ST/30E

PROXIMAL HUMERAL PLATE

- *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.
	Information about the next stages of the proceeding.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use supplied with the product. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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Document No ST/30E

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The manufacturer reserves the right to introduce design changes.

I. INTRODUCTION

Locking humeral plate **[3.4034]** is provided for treatment of humeral bone proximal section. Plate is an element of **ChLP** locking plates system developed by **ChM** company. Introduced range of implants is made of titanium and its alloys in agreement with ISO 5832 standard. Quality Management Systems ISO 9001 and EN ISO 13485, and fulfilling the requirements of 93/42/EEC Directive guarantee high quality of implants.

Set for proximal section of humeral bone consists of:
- implants *(humeral plate, locking screws and standard cortical screws)*,
- instrument set,
- instructions for use.

Indications
Main purpose of surgical treatment of humeral bone fractures with **[3.4034]** plate is anatomical structure reconstruction and faster recovery to public and vocational life. Stabilization with this method stands out with possibility of precise reduction, angle-stable fixation of bone fragments, with preservation of blood supply.

Plate is intended for treatment of:
- fractures in proximal part of humeral bone and fractures extended to femoral bone shaft,
- fractures with dislocation,
- osteopenic bone fractures,
- osteotomy,
- mal- and non-unions.

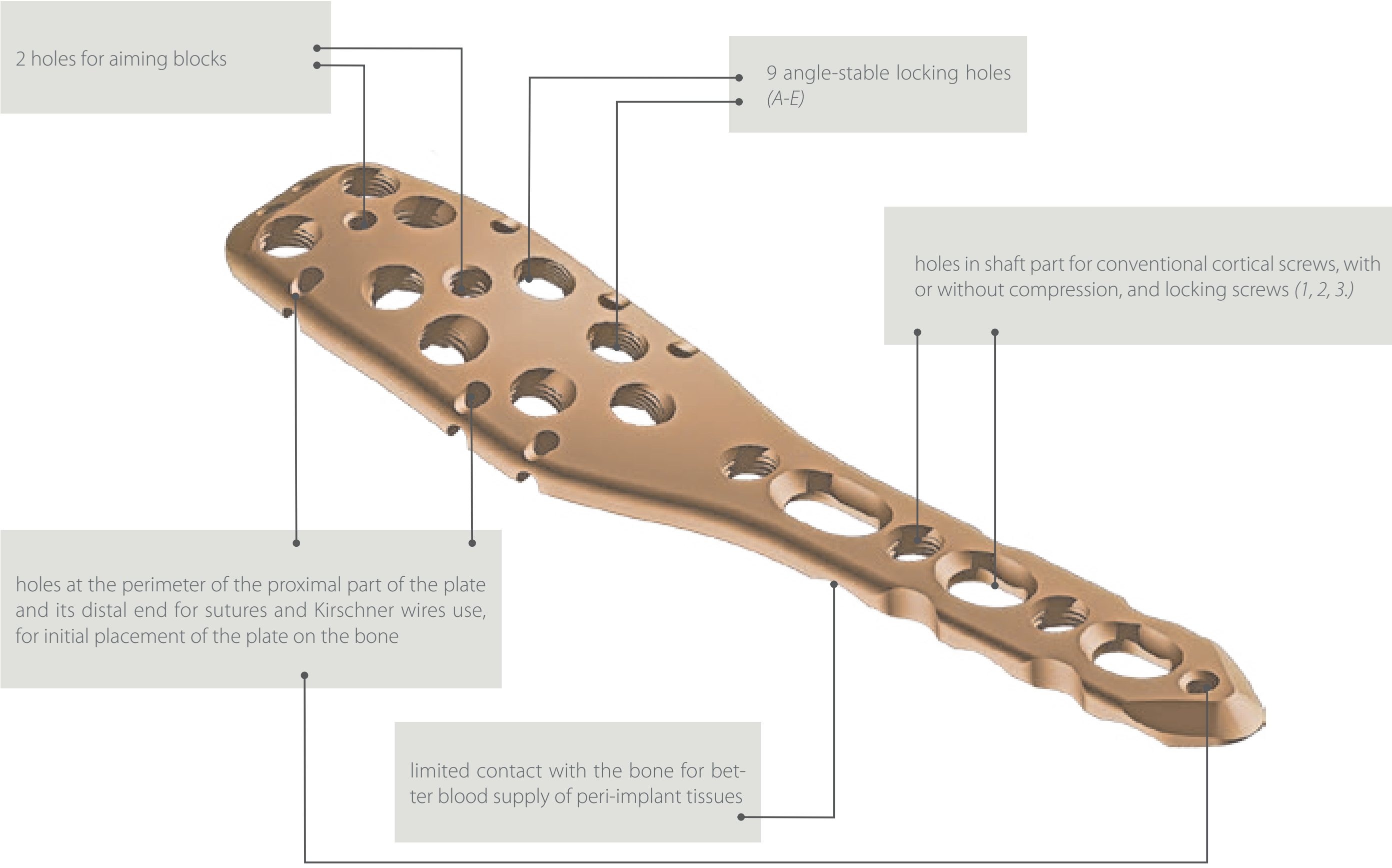
Contraindications
- infections,
- children in their growth phase.

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. IMPLANTS

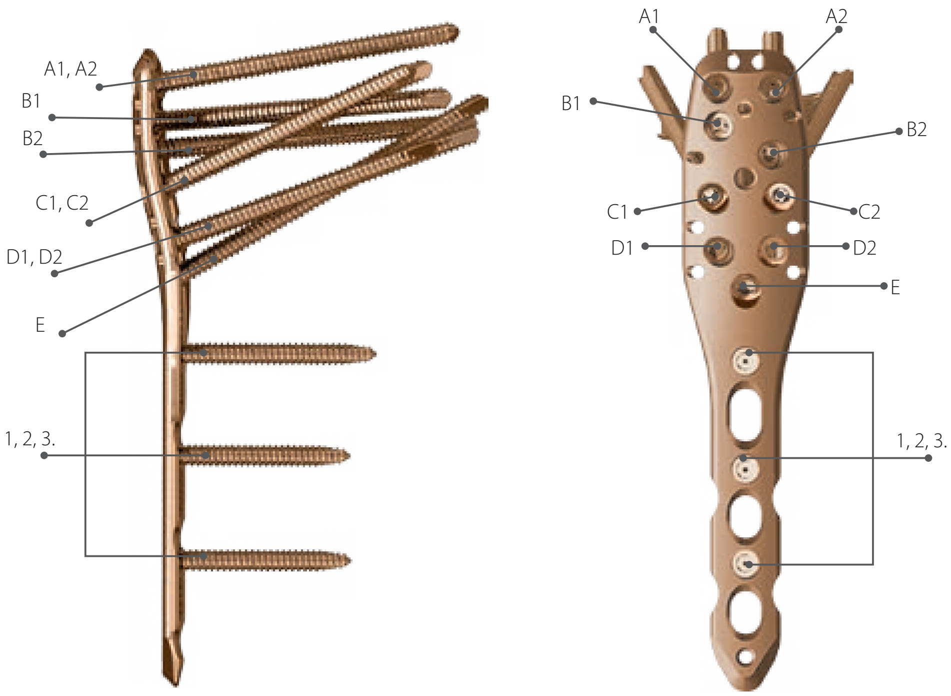
The plate 3.4034 is an element of **5.0ChLP** system. The system consists of plates and corresponding screws. For more comfortable usage both are of the same brown color.

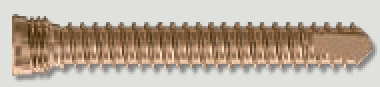
The plate shape is adapted to anatomical structure of humeral bone:



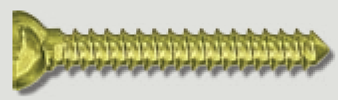
Locking holes in proximal part:

Various screws placement allows to supply different kinds of fractures by creating a number of unique constructions.





basic locking screw Ø3.5, self-tapping
[3.1289/3.5200]



standard cortical screw Ø3.5, self-tapping
[3.1283/3.1306]

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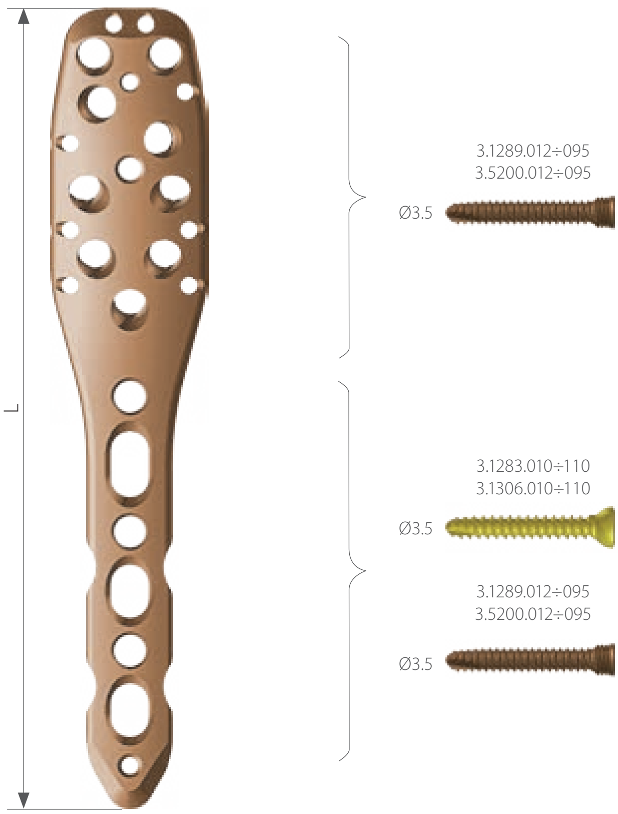
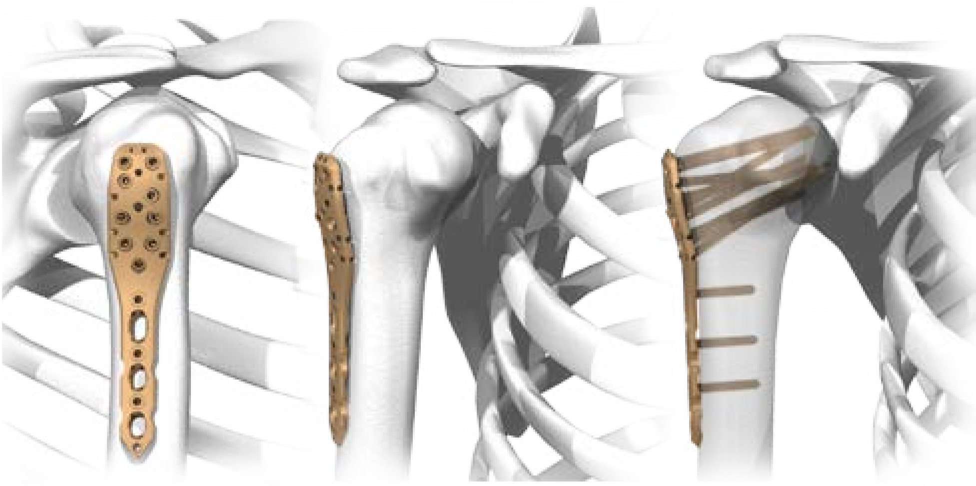
5.0ChLP HUMERAL PLATE

TITANIUM

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
7	161	3.4034.507
8	176	3.4034.508
9	191	3.4034.509
10	206	3.4034.510

O - threaded holes number in shaft part of the plate





PALETTE FOR 5.0ChLP PLATES - 3.4034

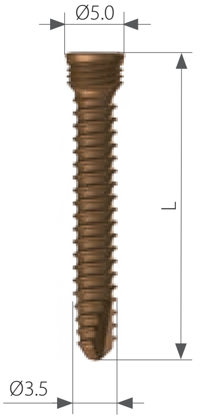
No.	Catalogue no.	Name	Pcs.		
1	40.5671.000	Aiming block	1	40.5758.010	40.5758.510
2	40.5672.000	Protective guide 7.0/5.0	2		
3	40.5758.210	Palette	1		
4	12.0751.100	Container solid bottom 1/2 306x272x85mm	1		
5	12.0751.200	Perforated aluminum lid 1/2 306x272x15mm Gray	1		

implants not included; with additional instruments

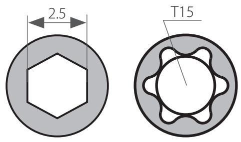
LOCKING ELEMENTS

TITANIUM Ti

5.0ChLP SCREW Ø3.5

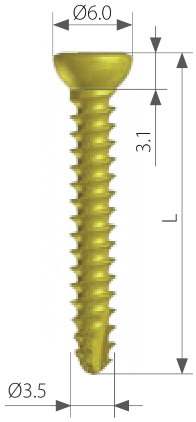



self-tapping

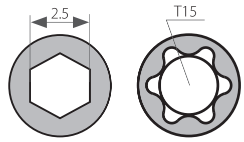


L [mm]	Catalogue no.	
12	3.1289.012	3.5200.012
14	3.1289.014	3.5200.014
16	3.1289.016	3.5200.016
18	3.1289.018	3.5200.018
20	3.1289.020	3.5200.020
22	3.1289.022	3.5200.022
24	3.1289.024	3.5200.024
26	3.1289.026	3.5200.026
28	3.1289.028	3.5200.028
30	3.1289.030	3.5200.030
32	3.1289.032	3.5200.032
34	3.1289.034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

CORTICAL SCREW Ø3.5




self-tapping



L [mm]	Catalogue no.	
14	3.1283.014	3.1306.014
16	3.1283.016	3.1306.016
18	3.1283.018	3.1306.018
20	3.1283.020	3.1306.020
22	3.1283.022	3.1306.022
24	3.1283.024	3.1306.024
26	3.1283.026	3.1306.026
28	3.1283.028	3.1306.028
30	3.1283.030	3.1306.030
32	3.1283.032	3.1306.032
34	3.1283.034	3.1306.034
36	3.1283.036	3.1306.036
38	3.1283.038	3.1306.038
40	3.1283.040	3.1306.040
45	3.1283.045	3.1306.045
50	3.1283.050	3.1306.050
55	3.1283.055	3.1306.055
60	3.1283.060	3.1306.060
65	3.1283.065	3.1306.065
70	3.1283.070	3.1306.070
75	3.1283.075	3.1306.075
80	3.1283.080	3.1306.080
85	3.1283.085	3.1306.085

Ø	core		2.8
Ø	drill with scale	40.5653.222	2.8
	guide sleeve	40.5673.728	5.0/2.8
	screwdriver tip	40.5676.000	S2.5
	screwdriver tip	40.5677.000	T15

Ø	core		2.4
Ø	drill bit for thread hole	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

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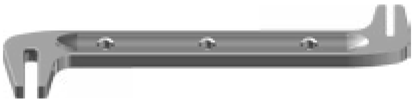
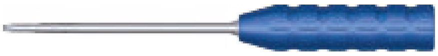
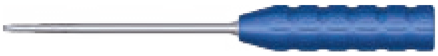
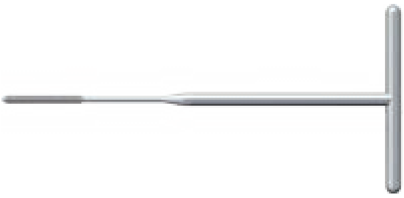
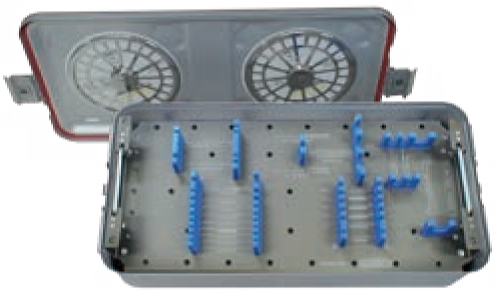
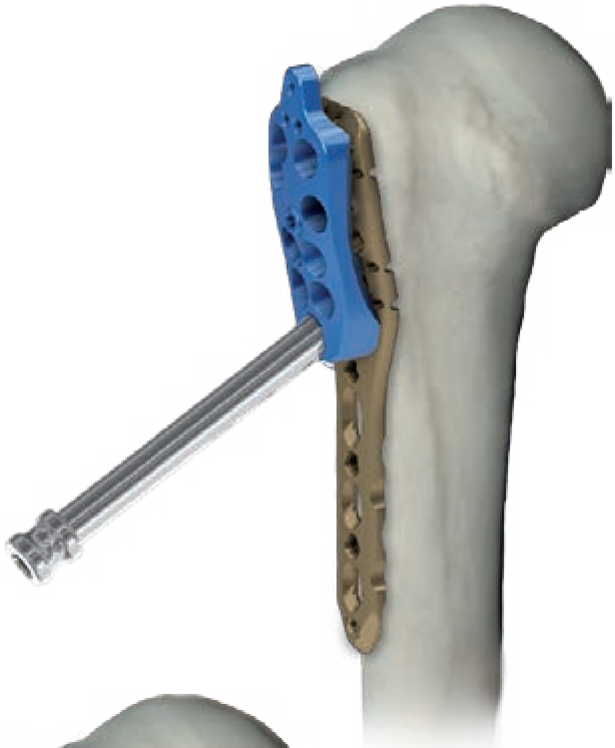
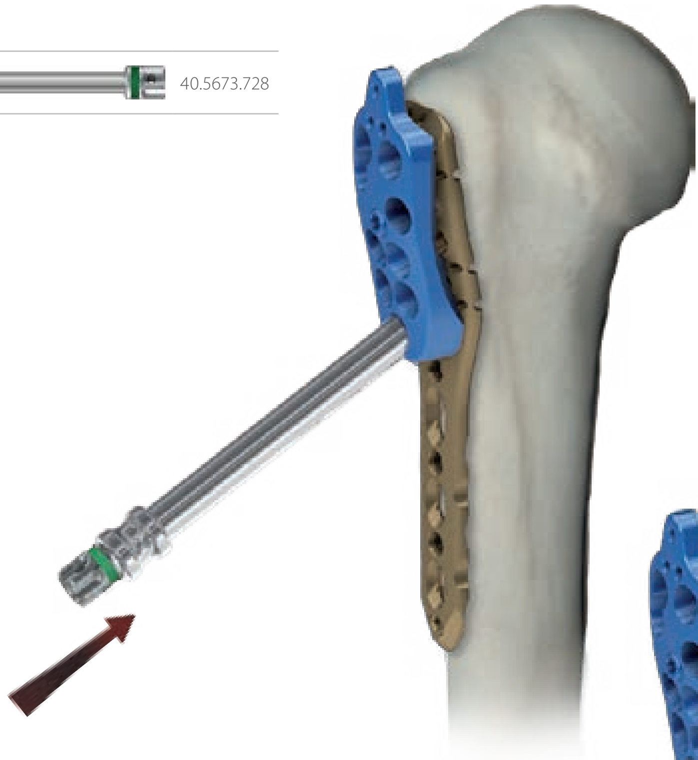
III. INSTRUMENTS

40.5667.700	Name	Pcs	Catalogue No.
	Guide sleeve 5.0/1.5	2	40.5673.715
	Guide sleeve 5.0/1.8	2	40.5673.718
	Guide sleeve 5.0/2.5	2	40.5673.725
	Guide sleeve 5.0/2.8	4	40.5673.728
	Compression guide 2.5/2.8	1	40.4804.700
	Drill 1.8/220	2	40.2063.222
	Drill with scale 2.5/220	2	40.5912.222
	Drill with scale 2.8/220	2	40.5653.222
	Kirschner wire 1,5/220	4	40.4592.220
	Kirschner wire2.0/220	2	40.4815.220
	Setting-compressing screw 2.8/180	2	40.5674.728
	Screw length measure	1	40.5675.100
	Depth measure	1	40.4639.500
	Screwdriver tip S2.5	1	40.5676.000
	Screwdriver tip T15	1	40.5677.000
	Torque handle 2.0Nm	1	40.5635.100
	Bender for plates 4/6	2	40.4250.000
	Hexagonal screwdriver S2.5	1	40.0321.000
	Star screwdriver T15	1	40.0670.000
	Cortical tap HA 3.5 with handle	1	40.2548.000
	Tap **5.0ChLP** - 3.5	1	40.5661.000
	Screwdriver	1	40.4746.000
	Stand for instrument set of **5.0ChLP** plate	1	40.5668.700
	Container with solid bottom 1/1 595x275x86mm	1	12.0750.100
	Perforated aluminum lid 1/1 595x275x15mm gray	1	12.0750.200

IV. IMPLANTATION GUIDES

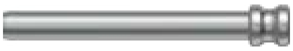
IV.1. INSERTION OF LOCKING SCREW 3.5 IN PROXIMAL PART





IV.1.1. INSERTION OF PROTECTIVE GUIDE

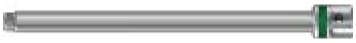
Insert the Protective Guide 7.0/5.0 **[40.5672.000]** into the proper hole of the Aiming Block **[40.5671.000]**.



40.5672.000

IV.1.2. INSERTION OF THE GUIDE SLEEVE

Insert the Guide Sleeve 5.0/2.8 **[40.5673.728]** through the Protective Guide into the plate hole.



40.5673.728

IV.1.3. DRILLING

Drill the hole using the Drill With Scale 2.8/220 **[40.5653.222]** under the X-Ray control.

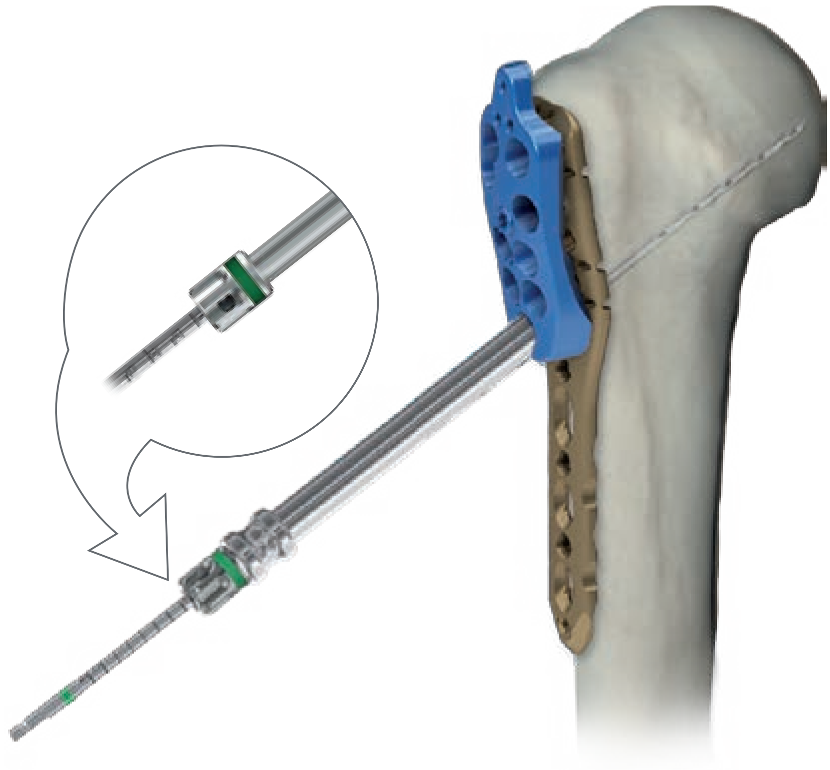
40.5653.222

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

IV.1.4. MEASUREMENT OF THE HOLE DEPTH

OPTION I:

Use the Drill With Scale **[40.5653.222]**



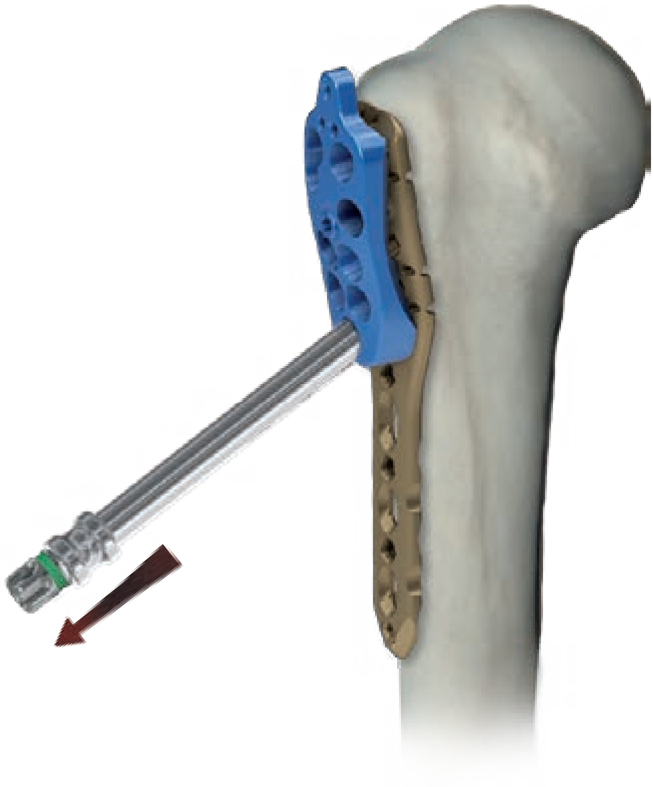
OPTION II:

Use the Screw Length Measure **[40.5675.100]**

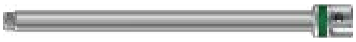
40.5675.100

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

IV.1.5. INSERTION OF THE SCREW

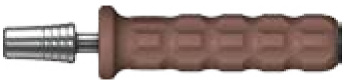


Remove the Guide Sleeve 5.0/2.8 **[40.5673.728]**.



40.5673.728

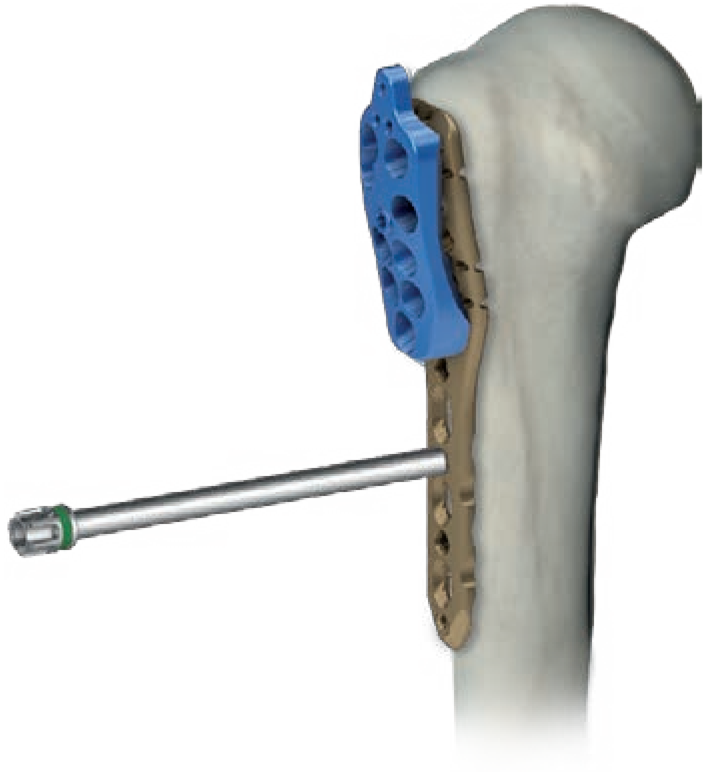
Insert the locking screw through the Protective Guide 7.0/5.0 **[40.5672.070]** using Torque handle **[40.5635.100]** and appropriate screwdriver tip.



40.5635.100

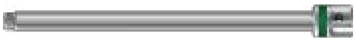
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

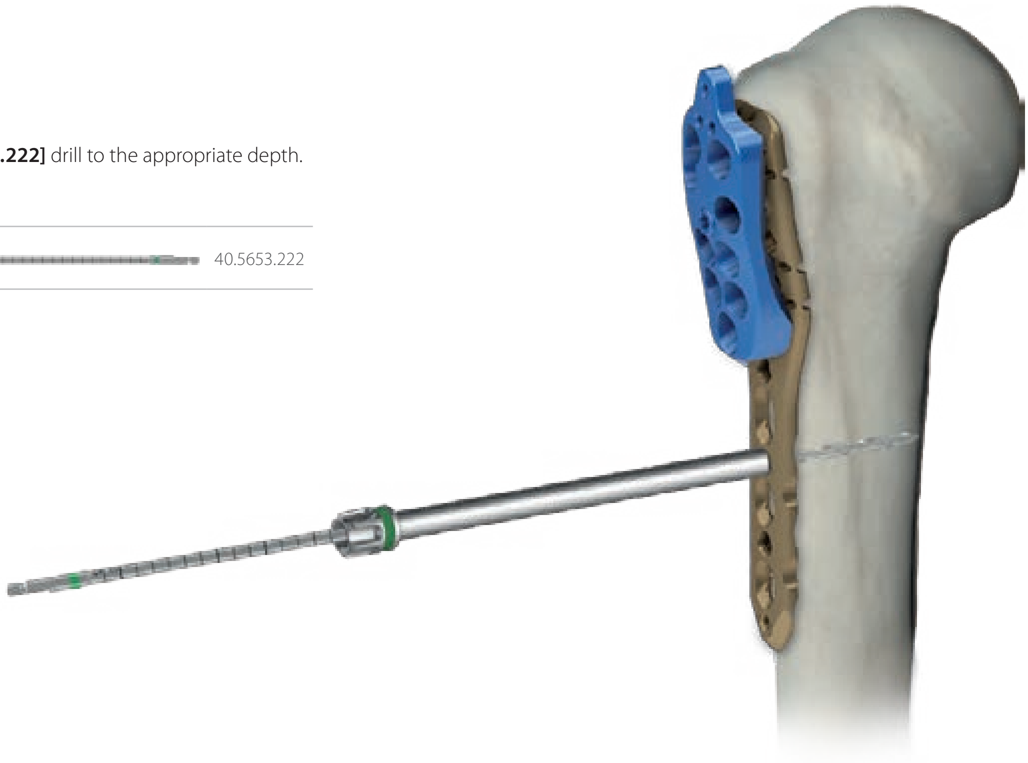
IV.2. INSERTION OF LOCKING SCREW 3.5 INTO THE SHAFT PART



IV.2.1. INSERTION OF THE GUIDE SLEEVE

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


40.5673.728



IV.2.2. DRILLING

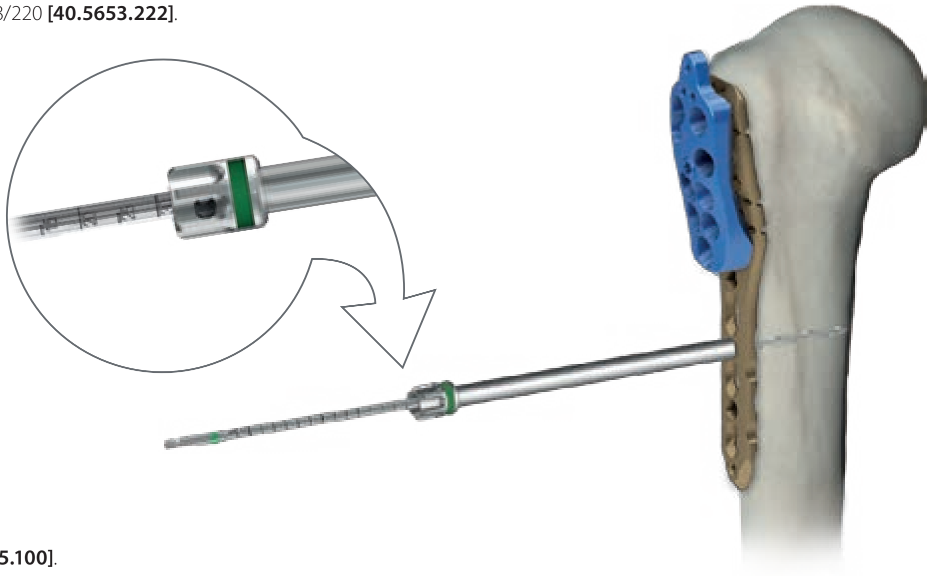
Using the Drill With Scale 2.8/220 **[40.5653.222]** drill to the appropriate depth.

40.5653.222

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

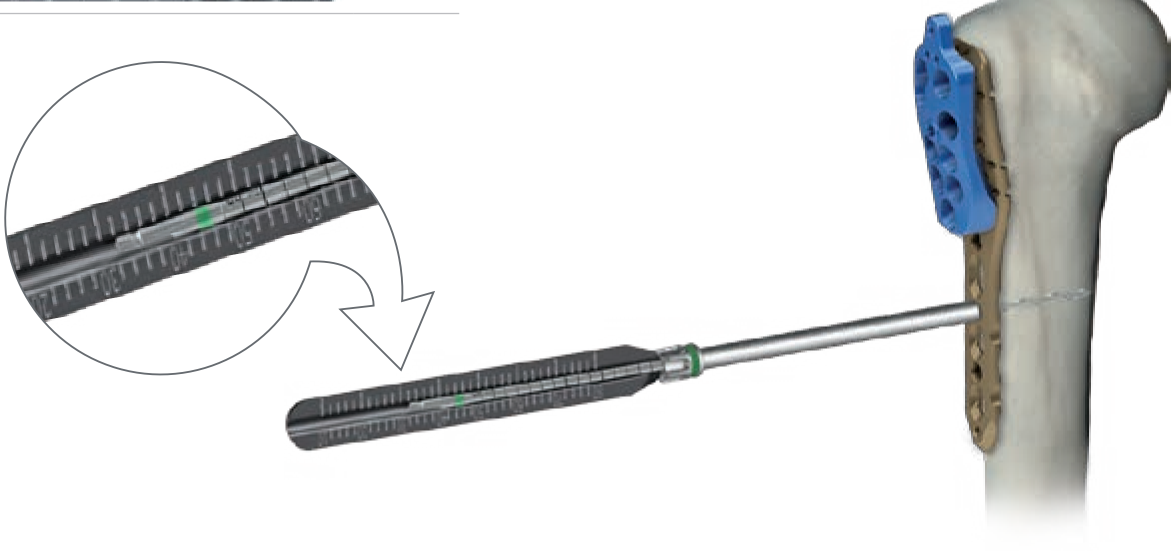
IV.2.3. MEASUREMENT OF HOLE DEPTH

OPTION I: Read the length from the Drill with scale 2.8/220 **[40.5653.222]**.



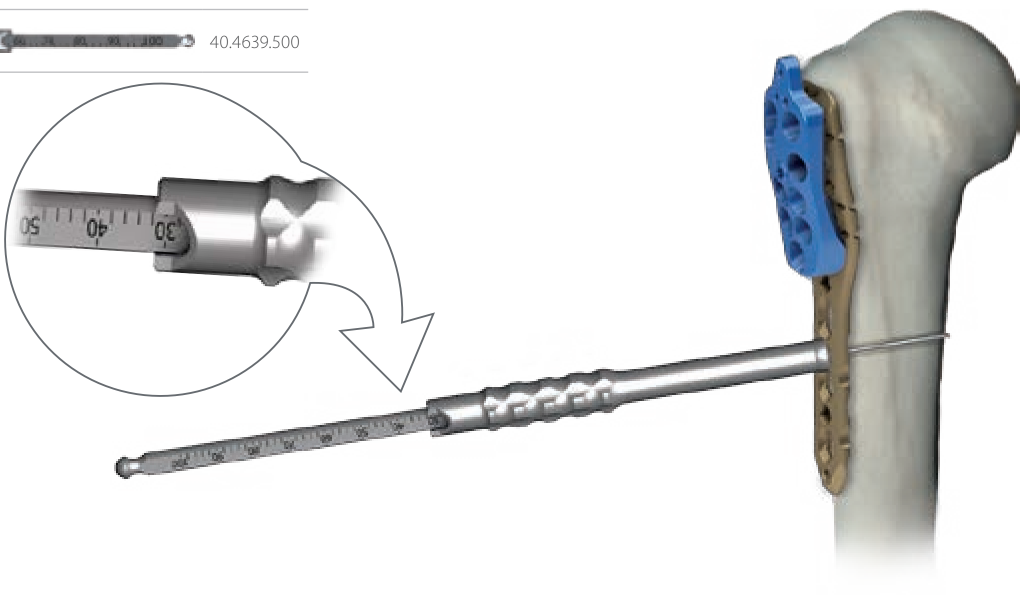
OPTION II: Or use the Screw Length Measure **[40.5675.100]**.

40.5675.100



OPTION III: After unscrewing the Guide Sleeve 5.0/2.8 **[40.5673.728]**, define the screw length using the Depth Measure **[40.4639.500]**.

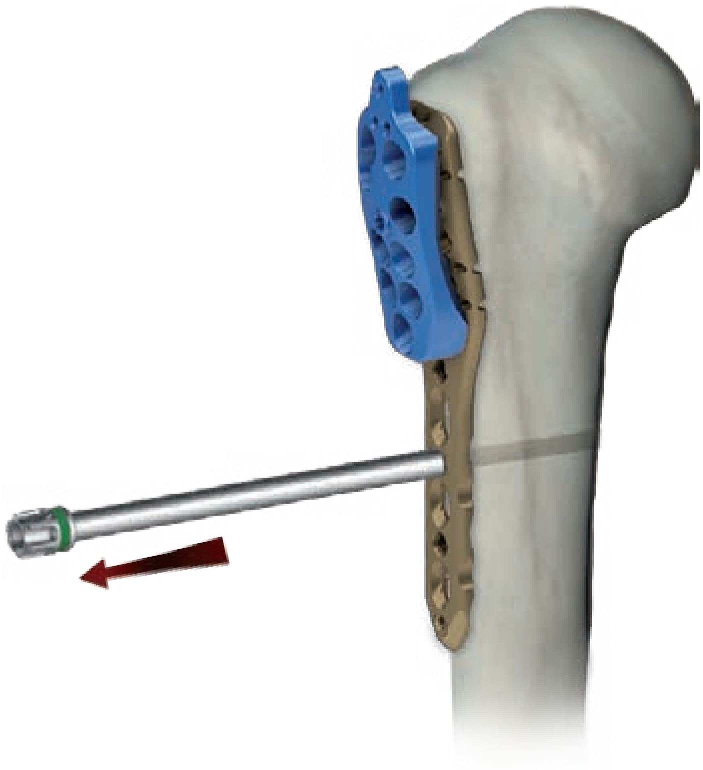
40.4639.500



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

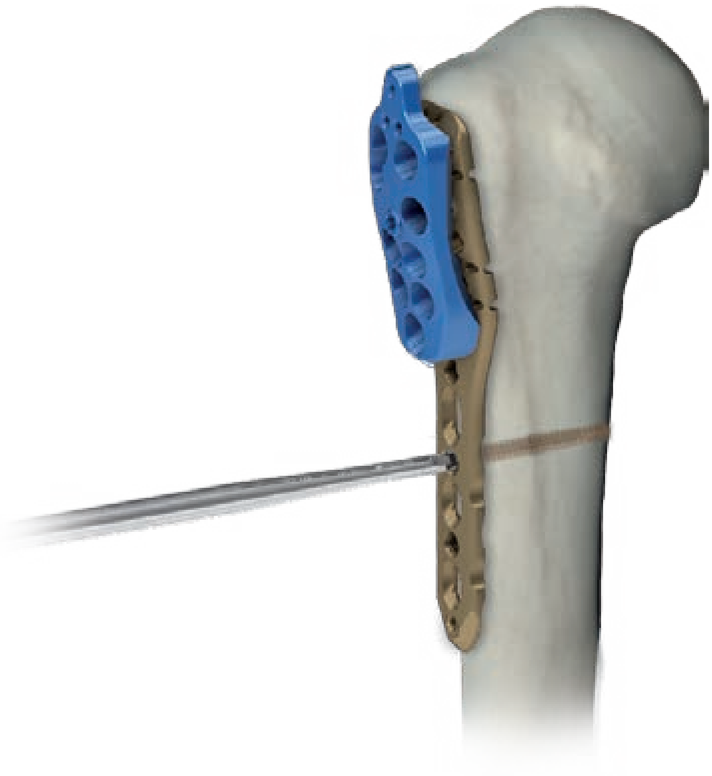
IV.2.4. INSERTION OF THE SCREW

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



Insert the locking screw using the Torque handle **[40.5635.100]** and appropriate screwdriver tip.

40.5635.100



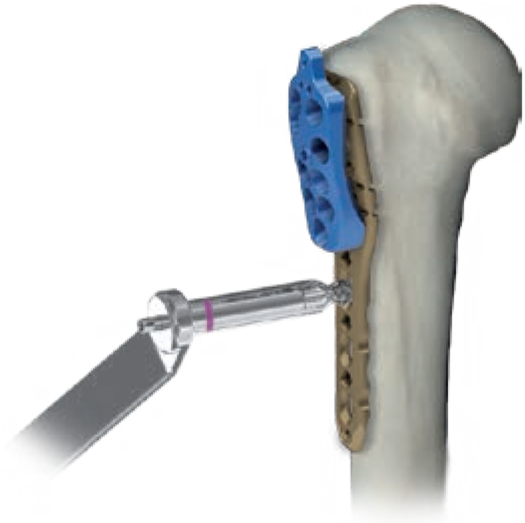
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.3. INSERTION OF THE CORTICAL SCREW 3.5 INTO THE SHAFT PART

IV.3.1. SETTING OF COMPRESSION GUIDE

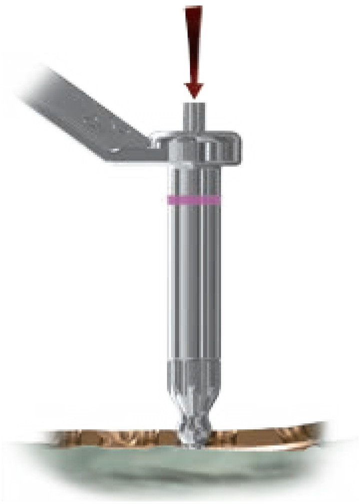
Set the Compression Guide 2.5 **[40.4804.700]** into the appropriate position:

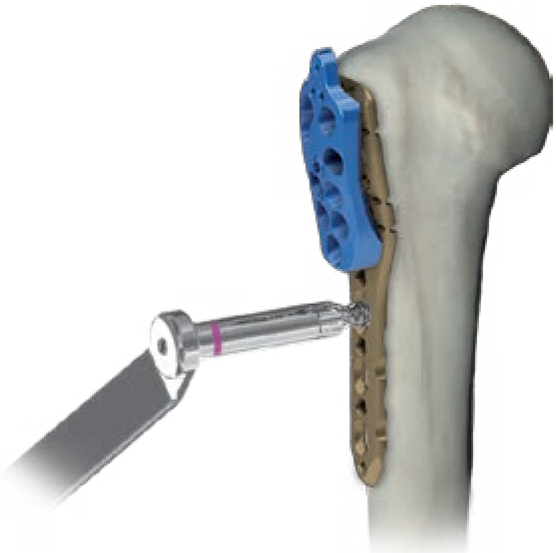
40.4804.700



IV.3.1.1. NEUTRAL POSITION

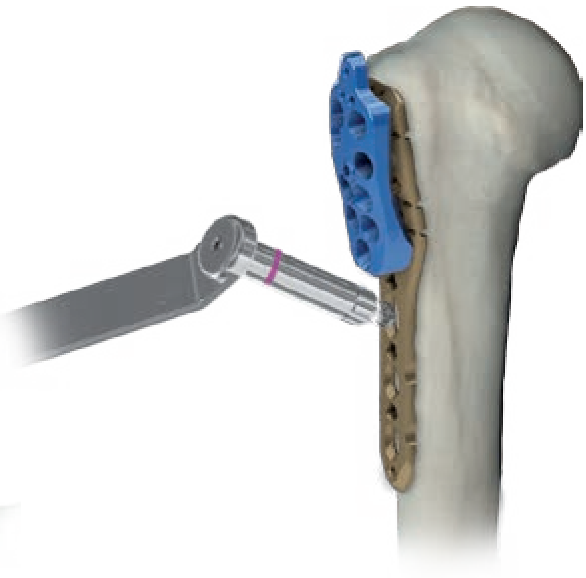
Press the guide to the plate. It will set in the position that allows neutral insertion of the screw.





IV.3.1.2. COMPRESSION POSITION

Move the guide without pressure to the edge of compression hole. Hole drilled in this position allows insertion of the screw in compression position.



IV.3.1.3. ANGULAR POSITION

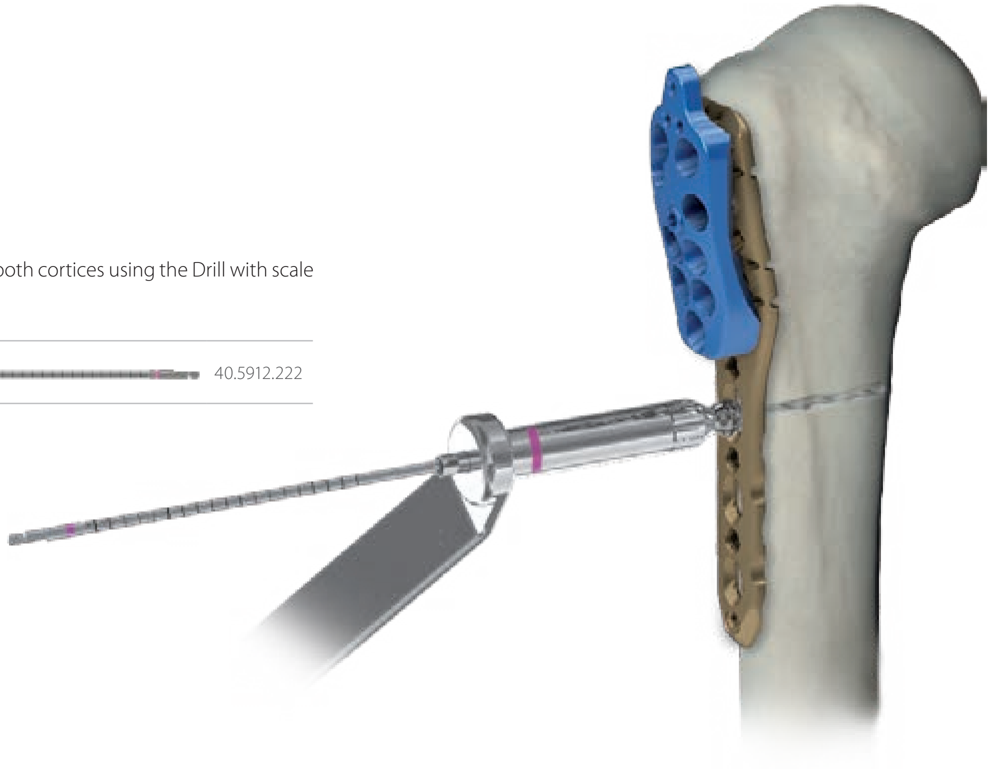
Angular position of the guide is also possible.

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

IV.3.2. DRILLING

Make a hole for Cortical Screw 3.5 through both cortices using the Drill with scale 2.5/220 **[40.5912.222]**.

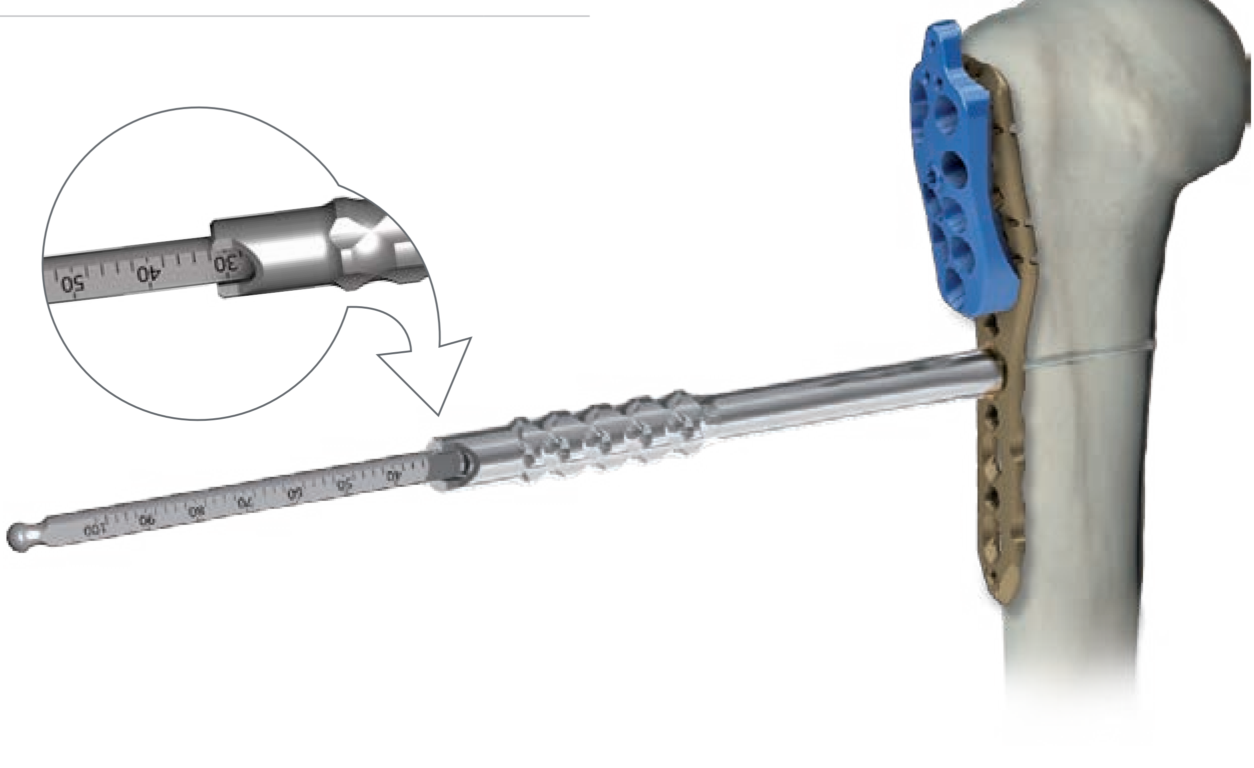
40.5912.222

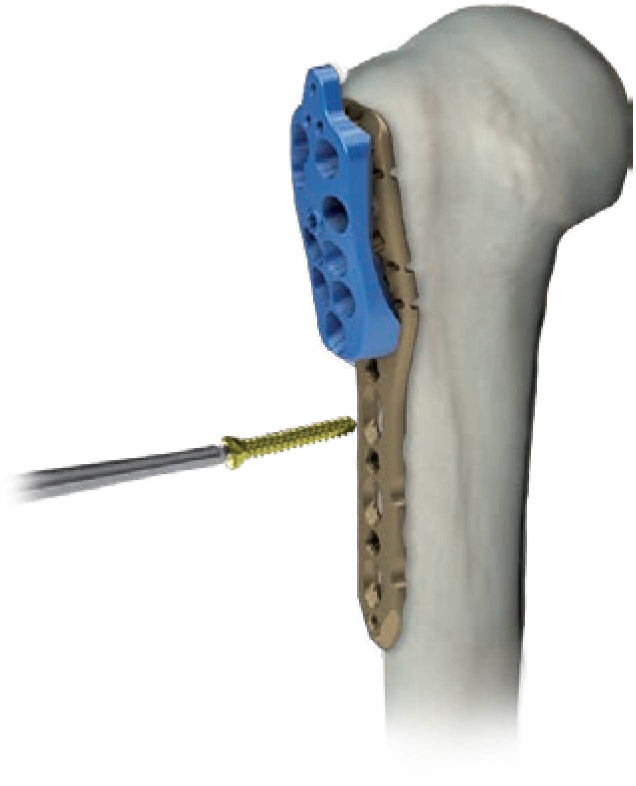


IV.3.3. SETTING OF COMPRESSION GUIDE

Insert the Depth Measure **[40.4639.500]** into the drilled hole until its hook reaches outer surface of opposite cortex bone.

40.4639.500





IV.3.4. INSERTION OF THE SCREW

Insert the Cortex Screw 3.5.

IV.4. USAGE OF KIRSCHNER WIRE 1.5

It is possible to use Kirschner wire 1.5/220 **[40.4592.220]** inserted into each locking hole for:

- temporary stabilization of fracture fragments and plate,
- defining correct position of plate or length of the locking screw in humeral bone using X-Ray image,

Insert Kirschner wire 1.5/220 **[40.4592.220]** through the Guide Sleeve 5.0/1.5 **[40.5673.715]** inserted into the locking hole of the plate. Use the Screw Length Measure **[40.5675.100]** to define the depth insertion.

40.4592.220

40.5673.715

40.5675.100

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

V. SURGERY TECHNIQUE

V.1. PATIENT POSITION

"Beach-chair" position is recommended for operation. Such position ensures easy approach to the shoulder.

V.2. SURGICAL APPROACH

Deltopectoral approach is recommended, between deltoid and pectoral muscles.

V.3. REDUCTION OF FRACTURE

It is necessary to perform anatomical reduction of head fragments and humeral bone tuberosity with Kirschner wires or sutures before applying locking screws. Stabilize temporarily head fragments and humeral bone tuberosity using Kirschner wires or additional independent screws for interfragmentary compression avoiding interference with later applied plate and screws. Confirm correct position of fragments taking X-Ray image. Fractured bone fragments can be stabilized also with bone clamps.

Option. It is possible to increase stability by insertion of sutures through the Ø2 holes at the proximal part of the plate perimeter. If use of sutures for fracture stabilization is necessary, it is recommended to perform insertion into adequate plate holes before mounting aiming block and applying it on the bone. If necessary, fix the sutures in tendons attachment region: supraspinatus, infraspinatus and subcapsularis. For fractures of the greater tuberosity tie plate with supraspinatus and/or infraspinatus tendon, whereas for lesser tuberosity fractures with subcapsularis.

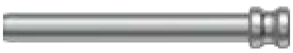
V.4. ATTACHMENT OF AIMING BLOCK

Place the Aiming Block **[40.5671.000]** on the plate.

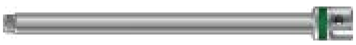
Tighten using the Screwdriver T15 **[40.5677.000]**.

40.5677.000

For easier insertion and positioning of the plate insert two Protective Guides 7.0/5.0 **[40.5672.000]** and the Guide Sleeves 5.0/2.8 **[40.5673.728]** for example in 2 nearer holes *(A1 and A2)*.



40.5672.000



40.5673.728

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

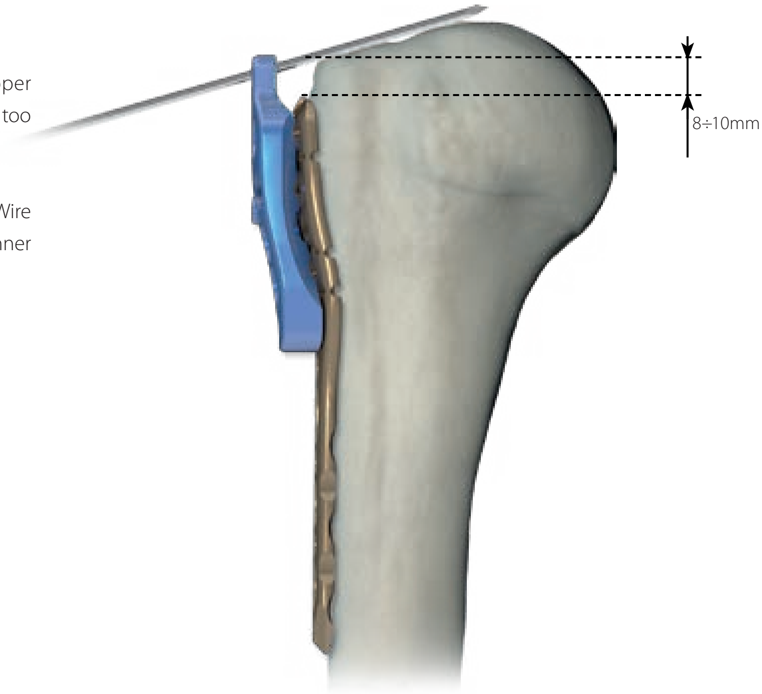
V.5. PLATE APPLICATION

Place the plate on the bone and check its position in two planes:

a) A/P position

Upper edge of the plate should be placed about 8÷10mm below upper edge of the greater tuberosity *(rotator cuff attachment)*. If the plate is placed too high, the risk of acromion impingement increases.

For easier determination of the correct plate in A/P position insert Kirschner Wire 2.0 **[40.4815.220]** through the proximal hole of the aiming block. The Kirschner wire should rest on top of the humeral head.

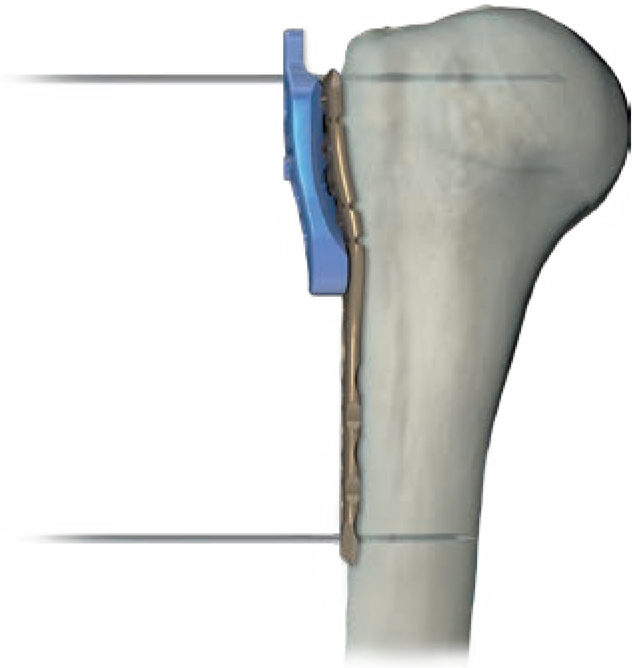


b) lateral position

The plate should be centered with greater tuberosity, that is 3÷5mm from lateral intertubercular sulcus of humerus.

V.6. TEMPORARY PLATE POSITIONING

40.4592.220

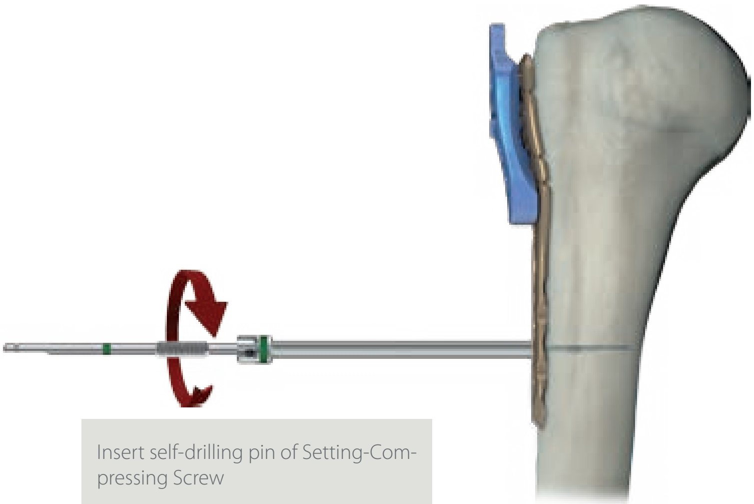


After reduction of the fragments and confirmation of plate position, it is necessary to temporary fix its position using 2.0 Kirschner wires **[40.4815.220]**. They may be placed in holes in proximal part of the plate and in the most distal hole of the plate.

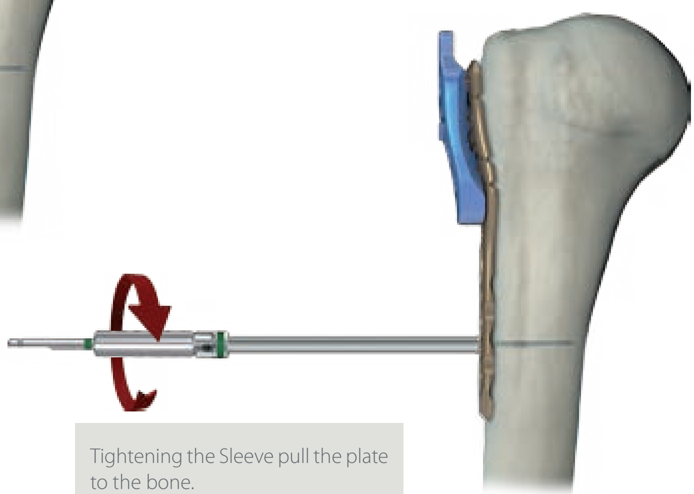
Confirm correct position by taking X-Ray image.

For temporary stabilization and tightening of the plate to the bone there is a possibility to use the Setting-Compressing Screw 2.8/180 **[40.5674.728]**. Insert the screw through the Guide Sleeve 5.0/2.8 **[40.5673.728]**.

Insertion of the above-mentioned screw may prevent insertion of some screws in proximal part because of interference of the angular position of guide sleeves. After the Setting - Compressing Screw 2.8/180 removal, the locking screw can be inserted into the hole.



Insert self-drilling pin of Setting-Compressing Screw



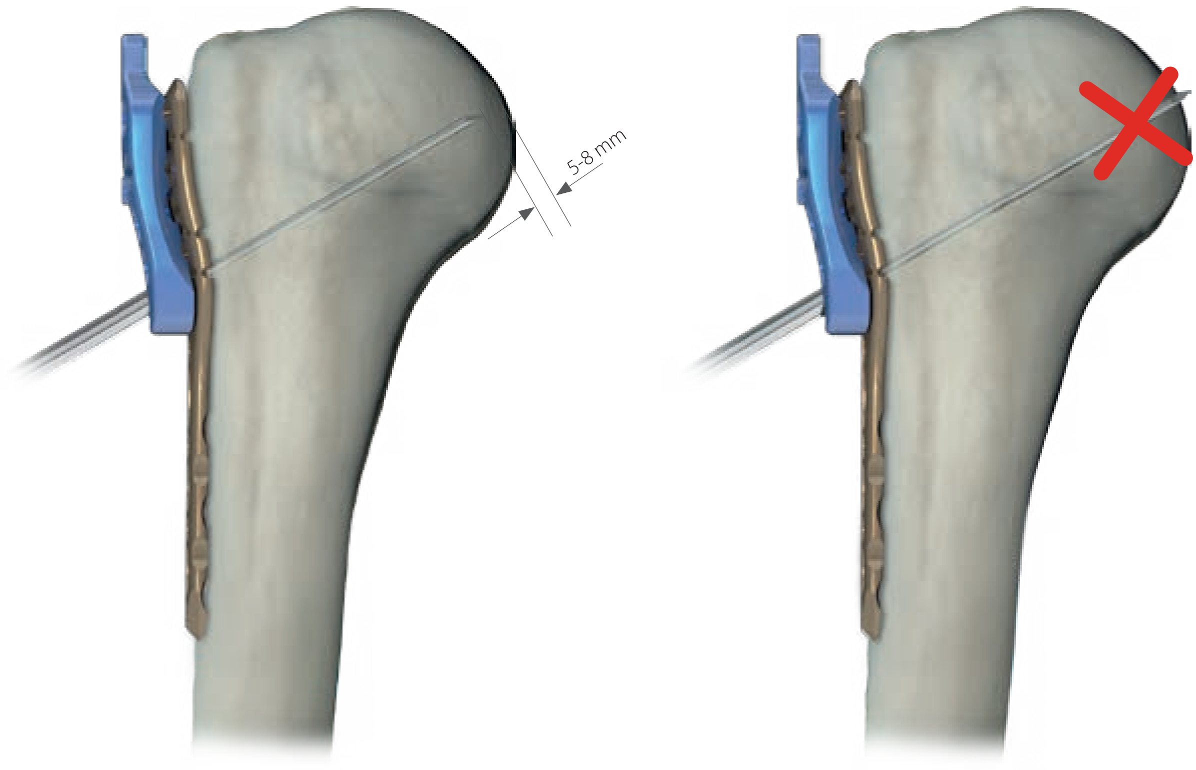
Tightening the Sleeve pull the plate to the bone.

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

V.7. INSERTION OF SCREWS

Initial screw selection depends on type and obtained reduction of fracture. 2 options *(option A and option B)* of insertion order are described below.

In humeral bone head holes should be drilled up to the depth when the resistance of the subchondral bone is felt. It is not always possible to feel this resistance, so it is recommended to use X-Ray control. The K-wire or drill tip should be placed as close to the subchondral bone as possible, i.e. about 5-8mm from the joint surface. Perforation of the joint surface by drilling the opposite cortex of the humeral bone head should be avoided.



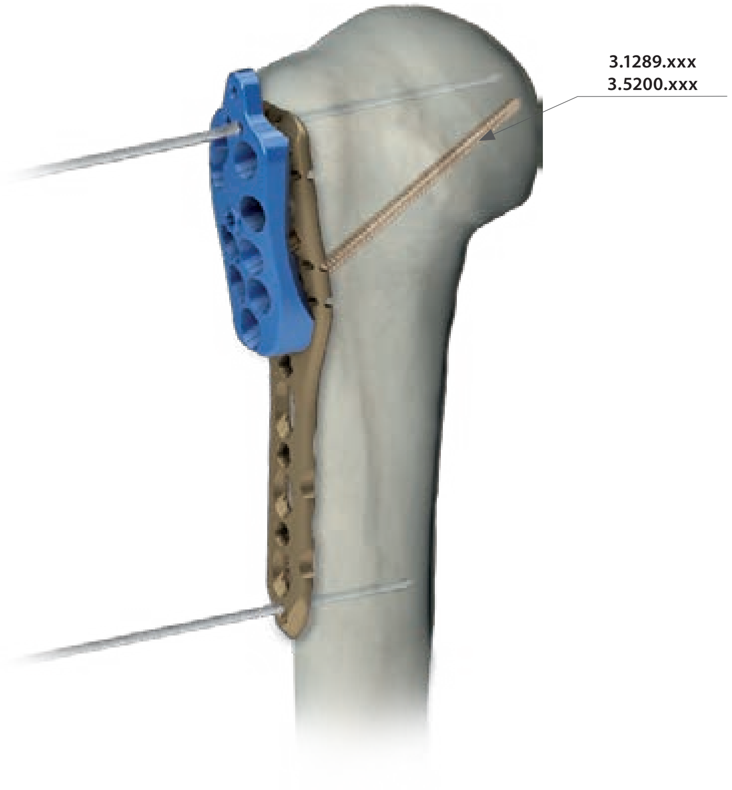
It is necessary to insert at least 4-6 screws or more at the proximal part of the plate, particularly when the bone quality is poor. While inserting locking screws in the shaft part, it is recommended to perform the insertion through both cortices to obtain better fixation.

V.7.1. OPTION A

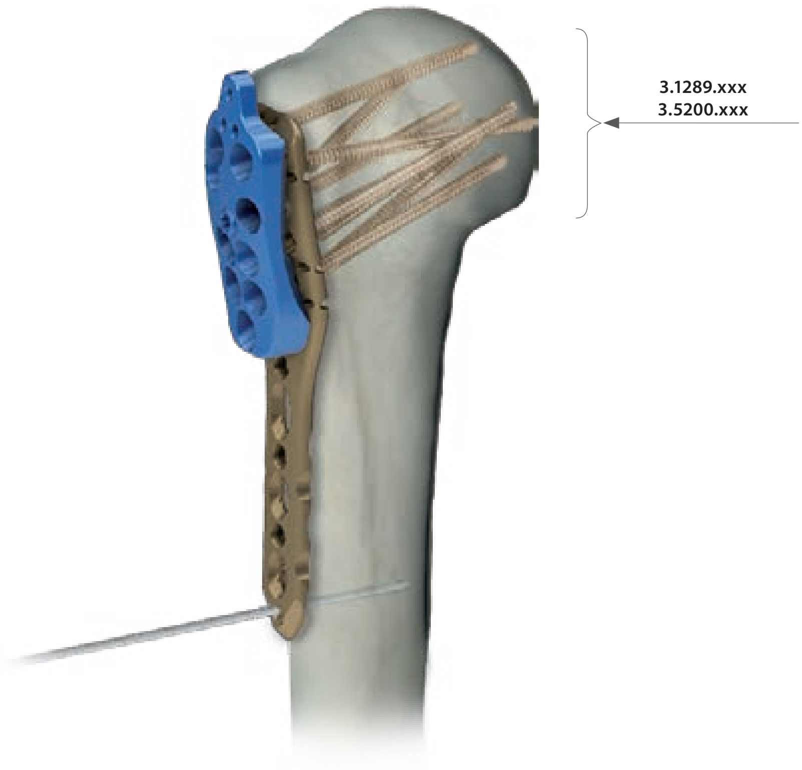
In this technique the bone fragments in proximal part are fixed as first. Then the distal part with or without compression is fixed.

V.7.1.1. HUMERAL BONE EPIPHYSIS STABILIZATION

Insert the Locking Screw 3.5 in hole E after temporary stabilization, compression of the fragments of fractured humeral bone head and X-Ray control of plate height.



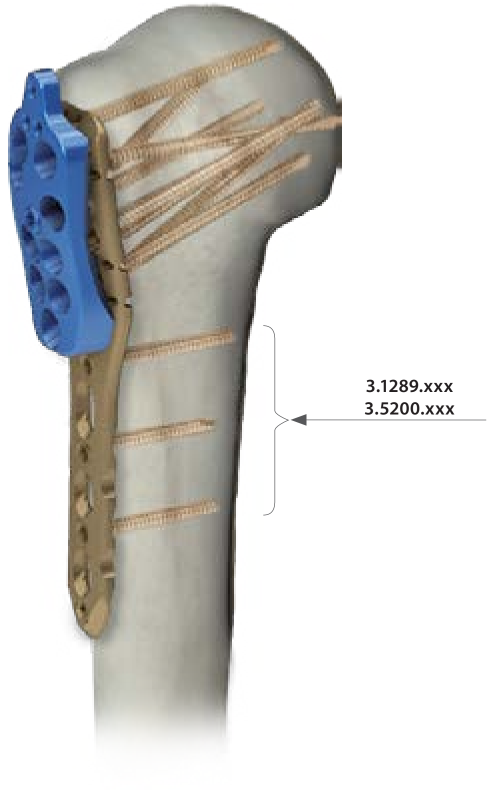
Insert locking screws in the appropiate holes in proximal part of the plate.



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

V.7.1.2. STABILIZATION OF HUMERAL BONE SHAFT

Insert the Locking Screw 3.5 **[3.1289.xxx/3.5200.xxx]** in distal holes of the plate.



If necessary, before insertion of the Locking Screws in distal part, use of cortical screws can accomplish compression of the fragments of fractured bone.

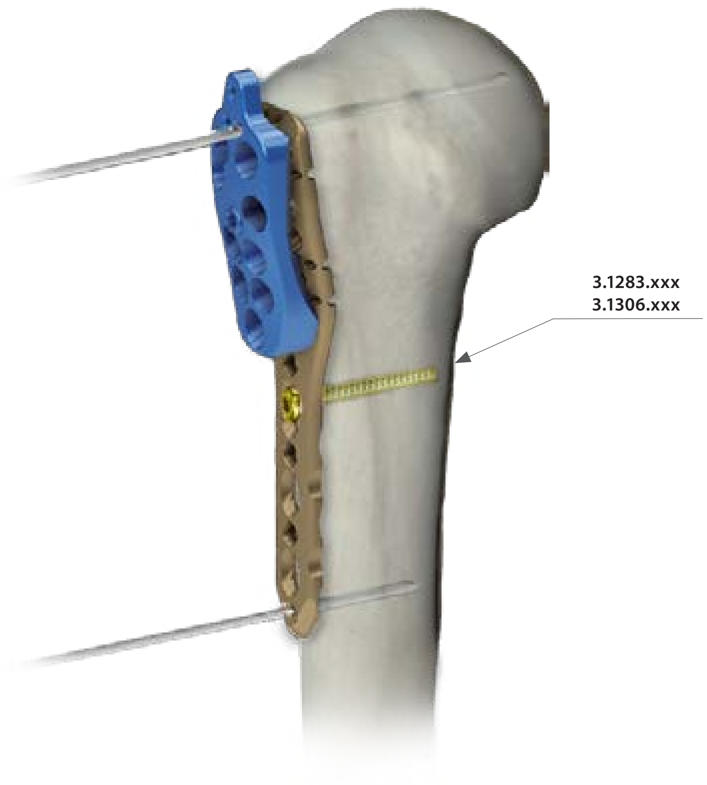
V.7.1.3. REMOVAL OF AIMING BLOCK [40.5671.000]

V.7.2. OPTION B

This technique reads as follows: a reduction of distal shaft part with plate is to be done as first and then the final adjustment of plates height and insertion of the screws in proximal part before inserting the other screws in shaft shall be performed.

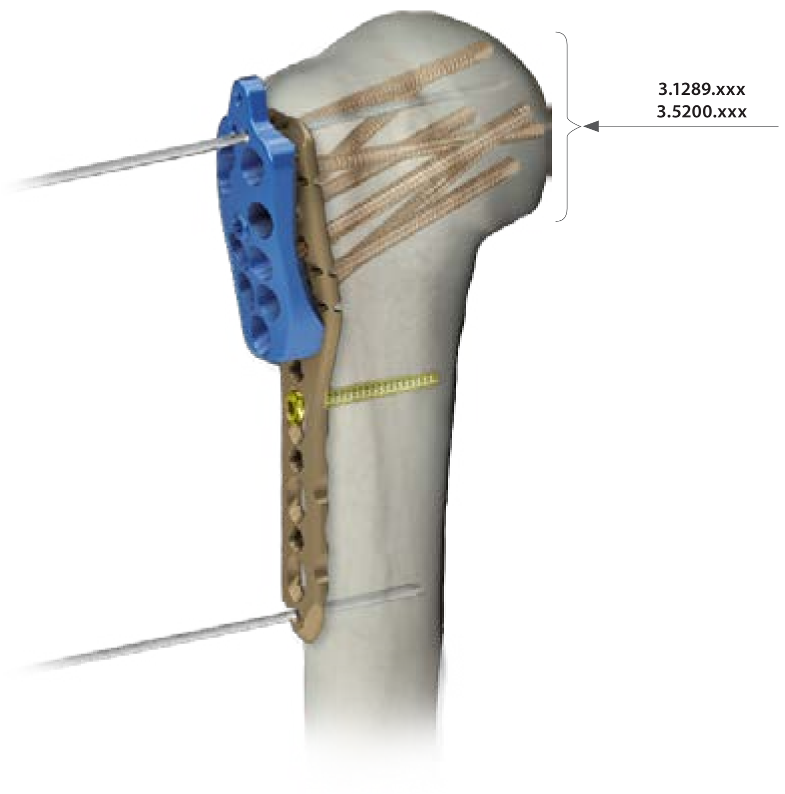
V.7.2.1. INSERTION OF CORTICAL SCREW 3.5

Insert the Cortical Screw 3.5 **[3.1283.xxx/3.1306.xxx]**, in neutral position, in first or second compression hole.



V.7.2.2. STABILIZATION OF HUMERAL BONE EPIPHYSIS

Insert the Locking Screws 3.5 [3.1289.xxx/3.5200.xxx] in the appropriate holes of humeral bone head.



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

V.7.2.3. STABILIZATION OF HUMERAL BONE SHAFT

Insert the Locking Screws 3.5 **[3.1289.xxx/3.5200.xxx]** in distal part of the plate, or perform compression in shaft section using the standard Bone Screws 3.5 **[3.1283.xxx/3.1306.xxx]**.

Any compression should be done before insertion of the Locking Screws. After locking screws insertion the compression is not possible without locking screws removal.

V.7.2.4. REMOVAL OF AIMING BLOCK [40.5671.000]

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

VI. POSTOPERATIVE PROCEDURE

To prevent lateral restriction of movement the patient should start exercising after surgery as soon as possible. However it is necessary to pay attention not to fully load the limb before complete union of fractured bone occurs.

VII. IMPLANT REMOVAL

For implant removal, it is necessary to first unlock all locking screws. Next completely remove screws from bone. It will prevent plate rotation when last locking screw is being removed.

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.

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ChM®

ISO 9001/ ISO 13485

CE 0197

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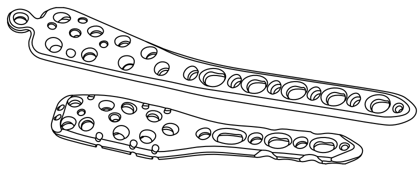
IFU-010/16



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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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	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
STERILIZE	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterlilizzare
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	Consult Instructions for Use • Zajrzyj do instrukcji używania • Обратитесь к инструкции по применению • Consultar instrucciones de uso • Siehe die Gebrauchsanweisung • Řiďte se návodem k použití • Consultare le instruzioni per l'uso
NON STERILE	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
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REF	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo
LOT	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto
Mat:	Material • Materiał • Материал • Material • Material • Materiál • Materiale
Qty:	Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita'
	Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il

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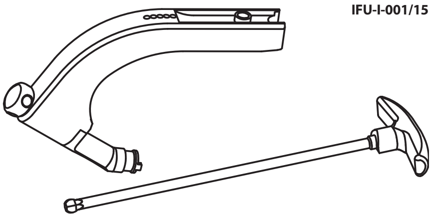

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INSTRUCTIONS FOR USE REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

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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Qty:	Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita'
	Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il

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