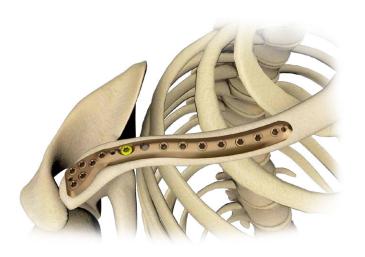




5.0ChLP clavicle S plate 3.7014; 3.7015 3.7048; 3.7049

- SURGICAL TECHNIQUE
- IMPLANTS
- INSTRUMENT SET



www.chm.eu

SYMBOLS DESCRIPTION

Ti	Titanium or titanium alloy	H	H length [mm]
Co	Cobalt		Angle
	Left	88 340	available lengths
R	Right	4-22	Available number of holes
LR	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
\odot	Cannulated		Cancellous
	Locking	Ster Non Ster	Available in sterile/ non- sterile condition
	Diameter [mm]		Refer to surgical technique
\triangle	Caution - pay attention to a special procedure.		
	Perform the activity under X-Ray control.		
i	Information about the next stages of a procedure.		

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

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

www.chm.eu

 Document No
 ST/80-518

 Date of issue
 24.06.2019

 Review date
 P-003-31.03.2022

Proceed to the next stage.

related to the use of the product.

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

Return to the specified stage and repeat the activity.



1. INTRODUCTION	5
2. IMPLANT DESCRIPTION	6
3. SURGICAL TECHNIQUE	
3.1. PATIENT'S POSITIONING	7
3.2. SURGICAL APPROACH	7
3.3, FRACTURE REDUCTION	7
3.4. IMPLANT SELECTION	7
3.5. PLATE INSERTION	8
3.6. TEMPORARY PLATE STABILIZATION	8
3.7. CORTICAL SCREWS INSERTION	8
3.8. LOCKING SCREWS INSERTION	9
3.9. WOUND CLOSURE	9
4. SURGICAL PROCEDURES	10
4.a. PROCEDURE OF TEMPORARY IMPLANT STABILIZATION	10
4.b. PROCEDURE OF CORTICAL SELF-TAPPING SCREW 3.5 [3.1306] INSERTION	11
4.c. PROCEDURE OF 5.0ChLP SELF-TAPPING SCREW 3.5 [3.5200] INSERTION	12
4.d. PROCEDURE OF 4.5ChLP SCREW 2.4 [3.5225] INSERTION	13
4.e. PROCEDURE OF 5.0ChLP SCREW VA 3.5 [4.5236] INSERTION	14
5. POSTOPERATIVE PROCEDURE	16
6. IMPLANT REMOVAL	16
7. CATALOGUE PAGES	17
7.a. INSTRUMENT SET	17
7.b. IMPLANTS	19
7.c. SCREWS	22



1. INTRODUCTION

This surgical technique applies to 5.0ChLP locked plating system used for fracture stabilization of clavicle in its shaft and distal parts. 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

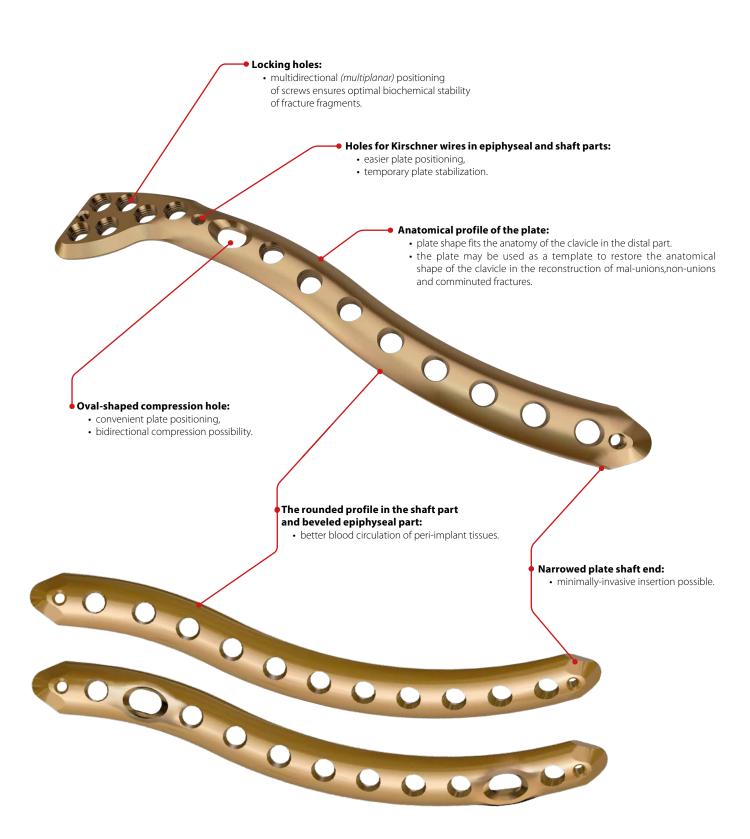
- fractures of the shaft and distal part of the clavicle
- mal-, and non-unions,

Plate selection and shaping

The plates are available in different lengths, separately for right and left side. This allows for optimal selection of the implant to the fracture type. Shaping of the plates in their epiphyseal part is not allowed.

2. IMPLANT DESCRIPTION

Clavicle S 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.



3. SURGICAL TECHNIQUE

3.1. PATIENT'S POSITIONING

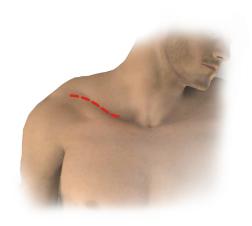
A beach-chair or supine position is recommended. Provide appropriate access to the clavicle for X-Rays imaging.





3.2. SURGICAL APPROACH

Horizontal parallel incision to the clavicle in the supraclavicular fossa or over the clavicular region.



3.3. FRACTURE REDUCTION

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

3.4. IMPLANT SELECTION

Select the right size of an implant to the type of fracture, bone size and structure. Use plate trials to determine the length of the implant.

Plate 3.7014.505 trial Plate 3.7015.505 trial	43.7014.505 43.7015.505
Plate 3.7048.508 trial Plate 3.7049.508 trial	43.7048.508 43.7049.508



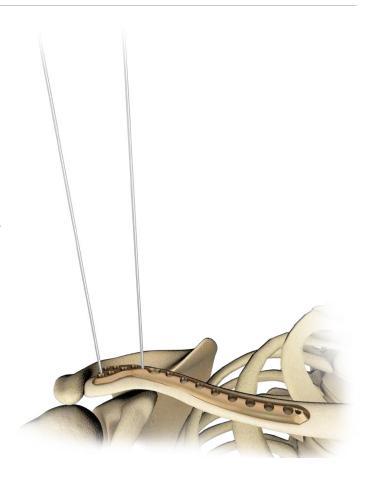


3.5. PLATE INSERTION

Position the implant correctly on the bone.

3.6. TEMPORARY PLATE STABILIZATION

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

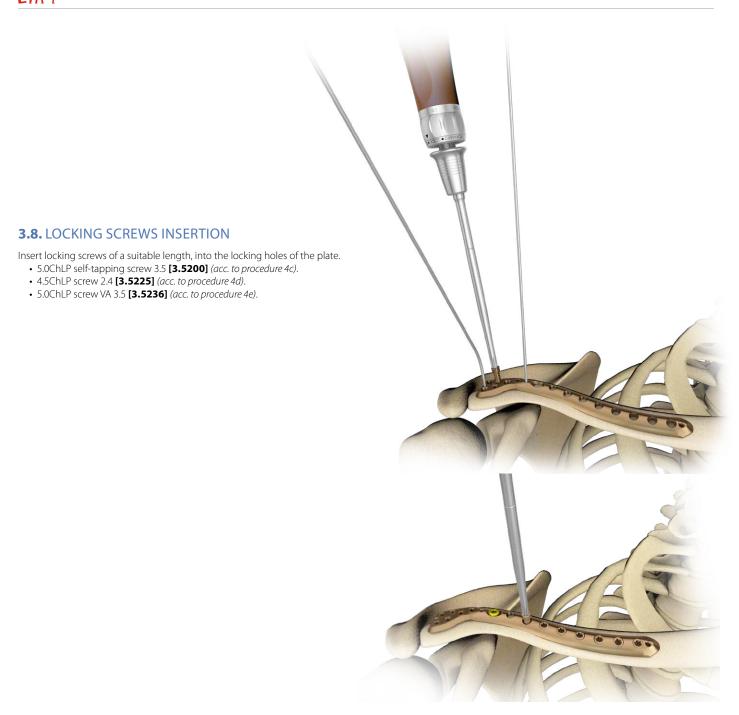


3.7. CORTICAL SCREWS INSERTION

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

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







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.

3.9. 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.

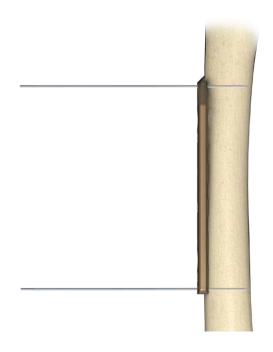
4. SURGICAL PROCEDURES

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.

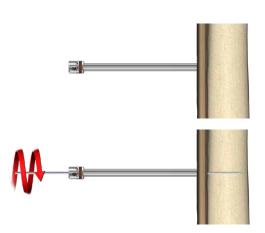
40.4592.210



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]**.

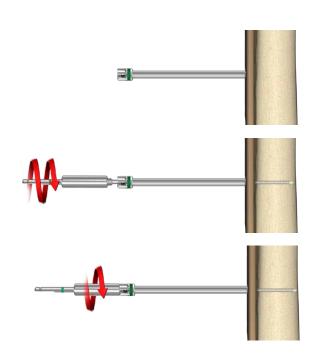




Stabilization using setting-compressing screw

- 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.





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:



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.



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.

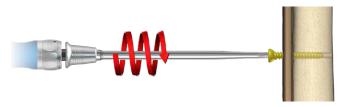




Screw insertion

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



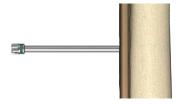


4.c. PROCEDURE OF 5.0ChLP SELF-TAPPING SCREW 3.5 [3.5200] INSERTION

Guide sleeve insertion

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





Hole drilling

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



Measurement of hole depth

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



OPTION II: or use screw length measure [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.



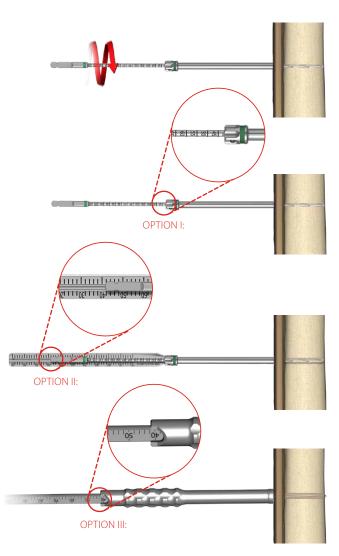
Screw insertion

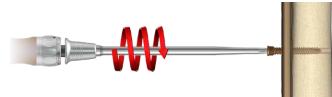
Remove the guide sleeve 5.0/2.8 **[40.5673.728]**. Use torque limiting ratchet handle 2Nm **[40.6652.000]** and screwdriver tip T15 **[40.5677.000]** to insert the locking screw.





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).



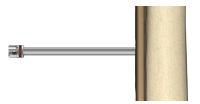


4.d. PROCEDURE OF 4.5ChLP SCREW 2.4 [3.5225] INSERTION

Guide sleeve insertion

• Insert guide sleeve 5.0/1.8 [40.5673.718] into a locking hole of the plate.





Hole drilling

Drill using drill with scale 1.8/210[40.2063.222] until desired depth is reached.





Measurement of hole depth

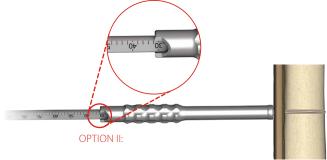
OPTION I: Read the length of the screw from screw length measure [40.5675.500].





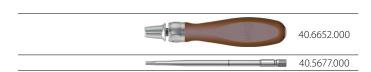
OPTION II: Having removed the guide sleeve 5.0/1.8 **[40.5673.718]**, use depth measure **[40.4639.550]** to determine the length of a screw.

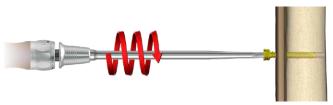




Screw insertion

Remove the guide sleeve 5.0/1.8 **[40.5673.718]**. Use torque limiting ratchet handle 2Nm **[40.6652.000]** and screwdriver tip T15 **[40.5677.000]** to insert the locking screw.





4.e. PROCEDURE OF 5.0ChLP SCREW VA 3.5 [4.5236] 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.

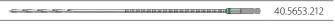




Exceeding the inclination angle of more than 15° may prevent proper locking of the VA screw in the plate hole.

Hole drilling

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





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].

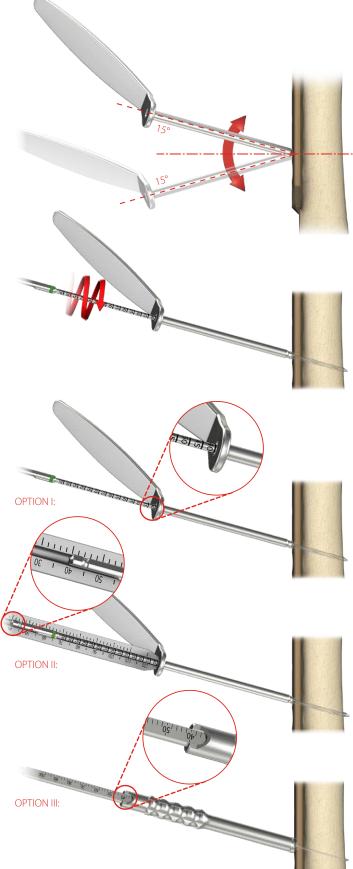


OPTION II: or use screw length measure [40.5675.500].



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







Screw insertion

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

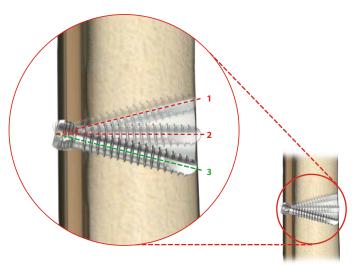






When using torque limiting handle to tighten the VA screw with large inclination in relation to the axis of the locking hole, the head of the screw may protrude above the plate. In this case, it may be necessary to use a handle ratchet device [40.6654] and screwdriver tip T15 [40.5677]. Use the instruments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





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 post-operative 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.



7. CATALOGUE PAGES

7.a. INSTRUMENT SET

Instrument set for 5.0ChLP 4x4 1/2H

15.0205.206

	Name	Catalogue No.	Pcs
The state of the s	Tray for 5.0ChLP instrument set 4x4 1/2H	14.0205.206	1
	Kirschner wire 1.5/210	40.4592.210	4
	Drill 1.8/210	40.2063.212	2
[9 5 10 15 10 15 15 15 15	Drill with scale 2.5/210	40.5912.212	2
N 181 31 31 31 31 31 31 31 31 31 31 31 31 31	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
	Guide VA 2.8	40.8206.028	1
	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

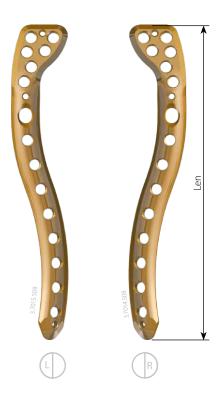
	Name	Catalogue No.	Pcs		
	Tray for 5.0ChLP instrument set 4x4 1/2H	14.0205.202	1		
——————————————————————————————————————	Setting-compressing screw 2.8/180	40.5674.728	1		
	Screw length measure	40.5675.500	1		
	Plates bender 5.0	40.4643.500	2		
	Tripod screwdriver tip 5.0ChLP	40.6271.500	1		
	T15 screwdriver 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		
Optiona	al instrument				
	Torque connector 2Nm	40.5927.020	1		



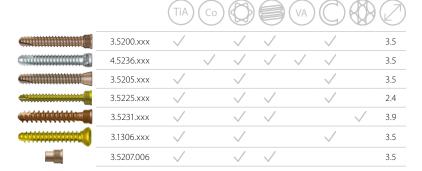
7.b. IMPLANTS

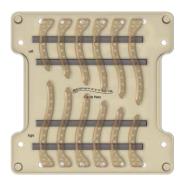


5.0ChLP clavicle S plate



	Len		R
3	71	3.7015.503	3.7014.503
4	80	3.7015.504	3.7014.504
5	90	3.7015.505	3.7014.505
6	99	3.7015.506	3.7014.506
7	108	3.7015.507	3.7014.507
8	116	3.7015.508	3.7014.508
9	125	3.7015.509	3.7014.509
10	134	3.7015.510	3.7014.510
11	143	3.7015.511	3.7014.511





Tray for plates 5.0ChLP 3.7014/3.7015 4x4 1/2H

14.0205.405



Plate 3.7014.505 trial

43.7014.505

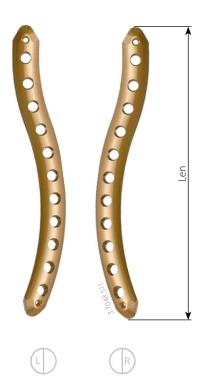
Plate 3.7015.505 trial

43.7015.505

* Tray does not include implants



5.0ChLP clavicle shaft S plate





(5-11)	(
	(1)

	TiA	Co			VA			
3.5200.xxx			_/	_/		_/		3.5
4.5236.xxx		_	_	_	_	_/		3.5
3.5205.xxx			\checkmark			_/		3.5
3.5225.xxx			_/	_/		_/		2.4
3.5231.xxx			_/	/			_/	3.9
3.5207.006	/		/	_/				3.5



Tray for plates 5.0ChLP 3.7048/3.7049 4x4 1/2H 14.0205.406

6

Plate 3.7048.508 trial

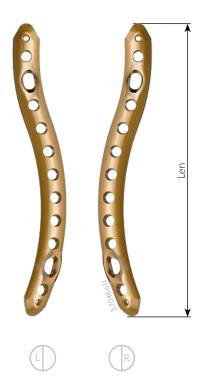
43.7048.508

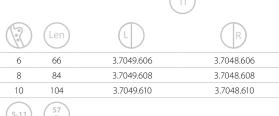
Plate 3.7049.508 trial 43.7049.508





5.0ChLP clavicle shaft S plate





	. \		57
D-1	')	1	114
_			

	TiA	Co			VA			
3.5200.xxx			_/	_/		_/		3.5
4.5236.xxx		_	_	_	_	_/		3.5
3.5205.xxx			_			_		3.5
3.5225.xxx			_	_		_		2.4
3.5231.xxx			/	_			_	3.9
3.1306.xxx	\checkmark		/			_/		3.5
3.5207.006			_					3.5



Tray for plates 5.0ChLP 3.7048/3.7049 4x4 1/2H

14.0205.406

^{*} Tray does not include implants

7.c. SCREWS

(hlpsystem

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			
90	4.5236.090			
95	4.5236.095			

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			

4.5ChLP screw 2.4





Len	Ti
16	3.5225.016
18	3.5225.018
20	3.5225.020
22	3.5225.022
24	3.5225.024
26	3.5225.026
28	3.5225.028
30	3.5225.030
32	3.5225.032
34	3.5225.034
36	3.5225.036
38	3.5225.038
40	3.5225.040
28 30 32 34 36 38	3.5225.028 3.5225.030 3.5225.032 3.5225.034 3.5225.036 3.5225.038

ChM sp. z o.o.

Lewickie 3b 16-061 Juchnowiec Kościelny Poland tel. +48 85 86 86 100 fax +48 85 86 86 101 chm@chm.eu www.chm.eu



C € 0197