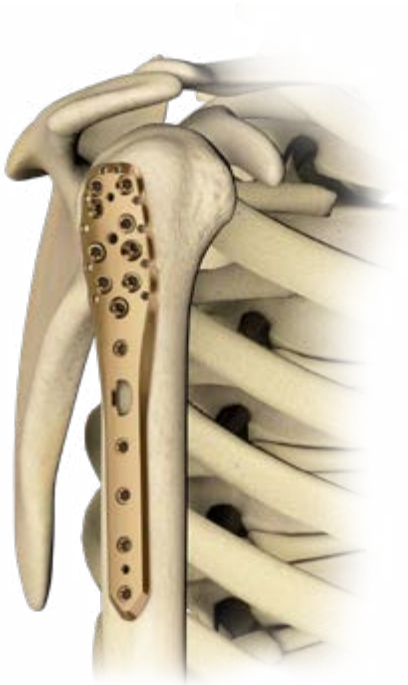
ST/80-514

ChM®

5,0 ChM Locked Plating ChLP system

5.0ChLP humerus plate
3.4034

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



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SYMBOLS DESCRIPTION

Ti	Titanium or titanium alloy	H	H length [mm]
Co	Cobalt		Angle
L	Left	88 - 340	available lengths
R	Right	4-22	Available number of holes
L R	Available versions: left/right	1.8	Thickness [mm]
Len	Length	1:1	Scale 1:1
	Torx drive		Number of threaded holes in the shaft part of the plate
	Torx drive cannulated		Number of locking holes in the plate
	Hexagonal drive	VA	Variable angle
	Hexagonal drive cannulated		Cortical
	Cannulated		Cancellous
	Locking	Ster Non Ster	Available in sterile/ non- sterile condition
	Diameter [mm]		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 stabilization of proximal humerus fractures. 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 includes:
- implants *(plates and screws)*,
- instrument set used in the surgery,
- surgical technique.

Indications

- Comminuted fractures of the head and proximal metaphysis of humerus.
- Dislocated fractures.
- Fractures of osteopenic and osteoporotic bones.
- Mal-unions and non-unions.

Plate selection and shaping

The plates are available in various lengths for optimal selection of the implant to the fracture type.
Shaping of the plates in their epiphyseal 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

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

Locking hole design
- the screws heads do not protrude above the surface of the plate what significantly reduces the irritation of periimplant tissues
- increased strength of the screw-to-plate threaded connection
- bottom protrusion reduces surface area of the contact with the bone

Variable-Angle screws
- high strength cobalt alloy material
- compatible with all locking holes
- 30° angulation cone
- re-locking possible

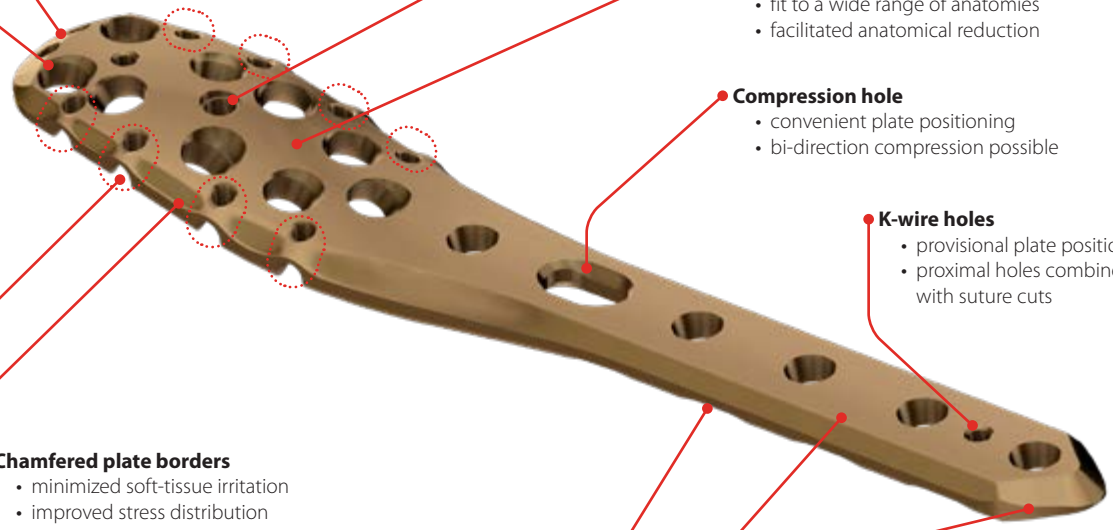
Beveled proximal part
- reduced risk of collision of the plate with the acromion
- minimized periimplant soft-tissue irritation

Aiming block
- fast, collision-free insertion of screws in pre-determined directions

Design aligned with anatomy
- optimized anatomical profile
- fit to a wide range of anatomies
- facilitated anatomical reduction

Compression hole
- convenient plate positioning
- bi-direction compression possible

K-wire holes
- provisional plate positioning
- proximal holes combined with suture cuts



Chamfered plate borders
- minimized soft-tissue irritation
- improved stress distribution

Peripheral holes in the epiphyseal part
- holes for periimplant soft tissues suturing and initial K-wire stabilization

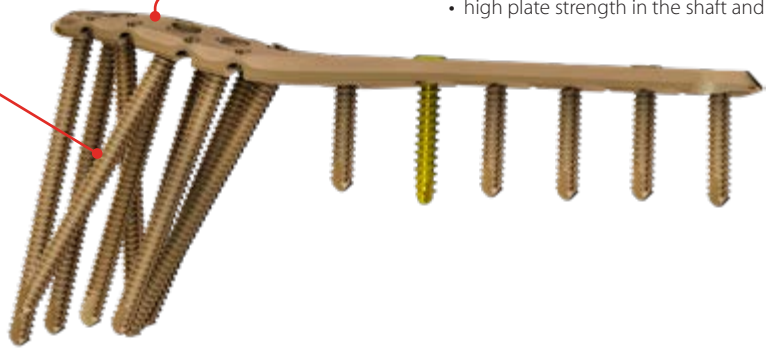
Narrowed plate end
- facilitated minimally invasive insertion

Reinforced long plates
- increased shaft thickness
- for use with fractures extending to the shaft

9 anatomical proximal screws
- reinforced anchoring in the osteoporotic bone
- enhanced fixation in comminuted fractures

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

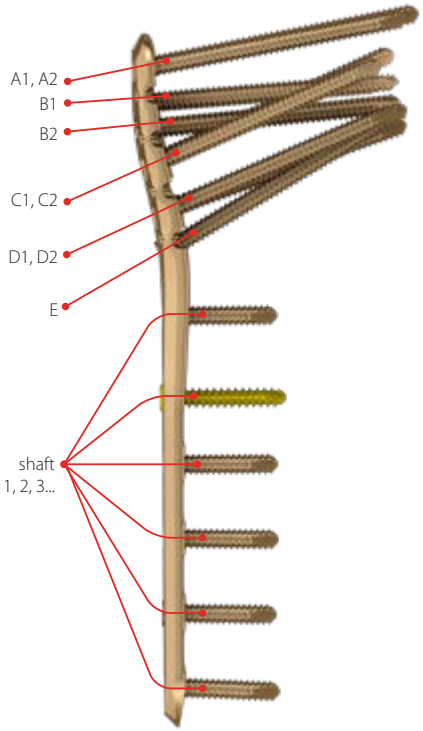
Tapered plate thickness
- minimized soft-tissue irritation in epiphysis
- high plate strength in the shaft and metaphysis

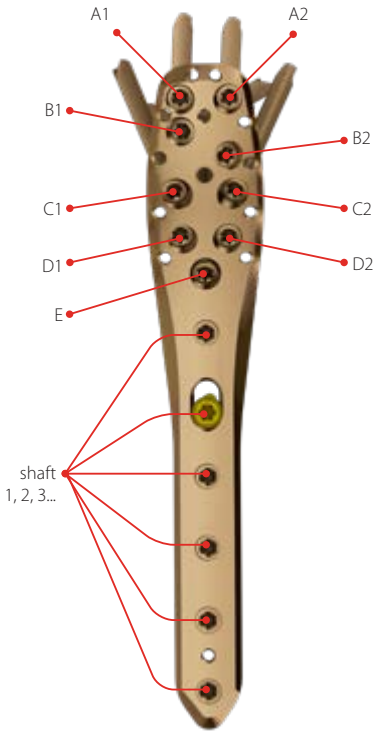


5.0ChLP humerus plate

Proximal locking holes:

Provide flexibility in screws placement, allowing different types of fractures be treated with use of different constructs.

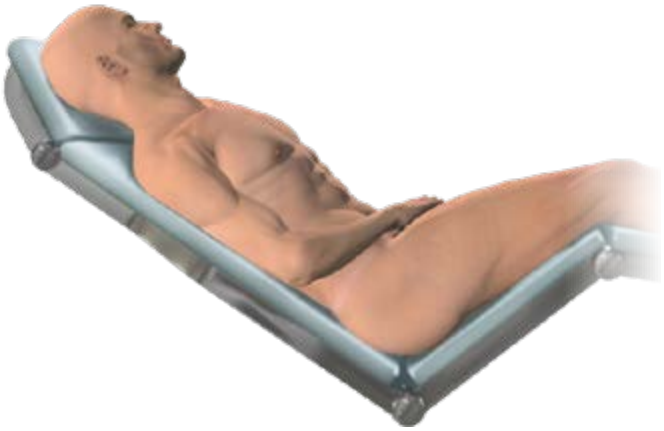




3. SURGICAL TECHNIQUE

3.1. PATIENT'S POSITIONING

A beach-chair position is recommended to provide easy access to the shoulder.



3.2. SURGICAL APPROACH

Deltopectoral approach with the incision between the deltoid and pectoral muscles is recommended.

3.3. FRACTURE REDUCTION

Perform fracture reduction. If need be, temporarily stabilize the bone fragments with Kirschner wires and/or reduction pliers.

Sutures may also be used for achieving the stability of the construct.

3.4. IMPLANT SELECTION

Select the right size of an implant to the type of fracture, bone size and structure.

3.5. USE OF AIMING BLOCK

Attach compatible aiming block to the plate by tightening the fixing screw of the block using screwdriver tip T15 **[40.5677.000]**.

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Most ChLP locking plates are available with aiming blocks as additional supplementary instruments. The use of aiming blocks ensures proper guide sleeves locking in the plate epiphyseal locking holes. Aiming blocks facilitate also the surgery procedure, shorten its time and ensure drilling in the axis of the locking hole.

Not using aiming blocks may lead to improper device implantation. Incorrectly locked screws can cause complications when removing the plates.

3.6. PLATE INSERTION

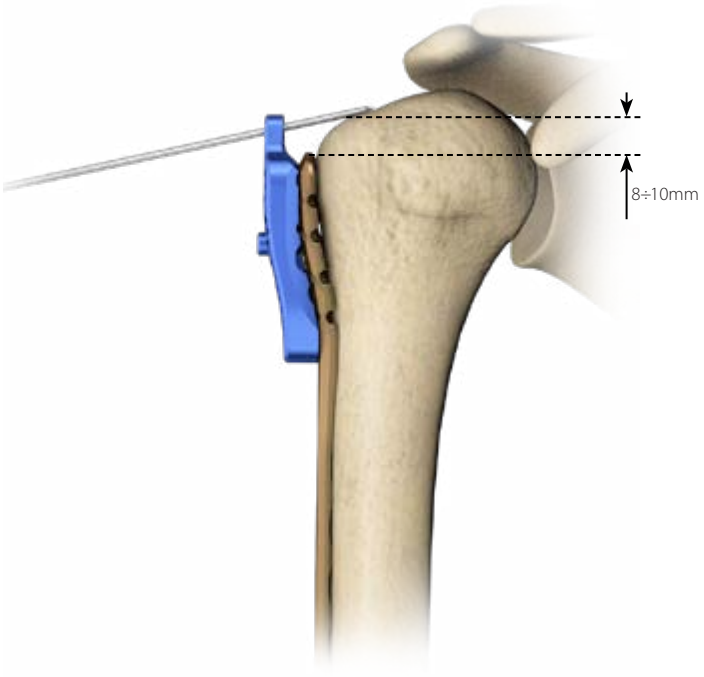
Position the implant on the bone and verify in two planes:

a) Positioning from AP view

The upper edge of the plate should be placed approximately 8÷10 mm distal to the rotator cuff attachment on the upper edge of the greater tuberosity. Placing the plate too high increases the risk of subacromial impingement.

To facilitate plate positioning, introduce Kirschner wire 1.5/210 **[40.4592.210]** through the proximal hole of the aiming block so that the wire rests on top of the humeral head.

	40.4592.210

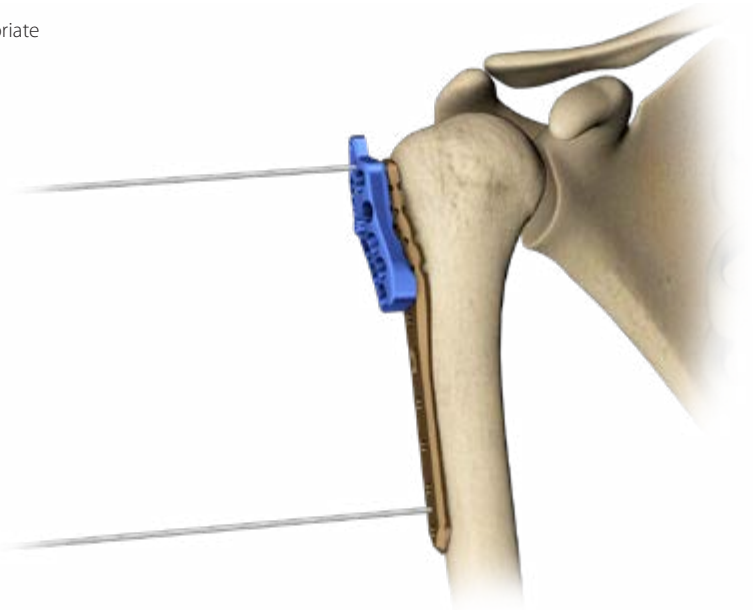


b) Positioning from a lateral view

The plate should be centered against the lateral aspect of the greater tuberosity, i.e. about 3÷5mm against the lateral aspect of bicipital groove.

3.7. TEMPORARY PLATE STABILIZATION

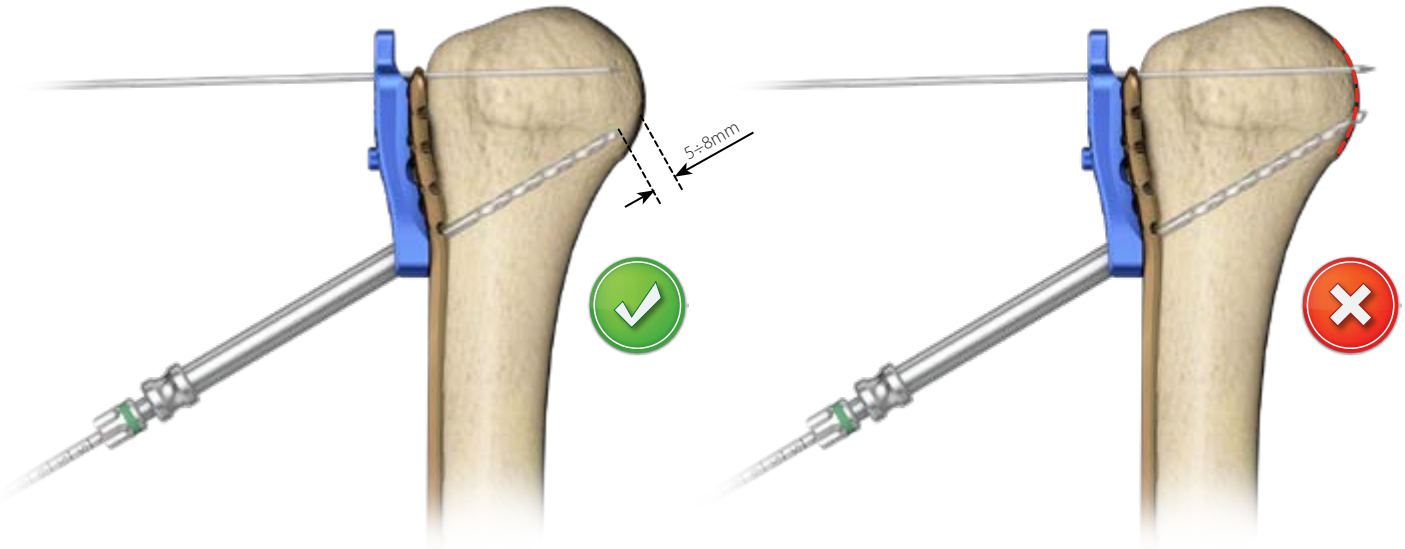
Stabilize the position of the implant inserting Kirschner wires into appropriate holes or using setting-compressing screw *(acc. to procedure 4a)*.



3.8. SCREWS INSERTION

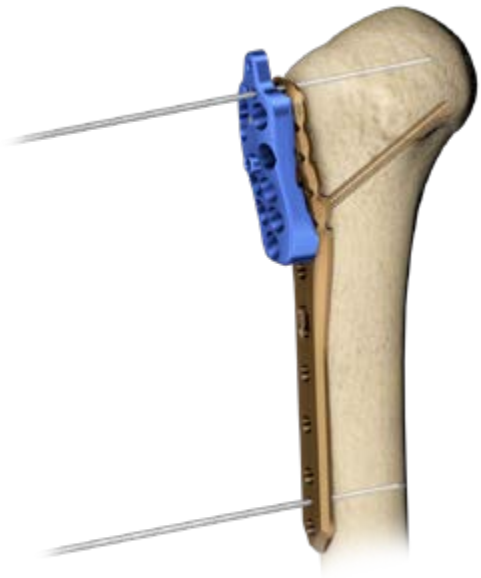
The choice of the first screw to be inserted depends on the fracture type and reduction achieved. Two screws insertion options *(option A and option B)* are described below.

Continue drilling a hole in the humeral head until sub-cartilage bone is reached. It is recommended to drill under X-Ray control. The tip of K-wire or a drill should be placed as close as possible to the sub-cartilage bone, i.e. approx. 5-8 mm from the joint surface. Do not penetrate the joint surface of the humeral head.



3.8.A. OPTION A

This technique permits fixation of the proximal fragments first and then fixation with or without compression distally.



STABILISATION OF HUMERAL EPIPHYSIS

After initial stabilization, compression of the bone fragments of the humeral head and X-Ray control of the plate height, insert the locking screw into the E hole of the plate.

- 5.0ChLP self-tapping screw 3.5 **[3.5200]** *(acc. to procedure 4c)*.

Insert protective guide 7/5 **[40.5672]** into the aiming block hole.

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Insert the remaining locking screws of a suitable length into the proximal locking holes of the plate.

- 5.0ChLP screw VA 3.5 **[3.5236]** *(acc. to procedure 4d)*.

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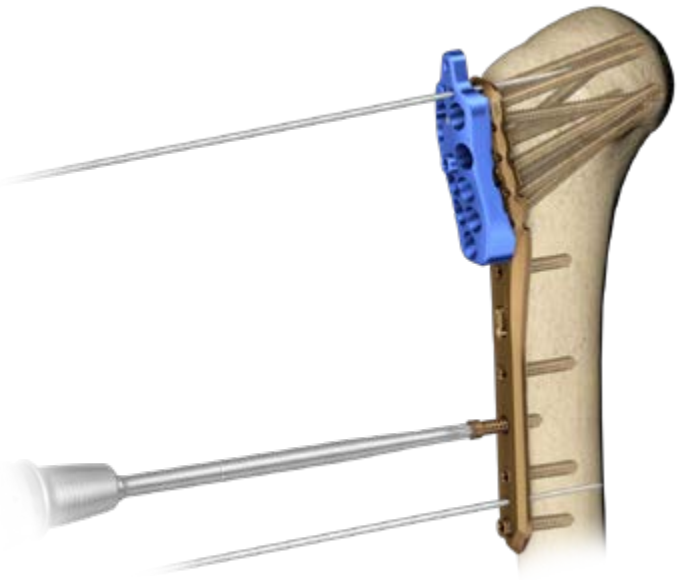
STABILISATION OF HUMERAL SHAFT

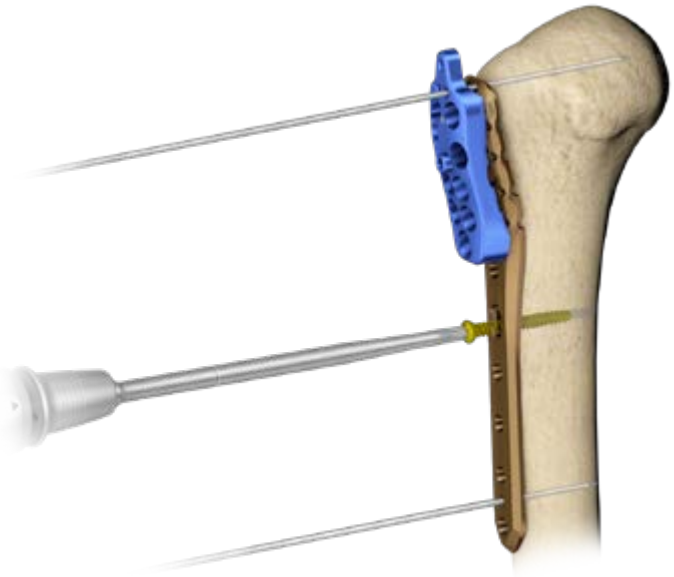
Insert 5.0ChLP self-tapping screw 3.5 **[3.5200]** distally *(acc. to procedure 4c)*.

If necessary, use cortical screws to perform compression of bone fragments prior to inserting the distal locking screws.



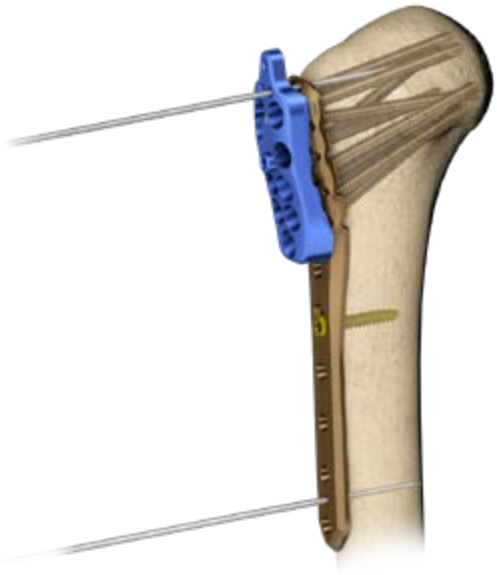
3.8.B. OPTION B

This technique permits reduction of the distal shaft fragment against the plate and a final height adjustment prior to the insertion of the other screws in the shaft.



Cortical self-tapping screw 3.5 insertion

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



Stabilisation of humeral epiphysis

Insert locking screws into the locking holes of the plate.

- 5.0ChLP self-tapping screw 3.5 **[3.5200]** *(acc. to procedure 4c)*.
  Insert protective guide 7/5 **[40.5672]** into the aiming block hole.

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- 5.0ChLP screw VA 3.5 **[3.5236]** *(acc. to procedure 4d)*.

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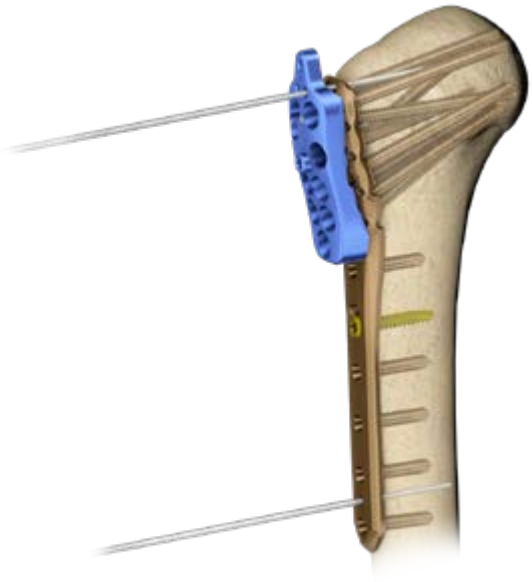
Stabilisation of humeral shaft

Insert remaining 5.0ChLP self-tapping screws 3.5 **[3.5200]** distally *(acc. to procedure 4c)*.



Insert cortical screws 3.5 into a bone fragment before inserting the locking screws.

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

3.9. AIMING BLOCK REMOVAL

Use screwdriver tip T15 **[40.5677.000]** to remove the aiming block from the plate.

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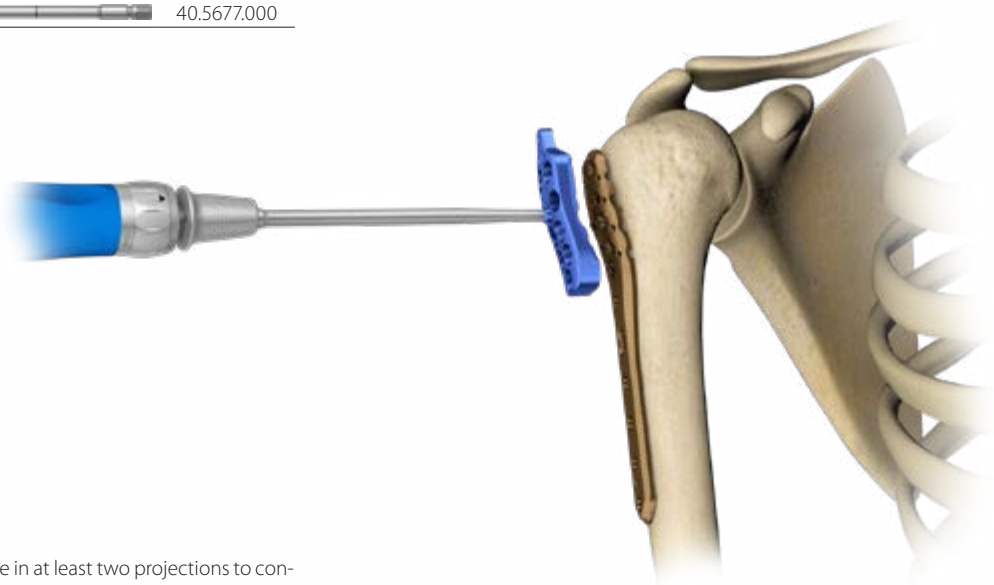


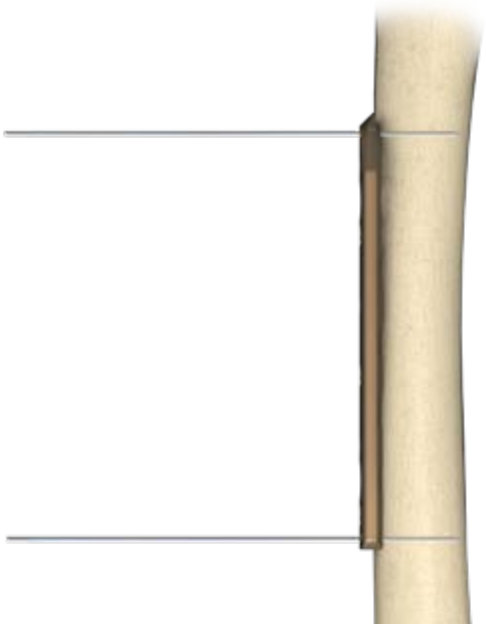
3.10. WOUND CLOSURE

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

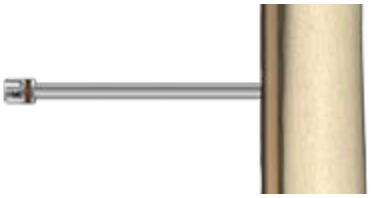
4a. PROCEDURE OF TEMPORARY IMPLANT STABILIZATION



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.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40.5674.728

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

Compression guide positioning

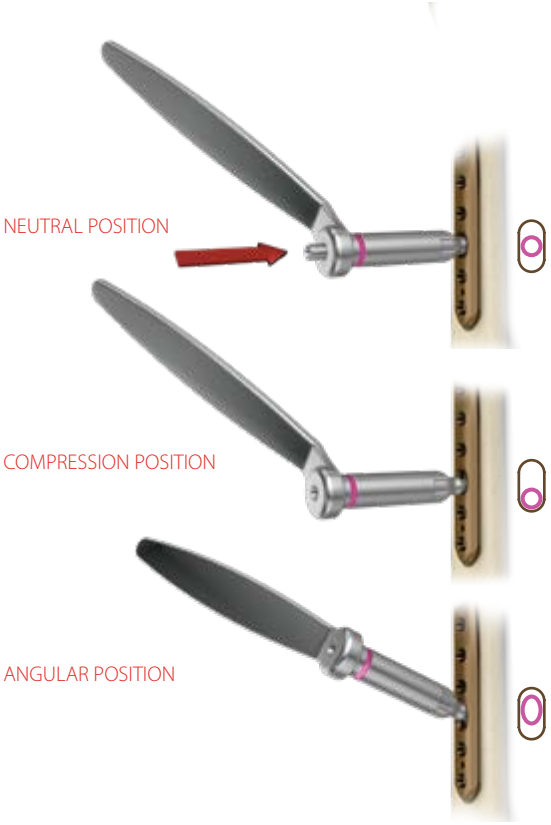
Position the compression guide 2.5 **[40.4804.725]** in a desired position:

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.

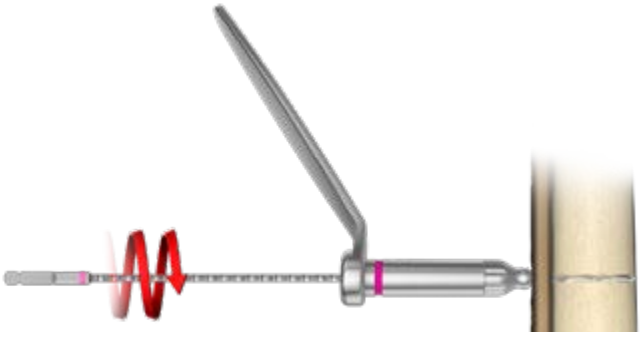
ANGULAR POSITION: Angular position of the guide may also be applied.



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.

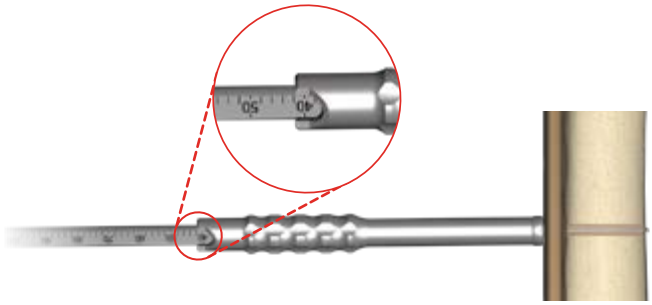
40.5912.212



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]**.

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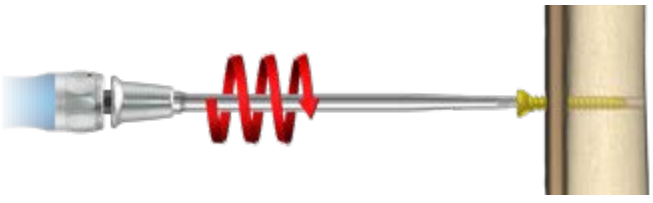

4c. PROCEDURE OF 5.0ChLP SELF-TAPPING SCREW 3.5 [3.5200] INSERTION

Guide sleeve insertion

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


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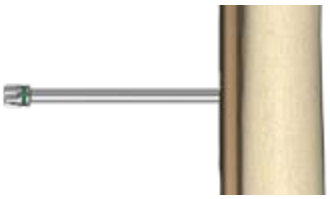
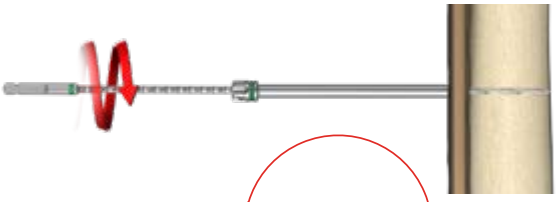


Hole drilling

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

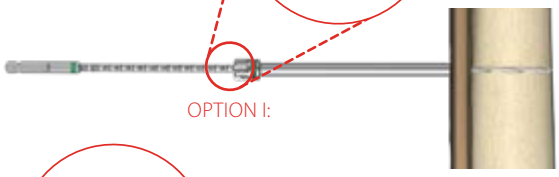
40.5653.212



Measurement of hole depth

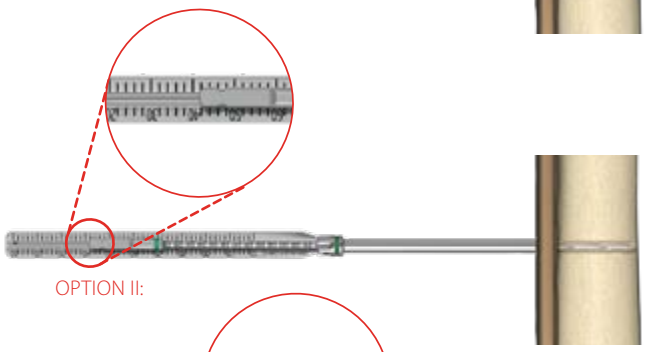
OPTION I: Read the length of the screw from the drill measure **[40.5653.212]**

40.5653.212



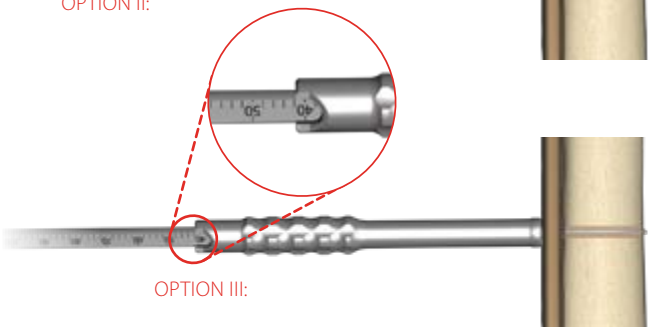
OPTION II: or use screw length measure **[40.5675.500]**.


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.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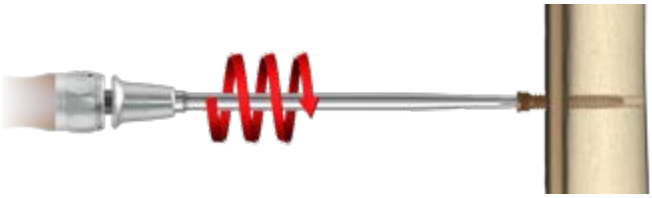


The final tightening of the locking screw, especially when a drive is used, should always be performed with the use of torque limiting handle. Failure to use the torque limiting handle may lead to intraoperative and postoperative complications *(during later removal of the plate and locking screws)*.

4d. PROCEDURE OF 5.0ChLP VA SCREW 3.5 [3.5236] INSERTION

When using variable angle *(VA)* screws, there is a risk of collision of screws or a drill with already implanted screws.
Well-thought-out trajectory of inserted screws and intraoperative X-Ray control of drilling reduces the risk of the collision.

Guide VA positioning

- Insert the guide VA 2.8 **[40.8206.028]** into the locking hole co-axially.
- Set the desired inclination of the guide in relation to the locking hole axis. The guide enables the inclination of 15° in each direction with respect to the axis of the locking hole.

40.8206.028

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

Hole drilling

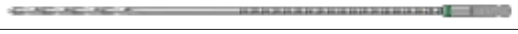
- Drill using drill with scale 2.8/210 **[40.5653.212]** until desired depth is reached.

40.5653.212

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

Measurement of hole depth

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



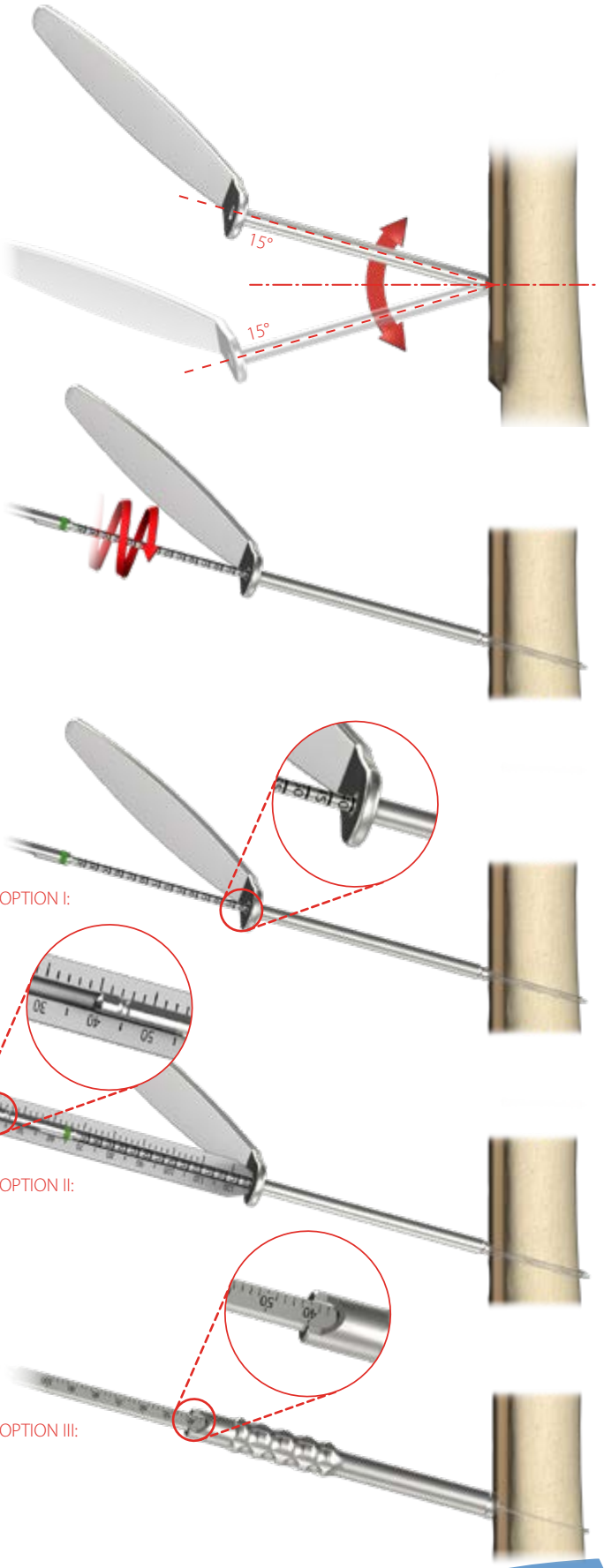
40.5653.212

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

40.5675.500

OPTION III: Having removed the guide VA, use depth measure **[40.4639.550]** to determine the length of the screw.

40.4639.550



Screw insertion

Use torque limiting ratchet handle 2Nm **[40.6652.000]** and screwdriver tip T15 **[40.5677.000]** to insert the VA screw.


40.6652.000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When using torque limiting handle to tighten the VA screw with large inclination in relation to the axis of the locking hole, the head of the screw may protrude above the plate. In this case, it may be necessary to use a handle ratchet device **[40.6654]** and screwdriver tip T15 **[40.5677]**. Use the instruments carefully to tighten the VA screw. Avoid damaging the screw socket or screwdriver tip. Do not insert the screw too deep into the plate.


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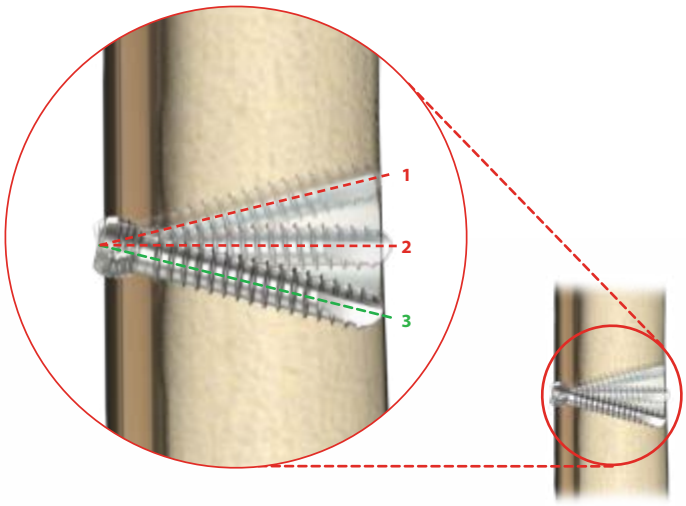

Change of the VA screw positioning

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.

5. POSTOPERATIVE PROCEDURE

Introduce appropriate postoperative treatment. The physician decides on the post-operative treatment and its conduct. In order to avoid patient's movement limitations, introduce exercises as soon after surgery as possible. However, make sure that the limb is not fully loaded before fragments osteosynthesis is complete.

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.

Having cleaned the outer surface of the plate and the screws sockets, it is recommended to attach the aiming block to the plate. Using aiming block and protective sleeve ensures positioning of the screwdriver tip in the axis of the screw, its full placement in the recess, and reduces the risk of twisting the screw while removing.

7. CATALOGUE PAGES

7a. 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

5.0ChLP humerus plate

**	Len	Ti
4	95	3.4034.604
5	108	3.4034.605
6	121	3.4034.606
8	147	3.4034.608*
10	173	3.4034.610*
12	199	3.4034.612*
14	225	3.4034.614*
16	251	3.4034.616*
18	277	3.4034.618*

** - holes number in shaft part of the plate

* - increased thickness of the shaft part

Tray for plates 5.0ChLP 3.4034 4x4 1/2H 14.0205.401

Aiming block 40.5671.000

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

5.0ChLP screw VA 3.5

Len	Co
12	4.5236.012
14	4.5236.014
16	4.5236.016
18	4.5236.018
20	4.5236.020
22	4.5236.022
24	4.5236.024
26	4.5236.026
28	4.5236.028
30	4.5236.030
32	4.5236.032
34	4.5236.034
36	4.5236.036
38	4.5236.038
40	4.5236.040
42	4.5236.042
44	4.5236.044
46	4.5236.046
48	4.5236.048
50	4.5236.050
52	4.5236.052
54	4.5236.054
56	4.5236.056
58	4.5236.058
60	4.5236.060
65	4.5236.065
70	4.5236.070
75	4.5236.075
80	4.5236.080
85	4.5236.085

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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