ChM®

PROXIMAL HUMERAL PLATE

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

www.chm.eu

SYMBOLS DESCRIPTION

	Caution - pay attention to a special procedure.
	Perform the activity under X-Ray control.
	Information about the next stages of a procedure.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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

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. The presented range of implants is made of titanium, titanium alloys and cobalt alloy in accordance with ISO 5832 standard. Compliance with the requirements of quality management systems and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered 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

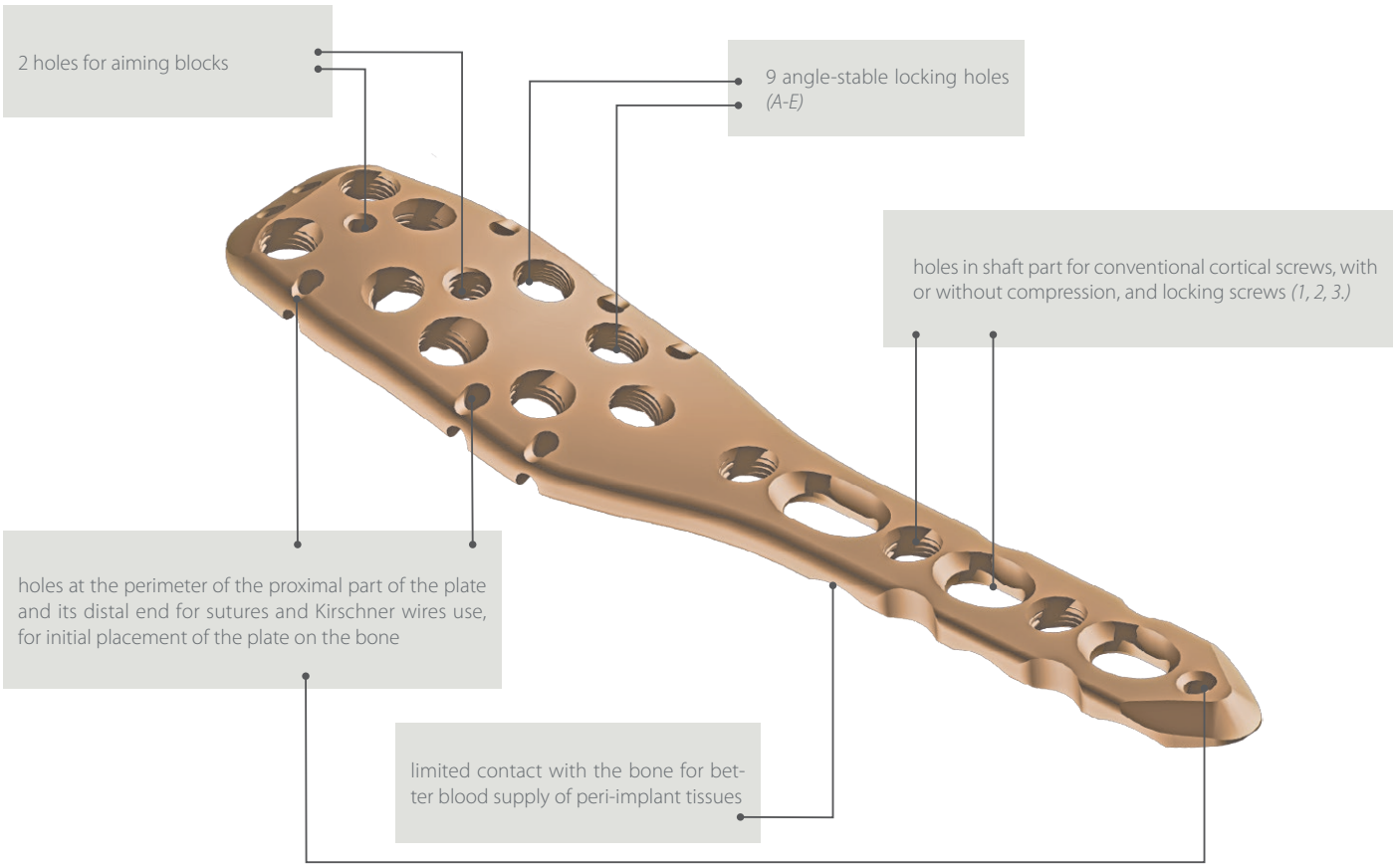
- infections,
- children in their growth phase.

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

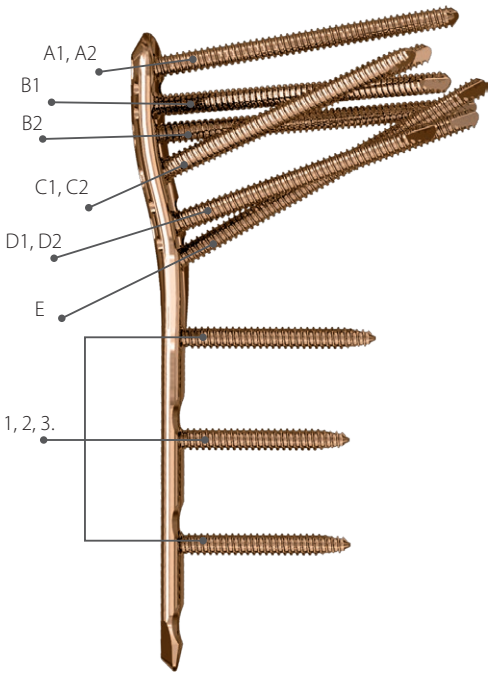
The plate 3.4034 is an element of **5.0ChLP** system. The system consists of plates and corresponding screws. For more comfortable usage both are of the same brown color.

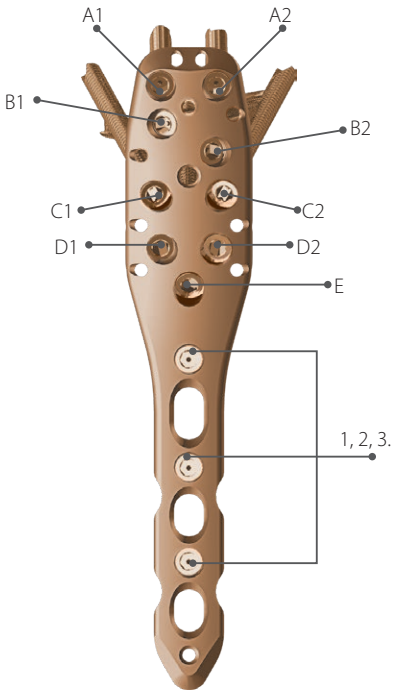
The plate shape is adapted to anatomical structure of humeral bone:



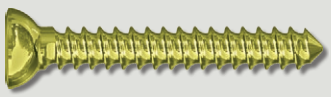
Locking holes in proximal part:

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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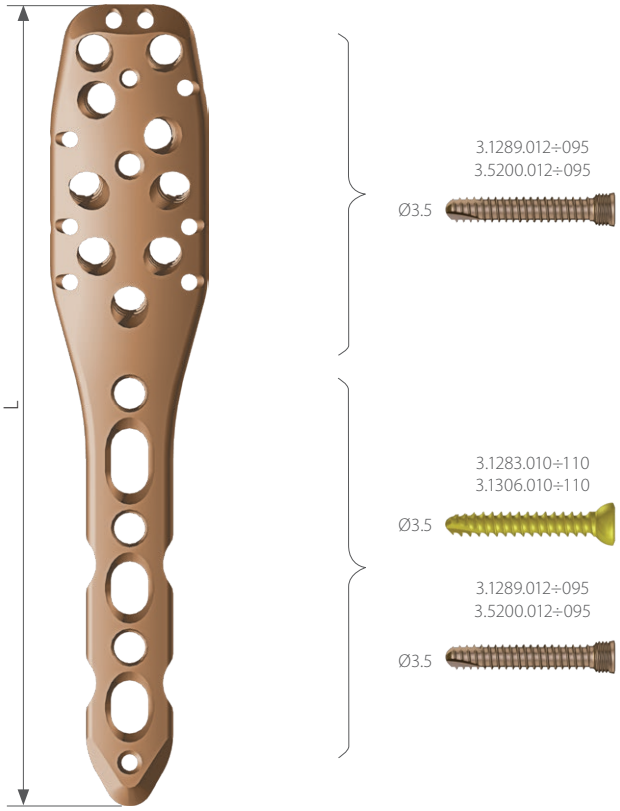
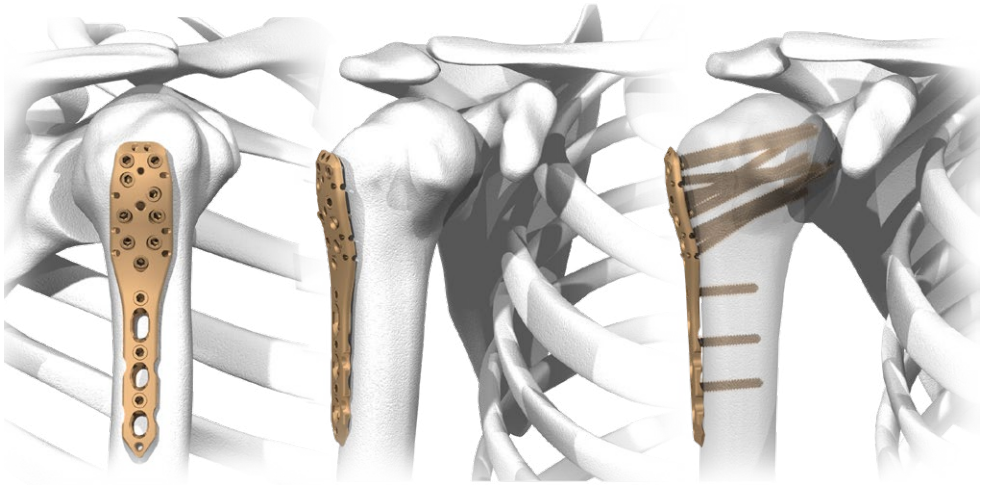
5.0ChLP HUMERAL PLATE

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

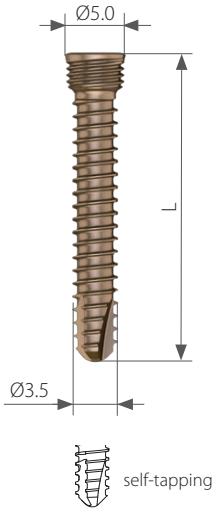
No.	Catalogue no.	Name	Pcs.		
1	40.5671.000	Aiming block	1	40.5758.010	40.5758.510
2	40.5672.000	Protective guide 7.0/5.0	2		
3	40.5758.210	Palette	1		
4	12.0751.100	Container solid bottom 1/2 306x272x85mm	1		
5	12.0751.200	Perforated aluminum lid 1/2 306x272x15mm Gray	1		

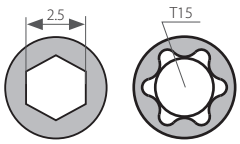
implants not included; with additional instruments

LOCKING ELEMENTS

TITANIUM

5.0ChLP SCREW Ø3.5

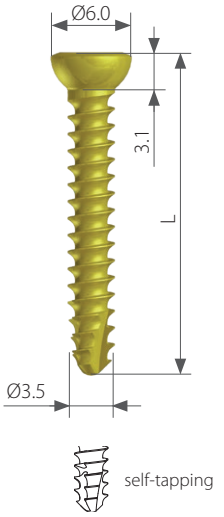


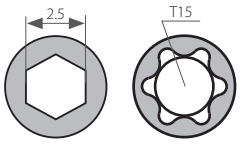


L [mm]	Catalogue no.	
12	3.1289.012	3.5200.012
14	3.1289.014	3.5200.014
16	3.1289.016	3.5200.016
18	3.1289.018	3.5200.018
20	3.1289.020	3.5200.020
22	3.1289.022	3.5200.022
24	3.1289.024	3.5200.024
26	3.1289.026	3.5200.026
28	3.1289.028	3.5200.028
30	3.1289.030	3.5200.030
32	3.1289.032	3.5200.032
34	3.1289.034	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

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

CORTICAL SCREW Ø3.5





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		2.4
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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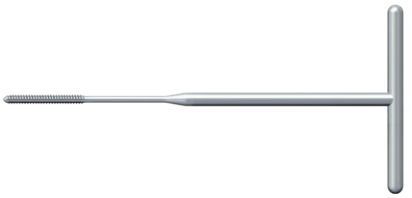
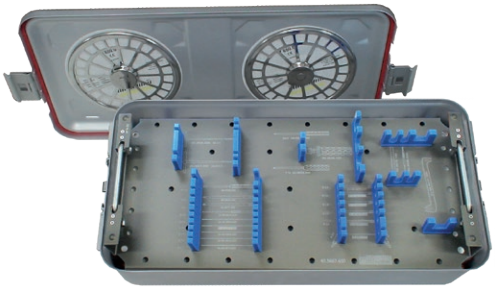
III. INSTRUMENTS

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

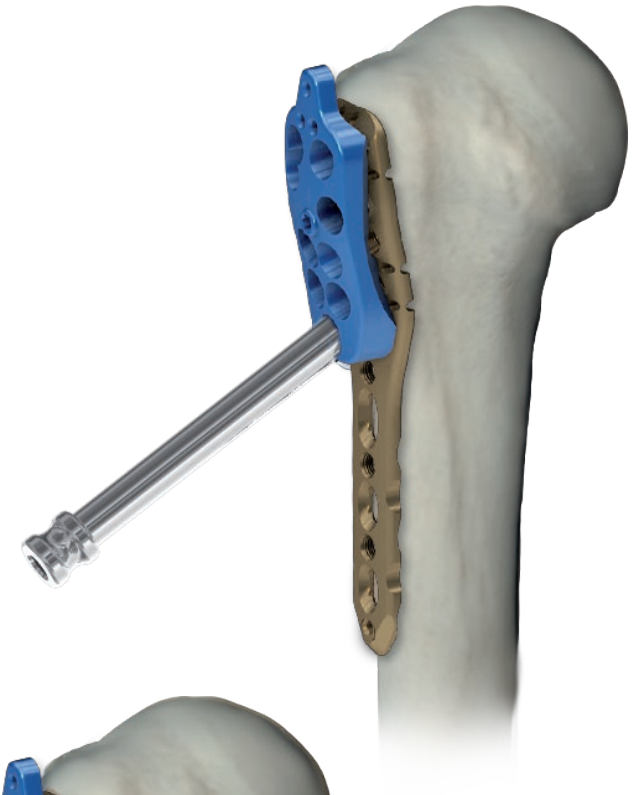
IV. IMPLANTATION GUIDES

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]**.

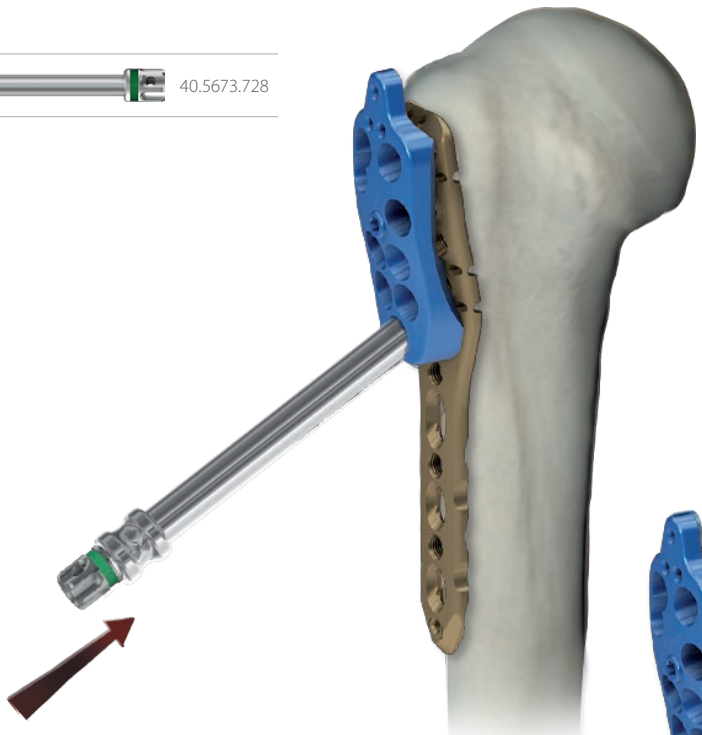

40.5672.000



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.

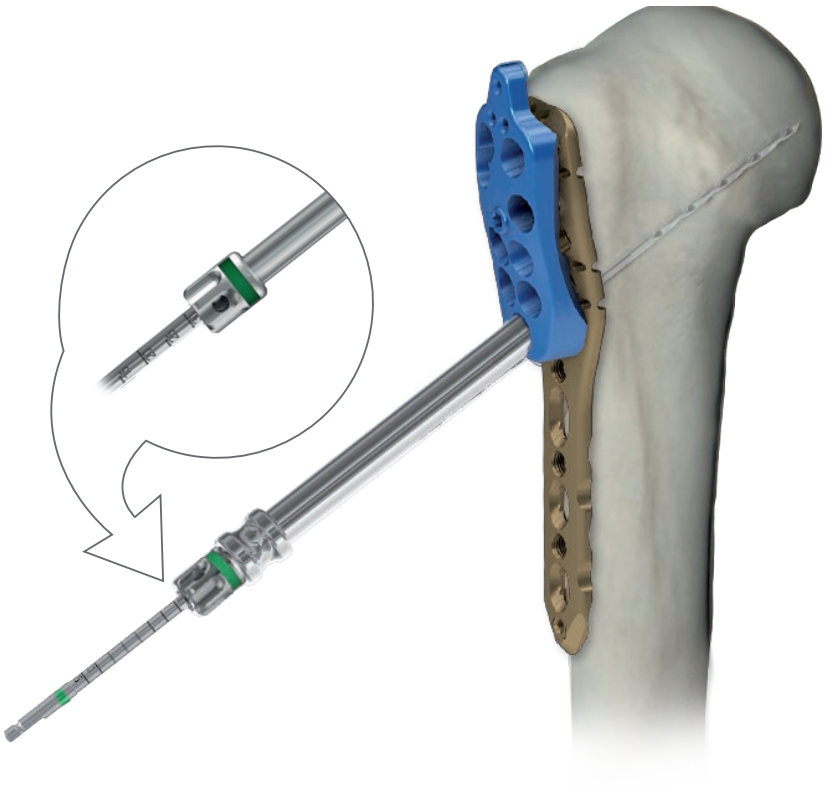
40.5653.222

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]**

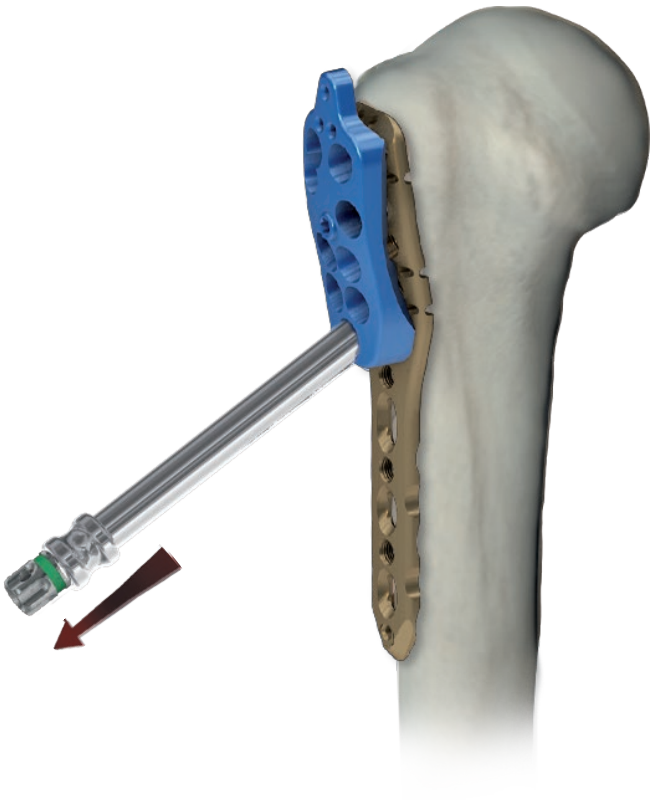
40.5675.100

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

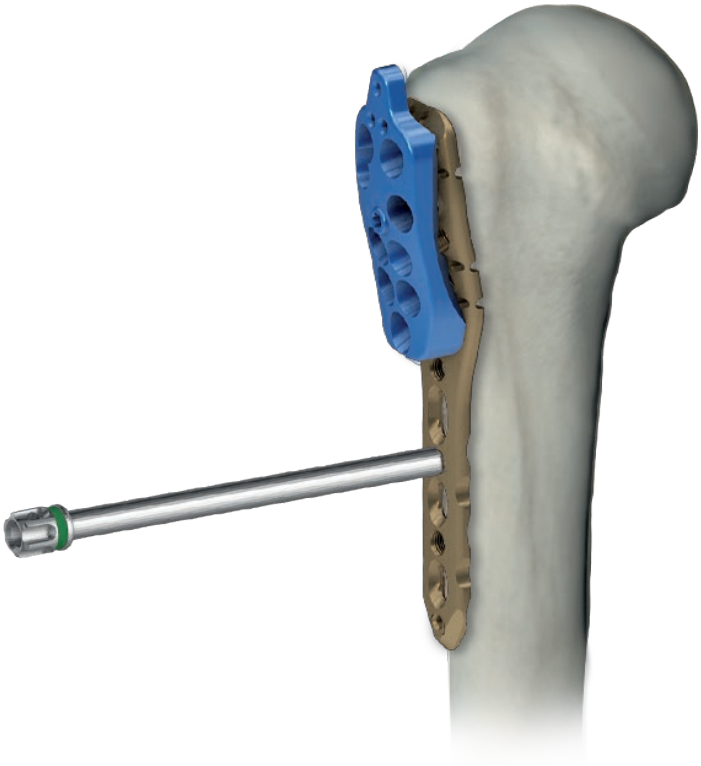
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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.

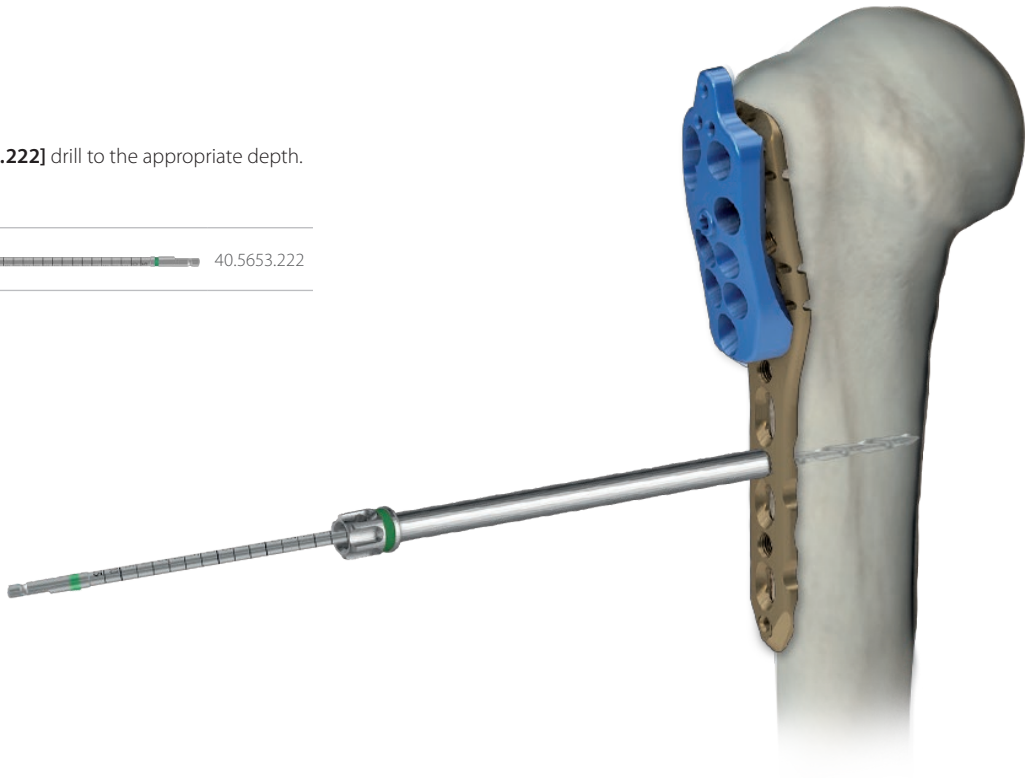

40.5673.728



IV.2.2. DRILLING

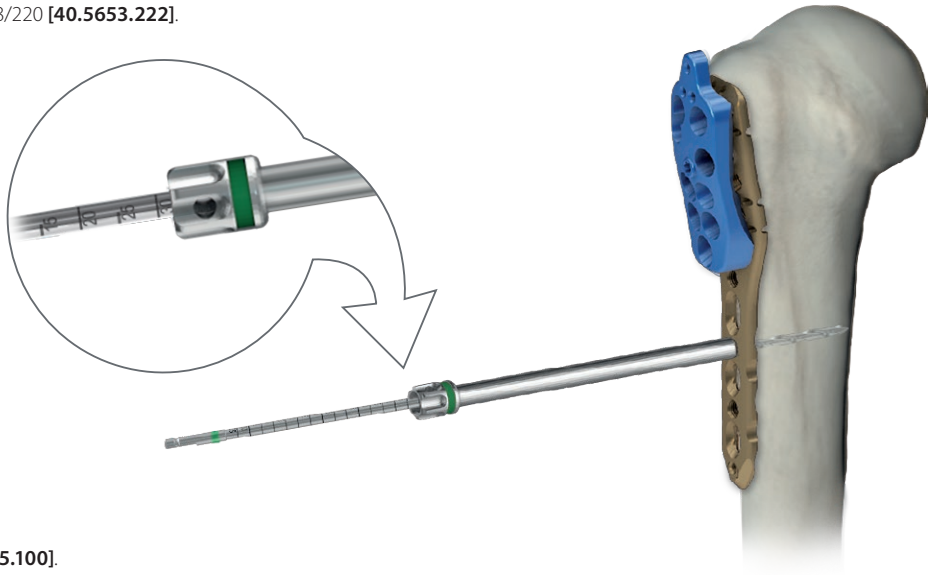
Using the Drill With Scale 2.8/220 **[40.5653.222]** drill to the appropriate depth.

40.5653.222



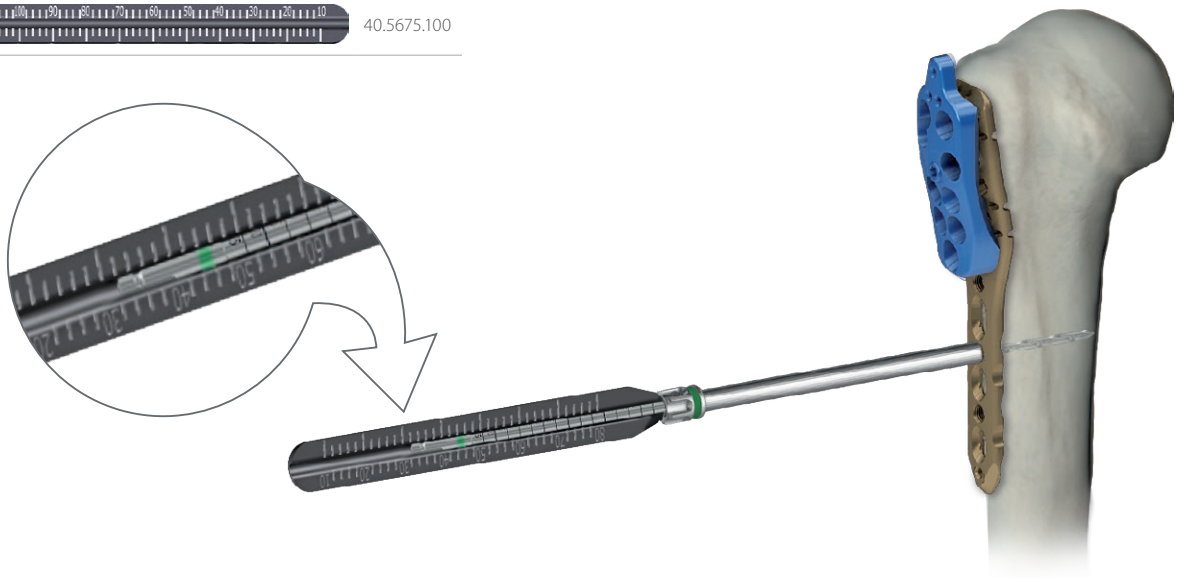
IV.2.3. MEASUREMENT OF HOLE DEPTH

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



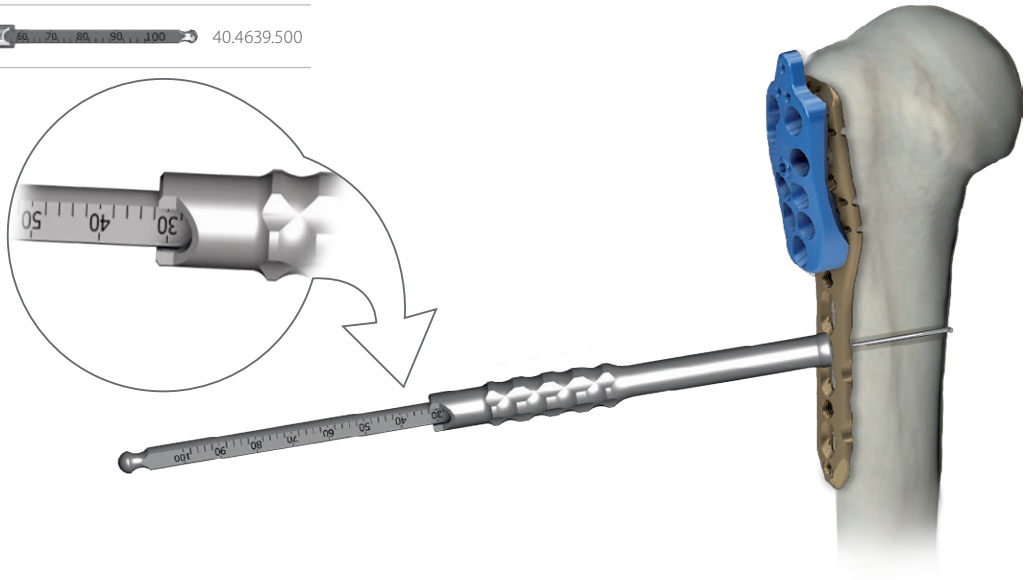
OPTION II: Or use the Screw Length Measure **[40.5675.100]**.


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]**.

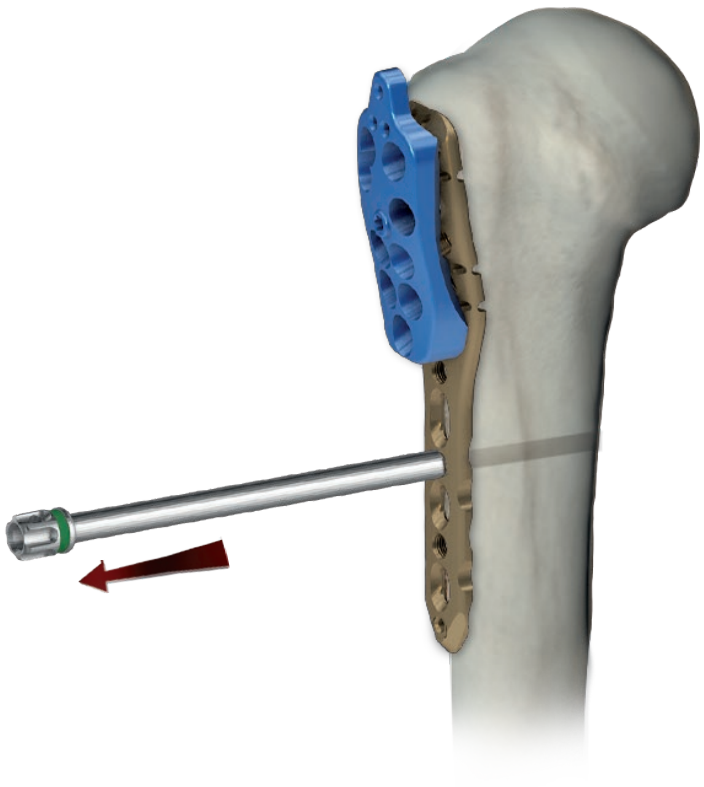

40.4639.500



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

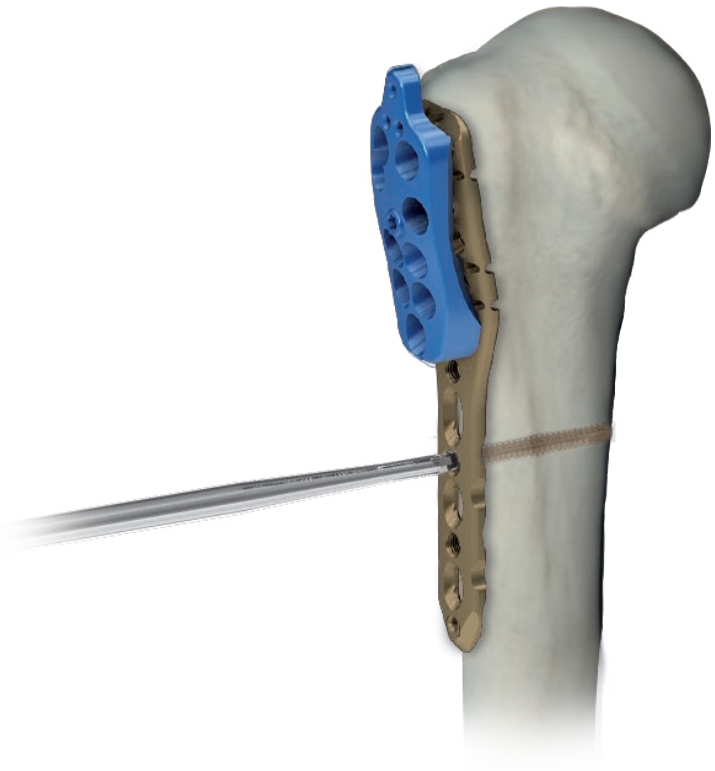
IV.2.4. INSERTION OF THE SCREW

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



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

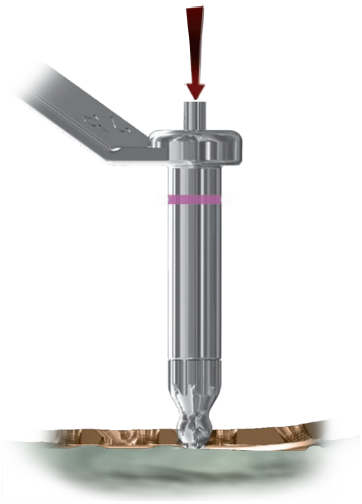
IV.3.1. SETTING OF COMPRESSION GUIDE

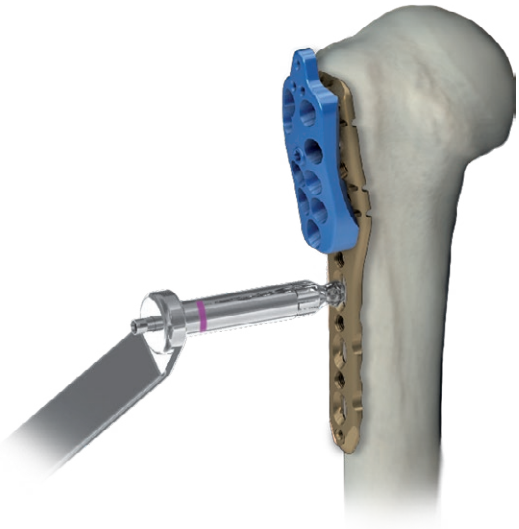
Set the Compression Guide 2.5 **[40.4804.700]** into the appropriate position:

40.4804.700

IV.3.1.1. NEUTRAL POSITION

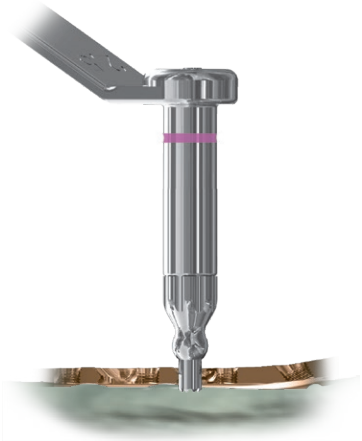
Press the guide to the plate. It will set in the position that allows neutral insertion of the screw.

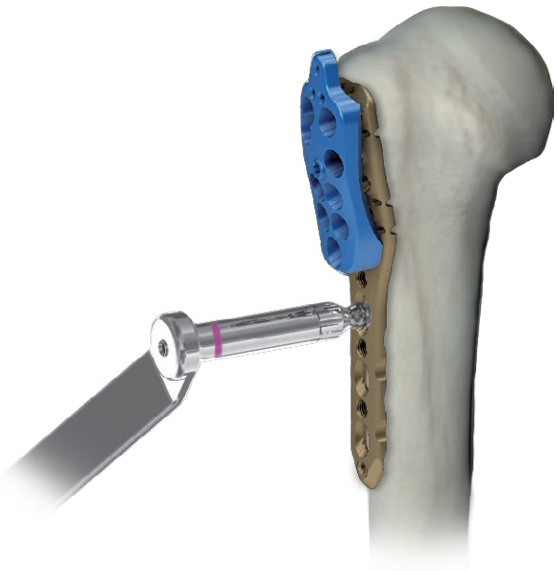




IV.3.1.2. COMPRESSION POSITION

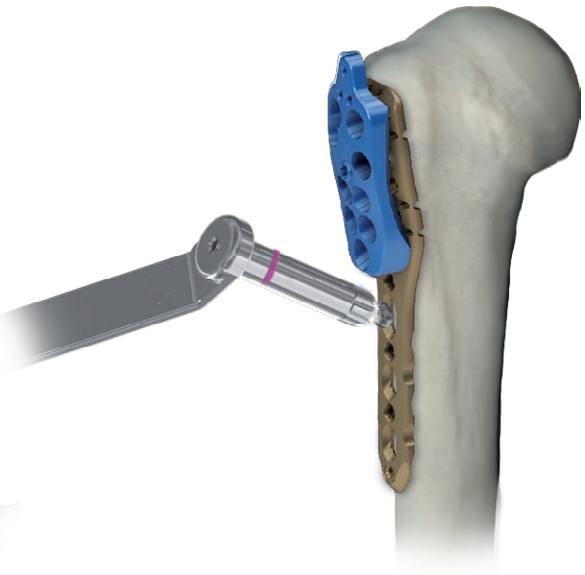
Move the guide without pressure to the edge of compression hole. Hole drilled in this position allows insertion of the screw in compression position.





IV.3.1.3. ANGULAR POSITION

Angular position of the guide is also possible.

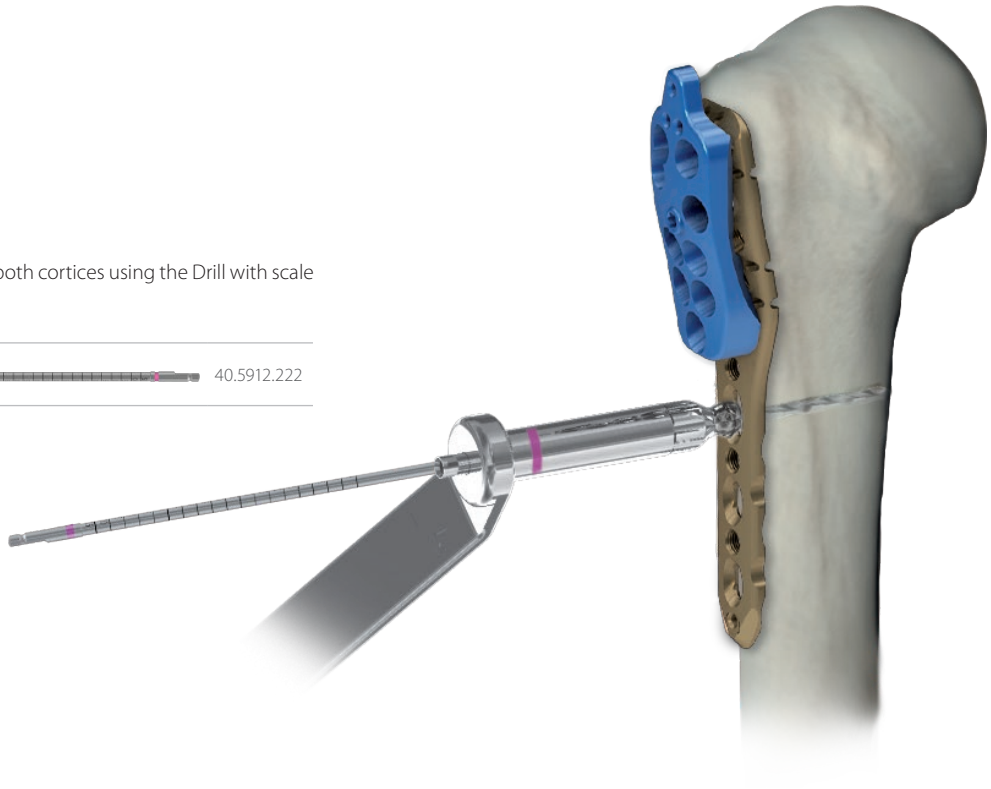


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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]**.

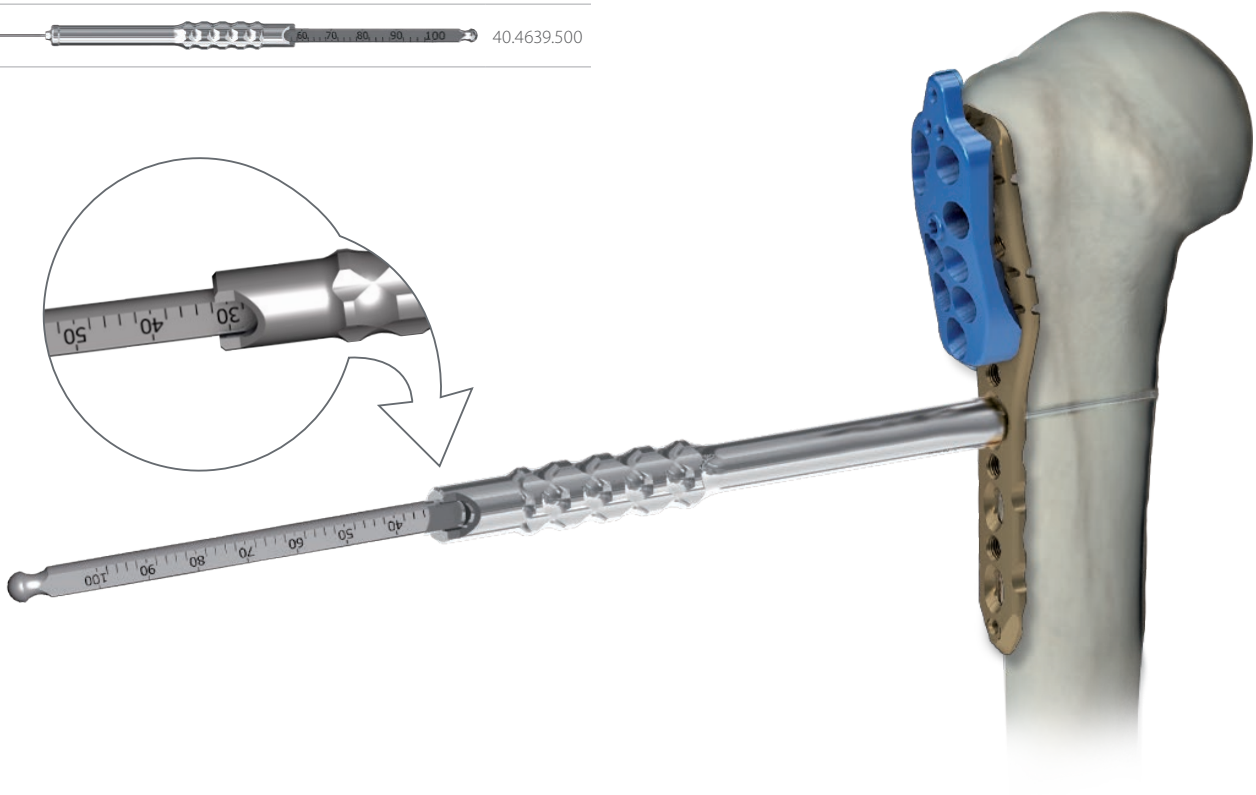
40.5912.222



IV.3.3. SETTING OF COMPRESSION GUIDE

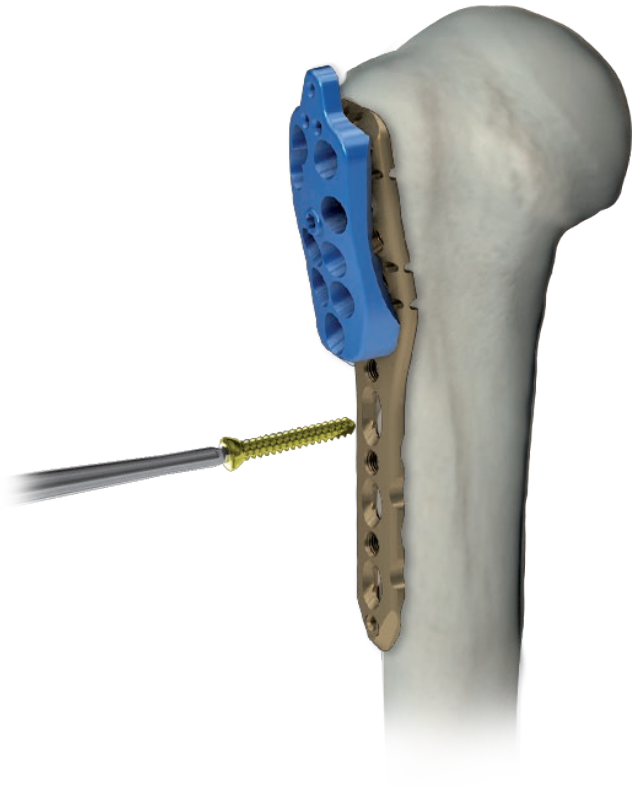
Insert the Depth Measure **[40.4639.500]** into the drilled hole until its hook reaches outer surface of opposite cortex bone.

40.4639.500



IV.3.4. INSERTION OF THE SCREW

Insert the Cortex Screw 3.5.



IV.4. USAGE OF KIRSCHNER WIRE 1.5

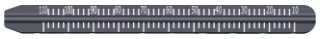
It is possible to use Kirschner wire 1.5/220 **[40.4592.220]** inserted into each locking hole for:

- 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.

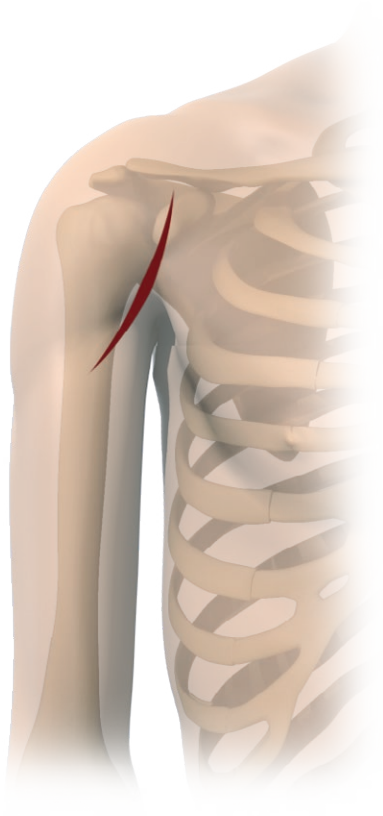
V. SURGERY TECHNIQUE

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.

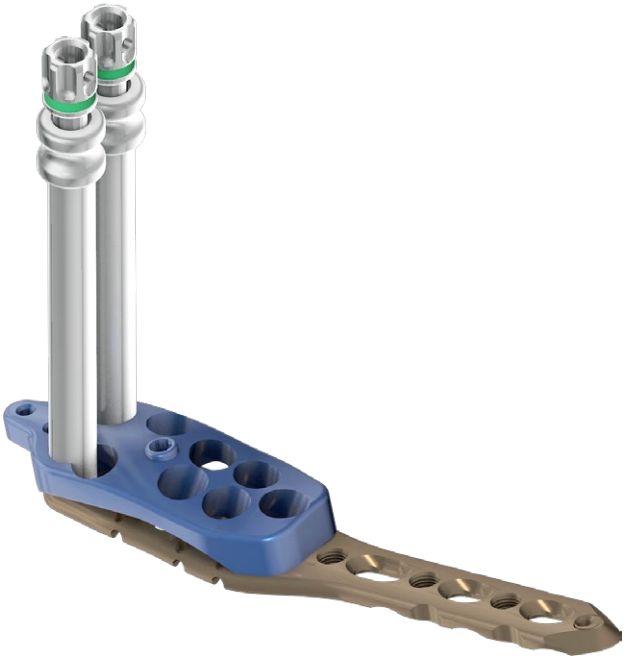
V.4. ATTACHMENT OF AIMING BLOCK

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.

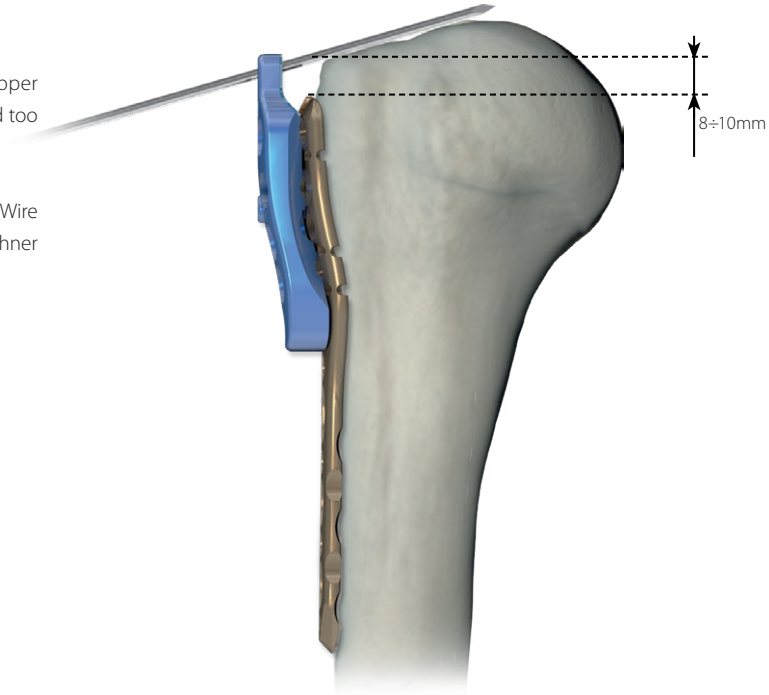
V.5. PLATE APPLICATION

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.



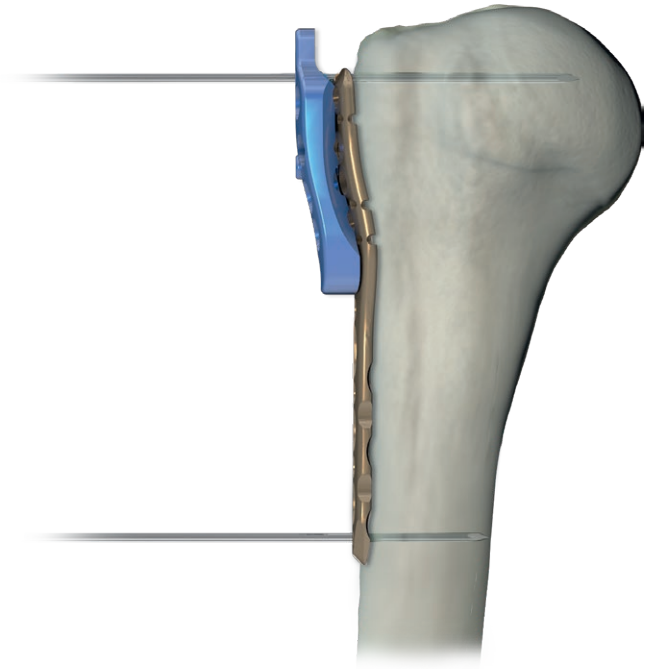
b) lateral position

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

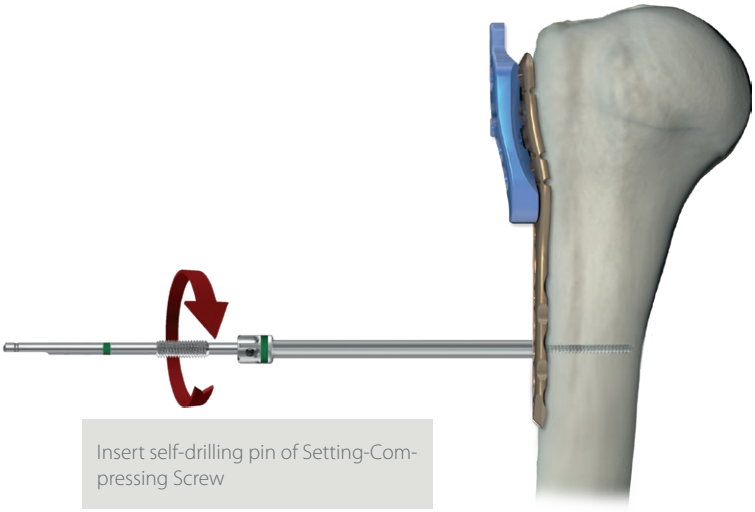
After reduction of the fragments and confirmation of plate position, it is necessary to temporary fix its position using 2.0 Kirschner wires **[40.4815.220]**. They may be placed in holes in proximal part of the plate and in the most distal hole of the plate.



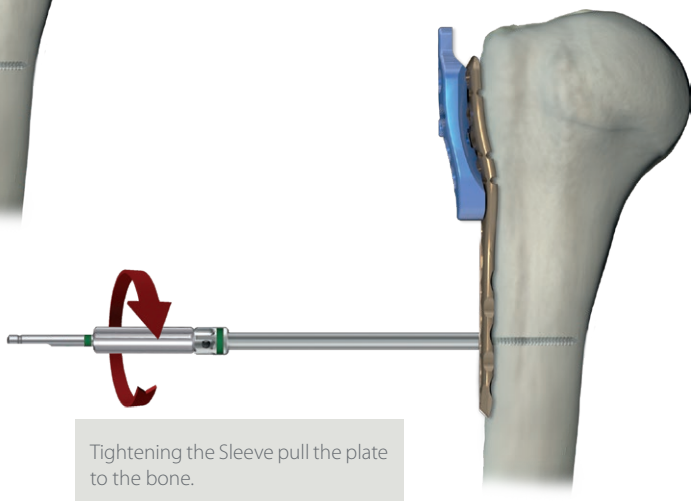
Confirm correct position by taking X-Ray image.

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.



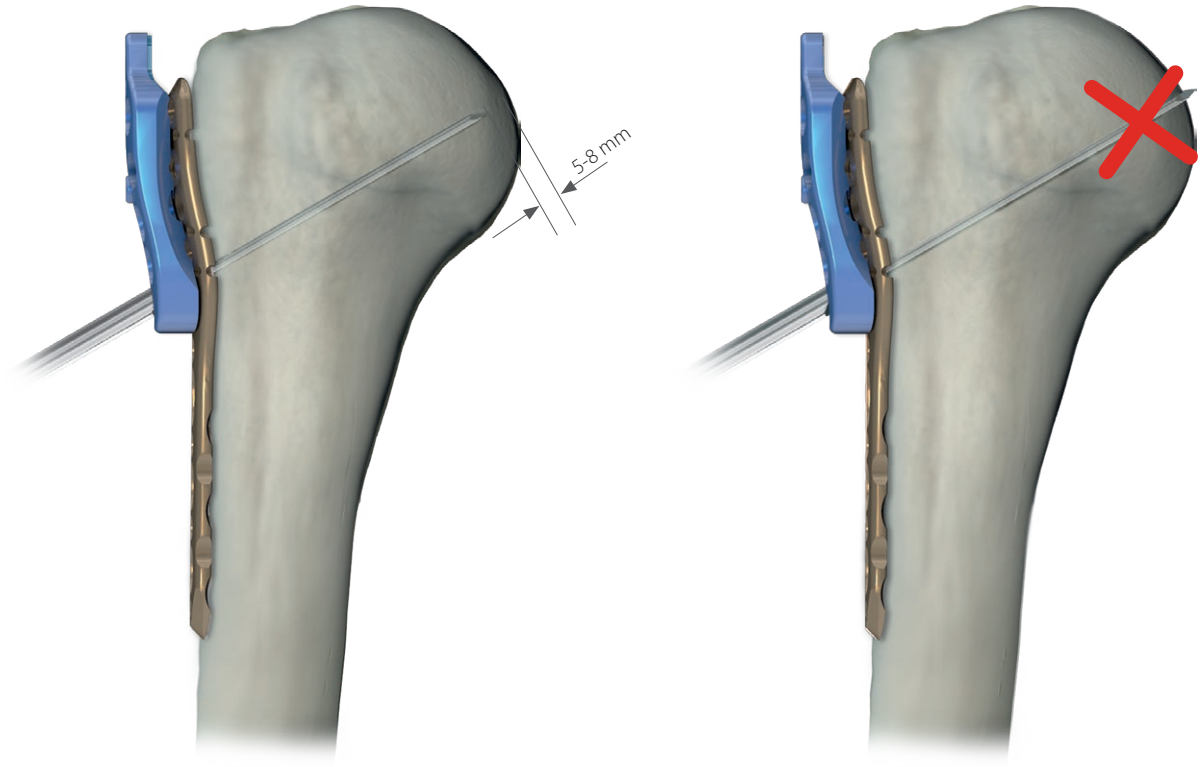
Insert self-drilling pin of Setting-Compressing Screw



Tightening the Sleeve pull the plate to the bone.

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.



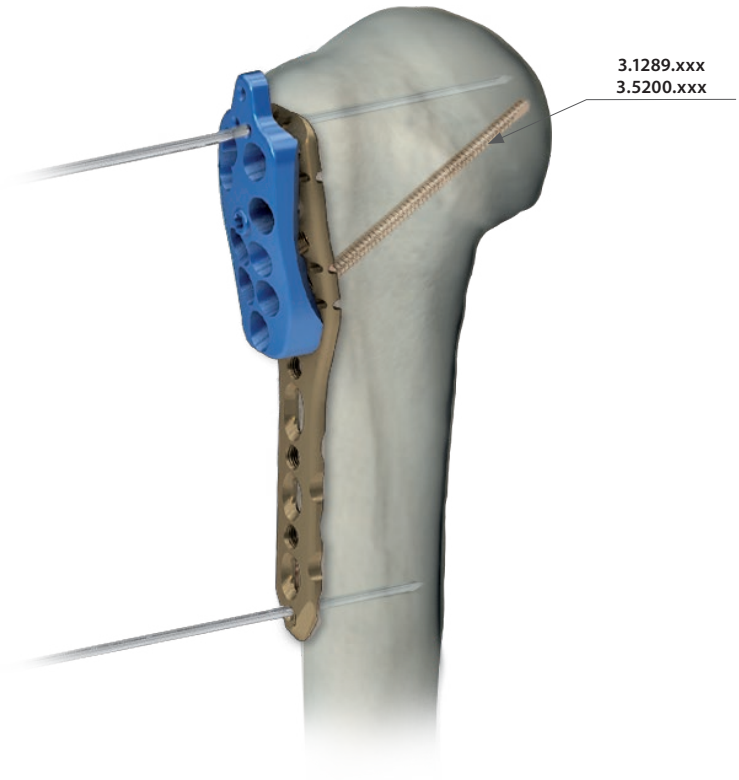
It is necessary to insert at least 4-6 screws or more at the proximal part of the plate, particularly when the bone quality is poor. While inserting locking screws in the shaft part, it is recommended to perform the insertion through both cortices to obtain better fixation.

V.7.1. OPTION A

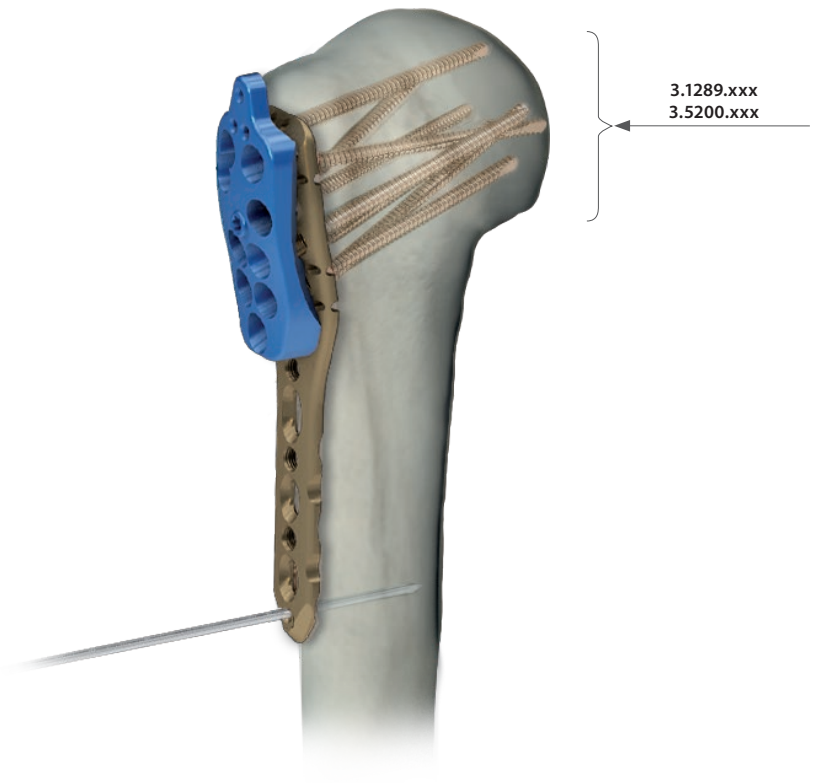
In this technique the bone fragments in proximal part are fixed as first. Then the distal part with or without compression is fixed.

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.



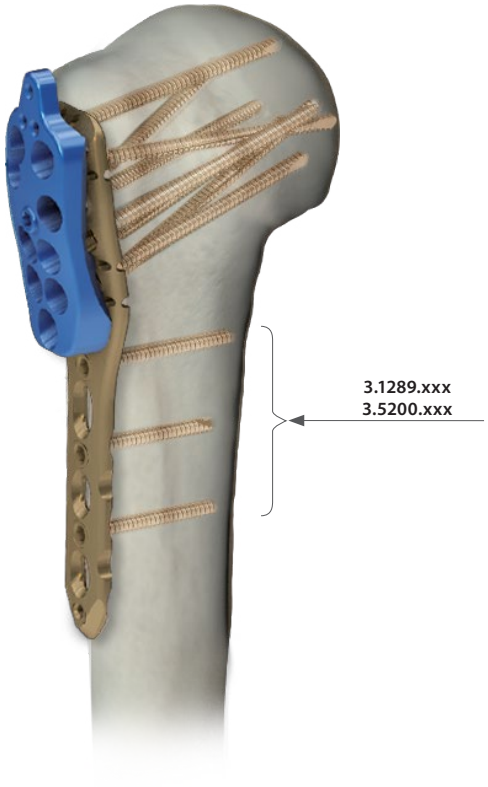
Insert locking screws in the appropiate holes in proximal part of the plate.



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.

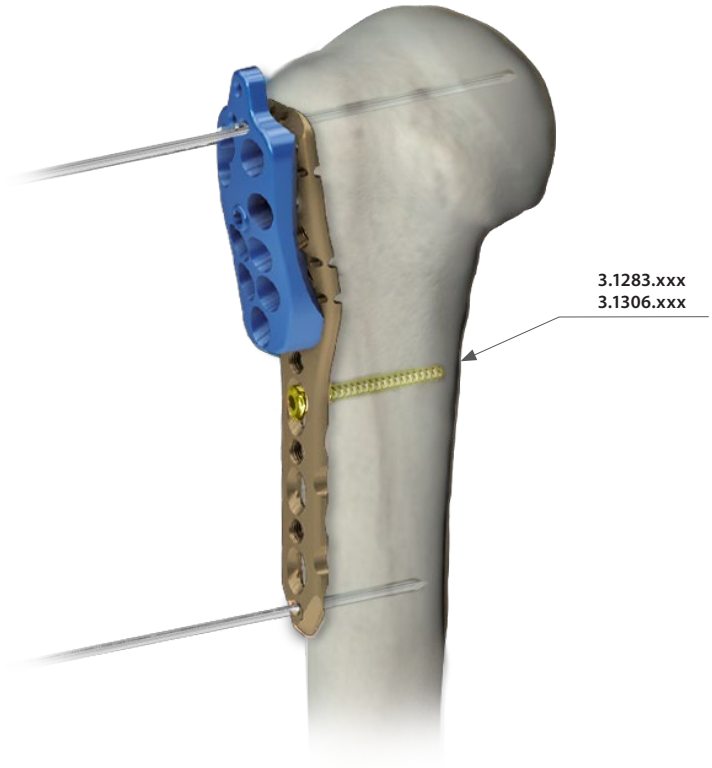
V.7.1.3. REMOVAL OF AIMING BLOCK [40.5671.000]

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.

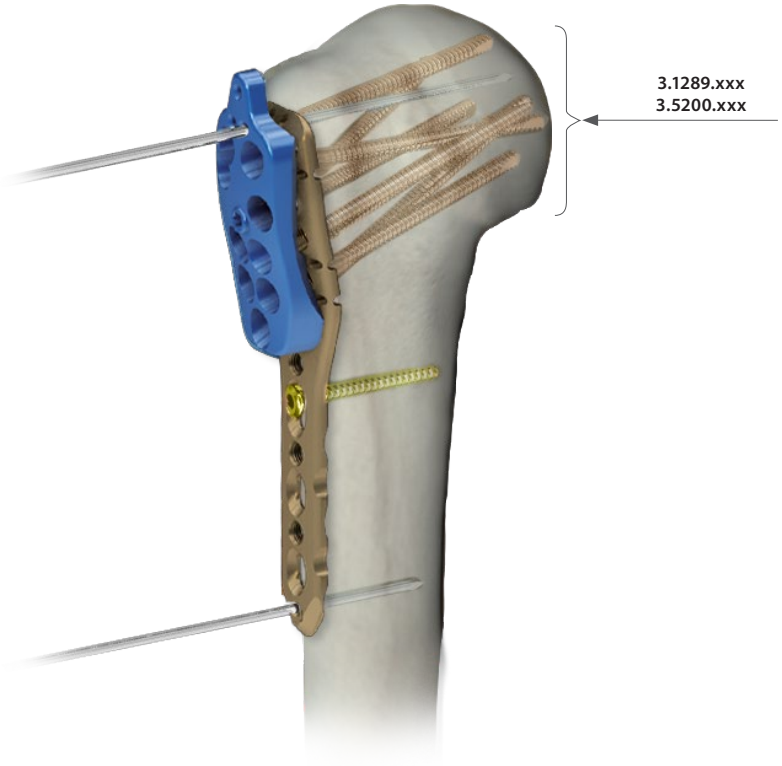
V.7.2.1. INSERTION OF CORTICAL SCREW 3.5

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]

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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