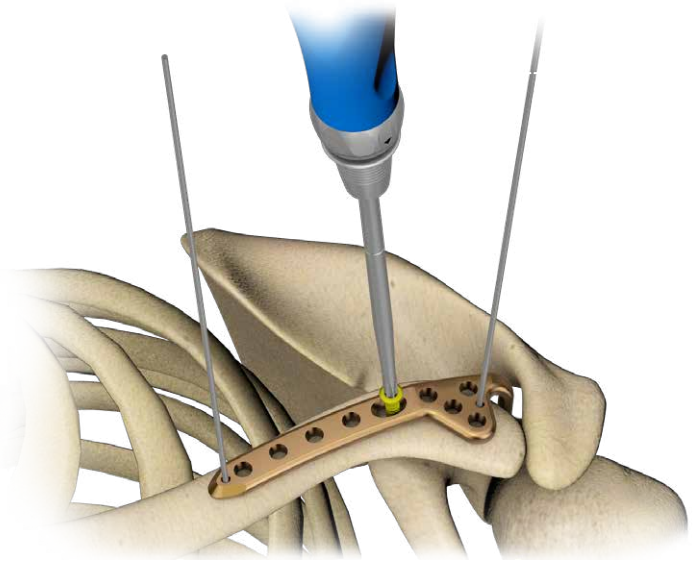
3.6. TEMPORARY PLATE STABILIZATION

The position of the implant may be stabilized by inserting Kirschner wires into appropriate holes or using setting-compressing screw *(acc. to procedure 4a)*.

3.7. CORTICAL SCREW INSERTION

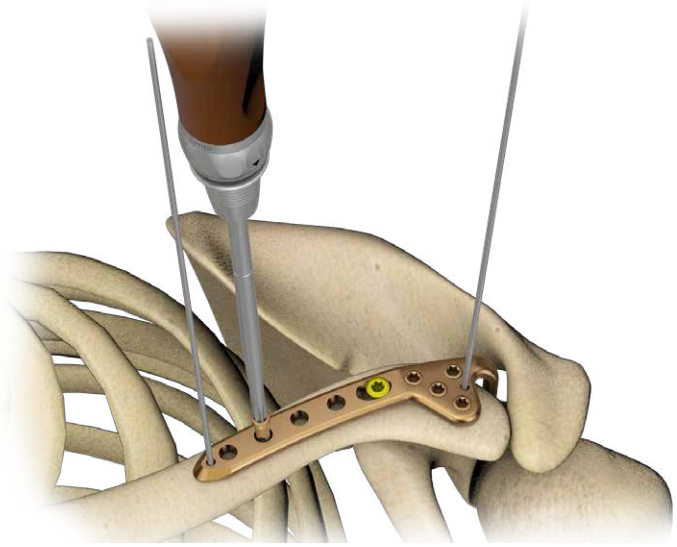
Insert cortical self-tapping screw 3.5 **[3.1306]** into the oval-shaped hole of the plate *(acc. to procedure 4b)*

The oval-shaped compression hole can be used to determine the correct position of the plate on the bone and its initial stabilization.



3.8. LOCKING SCREWS INSERTION

Insert 5.0ChLP self-tapping screw 3.5 **[3.5200]** of a suitable length, into the locking holes of the plate *(acc. to procedure 4c)*.



Insert the cortical screws 3.5 into the fracture before inserting the locking screws.

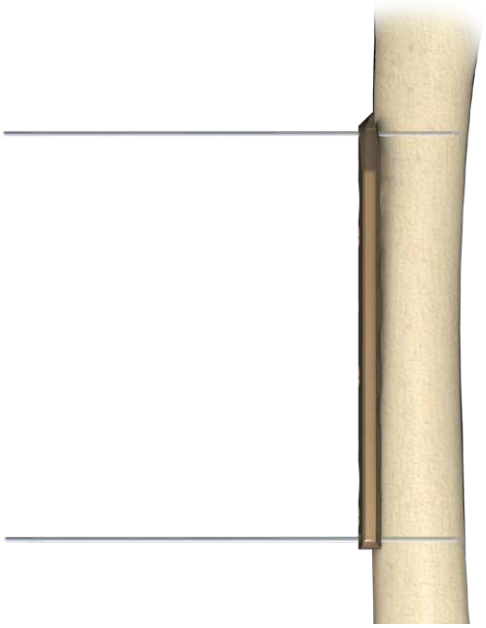
The doctor decides about the order and number of locking and cortical screws to be inserted.

3.10. WOUND CLOSURE

Before closing the wound, take an X-Ray image in at least two projections to confirm implant position and fracture reduction. Make sure all the screws are properly tightened and do not penetrate the joint surface.
Use appropriate surgical technique to close the wound.

4. SURGICAL PROCEDURES

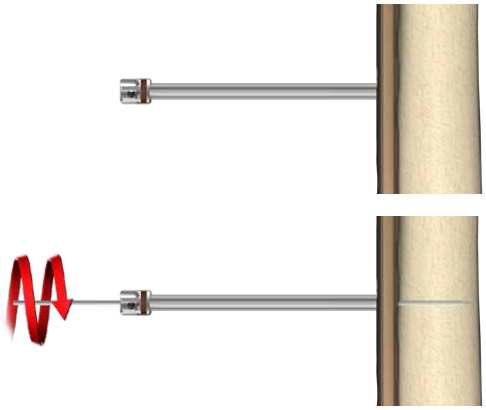
4.a. PROCEDURE OF TEMPORARY IMPLANT STABILIZATION



Stabilization using Kirschner wires

- Stabilize temporary the implant inserting Kirschner wires 1.5/210 **[40.4592.210]** into dedicated holes in the plate.

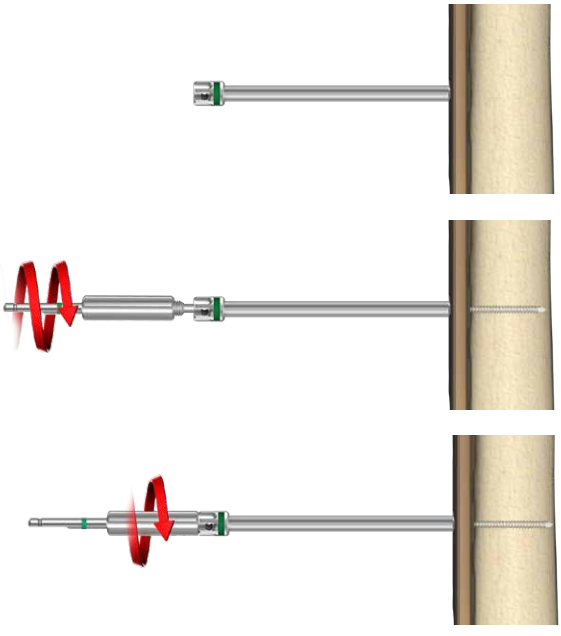
	40.4592.210



Stabilization in locking holes using Kirschner wires

- Insert guide sleeve 5.0/1.8 **[40.5673.718]** into the locking hole of the plate.
- Insert Kirschner wire **[40.4592.210]** through the guide sleeve 5.0/1.8 **[40.5673.718]**.

	40.5673.718
	40.4592.210



Stabilization using setting-compressing screw

- Insert guide sleeve 5.0/2.8 **[40.5673.728]** into the locking hole of the plate.
- Insert setting-compressing screw 2.8/180 **[40.5674.728]** through the guide sleeve 5.0/2.8 **[40.5673.728]**.
- Tighten the nut of the setting-compressing screw **[40.5674.728]** and push the plate to the bone.

	**40.5673.728**
	**40.5674.728**

4.b. PROCEDURE OF CORTICAL SELF-TAPPING SCREW 3.5 [3.1306] INSERTION

Compression guide positioning

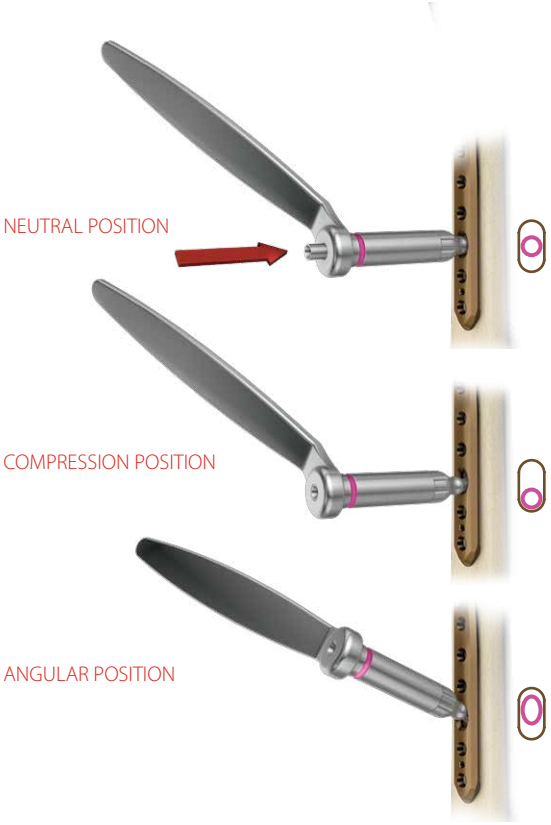
Position the compression guide 2.5 **[40.4804.725]** in a desired position:

40.4804.725

NEUTRAL POSITION: Push the guide to the plate. It will position itself so as neutral insertion of the screw is allowed.

COMPRESSION POSITION: Do not push the guide and move it to the edge of the compression hole. The hole drilled in this position allows compressive insertion of the screw.

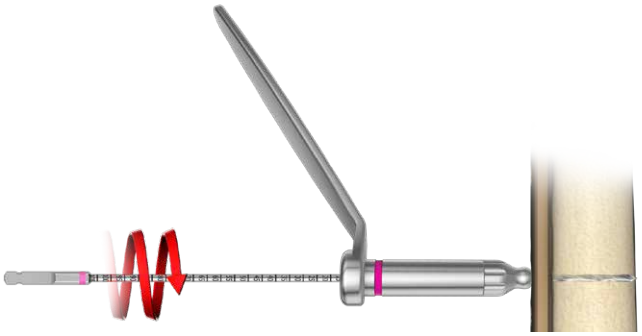
ANGULAR POSITION: Angular position of the guide may also be applied.



Hole drilling

Perform a hole through both cortices for a cortical screw 3.5 insertion. For drilling, use drill with scale 2.5/210 **[40.5912.212]** and compression guide in a desired position.

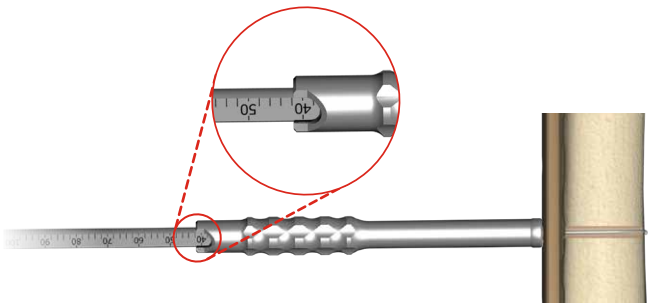
40.5912.212



Measurement of hole depth

Insert depth measure **[40.4639.550]** into drilled hole until the hook of the measure rests against the outer surface of the second cortex.

40.4639.550

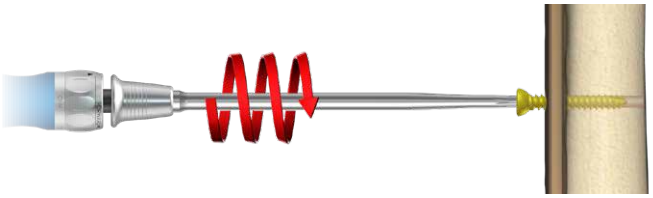


Screw insertion

Insert cortical screw using handle ratchet device **[40.6654.000]** and screwdriver tip T15 **[40.5677.000]**.

40.6654.000

40.5677.000

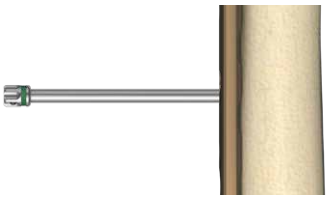


4.c. PROCEDURE OF 5.0ChLP SELF-TAPPING SCREW 3.5 [3.5200] INSERTION

Guide sleeve insertion

- Insert guide sleeve 5.0/2.8 **[40.5673.728]** into a locking hole of the plate.

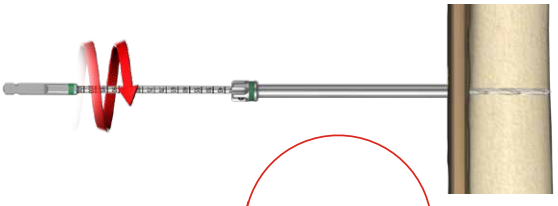

40.5673.728



Hole drilling

Drill using drill with scale 2.8/210**[40.5653.212]** until desired depth is reached.

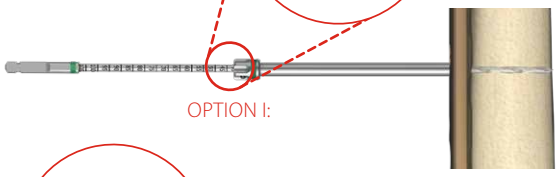
40.5653.212



Measurement of hole depth

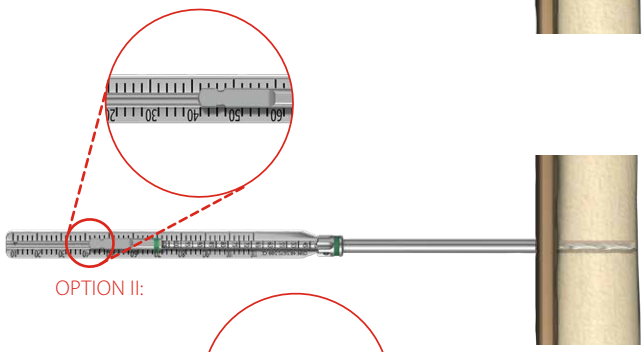
OPTION I: Read the length of the screw from the drill measure **[40.5653.212]**

40.5653.212



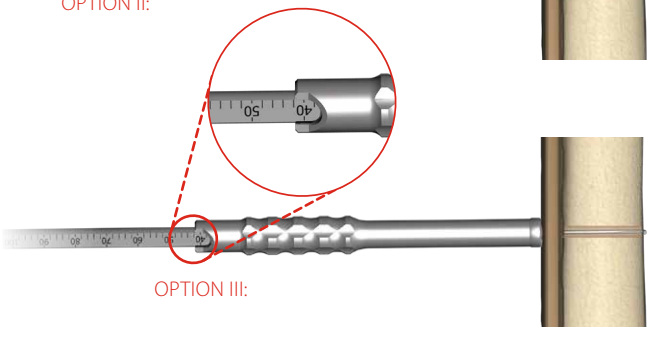
OPTION II: or use screw length measure **[40.5675.500]**.


40.5675.500



OPTION III: Having removed the guide sleeve 5.0/2.8 **[40.5673.728]**, use depth measure **[40.4639.550]** to determine the length of a screw.


40.4639.550

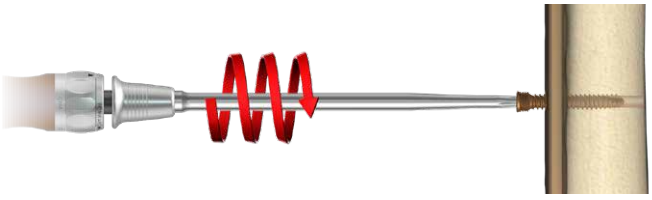


Screw insertion

Remove the guide sleeve 5.0/2.8 **[40.5673.728]**. Use torque limiting ratchet handle 2Nm **[40.6652.000]** and screwdriver tip T15 **[40.5677.000]** to insert the locking screw.


40.6652.000


40.5677.000



The final tightening of the locking screw, especially when a drive 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)*.

5. POSTOPERATIVE PROCEDURE

Introduce appropriate postoperative treatment that is determined by the physician. In order to avoid patient's movement limitations, introduce exercises as soon after surgery as possible. However, make sure that the limb is not fully loaded before fragments osteosynthesis is complete.

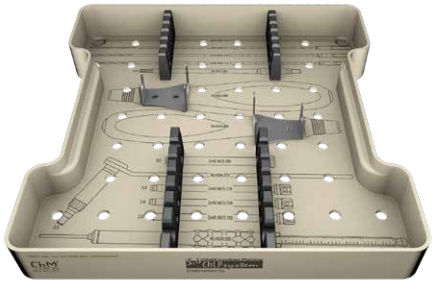
6. IMPLANT REMOVAL

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

7. CATALOGUE PAGES

7.a. INSTRUMENT SET

Instrument set for 5.0ChLP 4x4 1/2H — 15.0205.201

	Name	Catalogue No.	Pcs
	Tray for 5.0ChLP instrument set 4x4 1/2H	**14.0205.201**	1
	Kirschner wire 1.5/210	**40.4592.210**	4
	Drill 1.8/210	**40.2063.212**	2
	Drill with scale 2.5/210	**40.5912.212**	2
	Drill with scale 2.8/210	**40.5653.212**	2
	Screwdriver tip T15	**40.5677.000**	1
	Torque limiting ratchet handle 2Nm	**40.6652.000**	1
	Handle ratchet device	**40.6654.000**	1
	Protective guide 7/5	**40.5672.000**	2
	Compression guide 2.5	**40.4804.725**	1
	Guide sleeve 5.0/1.8	**40.5673.718**	2
	Guide sleeve 5.0/2.8	**40.5673.728**	4
	Depth measure	**40.4639.550**	1

Instrument set for 5.0ChLP 4x4 1/2H

15.0205.202

	Name	Catalogue No.	Pcs
	Tray for 5.0ChLP instrument set 4x4 1/2H	**14.0205.202**	1
	Setting-compressing screw 2.8/180	**40.5674.728**	1
	Screw length measure	**40.5675.500**	1
	Plates bender 5.0	**40.4643.500**	2
	Tripod screwdriver tip 5.0ChLP	**40.6271.500**	1
	T15 screwdriver tip with holder	**40.6254.000**	1
	Cortical tap HA 3.5 with handle	**40.2548.200**	1
	Tap 5.0ChLP-3.5	**40.5661.000**	1
	Optional instrument		
	Torque connector 2Nm	**40.5927.020**	1

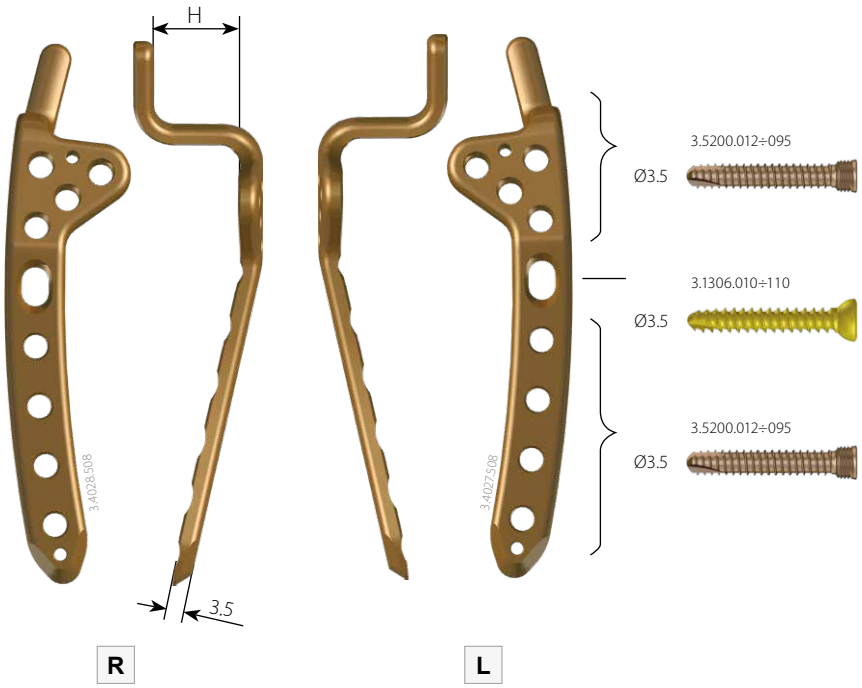
Plate trial

H	L	R
12	43.4025.505	43.4026.505
15	43.4027.505	43.4028.505
18	43.4029.505	43.4030.505

4.5ChLP clavicular hook plate

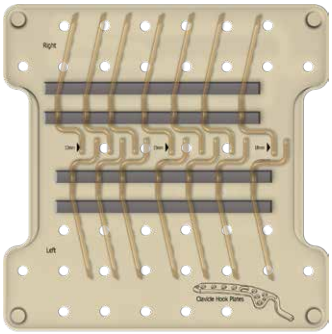
Ti | Ster Non Ster

H		L	R
12	5	3.4025.505	3.4026.505
	6	3.4025.506	3.4026.506
	7	3.4025.507	3.4026.507
	8	3.4025.508	3.4026.508
15	5	3.4027.505	3.4028.505
	6	3.4027.506	3.4028.506
	7	3.4027.507	3.4028.507
	8	3.4027.508	3.4028.508
18	5	3.4029.505	3.4030.505
	6	3.4029.506	3.4030.506
	7	3.4029.507	3.4030.507
	8	3.4029.508	3.4030.508



Tray for plates 5.0ChLP 3.4025-3.4030 4x4 1/2H

14.0205.403



4.5ChLP Clavicular hook plate	
Catalogue No.	**3.4025.5xx ÷ 3.4029.5xx**
Pcs	7
4.5ChLP Clavicular hook plate	
Catalogue No.	**3.4026.5xx ÷ 3.4030.5xx**
Pcs	7

* Tray does not include implants

Ti | Ster Non Ster

5.0ChLP self-tapping screw 3.5

Len	Ti
12	3.5200.012
14	3.5200.014
16	3.5200.016
18	3.5200.018
20	3.5200.020
22	3.5200.022
24	3.5200.024
26	3.5200.026
28	3.5200.028
30	3.5200.030
32	3.5200.032
34	3.5200.034
36	3.5200.036
38	3.5200.038
40	3.5200.040
42	3.5200.042
44	3.5200.044
46	3.5200.046
48	3.5200.048
50	3.5200.050
52	3.5200.052
54	3.5200.054
56	3.5200.056
58	3.5200.058
60	3.5200.060
65	3.5200.065
70	3.5200.070
75	3.5200.075
80	3.5200.080
85	3.5200.085

Cortical self-tapping screw 3.5

Len	Ti
10	3.1306.010
12	3.1306.012
14	3.1306.014
16	3.1306.016
18	3.1306.018
20	3.1306.020
22	3.1306.022
24	3.1306.024
26	3.1306.026
28	3.1306.028
30	3.1306.030
32	3.1306.032
34	3.1306.034
36	3.1306.036
38	3.1306.038
40	3.1306.040
45	3.1306.045
50	3.1306.050
55	3.1306.055
60	3.1306.060
65	3.1306.065
70	3.1306.070
75	3.1306.075
80	3.1306.080
85	3.1306.085

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