instruction

PROXIMAL HUMERAL PLATE

IMPLANTS ◦
INSTRUMENT SET ◦
SURGICAL TECHNIQUE ◦

30B

CE 0344
ISO 9001:2000
ISO 13485:2003

ChM®

Important Information

Proximal locking humeral plate **meets international quality standards.** Implants and surgical instruments are manufactured and delivered to the user in accordance with requirements of

- **ISO 9001/ISO 13485;**
- **Quality System;**
- **Council Directive 93/42/EEC.**

The instruments must be washed and sterilized before the every use.

After use the instruments should be washed immediately in order to remove any organic matter (blood, tissues). Washing may be carried out in warm water using polymeric brush and appropriate solutions (containing anti-corrosion agent) approved for use in medicine. Machined washing is recommended (in ultrasonic camber).

After washing and drying the instruments shall be placed in the case and closed with its lid. Instrument set should be stored in dry condition in temperature ranging from 5 to 30 °C and humidity not exceeding 70%.

The instrument set shall sterilized (in moist heat or dry heat up to 200 °C) in accordance with duly medical procedures. Sterilization in autoclave is recommended.

The instruments constituting the instrument set (made of stainless steel, aluminum alloys and polymers) are subjected to mechanical damages and corrosion process.

It is recommended to follow:

- **rules of use presented in the manual of the instrument set,**
- **appropriate medical rules concerning washing,**
- **sterilization and storage of medicall instruments.**

NON-STERILE
STERILIZE BEFORE USE

Edition 28A dated 11.08.2008, reviewed 12.08.2008

I. INTRODUCTION

Locking humeral plate 3.4034 is provided for humeral bone proximal section treatment. 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. ISO 9001:2000, EN ISO 13485:2003 Quality Management Systems and fulfill requirements of 93/42/EEC Directive, are high quality implants work guarantee.

Set for proximal section of humeral bone consists of:
- implants (humeral plate, locking screws and standard cortical screws),
- instrument set, consist of instruments used to perform the surgical procedure,
- instruction for use.

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

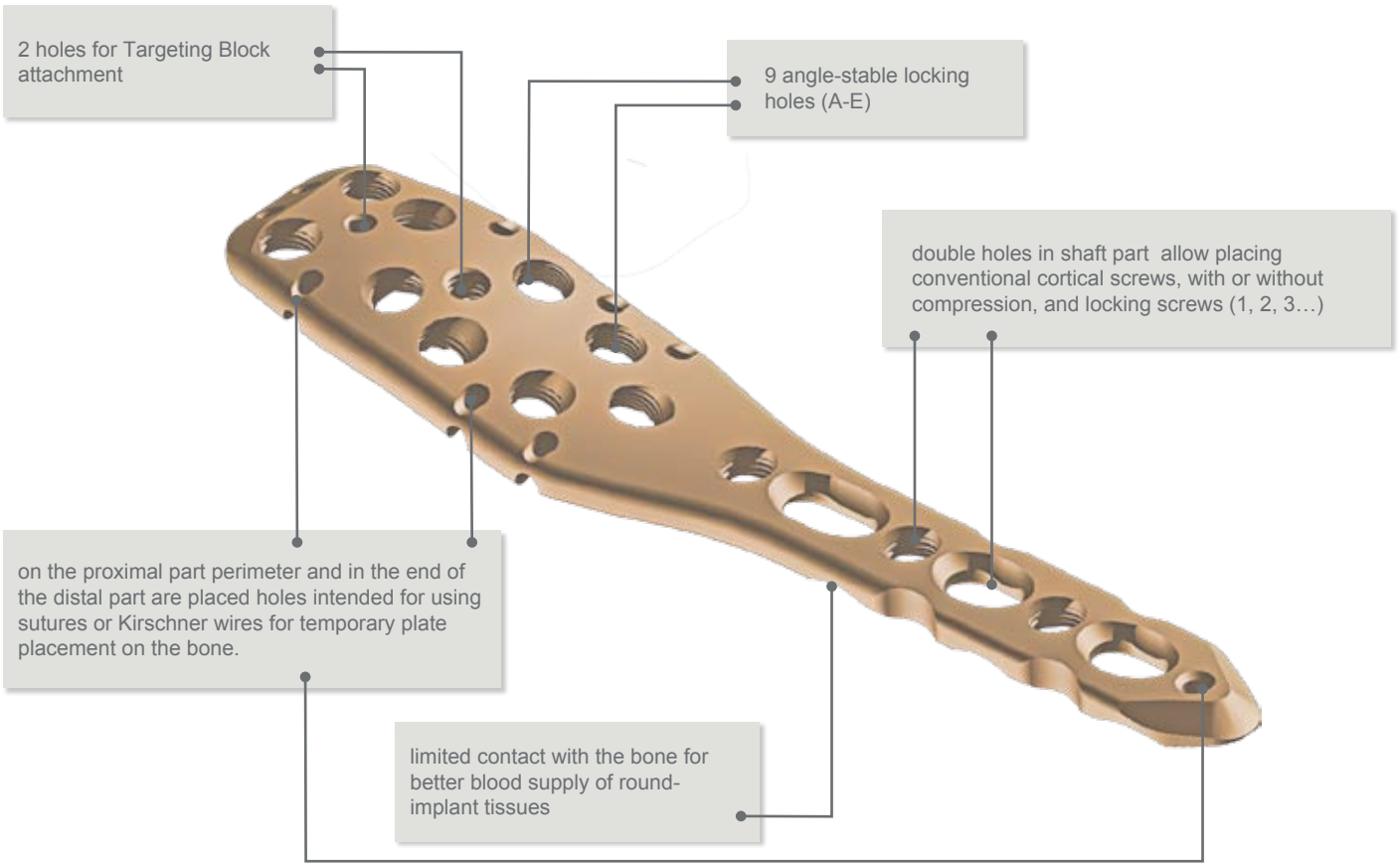
Plate is intended for treatment of:
- fractures in proximal part of humeral bone and fractures extended to femoral bone shaft,
- fractures witch dislocation,
- osteopenic bone fractures,
- osteotomy,
- malunion of the bone, non-union of bone fragments.

Contraindications
- infections,
- children in growth phase.

II. IMPLANTS

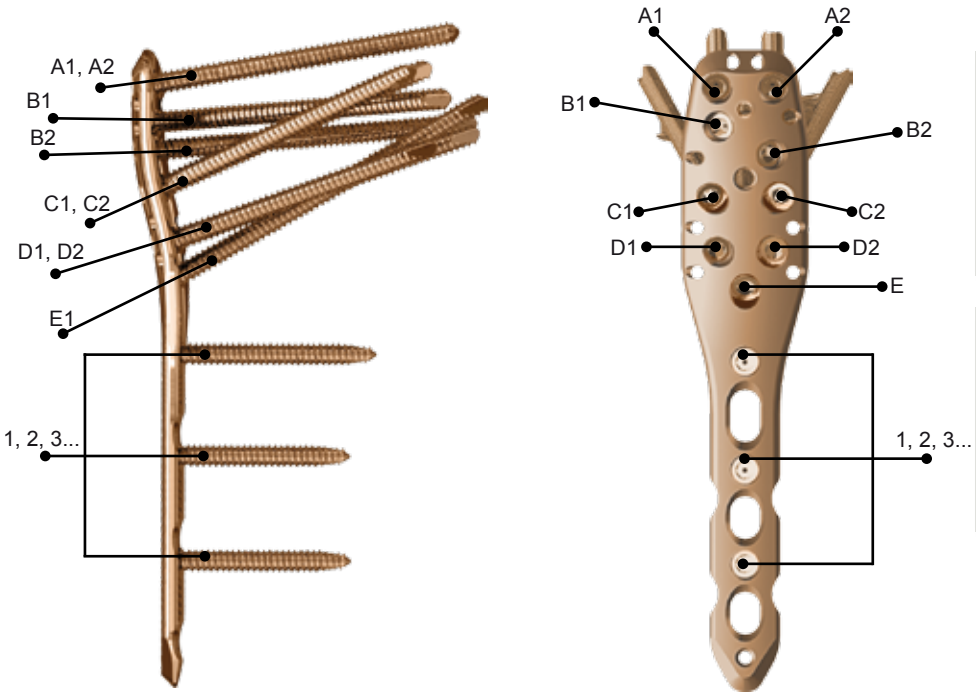
3.4034 plate is an element of 5,0ChLP system. System consist of plates and corresponding screws. For more confortable usage locking screws mating with plates are in the same brown color.

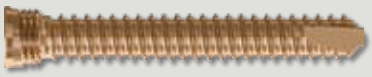
The plate shape is adapted to anatomical structure of humeral bone:



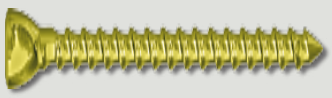
Locking holes in proximal part:

Various screws placement allows to supply different kind of fractures by creating a lot of unique constructions.





basic locking screw Ø3,5, self-tapping [3.1289.016-095]



standard cortical screw Ø3,5, self-tapping [3.1283.014-110]

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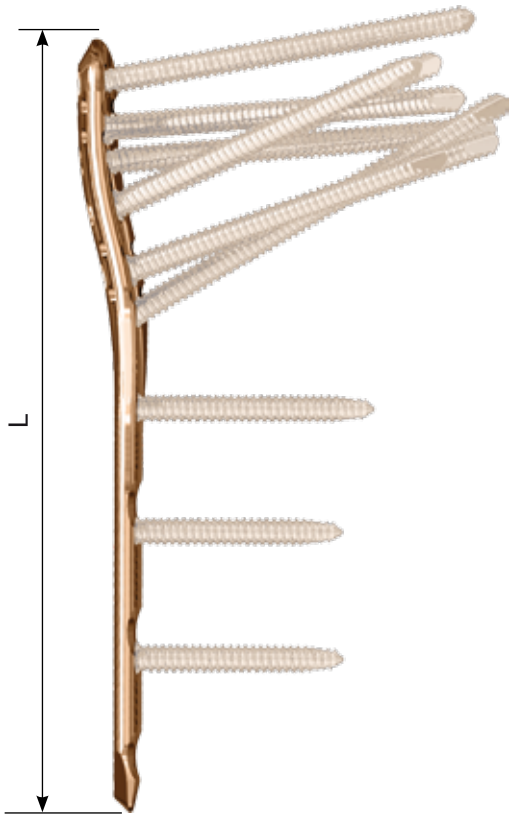
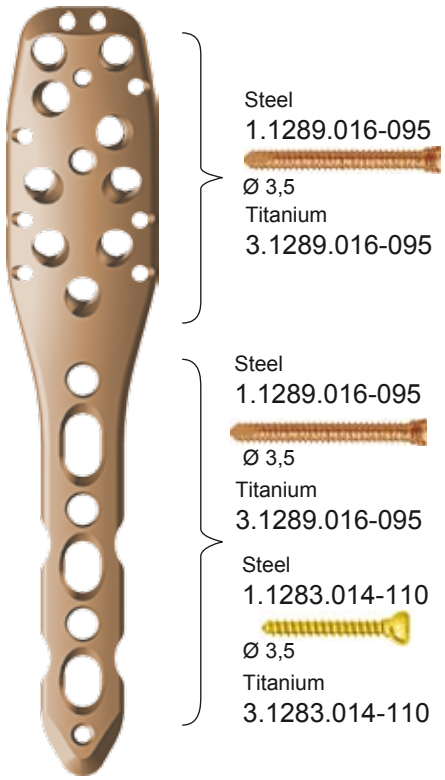
5,0 ChLP Humeral plate





5.0 ChLP Screw Ø 3.5

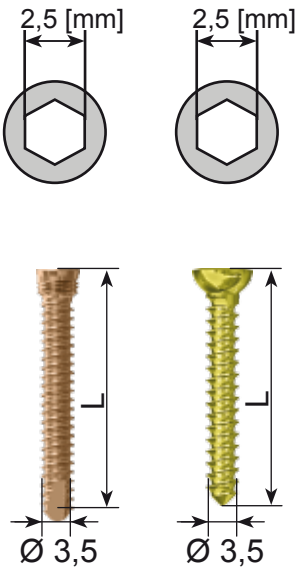
self - tapping

O	L [mm]	Catalogue No.	
		Steel	Titanium
3	92	1.4034.003	3.4034.003
4	105	1.4034.004	3.4034.004
5	118	1.4034.005	3.4034.005
6	131	1.4034.006	3.4034.006

Cortical Ø 3,5

self - tapping

L [mm]	Catalogue No.	
	Steel	Titanium
16	1.1289.016	3.1289.016
18	1.1289.018	3.1289.018
20	1.1289.020	3.1289.020
22	1.1289.022	3.1289.022
24	1.1289.024	3.1289.024
26	1.1289.026	3.1289.026
28	1.1289.028	3.1289.028
30	1.1289.030	3.1289.030
32	1.1289.032	3.1289.032
34	1.1289.034	3.1289.034
36	1.1289.036	3.1289.036
38	1.1289.038	3.1289.038
40	1.1289.040	3.1289.040
42	1.1289.042	3.1289.042
44	1.1289.044	3.1289.044
46	1.1289.046	3.1289.046
48	1.1289.048	3.1289.048
50	1.1289.050	3.1289.050
52	1.1289.052	3.1289.052
54	1.1289.054	3.1289.054
56	1.1289.056	3.1289.056
58	1.1289.058	3.1289.058
60	1.1289.060	3.1289.060
65	1.1289.065	3.1289.065
70	1.1289.070	3.1289.070
75	1.1289.075	3.1289.075
80	1.1289.080	3.1289.080
85	1.1289.085	3.1289.085
90	1.1289.090	3.1289.090
95	1.1289.095	3.1289.095



L [mm]	Catalogue no.	
	Steel	Titanium
14	1.1283.014	3.1283.014
16	1.1283.016	3.1283.016
18	1.1283.018	3.1283.018
20	1.1283.020	3.1283.020
22	1.1283.022	3.1283.022
24	1.1283.024	3.1283.024
26	1.1283.026	3.1283.026
28	1.1283.028	3.1283.028
30	1.1283.030	3.1283.030
32	1.1283.032	3.1283.032
34	1.1283.034	3.1283.034
36	1.1283.036	3.1283.036
38	1.1283.038	3.1283.038
40	1.1283.040	3.1283.040
45	1.1283.045	3.1283.045
50	1.1283.050	3.1283.050
55	1.1283.055	3.1283.055
60	1.1283.060	3.1283.060
65	1.1283.065	3.1283.065
70	1.1283.070	3.1283.070
75	1.1283.075	3.1283.075
80	1.1283.080	3.1283.080
85	1.1283.085	3.1283.085
90	1.1283.090	3.1283.090
95	1.1283.095	3.1283.095
100	1.1283.100	3.1283.100
105	1.1283.105	3.1283.105
110	1.1283.110	3.1283.110

III. INSTRUMENTS

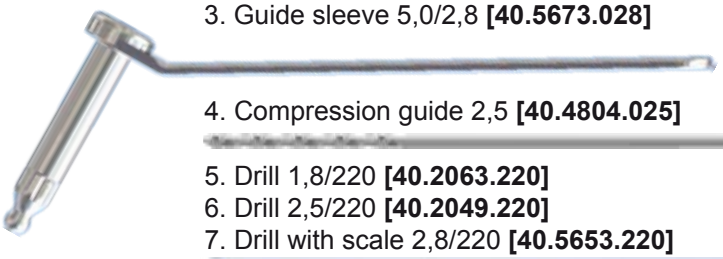
40.5666.010 **Set for 5.0 ChLP plate - 3.4034 (instruments and implants)**

No.	Catalogue No.	Name	Pcs
1	40.5667.000	Instruments for 5.0 ChLP plate	1
2	40.5669.010	Palette for 5.0 ChLP plates - 3.4034	1

40.5667.000 **Instruments for 5,0 ChLP plate**

No.	Catalogue No.	Name	Pcs
1	40.5673.010	Guide sleeve 5,0/1,0	2
2	40.5673.018	Guide sleeve 5,0/1,8	4
3	40.5673.028	Guide sleeve 5,0/2,8	4
4	40.4804.025	Compression guide 2.5	1
5	40.2063.220	Drill 1.8/220	2
6	40.2049.220	Drill 2.5/220	2
7	40.5653.220	Drill with scale 2.8/220	2
8	40.4814.220	Kirschner wire 1.0/220	4
9	40.4815.220	Kirschner wire 2.0/220	4
10	40.5674.028	Setting-compressing screw 2.8/180	2
11	40.5675.100	Screw length measure	1
12	40.4639.000	Depth measure	1
13	40.5676.000	Screwdriver tip S2.5	1
14	40.5677.000	Screwdriver tip T15	1
15	40.5635.100	Handle 2.0Nm	1
16	40.4250.000	Bender for plates 4/6	2
17	40.5668.000	Stand for instruments for 5,0 ChLP plate	1
18	40.4655.000	Stand for screws Ø 3.5	1
19	40.4694.050	Stand for ChLP 5.0 screws	1

1. Guide sleeve 5,0/1,0 **[40.5673.010]**
2. Guide sleeve 5,0/1,8 **[40.5673.018]**
3. Guide sleeve 5,0/2,8 **[40.5673.028]**



4. Compression guide 2,5 **[40.4804.025]**

5. Drill 1,8/220 **[40.2063.220]**
6. Drill 2,5/220 **[40.2049.220]**
7. Drill with scale 2,8/220 **[40.5653.220]**

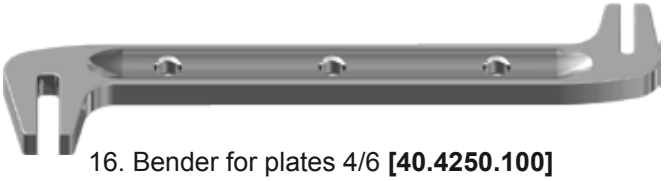
8. Kirschner wire 1,0/220 **[40.4814.220]**
9. Kirschner wire 2,0/220 **[40.4815.220]**

10. Setting-compressing screw 2,8/180 **[40.5674.028]**

11. Screw length measure **[40.5675.100]**

12. Depth measure **[40.4639.000]**

13. Screwdriver tip S2,5 **[40.5676]**
14. Screwdriver tip T15 **[40.5677]**
15. Handle 2,0Nm **[40.5635.100]**



16. Bender for plates 4/6 **[40.4250.100]**

17. Stand for instruments for 5,0 ChLP plate **[40.5668.000]**

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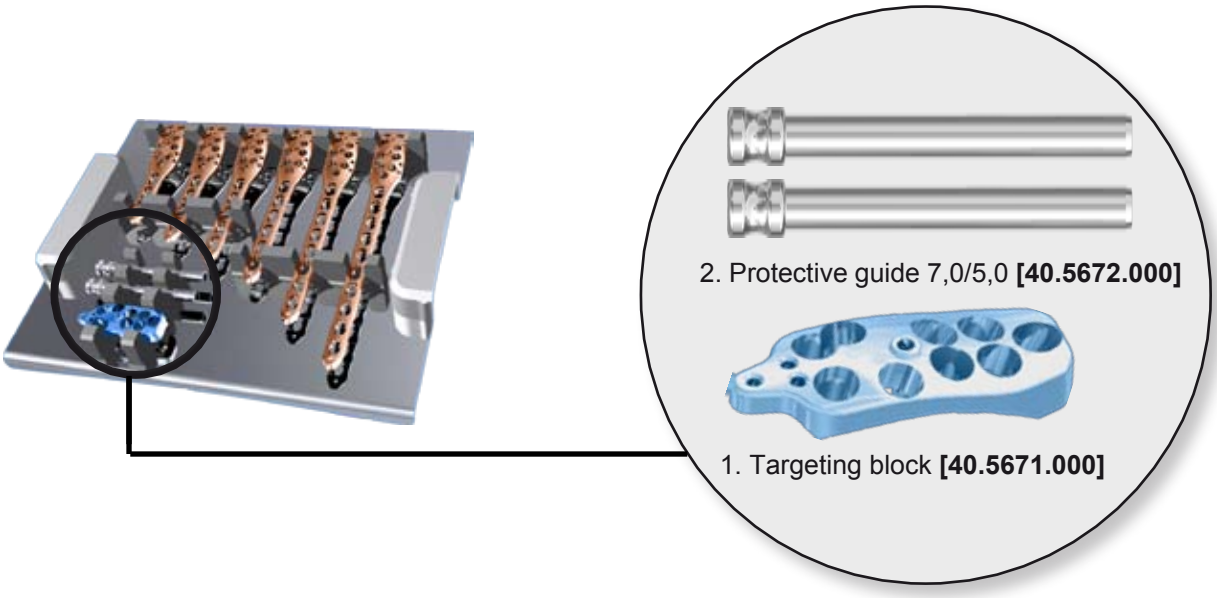
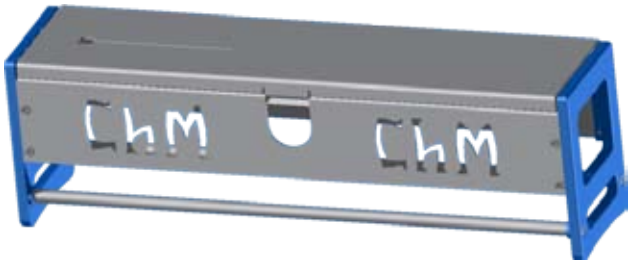
40.5669.010

Palette for 5,0ChLP plates - 3.4034
(with additional instruments)
Compatible with: 40.5667.000 - Instruments for 5,0ChLP plate

Lp.	Catalogue No.	Name	Pcs
1	40.5671.000	Targeting block	1
2	40.5672.000	Protective guide 7,0/5,0	2
3	40.5669.210	Palette	1





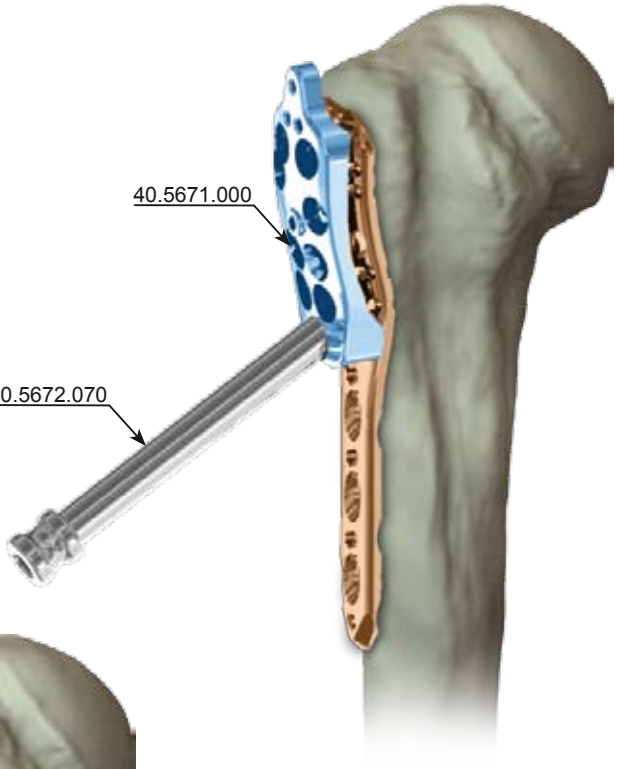
18. **[40.4655.000]** Stand for screws Ø 3.5
19. **[40.4694.050]** Stand for ChLP 5.0 screws

IV. PRIMARY INDICATIONS

IV.1. Locking screw Ø3,5 insertion in proximal part

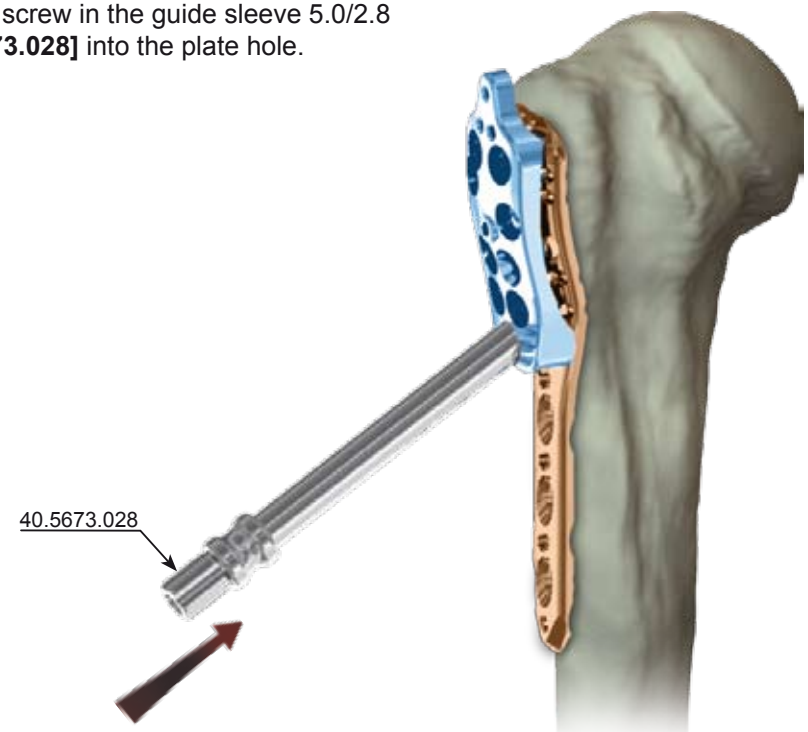
IV.1.1 Insertion of protective guide

In advisable hole of targeting block **[40.5671.000]** insert the protective guide 7,0/5,0 **[40.5672.070]**.



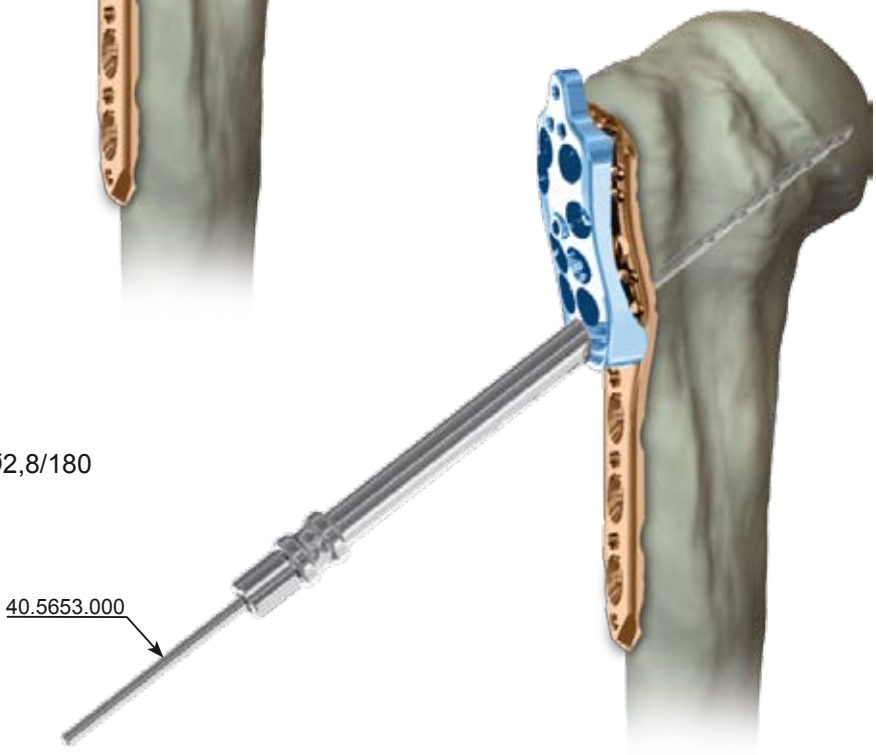
IV.1.2 Screwing in the guide sleeve

Next through the protective guide 7.0/5.0 screw in the guide sleeve 5.0/2.8 **[40.5673.028]** into the plate hole.



IV.1.3 Hole drilling

Drill the hole, under the X-ray control, with Ø2,8/180 drill with scale **[40.5653.000]**.



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

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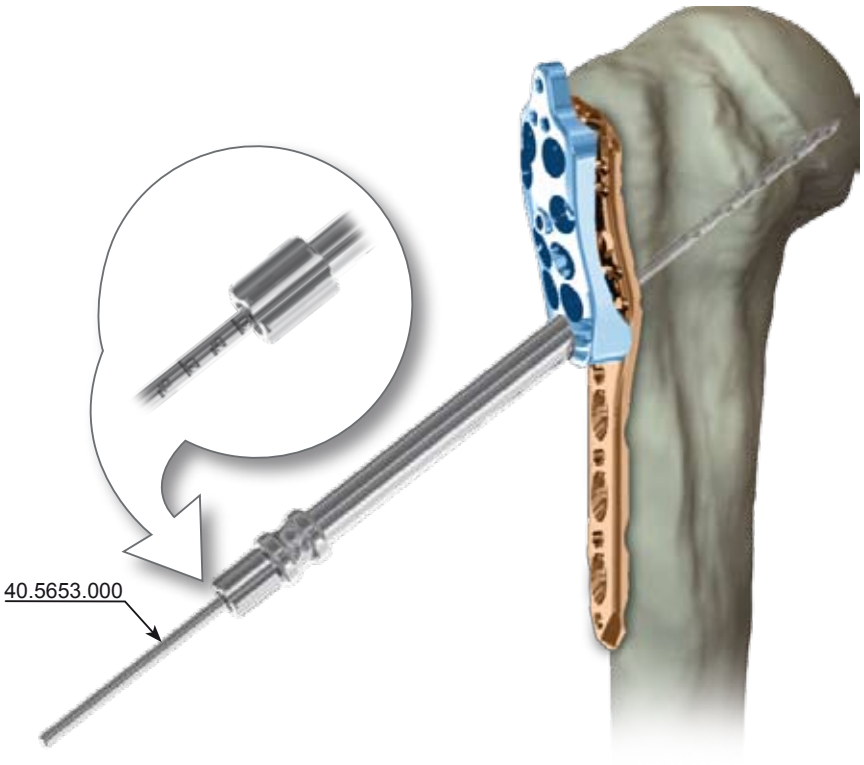
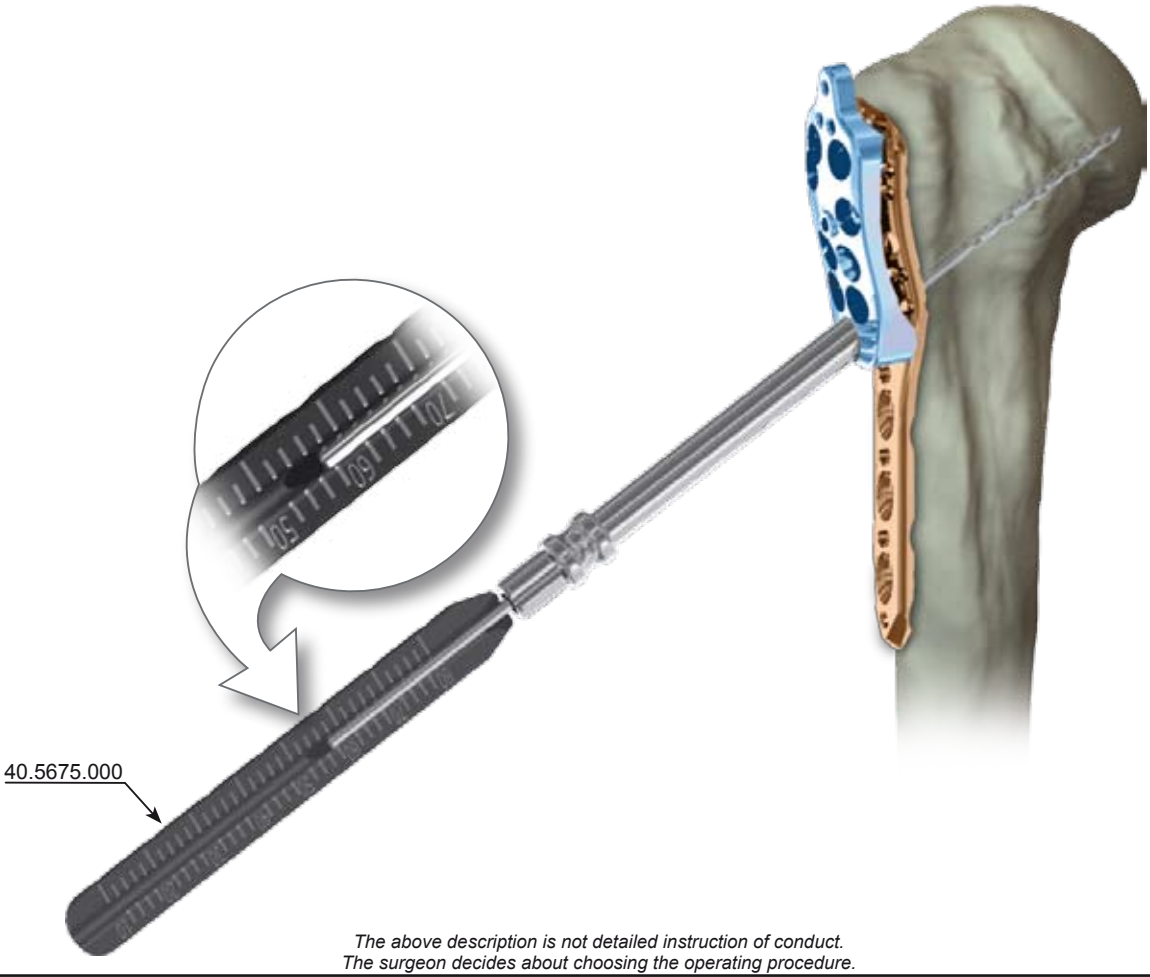
IV.1.4 Hole depth measurement

OPTION I:
from scale on the drill **[40.5653.000]**



OPTION II:
using screw length measure **[40.5675.000]**.



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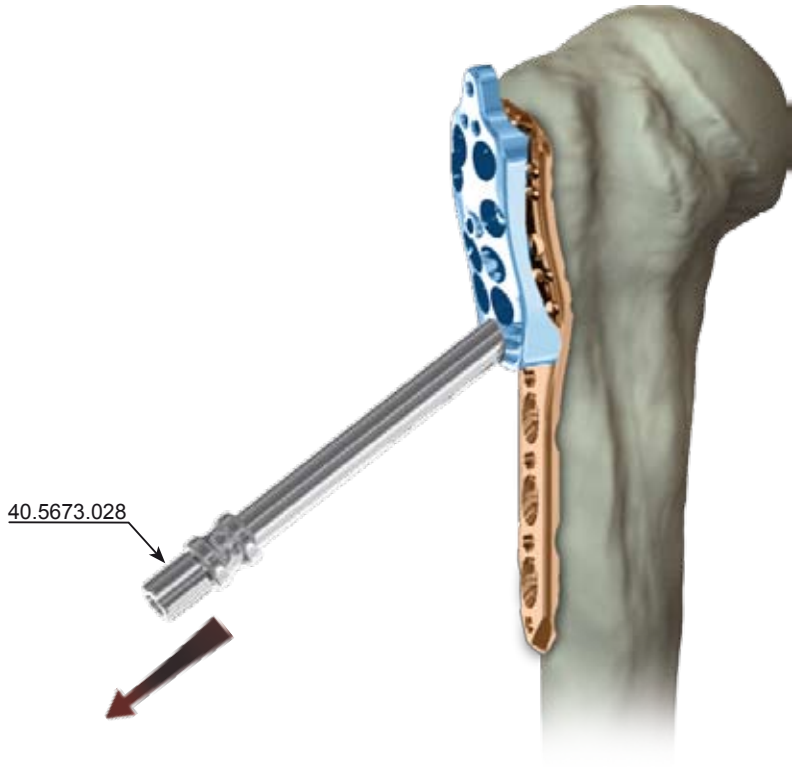
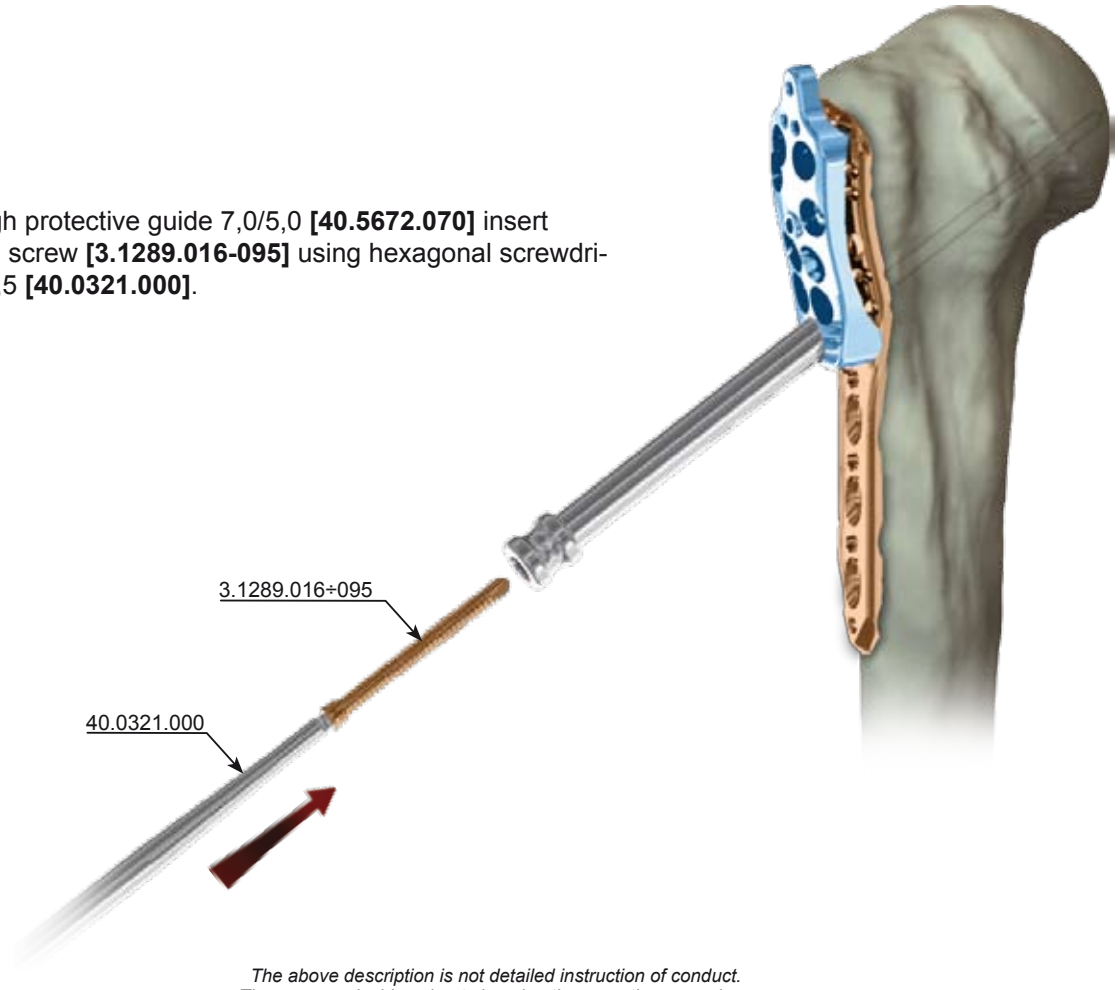
IV.1.5 Wprowadzenie wkręta



Remove guide sleeve 5.0/2.8 **[40.5673.028]**.

Through protective guide 7,0/5,0 **[40.5672.070]** insert locking screw **[3.1289.016-095]** using hexagonal screwdriver S2,5 **[40.0321.000]**.



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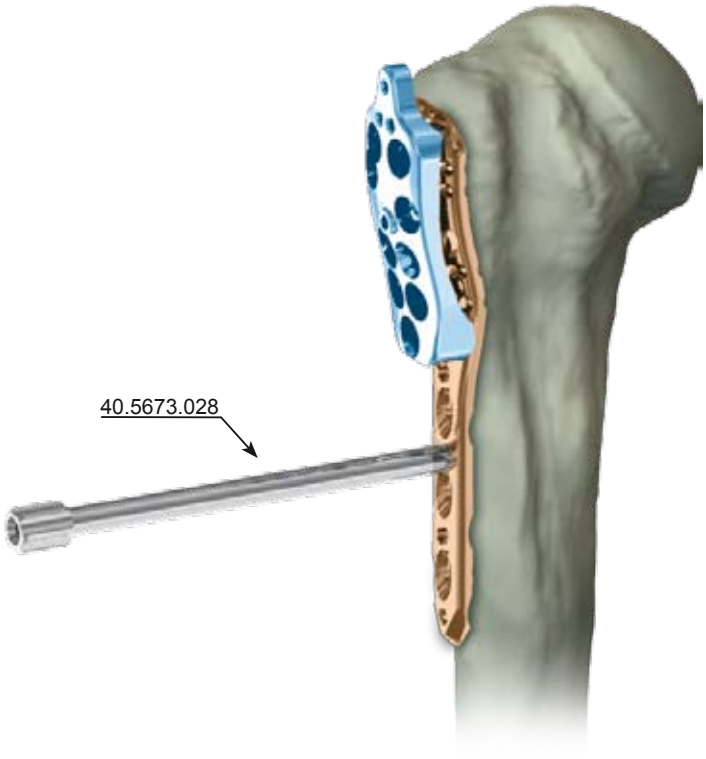
IV.2 Locking screw Ø3.5 insertion in shaft part

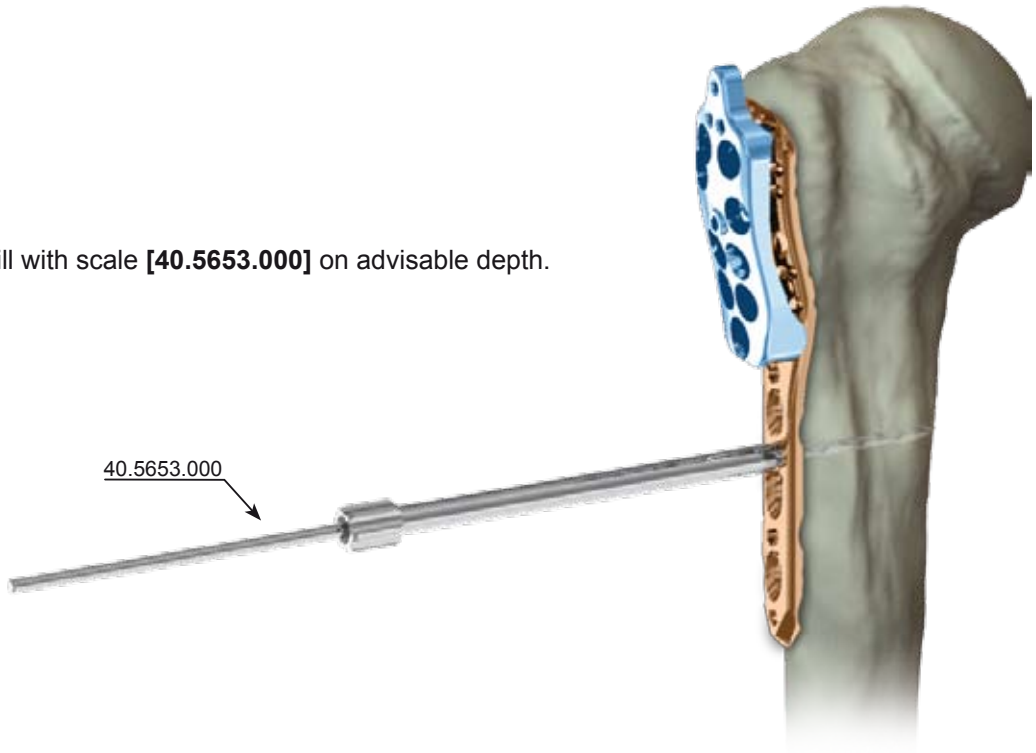
IV.2.1 Screwing in the guide sleeve

Screw in the guide sleeve 5,0/2,8 **[40.5673.000]** into the plate hole.



IV.2.2 Hole drilling

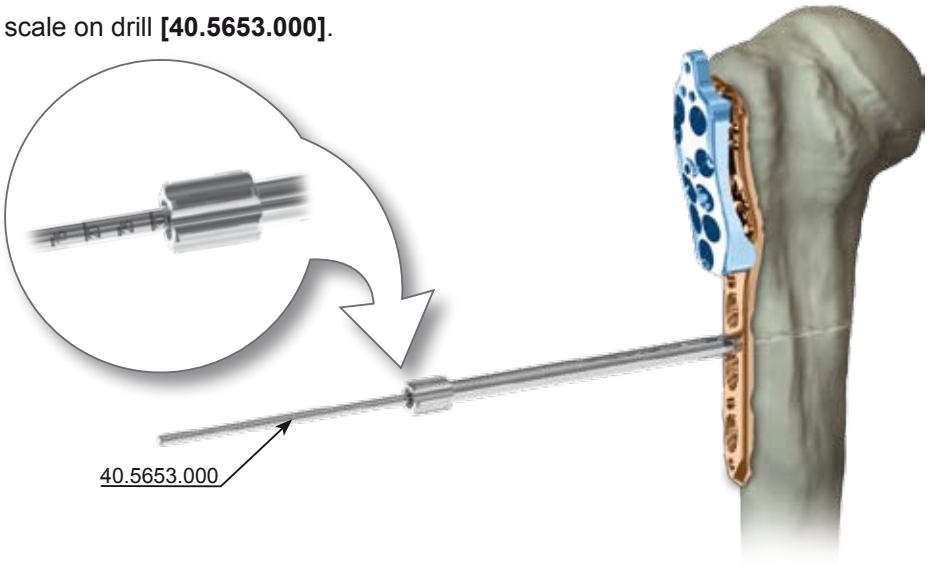
Drill with Ø2.8/180 drill with scale **[40.5653.000]** on advisable depth.



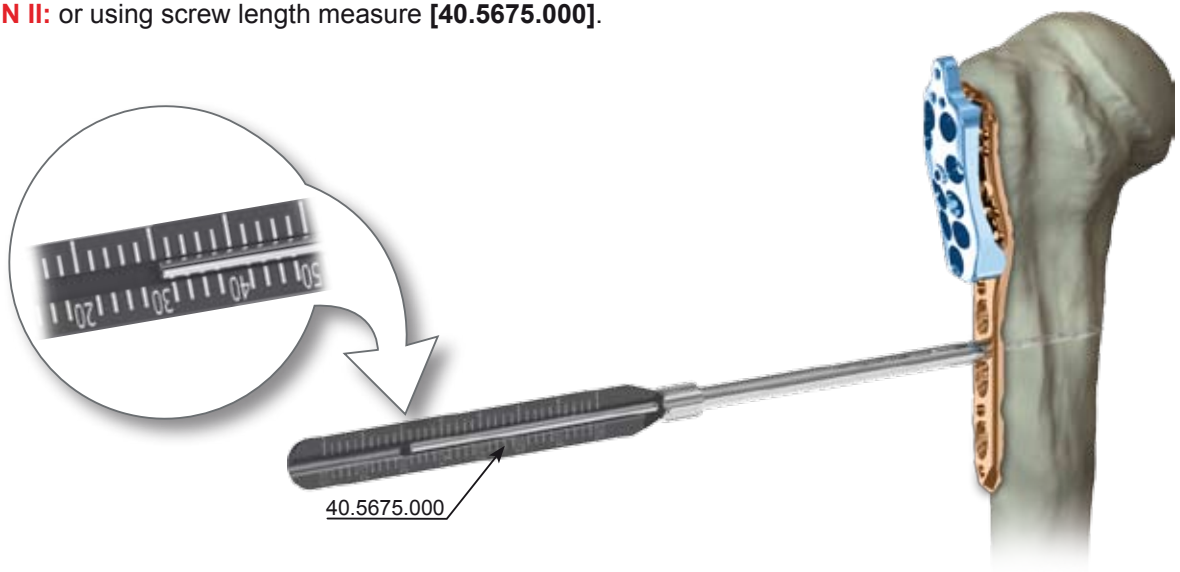
The above description is not detailed instruction of conduct.
The surgeon decides about choosing the operating procedure.

IV.2.3. Hole depth measurement

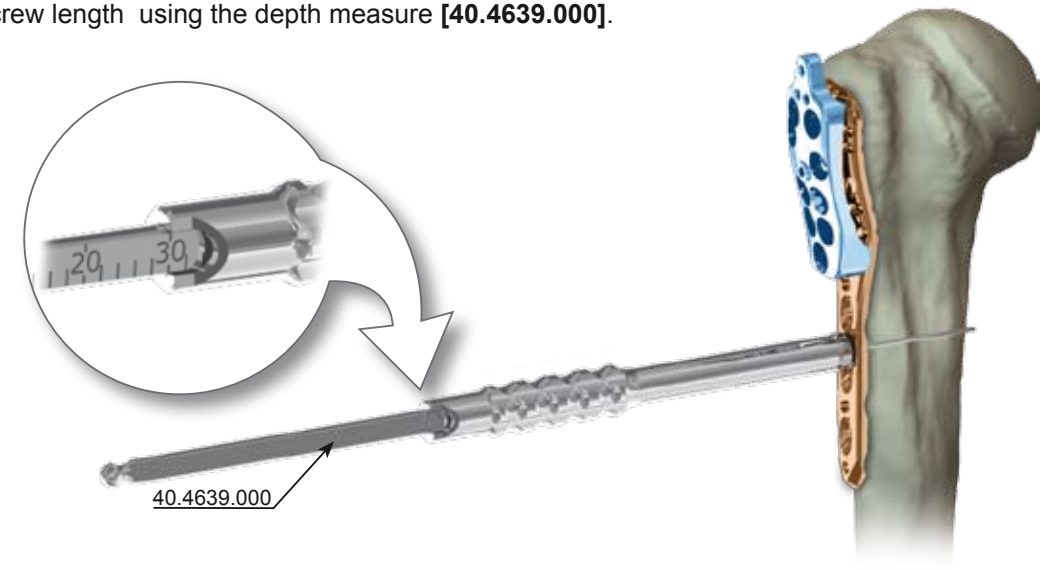
OPTION I: Read value from scale on drill **[40.5653.000]**.



OPTION II: or using screw length measure **[40.5675.000]**.



OPTION III: After guide sleeve 5,0/2,8 **[40.5673.028]** unscrewing, define the screw length using the depth measure **[40.4639.000]**.



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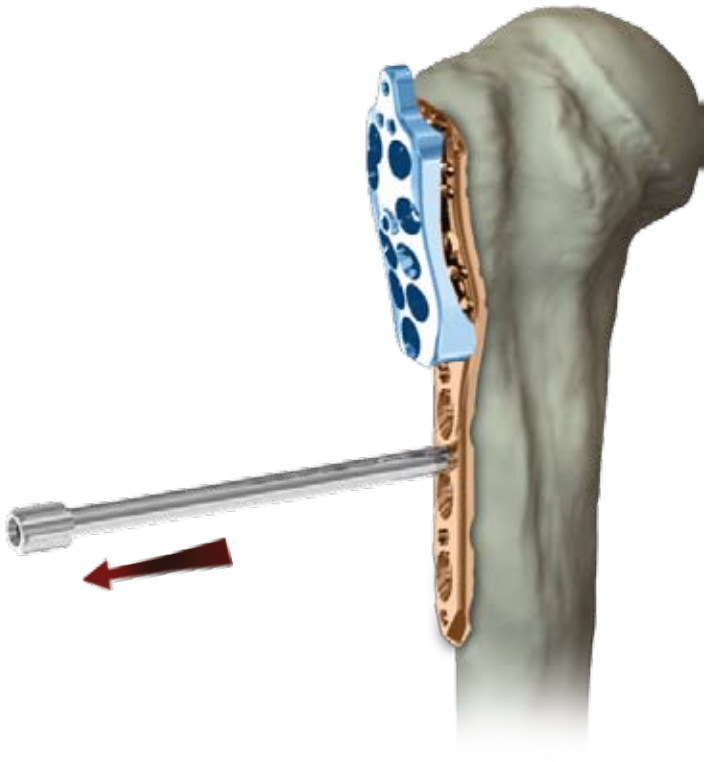
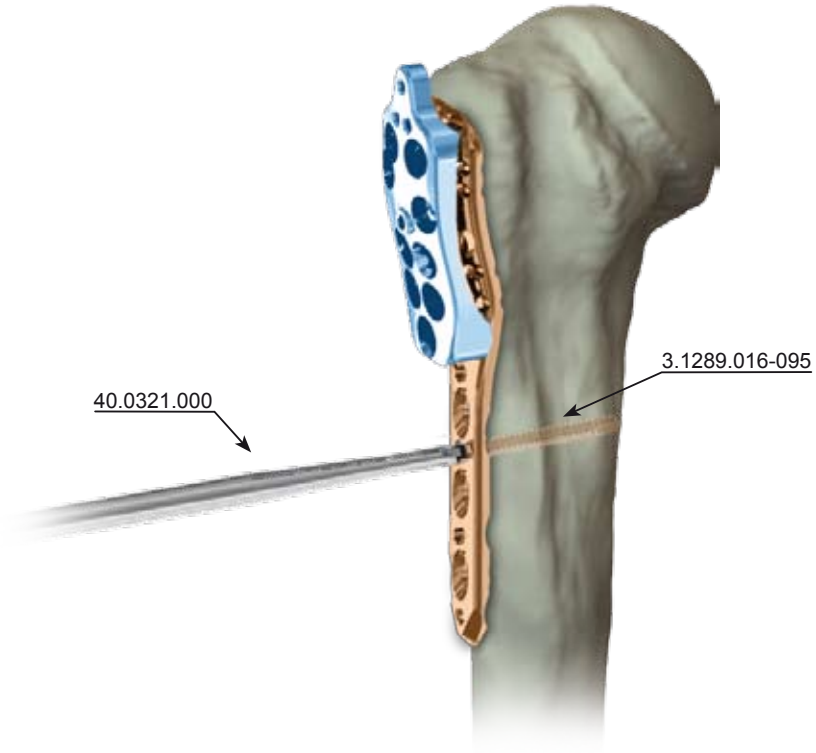
IV.2.4 Screw insertion

Remove guide sleeve 5.0/2.8 **[40.5673.028]**.



Insert locking screw **[3.1289.016-095]** using hexagonal screwdriver S2.5 **[40.0321.000]**.



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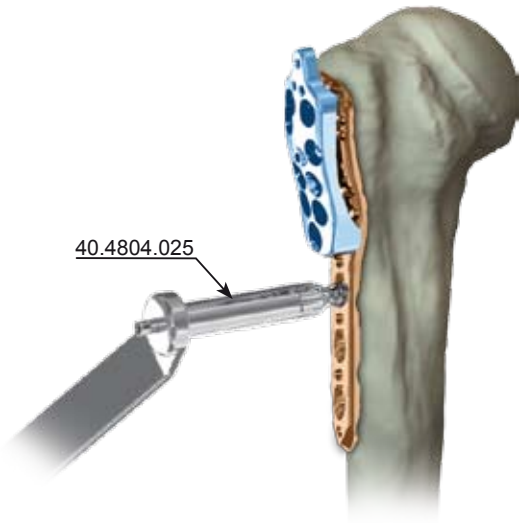
IV.3 Cortical screw Ø3.5 insertion in shaft part

IV.3.1 Compression guide setting

Set the compression guide 2,5 **[40.4804.025]** in advisable position:

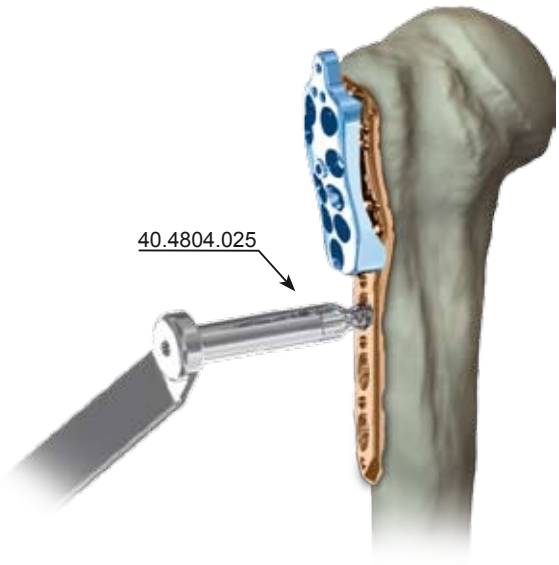
IV.3.1a Neutral position

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



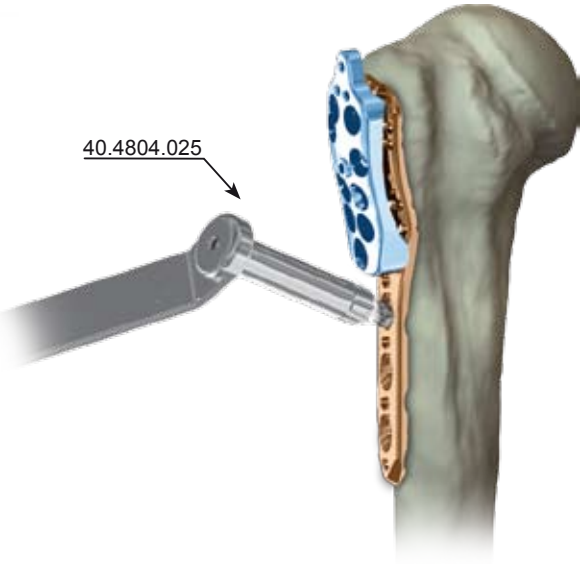
IV.3.1b Compression position

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



IV.3.1c Angular position

Angular positioning of the guide is also possible.



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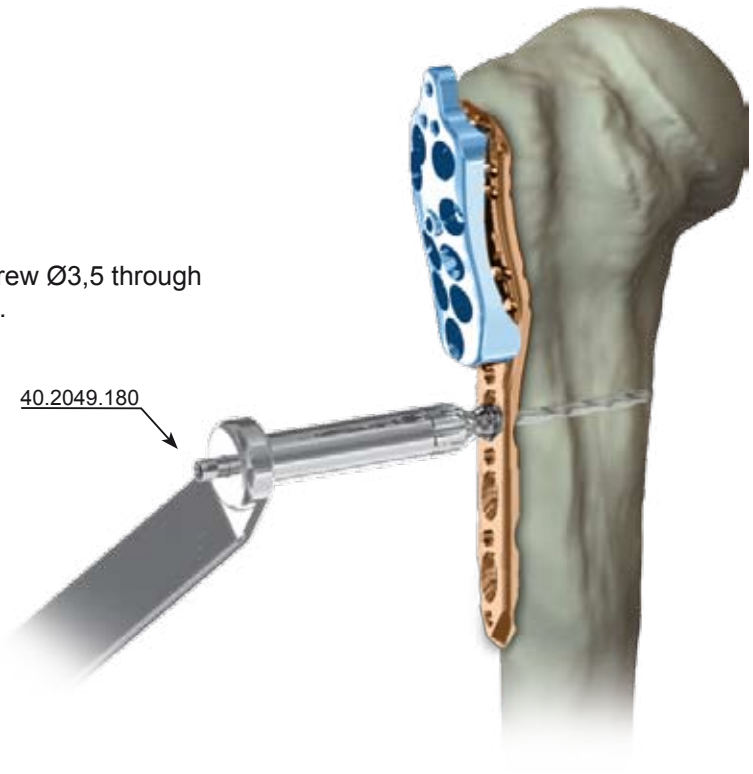
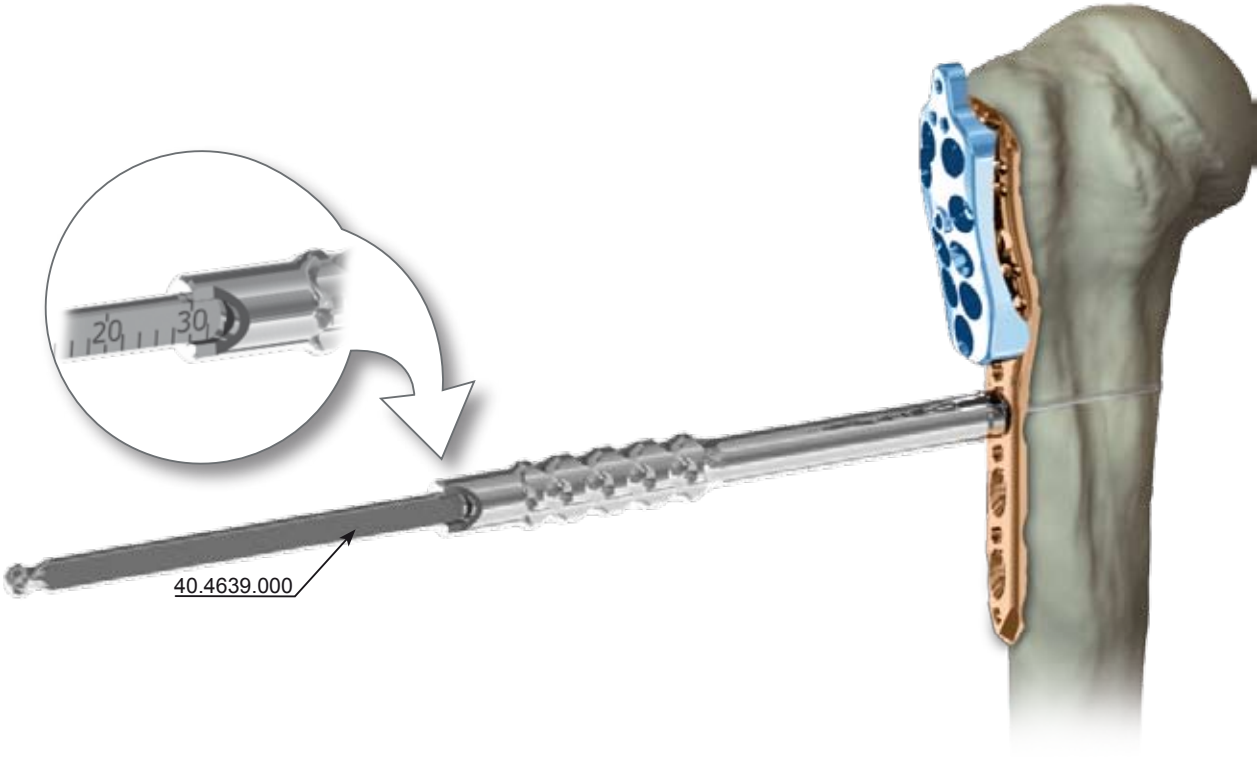
IV.3.2 Drilling

In advisable position make a hole for cortical screw Ø3,5 through both cortices using Ø2,5/180 drill **[40.2049.180]**.



IV.3.3 Hole depth measurement

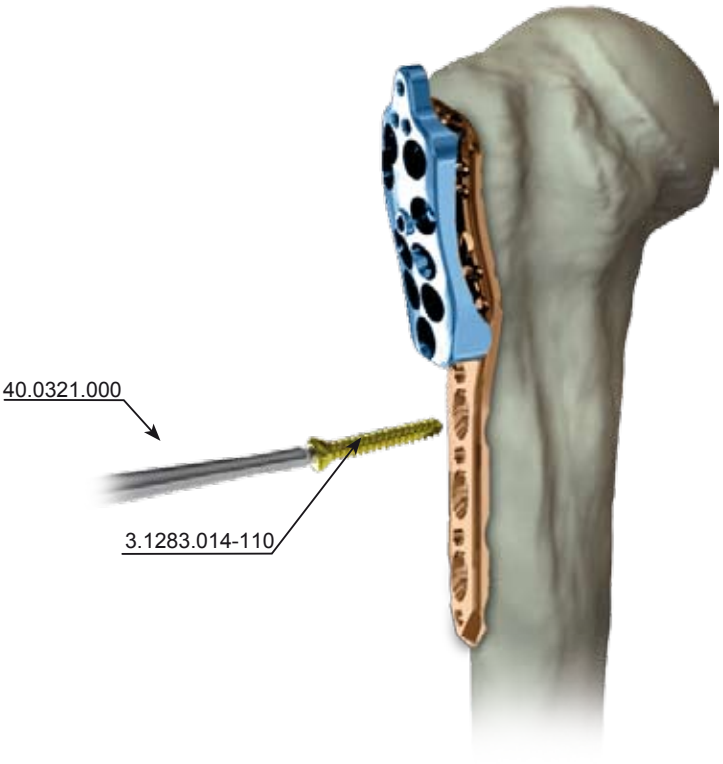
In drilled hole insert depth measure **[40.4639.000]** until its hook reaches outer surface of opposite cortex bone.



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

IV.3.4 Screwing the screw

Screw in the cortex screw Ø3,5.



V.4 Kirschner Ø1,0 wire usage

It's possible to use Kirschner wire Ø1,0/180 **[40.4815.000]**in each locking hole for:
- fragments of the fractured bone and plate temporary stabilization,
- defining correct positioning of plate or locking screw length in humeral bone using X-ray image,
- guidance for optional self-tapping cannuled screw Ø4,4 **[3.1466.016-090]**.

Insert Kirschner wire Ø1,0/180 **[40.4815.000]** through guide sleeve 5,0/1,0 **[40.5673.010]** screwed in locking hole in plate. Insertion depth define using screw length measure **[40.5675.000]**.

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VI. SURGERY TECHNIQUE

VI.1 Patient position

“Beach-chair” position is recommended for operation. It ensure easy approach to the shoulder.

VI.2 Surgical approach

Deltopectoral approach is recommended, between deltoid and pectoral muscles.

VI.3 Reduce the fracture

It’s necessary to perform anatomical reduction of head fragments and humeral bone tuberosity using Kirschner wires or sutures before applying humeral plate with locking screws. Head fragments and humeral bone tuberosity stabilize temporarily using Kirschner wires or additional independent screws for interfragmentary compression taking care that these don’t interfere with later applied plate and screws.
Confirm correct positioning of fragments making X-ray image.
Fractured bone fragments can be stabilized also with bone clamps.

Option. It’s possible to increase stability by insertion of sutures through the Ø2 holes on proximal part of the plate perimeter. If it’s planed to use sutures for fracture stabilization, it’s recommended to insert these in adequate plate holes before mounting targeting block and applying it on the bone. Fix the sutures, if necessary 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.

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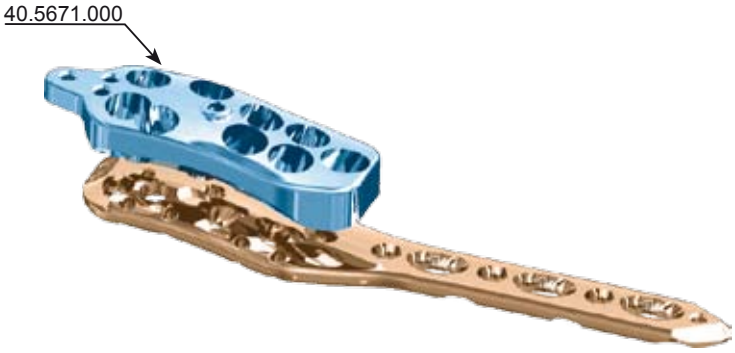
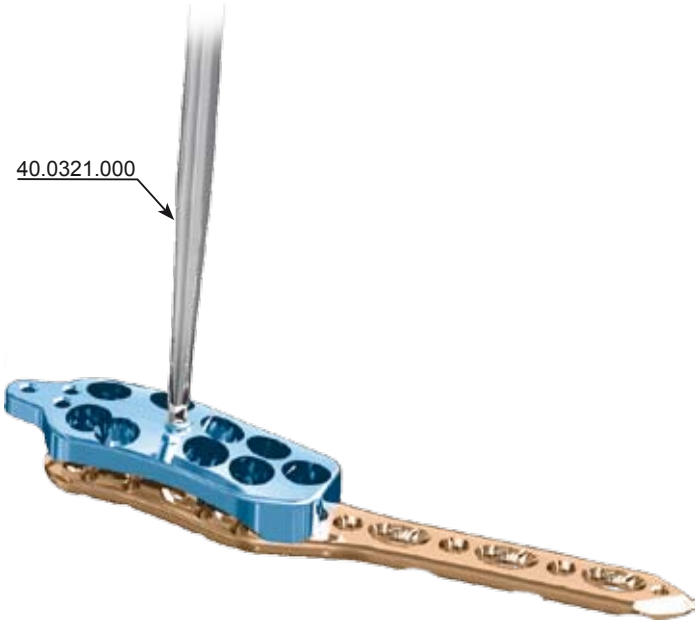
VI.4 Targeting block attachment

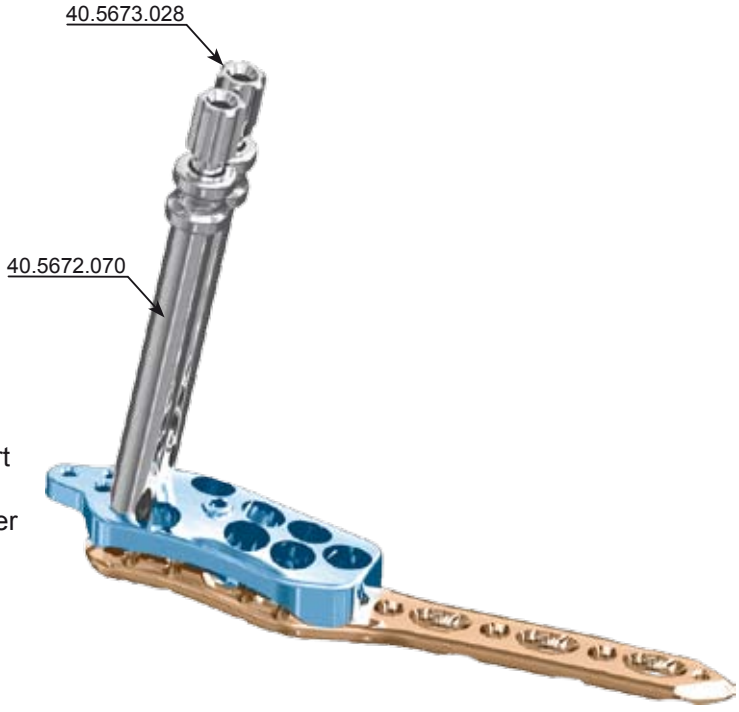
Place the targeting block **[40.5671.000]** on the plate.



Tighten using screwdriver S2,5 **[40.0321.000]**.



For easier insertion and positioning of the plate insert 2 protective guides 7,0/5,0 **[40.5672.070]** and guide sleeves 5,0/2,8 **[40.5673.028]** for example in 2 nearer holes (A1 and A2):



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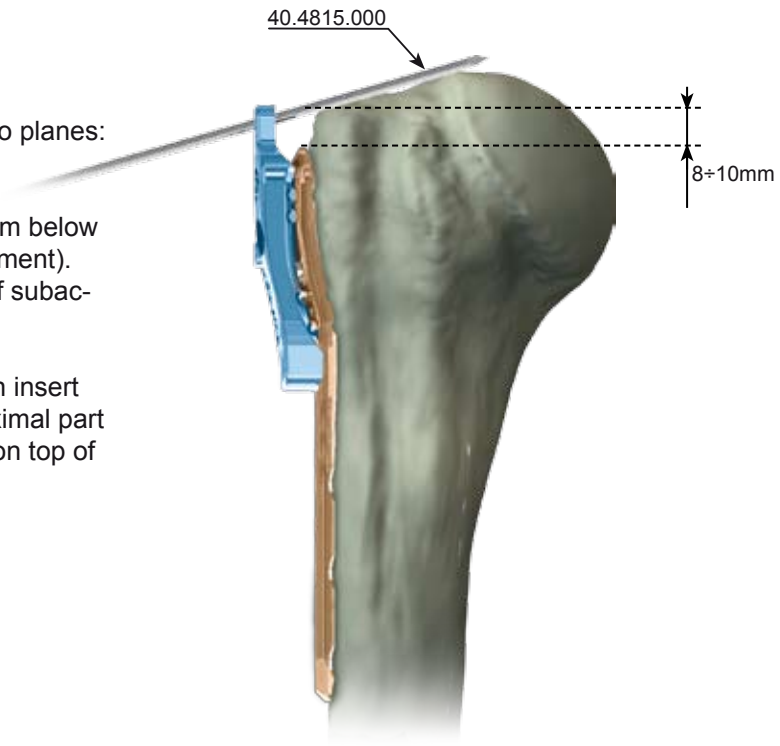
VI.5 Plate application



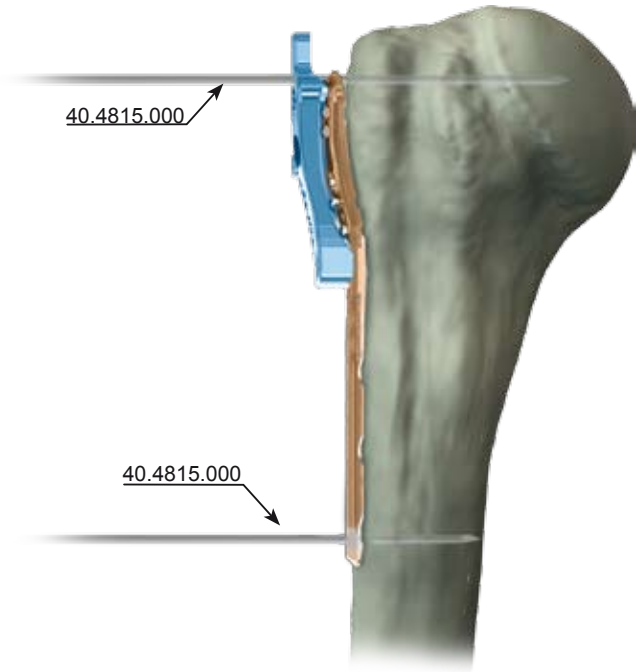
Place the plate on the bone and check its position in two planes:

a) anterior-posterior A/P position
Upper edge of the plate should be placed about 8÷10mm below upper edge of the greater tuberosity (rotator cuff attachment). Too high placement of the plate can increase the risk of subacromial impingement.

To easier determination of the correct plate A/P position insert the Ø2.0 Kirschner wire **[40.4815.000]** through the proximal part hole of targeting 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 bicipital groove.

VI.6 Temporary plate positioning

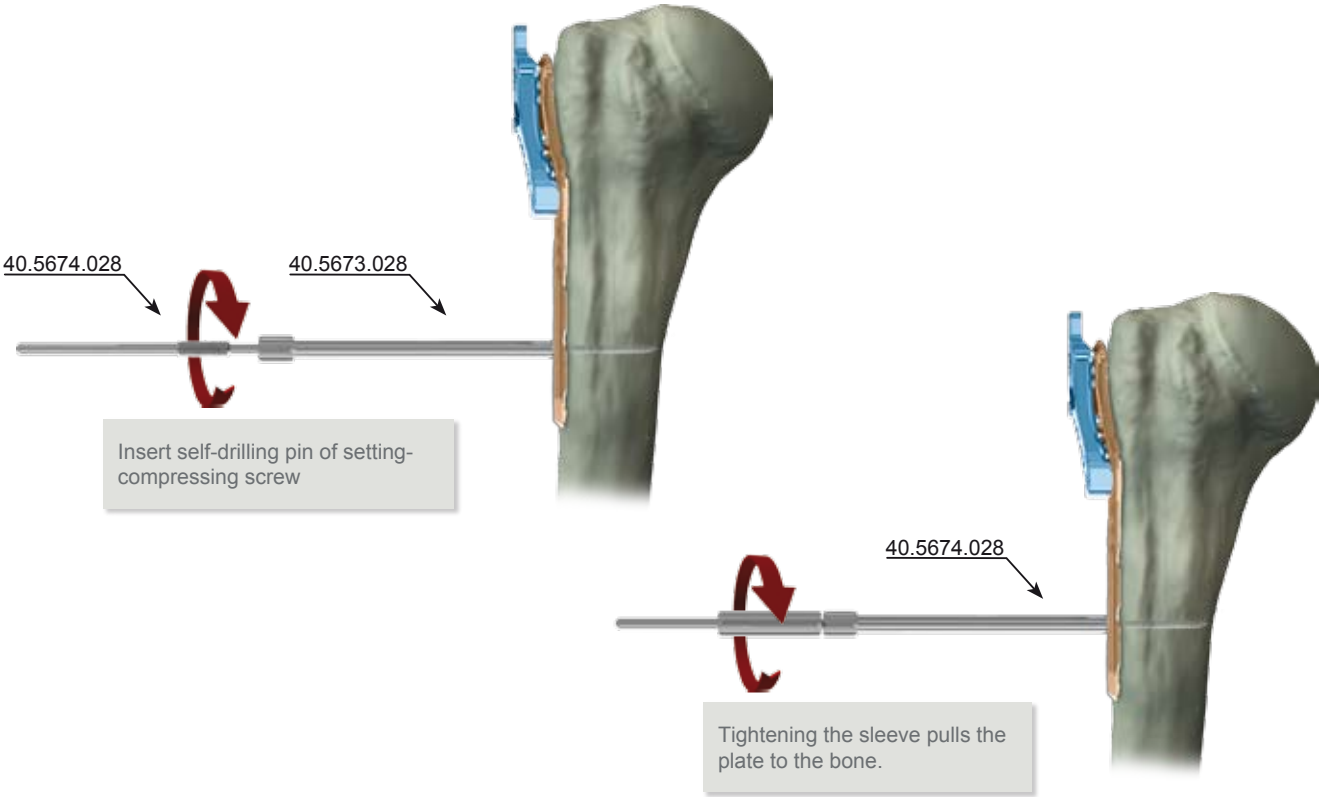


After reduction of the fragments of the fractured bone and confirmation of plate position correctness on bone it is necessary to temporary fix its position using Ø2.0 Kirschner wires **[40.4815.000]**. These may be placed in holes in proximal part of the plate and in the most distal hole of the plate.

Confirm correct positioning taking X-ray image.

Attention:
For temporary stabilization and tightening the plate to the bone it's possible to use setting-compressing screw 2,8/180 **[40.5674.028]**. Insert these through guide sleeve 5,0/2,8 **[40.5673.028]**.

Insertion of a.m. screw can unable insertion of some screws in proximal part because of interference angular positioned guide sleeves.
Into the hole after setting-compressing screw 2,8/180 removal, a locking screw Ø3,5 **[3.1289.016-095]** can be inserted.



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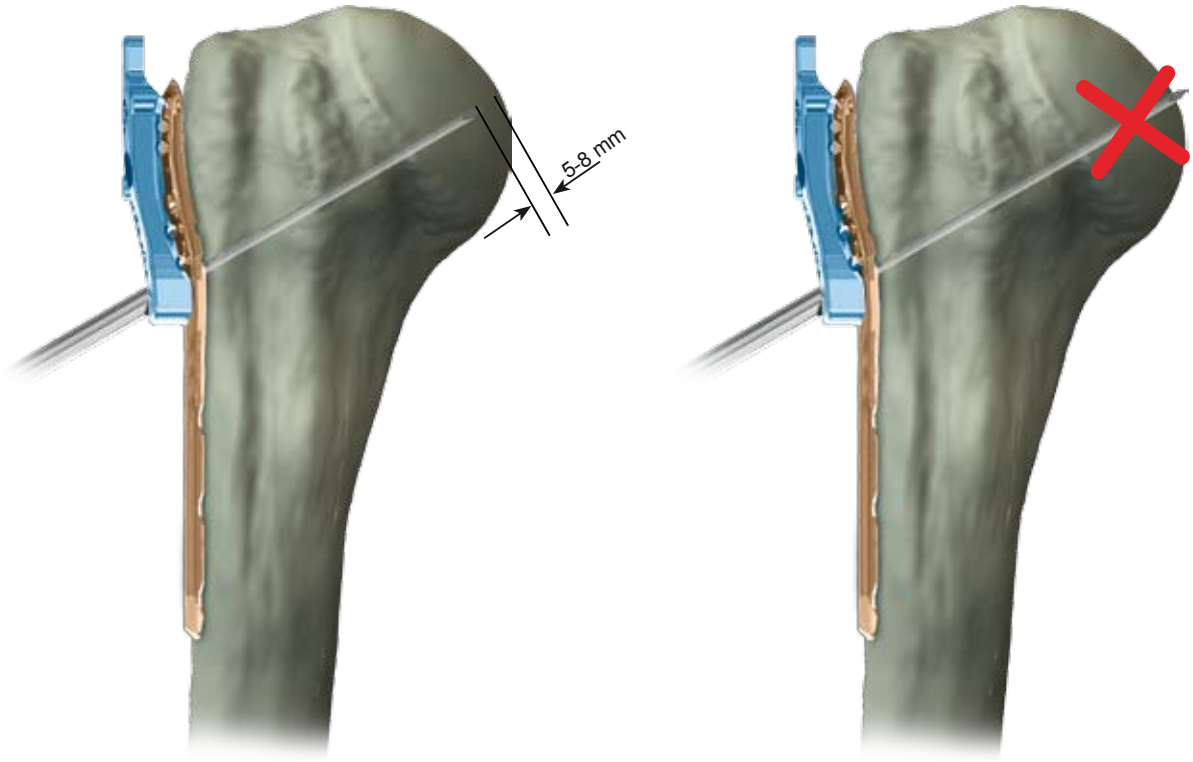
VI.7 Screws insertion

Initial screw selection depends on fracture 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 on depth when feeling the resistance from the subchondral bone. It isn't always possible to feel this resistance so it is recommended to use image intensification. The K-wire or drill tip should be placed as close as it is possible to the subchondral bone, i.e. about 5-8mm from the joint surface.
One should avoid breaking the joint surface by reboring the opposite cortex of the humeral bone head.



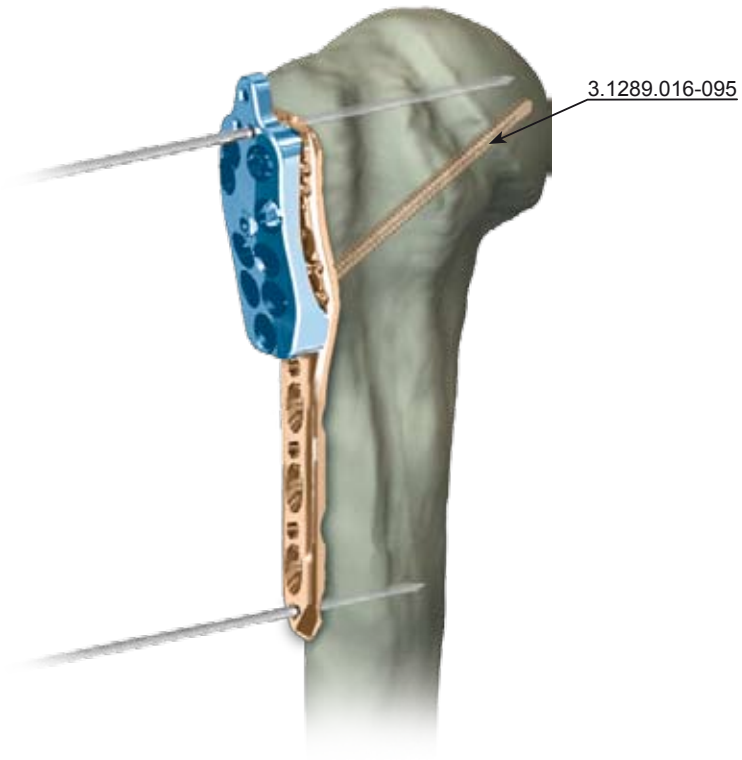
It is necessary to insert at least 4-6 screws or more in the proximal part of the plate, particularly when the bone quality is low. When inserting locking screws in shaft, to obtain better fixation it's recommended to insert these through both cortices.

VI.7.1 Option A

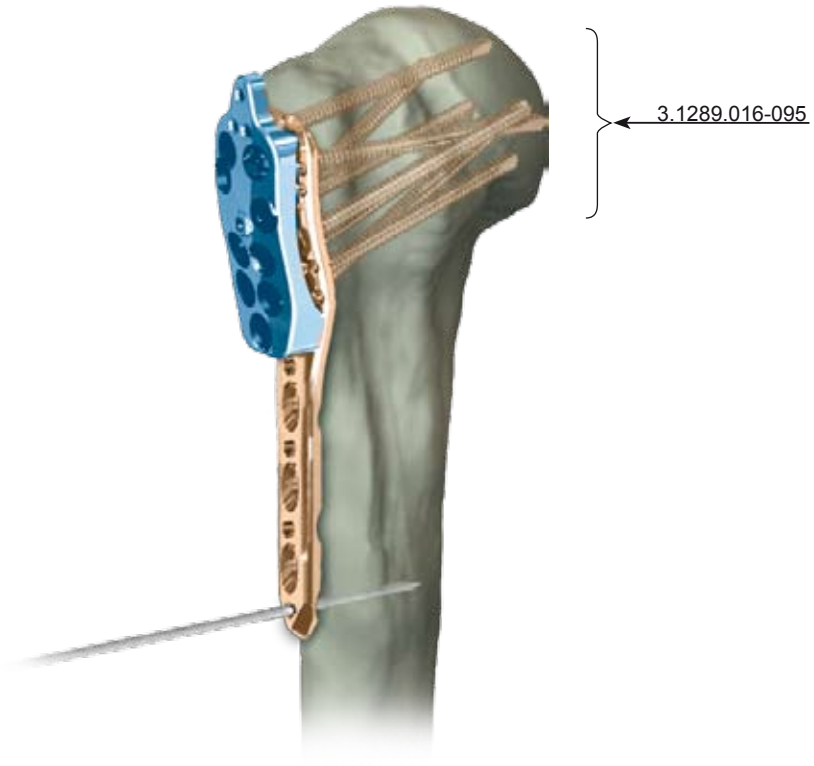
In this technique the bone fragments in proximal part are fixed first, next the distal part with or without compression is fixed.

VI.7.1.1. Humeral bone epiphysis stabilization

After temporary stabilization, compression the fragments of fractured humeral bone head and image intensification of plate height insert locking screw Ø3,5 in hole E.



Insert other locking screws in advisable holes in proximal part of the plate.



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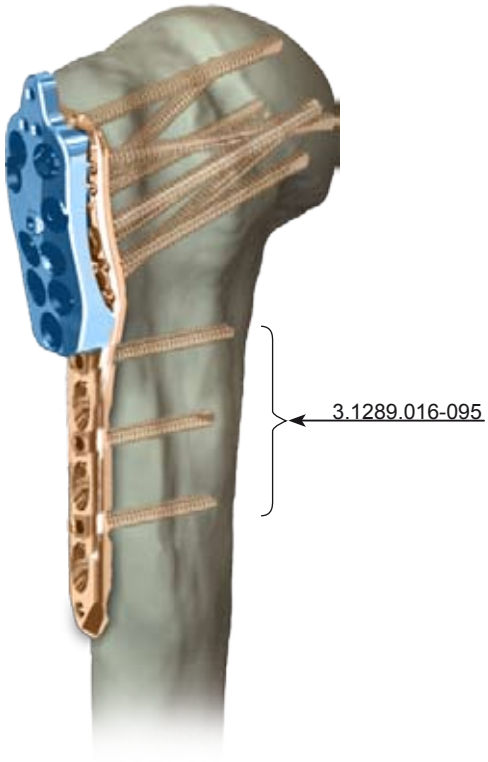
VI.7.1.2 Humeral bone shaft stabilization

Insert locking screws Ø3.5 **[3.1289.016-095]** in distal part of plate holes.



If it's necessary, before insertion of locking screws in distal part, using cortical screws accomplish compression of the fragments of fractured bone.

VI.7.1.3 Targeting block [40.5671.000] removal

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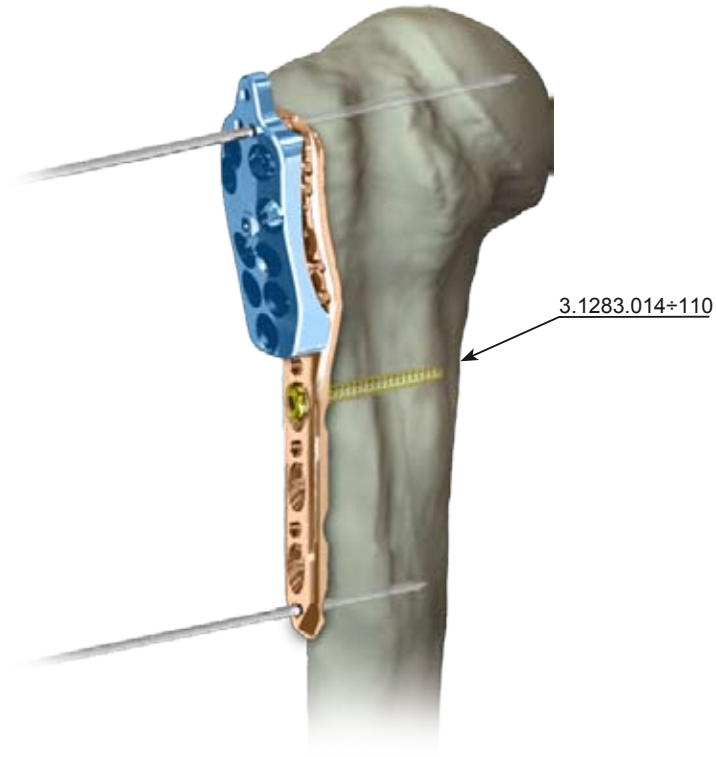
VI.7.2 Option B

In this technique reduction of distal shaft part with plate is done first, next the final adjustment of plates height and insertion of the screws in proximal part before inserting the other screws in shaft.

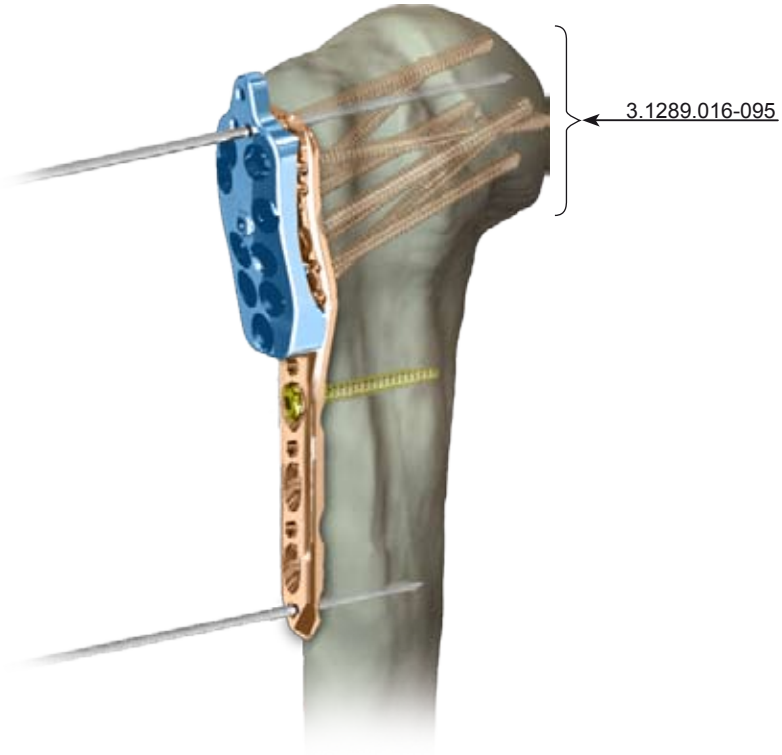
VI.7.2.1 Cortical screw Ø3,5 insertion

Insert cortical screw Ø3,5 **[3.1283.014÷110]**, in neutral position, in first or second compression hole.



VI.7.2.2 Humeral bone epiphysis stabilization

In advisable holes insert locking screws Ø3.5 **[3.1289.016÷95]** in humeral bone head.



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VI.7.2.3 Humeral bone shaft stabilization

Insert other locking screws Ø3,5 **[3.1289.016÷095]** in distal part of the plate, or accomplish eventual compression in shaft section using standard bone screws Ø3,5 **[3.1283.014÷110]**.

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

VI.7.2.4 Targeting block [40.5671.000] removal

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VII. POSTOPERATIVE PROCEDURE

To prevent lateral restrtiction of movement start patient exercises as soon as possible after surgery. However it is necessary to pay heed not to load the limb with full load before complete union of fractured bone.

VIII. IMPLANT REMOVAL

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

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20A	Radial Head Prosthesis KPS
23B	Intramedullary osteosynthesis of femur (reversed method) 40.3660
24B	Intramedullary osteosynthesis of femur 40.5060.000
25A	Intramedullary osteosynthesis of tibia 40.5000.100
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