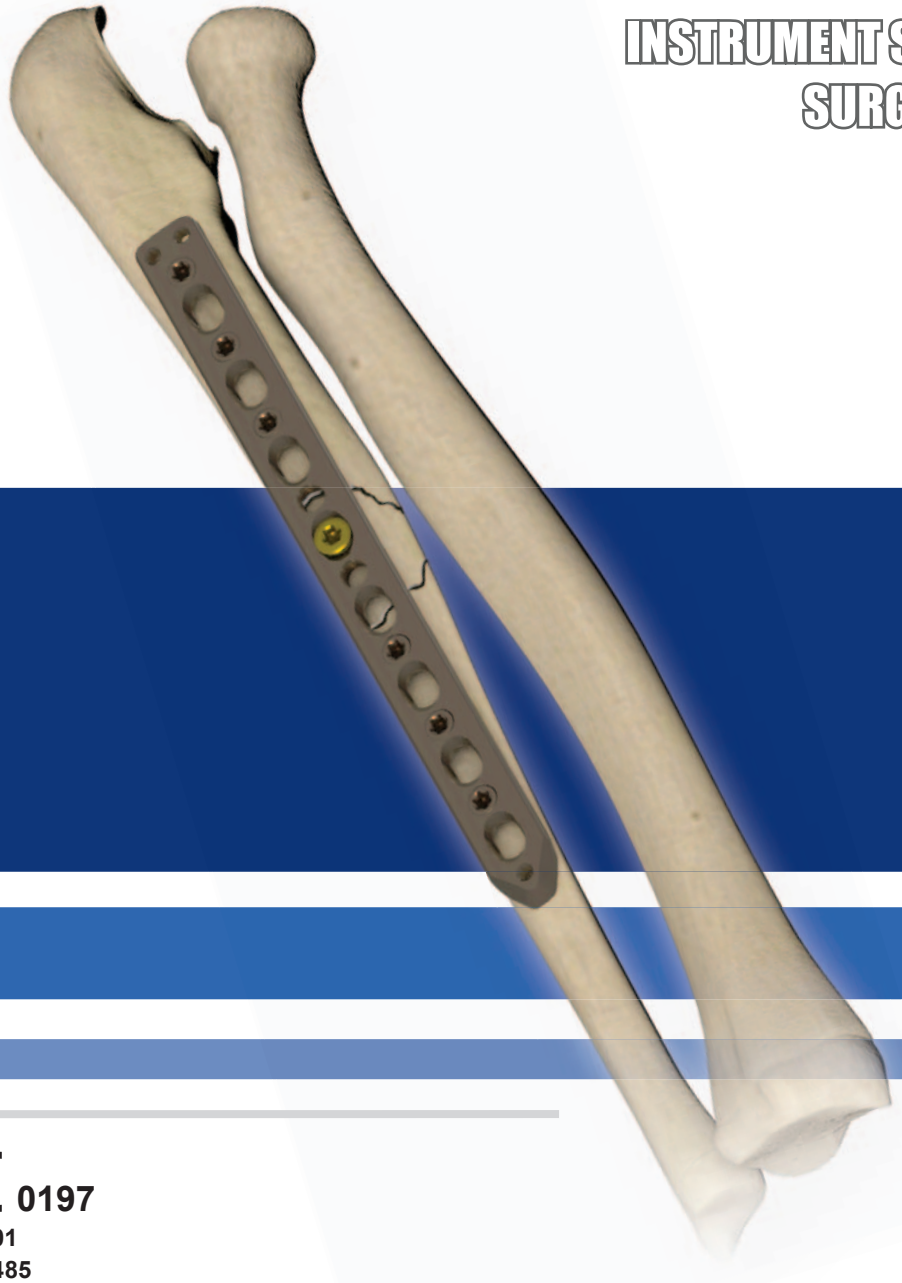
instruction

5.0ChLP STRAIGHT LOCKING PLATE

IMPLANTS ◦
INSTRUMENT SET 40.5923.500 ◦
SURGICAL TECHNIQUE ◦



5,0 ChM Locked Plating ChLP system

57A

CE 0197
ISO 9001
ISO 13485

ChM®

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec K., POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

I. INTRODUCTION

Narrow compression limited contact plate **[3.3157]** is used for the treatment of the fractures of long bones such as the humerus, fibula, the bone of the forearm. The plate is a part of the ChLP locking plates system developed by **ChM** company. The presented range of implants is made of titanium and its alloys in accordance with ISO 5832 standard. Quality Management Systems, ISO 9001:2000, EN ISO 13485:2003 and the compliance with the requirements of Directive 93/42/EEC guarantee high quality of the offered implants.

The system included:
- implants *(narrow compression plate, locking screws and standard cortical screws)*,
- instrument set used for plates implantation,
- surgical technique.

The plate is intended for the treatment of:
- comminuted fractures of the long bones,
- long bones fractures,
- mal-, and non-unions.

Contraindications:
- infections,
- growing children.

Plate selection
A wide range of dimensions of the locking plates system allows plate proper selection.
It is recommended to use longer locking plates. The advantage of longer plates over the shorter ones is more favourable distribution of forces.

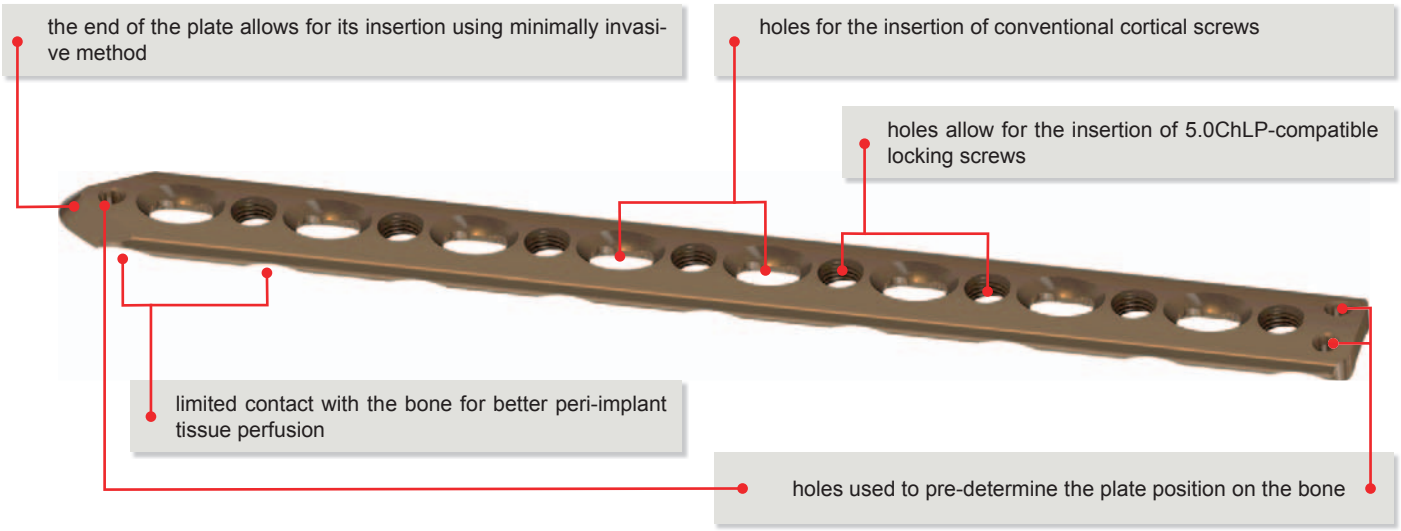
Plate shaping
Shaping of the locking plates in percutaneous method that uses targeters is not allowed. Plate shaping prevents its proper functioning with the targeter.

Before use, read carefully the instructions for use supplied with the product and attached at the end of this document. It contains: indications, contraindications, adverse effects, recommendations, warnings, etc., related to the use of the product.

II. IMPLANTS

Plates **[3.3157]** are a part of the 5.0ChLP system. The system includes plates and screws. Both locking plates and screws are coloured brown.

Plate properties:

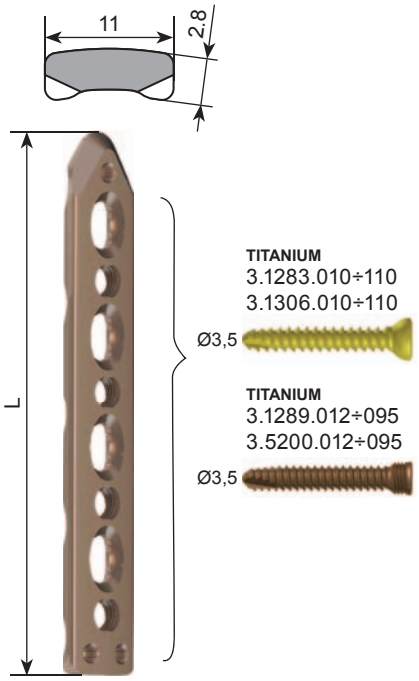


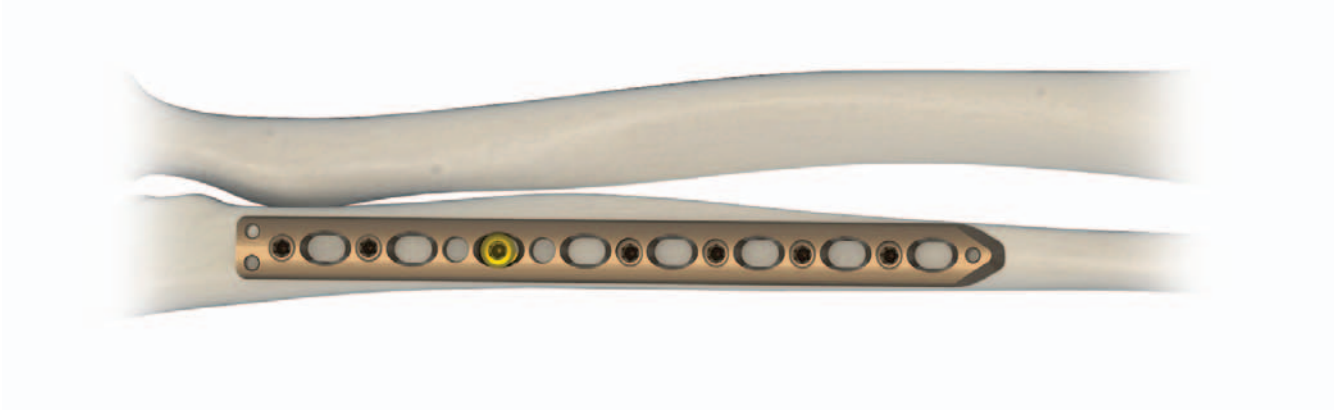
ChM Ltd., Lewickie 3b, 16-061 Juchnowiec K., POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

5.0ChLP narrow compression limited contact plate

O	L [mm]	Catalogue no. TITANIUM
4	73	3.3157.504
5	88	3.3157.505
6	103	3.3157.506
7	118	3.3157.507
8	133	3.3157.508
9	148	3.3157.509
10	163	3.3157.510
11	178	3.3157.511
12	193	3.3157.512
13	208	3.3157.513
14	223	3.3157.514
15	238	3.3157.515
16	253	3.3157.516
17	268	3.3157.517
18	283	3.3157.518

O - total number of threaded holes in the plate





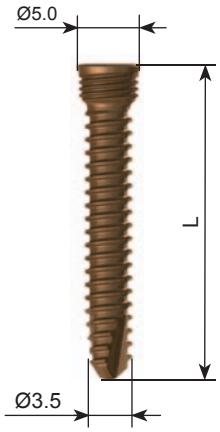
Palette for 5.0ChLP straight plates

No.	Catalogue no.	Name	Pcs.	
1	40.5758.050	Palette for 5.0ChLP straight plates	1	40.5758.550
2	12.0751.100	Container with solid bottom 1/2 306x272x85mm	1	
3	12.0751.200	Perforated aluminum lid 1/2 306x272x15mm gray	1	

implants not included

LOCKING ELEMENTS

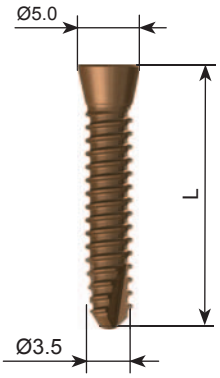
5.0ChLP Screw Ø3.5



self-tapping

L [mm]	Catalogue no. TITANIUM	
12	3.1289.012	3.5200.012
14	3.1289.014	3.5200.014
16	3.1289.016	3.5200.016
18	3.1289.018	3.5200.018
20	3.1289.020	3.5200.020
22	3.1289.022	3.5200.022
24	3.1289.024	3.5200.024
26	3.1289.026	3.5200.026
28	3.1289.028	3.5200.028
30	3.1289.030	3.5200.030
32	3.1289.032	3.5200.032
34	3.1289.034	3.5200.034
36	3.1289.036	3.5200.036
38	3.1289.038	3.5200.038
40	3.1289.040	3.5200.040
42	3.1289.042	3.5200.042
44	3.1289.044	3.5200.044
46	3.1289.046	3.5200.046
48	3.1289.048	3.5200.048
50	3.1289.050	3.5200.050
52	3.1289.052	3.5200.052
54	3.1289.054	3.5200.054
56	3.1289.056	3.5200.056
58	3.1289.058	3.5200.058
60	3.1289.060	3.5200.060
65	3.1289.065	3.5200.065
70	3.1289.070	3.5200.070
75	3.1289.075	3.5200.075
80	3.1289.080	3.5200.080
85	3.1289.085	3.5200.085
90	3.1289.090	3.5200.090
95	3.1289.095	3.5200.095

5,0 ChLP Conical screw Ø3.5



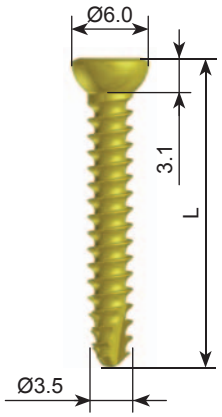
self-tapping

L [mm]	Catalogue no. TITANIUM	
18	3.1290.018	3.5205.018
20	3.1290.020	3.5205.020
22	3.1290.022	3.5205.022
24	3.1290.024	3.5205.024
26	3.1290.026	3.5205.026
28	3.1290.028	3.5205.028
30	3.1290.030	3.5205.030
35	3.1290.035	3.5205.035
40	3.1290.040	3.5205.040
45	3.1290.045	3.5205.045
50	3.1290.050	3.5205.050
55	3.1290.055	3.5205.055
60	3.1290.060	3.5205.060
65	3.1290.065	3.5205.065
70	3.1290.070	3.5205.070
75	3.1290.075	3.5205.075
80	3.1290.080	3.5205.080
85	3.1290.085	3.5205.085
90	3.1290.090	3.5205.090

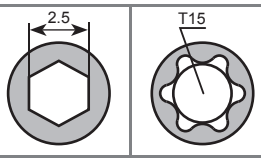
Ø core		**2.8**
Ø drill with scale	**40.5653.300**	**2.8**
guide sleeve	**40.4884.028**	**5.0/2.8**
screwdriver tip	**40.5676.200**	**S2.5**
screwdriver tip	**40.5677.200**	**T15**
tap	**40.5925.000**	**3.5**
protective guide	**40.4885.050**	**7.0/5.0**

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec K., POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

Cortical screw Ø3.5



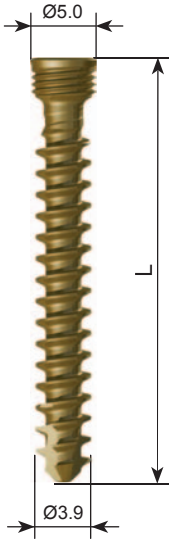
self-tapping



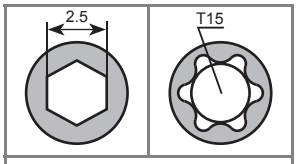
L [mm]	Catalogue no. TITANIUM	
10	3.1283.010	3.1306.010
12	3.1283.012	3.1306.012
14	3.1283.014	3.1306.014
16	3.1283.016	3.1306.016
18	3.1283.018	3.1306.018
20	3.1283.020	3.1306.020
22	3.1283.022	3.1306.022
24	3.1283.024	3.1306.024
26	3.1283.026	3.1306.026
28	3.1283.028	3.1306.028
30	3.1283.030	3.1306.030
32	3.1283.032	3.1306.032
34	3.1283.034	3.1306.034
36	3.1283.036	3.1306.036
38	3.1283.038	3.1306.038
40	3.1283.040	3.1306.040
45	3.1283.045	3.1306.045
50	3.1283.050	3.1306.050
55	3.1283.055	3.1306.055
60	3.1283.060	3.1306.060
65	3.1283.065	3.1306.065
70	3.1283.070	3.1306.070
75	3.1283.075	3.1306.075
80	3.1283.080	3.1306.080
85	3.1283.085	3.1306.085
90	3.1283.090	3.1306.090
95	3.1283.095	3.1306.095
100	3.1283.100	3.1306.100
105	3.1283.105	3.1306.105
110	3.1283.110	3.1306.110

Ø core		2.4
Ø drill with scale	40.5912.300	2.5
guide sleeve	40.4893.025	6.0/2.5
screwdriver tip	40.5676.200	S2.5
screwdriver tip	40.5677.200	T15
tap	40.5926.000	HA3.5
protective guide	40.4892.060	8.0/6.0

5.0ChLP Cancellous screw Ø3.9



self-tapping



L [mm]	Catalogue no. TITANIUM	
30	3.1379.030	3.5231.030
35	3.1379.035	3.5231.035
40	3.1379.040	3.5231.040
45	3.1379.045	3.5231.045
50	3.1379.050	3.5231.050
55	3.1379.055	3.5231.055
60	3.1379.060	3.5231.060
65	3.1379.065	3.5231.065
70	3.1379.070	3.5231.070
75	3.1379.075	3.5231.075
80	3.1379.080	3.5231.080
85	3.1379.085	3.5231.085
90	3.1379.090	3.5231.090

Ø core		2.5
Ø drill with scale	40.5912.300	2.5
guide sleeve	40.4884.025	5.0/2.5
screwdriver tip	40.5676.200	S2.5
screwdriver tip	40.5677.200	T15
protective guide	40.4885.050	7.0/5.0

Stand for screws 5.0ChLP

No.	Catalogue no.	Name	Pcs.	
1	40.5748.400	Stand for 5.0ChLP screws	**1**	**40.5748.700**
2	12.0751.102	Container with solid bottom1/2 306x272x135mm	1	
3	12.0751.200	Perforated aluminum lid 1/2 306x272x15mm Gray	1	

implants not included

40.5748.600

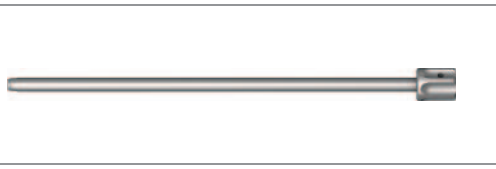
40.5748.700

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec K., POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

III. INSTRUMENTS

5.0ChLP Instrument set *(percutaneous)*

40.5923.500

No.		Name	Catalogue no.	Pcs.
1		Fixation sleeve 5.0/2.8	**40.4878.000**	2
2		Guide sleeve 5.0/2.0	**40.4884.020**	2
3		Guide sleeve 5.0/2.5	**40.4884.025**	2
4		Guide sleeve 5.0/2.8	**40.4884.028**	4
5		Guide sleeve 6.0/2.5	**40.4893.025**	2
6		Protective guide 7.0/5.0	**40.4885.050**	4
7		Protective guide 8.0/6.0	**40.4892.060**	2
8		Trocar 5.0	**40.4886.050**	1
9		Trocar 6.0	**40.4894.060**	1
10		Setting-compressing screw 2.8/160	**40.4875.000**	2
11		Screw length measure	**40.5700.000**	1
12		Drill with scale 2.5/300	**40.5912.300**	2
13		Drill with scale 2.8/300	**40.5653.300**	2
14		Kirschner wire 2.0/300	**40.4815.300**	8
15		Tap 5.0ChLP -3.5	**40.5925.000**	1
16		Cortical tap HA 3.5	**40.5926.000**	1
17		Screwdriver tip S2.5	**40.5676.200**	1
18		Screwdriver tip T15	**40.5677.200**	1
19		Torque handle 2.0Nm	**40.5635.100**	1
20		Raspatory long	**40.5627.000**	1
21		Connector AO-5.0ChLP	**40.4898.050**	1
22		Targeter end cap	**40.4887.000**	15
23		Stand for instrument set of 5.0ChLP *(percut.)*	**40.5924.400**	1
24		Container with solid bottom 1/1 595x275x86mm	**12.0523.000**	1
25		Perforated aluminum cover 1/1 595x275x15mm gray	**12.0524.000**	1

5.0ChLP Instrument set *(percutaneous)* **-straight plates**
40.5921.500

No.		Name	Catalogue no.	Pcs.
1		Targeter for straight plate-handle	**40.5919.000**	1
2		Targeter for straight plate-arm	**40.5920.000**	1
5		Stand for inst.set of 5.0ChLP(percut.)-str.plates	**40.5922.400**	1
6		Container with solid bottom 1/2 306x272x85mm	**12.0751.100**	1
7		Perforated aluminum lid 1/2 306x272x-15mm gray	**12.0751.200**	1

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec K., POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

IV. SURGICAL TECHNIQUE

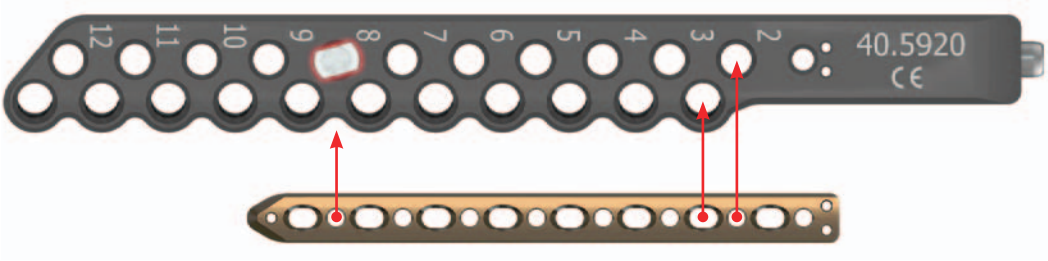
IV.1. FRACTURE REDUCTION

It is necessary to perform accurate anatomical fracture reduction prior to applying plates with locking screws. Reduce and temporarily stabilize the fracture fragments using Kirschner wires and / or reduction forceps.

Confirm the correct positioning of the fragments using X-Ray..

IV.2. TARGETER HOLES MARKING

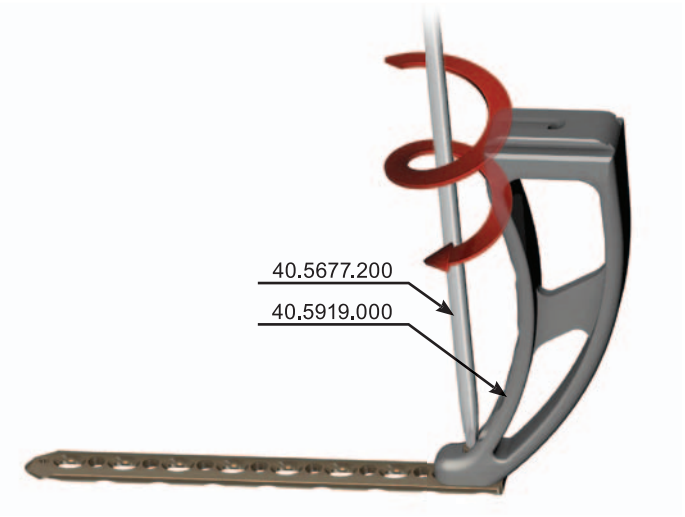
On the targeter beam, the holes corresponding to the holes of the plate 3.3157 are marked with numbers 2÷12. The hole located closer to the number is used to insert 5.0ChLP locking screw and the other one is used to insert the cortical screw 3.5. .



Note:
Use end cap [40.4887.000] to mark in the targeter arm the last locking hole of the plate.

IV.3. ATTACHING PLATE TO THE TARGETER

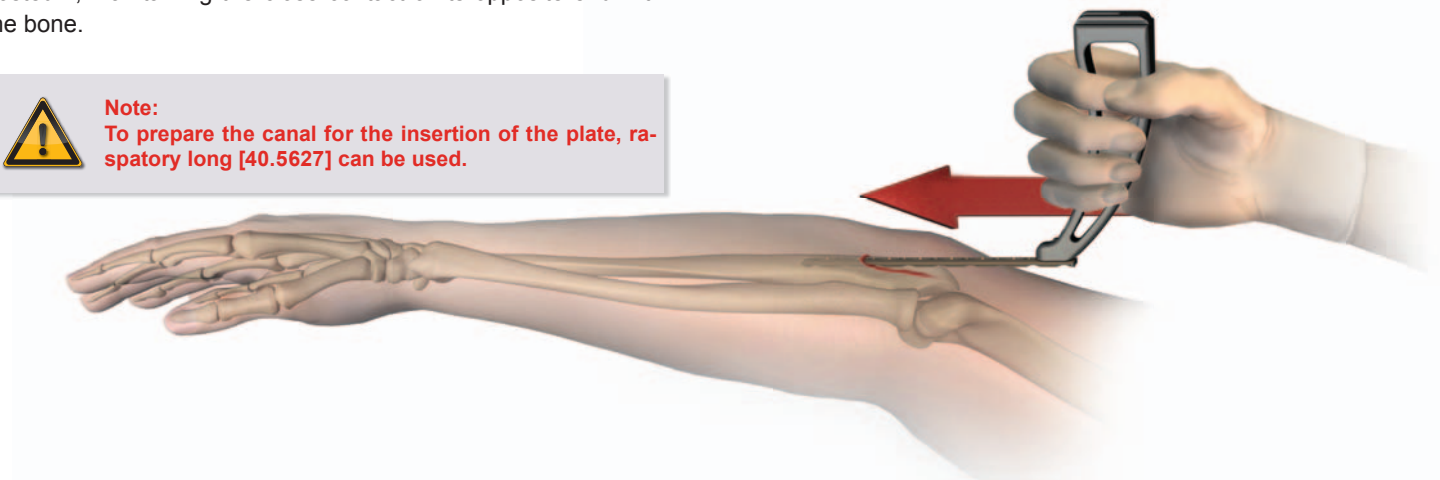
Attach targeter for straight plate-handle **[40.5919.000]** and tighten up the setting screw..



IV.4. PLATE INSERTION

Enter the plate on the bone between the muscle and the periosteum, maintaining the close contact of its opposite end with the bone.

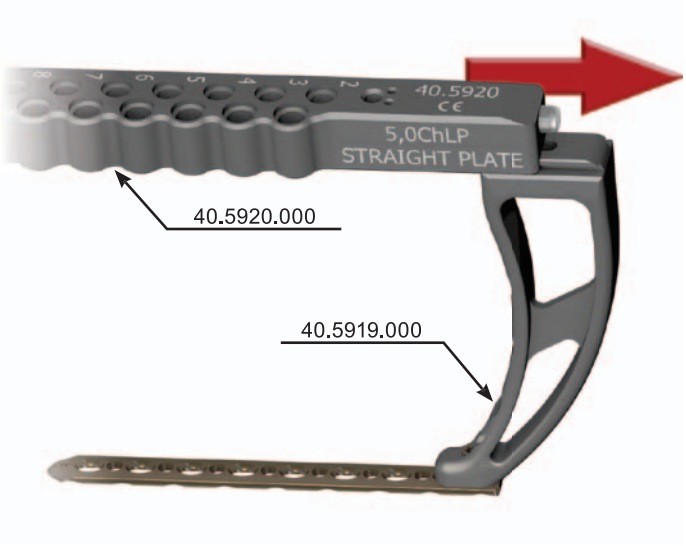
Note:
To prepare the canal for the insertion of the plate, raspatory long [40.5627] can be used.



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

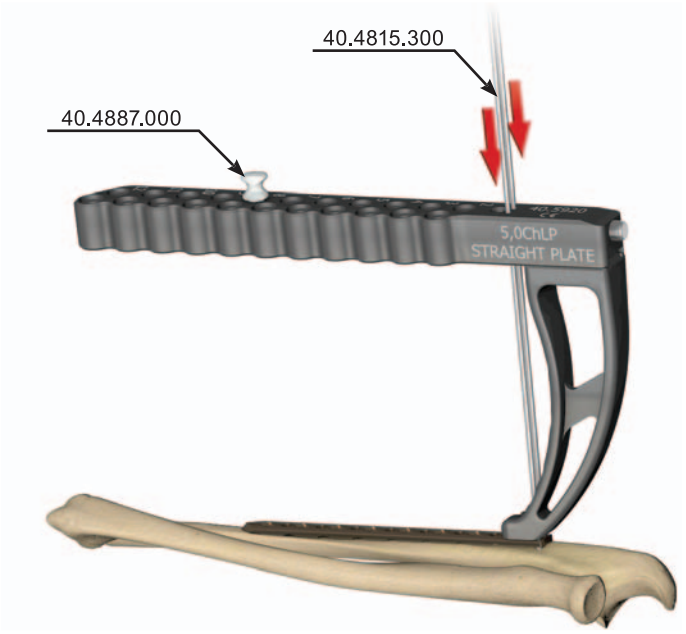
IV.5. TARGETER ASSEMBLY

By pressing the lock button, slide the targeter arm **[40.5920]** in the targeter handle **[40.5919]** until the targeter lock closure - correct arm position. Release the lock button.



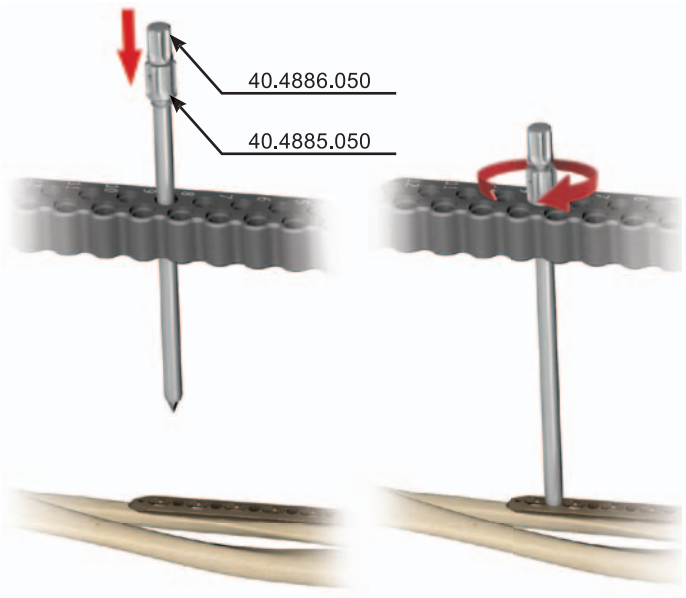
IV.6. TEMPORARY PLATE STABILIZATION

Insert Kirschner wire 2.0/300 **[40.4815.300]** through the holes in the targeter to obtain a provisional stabilization of the plate at the targeter holder..



IV.7. ARRANGEMENT OF THE PLATE WITH THE TARGETER

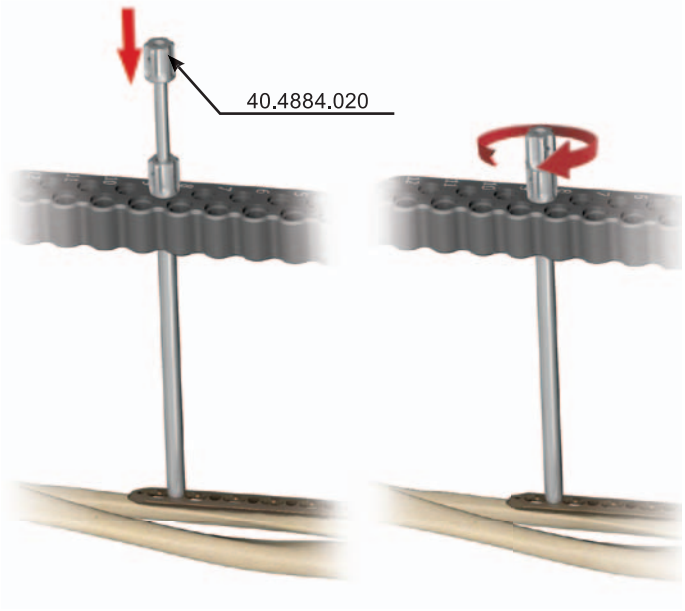
In the marked last locking hole insert protective guide 7.0/5.0 **[40.4885.050]** with trocar 5.0 **[40.4886.050]** and mark the incision place. Perform a small incision and push trocar with protective guide to the plate. Lock the guide in the targeter arm.



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

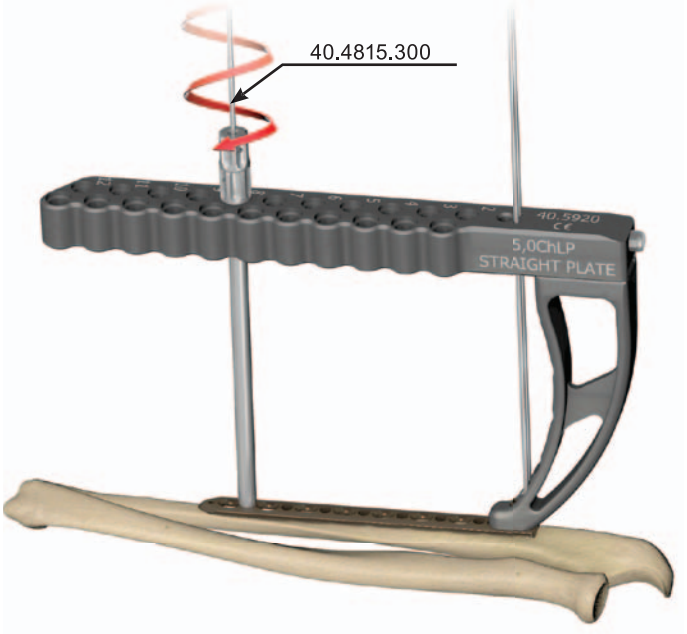
ChM Ltd., Lewickie 3b, 16-061 Juchnowiec K., POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

Remove the trocar 5.0 **[40.4886.050]** and enter the guide sleeve 5.0/2.0 **[40.4884.020]**. Lock the sleeve in the locking hole of the plate to receive the rigid plate-targeter system structure.



IV.8. TEMPORARY STABILIZATION

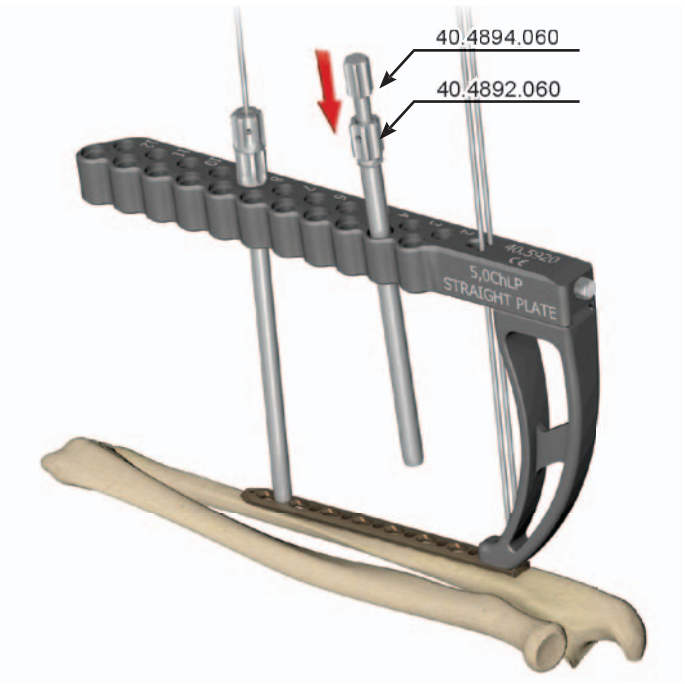
Insert Kirschner wire 2.0/300 **[40.4815.300]** through guide sleeve 5.0/2.0 **[40.4884.020]** to obtain the provisional stabilization of the plate.



IV.9. CORTICAL SCREW 3.5 INSERTION TECHNIQUE

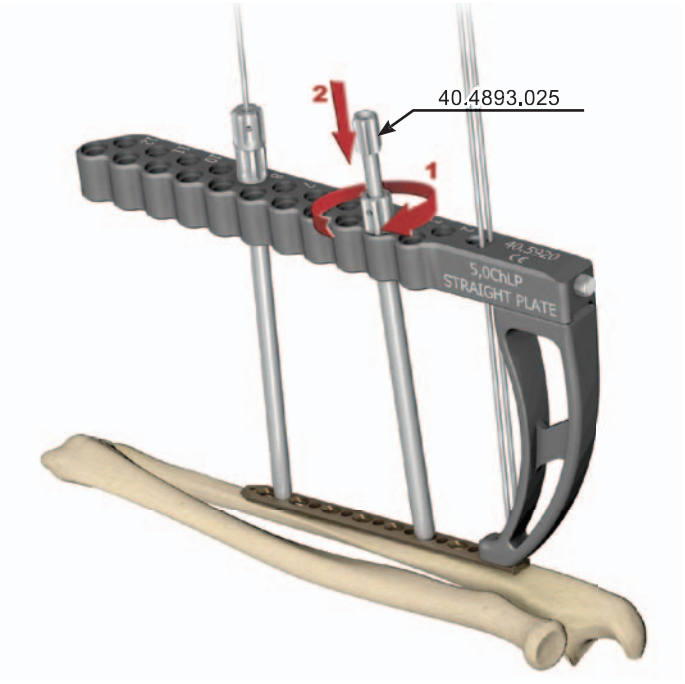
Insert cortical screws 3.5 **[3.1306.010÷110]** to the desired plate holes as described below.

a) Insert protective guide 8.0/6.0 **[40.4892.060]** and trocar 6.0 **[40.4894.060]** in a chosen hole in the targeter and mark the incision point. Perform a small incision and push trocar with protective guide to the plate..



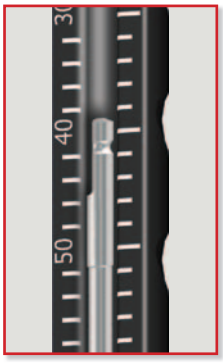
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

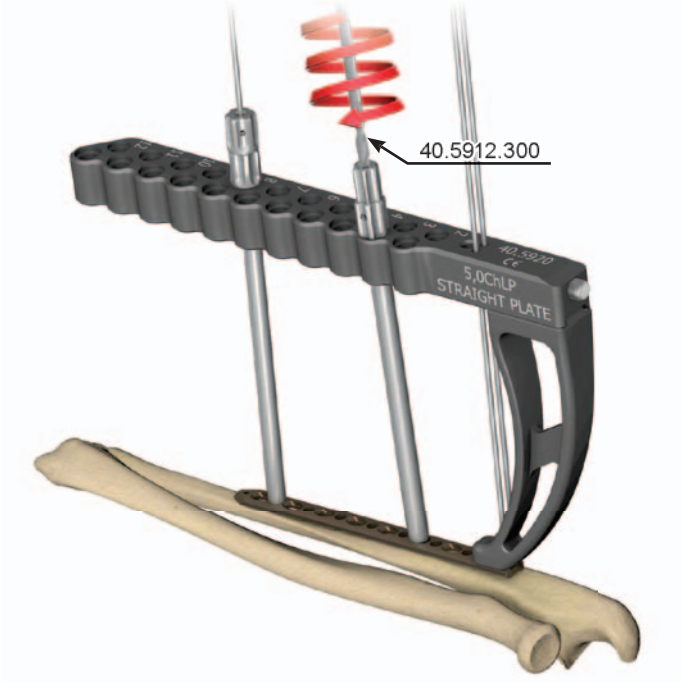
b) Lock the protective guide 8.0/6.0 **[40.4892.060]** in the targeter arm. Remove the trocar 6.0 and insert guide sleeve 6.0/2.5 **[40.4893.025]**.



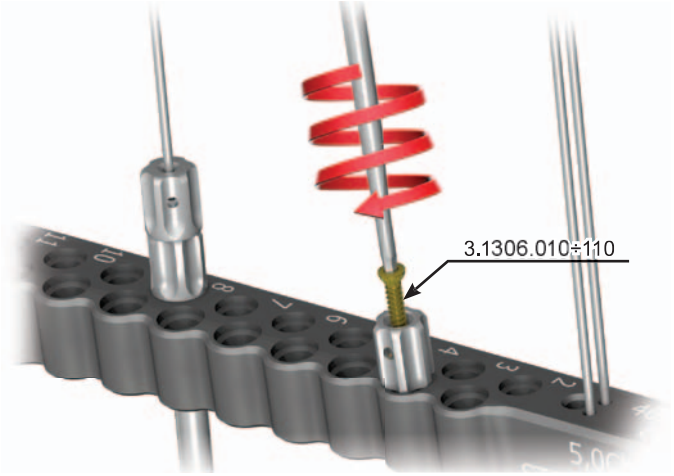
c) Drill using drill with scale 2.5/300 **[40.5912.300]** through both cortical layers.i

Determine the length of the screw on the basis of the scale on the drill or with the help of the screw length measure [40.5700].





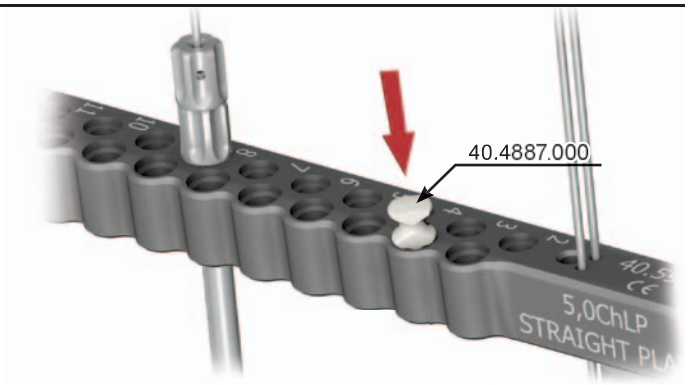
d) Remove the guide sleeve 6.0/2.5 **[40.4893.025]** and insert the self-tapping cortical screw 3.5 **[3.1306.010÷110]**.



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

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec K., POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

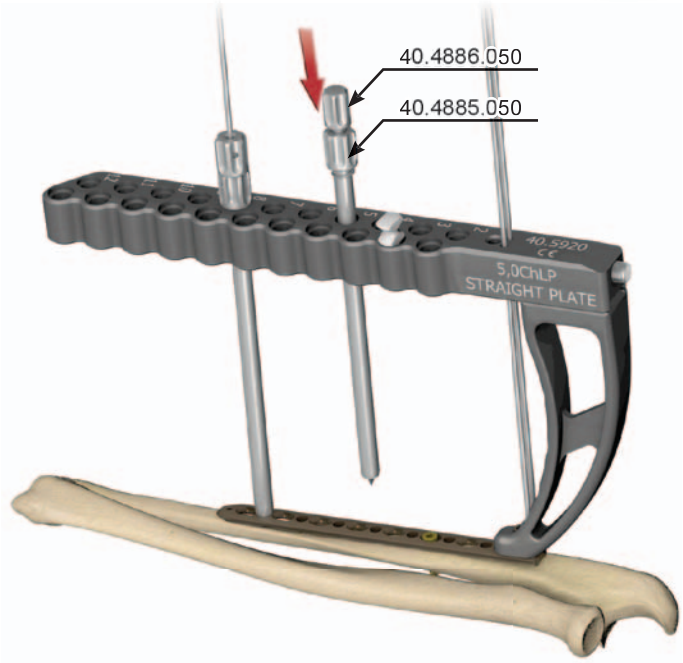
e) Remove the protective guide 8.0/6.0 **[40.4892.060]** and mark the hole using end cap.



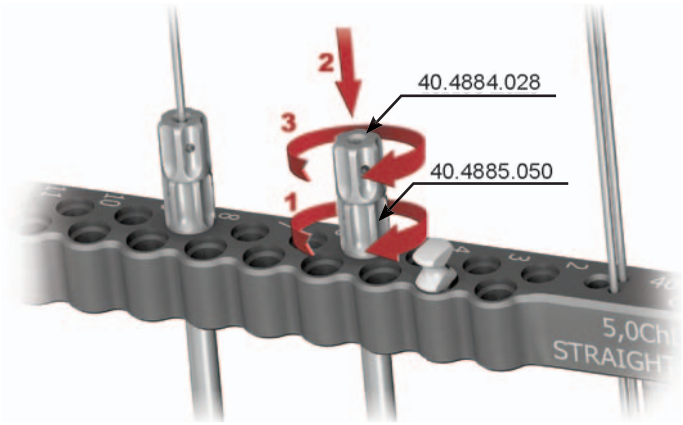
IV.10. LOCKING SCREW INSERTION TECHNIQUE

Insert 5.0ChLP screws 3.5 **[3.5200.012÷095]** to the desired plate holes as described below.

a) Insert protective guide 7.0/5.0 **[40.4885.050]** and trocar 5.0 **[40.4886.050]** in a chosen hole in the targeter and mark the incision point. Perform a small incision and push trocar with protective guide to the plate.

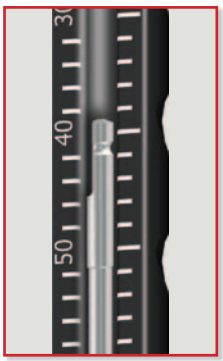


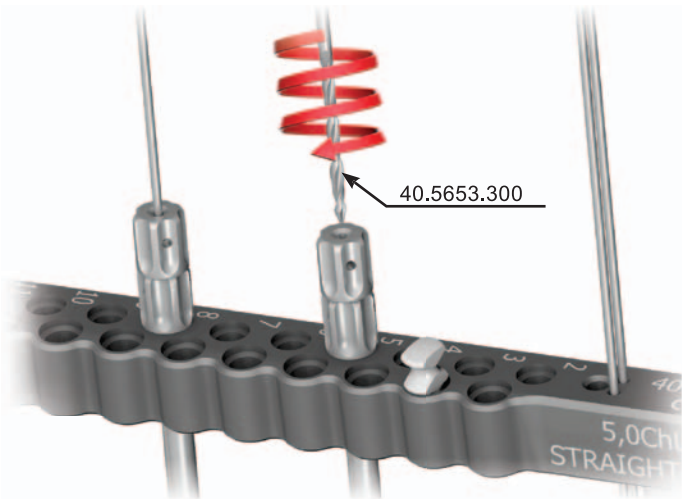
b) Lock the protective guide 7.0/5.0 **[40.4885.050]** in the targeter arm. Remove the trocar 5.0 and insert guide sleeve 5.0/2.8 **[40.4884.028]**. Tighten it up and lock in the plate hole.



c) Drill using drill with scale 2.8/300 **[40.5653.300]**.

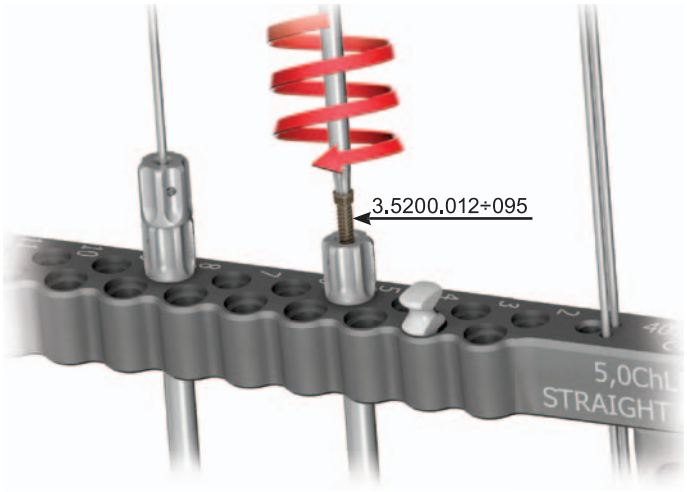
Determine the length of the screw on the basis of the scale on the drill or with the help of the screw length measure **[40.5700]**.



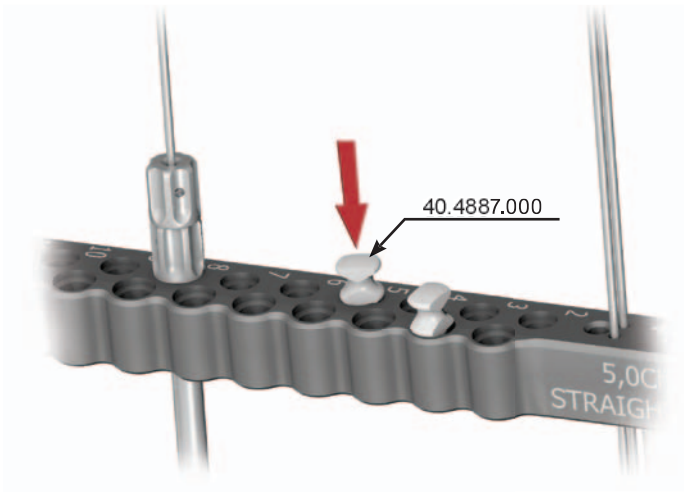


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

d) Insert the 5.0ChLP screw 3.5 **[3.5200.012÷095]**.



e) Remove the protective guide 7.0/5.0 **[40.4885.050]** and mark the hole using end cap **[40.4887]**



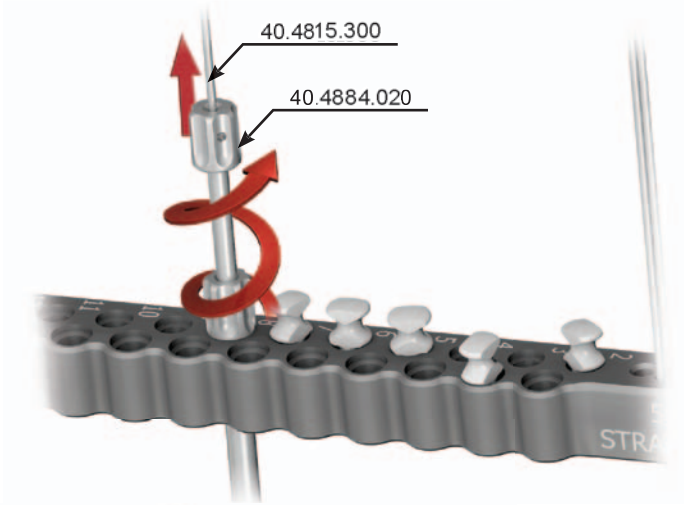
Similarly insert other locking screws

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

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec K., POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

IV.11. LOCKING SCREW INSERTION IN THE LAST PLATE HOLE

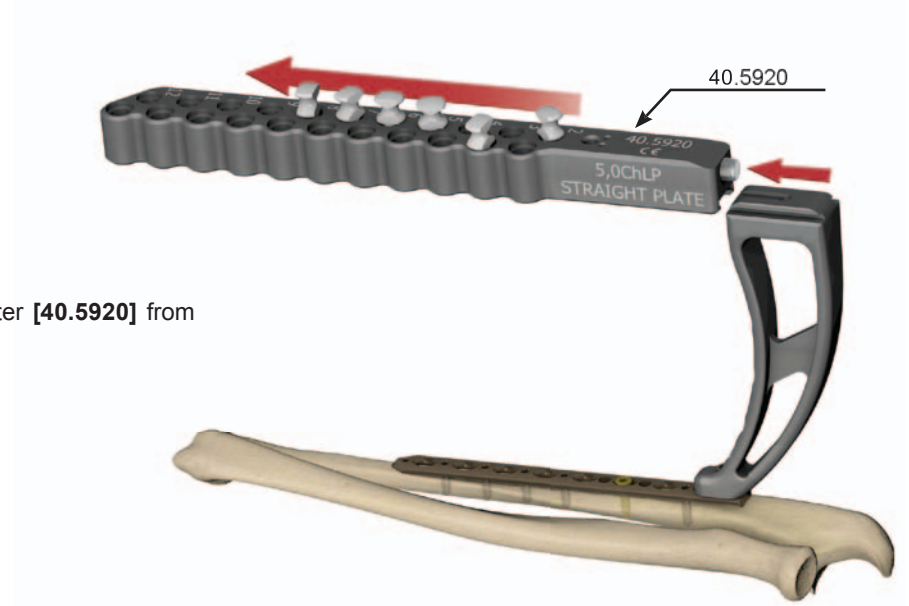
Remove Kirschner wire 2.0/300 **[40.4815.300]** and guide sleeve 5.0/2.0 **[40.4884.020]**



Insert 5.0ChLP screw as described in chapter IV.9

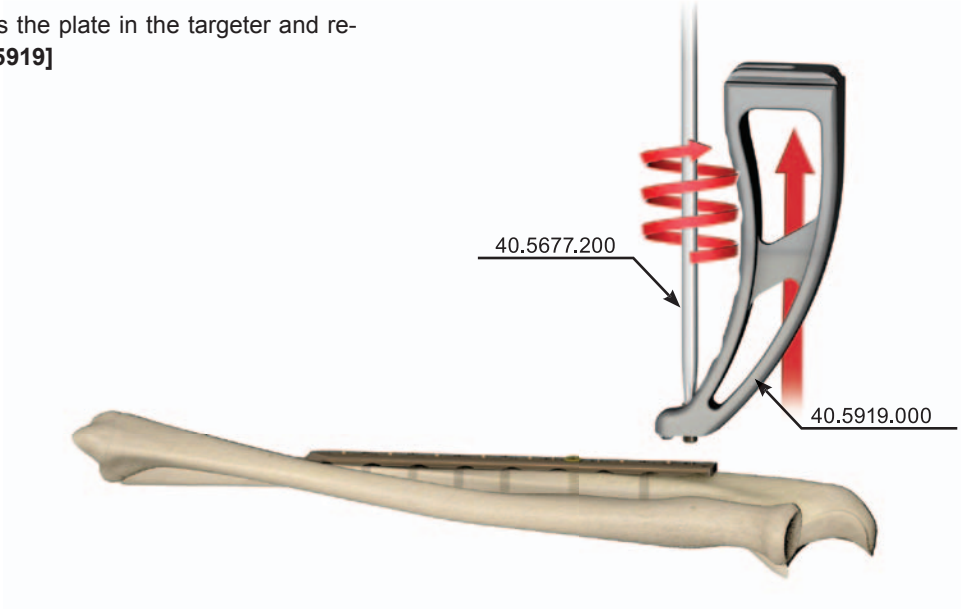
IV.12. TARGETER DISASSEMBLY

Press the lock button and pull out the targeter **[40.5920]** from the holder.



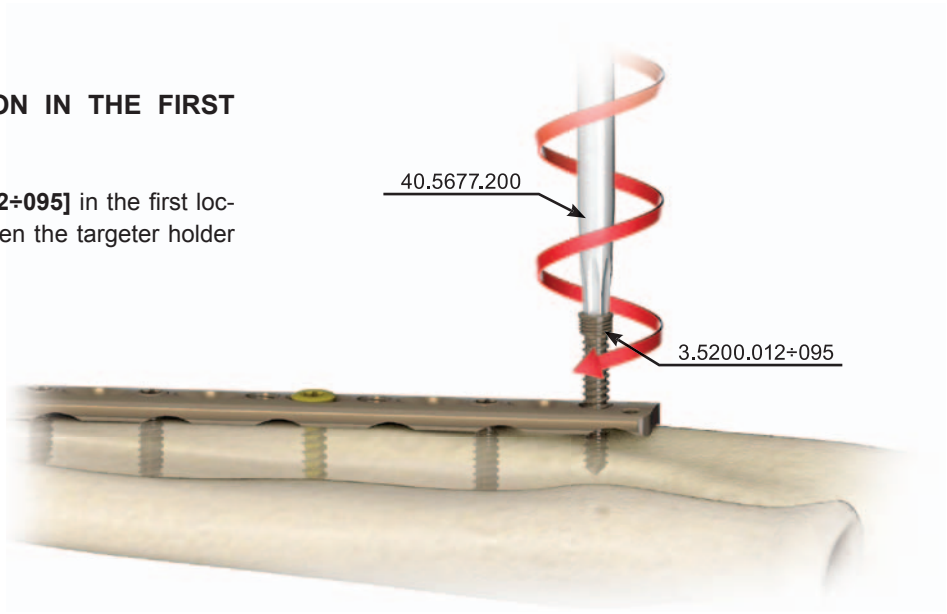
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

Loosen the screw that secures the plate in the targeter and remove the targeter handle **[40.5919]**



IV.13. LOCKING SCREW INSERTION IN THE FIRST HOLE OF THE PLATE

Insertion of the locking screw **[3.5200.012÷095]** in the first locking hole of the plate is possible only when the targeter holder **[40.5919]** is removed.



IV.14. WOUND CLOSURE

Use the appropriate surgical technique for closing the wound. Before closing, make sure that all screws are properly tightened.

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

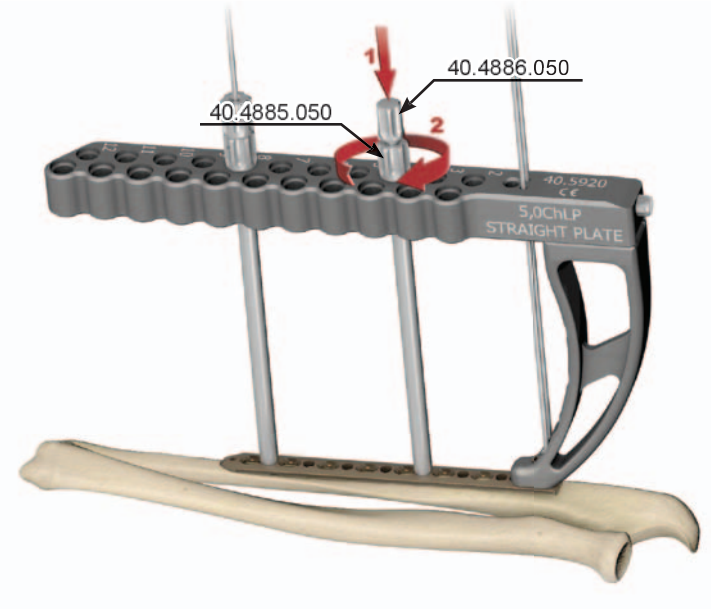
ChM Ltd., Lewickie 3b, 16-061 Juchnowiec K., POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

V. GENERAL COMMENTS

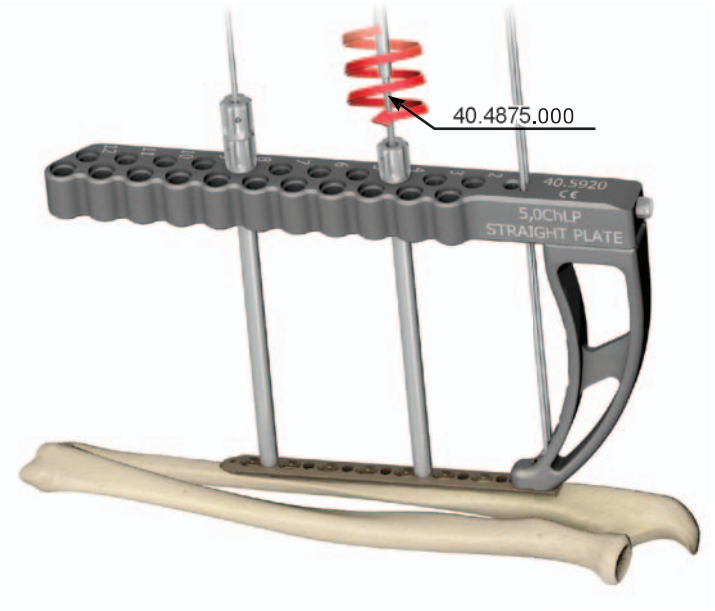
V.1. THE USE OF SETTING-COMPRESSING SCREW

Setting-compressing screw 2.8/160 **[40.4875]** may be used to tighten or loosen the bone fragments in relation to the plate. It stabilizes the plate position against the major fragments and allows for additional corrections before the insertion of the locking screws. A 5.0ChLP screw **[3.5200]** may be inserted in the hole after removing the setting-compressing screw.

a) Insert protective guide 7.0/5.0 **[40.4885.050]** and trocar 5.0 **[40.4886.050]** in a hole in the targeter. Perform a small incision and push trocar with protective guide to the plate. Lock the protective guide 7.0/5.0 **[40.4885.050]** in the targeter arm.

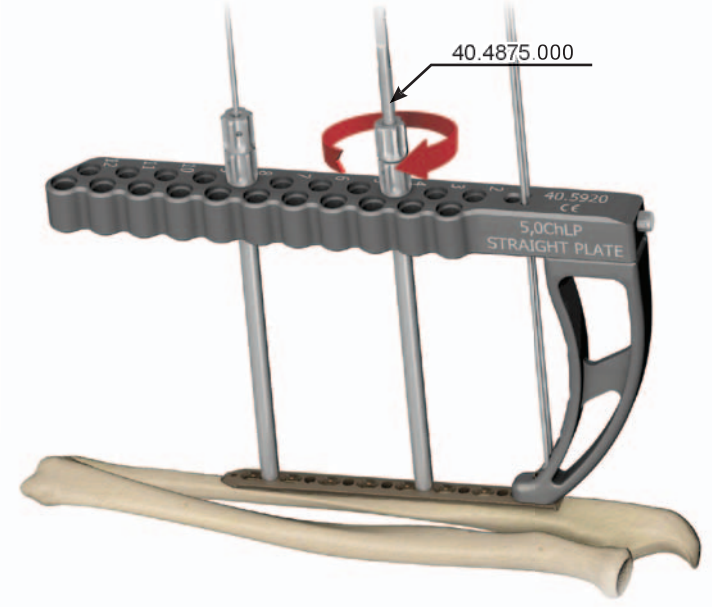


b) Remove the trocar 5.0 and insert self-drilling and self-tapping tip of the setting-compressing screw 2.8/160 **[40.4875]**.



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

c) Tighten the screw of setting-compressing screw **[40.4875]** under X-Ray control until the desired bone fragments setting is achieved.



VI. POSTOPERATIVE RECOMMENDATIONS

Recommendations are similar as for standard surgical techniques of internal fixation. To avoid restrictions in the patient's movement, exercises should be introduced as soon as possible after the surgery. However, it is necessary not to overload the limb before the complete fracture union.

VII. IMPLANT REMOVAL

The implant may be removed only after full healing of fracture and reconstruction of the intramedullary canal.

a) Make the incision over the plate end at the targeter handle mounting.
b) Apply the targeter handle **[40.5919]** to facilitate removal of the plate.
c) Remove the screws via small incisions

Remember to unlock all locking screws from the plate first and then remove them completely.

d) Holding the targeter **[40.5919]**, remove the plate.

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

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec K., POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

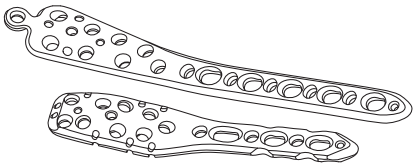
GB

ISO 9001/ ISO 13485

CE 0197

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

IFU-010/14



ChM Locked Plating ChLPsystem

GB

INSTRUCTIONS FOR USE

Important product information for

LOCKING PLATES AND SCREWS

STERILE R

PURPOSE AND INDICATIONS

Locking Plates Systems are intended for surgical treatment of diaphysis and epiphysis fractures and for arthrodesis.

Indications for implantation:
- comminuted fractures,
- transverse fractures,
- spiral fractures,
- compression fractures,
- delayed union of fractures.

Locking Plates are to be implanted with specified screws which are listed in **ChM** Ltd Product Catalogue.

ChM Ltd does not recommend any specific treatment method for a particular patient.

CONTRAINDICATIONS

- *Infection or inflammation in the operative site.*
- *Suspected or documented allergy or intolerance to implant materials. When material sensitivity is suspected, testing is to be completed before implant insertion.*
- *Blood supply limitation in fracture site or in operative site.*
- *Any patient having inadequate tissue coverage of the operative site.*
- *Insufficient bone quality (caused by illness, infection or prior implantation) that does not provide proper implant mounting/stabilization.*
- *Morbid obesity (according to the W.H.O. standards) – would cause implant or fixation failure.*
- *Neuromuscular disorder which would create unacceptable risk of fixation failure or complications in postoperative care.*
- *Any other condition which would preclude the potential benefit of implant usage and disturb the normal process of bone remodeling, e.g. the presence of tumors or congenital abnormalities, elevated ESR or high CRP unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.*
- *Any patient unwilling to cooperate with postoperative instructions; mental illness, a condition of senility or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the implant usage.*
- *Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.*
- *Any case where the implant components selected for use would be too large or too small to achieve a successful result.*
- *Any situation in which the implant usage would interfere with the anatomical structures or physiological performance.*
- *Any situation in which the implant usage should be considered (e.g. pregnancy).*
- *Any other medical conditions which exclude the potential benefits of surgery.*
- *Situation in which acc. to the physician's assessment there is any contraindication against metal implant fixation.*

The above list is not exhaustive.

ADVERSE EFFECTS

The adverse effects may necessitate reoperation or revision. The surgeon should warn the patient about possibility of adverse effects occurrence.

Potential adverse events include but are not limited to:
- *Infection and other adverse inflammatory reactions.*
- *Late bone fusion, non-union or pseudoarthrosis.*
- *Loss of anatomic position with non-union or abnormal adhesion of bone with rotation or angle change.*
- *Implant loosening, bending, breakage.*
- *Loss of stability due to non-union, osteoporosis or unstable complex fractures.*
- *Implant migration.*
- *Implant compressing the surrounding tissue or organs.*
- *Reaction to implants as foreign bodies, e.g. the possibility of tumor metaplasia, developing autoimmune disease and/or scarring.*
- *Loss of proper curvature and length of bone.*
- *Bone fractures or "stress shielding" phenomenon causing loss of bone above, below or at the operative site.*
- *Haemorrhage of blood vessels and / or hematomas.*
- *Deep vein thrombosis, thrombophlebitis or pulmonary embolism.*
- *Complications in donor site area.*
- *Early or late loosening, or displacement of the implant.*
- *Scar formation that could cause neurological impairment, or nerves compression and/or pain.*
- *Respiratory complications such as pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.*
- *Mental condition changes.*
- *Limitations of the normal, everyday activities.*
- *Death.*

WARNINGS

The important medical information given in this document should be conveyed to the patient.

The selection of proper shape and size of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for selecting an implant proper size. Preoperative and operating procedures, including knowledge of surgical techniques, proper fracture reduction, and correct selection and placement of the implants are important and shall be considered by the surgeon in order to achieve the successful utilization of the system.

A successful result is not always achieved in every surgical case. This principle applies especially to cases where other factors related to the patient's condition may prevent from achieving desired results.

Moreover, it is crucial to the success of the surgery that the patient follow instructions given by the physician. Patients who smoke have been shown to have a higher incidence of bone non-, mal-union. These patients should be adequately informed of this fact and warned of this consequence.

The implants are intended as a guide to healing process and are **NOT** intended to replace normal body structure or bear the weight of the body. In such event or in the case of delayed union or non-union, excessive implant loading or weight bearing might eventually cause the implant bending, loosening, disassembling or fatigue breakage.

No implant can withstand body loads without the support of bone.

All metal surgical implants are subjected to repeated stresses, which can result in material fatigue and failure of the implant. The surgeon should inform the patient that the device cannot and does not restore flexibility, strength, reliability and durability of normal, healthy bones.

Overweight may cause in implant additional stresses and strains which can lead to fatigue and deformation or, in consequence, failure of the implant.

The implant may break or become damaged as a result of strenuous activity or trauma, and the device may need to be replaced. To avoid excessive stress on the implant, which could lead to non-union or implant failure and clinical problems, the surgeon shall instruct the patient about the physical activity limitations during the formation and maturation of bony mass.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant *(e.g. substantial walking, running, lifting, or muscle strain)* the surgeon must advise the patient that resultant forces can cause implant failure.

The plates structure allows for an intraoperative bending, though it should be done carefully.

Limitations and instructions issued by the manufacturer should be obeyed. Due to the fact that titanium bending influences its strength parameters, disobeying the instructions may result in postoperative complications like implant breakage.

If there is a necessity to bend the plate, please, remember that:
- before bending it is advisable to insert the locking screws near the bending area, as deformed holes may not provide appropriate cooperation between plate and screws,
- only the shaft part of the plate may be shaped,
- it is forbidden to bend a short fragment of the plate or to bend with a small bending radius,
- it is forbidden to bend a plate back and forth,
- it is forbidden to bend a plate which was already bent,
- the bending should occur between plates holes,
- the plate should not be bent more that 20°÷25°.

If a plate was shortened to adjust its length, the remaining cut part shall not be implanted.

While inserting the screw, it is essential to correctly set the screwdriver. Screwdriver should be set in the screw axis and proper axial pressure shall be applied to ensure that the screwdriver goes as deep in the head of the bone screw as possible. Careful tightening of the screw must be exercised in the case of nonlocking screws without using a torque wrench. Given instructions reduce the risk of mechanical damage to the screw, screwdriver, or bony hole.

PRODUCT DESCRIPTION

1. Additional identification system for the plates and screws has been introduced. On the surfaces of implantable stainless steel and titanium plates additional feature *"System e.g. 4.0, 4.5, 5.0, 7.0."* has been placed. Additional information help to state that particular screw *(head diameter 4.0, 4.5, 5.0, 7.0.)* cooperates with particular plate. Additionally, plate and screws included in the system, made of titanium, are color coded: System 4.0 - green, System 4.5 - gold, System 5.0 – brown, System 7.0 - blue.

2. Implants are single-use devices, provided sterile or non-sterile.

3. Not labeled implants are non-sterile.

4. Package of each component should be intact at the time of receipt.

5. The unit package contains:

a) **Sterile version**: one piece of the product in sterile condition. A double package made of Tyvek-foil or a single blister are typical packaging material.

b) **Non-sterile version**: one piece of the product. Clear plastic bags are typical packaging material.

6. A sterile indicator is put on the sterile package.

7. The packaging is equipped with the product label. The label *(as primary label)* contains:

a) **Sterile product:**
- **ChM** logo and address of manufacturer; trade-mark: ChLP system,
- name and size of the product,
- batch code *(LOT)*, for example, *"0900000"*,
- STERILE sign: indicates sterilized product,
- Sterilization batch number S-1234567,
- expiration date and sterilization method,
- catalogue number *(REF)*, e.g. *"3.4034.503" (first digit indicates the material type e.g. 1.4034.503 /1-implantable stainless steel, 3.4034.503 /3-titanium, 4.4034.503 /4-cobalt alloy)*.

b) **Non-Sterile product:**
- **ChM** logo and address of manufacturer; trade-mark: ChLP system,
- name and size of the product,
- batch code *(LOT)*, for example, *"0900000"*,
- NON-STERILE sign: indicates non-sterilized product,
- catalogue number *(REF)*, e.g. *"3.4034.503" (first digit indicates the material type e.g. 1.4034.503 /1-implantable stainless steel, 3.4034.503 /3-titanium, 4.4034.503 /4-cobalt alloy)*.

8. In addition to the product primary label, an auxiliary label with specific market requirements of a given area may be placed on the unit package *(e.g. legal requirements of the country in which the product will be distributed)*.

9. Additionally, the package contains: instructions for use and labels to be placed in a patient's medical record.

10. Depending on the size or type of plate, the following information may be marked on its surface:
- manufacturer's logo: **ChM**,
- system *"System 4.0, 4.5, 5.0, 7.0" (see paragraph 1. PRODUCT DESCRIPTION)*,
- production batch no. *(LOT)*, e.g. *"1000000"*,
- catalogue number *(REF)*, e.g. *"1.3155.506" (first digit indicates the material type e.g. 1.4034.503 /1-implantable stainless steel, 3.4034.503 /3-titanium)*,
- type of material is indicated: S - implantable stainless steel, T - titanium,
- number of holes e.g. *"6 holes"*.

11. Depending on the size or type of screw, the following information may be marked on its surface:
- manufacturer's logo: **ChM**,
- production batch no. *(LOT)*, e.g. *"1000000"*,
- catalogue number *(REF)*, e.g. *"1.3155.506" (first digit indicates the material type e.g. 1.3155.506 /1-implantable stainless steel, 3.3155.506 /3-titanium, 4.1289.020 /4-cobalt alloy)*,
- type of material is indicated: S - implantable stainless steel, T - titanium, CoCrMo - cobalt alloy.

- *Only screws produced by* **ChM** *Ltd. (marked* **ChM***) shall be used to lock the plate. Surgeon takes responsibility for using screws produced by other companies.*
- *Bending the plates in order to match the bone anatomy can be performed only with aid of instruments intended for this purpose.*
- *Only instruments produced by* **ChM** *Ltd. shall be used for insertion and removal of* **ChM** *implants. Intraoperative fracture or breakage of instruments has been occasionally reported. Instruments which have experienced extensive use or excessive force are susceptible to fracture.* **ChM** *Ltd. recommends that all instruments be regularly inspected for wear and disfigurement.*

PRODUCT MATERIAL

- **plates and screws** made of implantable stainless steel according to ISO 5832/1, 5832/9 standards

Alloy *(content in %)* – max values					
Cr	**Ni**	**Cu**	**Mo**	**C**	**Si**
22.0	15.0	0.5	3.0	0.08	1.0
Mn	**P**	**S**	**N**	**Nb**	**Fe**
4.25	0.025	0.01	0.5	0.8	rest

- **plates** made of titanium according to 5832/2 standard

Chemical *(content in %)* – max values					
N	**C**	**H**	**Fe**	**O**	**Ti**
0.05	0.10	0.0125	0.40	0.40	rest

- **screws** made of titanium alloy according to 5832/3, 5832/11 standards

Alloy *(content in %)* – max values				
Al	**Fe**	**C**	**N**	**O**
6.75	0.3	0.08	0.05	0.2
H	**V**	**Nb**	**Ta**	**Ti**
0.015	4.5	7.5	0.5	rest

- **screws** made of cobalt alloy according to ISO 5832/12 standard

Alloy *(content in %)* – max values								
Cr	**Ni**	**Fe**	**Mo**	**C**	**N**	**Si**	**Mn**	**Co**
	1.0	0.75	5.0÷7.0	0.35	0.25	1.0	1.0	rest

Implantable titanium, titanium alloy and/or implantable cobalt alloy may be used together in the same construct.

Never use titanium, titanium alloy and/or cobalt alloy with implantable stainless steel components in the same construct.

The type of the material is marked on the label of the device and on the device.

Magnetic Resonance compatibility:
- for implants made of **implantable stainless steel** it is prohibited to carry out magnetic resonance imaging *(MRI)*,
- implants made of **titanium, titanium alloys and cobalt alloys** are conditionally compatible with magnetic resonance imaging. A patient can be scanned safely under the following conditions:
  - static magnetic field of ≤ 3 Tesla,
  - maximum spatial gradient magnetic field of ≤ 720 Gauss/cm,
  - maximum MR system reported whole-body-averaged specific absorption rate *(SAR)* of 3W/kg for 15 minutes of scanning.

However, the user should be absolutely familiar with the contraindications and warnings established by the manufacturer of the MRI scanner.

MR imaging may be interfered if the area of interest is in the exact same area or relatively close to the position of the implant.

PRE-OPERATIVE RECOMMENDATION

1. Only patients that meet the criteria described in the INDICATIONS should be selected.

2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.

3. Before deciding about implantation, the surgeon shall inform the patient about indications and contraindications of such procedure and possibility of complications occurrence after the operation. Patient shall be introduced to the purpose and manner of the procedure, and to functional and esthetic effects of such treatment. Proper clinical diagnosis and accurate operation planning and performance are needed to achieve a good final result of treatment.

4. Each implant shall be stored in separate protective package. The package shall not be opened until surgical procedure starts.

5. Do not use the implant if the sterile packaging is damaged. Sterility cannot be guaranteed if the package is not intact. The package shall be carefully verified before using.

6. The implantation shall be carried out by the surgeon familiar and experienced with adequate operating techniques and having undergone the necessary specific training in use of instruments produced by **ChM** Ltd. Surgical technique adequate for specific patient shall be chosen by the surgeon.

7. The operation procedure shall be carefully planned. The size of implant should be determined prior to the beginning of the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

8. Unless supplied sterile, all implants should be cleaned and sterilized before use. Additional sterile components should be available in case of any unexpected need. Before surgery, the surgeon should ascertain that all implants and instruments are sterilized.

9. Before procedure, all components including instruments should be carefully checked to ensure that there is no damage on the implant surface. Any damaged implant *(surface damage, shape deformations)* shall not be used.

10. The surgeon should be familiar with each element before using and should personally verify all needed devices before the surgery.

11. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation. Alloying elements of implant material are presented in section IMPLANT MATERIAL.

RECOMMENDATIONS FOR IMPLANT PROVIDED STERILE

Sterile implant - is delivered in sterile package, with the inscription: *"STERILE"*. Such product is sterile and the manufacturer is responsible for the process of sterilization. Products have been exposed to a minimum of **25kGy** of gamma radiation process.

Before using the sterile product, the following rules must be applied:

a) Check out the expiration date of sterilization.
Do not use the devices with overstepped sterility date.

b) Check out if the sterile package is not opened and damaged.
Do not use the devices if the sterile package is damaged.

c) Check out if sterility indicator on the sterile packaging is red, which indicates that radiation sterilization of the product was performed.
Do not use devices when the sterility indicator is other than red.

RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE

Before using the non-sterile product, the following rules must be applied:

a) The device must undergo cleaning, disinfecting and sterilization procedures. It is recommended to use an automated procedure for cleaning and disinfecting *(washer-disinfector)*.

b) Labels to be placed in patient's medical records *(delivered together with the implant)* must be protected against loss or damage during the implant washing and sterilization.

Preparation for cleaning

Remove possible surface contamination using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*. Do not use brushes made of metal, bristles or materials which can cause implant failure.

Cleaning and disinfecting process

Chosen washing and disinfecting detergents must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of those detergents. It is recommended to use water solutions of cleaning-disinfecting agents with a neutral pH.

Manual cleaning

- Brushing carefully, apply washing detergent *(e.g. MEDICLEAN)* to implant surfaces. A suitable brush must be used for holes cleaning.
- If applicable, ultrasonic cleaning may be performed. The ultrasonic bath must be prepared according to the manufacturer's instructions.
- Next rinse thoroughly under running water. It is recommended to use demineralized water.
- Visually inspect the entire surface of the device for any damage and contaminants. Damaged implants must be removed. For contaminated implants, the cleaning process should be repeated.

Cleaning with washer-disinfector

The device should undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for medical devices)*.

Procedure of washing with the washer-disinfector shall be performed according to hospital procedures, recommendations of the washing machine manufacturer, and instructions for use prepared by the manufacturer of washing and disinfecting agents.

Disinfection should be carried out at 93°C *(soak for 10 minutes in demineralized water)* without the use of detergents.

Drying

Drying must be performed as a part of the cleaning/disinfection process.

Sterilization

Disinfected, washed, and dried device shall undergo the sterilization process in accordance with the obligatory client procedures. The recommended method of sterilization is steam sterilization *(in water vapor)* under overpressure:

- temperature: 134°C,
- pressure: 2 atm. of pressure above atmospheric *(overpressure)*,
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

CAUTION:

- *Sterilization must be effective and in accordance with requirements of the EN 556 standard, which states that theoretical probability of a living microorganism presence is less than $1/10^6$ ($SAL=10^{-6}$, where SAL stands for Sterility Assurance Level).*
- *Implant must not be sterilized in the package in which it was delivered.*
- *Validated sterilization methods are allowed.*
- *The above-mentioned rules of cleaning and sterilization must be followed when dealing with any device intended for implantation.*
- *Surgical instruments set, which is used for device implantation, shall also be included into the cleaning and sterilization procedure.*

RE-STERILIZATION

ATTENTION: *The user of the product bears all responsibility for re-sterilization. In such case the device shall be cleaned and sterilized in a way described in chapter RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE.*

PRECAUTIONS

1. Implant is intended for single use only. After removing the implant from the patient's body, it must not be re-used. Final disposal of implant shall be carried out in accordance with current hospital procedures.

2. Under no circumstances is it allowed to reuse or reimplant once used device. Even if the removed implant appears to be undamaged, it may have small latent defects or internal stresses, which could lead to an early implant breakage.

3. Implant which had contact with tissues and body fluids of another patient cannot be implanted due to a potential risk of cross infection caused by viruses, bacteria and prions.

4. Avoid damaging implant surface and the deformation of implant shape during the implantation, the damaged implant cannot be left or implanted in the patient's body.

5. Slippage or misuse of instruments or implants may cause injury to the patient or operative personnel.

6. Insertion, removal and adjustment of implants must only be done with instruments specially designated for those implants, and manufactured by **ChM** Ltd.
Usage of ChM's implants and instruments in combination with implants and instruments from other manufacturers may cause damage or failure of those implants or instruments and may lead to improper course of surgery and healing process.

7. Intraoperative fracture or breaking of instruments has been occasionally reported. Instruments which have subjected to extensive use or excessive force are susceptible to fracture. It is recommended to inspect all instruments for wear and disfigurement. Instruments should be examined for wear or damage prior to surgery.

POST-OPERATIVE RECOMMENDATION

It is essential to follow all physician's postoperative directions and warnings.

1. It is essential to confirm proper position of the implant by roentgenographic examination.

2. In postoperative period, an immobilization of union should be confirmed by roentgenographic examination. If non-union occurs or if any components loosen, migrate, and/or break, the devices should be revised and/or removed immediately to avoid serious injury.

3. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation of the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure accompanied by other clinical problems. The implant can break or become damaged as a result of strenuous activity or trauma, and the device may need to be replaced in the future.

4. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant *(e.g. substantial walking, running, lifting, or muscle strain)* the surgeon must advice the patient that resultant forces can cause failure of the device.

5. The patient should be warned about the risk should he fail to follow the above-mentioned rules, or should he be unavailable for follow-up examination.

6. Surgeon must instruct the patient to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if any change at the site has been detected.

7. The patient should be informed about the type of implant material *(implantable stainless steel or titanium alloy)*.

8. The patient should be advised not to smoke or consume alcohol excessively during period of the bone fusion process.

CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING

Implantable stainless steel implant shall be removed after period of not more than two years after its implantation.

When bone union is achieved, the implants serve no functional purpose and may be removed. The possibility of another surgical procedure and associated risks must be analyzed and discussed with the patient. The final decision on implant removal is up to the surgeon. In most patients, removal is indicated because the implants are not intended to transfer forces developed during normal activities.

If the device is not removed following completion of its intended use, one or more complications may occur, in particular:

1. Corrosion, with localized tissue reaction or pain.
2. Migration of the implant, possibly resulting in injury.
3. Risk of additional injury from postoperative trauma.
4. Bending, loosening and breakage, which could make removal impractical or difficult.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Increased risk of infection.
7. Bone loss due to stress shielding.
8. Potentially unknown and/or unexpected long term effects.

Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.

If this instruction appears unclear, please contact the manufacturer, who shall provide all required explanations.

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

IFU-010/14; Date of verification: March 2014

SYMBOL TRANSLATION • OBJAŚNIENIA SYMBOLI • ПОЯСНЕНИЕ ОБОЗНАЧЕНИЙ
EXPLICACIÓN DE LOS SÍMBOLOS • SYMBOLERKLÄRUNG • SYMBOLY PŘEKLADY

Do not reuse Nie używać powtórnie Не использовать повторно No reutilizar Nicht wiederverwenden Nepoužívejte opakovaně	Do not resterilize Nie sterylizować ponownie Не стерилизовать повторно No reesterilizar Nicht resterilisieren Nepoužívejte resterilizaci	Do not use if package is damaged Nie używać jeśli opakowanie jest uszkodzone Не используйте при поврежденной упаковке No utilizar si el envase está dañado Nicht verwenden falls Verpackung beschädigt ist Nepoužívejte, pokud je obal poškozen
Sterilized using irradiation Sterylizowany przez napromieniowanie Стерилизация облучением Esterilizado mediante radiación Sterilisiert durch Bestrahlung Sterilizovat zářením STERILE R	Sterilized using ethylene oxide Sterylizowany tlenkiem etylenu Стерилизация окисью этилена Esterilizado mediante óxido de etileno Sterilisiert mit Ethylenoxid Sterilizovat ethylenoxidem STERILE EO	Non-sterile Niesterylny Нестерильно No estéril Unsterile Nesterilní
Catalogue number Numer katalogowy Номер по каталогу Número de catálogo Katalognummer Katalogové číslo REF	Batch code Kod partii Код партии Código de lote Chargennummer Číslo šarže LOT	Consult instruction for use Zajrzyj do instrukcji uzywania Смотри инструкцию по применению Consultar instrucciones de uso Siehe die Gebrauchsanweisung Řidte se návodem k použití
Material Materiał Материал Material Material Materiál Mat:	Quantity Ilość Количество Cantidad Menge Množství Qty:	Use by Użyć do Срок годности Fecha de caducidad Verwenden bis Použijte do
	Caution Ostrzeżenie Предупреждение Advertencia Vorsicht Varování	

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

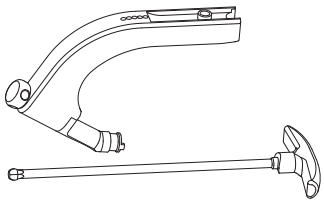
GB

ISO 9001/ ISO 13485

CE

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

IFU-I-001/14



GB

INSTRUCTIONS FOR USE

REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

Instruments manufactured by **ChM** Ltd. are made of steel, aluminium alloys and plastics according to ISO standards. Each medical instrument is exposed to occurrence of corrosion, stains and damage if not treated with special care and according to recommendations provided below.

MATERIALS

Devices are produced of corrosion-resistant steel. The protective layer *(passive layer)* against corrosion is formed on the surface of the steel due to high content of chromium.

Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as handles of screwdrivers, awls or wrenches, etc. The protective oxide layer, which may be dyed or stay in natural colour *(silvery-grey)*, is formed on the aluminium as an effect of electrochemical treatment on its surface.

Devices made of aluminium with processed layer have a good corrosion resistance. The contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference on the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: POM-C *(Polyoxymethylene Copolymer)*, PEEK *(Polyetheretherketone)* and teflon *(PTFE)*. The above mentioned materials can be processed *(washed, cleaned, sterilized)* at temperatures not higher than 140°C, they are stable in aqueous solution of washing-disinfecting agents with pH values from 4 to 9.5.

- *If the material of the device cannot be specified, please contact* **ChM** *Ltd. company representative.*

DISINFECTION AND CLEANING

Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quality of used detergent, the technique of cleaning *(manual/machine)*, the correct rinsing and drying, the proper preparation of the instrument, the time, the temperature. Internal procedures of sterilization rooms, recommendations of cleaning and disinfecting agents, as well as recommendations for cleaning and sterilization in automatic machines shall be observed.

- *Read and follow the instructions and restrictions specified by the manufacturers of the agents used for disinfection and cleaning procedures.*

1. Before the first use, the product has to be thoroughly washed in the warm water with washing-disinfecting detergent. It is important to follow the instructions and restrictions specified by the producer of those detergents. It is recommended to use water solutions of cleaning-disinfecting agents with a neutral pH.
2. After use, for at least 10 minutes the product has to be immediately soaked in an aqueous disinfectant solution of enzyme detergent with a neutral pH *(with a disinfecting properties)* normally used for reusable medical devices *(remember to prevent drying out of any organic remains on the product surface)*. Follow all the instructions specified by the producer of those enzyme detergents.
3. Carefully scrub/clean the surfaces and crevices of the product using a soft cloth without leaving threads, or brushes made of plastic, the nylon brushes are recommended. Do not use brushes made of metal, bristles or another damaging material as they can cause physical or chemical corrosion.
4. Next, thoroughly rinse the instrument under the warm running water, paying particular attention to rinse the slots carefully. Use nylon brushes making multiple moves back and forth on the surface of the product. It is recommended to rinse under demineralized water, in order to avoid water stains and corrosion caused by chlorides, found in the ordinary water, and to avoid forming the stains on the surface *(e.g. anodized one)*. During the rinsing, manually remove the adherent remains.
5. Visually inspect the entire surface of the product to ensure that all contaminants are removed.

- *If there are any residues of human tissue or any other contamination, repeat all stages of the cleaning process.*

6. Then, the instrument has to undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for reusable medical devices and instruments)*.

- *Procedure of washing with the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and instructions for use prepared by the washing-disinfecting agents manufacturer.*

ATTENTION! *The manufacturer does not recommend using any preservatives on surgical and orthopedic devices.*

STERILIZATION

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds like residues after disinfection and sterilization processes, without structure damage *(cracks, fractures, bending, peeling)*. Remember that sterilization is not a substitute for cleaning process!

- *Devices manufactured out of plastics (PEEK, PTFE, POM-C) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.*

Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards. It is recommended to sterilize in steam sterilizers where sterilizing agent is water vapour. Recommended parameters of the sterilization method:

- temperature: 134°C,
- pressure: 2 atm. of pressure above atmospheric *(overpressure)*,
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

Validated sterilization methods are allowed. Durability and strength of instruments to a considerable degree depend on how they are used. Careful usage consistent with intended use of the product protects it against damage and prolongs its life.

If this instruction appears unclear, please contact the manufacturer, who shall provide all required explanations.

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

IFU-I-001/14; Date of verification: March 2014

SYMBOL TRANSLATION • OBJAŚNIENIA SYMBOLI • ПОЯСНЕНИЕ ОБОЗНАЧЕНИЙ
EXPLICACIÓN DE LOS SÍMBOLOS • SYMBOLERKLÄRUNG • SYMBOLY PŘEKLADY

Do not reuse Nie używać powtórnie Не использовать повторно No reutilizar Nicht wiederverwenden Nepoužívejte opakovaně	Do not resterilize Nie sterylizować ponownie Не стерилизовать повторно No reesterilizar Nicht resterilisieren Nepoužívejte resterilizaci	Do not use if package is damaged Nie używać jeśli opakowanie jest uszkodzone Не используйте при поврежденной упаковке No utilizar si el envase está dañado Nicht verwenden falls Verpackung beschädigt ist Nepoužívejte, pokud je obal poškozen
Sterylized using irradiation Sterylizowany przez napromieniowanie Стерилизация облучением Esterilizado mediante radiación Sterilisiert durch Bestrahlung Sterilizovat zářením **STERILE R**	Sterylized using ethylene oxide Sterylizowany tlenkiem etylenu Стерилизация окисью этилена Esterilizado mediante óxido de etileno Sterilisiert mit Ethylenoxid Sterilizovat ethylenoxidem **STERILE EO**	Non-sterile Niesterylny Нестерильно No estéril Unsteril Nesterilní
Catalogue number Numer katalogowy Номер по каталогу Número de catálogo Katalognummer Katalogové číslo **REF**	Batch code Kod partii Код партии Código de lote Chargennummer Číslo šarže **LOT**	Consult instruction for use Zajrzyj do instrukcji używania Смотри инструкцию по применению Consultar instrucciones de uso Siehe die Gebrauchsanweisung Řiďte se návodem k použití
Material Material Материал Material Material Material **Mat:**	Quantity Ilość Количество Cantidad Menge Množství **Qty:**	Use by Użyć do Срок годности Fecha de caducidad Verwenden bis Použijte do
	Caution Ostrzeżenie Предупреждение Advertencia Vorsicht Varování	

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

ChM Ltd.

Lewickie 3b
16-061 Juchnowiec K.
Poland

tel. +48 85 713-13-20
fax +48 85 713-13-19
e-mail: chm@chm.eu

SALES OFFICE
tel.: + 48 85 713-13-30 ÷ 38
fax: + 48 85 713-13-39