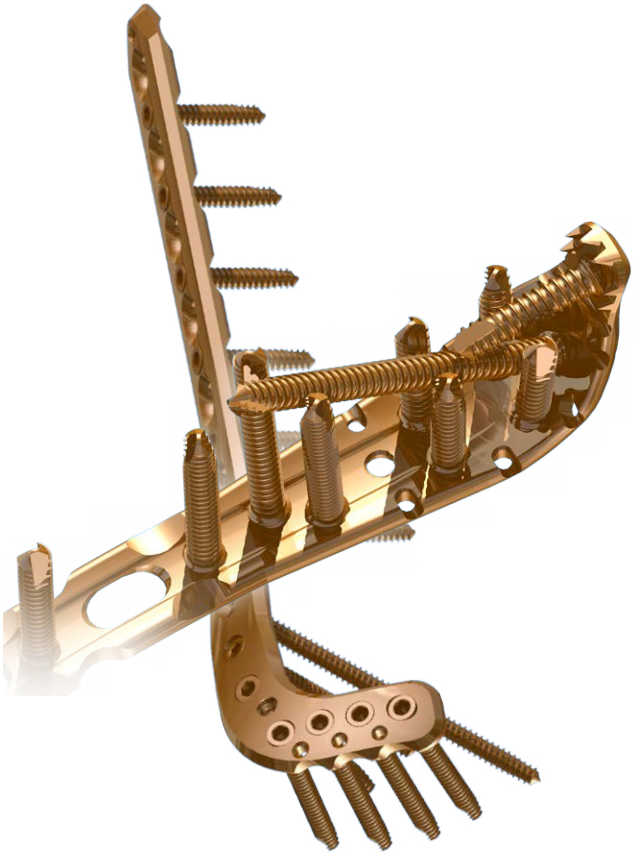
ST/47C

ChM®

5,0 ChM Locked Plating ChLPsystem

LOCKING PLATES 5.0ChLP

- *IMPLANTS*
- *INSTRUMENT SET 40.5667.700*
- *SURGICAL TECHNIQUE*



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SYMBOLS DESCRIPTIONS	
	Caution - pay attention to the particular proceeding.
	Perform the activity with X-Ray control.
	Consult the Instructions For Use.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.

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The manufacturer reserves the right to introduce design changes.

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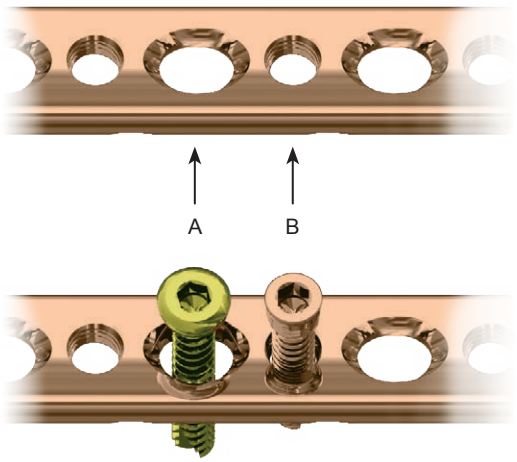
I. INTRODUCTION

The main purpose of surgical treatment of bone fractures is to reconstruct the anatomical bone structure and to restore its function. Internal stabilization with locking plates enables accurate fracture reduction, stable fixation, blood flow preservation and functional activation of injured limb.

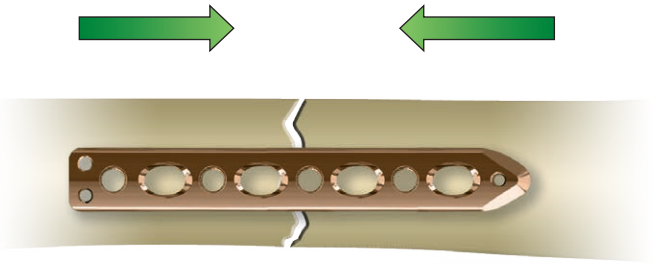
System **ChLP** consists of titanium plates and screws combining locking screws technique with conventional treatment techniques using plates. This system is the improvement of existing stabilization methods. Locking screws system enables angular fixation using conventional surgical techniques. It is particularly indicated in:

- multifragmental fractures;
- non-unions or malunions;
- osteopenia;
- osteotomy stabilization;
- when conventional screws applying is insufficient or does not bring expected effects.

Locking plates are provided with holes A for conventional cortical screws with or without compression and with threaded holes B for locking screws.
Compression holes designed in ChLP System enable compression in both directions.



Plates design allows to perform classical dynamic compression.



Advantages of using locking plates system over conventional methods of fracture treatment using plates:

- enable stable fixation ensuring angular stabilization in fracture site;
- enable compression using conventional cortical and cancellous screws, combination with conventional and locking screws is available;
- reduced bone-plate contact ensures better blood flow of perimplant tissues;
- locking screws enable uni-cortical plate position against the bone;
- plates can be contoured to match the anatomical bone shape that is particularly important in periarticular fractures.

The following instruction does not refer to particular fracture types as the locking plates system includes different plates that are relevant to many different fractures.

ChLP System was divided as follows:

- 4.0ChLP System;
- 4.5ChLP System;
- 5.0ChLP System;
- 7.0ChLP System.

Division is based on the screw head diameter; however, screws with different cortical thread diameter in one system range are available.

Additionally, systems were differentiated with colors as follows:

- 4.0ChLP System – green;
- 4.5ChLP System – gold;
- 5.0ChLP System – brown;
- 7.0ChLP System – blue.

Before product usage, read the Instructions For Use carefully. The IFU is supplied with the product and attached at the end of this document. It includes, among others: the indications, contraindications, adverse effects, warnings and recommendations associated with product usage.

II. PLATE SELECTION AND CONTOURING

Wide size range of locking plates enables proper plate selection.
Locking plate contouring is not recommended due to possiblity of threaded holes damaging.
Bottom surface of the plate does not have to contact with the bone if locking screws are used. There is no necessity of accurate plates contouring. Advanced shaped plates do not require additional bending in most cases.

If the plate bending is necessary, remember not to deform threaded holes excessively.
- perform it between locking holes;
- do not bend the plate more than 20° – 25°;
- do not bend the plate back and forth;
- before bending insert the locking screws in the bending area, that decreases the threaded holes deformation degree.

II.1. INDICATIONS

5.0 locking plate system is designed to stabilize the fracture, osteotomy, and is indicated in the case of non-union of fractured bone, such as:
- clavicle,
- shoulder-blade,
- humeral bone,
- radial bone,
- elbow bone,
- tibial bone,
- calf bone.

III. CATALOGUE PAGES

III.1. PLATES

5.0ChLP clavicular hook plate

H	O	Catalogue no. Left	Right
12	5	3.4025.505	3.4026.505
	6	3.4025.506	3.4026.506
	7	3.4025.507	3.4026.507
	8	3.4025.508	3.4026.508
15	5	3.4027.505	3.4028.505
	6	3.4027.506	3.4028.506
	7	3.4027.507	3.4028.507
	8	3.4027.508	3.4028.508
18	5	3.4029.505	3.4030.505
	6	3.4029.506	3.4030.506
	7	3.4029.507	3.4030.507
	8	3.4029.508	3.4030.508

O - all threaded holes number in the plate

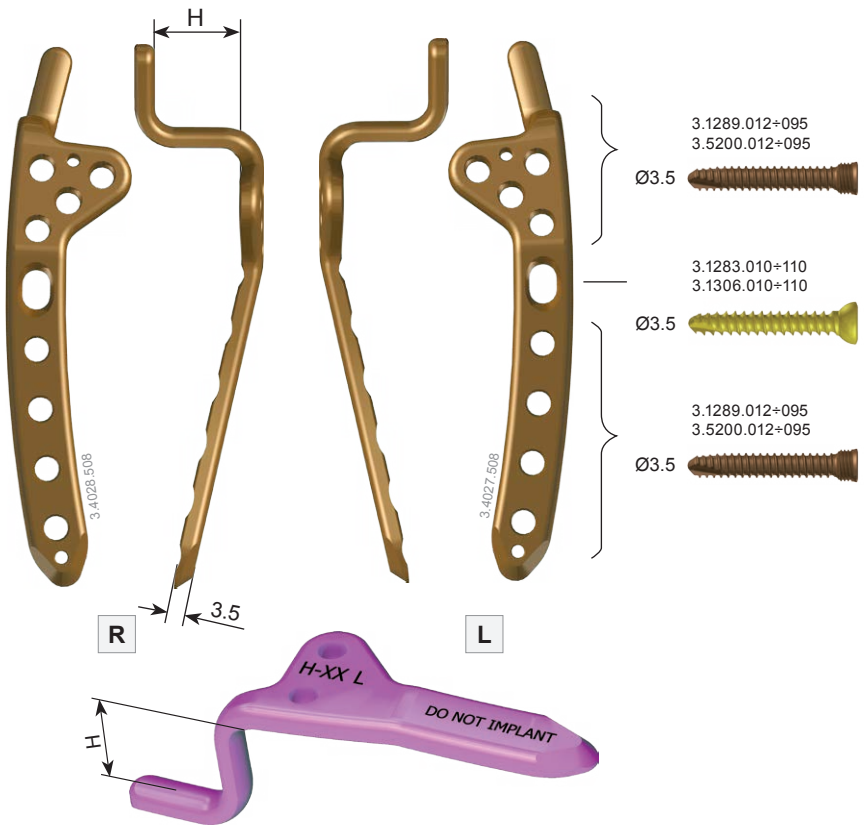
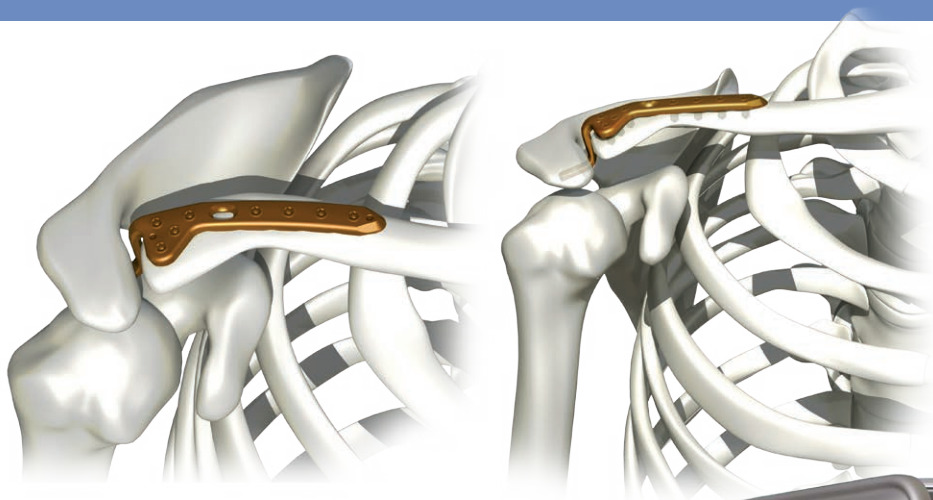


Plate trial

H [mm]	Catalogue no. Left	Right
12	43.4025.505	43.4026.505
15	43.4027.505	43.4028.505
18	43.4029.505	43.4030.505



Palette for 5.0ChLP plates - 3.4025÷3.4030

No.	Catalogue no.	Name	Pcs	
1	40.5758.150	Palette	1	40.5758.650
2	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1	
3	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1	

implants not included

ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 713 13 20, fax + 48 85 713 13 19, chm@chm.eu, www.chm.eu

Indications

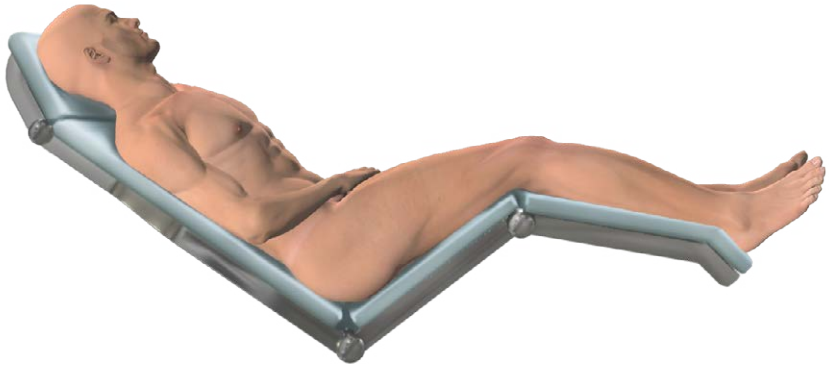
- The clavicle shoulder end fractures.
- Acute and inveterate dislocation of the acromioclavicular joint.

Contraindications

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

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

The patient's position



Surgical approach

Anterior-upper approach of the sabre cut type.

Procedure stages

The fracture of the end of the clavicle connecting to the shoulder

- Uncovering the fracture.
- The choice of implants – determining the length and depth of the hook and the position of the implant.
- Installing the plate and adjusting the fracture *„to the plate."*
- The installation of locking and/or compression screws.

Dislocation of the acromioclavicular joint

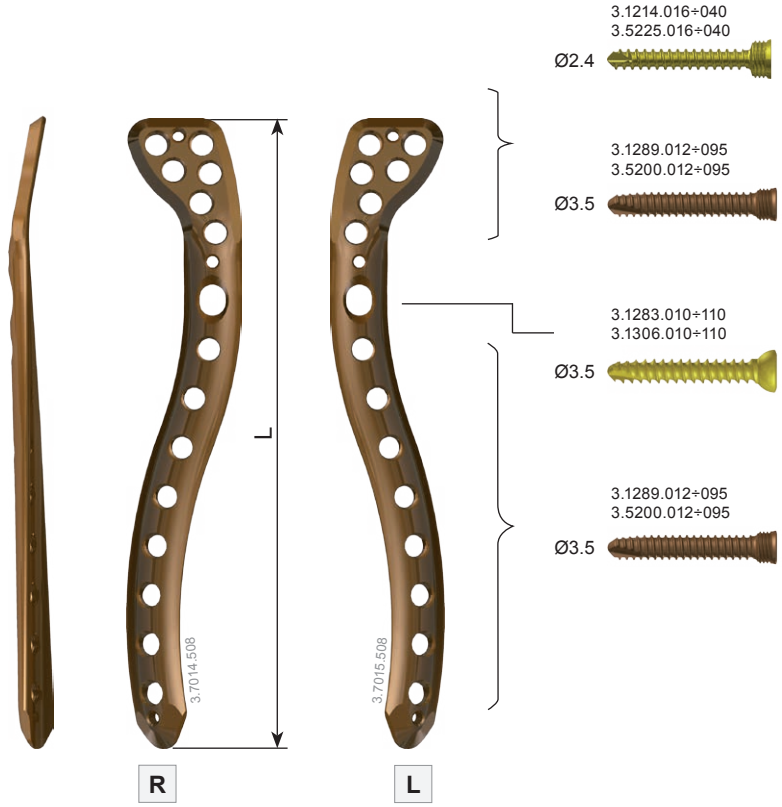
- Covering and *"cleansing"* of the joint - the possibility of the meniscus damage.
- The choice of implants – determining the length and depth of the hook and the position of the implant.
- Initial positioning and installing of the chosen plate. Ligamentous-capsularis reconstruction indicated.
- The installation of locking and/or compression screws.

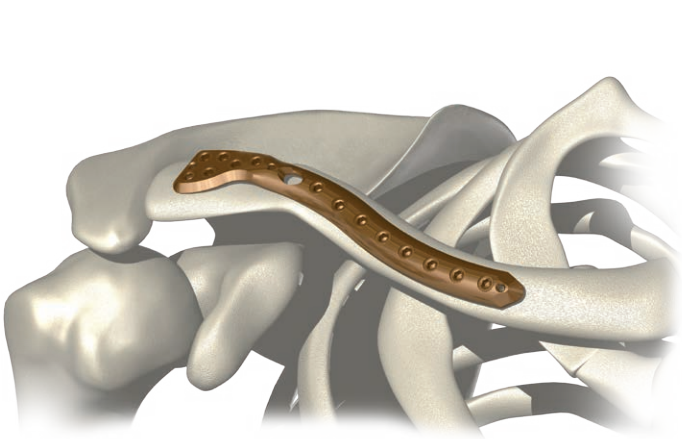
5.0ChLP clavicle S plate

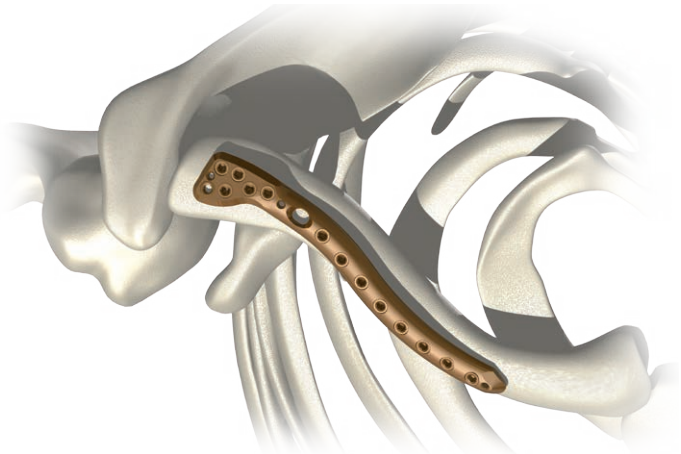
O	L [mm]	Catalogue no. Left	Catalogue no. Right
3	71	3.7015.503	3.7014.503
4	80	3.7015.504	3.7014.504
5	90	3.7015.505	3.7014.505
6	99	3.7015.506	3.7014.506
8	116	3.7015.508	3.7014.508

O – threaded holes number in shaft part of the plate

available	**3 - 11 holes** *(71 mm - 143 mm)*







Palette for 5.0ChLP plates - 3.7014/3.7015

No.	Catalogue no.	Name	Pcs	
1	40.5758.130	Palette	1	40.5758.630
2	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1	
3	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1	

implants not included

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Indications

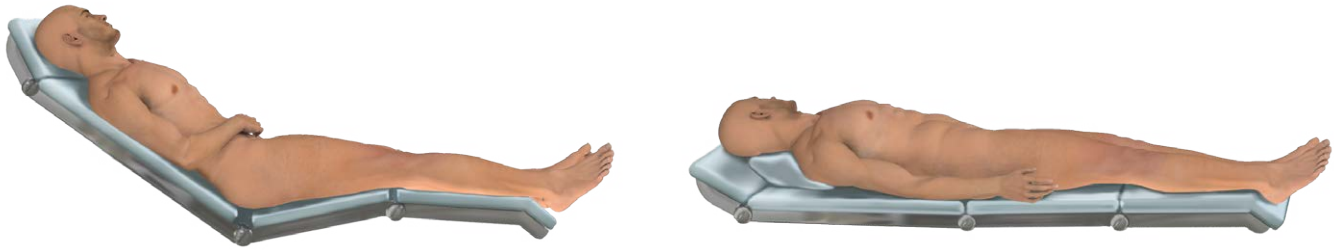
- The clavicle fractures.
- Non-union or malunions of clavicle.

Contraindications

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

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

The patient's position



Beach-chair or lying on the back position.

Surgical approach

Horizontal incision parallel to the clavicle in the supraclavicular fossae or above the clavicular area.

Procedure stages

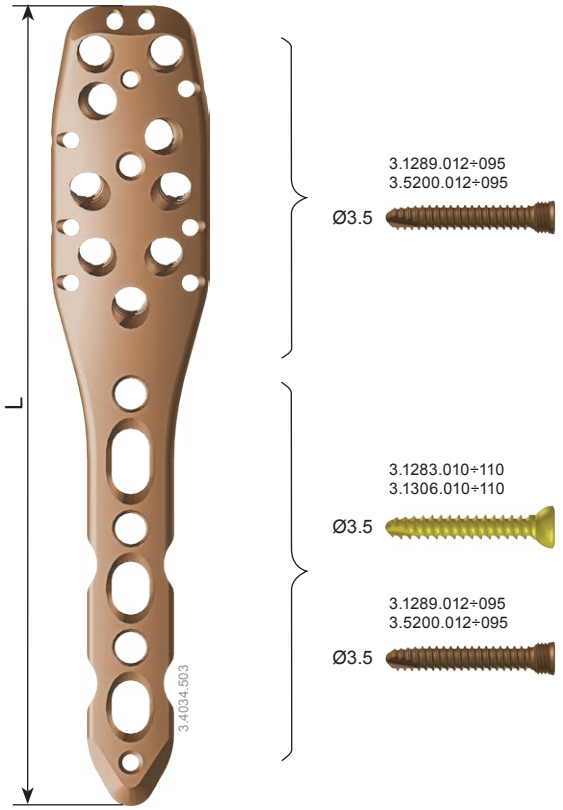
- Surgical approach and revealing the fracture.
- The initial reduction of fracture.
- The choice of implants – determining the length and position of the implant.
- Initial stabilization of the plate using bone forceps or compression screws.
- Insertion of the screws.

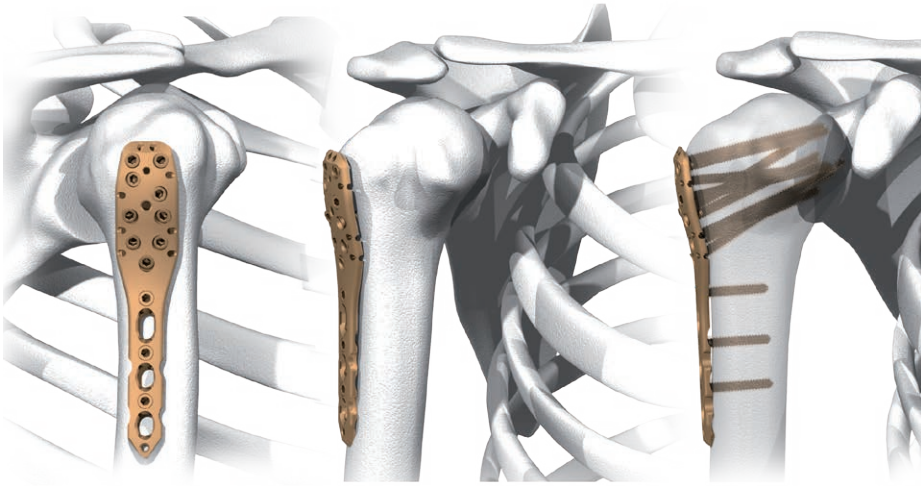
5.0ChLP humerus plate

O	L [mm]	Catalogue no.
3	101	3.4034.503
4	116	3.4034.504
5	131	3.4034.505
6	146	3.4034.506
8	176	3.4034.508

O – threaded holes number in shaft part of the plate

available	**3 - 12 holes** *(101 mm - 236 mm)*





Palette for 5.0ChLP plates - 3.4034

No.	Catalogue no.	Name	Pcs		
1	40.5671.000	Aiming block	1	40.5758.010	40.5758.510
2	40.5672.000	Protective guide 7.0/5.0	2		
3	40.5758.210	Palette	1		
4	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1		
5	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1		

implants not included; with additional instruments

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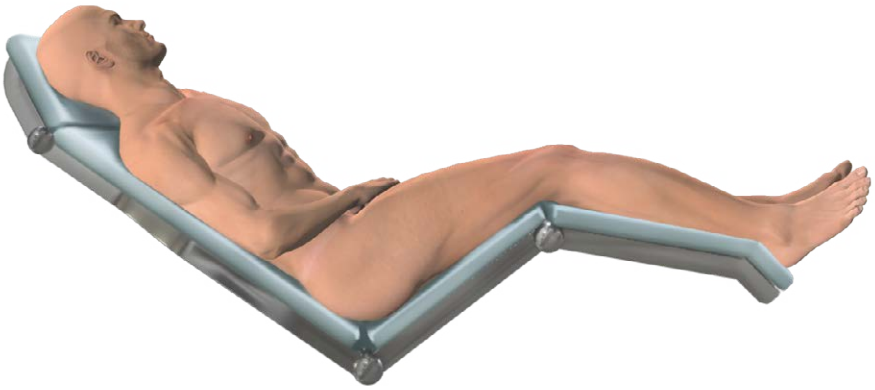
Indications

- Comminuted fracture of the head and the proximal humeral metaphysis.
- Fracture-dislocations.
- Osteopenic and osteoporotic bone fractures.
- Non-union or malunions of fractured bone.

Contraindications

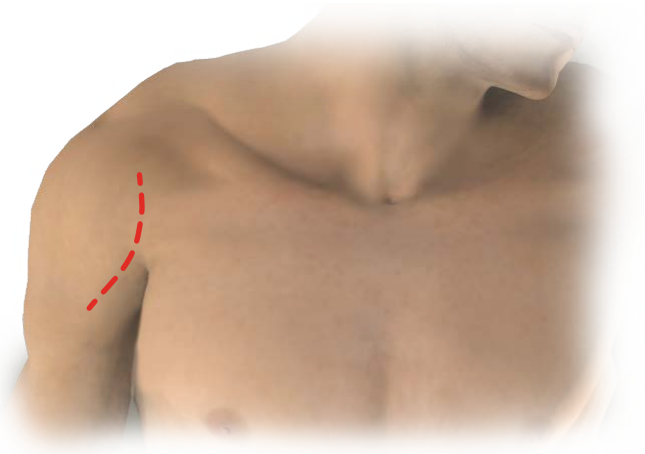
- Abnormal perfusion of fracture area or surgical site.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create a risk of fusion failure or complications in the postoperative period.
- Other medical conditions that exclude the potential benefits of the treatment.

The patient's position



Beach-chair or lying on the back position.

Surgical approach



The deltopectoral approach is intended.

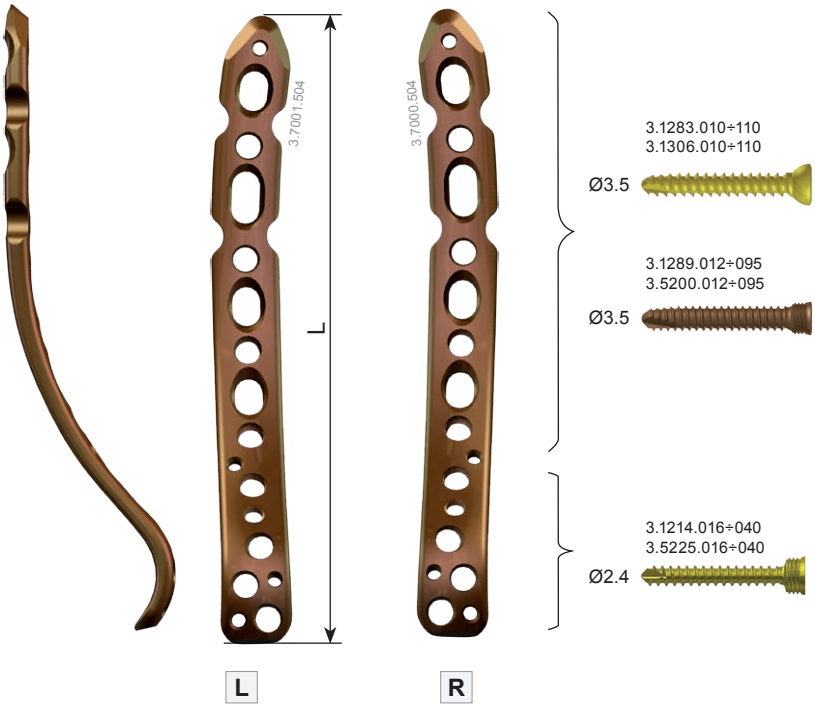
Procedure stages

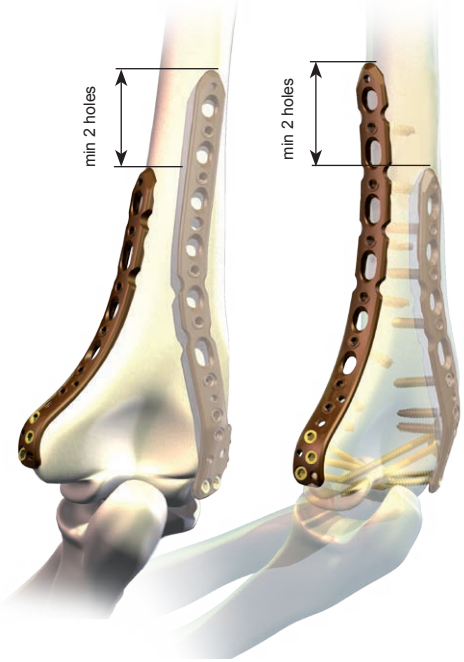
- The initial reduction of fracture, stabilization using Kirschner wires and applying sutures for the detached tendons with bone fragments.
- The choice of implants - determining the length and position of the implant.
- Insertion of the aiming block to the plate and its positioning under the X-Ray control.
- Introduction of the plate - the lateral position from the LHBT groove.
- Introduction of the cortical screw to the hole for positioning.
- The introduction of the screws to the head of the humeral bone under the X-Ray control.
- Applying soft tissues to the plate.
- Stabilization of the shaft of the plate.
- Removal of the aiming block.
- Closing the wound.

5.0ChLP distal medial humerus plate

O	L [mm]	Catalogue no. Left	Catalogue no. Right
3	89	3.7001.503	3.7000.503
4	107	3.7001.504	3.7000.504
5	121	3.7001.505	3.7000.505
6	136	3.7001.506	3.7000.506

O – threaded holes number in shaft part of the plate





Palette for 5.0ChLP plates - 3.7000-3.7003

No.	Catalogue no.	Name	Pcs		
1	40.5729.100	Aiming block L **[3.7003]**	1	40.5758.110	40.5758.610
2	40.5729.200	Aiming block R **[3.7002]**	1		
3	40.5728.100	Aiming block L **[3.7001]**	1		
4	40.5728.200	Aiming block R **[3.7000]**	1		
5	40.5672.000	Protective guide 7.0/5.0	2		
6	40.5758.310	Palette	1		
7	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1		
8	12.0751.200	Perforated aluminum lid 1/2 306x272x55 mm Gray	1		

implants not included; with additional instruments

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Indications

- Inner and periarticular fractures of the distal end of the humeral bone.
- Fractures of the distal end of the humeral bone extending to the shaft.
- Corrective osteotomy.
- Non-union of fractured bone.

Contraindications

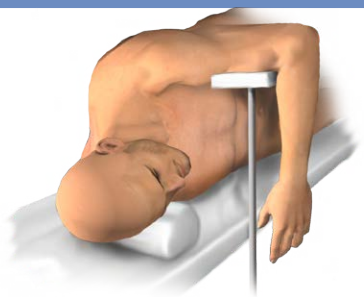
Absolute:

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

Relative:

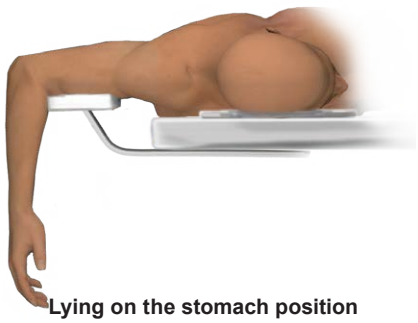
- Significant weakening of the bone *(by disease, infection or prior implantation)* making it impossible to install/stabilize the implant properly.
- Abnormal perfusion of fracture area or surgical site.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create a risk of fusion failure or complications in the postoperative period.
- Other medical conditions that exclude the potential benefits of the treatment.

The patient's position



Lateral lying position

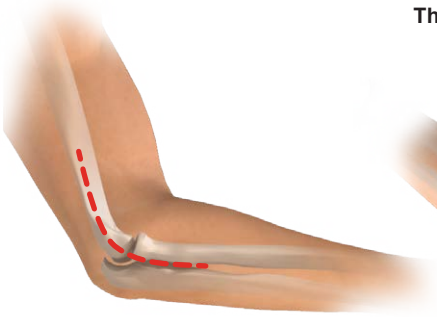
Lying on the back position



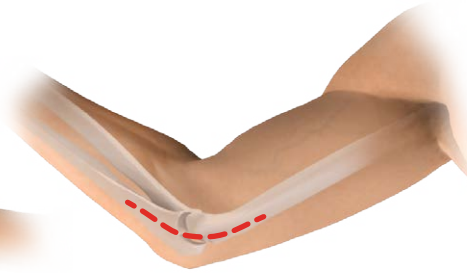
Lying on the stomach position

Surgical approach

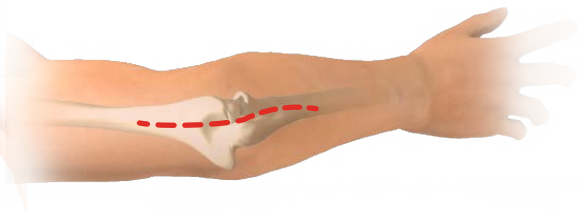
The approach is dependent on the fracture type



Lateral approach



Medial approach



Posterior approach

Particular attention should be paid to the ulnar nerve - it is essential to expose it.
Lateral, medial or both approaches simultaneously may be implemented.
Posterior approach that bypasses the olecranon makes it possible to conduct the osteotomy of the olecranon which in result allows a better view of the fracture site.

Procedure stages

- Reduction of fracture and stabilization of the fracture fragments with Kirschner wires - particular attention should be paid to the reconstruction of the articular surfaces. Please note that the plates are provided with holes for initial stabilization using Kirschner wires.
- The choice of implants - determining the length and position of the implant.

ATTENTION: In the case of stabilization using two plates, the implants should be of different length as to avoid overloading of the shaft of the humeral bone. Two-holes difference in length is indicated.

- Adjusting the shape of the implant, if necessary.
- Positioning of the plate using the compression screw in the extended hole.
- Temporary stabilization of the implant using Kirschner wires.
- Introduction of the screws in the distal parts of the plate.

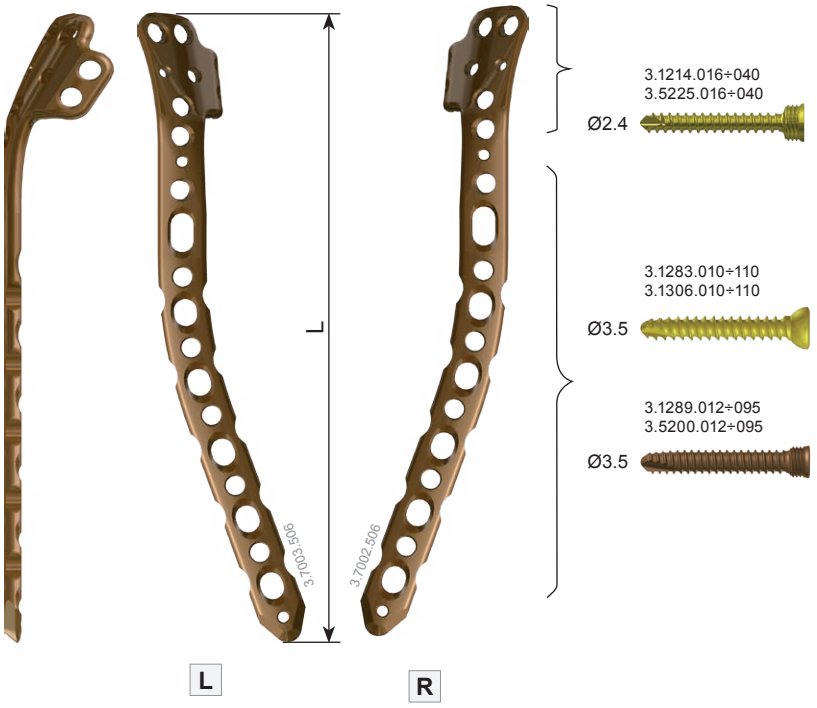
ATTENTION: When inserting the screws in the distal parts of the plate make sure they do not move into the articular surfaces or olecranon fossae.

- Stabilization of the shaft using locking or compression screws.

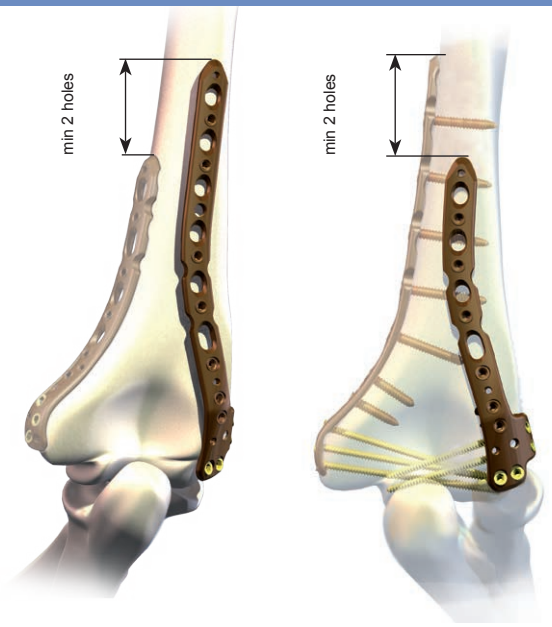
5.0ChLP distal dorso-lateral humerus plate

O	L [mm]	Catalogue no. Left	Right
3	95	3.7003.503	3.7002.503
4	109	3.7003.504	3.7002.504
5	123	3.7003.505	3.7002.505
6	137	3.7003.506	3.7002.506

O – threaded holes number in shaft part of the plate



Palette for 5.0ChLP plates - 3.7000-3.7003



No.	Catalogue no.	Name	Pcs		
1	40.5729.100	Aiming block L **[3.7003]**	1	40.5758.110	40.5758.610
2	40.5729.200	Aiming block R **[3.7002]**	1		
3	40.5728.100	Aiming block L **[3.7001]**	1		
4	40.5728.200	Aiming block R **[3.7000]**	1		
5	40.5672.000	Protective guide 7.0/5.0	2		
6	40.5758.310	Palette	1		
7	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1		
8	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1		

implants not included; with additional instruments

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Indications

- Inner and periarticular fractures of the distal end of the humeral bone.
- Fractures of the distal end of the humeral bone extending to the shaft.
- Corrective osteotomy.
- Non-union of fractured bone.

Contraindications

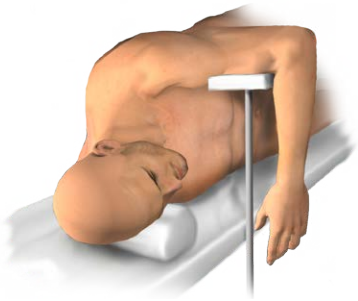
Absolute:

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

Relative:

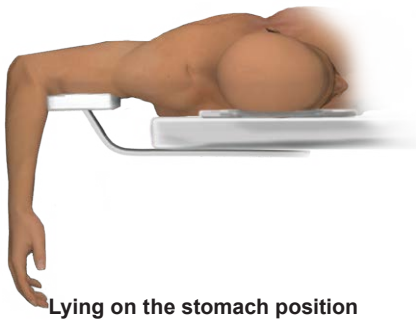
- Significant weakening of the bone making it impossible to install/stabilize the implant properly.
- Abnormal perfusion of fracture area or surgical site.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create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

The patient's position



Lateral lying position

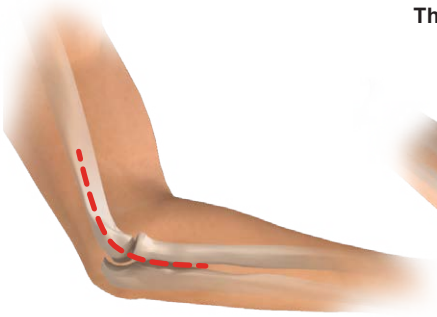
Lying on the back position



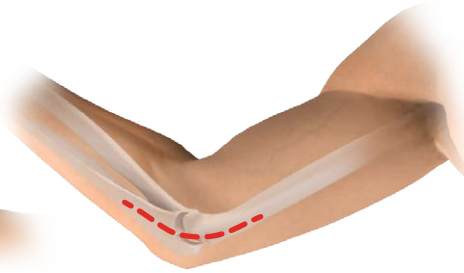
Lying on the stomach position

Surgical approach

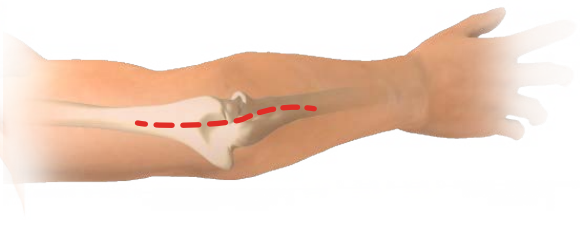
The approach is dependent on the fracture type



Lateral approach



Medial approach



Posterior approach

Particular attention should be paid to the ulnar nerve - it is essential to expose it.
Lateral, medial or both approaches simultaneously may be implemented.
Posterior approach that bypasses the olecranon makes it possible to conduct the osteotomy of the olecranon which in result allows a better view of the fracture site.

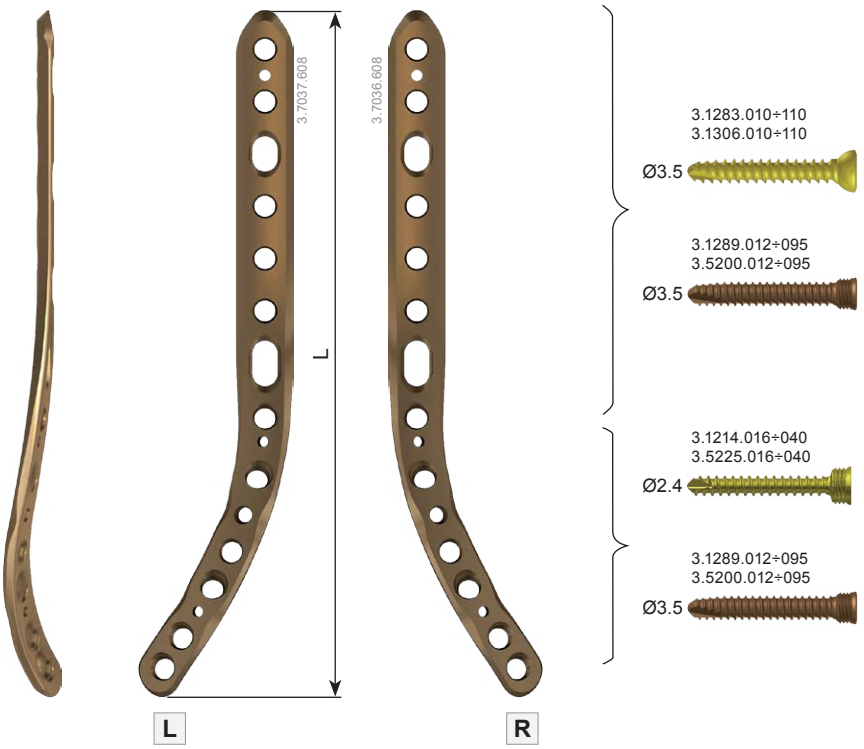
Procedure stages

- Reduction of fracture and stabilization of the fracture fragments using Kirschner wires - particular attention should be paid to the reconstruction of the articular surfaces. Please note that the plates are provided with holes for initial stabilization using Kirschner wires.
- The choice of implants - determining the length and position of the implant.
  Attention: In the case of stabilization using two plates, the implants should be of different length as to avoid overloading of the shaft of the humeral bone. Two holes difference in length is indicated.
- Adjusting the shape of the implant, if necessary.
- Positioning of the plate using the compression screw in the extended hole.
- Temporary stabilization of the implant using Kirschner wires.
- Introduction of the screws in the distal parts of the plate.
  Attention: When inserting the screws in the distal parts of the plate make sure they do not move into the articular surfaces or olecranon fossae.
- Stabilization of the shaft using locking or compression screws.

5.0ChLP distal lateral humerus plate

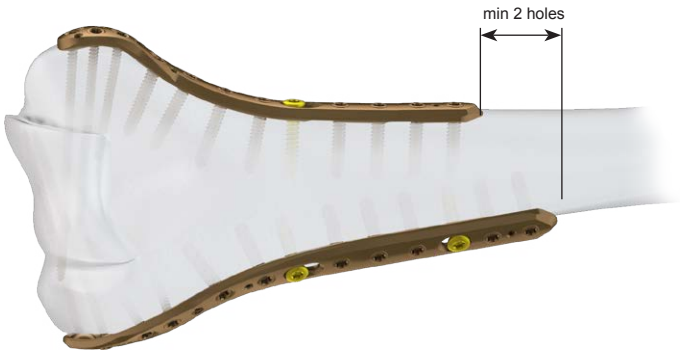
O	L [mm]	Catalogue no. Right	Left
4	91	3.7036.604	3.7037.604
6	111	3.7036.606	3.7037.606
8	131	3.7036.608	3.7037.608
10	151	3.7036.610	3.7037.610
12	171	3.7036.612	3.7037.612

O - holes number in shaft part of the plate



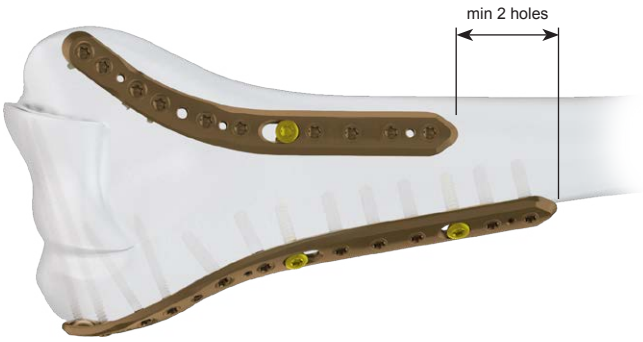
180°

3.7071 / 3.7072 5.0ChLP distal medial humerus plate + **3.7036 / 3.7037** 5.0ChLP distal lateral humerus plate



90°

3.7040 / 3.7041 5.0ChLP distal posterior medial humerus plate + **3.7036 / 3.7037** 5.0ChLP distal lateral humerus plate



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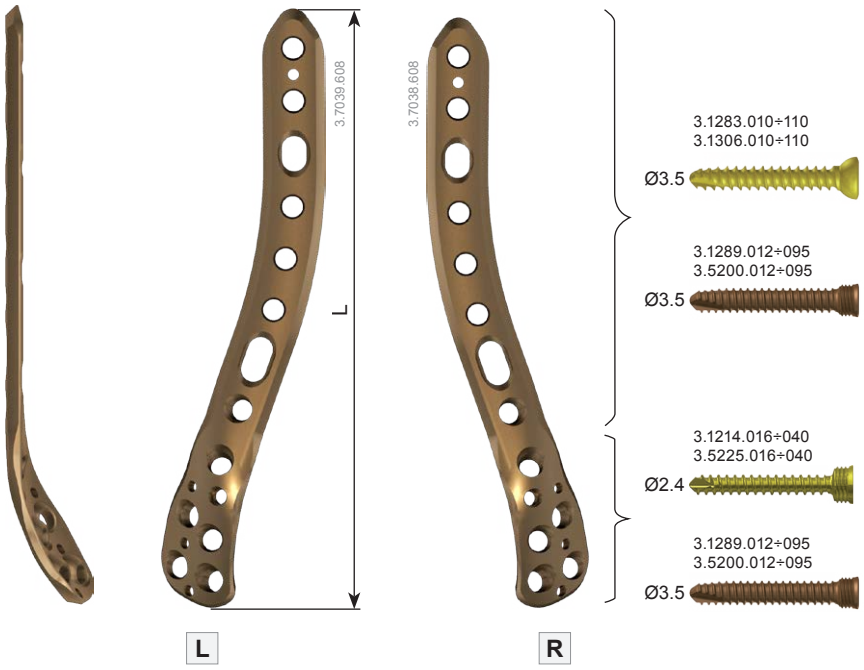
5.0ChLP distal posterior lateral humerus plate

O	L [mm]	Catalogue no. Right	Left
4	75	3.7038.604	3.7039.604
6	94	3.7038.606	3.7039.606
8	113	3.7038.608	3.7039.608
10	131	3.7038.610	3.7039.610
12	150	3.7038.612	3.7039.612

O - holes number in shaft part of the plate



90°

3.7071 / 3.7072
5.0ChLP distal medial humerus plate

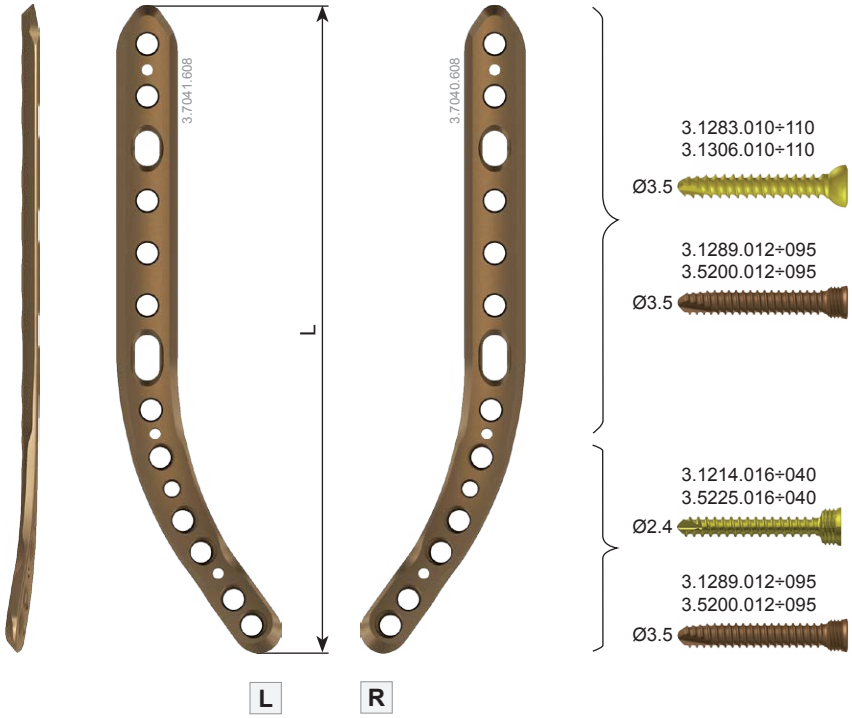
+

3.7038 / 3.7039
5.0ChLP distal dorsolateral humerus plate

5.0ChLP distal posterior medial humerus plate

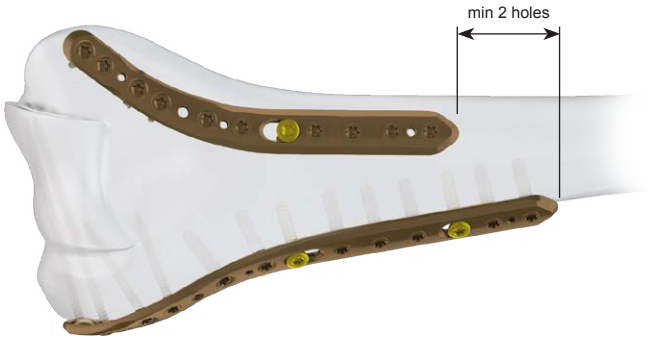
O	L [mm]	Catalogue no. Right	Left
4	84	3.7040.604	3.7041.604
6	104	3.7040.606	3.7041.606
8	124	3.7040.608	3.7041.608
10	144	3.7040.610	3.7041.610
12	164	3.7040.612	3.7041.612

O - holes number in shaft part of the plate



90°

3.7040 / 3.7041 5.0ChLP distal posterior medial humerus plate **+** **3.7036 / 3.7037** 5.0ChLP distal lateral humerus plate



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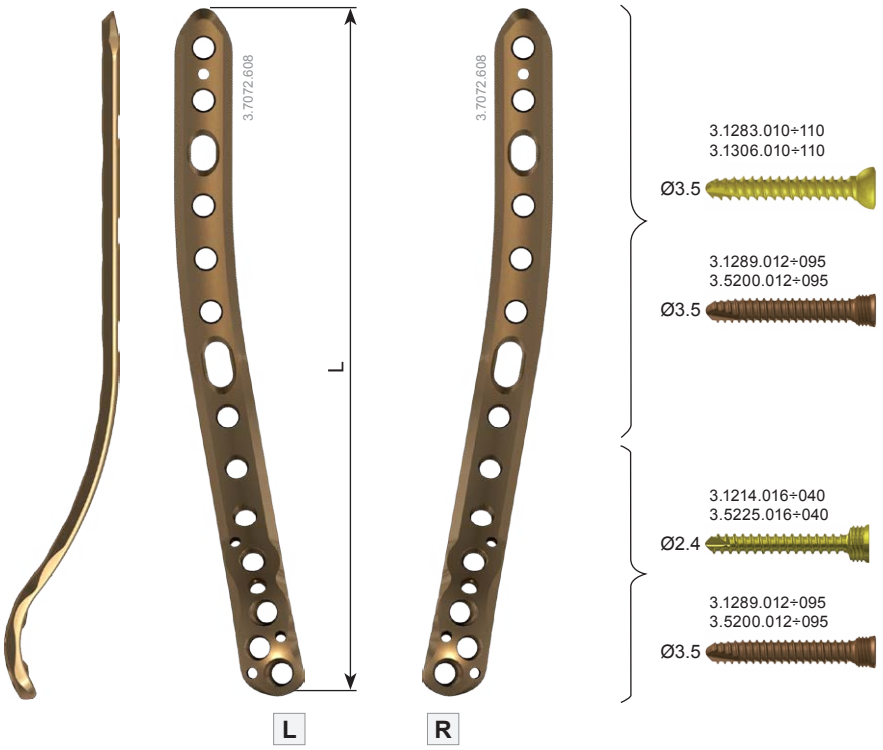
5.0ChLP distal medial humerus plate

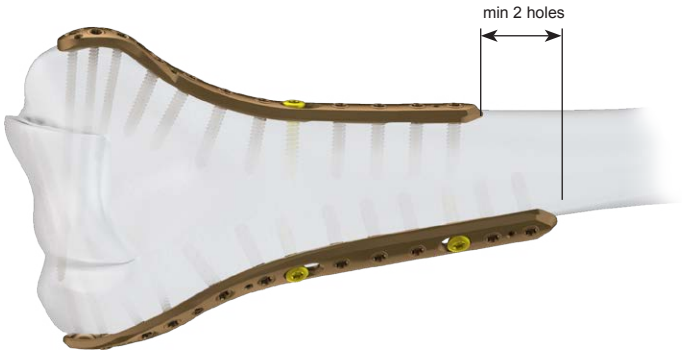
O	L [mm]	Catalogue no. Right	Left
4	91	3.7072.604	3.7071.604
6	111	3.7072.606	3.7071.606
8	131	3.7072.608	3.7071.608
10	151	3.7072.610	3.7071.610
12	170	3.7072.612	3.7071.612

O - holes number in shaft part of the plate



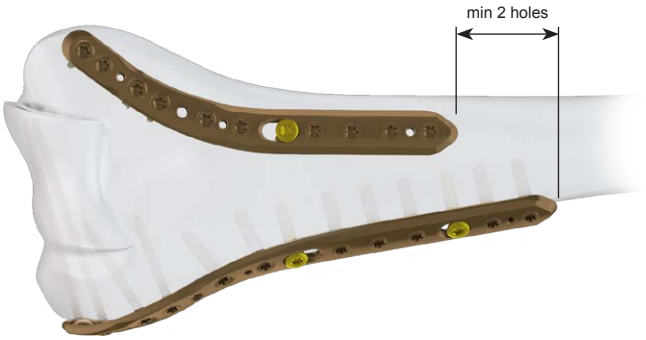
180°

3.7071 / 3.7072 5.0ChLP distal medial humerus plate **+** **3.7036 / 3.7037** 5.0ChLP distal lateral humerus plate



90°

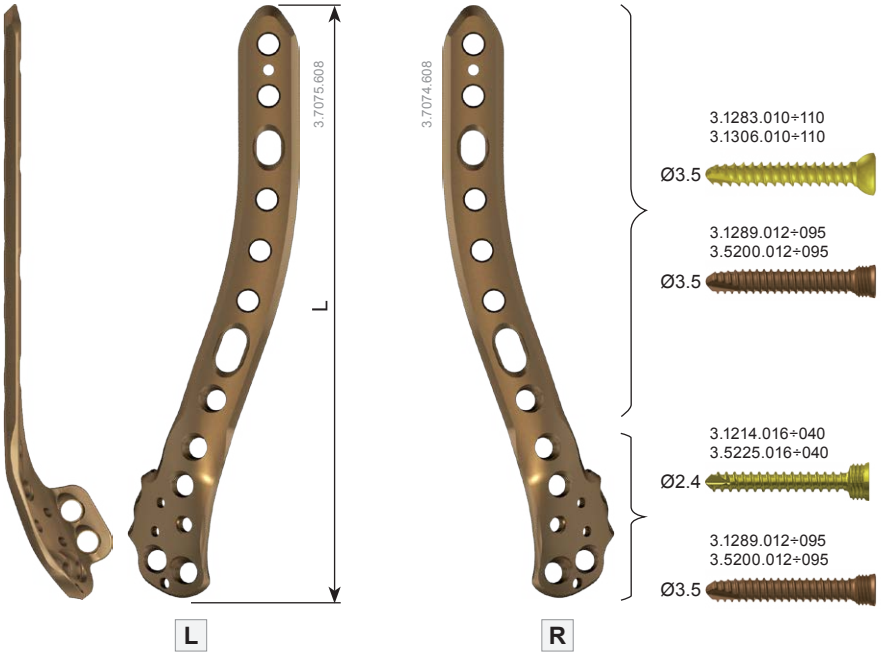
3.7040 / 3.7041 5.0ChLP distal posterior medial humerus plate **+** **3.7036 / 3.7037** 5.0ChLP distal lateral humerus plate



5.0ChLP distal dorsolateral humerus plate

O	L [mm]	Catalogue no. Right	Catalogue no. Left
4	75	3.7074.604	3.7073.604
6	94	3.7074.606	3.7073.606
8	113	3.7074.608	3.7073.608
10	132	3.7074.610	3.7073.610
12	151	3.7074.612	3.7073.612

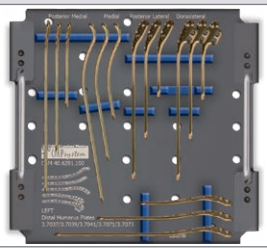
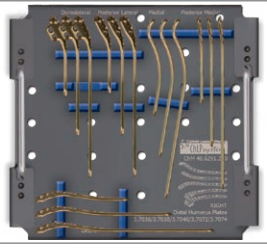
O - holes number in shaft part of the plate



90°

3.7071 / 3.7072 5.0ChLP distal medial humerus plate + **3.7073 / 3.7074** 5.0ChLP distal posterior medial humerus plate

Palette for 5.0ChLP plates **40.6291.000**

No.		Name	Catalogue no.	Pcs
1		Palette *(3.7037/3.7039/3.7041/3.7071/3.7073)*	40.6291.100	1
2		Palette *(3.7036/3.7038/3.7040/3.7072/3.7074)*	40.6291.200	1
3		Container solid bottom 1/2 306x272x135 mm	12.0751.102	1
4		Perforated aluminum lid 1/2 306x272x15 mm Gray	12.0751.200	1

implants not included;

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Indications

- Inner and periarticular fractures of the distal end of the humeral bone.
- Fractures of the distal end of the humeral bone extending to the shaft.
- Corrective osteotomy.
- Non-union of fractured bone.

Contraindications

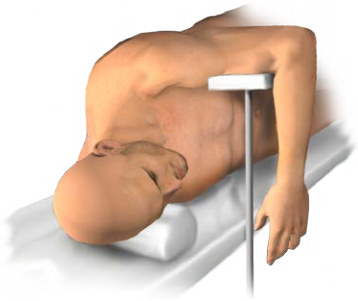
Absolute:

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

Relative:

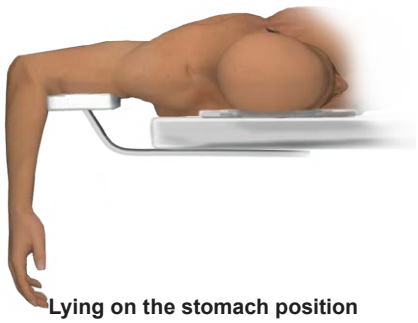
- Significant weakening of the bone making it impossible to install/stabilize the implant properly.
- Abnormal perfusion of fracture area or surgical site.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create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

The patient's position



Lateral lying position

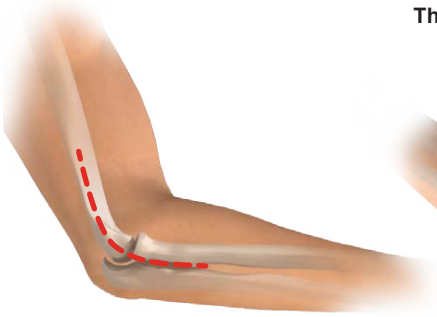
Lying on the back position



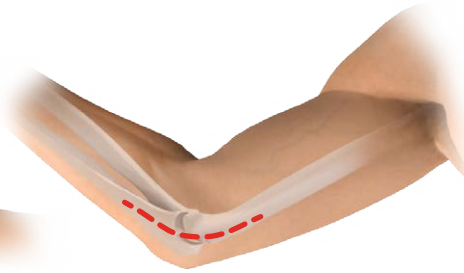
Lying on the stomach position

Surgical approach

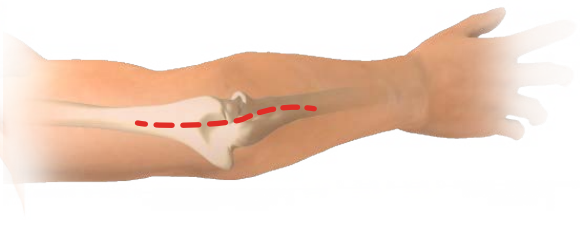
The approach is dependent on the fracture type



Lateral approach



Medial approach



Posterior approach

Particular attention should be paid to the ulnar nerve - it is essential to expose it.
Lateral, medial or both approaches simultaneously may be implemented.
Posterior approach that bypasses the olecranon makes it possible to conduct the osteotomy of the olecranon which in result allows a better view of the fracture site.

Procedure stages

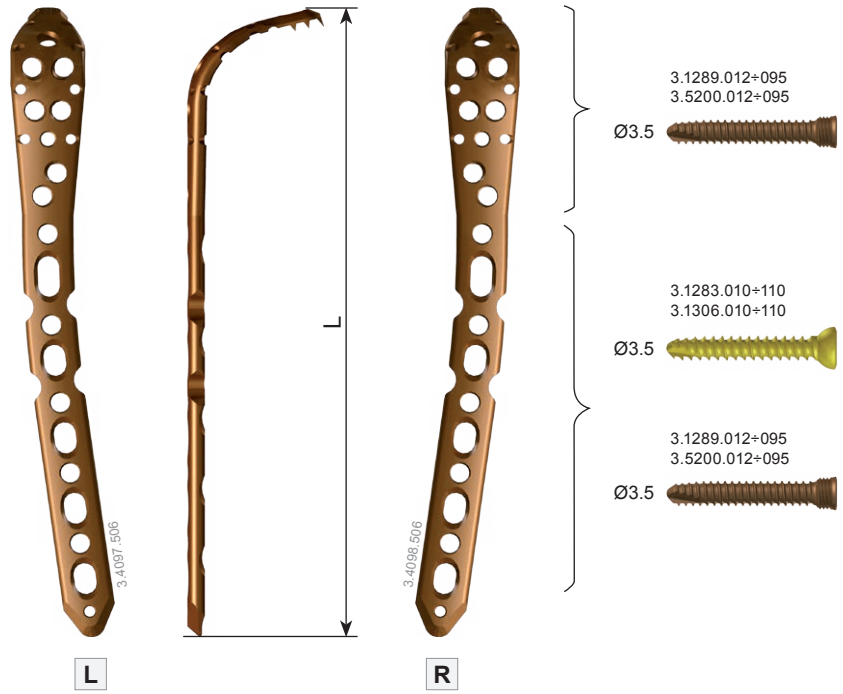
- Reduction of fracture and stabilization of the fracture fragments using Kirschner wires - particular attention should be paid to the reconstruction of the articular surfaces. Please note that the plates are provided with holes for initial stabilization using Kirschner wires.
- The choice of implants - determining the length and position of the implant.
  Attention: In the case of stabilization using two plates, the implants should be of different length as to avoid overloading of the shaft of the humeral bone. Two holes difference in length is indicated.
- Adjusting the shape of the implant, if necessary.
- Positioning of the plate using the compression screw in the extended hole.
- Temporary stabilization of the implant using Kirschner wires.
- Introduction of the screws in the distal parts of the plate.
  Attention: When inserting the screws in the distal parts of the plate make sure they do not move into the articular surfaces or olecranon fossae.
- Stabilization of the shaft using locking or compression screws.

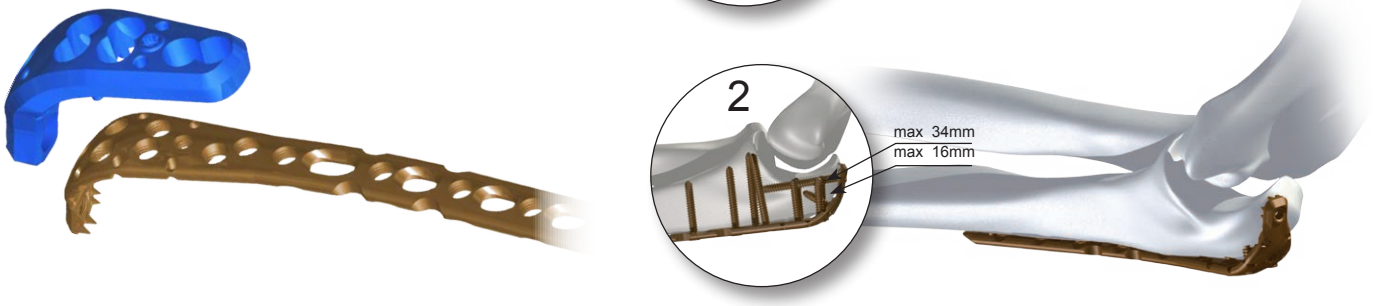
5.0ChLP olecranon plate

O	L [mm]	Catalogue no. Left	Catalogue no. Right
2	88	3.4097.502	3.4098.502
4	121	3.4097.504	3.4098.504
6	151	3.4097.506	3.4098.506
8	181	3.4097.508	3.4098.508
10	210	3.4097.510	3.4098.510

O – threaded holes number in shaft part of the plate

available	**2 - 12 holes** *(88 mm - 240 mm)*





Palette for 5.0ChLP plates - 3.4097/3.4098

No.	Catalogue no.	Name	Pcs		
1	40.5731.100	Aiming block L **[3.4097]**	1	40.5758.120	40.5758.620
2	40.5731.200	Aiming block R **[3.4098]**	1		
3	40.5672.000	Protective guide 7.0/5.0	2		
4	40.5758.320	Palette	1		
5	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1		
6	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1		

implants not included; with additional instruments

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Indications

- The intra-articular and extra-articular fractures of proximal end of the elbow bone.
- Fractures of the proximal end of the elbow bone extending to the shaft of the bone.
- Corrective osteotomy.
- Non-union of fractured bone.

Contraindications

Absolute:

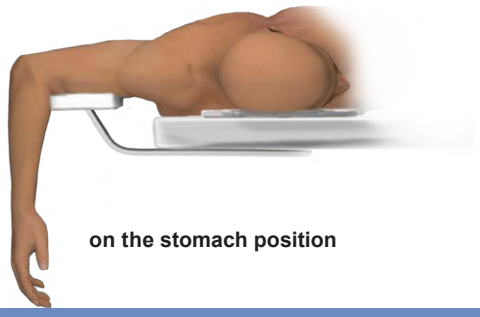
- Health condition precluding surgery.
- Allergic reactions to the metal from which the implant is made.
- Active infection.

Relative:

- Weakened bone *(by disease, infection or prior implantation)* making it impossible to install/stabilize the implant properly.
- Abnormal perfusion of fracture area.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create a risk of fusion failure or complications in the postoperative period.
- Other medical conditions that exclude the potential benefits of the treatment.

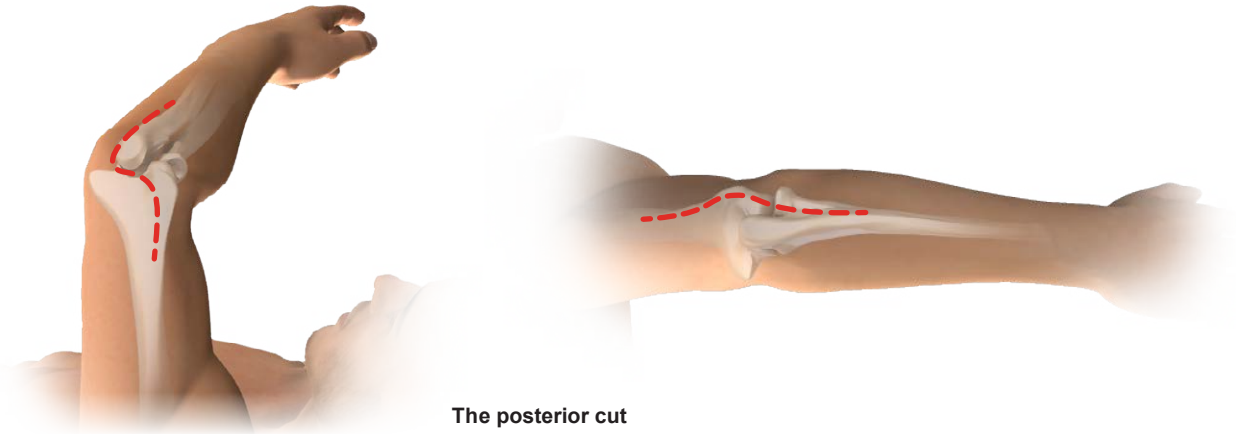
The patient's position

on the back position



on the stomach position

Surgical approach



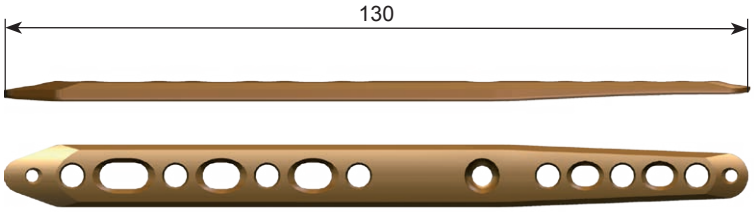
The posterior cut

Particular attention should be paid to the ulnar nerve - it is essential to expose it.

Procedure stages

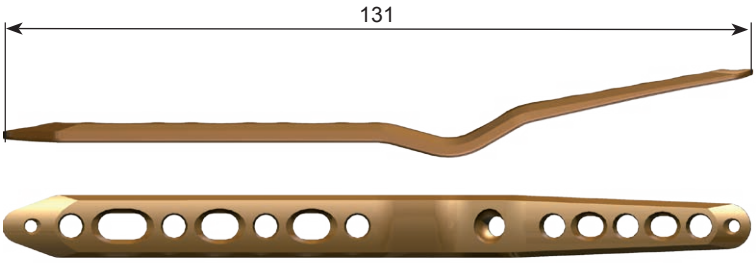
- Reduction of fracture and stabilization of the fracture fragments using Kirschner wires - particular attention should be paid to the re-construction of the articular surfaces. Please note that the plates are provided with holes for initial stabilization using Kirschner wires.
- The choice of implants - determining the length and position of the implant.
- Adjusting the shape of the implant carefully, if necessary.
- Positioning of the plate using the compression screw in the extended hole.
- Restoring the continuity of the articular surfaces.
- Radiological control.
- Introduction of the screws in the distal and proximal parts of the plate under the X-Ray control.
  Attention: When inserting the screws in the distal parts of the plate make sure they do not move into the articular surfaces.
- Wound drainage according to the situation.
- Provided that the anastomosis is stable, increasing of efficiency shall not be implemented until the second postoperative day.

5.0ChLP wrist arthrodesis plate - straight



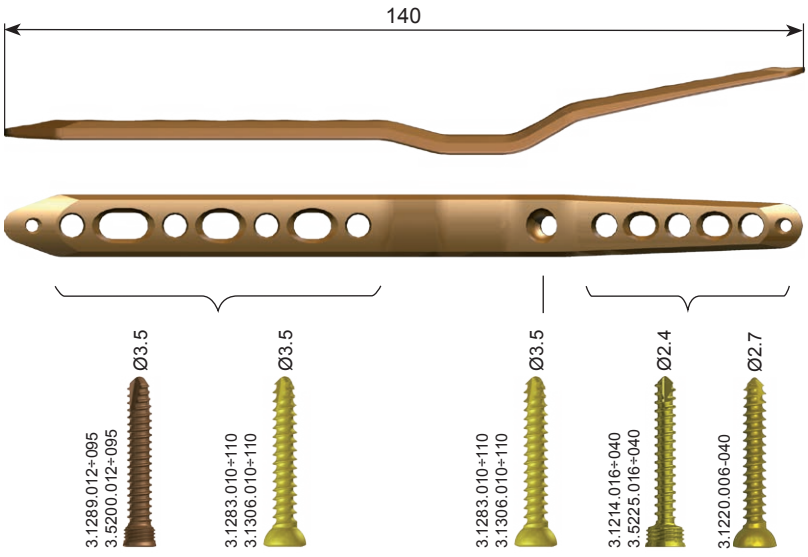
L [mm]	Catalogue no.
130	3.7033.004

5.0ChLP wrist arthrodesis plate - short bend



L [mm]	Catalogue no.
131	3.7034.004

5.0ChLP wrist arthrodesis plate - standard bend



L [mm]	Catalogue no.
140	3.7035.004

Palette for 5.0ChLP plates - 3.7033-3.7035

No.	Catalogue no.	Name	Pcs	
1	40.5758.160	Palette	1	40.5758.660
2	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1	
3	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1	

implants not included

ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 713 13 20, fax + 48 85 713 13 19, chm@chm.eu, www.chm.eu

Indications

- Post-traumatic wrist arthrosis
- Advanced wrist arthrosis with instability, after infection past.
- Spastic deformities.
- Paresis after brachial plexus injury.
- Rheumatoid joint inflammations.

Contraindications

Absolute:

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

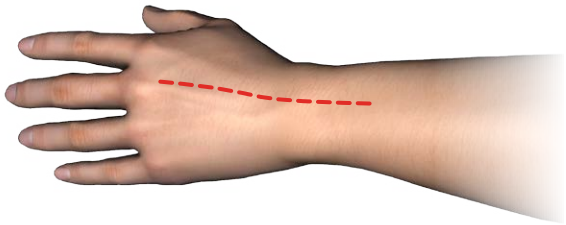
Relative:

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

The patient's position

Lying on the back position

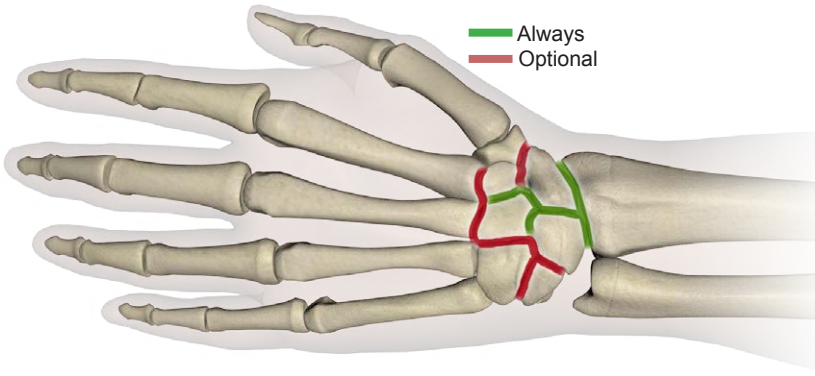
Surgical approach



Incision *„smooth S"* at dorsal wrist side below Lister's tubercle to the 1/3 distal end of the 3rd metacarpal.

Procedure stages

- Remove cartilage from the fused joints *(according to the drawing)*.
- Dorsal surface decortication of the: radial, scaphoid, lunar, capitate bone and Lister's tubercle removing.
- Insert bone graft.
- Insertion of the plate and its positioning.
- Temporary stabilization of the implant using Kirschner wires.
- Introduction of the screws in the distal part of the plate.
- Introduction of the screws in the proximal part of the plate.
- Making X-Ray film to make sure the plate and screws are positioned properly.
- Closing the wound.

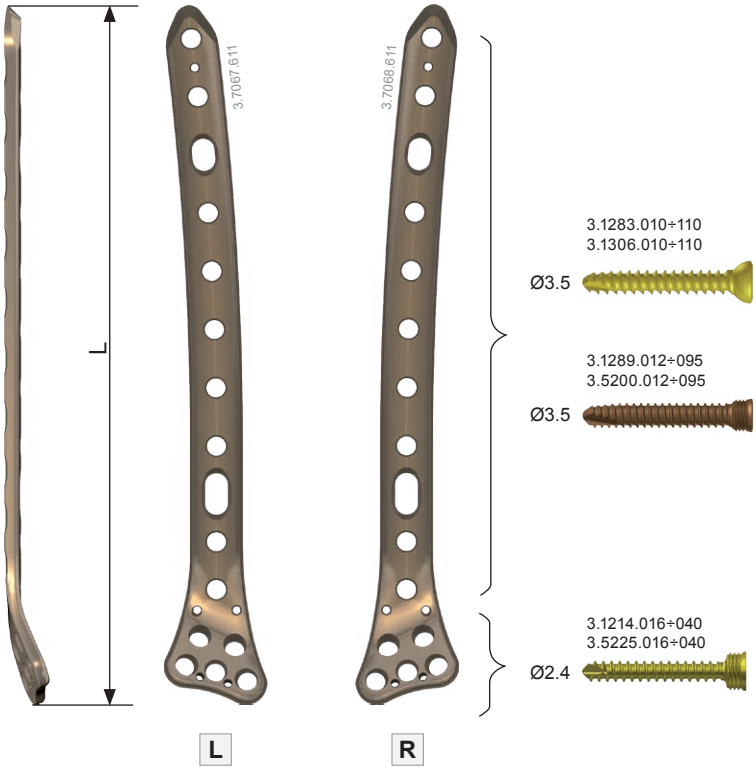


5.0ChLP radius volar plate

O	L [mm]	Catalogue no. Left	Catalogue no. Right
5	73	3.7067.605	3.7068.605
7	97	3.7067.607	3.7068.607
9	122	3.7067.609	3.7068.609
11	148	3.7067.611	3.7068.611

O -all holes number in shaft part of the plate

available	**13; 15 holes** *(170 mm; 194 mm)*



Palette for 5.0ChLP plates - 3.7067/3.7068

No.	Catalogue no.	Name	Pcs	
1	40.5742.100	Aiming block L **[3.7067]**	1	40.6269.000
2	40.5742.200	Aiming block R **[3.7067]**	1	
3	40.5672.000	Protective guide 7.0/5.0	2	
4	40.6268.000	Palette	1	
5	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1	
6	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1	

implants not included; with additional instruments

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Indications

- Fractures of the distal part of the radius and the fractures extending to the shaft of the radius.
- Non-union or malunions of fractured bone.

Contraindications

Absolute:

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

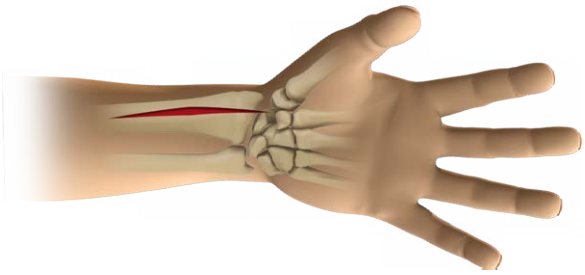
Relative:

- Weakened bone *(by disease, infection or prior implantation)* making it impossible to install/stabilize the implant properly.
- Abnormal perfusion of fracture area.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create a risk of fusion failure or complications in the postoperative period.
- Other medical conditions that exclude the potential benefits of the treatment.

Pozycja pacjenta

Lying on the back position.

Surgical approach



In volar approach, make a longitudinal incision between the radial wrist flexor tendon and the radial artery.

Procedure stages

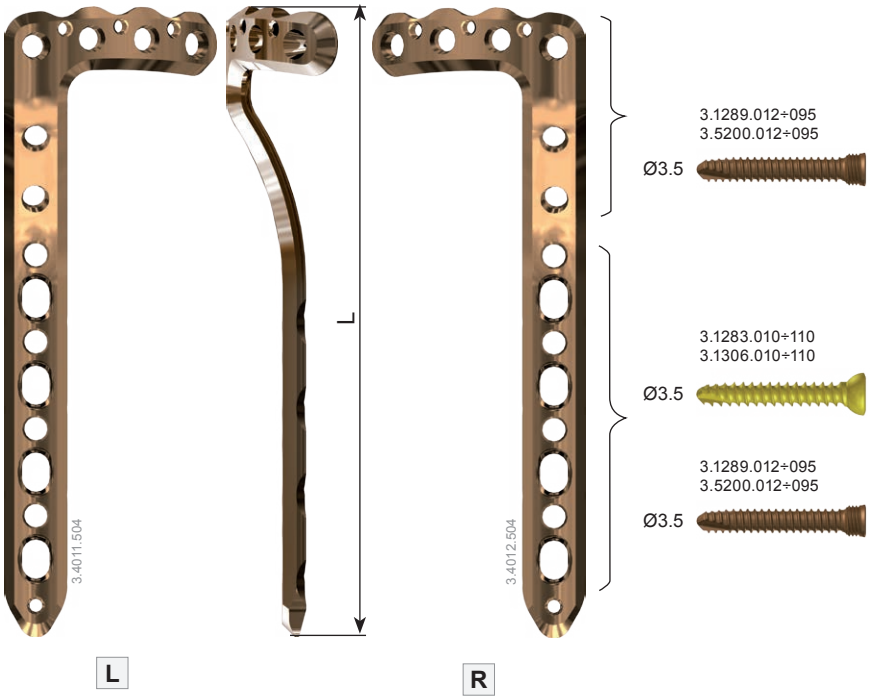
- Reduction of fracture and stabilization of the fracture fragments using Kirschner wires.
- The choice of implants - determining the length and position of the implant.
- Insertion of the plate and its positioning.
- Temporary stabilization of the implant using Kirschner wires.
- Introduction of the screws in the distal parts of the plate.
- Stabilization of the shaft using locking or compression screws.
- Making X-Ray films as to make sure the plate and screws are positioned properly.
- Wound closure.

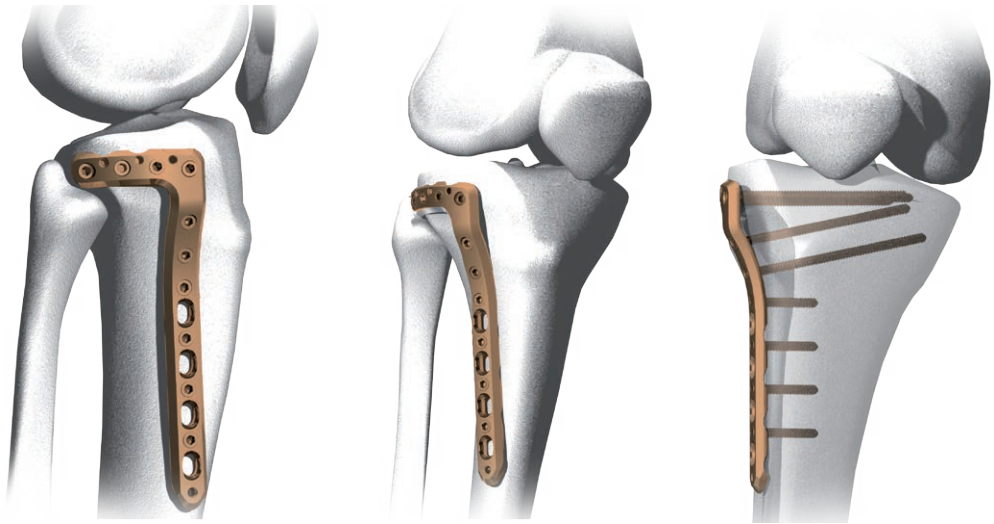
5.0ChLP narrow tibial plate

O	L [mm]	Catalogue no. Left	Catalogue no. Right
4	109	3.4011.504	3.4012.504
5	124	3.4011.505	3.4012.505
6	139	3.4011.506	3.4012.506
8	169	3.4011.508	3.4012.508

O – threaded holes number in shaft part of the plate

available	**4 - 16 holes** *(109 mm - 289 mm)*





Palette for 5.0ChLP plates -3.4011/3.4012

No.	Catalogue no.	Name	Pcs	
1	40.5758.020	Palette	1	40.5758.520
2	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1	
3	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1	

implants not included

ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 713 13 20, fax + 48 85 713 13 19, chm@chm.eu, www.chm.eu

Indications

- Articular and extra-articular, metaphysial and epiphysial comminuted fractures of the proximal part of the tibia and fractures extending to the shaft of the tibia.
- Non-union or malunions of fractured bone.

Contraindications

Absolute:

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

Relative:

- Weakened bone *(by disease, infection or prior implantation)* making it impossible to install/stabilize the implant properly.
- Abnormal perfusion of fracture area.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create a risk of fusion failure or complications in the postoperative period.
- Other medical conditions that exclude the potential benefits of the treatment.

The patient's position

Surgical approach

Lateral S cut - recommended for simple articular and extra-articular fractures

Straight anterior-lateral cut - recommended for more complex articular fractures.

Anterior-lateral approach. The cut performed between the tibia and fibula bone and should begin approximately 1 cm proximally from the lateral condyle of the tibia to the desired length of the plate. In the minimally invasive technique, a short cut and additional cuts for the access to the holes of the shaft of the plate should be performed.

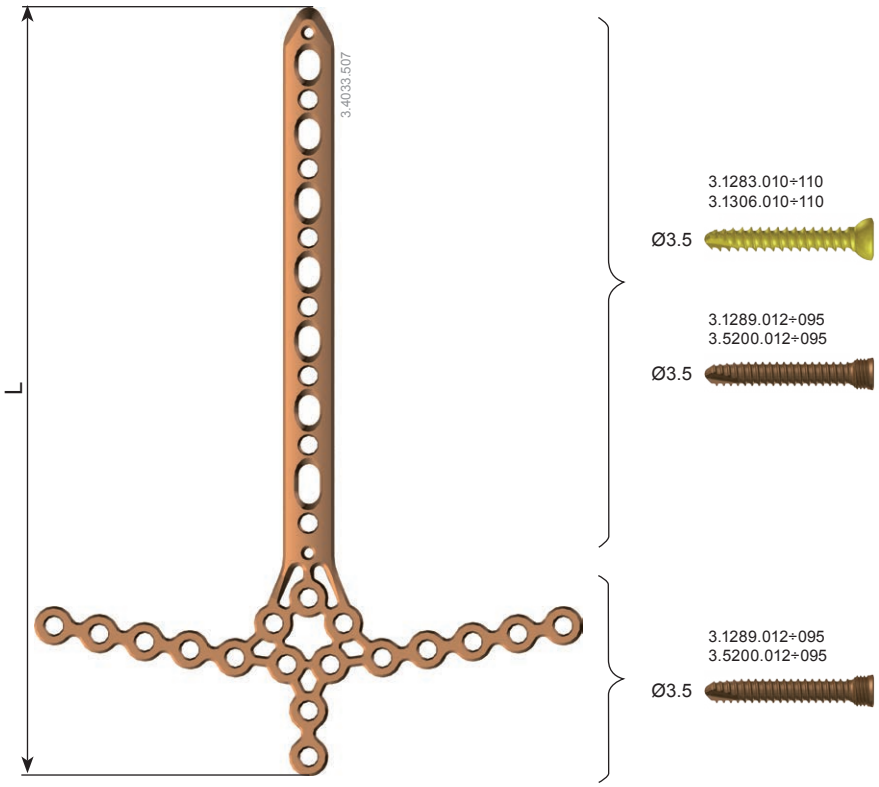
Procedure stages

- Reduction of fracture and stabilization of the fracture fragments using Kirschner wires.
- The choice of implants - determining the length and position of the implant.
- Insertion of the plate and its positioning.
- Temporary stabilization of the implant using Kirschner wires.
- Introduction of the screws in the distal parts of the plate.
- Stabilization of the shaft using locking or compression screws.
- Positioning of the plate using the compression screw in the extended hole.
- Making X-Ray film in both A-P and lateral position as to make sure the plate and screws are positioned properly.
- Closing the wound.

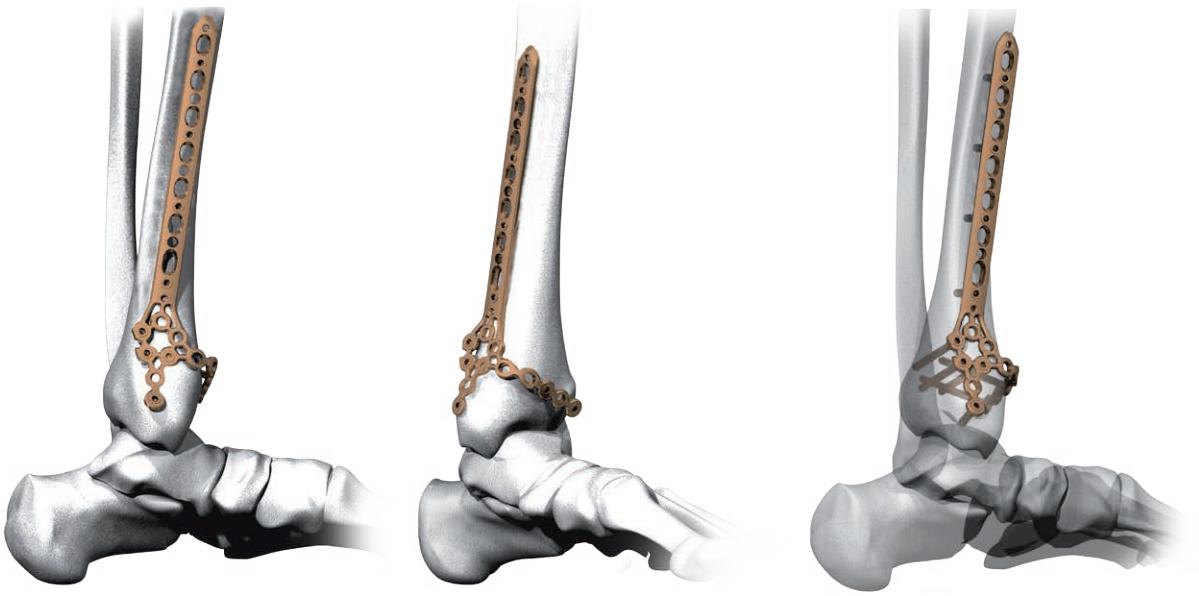
5.0ChLP distal medial tibial plate

O	L [mm]	Catalogue no.
7	167	3.4033.507
9	197	3.4033.509

O – threaded holes number in shaft part of the plate



Additional equipment :
40.5394.501
5.0ChLP - 3.4033.5xx plate trial



Palette for 5.0ChLP plates -3.4033

No.	Catalogue no.	Name	Pcs	
1	40.5758.060	Palette	1	40.5758.560
2	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1	
3	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1	

implants not included

ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 713 13 20, fax + 48 85 713 13 19, chm@chm.eu, www.chm.eu

Indications

- Comminuted fractures of the distal part of the tibial bone.
- Non-union or malunions of fractured bone.

Contraindications

Absolute:

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

Relative:

- Weakened bone *(by disease, infection or prior implantation)* making it impossible to install/stabilize the implant properly.
- Abnormal perfusion of fracture area.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create a risk of fusion failure or complications in the postoperative period.
- Other medical conditions that exclude the potential benefits of the treatment.

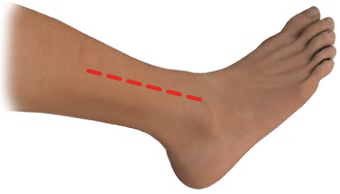
The patient's position

Lying on the back position

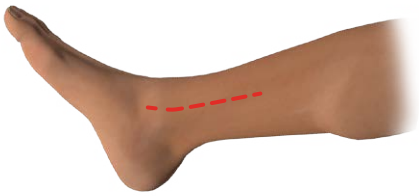
Surgical approach

Surgical approach depends on the positioning of the implant on the distal base of the tibia. Different surgical approaches may be applied: anterior, anterior-lateral or medial one.

Anterior approach.



Medial approach.



Anterio-lateral approach.

Procedure stages

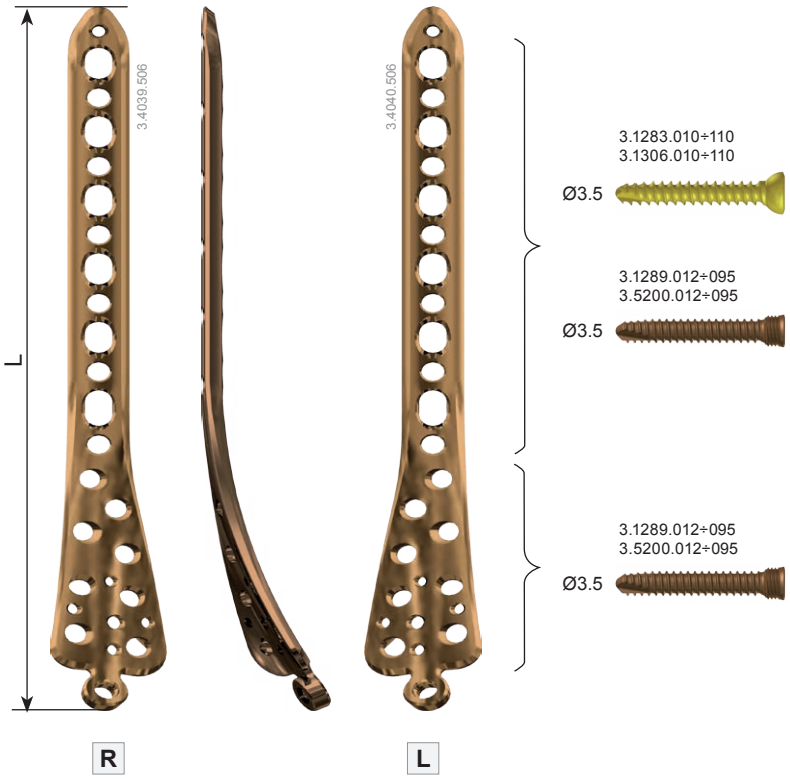
- Reduction of fracture and stabilization of the fracture fragments using Kirschner wires.
- The choice of implants - determining the length and position of the implant.
- Shaping the implant - bending arms of the plate, cutting away unnecessary holes.
- Insertion of the plate and its positioning.
- Temporary stabilization of the implant using Kirschner wires, setting-compressing screw or compression screw.
- Introduction of the screws in the distal parts of the plate *(Attention: Reduction of the bone fragments will not be possible after using locking screws. Avoid clashes of the screws!)*.
- Stabilization of the shaft using locking or compression screws.
- Making X-Ray film in both A-P and lateral position as to make sure the plate and screws are positioned properly.
- Closing the wound.

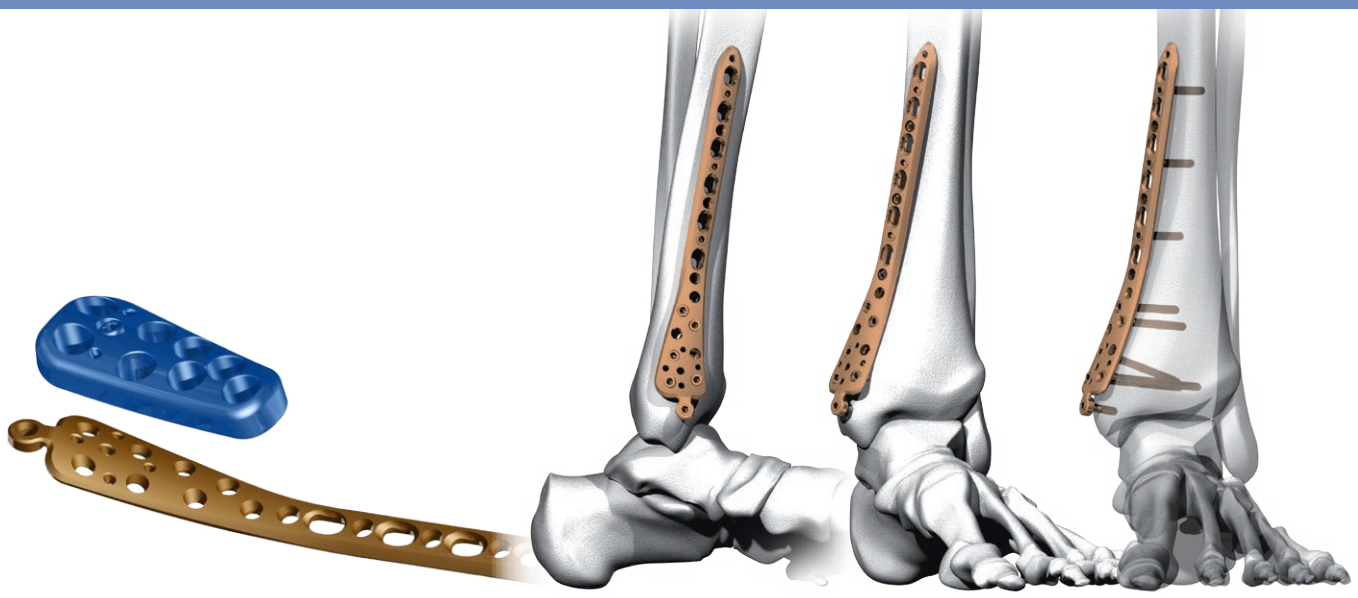
5.0ChLP tibial distal medial plate

O	L [mm]	Catalogue no. Left	Catalogue no. Right
4	123	3.4039.504	3.4040.504
6	153	3.4039.506	3.4040.506
8	183	3.4039.508	3.4040.508

O – threaded holes number in shaft part of the plate

available	**4 - 14 holes** *(123 mm - 273 mm)*





Palette for 5.0ChLP plates -3.4039/3.4040

No.	Catalogue no.	Name	Pcs		
1	40.5726.100	Aiming block L **[3.4039]**	1	40.5758.070	40.5758.570
2	40.5726.200	Aiming block R **[3.4040]**	1		
3	40.5672.000	Protective guide 7.0/5.0	2		
4	40.5758.270	Palette	1		
5	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1		
6	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1		

implants not included; with additional instruments

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Indications

- Comminuted fractures of the distal part of the tibial bone and the fractures extending to the shaft of the tibia.
- Non-union or malunions of fractured bone.

Contraindications

Absolute:

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

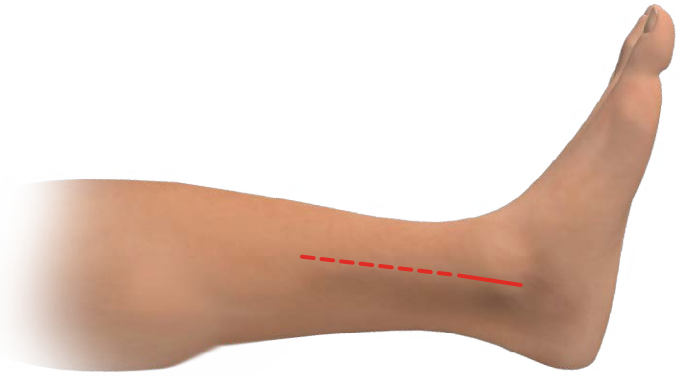
Relative:

- Weakened bone *(by disease, infection or prior implantation)* making it impossible to install/stabilize the implant properly.
- Abnormal perfusion of fracture area.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create a risk of fusion failure or complications in the postoperative period.
- Other medical conditions that exclude the potential benefits of the treatment.

The patient's position

Lying on the back position

Surgical approach



Medial approach. The cut begins approximately 1 cm proximally from the medial ankle to the desired length of the plate. In the minimally invasive technique, a cut above the medial ankle and short cuts for the access to the holes of the shaft of the plate should be performed.

Procedure stages

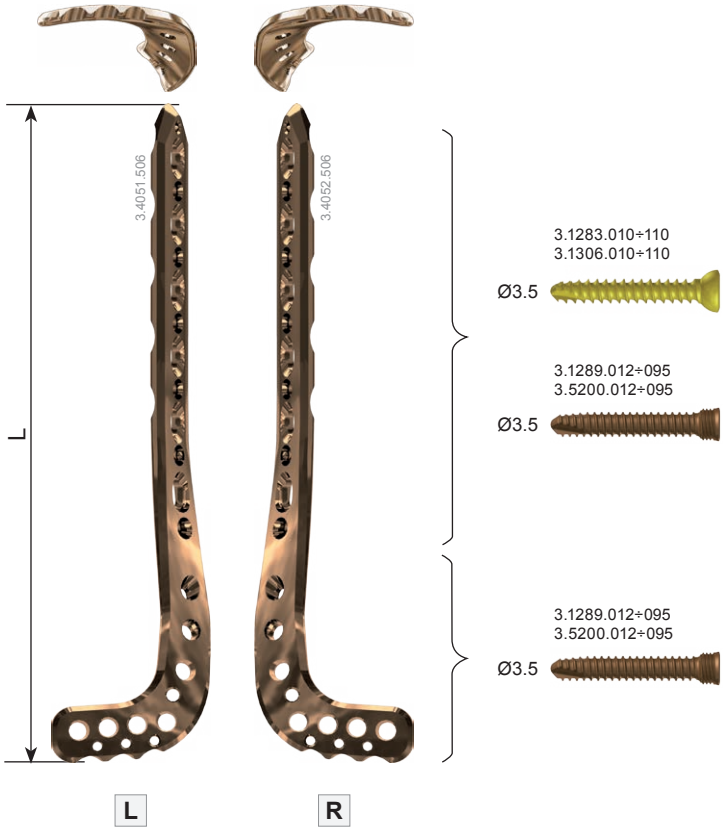
- Reduction of fracture and stabilization of the fracture fragments using Kirschner wires.
- The choice of implants - determining the length and position of the implant.
- Insertion of the plate and its positioning.
- Temporary stabilization of the implant using Kirschner wires.
- Introduction of the screws in the distal parts of the plate.
- Stabilization of the shaft using locking or compression screws.
- Making X-Ray film in both A-P and lateral position as to make sure the plate and screws are positioned properly.
- Closing the wound.

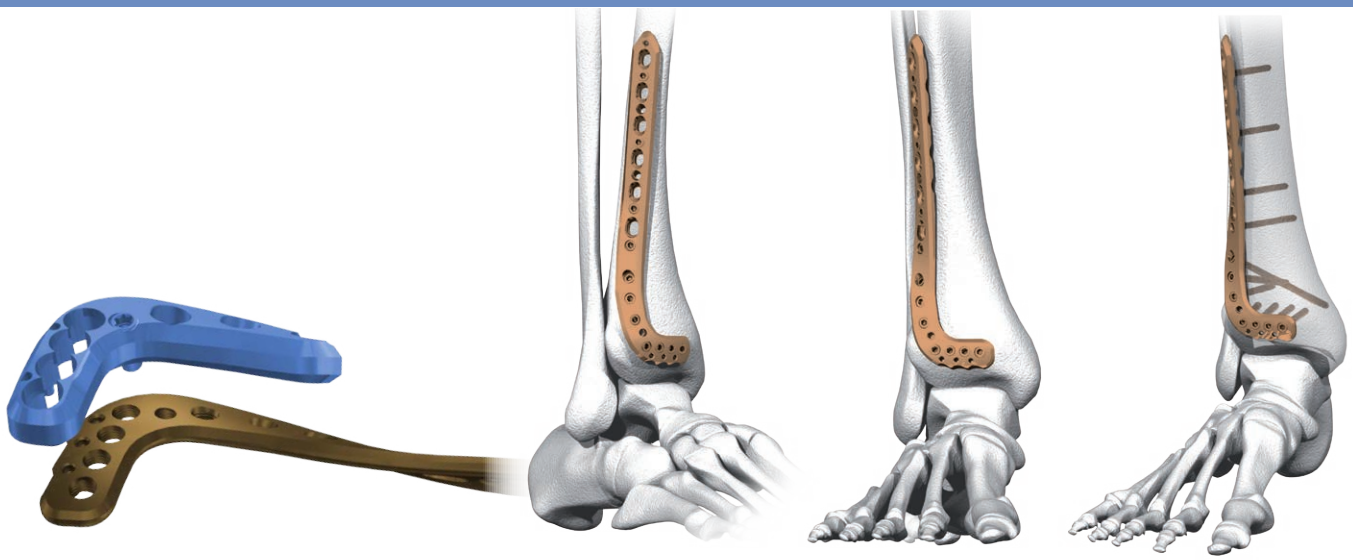
5.0ChLP distal tibial L plate

O	L [mm]	Catalogue no. Left	Right
4	120	3.4051.504	3.4052.504
6	150	3.4051.506	3.4052.506
8	180	3.4051.508	3.4052.508

O – threaded holes number in shaft part of the plate

available	**3 - 16 holes** *(105 mm - 300 mm)*





Palette for 5.0ChLP plates - 3.4051/3.4052

No.	Catalogue no.	Name	Pcs		
1	40.5723.100	Aiming block L **[3.4051]**	1	40.5758.080	40.5758.580
2	40.5723.200	Aiming block R **[3.4052]**	1		
3	40.5672.000	Protective guide 7.0/5.0	2		
4	40.5758.280	Palette	1		
5	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1		
6	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1		

implants not included; with additional instruments

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Indications

- Comminuted fractures of the distal part of the tibial bone and the fractures extending to the shaft of the tibia.
- Non-union or malunions of fractured bone.

Contraindications

Absolute:

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

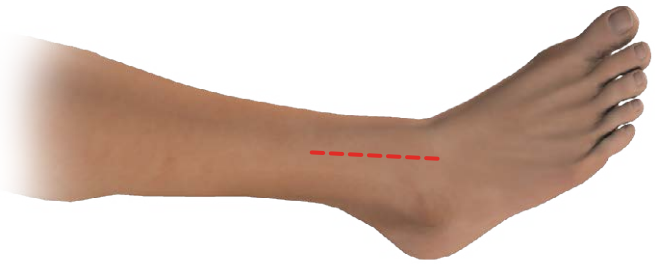
Relative:

- Weakened bone *(by disease, infection or prior implantation)* making it impossible to install/stabilize the implant properly.
- Abnormal perfusion of fracture area.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create a risk of fusion failure or complications in the postoperative period.
- Other medical conditions that exclude the potential benefits of the treatment.

The patient's position

Lying on the back position

Surgical approach



Anterior-lateral approach. The cut performed between the tibia and fibula bone and should begin approximately 1 cm proximally from the medial ankle to the desired length of the plate. In the minimally invasive technique, a short cut and additional cuts for the access to the holes of the shaft of the plate should be performed.

Procedure stages

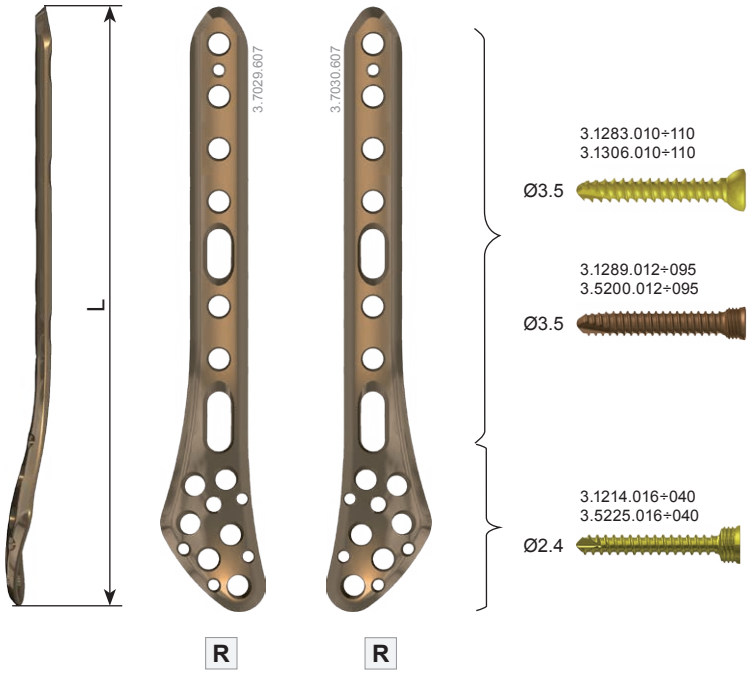
- Reduction of fracture and stabilization of the fracture fragments using Kirschner wires.
- The choice of implants - determining the length and position of the implant.
- Insertion of the plate and its positioning.
- Temporary stabilization of the implant using Kirschner wires.
- Introduction of the screws in the distal parts of the plate.
- Stabilization of the shaft using locking or compression screws.
- Making X-Ray film in both A-P and lateral position as to make sure the plate and screws are positioned properly.
- Closing the wound.

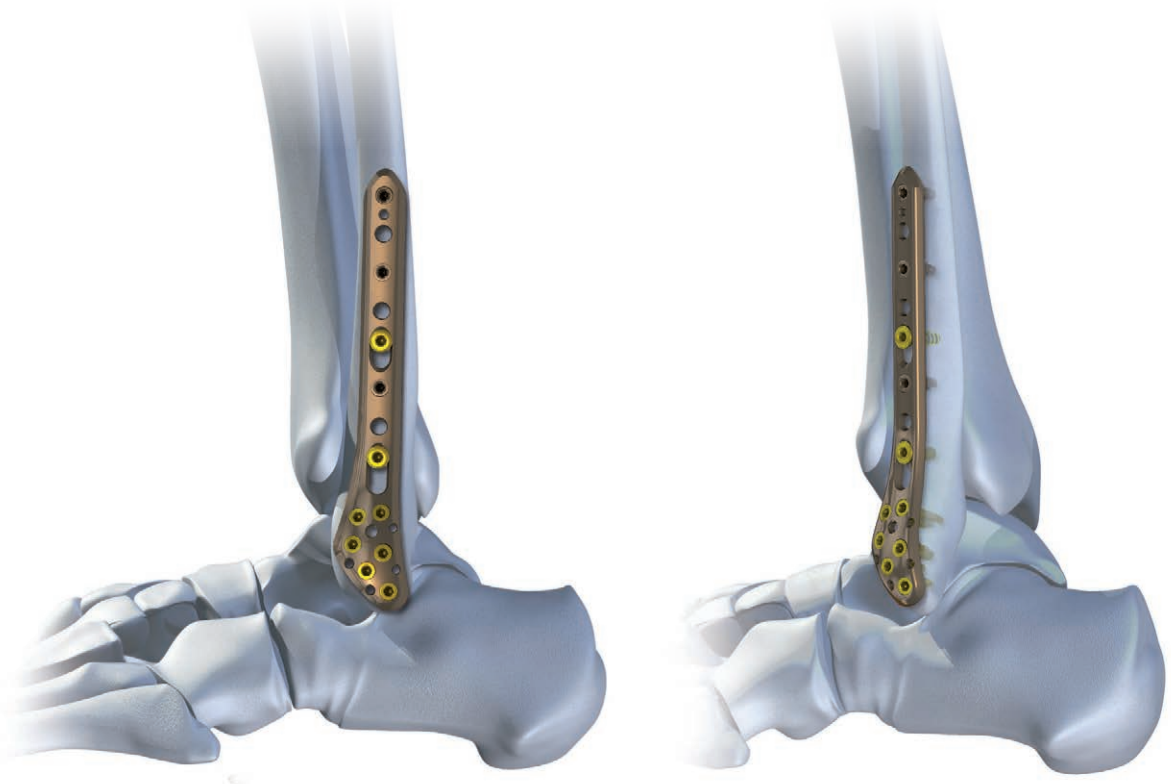
5.0ChLP distal lateral fibula plate

O	L [mm]	Catalogue no. Left	Right
4	85	3.7029.604	3.7030.604
5	95	3.7029.605	3.7030.605
6	105	3.7029.606	3.7030.606
7	115	3.7029.607	3.7030.607
8	125	3.7029.608	3.7030.608

O -all holes number in shaft part of the plate

available	**4 - 12 holes** *(85 mm - 165 mm)*





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Indications

- Comminuted fractures of fibula in its distal part with or without the damage to tibiofibular syndesmosis.
- Non-union or malunions of fractured bone.

Contraindications

Absolute:

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

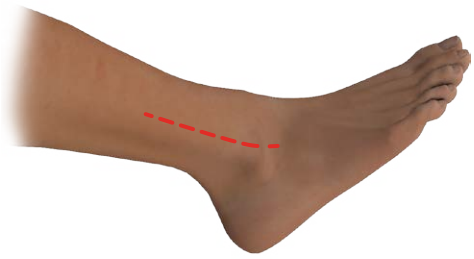
Relative:

- Weakened bone *(by disease, infection or prior implantation)* making it impossible to install/stabilize the implant properly.
- Abnormal perfusion of fracture area.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create a risk of fusion failure or complications in the postoperative period.
- Other medical conditions that exclude the potential benefits of the treatment.

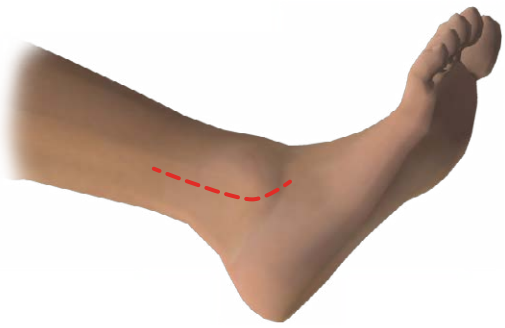
The patient's position

Lying on the back position.

Surgical approach



Lateral approach.



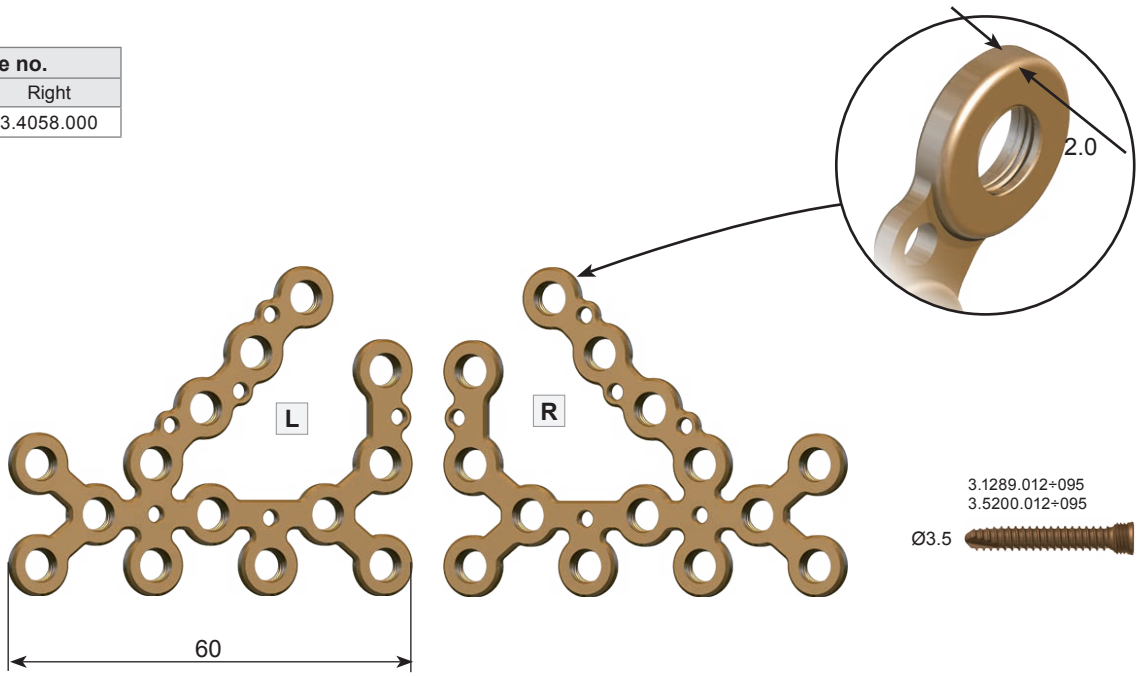
Postero-lateral approach.

Procedure stages

- Reduction of fracture and stabilization of the fracture fragments using Kirschner wires.
- The choice of implants - determining the length and position of the implant.
- Insertion of the plate and its positioning.
- Temporary stabilization of the implant using Kirschner wires.
- Introduction of the screws in the distal parts of the plate.
- Stabilization of the shaft using locking or compression screws.
- Making X-Ray film in both A-P and lateral position as to make sure the plate and screws are positioned properly.
- Closing the wound.

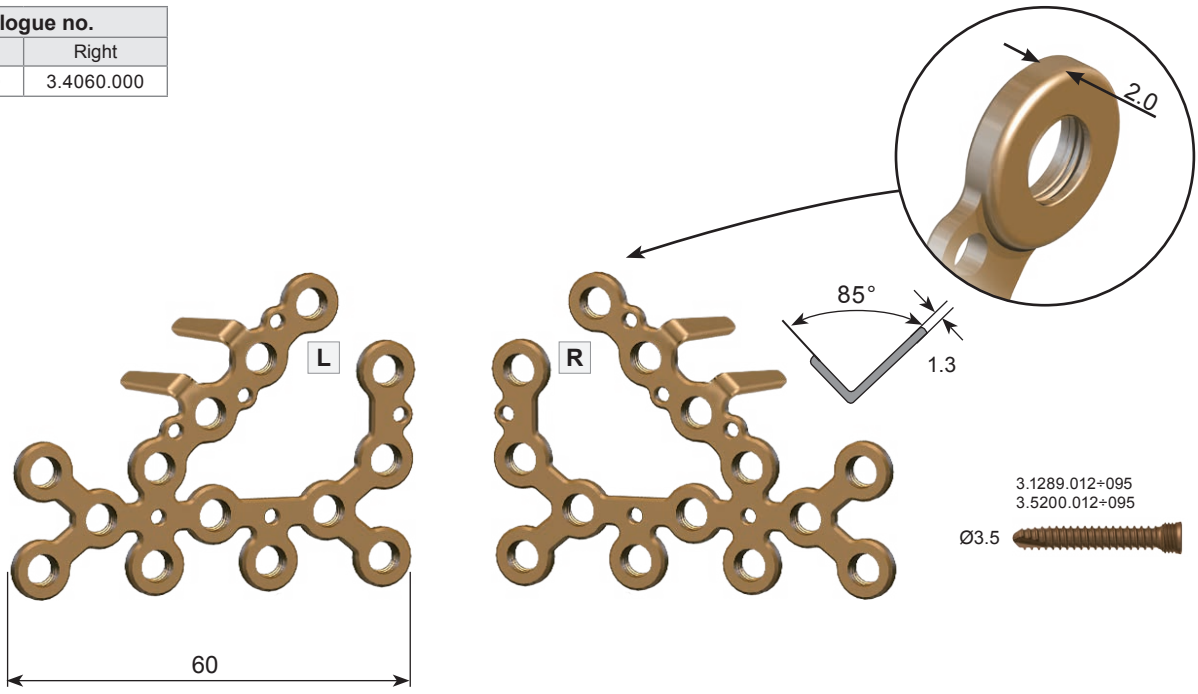
5.0ChLP calcaneal plate

Catalogue no.	
Left	Right
3.4057.000	3.4058.000



5.0ChLP calcaneal plates with hook

Catalogue no.	
Left	Right
3.4059.000	3.4060.000



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Indications

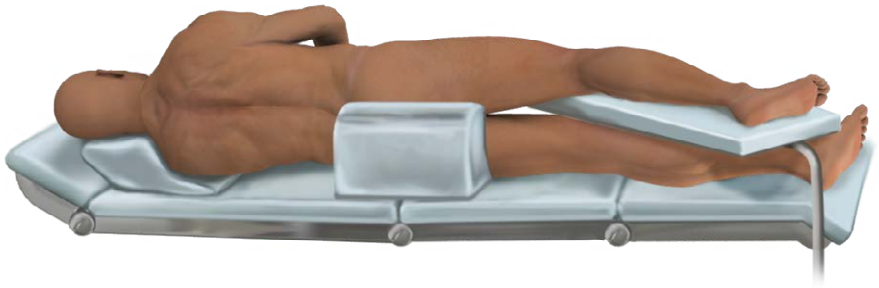
- Articular, extra-articular fractures and comminuted fractures of calcaneus.

Contraindications

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

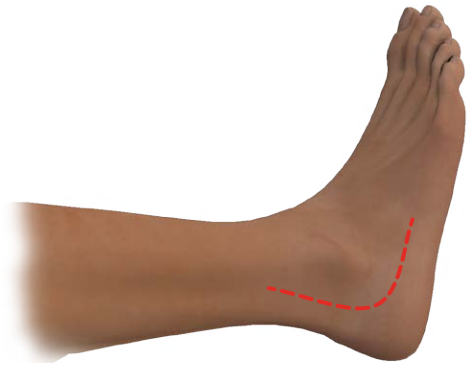
Relative:
- Weakened bone *(by disease, infection or prior implantation)* making it impossible to install/stabilize the implant properly.
- Abnormal perfusion of fracture area.
- Excessive obesity.
- Lack of adequate tissue coverage.
- Psychiatric disorders or the disorders of the musculoskeletal system which may create a risk of fusion failure or complications in the postoperative period.
- Other medical conditions that exclude the potential benefits of the treatment.

The patient's position



Position: laying on the side.

Surgical approach



Lateral approach.

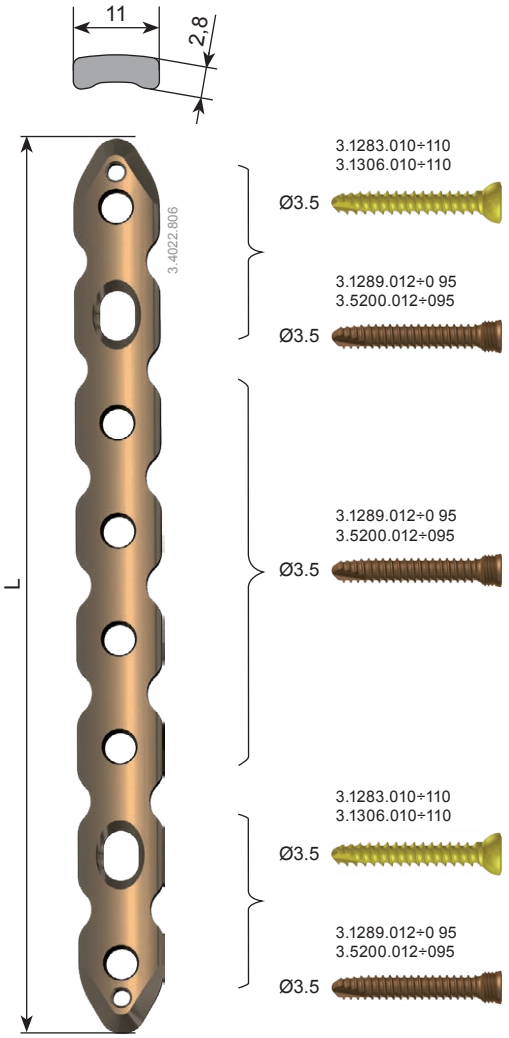
Procedure stages

- Reduction of fracture and stabilization of the fracture fragments using Kirschner wires.
- The choice of implants - determining the length and position of the implant.
- Shaping the implant - bending arms of the plate, cutting away unnecessary holes.
- Insertion of the plate and its positioning.
- Temporary stabilization of the implant using Kirschner wires,
- Introduction of the screws *(Attention: Reduction of the bone fragments will not be possible after using locking screws. Avoid clashes of the screws!)*.
- Making X-Ray film in both A-P and lateral position as to make sure the plate and screws are positioned properly.
- Closing the wound.

5.0ChLP reconstruction straight plate

O	L [mm]	Catalogue no.
4	88	3.4022.804
5	102	3.4022.805
6	116	3.4022.806
7	130	3.4022.807
8	144	3.4022.808
9	158	3.4022.809
10	172	3.4022.810
11	186	3.4022.811
12	200	3.4022.812
13	214	3.4022.813
14	228	3.4022.814
15	242	3.4022.815
16	256	3.4022.816
17	270	3.4022.817
18	284	3.4022.818
19	298	3.4022.819
20	312	3.4022.820
21	326	3.4022.821
22	340	3.4022.822

O - all threaded holes number in the plate



Palette for 5.0ChLP reconstruction plates

No.	Catalogue no.	Name	Pcs	
1	40.5758.100	Palette	1	40.5758.600
2	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1	
3	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1	

implants not included

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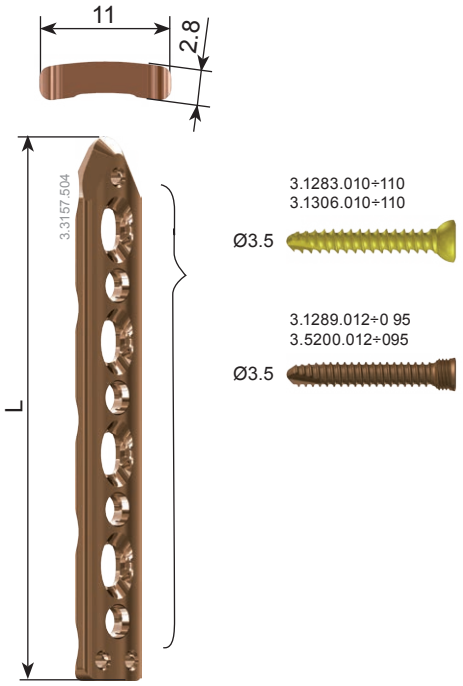
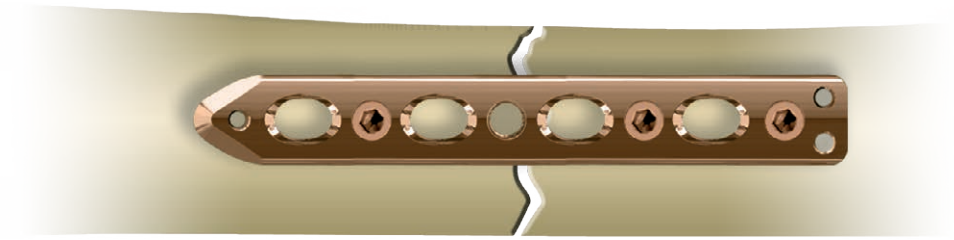
5.0ChLP narrow compression plate with limited contact

O	L [mm]	Catalogue no.
5	88	3.3157.505
6	103	3.3157.506
7	118	3.3157.507
8	133	3.3157.508
10	163	3.3157.510
12	193	3.3157.512

O - all threaded holes number in the plate

available	**4 - 18 holes** *(73 mm - 283 mm)*





Palette for 5.0ChLP plates - straight

No.	Catalogue no.	Name	Pcs	
1	40.5758.050	Palette	1	40.5758.550
2	12.0751.100	Container solid bottom 1/2 306x272x85 mm	1	
3	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1	

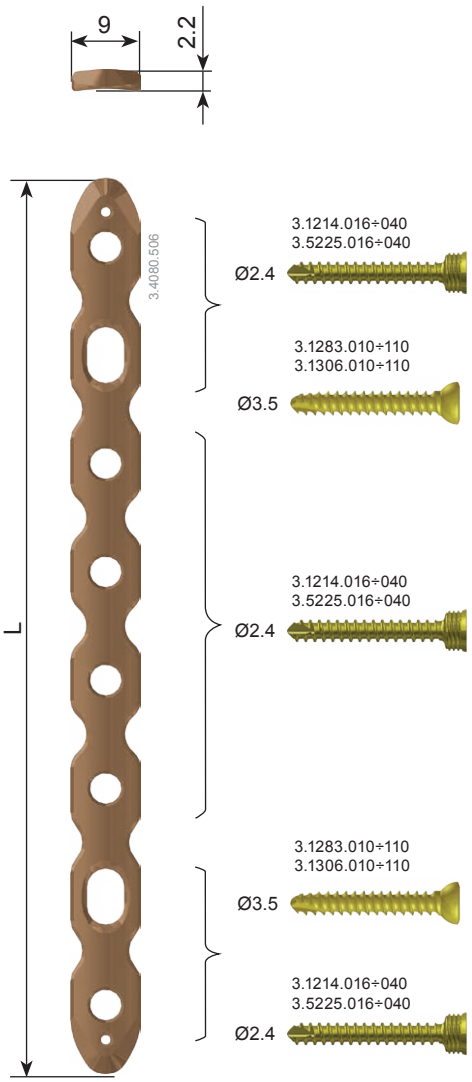
implants not included

4.5ChLP narrow straight reconstruction plate

O	L [mm]	Catalogue no.
4	88	3.4080.504
5	102	3.4080.505
6	116	3.4080.506
7	130	3.4080.507
8	144	3.4080.508
10	172	3.4080.510

O - all threaded holes number in the plate

available	**4 - 22 holes** *(88 mm - 340 mm)*



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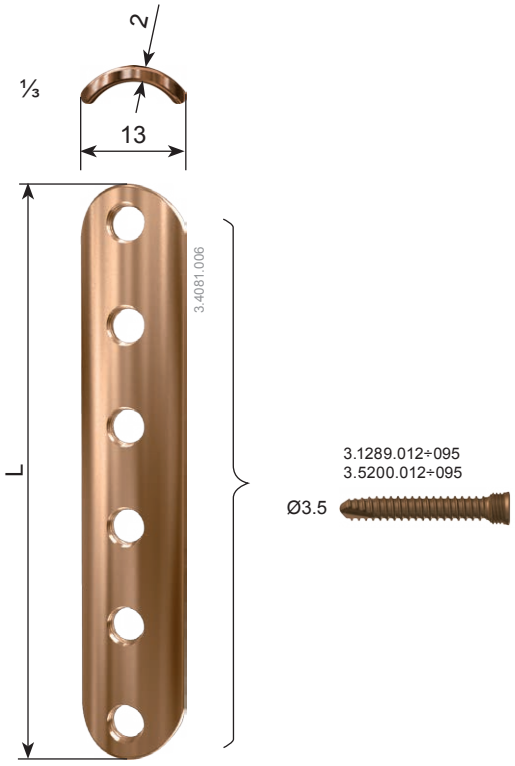
5.0ChLP tubular straight plate ⅓

O	L [mm]	Catalogue no.
4	45	3.4081.004
5	57	3.4081.005
6	69	3.4081.006
7	81	3.4081.007
8	93	3.4081.008
10	117	3.4081.010

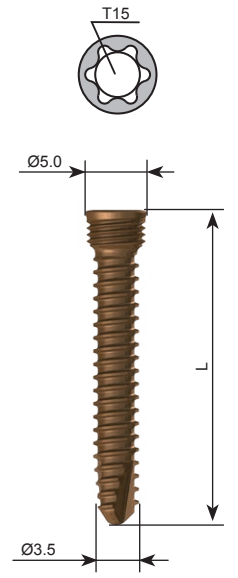
O - all threaded holes number in the plate

available	**3 - 12 holes** *(33 mm - 141 mm)*



III.2. SCREWS

5.0ChLP screw 3.5

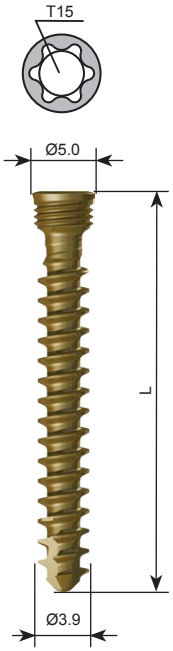


self-tapping

L [mm]	Catalogue no.
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
90	3.5200.090
95	3.5200.095

Ø Core		2.8
Ø Drill with scale	40.5653.212	2.8
Guide sleeve	40.5673.728	5.0/2.8
Screwdriver tip	40.5676.000	S2.5
Screwdriver tip	40.5677.000	T15
Tap	40.5661.000	3.5

5.0ChLP cancellous screw Ø3.9

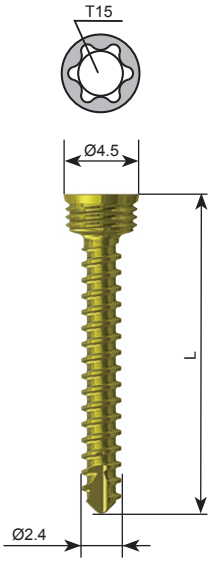


self-tapping

L [mm]	Catalogue no.
30	3.5231.030
35	3.5231.035
40	3.5231.040
45	3.5231.045
50	3.5231.050
55	3.5231.055
60	3.5231.060
65	3.5231.065
70	3.5231.070
75	3.5231.075
80	3.5231.080
85	3.5231.085
90	3.5231.090

Ø Core		2.5
Ø Drill with scale	40.5912.222	2.5
Guide sleeve	40.5673.725	2.5
Screwdriver tip	40.5676.000	S2.5
Screwdriver tip	40.5677.000	T15

4.5ChLP screw Ø2.4



self-tapping

L [mm]	Catalogue no.
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

Ø Core		1.8
Ø Drill	40.2063.220	1.8
Guide sleeve	40.5673.718	5.0/1.8
Screwdriver tip	40.5676.000	S2.5
Screwdriver tip	40.5677.000	T15

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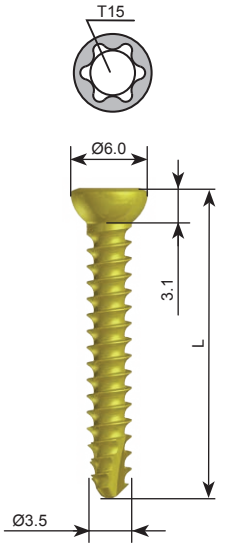
Cortical screw 3.5

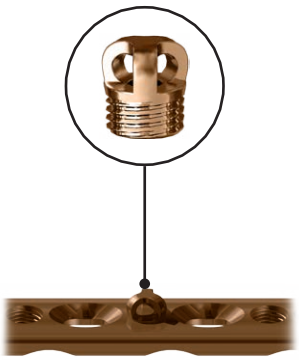


self-tapping

L [mm]	Catalogue no.
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
90	3.1306.090
95	3.1306.095
100	3.1306.100
105	3.1306.105
110	3.1306.110

Ø	Core		**2.4**
Ø	Drill	**40.5912.222**	**2.5**
	Compression guide	**40.4804.700**	**2.5**
	Screwdriver tip	**40.5676.000**	**S2.5**
	Screwdriver tip	**40.5677.000**	**T15**
	Tap	**40.2548.000**	**HA3.5**

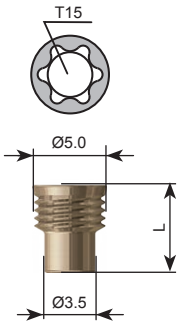
5.0ChLP cerclage screws



Catalogue no.
3.1221.050

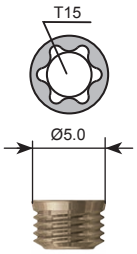
Screwdriver	**40.4746**

5.0ChLP distance screw



L [mm]	Catalogue no.
6	3.5207.006

5.0ChLP screw hole insert



Catalogue no.
3.5208.000

Stand for screws 5.0ChLP

40.5748.600

40.5748.700

No.	Catalogue no.	Name	Pcs
1	40.5748.600	Stand for screws 5.0ChLP	1
2	12.0751.102	Container solid bottom 1/2 306x272x135 mm	1
3	12.0751.200	Perforated aluminum lid 1/2 306x272x15 mm Gray	1

40.5748.700

implants not included

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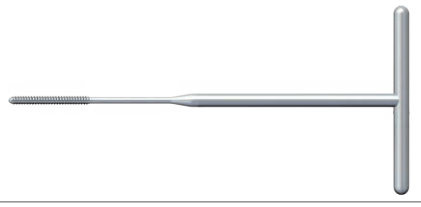
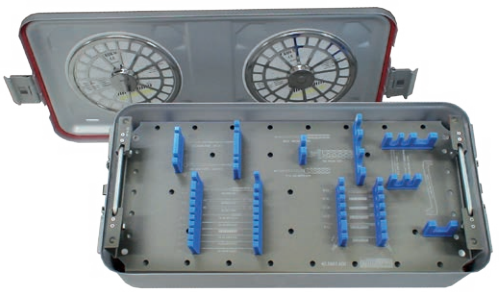
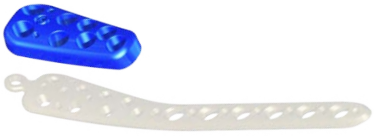
III.3. INSTRUMENTS FOR 5.0ChLP PLATE

A. Universal instrument set

40.5667.700				
No.		**Name**	**Catalogue No.**	**Pcs**
1		Guide sleeve 5.0/1.5	40.5673.715	2
2		Guide sleeve 5.0/1.8	40.5673.718	2
3		Guide sleeve 5.0/2.5	40.5673.725	2
4		Guide sleeve 5.0/2.8	40.5673.728	4
5		Compression guide 2.5/2.8	40.4804.700	1
6		Drill 1.8/220	40.2063.222	2
7		Drill with scale 2.5/220	40.5912.222	2
8		Drill with scale 2.8/220	40.5653.222	2
9		Kirschner wire 1.5/220	40.4592.220	4
10		Kirschner wire 2.0/220	40.4815.220	2
11		Setting-compressing screw 2.8/180	40.5674.728	2
12		Screw length measure	40.5675.100	1
13		Depth measure	40.4639.500	1
14		Screwdriver tip S2.5	40.5676.000	1
15		Screwdriver tip T15	40.5677.000	1
16		Torque handle 2.0Nm	40.5635.100	1
17		Bender for plates 4/6	40.4250.000	2
18		Hexagonal screwdriver S2.5	40.0321.000	1
19		Star screwdriver T15	40.0670.000	1
20		Cortical tap HA 3.5 with handle	40.2548.000	1
21		Tap 5.0ChLP - 3.5	40.5661.000	1
22		Screwdriver	40.4746.000	1
23		Stand for instrument set of 5.0ChLP plate	40.5668.700	1
		Container with solid bottom 1/1 595x275x86mm	12.0750.100	1
		Perforated aluminum lid 1/1 595x275x15mm gray	12.0750.200	1

B. Additional instruments

Instruments not included in the instrument set [40.5667.700]

No.		Name	Pcs	Catalogue No.
1		Protective guide 7.0/5.0	2	**40.5672.000**
2		Aiming block **[3.4034]**	1	**40.5671.000**
3		Aiming block L **[3.7003]**	1	**40.5729.100**
4		Aiming block R **[3.7002]**	1	**40.5729.200**
5		Aiming block L **[3.7001]**	1	**40.5728.100**
6		Aiming block R **[3.7000]**	1	**40.5728.200**
7		Aiming block L **[3.4097]**	1	**40.5731.100**
8		Aiming block R **[3.4098]**	1	**40.5731.200**
9		Aiming block L **[3.4039]**	1	**40.5726.100**
10		Aiming block R **[3.4040]**	1	**40.5726.200**
11		Aiming block L **[3.4051]**	1	**40.5723.100**
12		Aiming block R **[3.4052]**	1	**40.5723.200**
13		Aiming block L **[3.7067]**	1	**40.5742.100**
14		Aiming block R **[3.7068]**	1	**40.5742.200**

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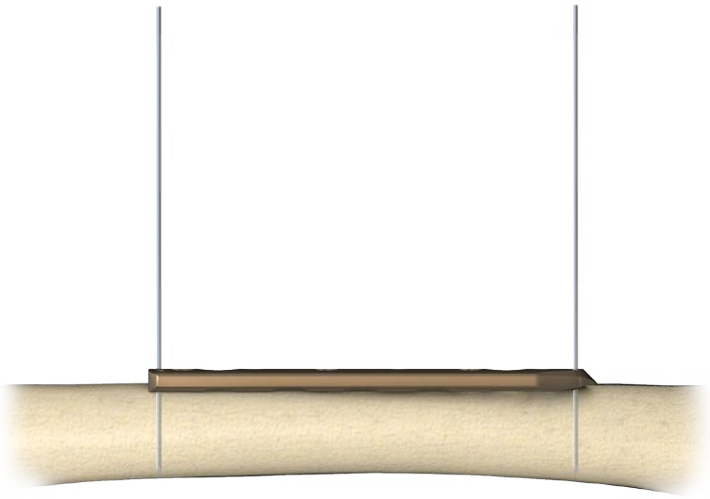
IV. SURGICAL TECHNIQUE

IV.1. TEMPORARY PLATE ATTACHMENT

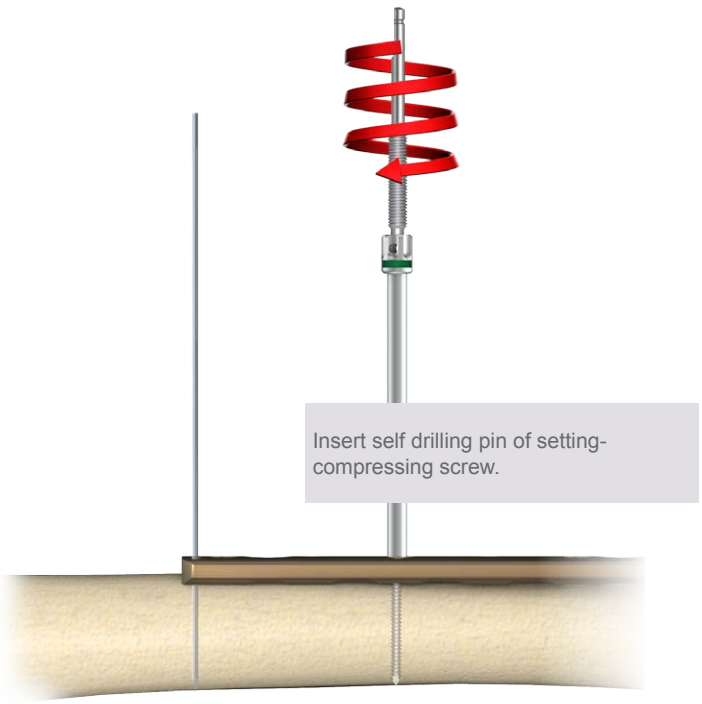
When fracture is reduced and the plate position is confirmed, determine its temporary location using Kirschner wires 2.0 **[40.4815.220]**.
Wires can be inserted in proximal holes of the plate and the most distal ones.



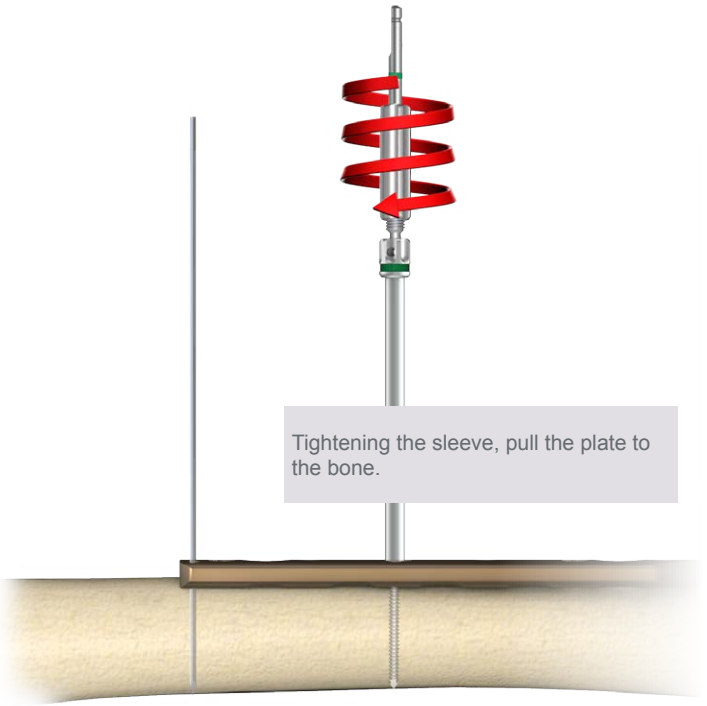
Confirm the plate position is correct taking X-ray image.

NOTE: The Setting-compressing screw 2.8/180 [40.5674.728] can be used to stabilize and tighten the plate up to the bone for temporary purposes. The screw is to be inserted via the Guide sleeve 5.0/2.8 [40.5673.728].

Locking screw Ø3.5 can be inserted in the hole after removal of the Setting-compressing screw 2.8/180.



Insert self drilling pin of setting-compressing screw.



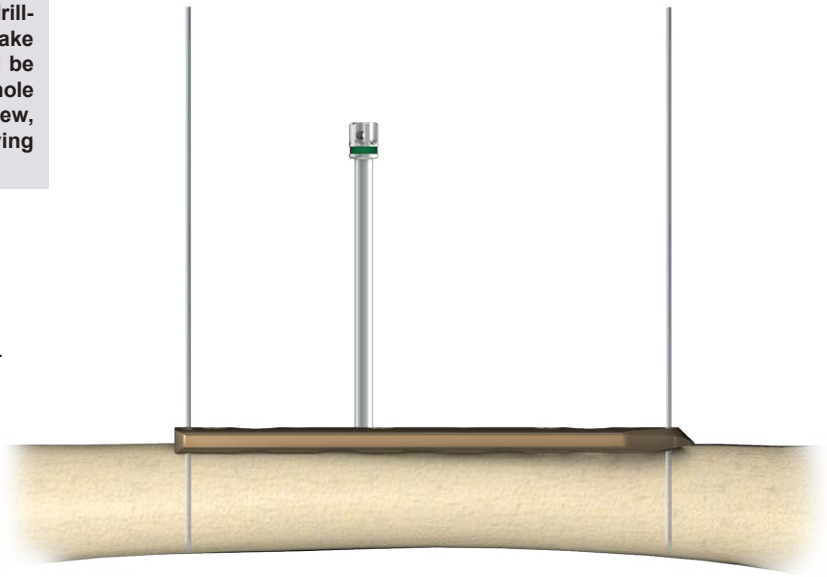
Tightening the sleeve, pull the plate to the bone.

IV.2. LOCKING SCREW Ø3.5 INSERTION

It is important to drill exactly in the axis of a locking hole. Use always the appropriate guide sleeve when drilling. The guide sleeve will ensure the locking screw take an axial position towards the hole of the plate and be correctly locked in the plate. Unprepared drilling of a hole can lead to: thread skewing and jamming the screw, incorrect screw locking and problems when removing the screws *(thread seizure)*.

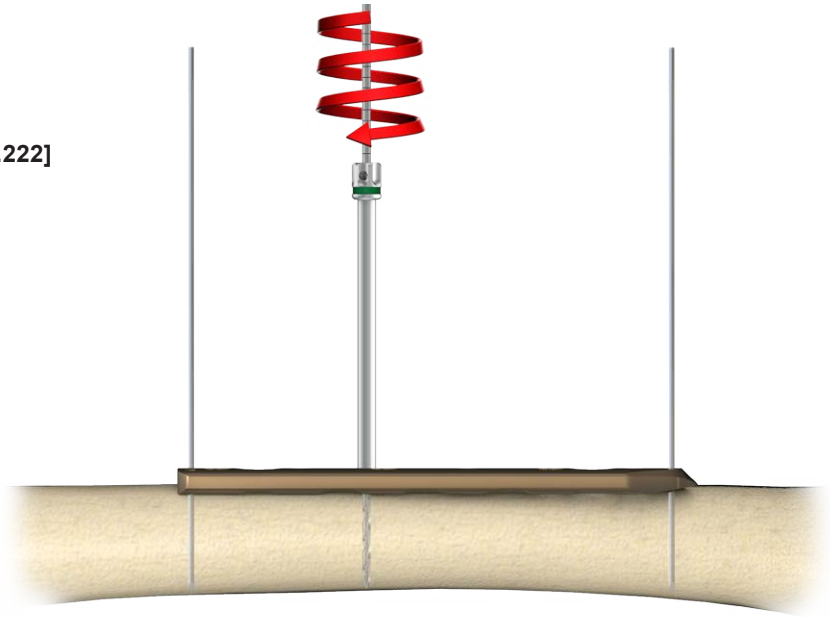
Guide sleeve screwing.

Insert the Guide sleeve 5.0/2.8 **[40.5673.728]** into the plate.



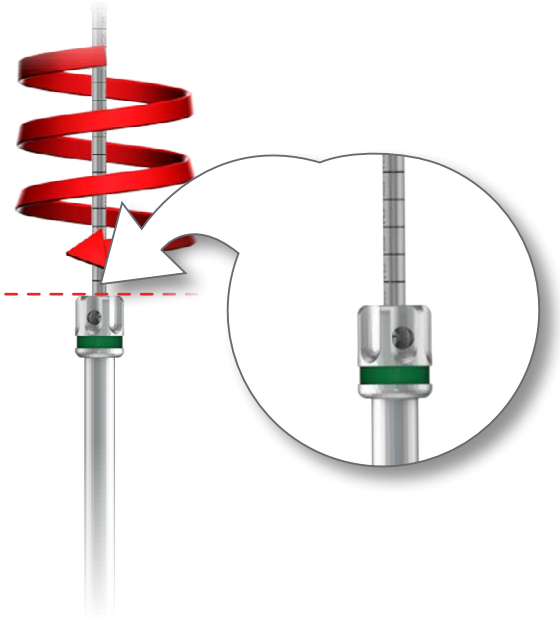
Drilling the hole

Ream the hole using the Drill with scale 2.8/220 **[40.5653.222]** until the desire depth is reached.



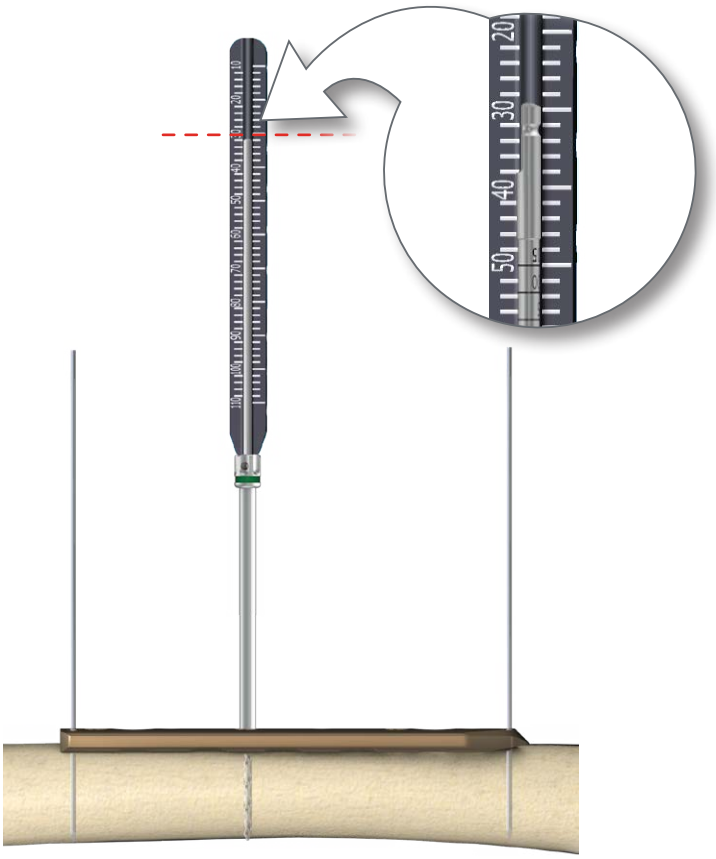
Hole depth measurement

OPTION I: Read the value on the Drill with scale **[40.5653.222]** or

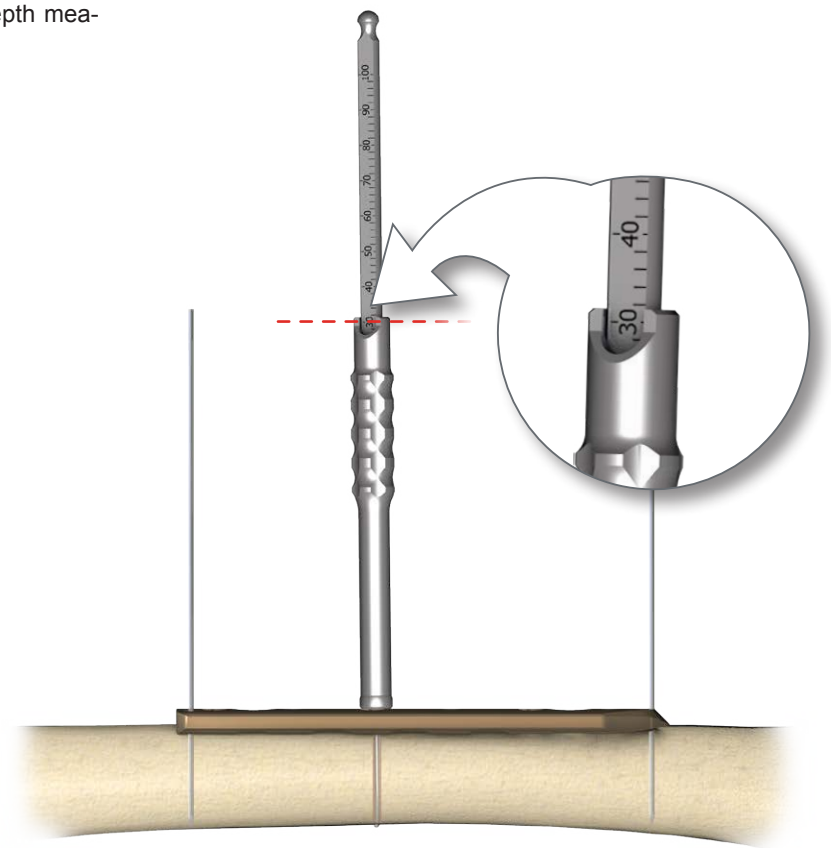


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

OPTION II: use the Screw length measure **[40.5675.100]**.

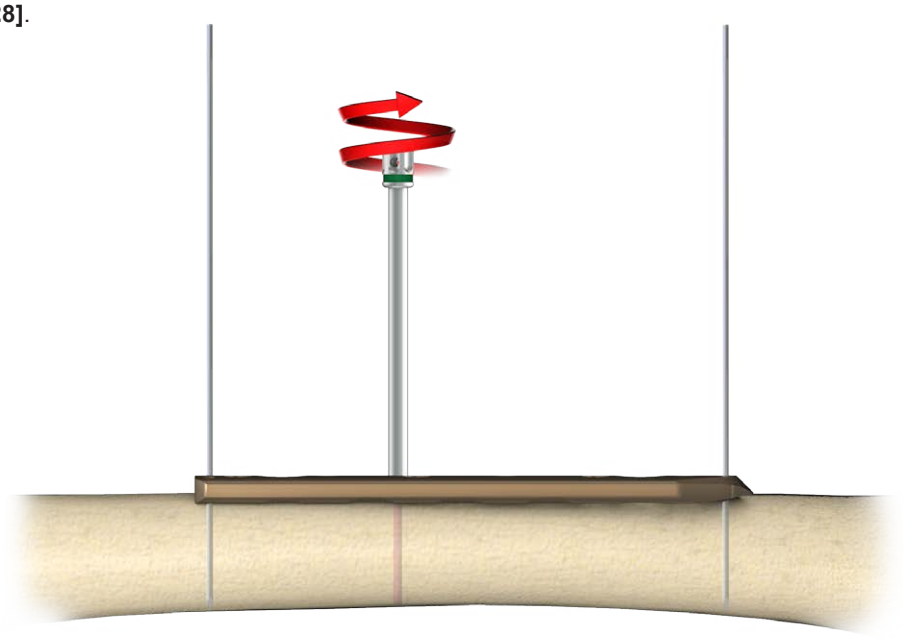


OPTION III: Unscrew the Guide sleeve 5.0/2.8 **[40.5673.728]** and define the screw length using the Depth measure **[40.4639.500]**.

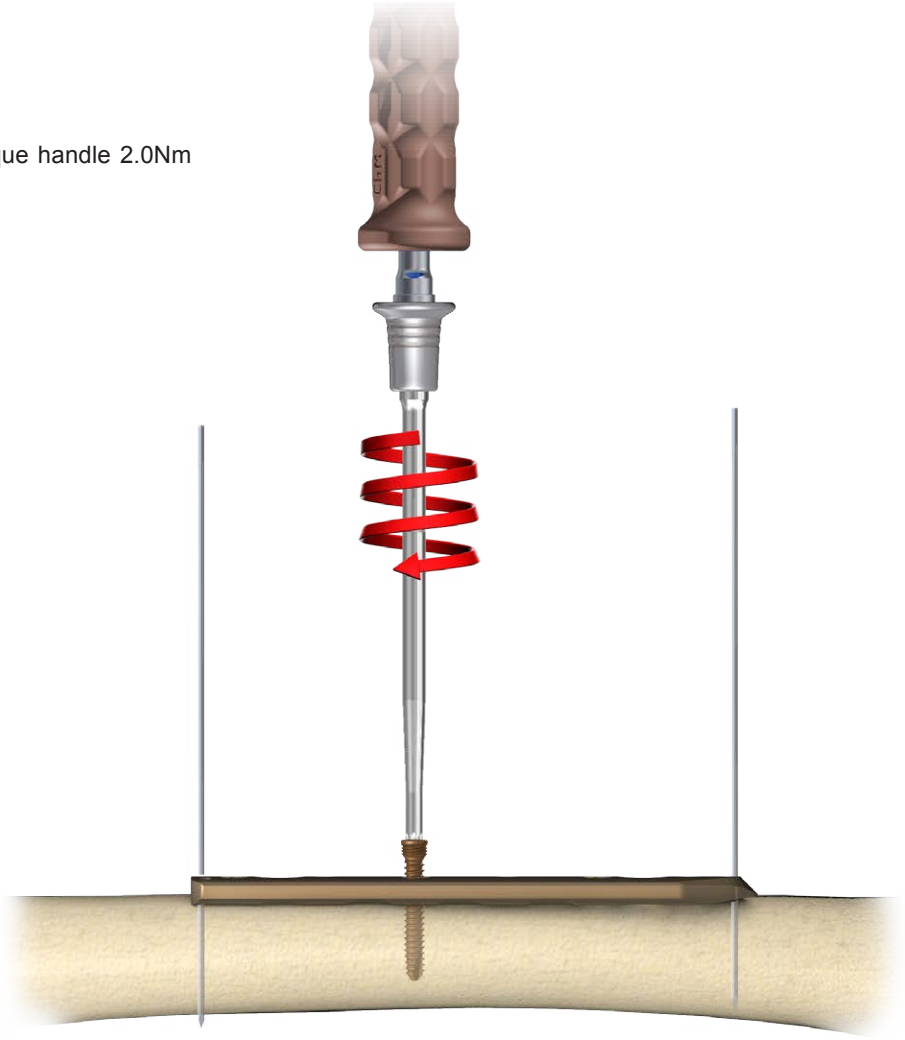


Screw insertion

Remove the Guide sleeve 5.0/2.8 **[40.5673.728]**.



Insert the locking screw Ø3.5 using the Torque handle 2.0Nm **[40.5635]** and proper screwdriver tip.



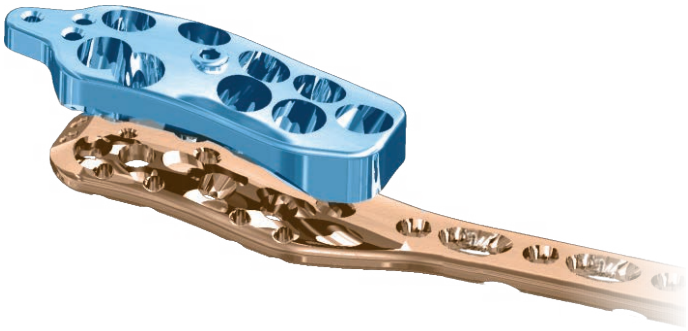
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.3. THE USE OF AIMING BLOCK

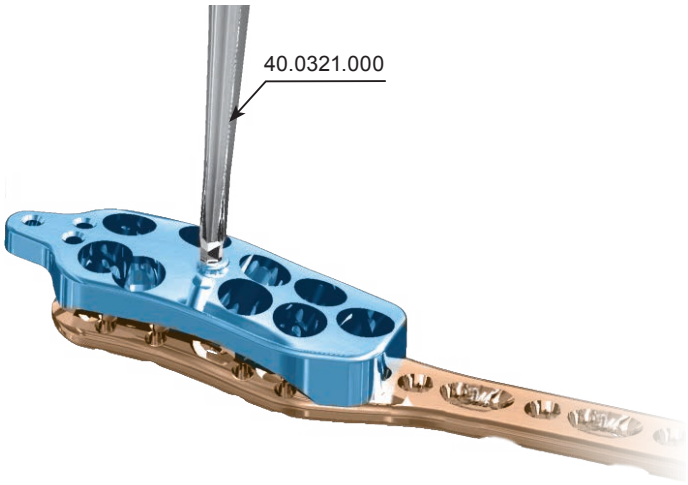
Most locking plates ChLP are available with aiming blocks, as additional complementary instruments. Using aiming blocks ensures proper fastening of guide sleeves into the locking holes, in the epiphyseal part of the plate. It facilitates also the smooth conduct of the procedure, reduces its duration, and ensures that drilling is performed in the axis of the locking hole *(note from point IV.2)*.

When aiming blocks are not used, the implantation can be incorrect. Improperly locked screws can cause complications when removing the plates.

Position the aiming block on the plate.



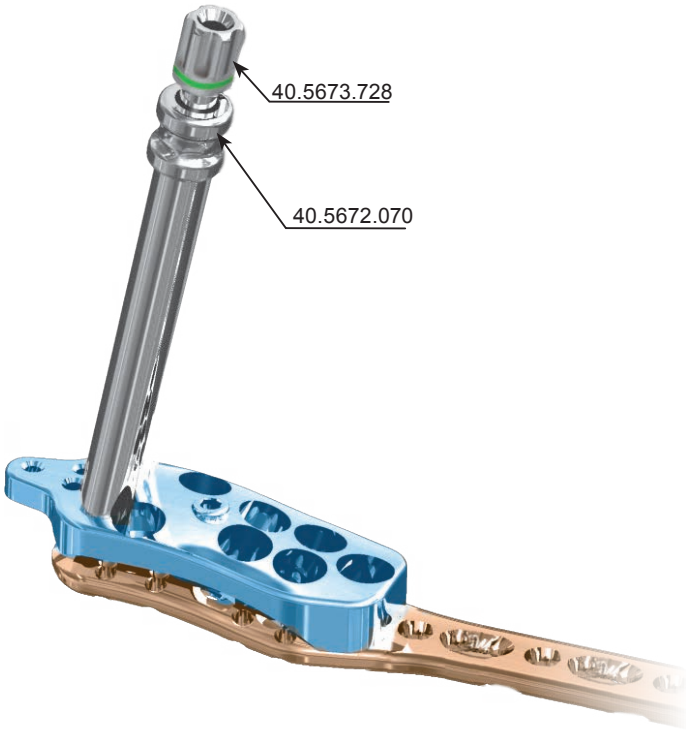
Tighten up with the Star screwdriver **[40.0670.000]**.



Insert Protective sleeve 7.0 / 5.0 **[40.5672.000]** in the desired hole of the Aiming block **[40.5671.000]**.

Then screw in the plate the Guide sleeve 5.0/2.8 **[40.5673.728]** through the Protective sleeve 7.0/5.0.

NOTE!
Further proceedings in accordance with the steps described in the point IV.2 on page 50.

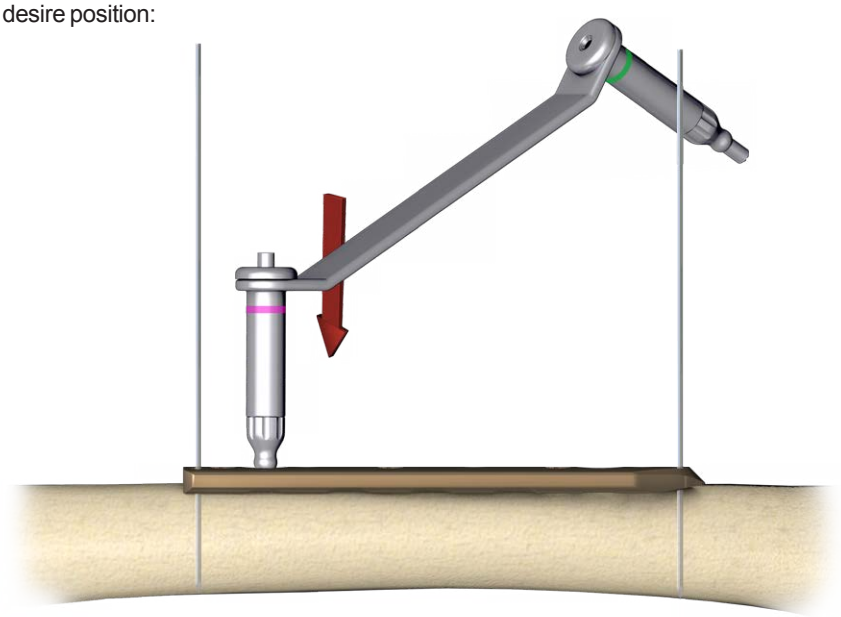


IV.4. CORTICAL SCREW Ø3.5 INSERTION

Compression guide setting
Set the Compression guide 2.5/2.8 **[40.4804.700]** in desire position:

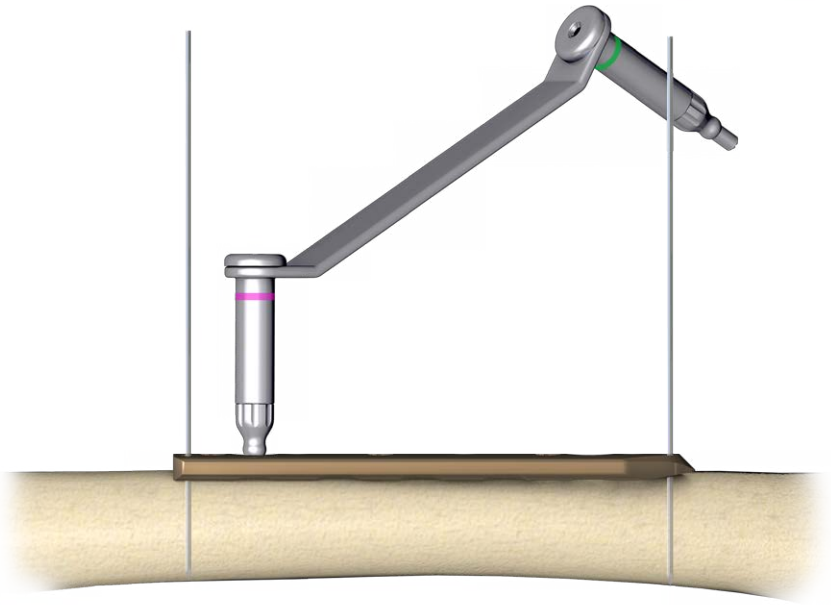
a. Neutral position

Press the guide to the plate to achieve the neutral position for screw insertion.



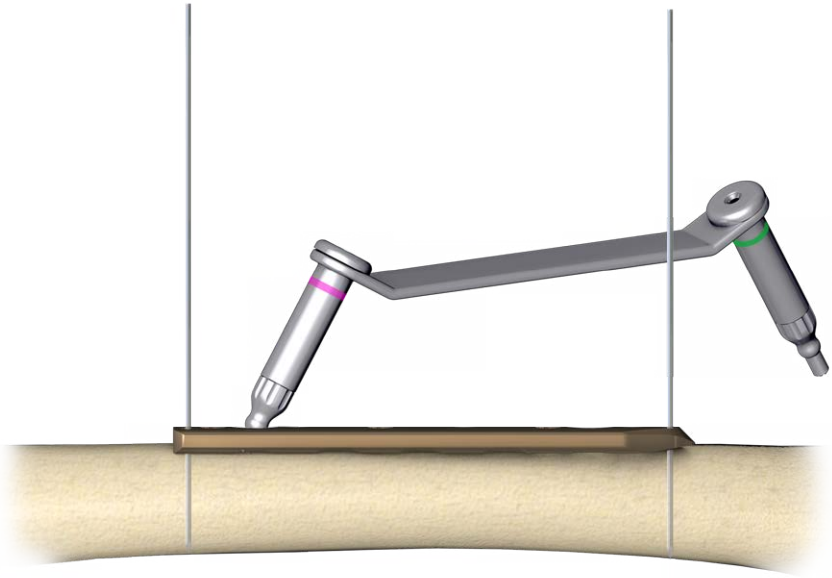
b. Compressive position

Move the guide without pressure to the edge of compression hole to achieve the compression position for screw insertion.



c. Angular position

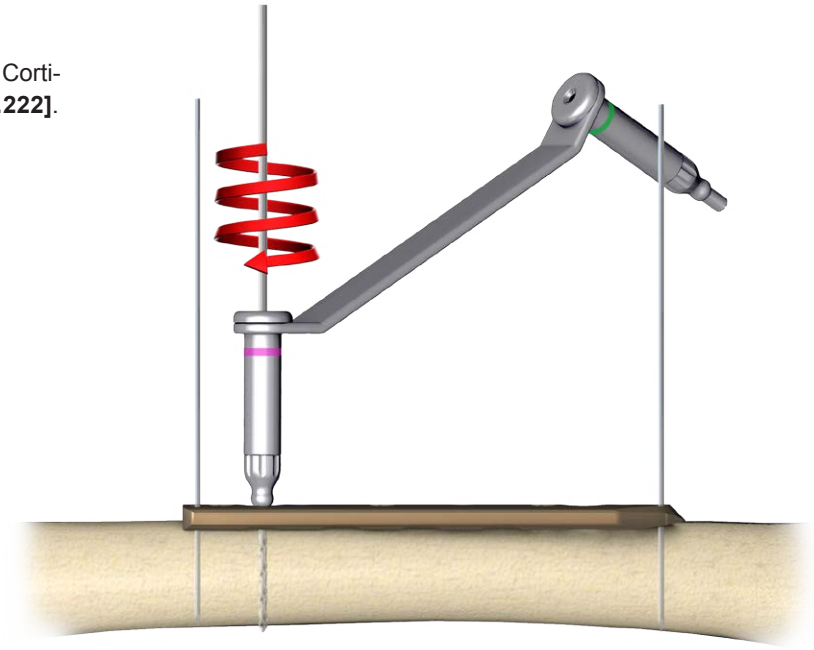
Angular positioning of the guide is also available.



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

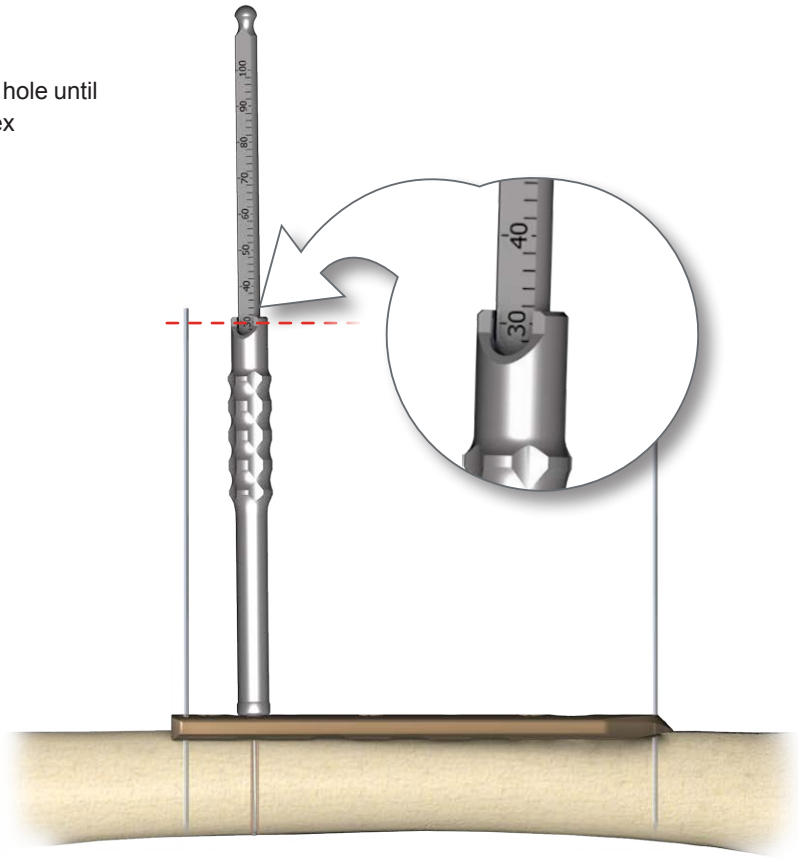
Drilling

Drill the hole through both cortices in desire position for the Cortical screw Ø3.5 insertion using the Drill Ø2.5/220 **[40.5912.222]**.



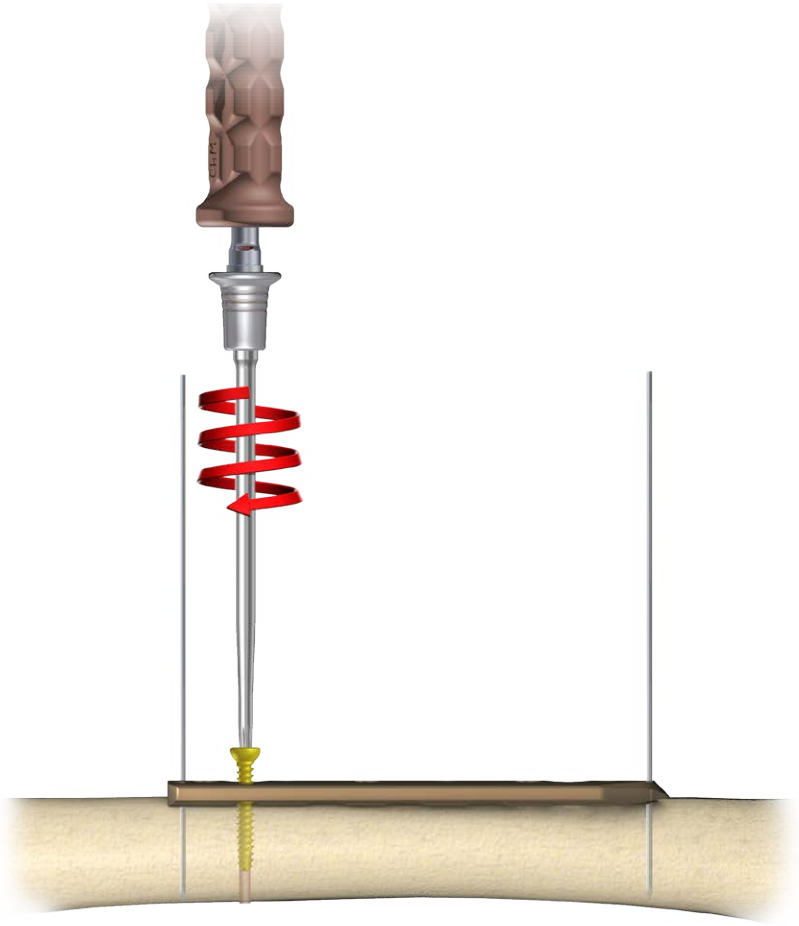
Hole depth measurement

Insert the Depth measure **[40.4639.500]** into the drilled hole until its hook anchors the outer surface of the opposite cortex



Screw insertion

Insert cortical screw Ø3.5.



V. POSTOPERATIVE TREATMENT

Postoperative treatment after locking plates does not differ from treatment after conventional stabilization.

VI. IMPLANT REMOVAL

In order to remove the screws, first unlock all locking screws from the plate. Then remove bone screws. This prevents the rotation of the plate while removing the last locking screw.

NOTE: After removing the tissues from the outer surface of plate and screws recesses, it is recommended to apply aiming block to the plate *(see point. IV.3)***. The use of a protective guide will ensure that: the screwdriver is positioned in the screw axis, the device is correctly placed in the screw recess and that the risk of twisting the recess while removing the screw is reduced.**

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

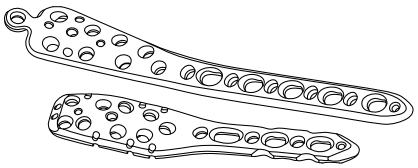
GB VII. INSTRUCTION FOR USE

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-010/16



GB

INSTRUCTIONS FOR USE

Important product information for

BONE PLATES, SCREWS AND WASHERS

ChM Locked Plating ChLP system | ChM Micro Plates ChMP system | ChM Pelvic System ChARPEL system

1 PURPOSE AND INDICATIONS

1. Bone plates, screws and washers are intended for stabilization and support of bone structure treatment. They are used for treatment of: bone fractures, non-unions, delayed unions, osteotomies and arthrodeses.
   1) Bone plates are fixed to the bone with the use of bone screws.
   2) Bone screws may be used independently, with bone washers or plates.
   3) Bone washers are used in conjunction with bone screws.
2. Compatible implants are presented on respective pages in a **ChM** sp. z o.o. catalogue.
3. **ChM** sp. z o.o. does not recommend any specific treatment method for a particular patient.

2 CONTRAINDICATIONS

1. Contraindications may be relative or absolute. The choice of particular device must be carefully weighed against patient's overall condition. Conditions listed below may preclude or reduce the chance of successful outcome:
   1) Infection local to the operative site.
   2) Signs of local inflammation.
   3) Fever or leukocytosis.
   4) Pregnancy.
   5) Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care.
   6) Any other condition which would preclude the potential benefit of implant insertion surgery and disturb the normal process of bone remodeling, e.g. the presence of tumours or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cells *(WBC)* count, or a marked left shift in the WBC differential count.
   7) Suspected or documented allergy or intolerance to implant materials. Surgeon shall find out if the patient develops allergic reaction to the material of the implant *(content of the implant material is presented in IMPLANT MATERIAL)*.
   8) Any case not needing a surgical intervention.
   9) Any case not described in the indications.
   10) 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.
   11) Any case where the implant components selected for use would be too large or too small to achieve a successful result.
   12) Any case that requires the simultaneous use of elements from different systems that are made of different metals.
   13) Any case in which implant utilization would disturb physiological processes.
   14) Blood supply limitation in the operative site.
   15) Morbid obesity *(defined according to the WHO standards)*.
   16) Any case in which there is inadequate tissue coverage of the operative site.
   17) Inadequate bone quality for stable implant fixation *(bone resorption, osteopenia, and/or osteoporosis)*. This surgical treatment should not be used in patients with a known hereditary or acquired osteogenesis imperfecta or calcification problems.
2. The above-mentioned list does not exhaust the topic of contraindications.

3 ADVERSE EFFECTS

1. The adverse effects may necessitate reoperation or revision. The surgeon should warn the patient about the possibility of adverse effects occurrence.
2. The undermentioned list does not exhaust the topic of adverse events. There is a risk of occurrence of adverse events with unknown aetiology which may be caused by many unpredictable factors.
3. Potential adverse events include but are not limited to:
   1) Implant damage *(fracture, deformation or detachment)*.
   2) Early or late loosening, or displacement of the implant from the initial place of insertion.
   3) Possibility of corrosion as a result of contact with other materials.
   4) Body reaction to implants as foreign bodies e.g. possibility of tumour metaplasia, autoimmune disease and/or scarring.
   5) Compression on the surrounding tissue or organs.
   6) Infection.
   7) Bone fractures or *"stress shielding"* phenomenon causing loss of bone above, below or at the operative site.
   8) Haemorrhage of blood vessels and /or hematomas.
   9) Pain.
   10) Inability to perform everyday activities.
   11) Mental condition changes.
   12) Death.
   13) Deep vein thrombosis, thrombophlebitis.
   14) Occurrence of respiratory complications, e.g.: pulmonary embolism, atelectasis, bronchitis, pneumonia, pulmonary infection, disturbed lung growth, respiratory acidosis, etc.
   15) Scar formation that could cause neurological impairment, or nerves compression and /or pain.
   16) Late bone fusion or no visible fusion mass and pseudoarthrosis.
   17) Loss of proper curvature and/or length of bone.
   18) Bone graft donor site complication.

4 WARNINGS

1. The important medical information given in this document should be conveyed to the patient.
2. The selection of proper shape and size of the implant appropriate for a specific patient is crucial to achieving success of the surgery. The surgeon is responsible for this choice.
3. Preoperative and operating procedures, including knowledge of surgical techniques, and correct placement of implants are important and shall be considered by the surgeon in order to achieve success during operation.
4. No implant can withstand body loads without the biomechanical continuity of the bone.
5. During normal use all surgical implants are subjected to repeated stresses which can result in material fatigue and failure of the implant.
6. To avoid excessive stress on the implant which could lead to non-union or implant failure and associated clinical problems, the surgeon must inform the patient about the physical activity limitations during the treatment period.
7. If the patient is involved in an occupation or activity *(e.g.: substantial walking, running, lifting weights, muscles strain)* which may apply excessive stress on the implant, the surgeon must inform the patient that resultant forces can cause implant failure.
8. A successful result is not always achieved in every surgical case. This fact is especially true in the case where other patient's conditions may compromise the results.
9. The proper selection, compliance of the patient and observance of post-operative recommendations will greatly affect the results. The bone union is less likely to occur among patients who smoke. These patients should be informed about this fact and warned of this consequence.
10. Overweight may cause additional stresses and strains within implant which can lead to fatigue and deformation of the implant.
11. Patients who are overweight, malnourished and/or abusing alcohol or drugs, with weak muscles and low quality bones and/or with nerve palsy are not the best candidates for the procedure of surgical stabilization. These patients are not able or not ready to observe the post-operative recommendations and limitations.
12. The implants are intended as an aid to the healing process and are **NOT** intended to replace body structures or bear the body weight when the treatment process has not yet finished.
13. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
14. The surgeon must warn the patient that the device cannot and does not restore the function and efficiency of a healthy bone.
15. In the case of delayed union or non-union, the load or weight bearing may eventually cause the implant bending, loosening, disassembling or fatigue breakage.

5 PACKAGING AND STORAGE

1. Implants are single-use devices, provided sterile or non-sterile.
2. Implants not labeled as sterile are non-sterile.
3. Implant packaging must be intact at the time of receipt.
4. The unit package contains:
   1) sterile version - one piece of the product in a sterile condition. A double package made of Tyvek-foil or a single blister are typical packaging material.
   2) non-sterile version - one piece of the product. Clear plastic bags are a typical packaging material.
5. A sterility indicator is placed on the sterile package.
6. The packaging is equipped with the product label. The label *(as a primary label)* contains e.g.:
   1) Sterile product
      a) Logo **ChM** and the address of the manufacturer.
      b) Name and size of the device and its catalogue number *(REF)*, e.g.: 3.XXXX.XXX.
      c) Production batch number *(LOT)*, e.g. XXXXXXX.
      d) Material of the implant *(see IMPLANT MATERIAL)*.
      e) STERILE sign - indicating a sterile device and the sterilization method used, e.g.: R or VH202 *(symbols are described in the footer of this Instructions For Use)*.
      f) Sterilization batch number, e.g.: S-XXXXXXX.
      g) Device pictogram and information symbols *(described in the footer of this Instructions For Use)*.
      h) Expiration date and sterilization method.
   2) Non-sterile product
      a) Logo **ChM** and the address of the manufacturer.
      b) Name and size of the device and its catalogue number *(REF)*, e.g.: 3.XXXX.XXX.
      c) Production batch number *(LOT)*, e.g. XXXXXXX.
      d) Material of the implant *(see IMPLANT MATERIAL)*.
      e) NON-STERILE sign - indicates non-sterile product.
      f) Device pictogram and information symbols *(described in the footer of this Instructions For Use)*.
7. In addition to the device 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 device will be distributed)*.
8. The package may contain: Instructions For Use and labels to be placed in a patient's medical record.
9. Depending on the size or type of the product, the following information may be marked on its surface: manufacturer's logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.
   1) Additional identification system for the ChLP locking plates has been introduced. On the surfaces of locking plates an additional feature *"System e.g. 4.0, 4.5, 5.0, 7.0."* has been placed. It informs that particular screws with head diameters of 4.0, 4.5, 5.0, 7.0. cooperate with particular plates. Additionally, plates and screws included in the system, made of titanium, are coloured: system 4.0 - green, system 4.5 - gold, system 5.0 – brown, system 7.0 - blue.
   2) Additional identification system for the ChMP microplates has been introduced. Plates and basic screws included in the system, made of titanium, are coloured: system 1.2 - blue, system 1.5 - gold, system 2.0 - green, system 2.7 - turquoise.
10. Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.

6 IMPLANT MATERIAL

1. Identification of the materials
   1) Depending on the material used, the following symbols may be marked on the device surface:
      a) Titanium and titanium alloys: symbol *(T)*.
      b) Cobalt alloy: symbol *(Co)*.
      c) Steel: symbol *(S)*.
   2) The plates are made of:
      a) Implantable stainless steel.
      b) Implantable titanium or titanium alloy.
      c) Implantable cobalt alloy.
   3) The screws are made of:
      a) Implantable stainless steel.
      b) Implantable titanium alloy.
      c) Implantable cobalt alloy.
   4) The bone washers are made of:
      a) Implantable stainless steel.
      b) Implantable titanium alloy.
   5) Percent composition of elements in the implantable materials *(max. values)*:
      a) Steel according to ISO 5832-1/ASTM F138: | C:0.03 | Si:1.0 | Mn:2.0 | P:0.025 | S:0.01 | N:0.1 | Cr:19.0 | Mo:3.0 | Ni: 15.0 | Cu:0.5 | Fe:rest.
      b) Steel according to ISO 5832-9/ASTM F1586: | C:0.08 | Si:0.75 | Mn:4.25 | P:0.025 | S:0.01 | N:0.5 | Cr:22.0 | Mo:3.0 | Nb:0.8 | Ni: 11.0 | Cu:0.25 | Fe:rest.
      c) Titanium according to ISO 5832-2/ASTM F67: | Fe:0.5 | O:0.4 | C:0.1 | N:0.05 | H:0.0125 | Ti:rest.
      d) Titanium alloy according to ISO 5832-3/ASTM F136: | Al:6.75 | V:4.5 | Fe:0.3 | O:0.2 | C:0.08 | N:0.05 | H:0.015 | Ti:rest.
      e) Titanium alloy according to ISO 5832-11/ASTM F1295: | Al:6.5 | Nb:7.5 | Ta:0.5 | Fe:0.25 | O:0.2 | C:0.08 | N:0.05 | H:0.009 | Ti:rest.
      f) Cobalt alloy according to ISO 5832-12/ASTM F1537: | Cr:30 | Mo:7 | Fe:0.75 | Mn:1 | Si:1 | C:0.14 | Ni:1 | N:0.25 | Co:rest.
   6) ATTENTION: 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 as it may lead to corrosion and reduction of mechanical strength of implants.
2. Magnetic Resonance compatibility
   1) **ChM**'s implants made completely from or containing elements made of implantable steel were not assessed for their safety and compatibility with magnetic resonance imaging procedures. The performance of MRI on these implants *(especially in the magnetic field with a significant induction)* may pose a potential risk of, i.a.:
      a) implant displacement or heating up,
      b) artifacts on MR images.
   2) Implants made of titanium, titanium alloys and cobalt alloys are conditionally compatible with magnetic resonance imaging.
   3) The patient can be scanned safely under the following conditions:
      a) static magnetic field of ≤ 3 Tesla,
      b) maximum magnetic field spatial gradient of ≤ 720 Gauss/cm,
      c) maximum MR system reported whole-body-averaged specific absorption rate *(SAR)* of 3W/kg for 15 minutes of scanning.
   4) CAUTION: the user should be absolutely familiar with the contraindications and warnings established by the manufacturer of the MRI scanner to be used for imaging procedure.
   5) MR imaging may be interfered with if the area of interest is in the exact same area or relatively close to the position of the implant.
   6) Do not perform MRI if there are doubts about the tissue integrity and the implant fixation or if the proper location of the implant is impossible to be established.

7 PRE-OPERATIVE RECOMMENDATIONS

1. Only patients that meet the criteria described in the PURPOSE AND INDICATIONS should be selected.
2. Patients' conditions and/or predispositions such as those addressed in the above-mentioned 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 aesthetic effects of such treatment. Proper clinical diagnosis and accurate operation planning and performance are needed to achieve good final result of treatment.
4. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation *(alloying elements of implant material are presented in IMPLANT MATERIAL)*.
5. The implantation shall be carried out by the surgeon familiar with adequate rules and operating techniques, and who has acquired practical skills of using **ChM** instrument set. The selection of surgical technique adequate for a specific patient remains surgeon's responsibility.
6. 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 implants with required sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. The surgeon should be familiar with all components of the implant system before use and should personally verify if all components and instruments are present before the surgery begins.
8. Do not use the implant if the original, sterile packaging is damaged. Sterility cannot be guaranteed if the packaging is not intact. The packaging shall be carefully checked prior to use.
9. Implants are delivered in protective packages. The package should be intact at the time of receipt.
10. Unless supplied sterile, all implants and instruments should be washed, disinfected and sterilized before use. Additional sterile components should be available in case of any unexpected need.
11. Before procedure begins, all implants should be carefully checked to ensure that there is no damage *(surface scratching, dents, signs of corrosion and shape deformations)*. Damaged implant cannot be inserted into the body.

8 RECOMMENDATIONS FOR IMPLANTS PROVIDED STERILE

1. 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. The sterilization is performed with the use of one of the following methods:
   1) gamma radiation, with a minimum dose of **25 kGy**,
   2) hydrogen peroxide vapour.
2. The symbol designating the sterilization method used is visible on the device label *(symbols are described in the footer of this Instructions For Use)*.
3. Prior to use of a sterile device the following rules apply:
   1) Check out the expiration date of sterilization. Do not use the device with an overstepped sterility date!
   2) Check out if the sterile package is not damaged. Do not use the device if the sterile package is damaged.
   3) Check out the colour of the sterility indicator on the sterile packaging which indicates that sterilization of the device was performed. Do not use the device if the sterility indicator colour is different than:
      a) red - for devices sterilized with gamma radiation,
      b) blue - for devices sterilized with hydrogen peroxide vapour.
4. CAUTION: products should be removed from their packages in accordance with aseptic rules.

9 RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE

1. Prior to use of a non-sterile device the following rules apply:
   1) The device must undergo washing, disinfection and sterilization procedures. It is recommended to use automated procedures for washing and disinfecting in the washer-disinfector.
   2) Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of cleaning *(manual, ultrasound, with the use of washing/disinfecting machine)*, the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process.
   3) 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.
2. Preparation for washing
   1) After taking the device out from the original package, remove possible surface contamination *(resulting from e.g.: damage to unit package)* using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*. Do not use brushes made of metal, bristles or materials which could damage the implant.
3. Cleaning and disinfection process
   1) The 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 aqueous solutions of washing-disinfecting agents with a pH value between 7 and 10.8.
4. Manual cleaning

1) Apply washing detergent *(e.g. MEDICLEAN)* to implant surface and brush carefully. Suitable brushes must be used for holes cleaning.
2) If applicable, ultrasonic cleaning may be performed. The ultrasonic bath must be prepared according to the manufacturer's instructions.
3) Rinse thoroughly under running water. It is recommended to rinse with demineralized water.
4) Visually inspect the entire surface of the device for damage and contaminants. Damaged implants must be removed.
5) For contaminated implants, the cleaning process should be repeated.

5. Cleaning in the washer-disinfector
1) The device should undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for medical devices)*. CAUTION: The equipment used for washing/disinfection should meet the requirements of ISO 15883.
2) Procedure of washing in 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 agent manufacturer. Disinfection should be carried out at temperature of 90°C *(soak in demineralized water)* for at least 10 minutes without the use of detergents.

6. Drying
1) Drying of the device must be performed as a part of the washing/disinfection process.

7. Packaging
1) The device supplied non-sterile must be repacked in a packaging intended for a specific sterilization method that meets the requirements of ISO 11607-1. The packaging procedure must be performed in controlled purity conditions. The device must be packed in such a way that during removal from the package, when used, there is no risk for its contamination. Sterilization package is designed to maintain the sterility of medical devices after the sterilization process and during their storage prior to use.

8. Sterilization
1) Washed, disinfected, and dried device shall undergo the sterilization process. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:
a) temperature: 134°C,
b) minimum exposure time: 7 min,
c) minimum drying time: 20 min.

9. CAUTION:
1) Sterilization must be effective and in accordance with requirements of the EN 556 standard to ensure the required level of guaranteed sterility SAL 10^{-6} *(where SAL stands for Sterility Assurance Level)*.
2) Implant must not be sterilized in the package in which it was delivered.
3) Validated sterilization methods used by sterilization facilities are allowed.
4) The above-mentioned rules of cleaning and sterilization must be followed when dealing with any device intended for implantation.
5) Surgical instrument set, which is used for device implantation, shall also be included into the cleaning and sterilization procedure.

10 RE-STERILIZATION

1. It is permitted to re-sterilize devices by end-user.
1) ATTENTION: The user of the product bears all responsibility for re-sterilization. In such case the device shall be washed and sterilized in a way described in RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE.

11 PRECAUTIONS

1. Implant is intended for single use only. After removing the implant from the patient's body, it must be secured against re-use, and then finally disposed of 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 early failure, fatigue wear, and as a result to e.g.: an implant breakage.
3. Implant which had contact with tissues or body fluids of another patient cannot be re-implanted due to a potential risk of cross-infection caused by viruses, bacteria and prions.
4. Misuse of instruments or implants may cause injury to the patient or operative personnel.
5. Avoid damaging implant surface and deforming its shape during the implantation; the damaged implant cannot be implanted or left in the patient's body.
6. Insertion, removal and adjustment of implants must only be done with instruments specially designated for those implants, and manufactured by **ChM** sp. z o.o.
7. Use 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.
8. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive force are more susceptible to fractures, depending on care taken during surgery, number of procedures performed and attention paid. Instruments should be examined for wear or damage prior to surgery.
9. 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 implant bending influences its strength parameters, causes surface defects and internal stresses that reduce its fatigue strength. Disobeying the above-mentioned may result in postoperative complications like implant fracture or breakage.
10. If there is a necessity to bend the implant, please, remember that:
1) it is forbidden to bend an implant which was already bent,
2) it is forbidden to bend a short fragment of the implant or to bend with a small bending radius,
3) the bending should occur between plates holes,
4) before bending the locking plates it is advisable to insert the locking screws near the bending area, as deformed holes may not provide appropriate plate-screw cooperation,
5) in locking shape plates only the shaft part may be shaped,
6) it is forbidden to bend a plate back and forth,
7) the plate should not be bent more than 20°÷25°,
8) the bending should be performed only with the use of instruments intended for bending.
11. If the operator decides to cut the bone plate, he must remember that:
1) cutting the plate may influence the strength characteristics of the implant and of the whole bone fixation,
2) the plate length and the number of holes for bone screws must be appropriate for a fixation conducted, allow for sufficient support and stable immobilization of the fixation,
3) it is recommended to cut the plate between the holes for bone screws,
4) during plate cutting special attention must be paid to not direct the cut-off fragment in the direction of the user, patient or third parties,
5) all sharp edges created by cutting on the external surfaces are to be eliminated,
6) it is important to ensure an unambiguous identification of the implant.
12. While inserting the screw, it is essential to correctly set the screwdriver in relation to the screw. Following the instructions given allows for reduction of the risk of mechanical damage to the screw, screwdriver, or bony hole:
1) screwdriver should be set in the screw axis,
2) apply proper axial pressure to ensure that the screwdriver goes as deep in the head of the bone screw as possible,
3) the final phase of tightening shall be performed carefully.

12 POST-OPERATIVE RECOMMENDATIONS

1. It is essential to follow all of physician's postoperative directions and warnings.
2. It is essential to confirm proper position of the implant by roentgenographic examination.
3. In postoperative period, in treatment, the correctness of implant positioning and immobilization of union should be confirmed by roentgenographic examination.
4. 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 clinical examination.
5. The surgeon must instruct the patient to report any unusual changes of the operative site to his/her physician. If any change at the site has been detected, the patient should be closely monitored.
6. The patient should be informed about the type of implant material.
7. The patient should be warned to inform the medical staff about the inserted implants prior to any MRI procedure.
8. The patient should be advised not to smoke or consume alcohol excessively during the period of treatment.
9. If the patient is involved in an occupation or activity which may apply excessive stress on the implant *(e.g. substantial walking, running, lifting, or muscle strain)* the surgeon must advise the patient that resultant forces can cause implant failure.
10. The surgeon must instruct the patient 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 and further clinical problems. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
11. Failure to perform appropriate immobilization of bone when delayed or non-union occurs may lead to excessive fatigue stresses in the implant. Fatigue stresses may be a potential cause of implant becoming bent, loosened or fractured. If non-union of fracture or implant bending, loosening or fracture occurs, the patient should be immediately revised, and the implants should be removed before any serious injuries occur. The patient must be appropriately warned about these risks and closely monitored to ensure compliance during the treatment until the bone union is confirmed.

13 CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER TREATMENT

1. When bone union is achieved, the implants serve no functional purpose and their removal is recommended. The possibility of another surgical procedure and associated risks must be analysed 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.
2. 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, or breakage, which could make implant removal difficult or impossible.
5) Pain, discomfort, or abnormal sensation due to the presence of the implant.
6) Increased risk of infection.
7) Bone loss due to the stress shielding.
8) Potentially unknown and/or unexpected long term effects.
3. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
4. Implantable stainless steel implant shall be removed after period of not more than two years after its implantation.

If these instructions appear 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-010/16; Date of verification: March 2016

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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

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

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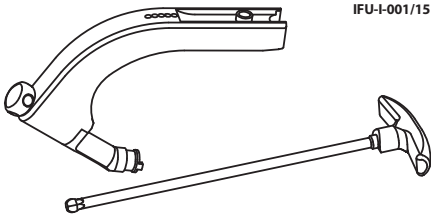

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INSTRUCTIONS FOR USE REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

DESCRIPTION AND INDICATIONS

Instruments manufactured by **ChM** sp. z o.o. are mainly made of steel, aluminium alloys and plastics used in medicine and in accordance with the applicable procedures.

Each medical instrument is exposed tooccurrence of corrosion, stains and damage if not treated with special care and according to recommendations provided below.

The use of instruments in accordance with their intended purpose prolongs their usability.

Instrument's durability is limited and highly related to the manner and frequency of its usage.

The unit package contains one piece of the product in non-sterile condition. The welded clear foil sleeve is typical packaging material. The products may also be supplied as complete sets *(arranged on trays and placed into specially designed sterilization containers)*.

This Instructions For Use is attached both to the unit package and to the instrument set as well.

The packaging is equipped with the product label. The label contains:
- **ChM** logo and the manufacturer's address,
- name, size and catalogue number of the device *(REF)*, e.g.: 40.XXXX.XXX,
- production batch number *(LOT)*, e.g.: XXXXXXX,
- NON-STERILE sign: indicates non-sterile product,
- information symbols *(described in the footer of this Instructions For Use)*.

Depending on the size or type of the product, the following information may be marked on its surface: **ChM** logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.

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 stays 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 with the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: PPSU *(Polyphenylsulfone)*, PEEK *(Polyetheretherketone)* and teflon *(PTFE - Polytetrafluoroethylene)*.

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 10.8.

If the material of the device cannot be specified, please contact ChM sp. z o.o. representative.

WARNINGS AND PRECAUTIONS

1. Reusable orthopaedic and surgical instruments are intended for use in operating room conditions only by skilled and trained medical professionals, specialists in surgery, who are familiar with their use and application.
2. The surgeon should be familiar with all components of the device before use and should personally verify if all components and devices are present before the surgery begins.
3. Prior to the device usage and before procedure begins, all components of instruments should be carefully inspected for proper functioning and condition.Blades of all cutting edges should be sharp and undamaged. Replace any damaged accessory immediately. Employing bent or damaged surgical instruments in surgery is not allowed.
4. Tissue structures close tooperative site must be protected.
5. Contact of the instrument with metal operating equipment, retractors or other devices may cause damage that necessitates intraoperative replacement of that instrument.
6. Do not apply excessive force when using the instrument – it may lead to its faulty operation and, in consequences, to permanent damage.
7. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to extensive use or extensive force are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed.
8. In the case of breakage and presence of instrument fragments in the patients' body, remove and dispose of them following the appropriate protocol of the unit.
9. In the case of suspected or documented allergy or intolerance to metallic materials, surgeon shall find out if the patient develops allergic reaction to the instrument material by ordering appropriate tests.
10. Improper or careless handling of the instruments and related chemical, electrochemical and physical damage may adversely affect the corrosion resistance and shorten the life of the instruments.
11. Reusable orthopaedic and surgical instruments are intended only for specific procedures and must be used strictly according to their intended purpose. Use of instruments not in accordance with their intended purpose may lead to malfunction, accelerated wear and – in consequences – damage of the instrument.
12. It is extremely important to follow the calibration deadline which is permanently marked on the torque instruments *(see CALIBRATION)*. Use of a torque instrument with an overstepped calibration date may lead to potential injury, implant or device damage, or loss of correction.
    If there appear any irregularities in device operation, e.g. due to heavy usage, prior to next calibration date, the instrument should be immediately sent to the manufacturer for its re-calibration.

CLEANING, DISINFECTION AND STERILIZATION

Prior to use of a non-sterile device the following rules apply:

- Before use, the device must undergo cleaning, disinfection and sterilization procedures. It is recommended to use an automated procedure *(washer-disinfector)* for cleaning and disinfecting.
- Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the techniques of cleaning *(manual, ultrasound, with the use of washing/disinfecting machine)*, the proper rinsing and drying, the proper preparation of the instrument, the time, the temperature and carefulness of the person conducting this process.

Preparation for cleaning

After removing the product from its original packaging and before each cleaning, remove possible surface contamination using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*.

It is not permitted to use brushes made of metal, bristles or materials which can cause damage to the device.

Cleaning and disinfection process

Chosen detergents and disinfectants must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of these detergents.

CAUTION:

To avoid product damage (pitting, rust), **DO NOT** *use highly aggressive agents (NaOH, NaOCl), salt solutions and other unsuitable cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 7 and 10.8.*

Manual cleaning

- Apply cleaning agent solution to the product surfaces with careful brushing. A suitable brush must be used for cleaning holes.
- If applicable, ultrasonic cleaning may be used. 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 damage and contaminants. Damaged products must be removed. For contaminated products, the cleaning process should be repeated.

CAUTION:

- *Never use metal brushes, files or sponges for contaminants removal.*
- *Rinse thoroughly and carefully. Sterile demineralized water facilitates water spots removal from the instrument's surface.*
- *Instruments with cannula should be blown through using compressed air gun, or air supplied from a syringe.*
- *If the accumulated in the cannula material cannot be removed in accordance with the instructions, the device should be considered at the end of its useful life and should be disposed of in accordance with the facility procedures and guidelines.*

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)*.

CAUTION: The cleaning/disinfecting appliances should be compliant with requirements specified in ISO 15883.

Procedure of washing in 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.

Disinfection should be carried out at 90° *(soak for at least 10 minutes in demineralized water)* without the use of detergents.

Drying

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

Inspection

Before preparing for sterilization, all medical devices should be inspected.

Generally, visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion. Particular attention should be paid to:

- soil traps such as mating surfaces, hinges, recesses, instruments shafts,
- holes, cannulations,
- places where soil may be pressed during use,
- cutting edges should be checked for sharpness and damage,
- special care should be taken to inspect the instruments for complete dryness prior to their storage.

Functional checks should be performed where possible:

- mating devices should be checked for proper assembly,
- all reusable orthopaedic and surgical instruments should be checked for straightness.

CAUTION:

The **ChM** *sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The life of these devices depends on many factors including the method, way and duration of each use, and the handling between uses.*
Inspection and functional testing of the device must be carried out before each use. In the case of identified damage, the instrument must not be used again.

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

Packaging

The product supplied non-sterile must be repacked in a packaging intended for a specific sterilization method that meets the requirements of ISO 11607-1 and is marked with CE sign. The packaging procedure must be performed in controlled purity conditions. The product must be packed in such a way that during removal from the package to be used, there is no risk for its contamination. Sterilization package is designed to maintain the sterility of medical devices after the sterilization process and during their storage prior to use.

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 and without structure damage *(cracks, fractures, bending, peeling)*. Remember that sterilization is not a substitute for cleaning process!

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

- temperature: 134°C,
- 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 means that theoretical probability of presence of a living microorganism is less than 1/10⁶ (SAL=10⁻⁶, where SAL stands for Sterility Assurance Level).*
- *Device must not be sterilized in the package in which it was delivered, except specially designed sterilization containers.*
- *Validated sterilization methods are allowed.*
- *Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards.*
- *Devices manufactured out of plastics (PPSU, PEEK, PTFE) 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.*

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.

STORAGE

The devices should be properly stored. When storing surgical instruments it is recommended that they never be stacked together. It may lead to damage of cutting edges *(nick or dull)* and/or initiation of corrosion centers. Instruments should be stored in dark, dry room, if possible – in suitable storage racks and placed into specially designed sterilization containers.

CALIBRATION

1. Regular calibration is required in case of torque wrenches, handles and connectors. Torque instruments are factory-calibrated, the nominal torque of a calibrated instrument is marked on the device *(e.g. 4 Nm)*.
   To maintain a high level of safety and accuracy of operation of a torque instrument, it is necessary to follow the calibration deadline which is marked on the device.
2. The calibration is conducted by the manufacturer – **ChM** sp. z o.o. Any unauthorized modifications of the structure or default, factory settings may lead to potential injury or device damage and are forbidden.

If this instructions 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-001/15; Date of verification: December 2015

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Poland
tel. +48 85 713 13 20
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