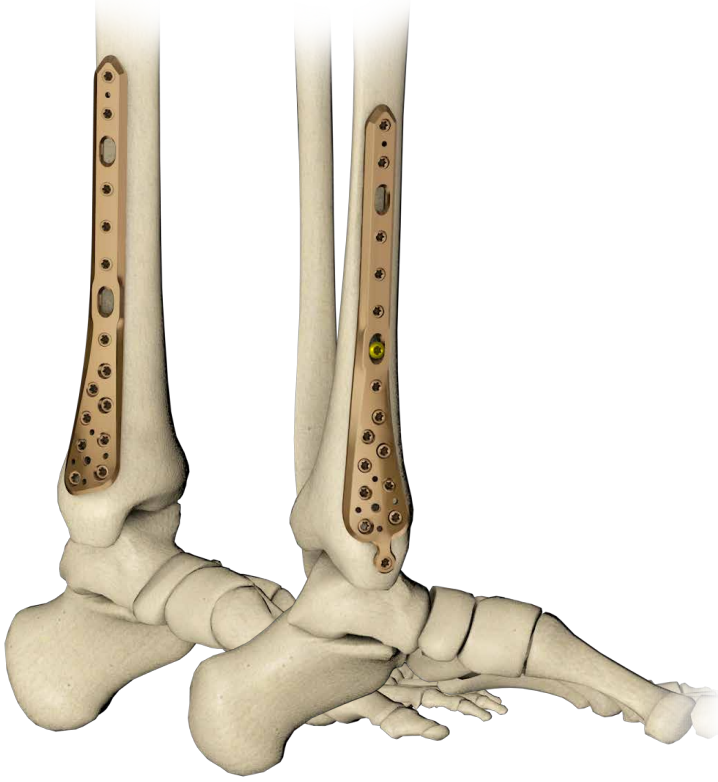
ST/80-503A

ChM®

5,0 ChM Locked Plating ChLP system

5.0ChLP distal medial tibia plate
3.4039; 3.4040
3.7018; 3.7019

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



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SYMBOLS DESCRIPTION

Ti	Titanium or titanium alloy	H	H length [mm]
Co	Cobalt		Angle
L	Left	88 - 340	available lengths
R	Right	4-22	Available number of holes
L R	Available versions: left/right	1.8	Thickness [mm]
Len	Length	1:1	Scale 1:1
	Torx drive		Number of threaded holes in the shaft part of the plate
	Torx drive cannulated		Number of locking holes in the plate
	Hexagonal drive	VA	Variable angle
	Hexagonal drive cannulated		Cortical
	Cannulated		Cancellous
	Locking	Ster Non Ster	Available in sterile/ non- sterile condition
	Diameter [mm]		Refer to surgical technique

	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

1. INTRODUCTION

This surgical technique applies to 5.0ChLP locked plating system used for distal tibia fragment fixation The plates are a part of the ChLP locked plating system developed by **ChM**. The presented range of implants is made of materials in accordance with ISO 5832 standards. 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.

The system includes:
- implants *(plates and screws)*,
- instrument set used during surgery,
- surgical technique.

Indications

- Comminuted distal tibia fractures and fractures extended to the tibial shaft.
- Mal-unions and non-unions.

Plate selection and shaping

The plates are available in various lengths and for left and right limb separately. This allows for optimal selection of the implant to the fracture type.
Shaping of the plates in their epiphyseal part is not allowed.

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.

2. IMPLANT DESCRIPTION

Distal medial tibia plates are a part of 5.0ChLP system. This system includes also compatible locking screws. To facilitate the identification, both titanium plate and screws are brown anodized.

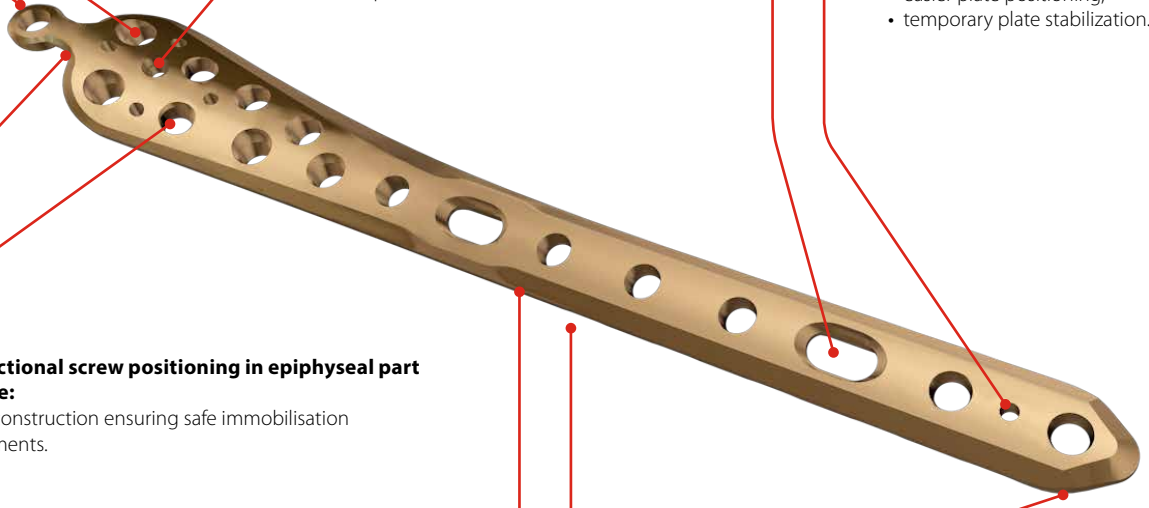
Additional hole in distal part:
- undercut facilitating shaping.

New locking hole design:
- the screws heads do not protrude above the surface of the plate what significantly reduces the irritation of periimplant tissues,
- increased strength of the screw-to-plate threaded connection,
- bottom protrusion reduces surface area of the contact with the bone.

Compression holes:
- convenient plate positioning,
- compression possibility.

Aiming block:
- fast, collision-free insertion of screws in pre-determined directions.

Holes for Kirschner wires in epiphyseal and shaft parts:
- easier plate positioning,
- temporary plate stabilization..



Multi-directional screw positioning in epiphyseal part of the plate:
- stable construction ensuring safe immobilisation of fragments.

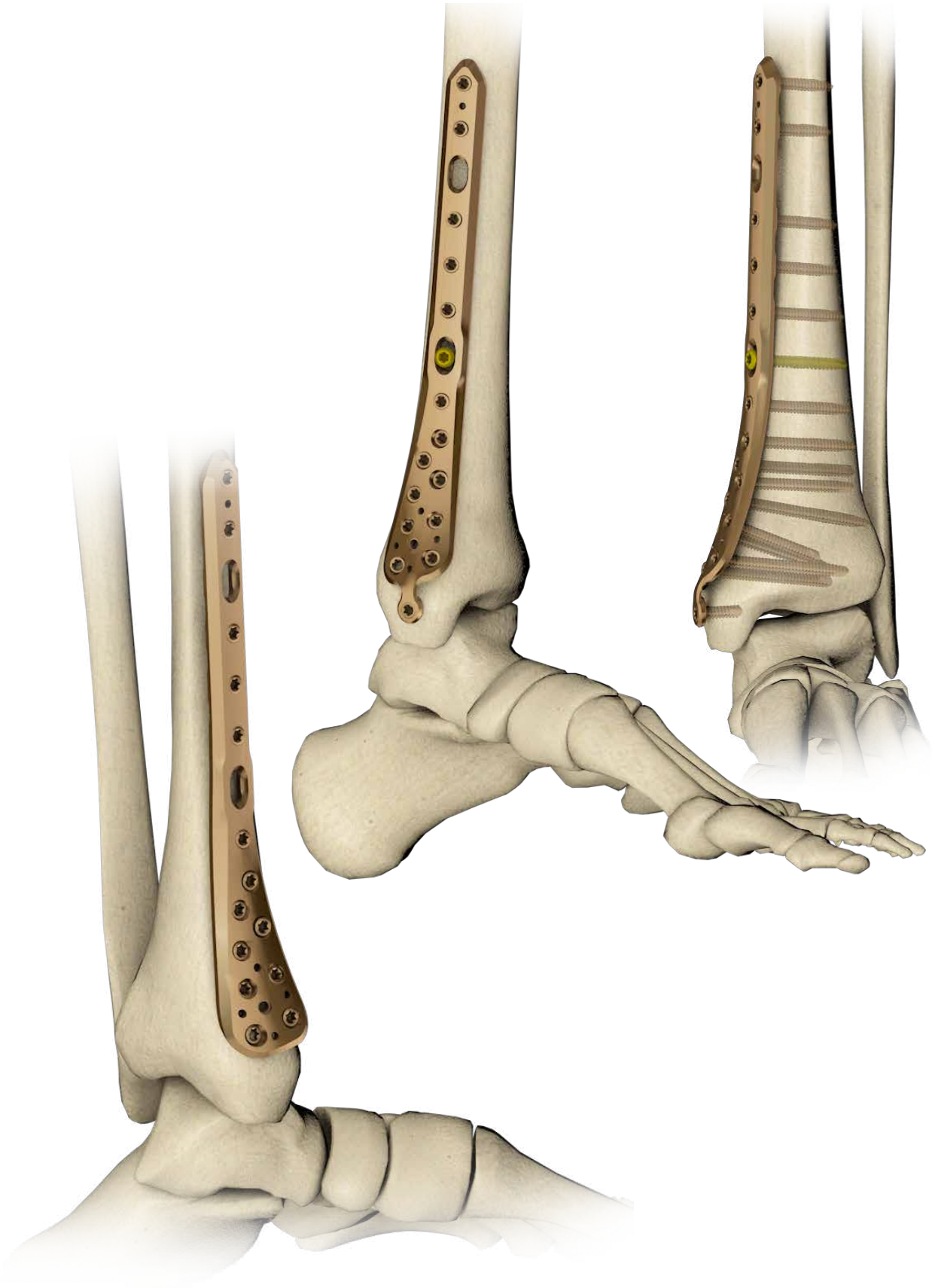
Narrowed plate end:
- minimal-invasive insertion possible.

Bottom undercuts of the shaft part:
- limited bone-to-plate contact,
- better blood circulation of periimplant tissues.

Plate design:
- anatomical profile fits the bone structure,
- narrowed shaft part,
- rounded upper edges.

Two types of plates:
- with an additional hole **[3.4039/3.4040]**
- without an additional hole **[3.7018/3.7019]**

5.0ChLP 5.0ChLP distal medial tibia plate



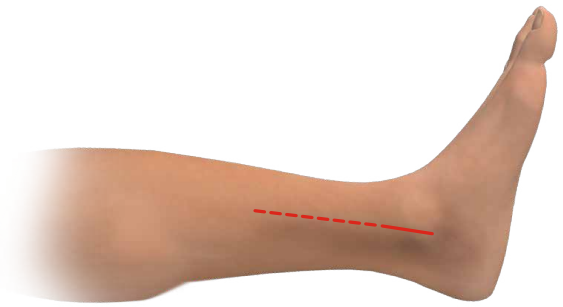
3. SURGICAL TECHNIQUE

3.1. PATIENT'S POSITIONING

It is recommended to place the patient supine. The affected limb should be higher so that the X-Ray images in the lateral and A-P view can be taken.

3.2. SURGICAL APPROACH

Medial access. Perform an incision about 1 cm above the posteromedial edge of the tibia that extends along its axis up to the apex of the medial ankle. The length of the incision depends on the length of the implant. Do not damage the saphenous vein.



3.3. FRACTURE REDUCTION

Perform fracture reduction. If need be, temporarily stabilize the bone fragments with Kirschner wires and/or reduction pliers.

3.4. IMPLANT SELECTION

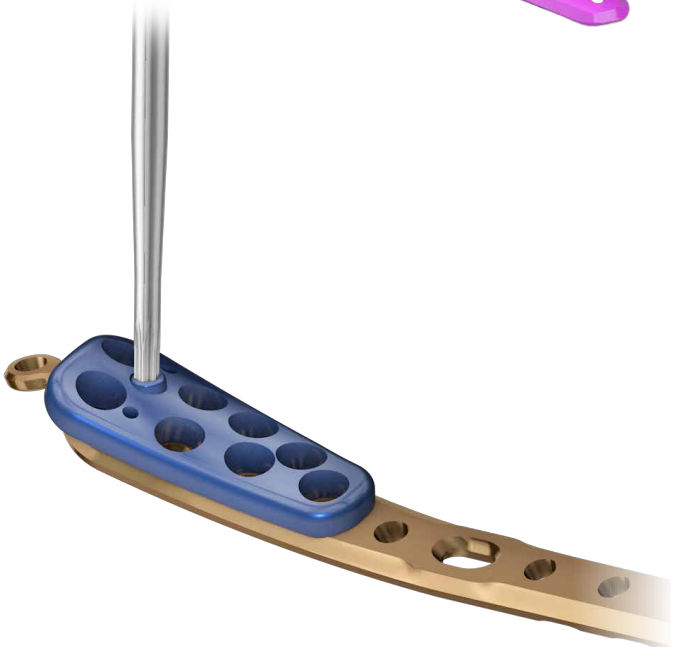
Select the right size of the implant to the type of fracture, bone size and structure. Use plate trials **[43.4039.608]**/**[43.4040.608]** to determine the length of the implant.

Plate 3.4039.608 trial Plate 3.4040.608 trial		43.4039.608 43.4040.608

3.5. AIMING BLOCK INSERTION

Attach appropriate aiming block to the plate by tightening the fixing screw of the block using screwdriver tip T15 **[40.5677.000]**.

Plate 3.4039 and 3.7019 Plate 3.4040 and 3.7018		40.5726.100 40.5726.200
		40.6654.000
		40.5677.000

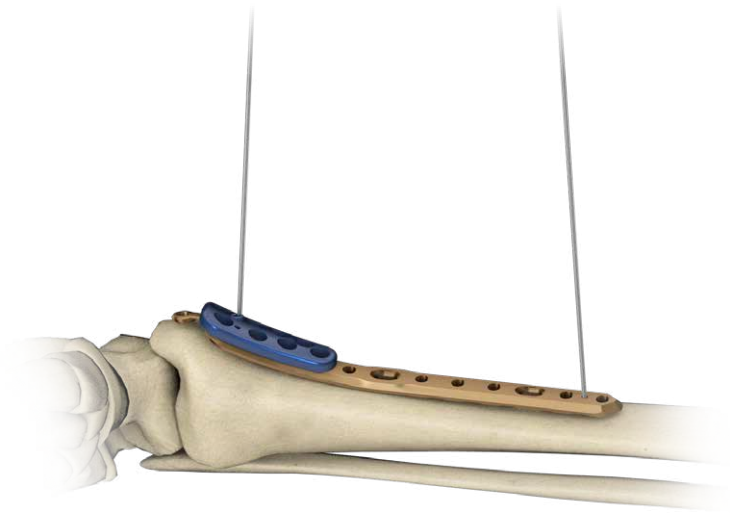


Most ChLP locking plates are available with aiming blocks as additional supplementary instruments. The use of aiming blocks ensures proper guide sleeves locking in the plate epiphyseal locking holes. Aiming blocks facilitate also the surgery procedure, shorten its time and ensure drilling in the axis of the locking hole.

Not using aiming blocks may lead to improper device implantation. Incorrectly locked screws can cause complications when removing the plates.

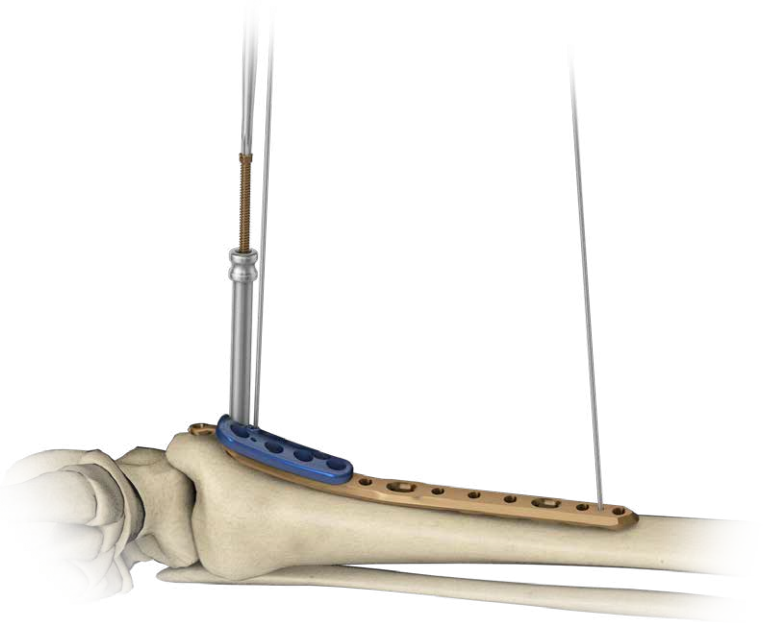
3.6. PLATE INSERTION

Position the implant correctly on the bone.



3.7. TEMPORARY PLATE STABILIZATION

Stabilize the position of the implant inserting Kirschner wires into appropriate holes or using setting-compressing screw *(acc. to procedure 4a)*.

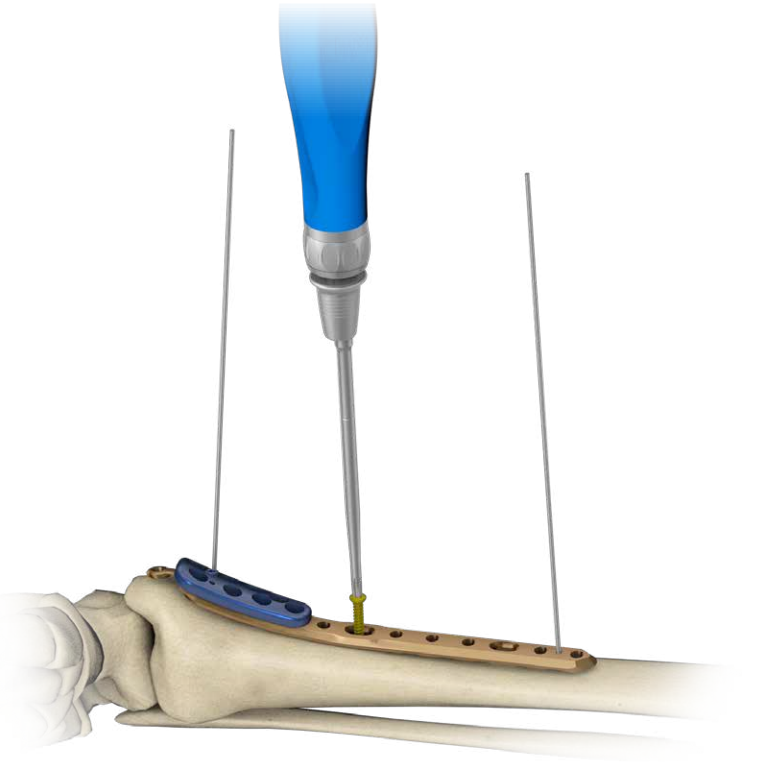


3.8. LOCKING SCREWS INSERTION IN THE EPIPHYSEAL PART OF THE PLATE

Insert protective guide 7/5 **[40.5672]** into the aiming block hole.

40.5672.000

Insert 5.0ChLP self-tapping screw 3.5 **[3.5200]** of a suitable length, through the guide, into the locking holes of the epiphyseal part of the plate *(acc. to procedure 4c)*.

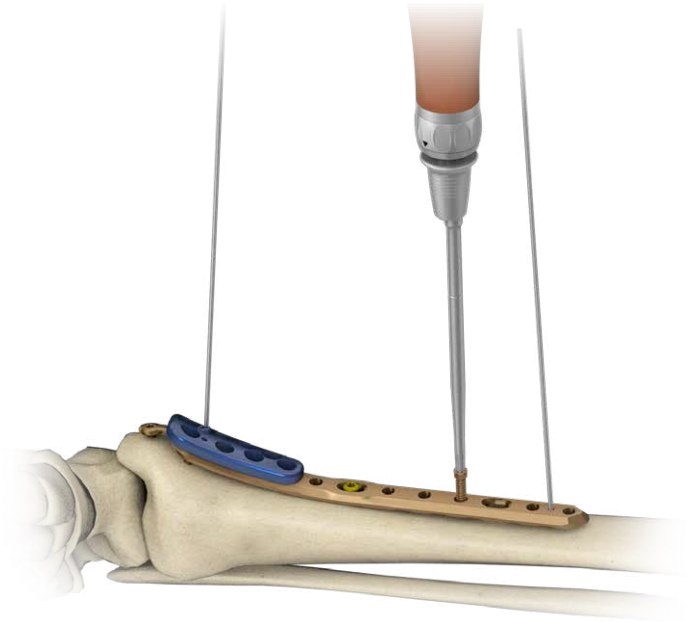


3.9. CORTICAL SCREW INSERTION

Insert cortical self-tapping screw 3.5 **[3.1306]** into the oval-shaped hole of the plate *(acc. to procedure 4b)*.

3.10. LOCKING SCREWS INSERTION IN THE SHAFT PART OF THE PLATE

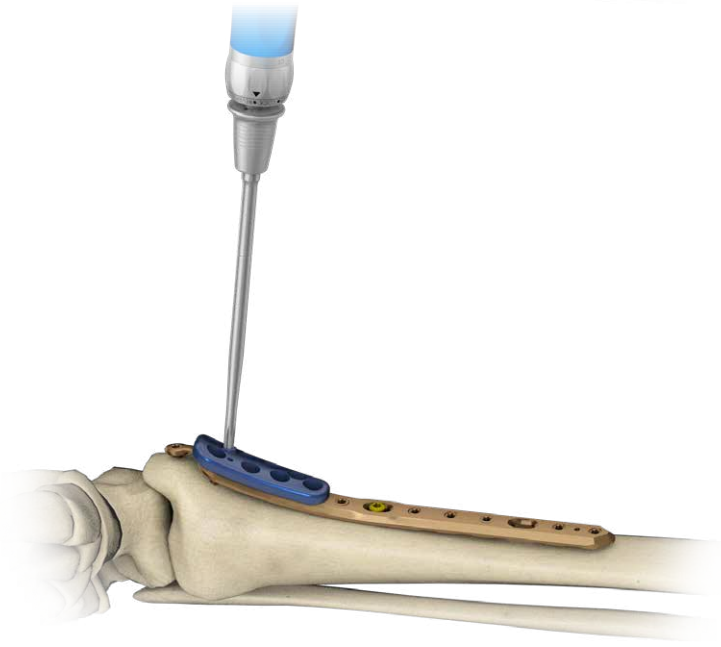
Insert 5.0ChLP self-tapping screw 3.5 **[3.5200]** of a suitable length into the locking holes of the shaft part of the plate *(acc. to procedure 4c)*.



3.11. AIMING BLOCK REMOVAL

Use screwdriver tip T15 **[40.5677.000]** to remove the aiming block from the plate.

	40.6654.000
	40.5677.000

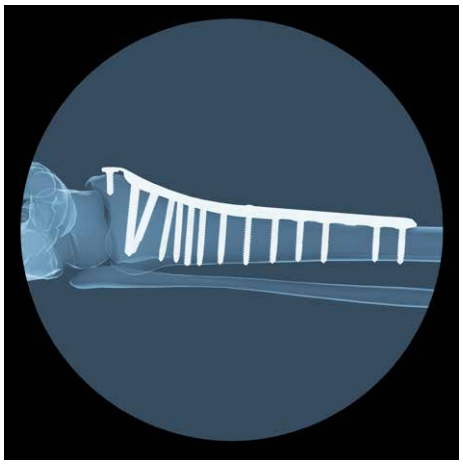


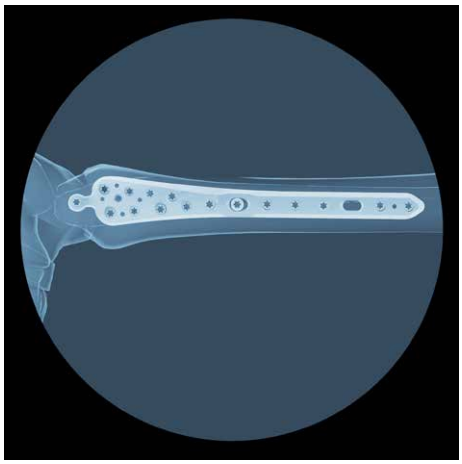
Insert the cortical screws 3.5 into the fracture before inserting the locking screws.

The doctor decides about the order and number of locking and cortical screws to be inserted.

3.12. WOUND CLOSURE

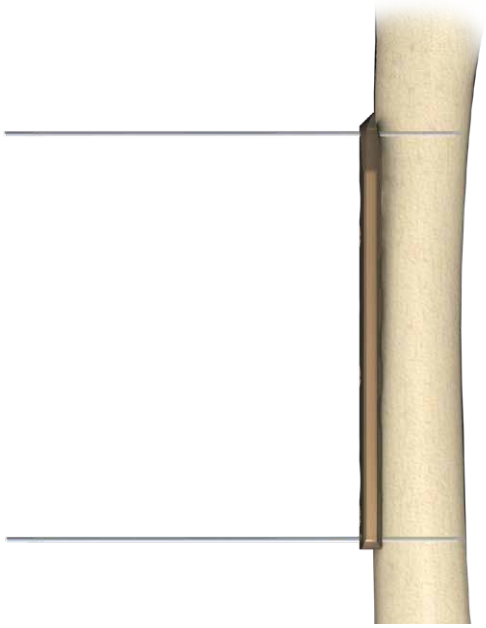
Before closing the wound, take an X-Ray image in at least two projections to confirm implant position and fracture reduction. Make sure all the screws are properly tightened and do not penetrate the joint surface.
Use appropriate surgical technique to close the wound.





4. SURGICAL PROCEDURES

4a. PROCEDURE OF TEMPORARY IMPLANT STABILIZATION

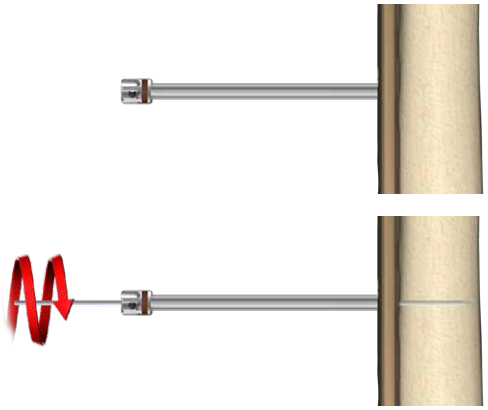


Stabilization using Kirschner wires

- Stabilize temporary the implant inserting Kirschner wires 1.5/210 **[40.4592.210]** into dedicated holes in the plate.

	40.4592.210

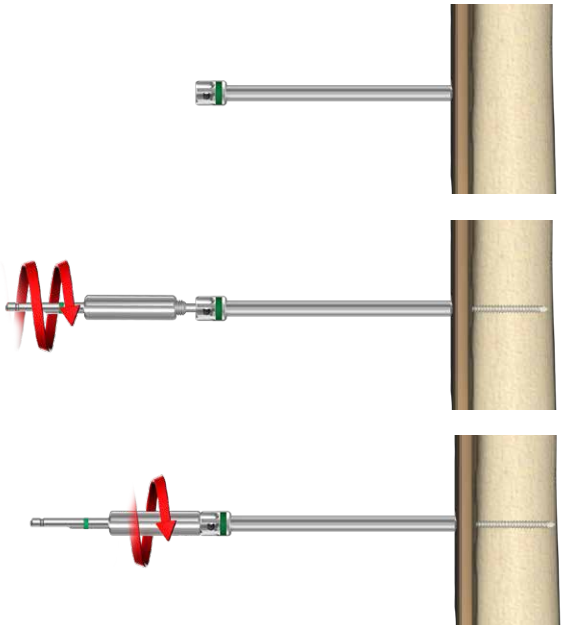
Stabilization in locking holes using Kirschner wires



- Insert guide sleeve 5.0/1.8 **[40.5673.718]** into the locking hole of the plate.
- Insert Kirschner wire **[40.4592.210]** through the guide sleeve 5.0/1.8 **[40.5673.718]**.

	40.5673.718
	40.4592.210

Stabilization using setting-compressing screw



- Insert guide sleeve 5.0/2.8 **[40.5673.728]** into the locking hole of the plate.
- Insert setting-compressing screw 2.8/180 **[40.5674.728]** through the guide sleeve 5.0/2.8 **[40.5673.728]**.
- Tighten the nut of the setting-compressing screw **[40.5674.728]** and push the plate to the bone.

	40.5673.728
	40.5674.728

4b. PROCEDURE OF CORTICAL SELF-TAPPING SCREW 3.5 **[3.1306]** INSERTION

Compression guide positioning

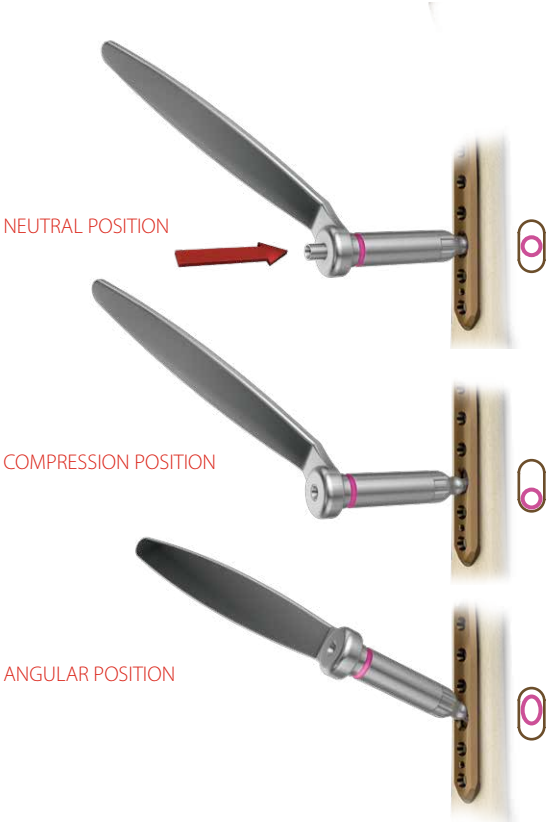
Position the compression guide 2.5 **[40.4804.725]** in a desired position:

40.4804.725

NEUTRAL POSITION: Push the guide to the plate. It will position itself so as neutral insertion of the screw is allowed.

COMPRESSION POSITION: Do not push the guide and move it to the edge of the compression hole. The hole drilled in this position allows compressive insertion of the screw.

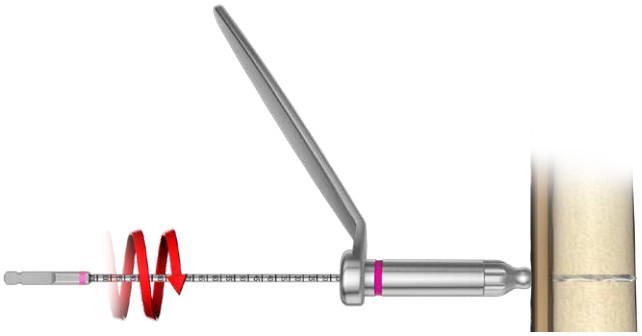
ANGULAR POSITION: Angular position of the guide may also be applied.



Hole drilling

Perform a hole through both cortices for a cortical screw 3.5 insertion. For drilling, use drill with scale 2.5/210 **[40.5912.212]** and compression guide in a desired position.

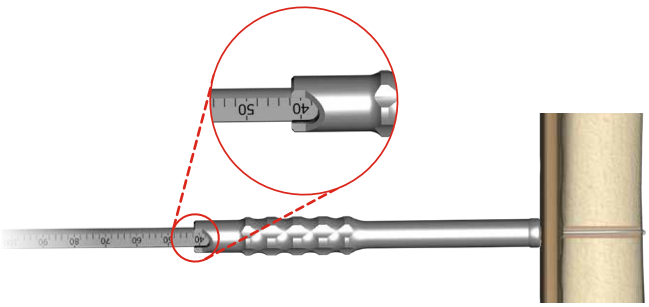
40.5912.212



Measurement of hole depth

Insert depth measure **[40.4639.550]** into drilled hole until the hook of the measure rests against the outer surface of the second cortex.

40.4639.550

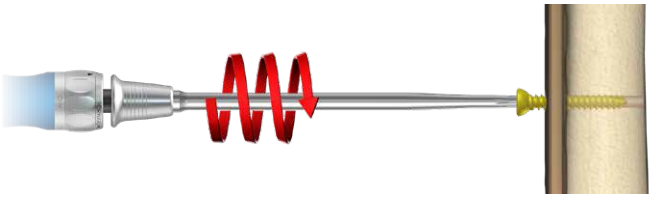


Screw insertion

Insert cortical screw using handle ratchet device **[40.6654.000]** and screwdriver tip T15 **[40.5677.000]**.

40.6654.000

40.5677.000

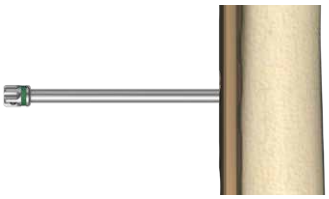


4c. PROCEDURE OF 5.0ChLP SELF-TAPPING SCREW 3.5 [3.5200] INSERTION

Guide sleeve insertion

- Insert guide sleeve 5.0/2.8 **[40.5673.728]** into a locking hole of the plate.

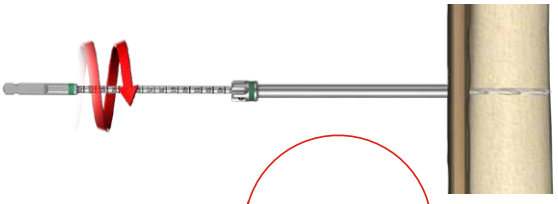

40.5673.728



Hole drilling

Drill using drill with scale 2.8/210**[40.5653.212]** until desired depth is reached.

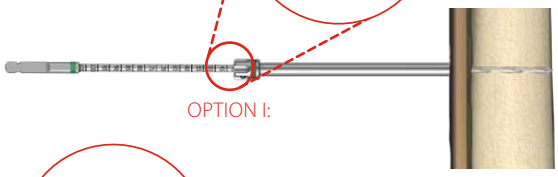
40.5653.212



Measurement of hole depth

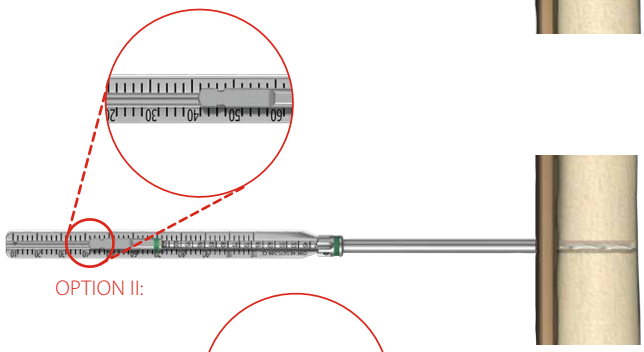
OPTION I: Read the length of the screw from the drill measure **[40.5653.212]**

40.5653.212



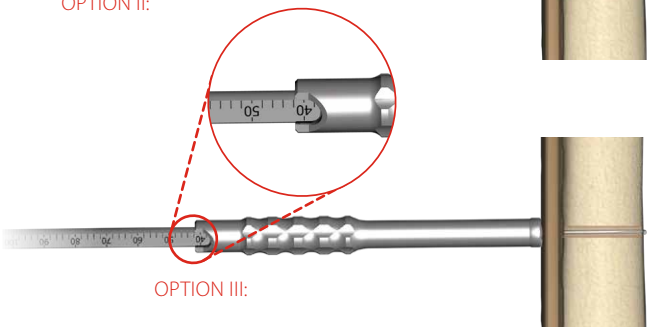
OPTION II: or use screw length measure **[40.5675.500]**.


40.5675.500



OPTION III: Having removed the guide sleeve 5.0/2.8 **[40.5673.728]**, use depth measure **[40.4639.550]** to determine the length of a screw.


40.4639.550

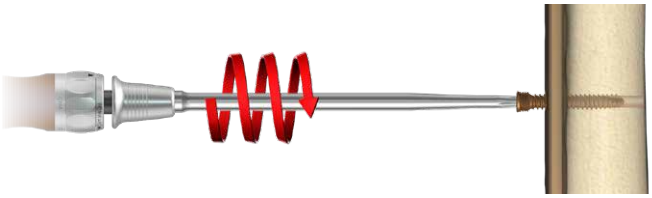


Screw insertion

Remove the guide sleeve 5.0/2.8 **[40.5673.728]**. Use torque limiting ratchet handle 2Nm **[40.6652.000]** and screwdriver tip T15 **[40.5677.000]** to insert the locking screw.


40.6652.000


40.5677.000



The final tightening of the locking screw, especially when a drive is used, should always be performed with the use of torque limiting handle. Failure to use the torque limiting handle may lead to intraoperative and postoperative complications *(during later removal of the plate and locking screws)*.

5. POSTOPERATIVE PROCEDURE

Introduce appropriate postoperative treatment. The physician decides on the post-operative treatment and its conduct. In order to avoid patient's movement limitations, introduce exercises as soon after surgery as possible. However, make sure that the limb is not fully loaded before fragments osteosynthesis is complete.

6. IMPLANT REMOVAL

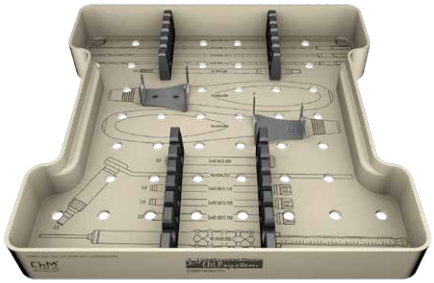
The physician decides about implant removal. In order to remove the implants from the body, unlock all the locking screws first and then remove them from the bone. This will prevent any rotation of the plate when removing the last locking screw.

Having cleaned the outer surface of the plate and the screws sockets, it is recommended to attach the aiming block to the plate. Using aiming block and protective sleeve ensures positioning of the screwdriver tip in the axis of the screw, its full placement in the recess, and reduces the risk of twisting the screw while removing.

7. CATALOGUE PAGES

7a. INSTRUMENT SET

Instrument set for 5.0ChLP 4x4 1/2H — 15.0205.201

	Name	Catalogue No.	Pcs
	Tray for 5.0ChLP instrument set 4x4 1/2H	**14.0205.201**	1
	Kirschner wire 1.5/210	**40.4592.210**	4
	Drill 1.8/210	**40.2063.212**	2
	Drill with scale 2.5/210	**40.5912.212**	2
	Drill with scale 2.8/210	**40.5653.212**	2
	Screwdriver tip T15	**40.5677.000**	1
	Torque limiting ratchet handle 2Nm	**40.6652.000**	1
	Handle ratchet device	**40.6654.000**	1
	Protective guide 7/5	**40.5672.000**	2
	Compression guide 2.5	**40.4804.725**	1
	Guide sleeve 5.0/1.8	**40.5673.718**	2
	Guide sleeve 5.0/2.8	**40.5673.728**	4
	Depth measure	**40.4639.550**	1

Instrument set for 5.0ChLP 4x4 1/2H

15.0205.202

	Name	Catalogue No.	Pcs
	Tray for 5.0ChLP instrument set 4x4 1/2H	**14.0205.202**	1
	Setting-compressing screw 2.8/180	**40.5674.728**	1
	Screw length measure	**40.5675.500**	1
	Plates bender 5.0	**40.4643.500**	2
	Tripod screwdriver tip 5.0ChLP	**40.6271.500**	1
	T15 screwdriver tip with holder	**40.6254.000**	1
	Cortical tap HA 3.5 with handle	**40.2548.200**	1
	Tap 5.0ChLP-3.5	**40.5661.000**	1
Optional instrument			
	Torque connector 2Nm	**40.5927.020**	1

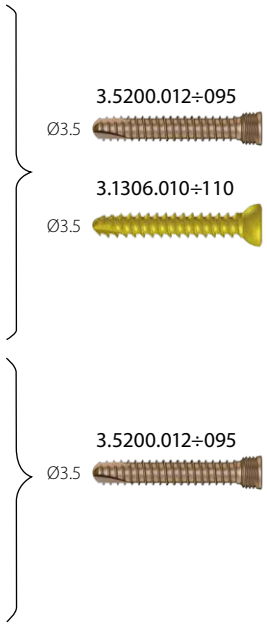
Ti

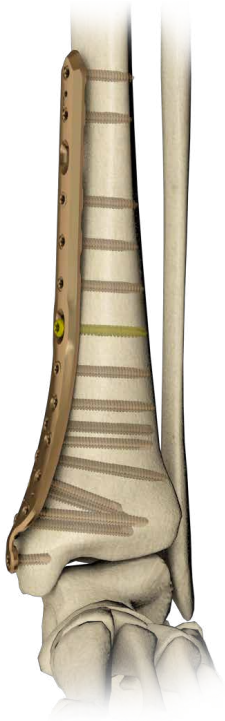
Ster Non Ster

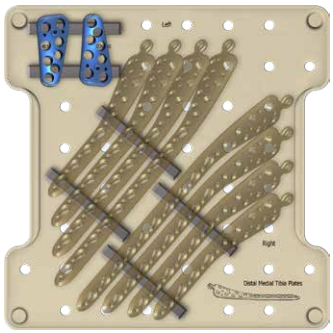
5.0ChLP tibial distal medial plate

*	Len	L	R
4	108	3.4039.604	3.4040.604
6	134	3.4039.606	3.4040.606
8	160	3.4039.608	3.4040.608
10	186	3.4039.610	3.4040.610
12	212	3.4039.612	3.4040.612
14	238	3.4039.614	3.4040.614
16	264	3.4039.616	3.4040.616

* holes number in shaft part of the plate







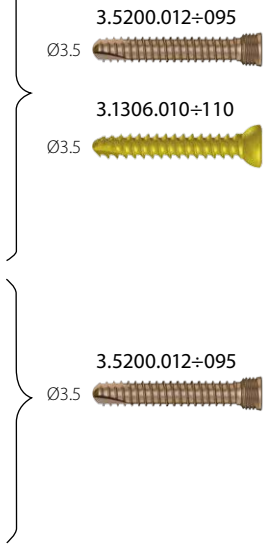
Tray for plates 5.0ChLP 3.4039/3.4040 4x4 1/2H	14.0205.415	Aiming block **[3.4039]**	40.5726.100	Plate 3.4039.608 trial	43.4039.608
		Aiming block **[3.4040]**	40.5726.200	Plate 3.4040.608 trial	43.4040.608

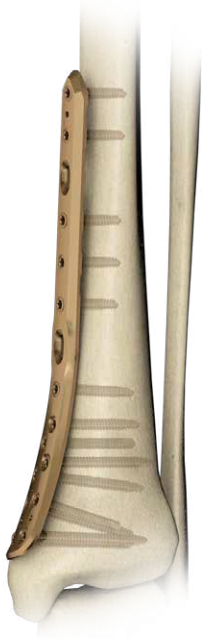
Ti Ster Non Ster

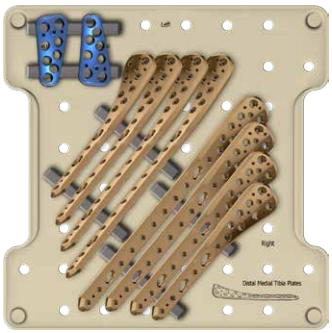
5.0ChLP tibial distal medial plate

*	Len	L	R
4	99	3.7019.604	3.7018.604
6	125	3.7019.606	3.7018.606
8	151	3.7019.608	3.7018.608
10	177	3.7019.610	3.7018.610
12	203	3.7019.612	3.7018.612
14	129	3.7019.614	3.7018.614
16	255	3.7019.616	3.7018.616

* holes number in shaft part of the plate







Tray for plates 5.0ChLP 3.7019/3.7018 4x4 1/2H	14.0205.425	Aiming block **[3.4039]**	40.5726.100
			40.5726.200

7c. SCREWS

Ti | Ster Non Ster

5.0ChLP self-tapping screw 3.5

Len	Ti
12	3.5200.012
14	3.5200.014
16	3.5200.016
18	3.5200.018
20	3.5200.020
22	3.5200.022
24	3.5200.024
26	3.5200.026
28	3.5200.028
30	3.5200.030
32	3.5200.032
34	3.5200.034
36	3.5200.036
38	3.5200.038
40	3.5200.040
42	3.5200.042
44	3.5200.044
46	3.5200.046
48	3.5200.048
50	3.5200.050
52	3.5200.052
54	3.5200.054
56	3.5200.056
58	3.5200.058
60	3.5200.060
65	3.5200.065
70	3.5200.070
75	3.5200.075
80	3.5200.080
85	3.5200.085

Cortical self-tapping screw 3.5

Len	Ti
10	3.1306.010
12	3.1306.012
14	3.1306.014
16	3.1306.016
18	3.1306.018
20	3.1306.020
22	3.1306.022
24	3.1306.024
26	3.1306.026
28	3.1306.028
30	3.1306.030
32	3.1306.032
34	3.1306.034
36	3.1306.036
38	3.1306.038
40	3.1306.040
45	3.1306.045
50	3.1306.050
55	3.1306.055
60	3.1306.060
65	3.1306.065
70	3.1306.070
75	3.1306.075
80	3.1306.080
85	3.1306.085

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