ST/21D-2

ChM®

OPENING WEDGE OSTEOTOMY

- *IMPLANTS*
- *INSTRUMENT SET 15.0207.001*
- *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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Document No ST/21D-2

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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

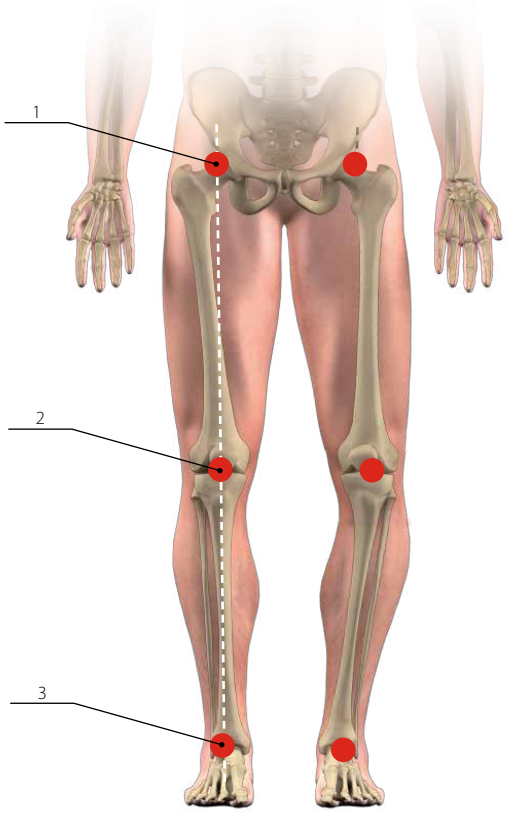
Instrument set for the correction of bone curvature with use of wedge-shaped incision consists of:

- implants (*wedge distance plates, screws*)
- instruments for bone incision and implants insertion
- Instructions for use.

The purpose of this treatment is to restore straightness of the lower limb.
The curved bone is incised and then the wedge distance plate, which maintains performed incision and required angle of correction, is implanted.

Straightness of the lower limb is defined by the line that is drawn between three characteristic points: the center of femoral head [**1**], the center of knee joint [**2**] and the center of distal tibia epiphysis [**3**]. If these 3 points cannot be connected by the straight line, the lower limb is considered curved.

The curved bone distributes unequal loads on the knee joint, which may cause its inflammation. Straightening the knee joint should restore equal distribution of knee loads. In the case of the knee inflammation, it is allowed to perform such correction, so the healthy side of the knee transfers greater loads.

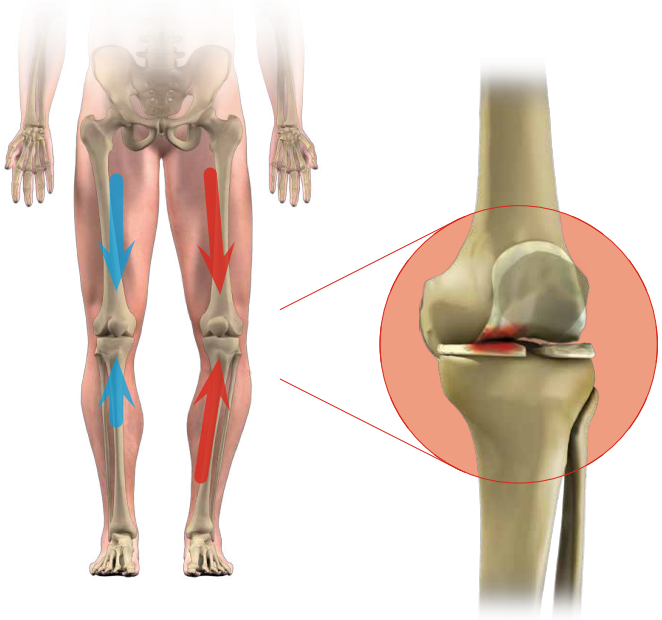


There are two methods of straightening the knee joint:

1. The closing wedge osteotomy
The surgeon performs a transverse incision of the tibia, or lateral or anterior incision of the femur (*it depends on the limb curvature*), removes the wedge piece of the bone, connects the open edges and unites the bone with a plate or staples.

2. The opening wedge osteotomy
The surgeon performs a transverse incision of the tibia, or lateral or anterior incision of the femur, then wedgely opens it and inserts: distance plate with wedge, or bone graft and distance plate without wedge, to hold the wedge opening.

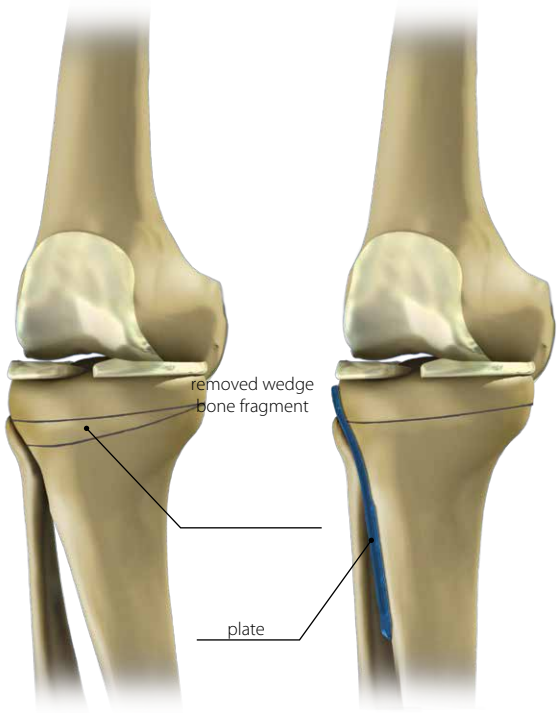
Each procedure of bone incision is called osteotomy.



1.1. THE CLOSING WEDGE OSTEOTOMY

The incision is made in the lateral or the anterior side of the knee to navigate the upper end of tibia or the lower end of the femur (*depending on the bone being corrected*). Muscles, nerves and blood vessels which pass through the knee joint should be protected from damaging.
After exposing the bone, perform two wedge-shaped osteotomies. Use the X-Rays or fluoroscopy to make sure the wedge is of proper size and is placed correctly.
Remove the wedge and connect both sides of the bone with metal plate or staples. The procedure changes the bone angle and helps to restore the alignment of knee axis.
Having connected the both edges of the bone with plate or staples, suture the skin and place the leg in the padded splint to protect the knee join.

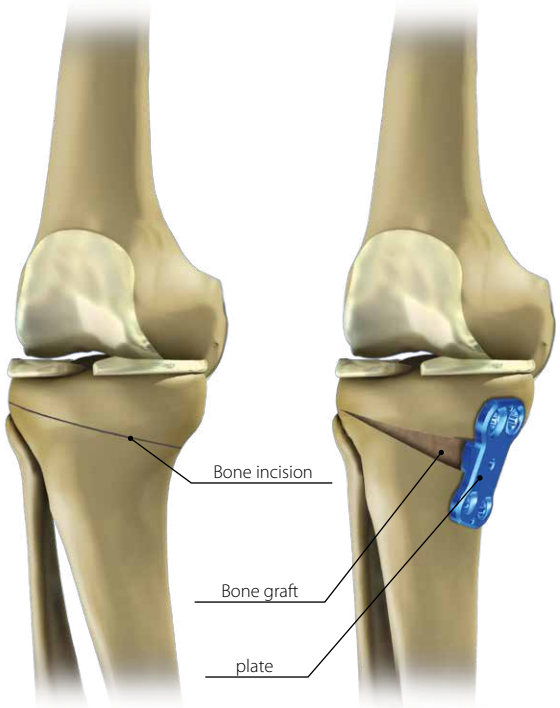
Surgical treatment should involve a minimum amount of pain and scarring.



1.2. THE OPENING WEDGE OSTEOTOMY

The opening method involves the lateral or anterior incision of the knee. Muscles, nerves and blood vessels which pass through the knee joint should be protected from damaging.
After exposing the bone, perform a single incision. Use the X-Rays or fluoroscopy to make sure the wedge is placed correctly.
Separate the both sides of incised bone in order to form the wedge-shaped opening and then fill it in with selected wedge distance plate or bone graft and distance plate without wedge, to hold the wedge opening. The bone graft is usually harvested from the pelvis and is held in place by the metal plate or staples.
Having connected the both edges of the bone with plate or staples, suture the skin and place the leg in the padded splint to protect the knee join.

Surgical treatment should involve a minimum amount of pain and scarring.

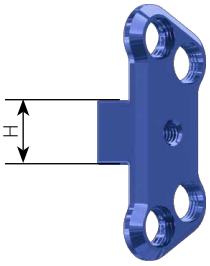


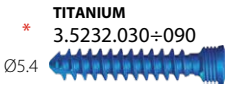
2. IMPLANTS

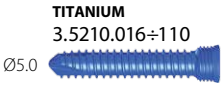
2.1. WEDGE DISTANCE PLATES

7.0ChLP tibial plate A/P

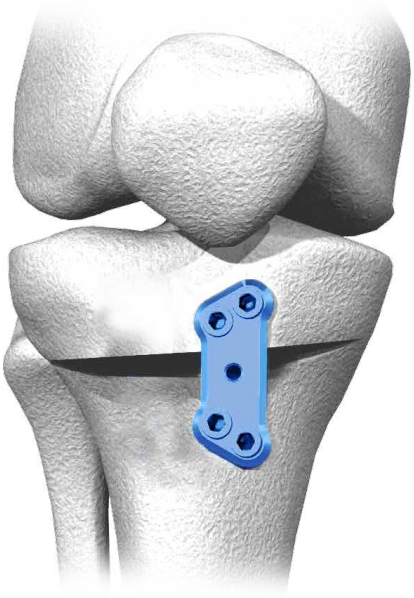
H [mm]	TITANIUM
3	3.3535.030
5	3.3535.050
7	3.3535.070
7.5	3.3535.075
9	3.3535.090
10	3.3535.100
11	3.3535.110
12.5	3.3535.125
15	3.3535.150
17.5	3.3535.175

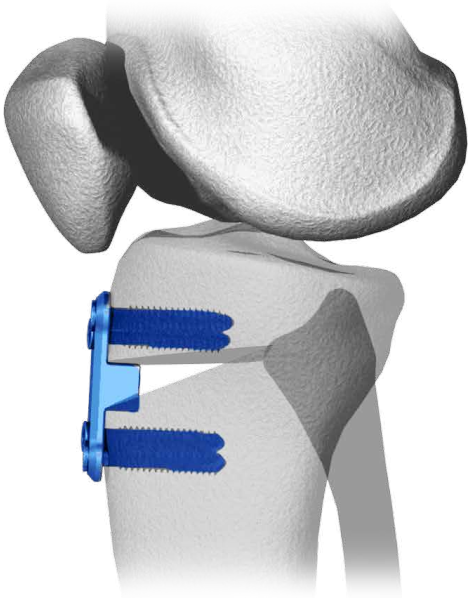






*Cancellous





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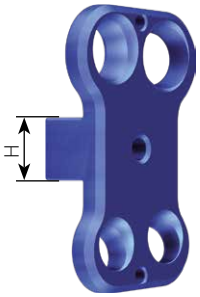
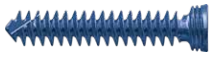
7.0ChLP distance tibial plate

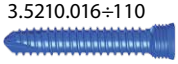
	Left	Right
H [mm]	TITANIUM	
3	3.7065.030	3.7066.030
5	3.7065.050	3.7066.050
7.5	3.7065.075	3.7066.075
9	3.7065.090	3.7066.090
10	3.7065.100	3.7066.100
11	3.7065.110	3.7066.110
12.5	3.7065.125	3.7066.125
15	3.7065.150	3.7066.150
17.5	3.7065.175	3.7066.175



TITANIUM
* 3.5228.030÷095
Ø6.5

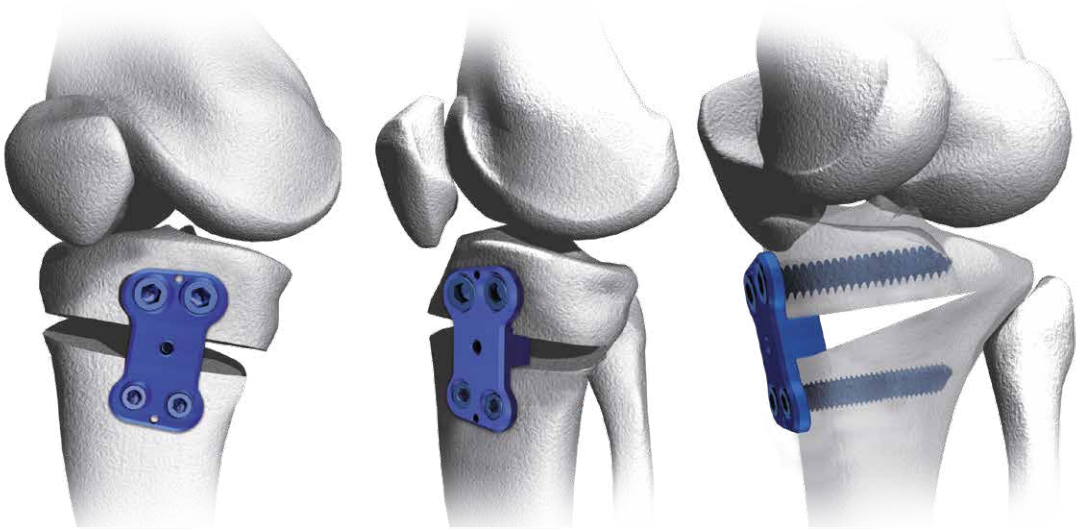


TITANIUM
3.5210.016÷110
Ø5.0



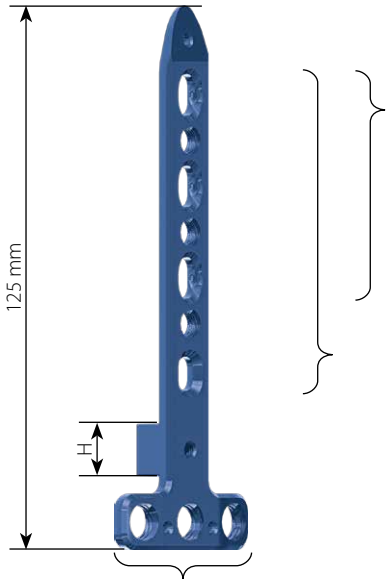
*Cancellous

L R

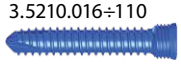


7.0ChLP distance femoral plate

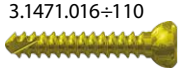
H [mm]	TITANIUM
3	3.3538.503
5	3.3538.505
7.5	3.3538.507
9	3.3538.509
10	3.3538.510
11	3.3538.511
12.5	3.3538.512
15	3.3538.515
17.5	3.3538.517



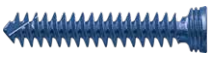
Titanium
3.5210.016÷110
Ø5.0



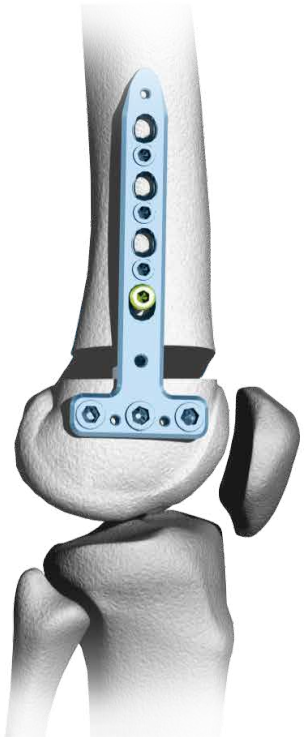
Titanium
3.1471.016÷110
Ø4.5

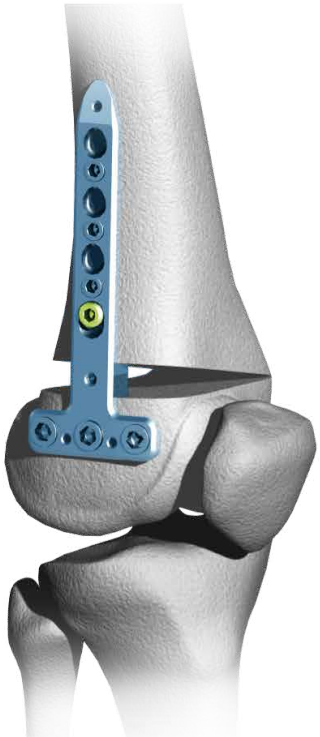


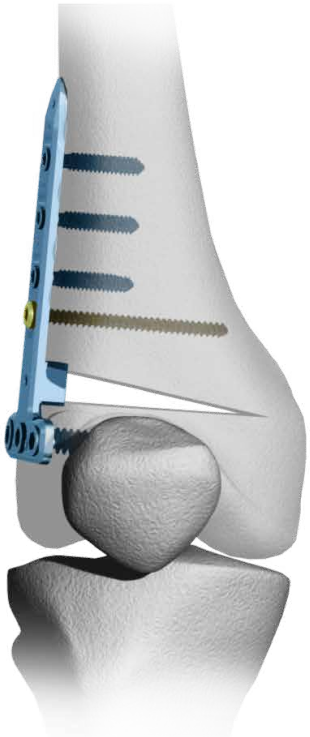
Titanium
* 3.5228.030÷095
Ø6.5



*Cancellous







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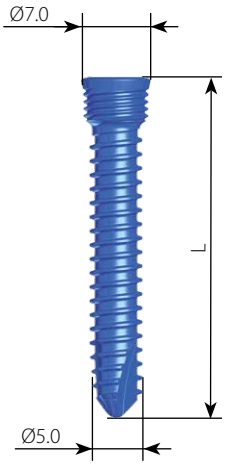
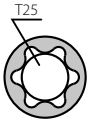
2.2. SCREWS

7.0 ChM Locked Plating ChLPsystem

7.0ChLP screw 5.0

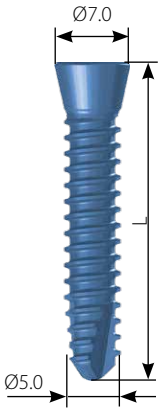


self-tapping

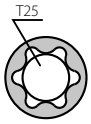


L [mm]	TITANIUM
16	3.5210.016
18	3.5210.018
20	3.5210.020
22	3.5210.022
24	3.5210.024
26	3.5210.026
28	3.5210.028
30	3.5210.030
32	3.5210.032
34	3.5210.034
36	3.5210.036
38	3.5210.038
40	3.5210.040
42	3.5210.042
44	3.5210.044
46	3.5210.046
48	3.5210.048
50	3.5210.050
52	3.5210.052
54	3.5210.054
56	3.5210.056
58	3.5210.058
60	3.5210.060
65	3.5210.065
70	3.5210.070
75	3.5210.075
80	3.5210.080
85	3.5210.085
90	3.5210.090
95	3.5210.095
100	3.5210.100
105	3.5210.105
110	3.5210.110

7.0ChLP conical self-tapping screw 5.0



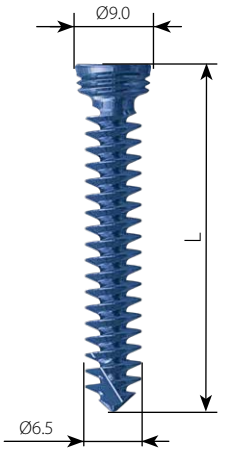
self-tapping



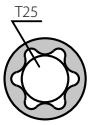
L [mm]	TITANIUM
30	3.5216.030
35	3.5216.035
40	3.5216.040
45	3.5216.045
50	3.5216.050
55	3.5216.055
60	3.5216.060
65	3.5216.065
70	3.5216.070
75	3.5216.075
80	3.5216.080
85	3.5216.085
90	3.5216.090

Ø core		**4.0**
Ø drill with scale	40.5651.212	**4.0**
guide sleeve	40.5705.840	**7.0/4.0**
screwdriver tip	40.5684.200	**T25**

7.0ChLP cancellous screw 6.5



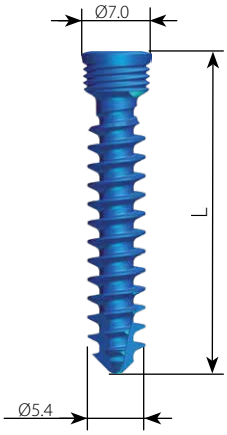
self-tapping



L [mm]	TITANIUM
30	3.5228.030
35	3.5228.035
40	3.5228.040
45	3.5228.045
50	3.5228.050
55	3.5228.055
60	3.5228.060
65	3.5228.065
70	3.5228.070
75	3.5228.075
80	3.5228.080
85	3.5228.085
90	3.5228.090
95	3.5228.095

Ø core		**3.0**
Ø drill with scale	40.5650.212	**3.2**
guide sleeve	40.5707.832	**3.2**
screwdriver tip	40.5685.200	**T30**

7.0ChLP cancellous screw 5.4



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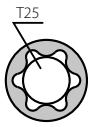
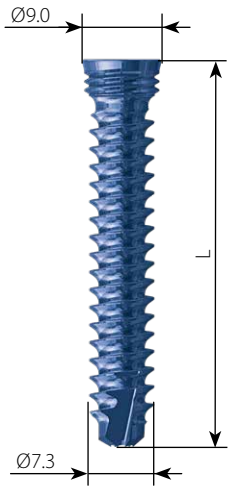


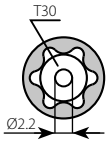
L [mm]	TITANIUM
30	3.5232.030
35	3.5232.035
40	3.5232.040
45	3.5232.045
50	3.5232.050
55	3.5232.055
60	3.5232.060
65	3.5232.065
70	3.5232.070
75	3.5232.075
80	3.5232.080
85	3.5232.085
90	3.5232.090

Ø core		**3.2**
Ø drill with scale	40.5650.212	**3.2**
guide sleeve	40.5707.832	**3.2**
screwdriver tip	40.5684.200	**T25**

7.0ChLP cannulated screw 7.3

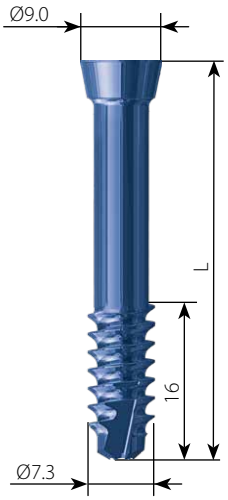


samowiercący
self-drilling
самосверлящий

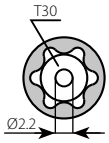


L [mm]	TITANIUM
30	3.5221.030
35	3.5221.035
40	3.5221.040
45	3.5221.045
50	3.5221.050
55	3.5221.055
60	3.5221.060
65	3.5221.065
70	3.5221.070
75	3.5221.075
80	3.5221.080
85	3.5221.085
90	3.5221.090
95	3.5221.095
100	3.5221.100

7.0ChLP conical cannulated screw 7.3



samowiercący
self-drilling
самосверлящий



L [mm]	TITANIUM
30	3.5224.030
35	3.5224.035
40	3.5224.040
45	3.5224.045
50	3.5224.050
55	3.5224.055
60	3.5224.060
65	3.5224.065
70	3.5224.070
75	3.5224.075
80	3.5224.080
85	3.5224.085
90	3.5224.090
95	3.5224.095

Ø core		**5.2**
Ø Kirschner wire	40.4815.210	**2.0**
guide sleeve	40.5654.120/**850**	**5.0/2.0**
Ø drill with scale	40.5652.212	**5.0/2.0**
screwdriver tip	40.5685.200	**T30**

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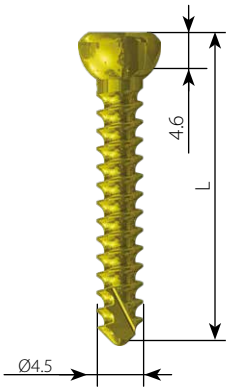
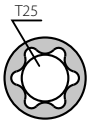
Cortical screw 4.5

7,0 ChM Locked Plating ChLP system




self-tapping

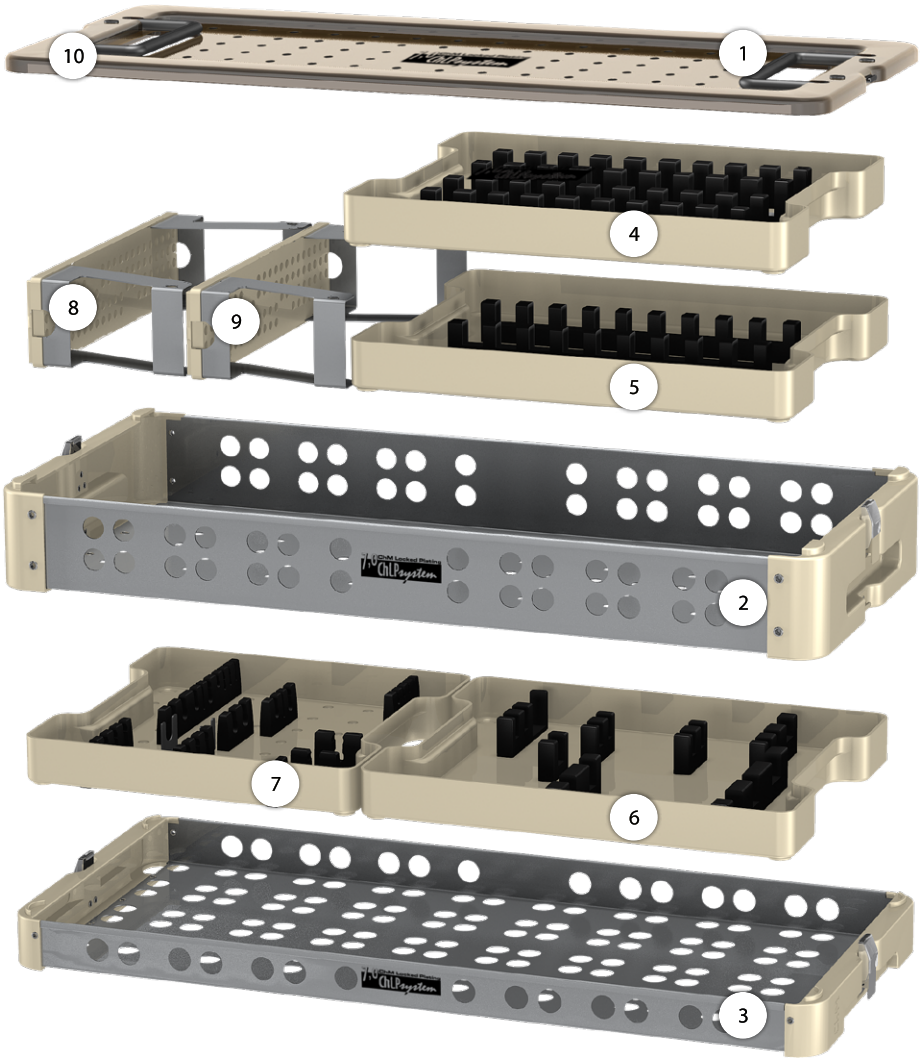


L [mm]	TITANIUM
16	3.1471.016
18	3.1471.018
20	3.1471.020
22	3.1471.022
24	3.1471.024
26	3.1471.026
28	3.1471.028
30	3.1471.030
32	3.1471.032
34	3.1471.034
36	3.1471.036
38	3.1471.038
40	3.1471.040
42	3.1471.042
44	3.1471.044
46	3.1471.046
48	3.1471.048
50	3.1471.050
52	3.1471.052
54	3.1471.054
56	3.1471.056
58	3.1471.058
60	3.1471.060
62	3.1471.062
64	3.1471.064
66	3.1471.066
68	3.1471.068
70	3.1471.070
72	3.1471.072
74	3.1471.074
76	3.1471.076
78	3.1471.078
80	3.1471.080
85	3.1471.085
90	3.1471.090
95	3.1471.095
100	3.1471.100
105	3.1471.105
110	3.1471.110

Ø core		**3.2**
Ø drill with scale	40.5650.212	**3.2**
compression guide	40.4802.732	**3.2**
screwdriver tip	40.5684.200	**T25**

3. INSTRUMENT SET

Set for 7.0ChLP osteotomy - modular set 15.0207.001



No.	Name	Catalogue no.	Pcs
1	Container lid for **7.0ChLP** osteotomy 9x4H	14.0207.109	1
2	Container for **7.0ChLP** osteotomy 9x4H	14.0207.107	1
3	Container for **7.0ChLP** osteotomy 9x4 1/2H	14.0207.108	1
4	Tray for **7.0ChLP** osteotomy plates 5x4 1/2H	14.0207.410	1
5	Tray for **7.0ChLP** osteotomy plates 5x4 1/2H	14.0207.411	1
6	Instrument set for **7.0ChLP** osteotomy 5x4 1/2H	15.0207.206	1
7	Instrument set for **7.0ChLP** 4x4 1/2H	15.0207.209	1
8	Stand for **7.0ChLP** screws 4x2H	14.0207.504	1
9	Stand for **7.0ChLP** screws 4x2H	14.0207.505	1
10	Guide pin with eyelet	40.3943.100	1

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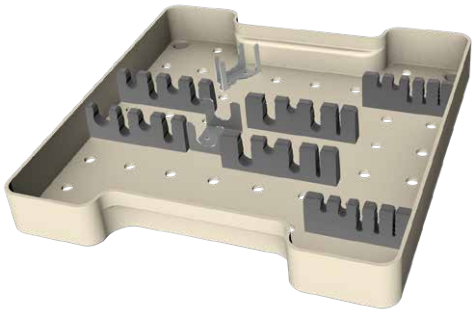
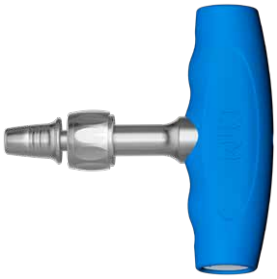
Instrument set for 7.0ChLP 4x4 1/2H

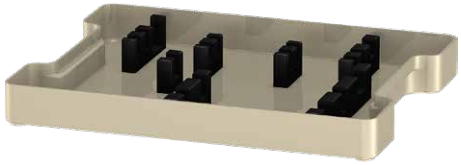
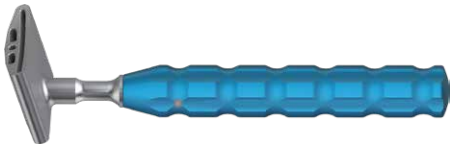
15.0207.209

	Name	Catalogue no.	Pcs.
	Tray for **7.0ChLP** instrument set 4x4 1/2H	14.0207.208	1
	Kirschner wire 2.0/210	40.4815.210	4
	Drill with scale 3.2/210	40.5650.212	2
	Drill with scale 4.0/210	40.5651.212	2
	Cannulated drill with scale 5.0/2.2/210	40.5652.212	1
	Guide VA 4.0	40.8207.040	1
	Guide sleeve 7.0/4.0	40.5705.840	2
	Guide sleeve 7.0/3.2	40.5705.832	2
	Guide sleeve 9/5.0	40.5654.850	1
	Guide sleeve 5.0/2.0	40.5654.120	1
	Guide sleeve 9.0/3.2	40.5707.832	1
	Torque limiting ratchet handle T 4Nm	40.6660.000	1
	Screwdriver tip T25-1/4	40.5684.200	1
	Cannulated screwdriver tip T30-1/4	40.5685.200	1
	Depth measure	40.4639.550	1

Optional instrument			
	Torque connector 4Nm	40.5927.040	0

Instrument set for 7.0ChLP 5x4 1/2H

15.0207.206

	Name	Catalogue no.	Pcs
	Tray for **7.0ChLP** instrument set 4x4 1/2H	**14.0207.206**	1
	Osteotome 25	**40.5361.000**	1
	Osteotome 35	**40.5362.000**	1
	Targeter for osteotomy	**40.3974.200**	1
	Instrument set for osteotomy	**40.5360.000**	1
	Reamer 16°	**40.5357.016**	2
	Reamer 20°	**40.5357.020**	2
	Applicator	**40.5369.000**	1

In addition, to perform the surgery, the following devices are needed which should be available in the orthopaedic operating theatre, such as:
- the electric drive,
- surgery hammers,
- and other (*pliers, a saw*).

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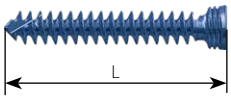
7,0 ChM Locked Plating ChLPsystem

Stand for 7.0ChLP screws 4x2 H

14.0207.504

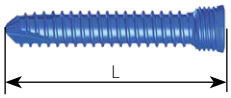
7.0ChLP cancellous screw Ø6.5



3.5228.0xx

L [mm]	30	35	40	45	50	55	60	65	70	75	80	85	90	95
Pcs	1	1	1	1	1	1	1	1	1	1	1	1	1	1

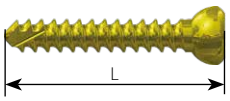
7.0ChLP screw Ø5.0



3.5210.0xx

L [mm]	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54
Pcs	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
L [mm]	56	58	60	65	70	75	80	85	90	95								
Pcs	1	1	1	1	1	1	1	1	1	1								

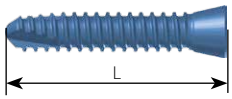
Cortical screw Ø4.5



3.1471.0xx

L [mm]	40	42	44	46	48	50	52	54	56	58	60	65	70	75	80	85	90	95
Pcs	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

7,0ChLP conical self - tapping screw Ø5.0



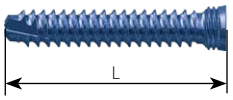
3.5216.0xx

L [mm]	28	30	35	40	45	50	55	60	65	70	75	80	85	90	95
Pcs	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

Stand for 7.0ChLP screws 4x2 H

14.0207.505

7.0ChLP cannulated screw Ø7.3



3.5221.0xx

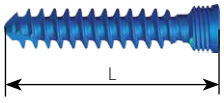
L [mm]	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Pcs	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

7.0ChLP conical cannulated screw Ø7.3

3.5224.xxx

L [mm]	30	35	40	45	50	55	60	65	70	75	80	85	90	95
Pcs	2	2	2	2	2	2	2	2	2	2	2	2	2	2

7.0ChLP cancellous screw Ø5.4

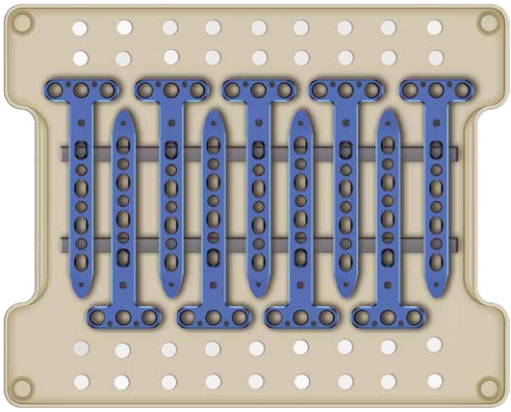


3.5232.0xx

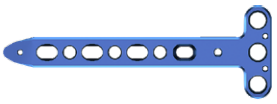
L [mm]	35	40	45	50	55	60	65	70	75	80
Pcs	2	2	2	2	2	2	2	2	2	2

Tray for 7.0ChLP osteotomy plates 5x4 1/2H

14.0207.411



7.0ChLP distance femur plate

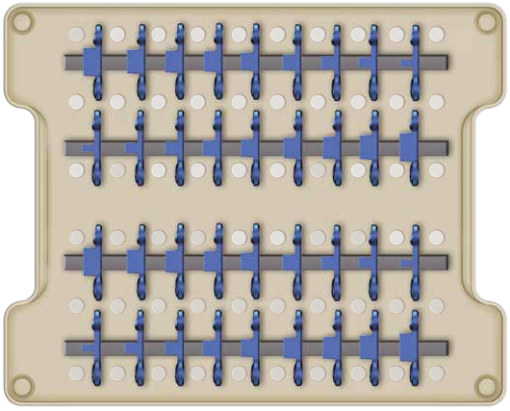


Catalogue No.	3.3538.503 ÷ 3.3538.517
Pcs	9

* Tray does not include implants

Tray for 7.0ChLP osteotomy plates 5x4 1/2H

14.0207.410



7.0ChLP distance tibial plate

Catalogue No.	3.7065.030 ÷ 3.7065.175
Pcs	18

7.0ChLP distance tibial plate

Catalogue No.	3.7066.030 ÷ 3.7066.175
Pcs	18

* Tray does not include implants

In addition, to perform the surgery, the following devices are needed which should be available in the orthopaedic operating theatre:

- electric drive,
- surgery hammers,
- other (*pliers, saw, etc.*).

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4. SURGICAL TECHNIQUE - TIBIA

4.1. INTRODUCTION

Each procedure of bone curvature correction by means of wedge incision has to be carefully planned.

Wedge distance plates [**Fig.1**] are used for connecting the incised bone in the opening method, while distance plates without wedge or staples [**Fig. 2**] are used in the closing method.

The decision regarding the method of bone curvature correction and the implants to be used is taken by the surgeon on the basis of the size and type of curvature and the correction to be achieved.

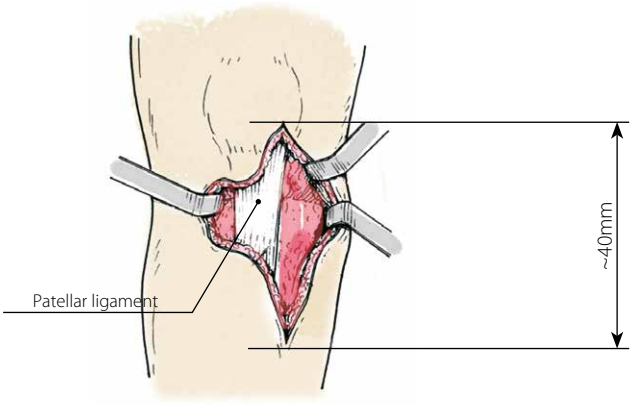
A procedure of tibia curvature correction by means of opening wedge osteotomy with use of wedge distance plate is presented below.

Figure 1
Opening wedge osteotomy with wedge distance plate.

Figure 2
Closing wedge osteotomy with staples.

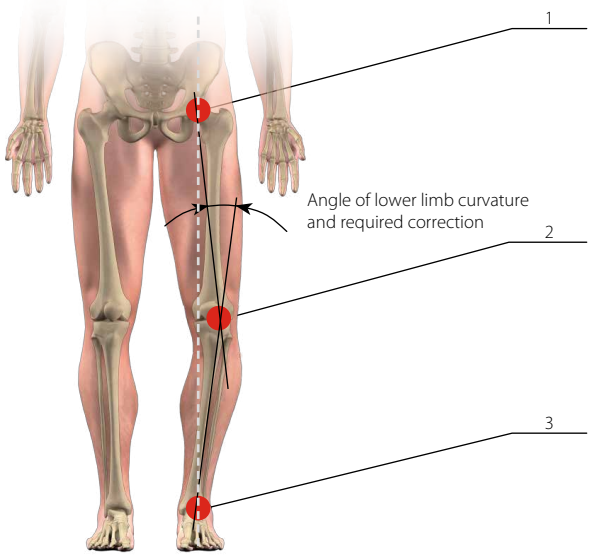
4.2. INCISION TO ACCESS TIBIA

Make the incision of the skin and tissues approximately 40mm in length in the median part of the knee, along the patellar ligament. Make sure not to damage the nerves, tendons and blood vessels that run through the knee joint.



4.3. ESTABLISHING THE CORRECTION ANGLE AND THE HEIGHT OF OPENING

The lower limb curvature angle and the necessary height of opening for correction of the curvature are to be determined on the basis of the X-Ray or fluoroscopy images. The curvature angle of a lower limb should be established by drawing two straight lines: one passing through the center of the femur head [**1**] and the center of the knee joint [**2**], the other passing through the center of the distal epiphysis of tibia [**3**] and the center of the knee joint [**2**]. Curvature and correction angles should be measured between the intersecting lines, as presented in the picture below.



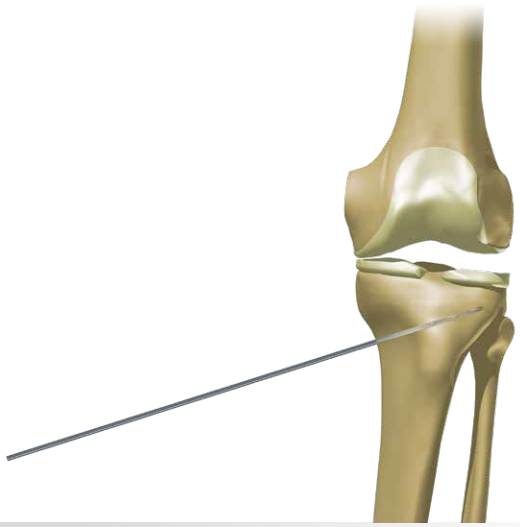
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

4.4. INSERTION OF GUIDE PIN WITH EYELET

Insert the guide pin with eyelet [**40.3943.100**] into exposed upper part of the tibia using an electric drive. The appropriate position of the pin is to be chosen by surgeon.

The blade of the guide pin [**40.3943.100**] should be placed about 10mm from the lateral cortex.

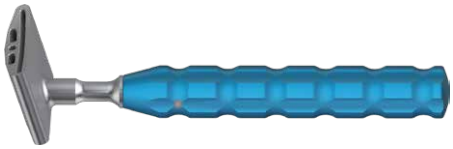
40.3943.100


4.4.

4.5. MOUNTING THE TARGETER FOR OSTEOTOMY ON THE GUIDE PIN

After inserting the guide pin [**40.3943.100**], mount the targeter for osteotomy [**40.3974.200**] on the pin.

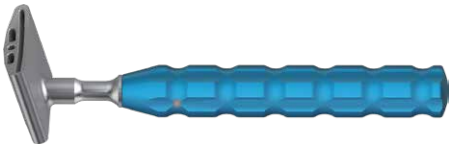
40.3943.100


40.3974.200

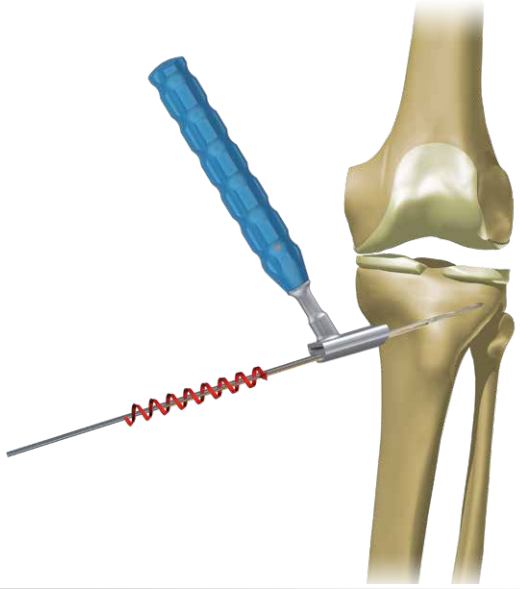

4.5.

4.6. INTRODUCTION OF KIRSCHNER WIRES

In order to establish the position of the targeter perpendicularly to the bone, insert the Kirscher wires [**40.4815.210**] through the holes of the targeter [**40.3974.200**] with the use of the electric drive.


40.3974.200

40.4815.210


4.6.

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

4.7. PREPARATION FOR BONE INCISION

Remove the guide pin [**40.3943.100**] from the bone, then bend the Kirscher wires [**40.4815.210**] so they do not hamper further procedures.

40.3943.100

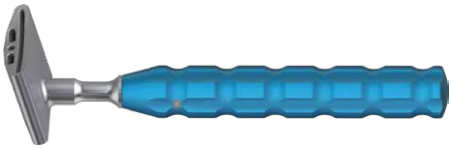
40.4815.210


4.7.

4.8. INITIAL INCISION WITH THE SAW AND FINAL WITH OSTEOTOME

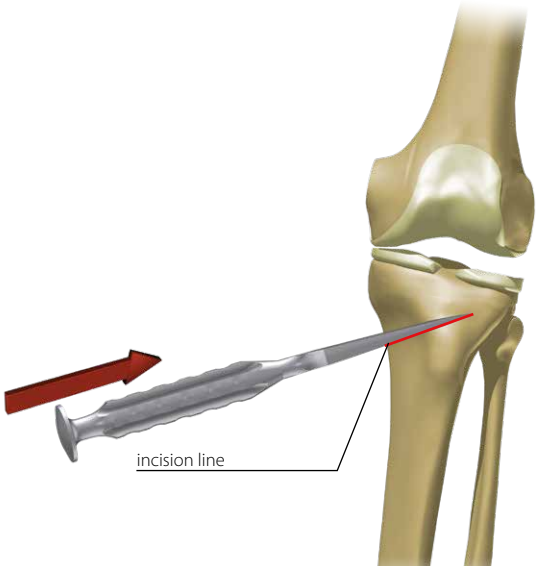
Perform the initial incision of the tibia with the saw by utilizing the slit in the targeter [**40.3974.200**].

After performing the initial incision with the saw, remove the targeter and Kirscher wires.
Then use an osteotome with blade of appropriate width [**40.5361.000; 40.5362.000**] to incise the bone. The osteotome should be carefully hit with a hammer, e.g. of *Bergman* type.


40.3974.200


40.5361

40.5362



4.8.

4.9. WEDGE OPENING WITH THE INSTRUMENT SET FOR OSTEOTOMY

Enter the appropriate instrument set for osteotomy [**40.5360.000**] with correctly chosen bone reamer in the incision, as described below:

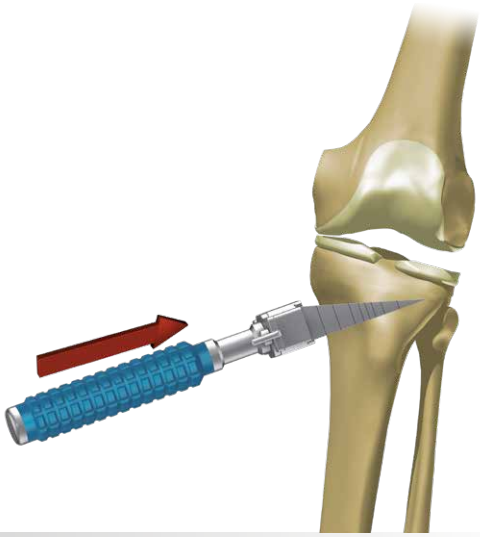
- [**40.5357.016**] - for smaller bones
- [**40.5357.020**] - for larger bones

at the length that matches the previously established height of the opening, which is marked on the upper, inclined surface of the reamers. It is permitted to carefully hit the inserted instrument set with a hammer, e.g. of *Bergman* type.

40.5360

40.5357.016

40.5357.020

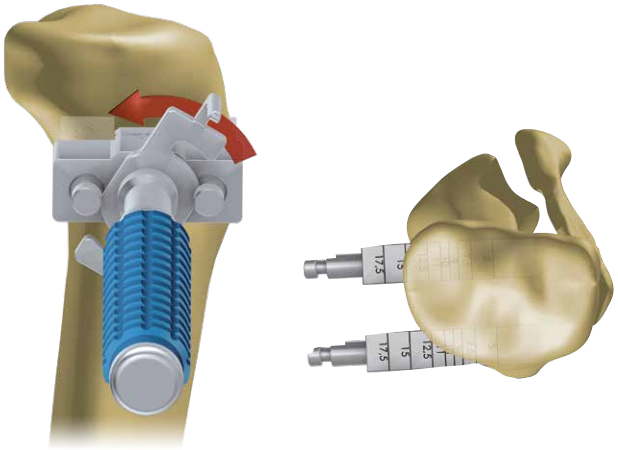


4.9.

4.10. CONTROL OF CORRECTION ANGLE AND THE HEIGHT OF WEDGE BONE OPENING

In order to check the correction angle and related wedge opening, it is necessary to use X-Ray or fluoroscopy imaging to assure the height of prepared wedge opening allows for achieving the selected correction angles and the height of the wedge bone opening.

If the fluoroscope is used that casts the images on the fluorescent screen, it is recommended to repeatedly verify the consecutive steps of the surgery.



4.11.

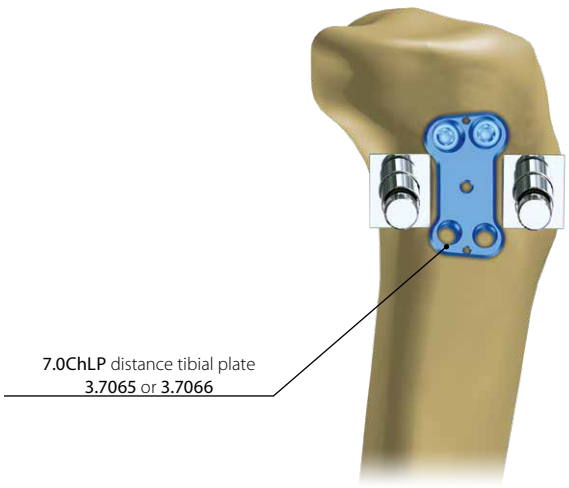
4.11. REMOVAL OF GRASPING PART OF THE SET AND CONTROL OF OPENING CORRECTNESS

To allow access to the place where a plate of appropriate size is to be placed, it is necessary to dismantle the grasping part of the instrument set for osteotomy [**40.5360.000**] in such a manner that only two reamers remain in the bone, either [**40.5357.020**] or [**40.5357.016**].

40.5360

40.5357.016

40.5357.020



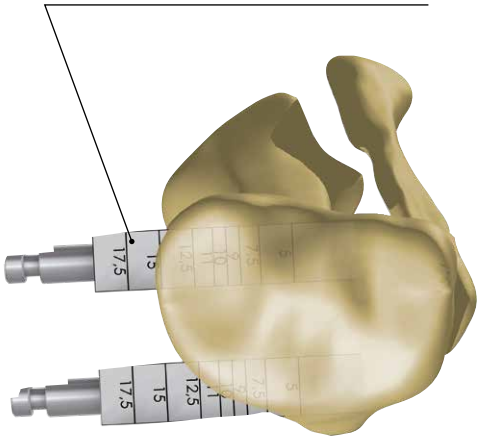
4.12.

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

4.12. SELECTION AND INSERTION OF WEDGE DISTANCE PLATE

The height of the plate wedge should be selected on the basis of the values provided on the upper, inclined surfaces of the reamers. After selecting the plate, use the applicator [**40.5369.000**] to insert the wedge of the plate into the wedge opening in the bone, between the reamers.

40.5369



4.12A. INSERTION OF SCREWS USED FOR MOUNTING THE WEDGE DISTANCE PLATE

Use the cancellous screws to install the plate in the upper part (*which is closer to the joint*); remove the reamers. For the lower part of the plate (*which is further from the joint*), use the locking screws. Torque limiting ratchet handle T 4Nm [**40.6660.000**] and screwdriver tip T 25-1/4 [**40.5684.200**] should be used for screws insertion. Afterwards, use X-Rays or a fluoroscope to verify the bone curvature correction. A straight line through the 3 characteristic points mentioned above should be possible to draw.

40.6660

40.5684.200

4.12A.

It is vital to drill precisely in the axis of the locking hole. An appropriate guide sleeve should always be used for drilling. It ensures an axial positioning of the locking screw in relation to the plate hole and its correct locking in the plate. Preparation of a hole with the use of free-hand technique may lead to: cross-threading and screw jamming, inappropriate locking and further problems during the removal of the screws (*seizing of the screw*).

4.12A.1. Insertion of a cancellous screw

Insertion of a guide sleeve

Insert the guide sleeve 9.0/3.2 [**40.5707.832**] into the plate.

Hole drilling

Drill a hole of a desired depth with the use of a drill with scale 3.2/210 [**40.5650.212**].

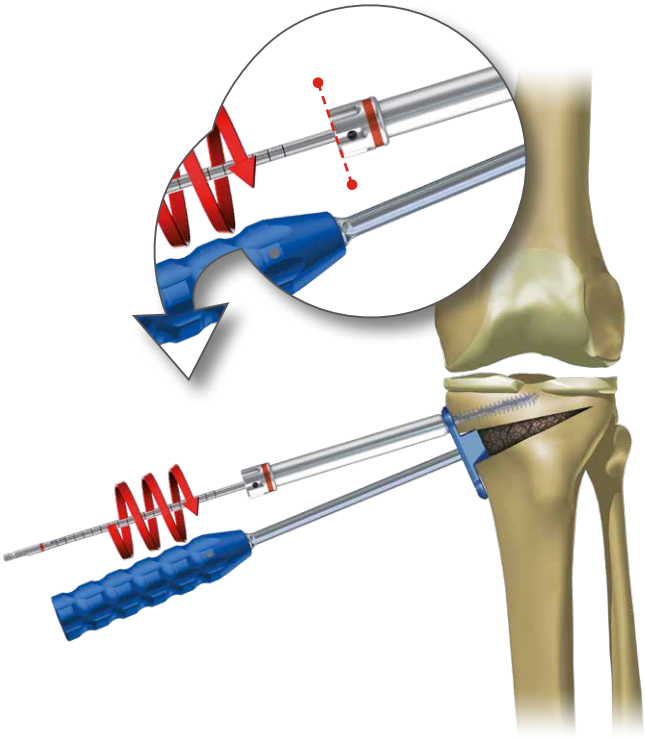
Measurement of the hole depth

OPTION I: Read the value from the scale on the drill [**40.5651.222**].


40.5707.832


40.5650.212

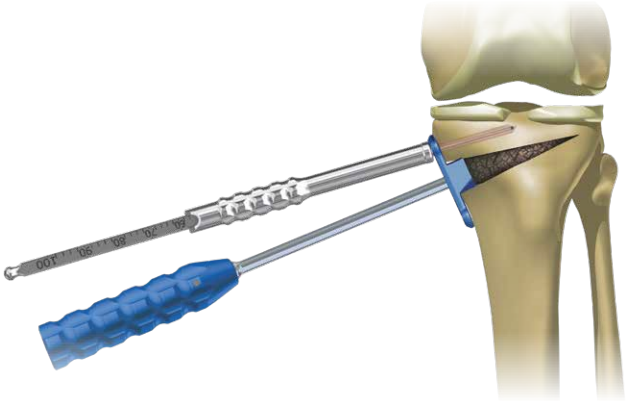

40.5650.212



OPTION II: Remove the guide sleeve 9.0/3.2 [**40.5707.832**] and use the depth measure [**40.4639.550**] to determine the screw length.

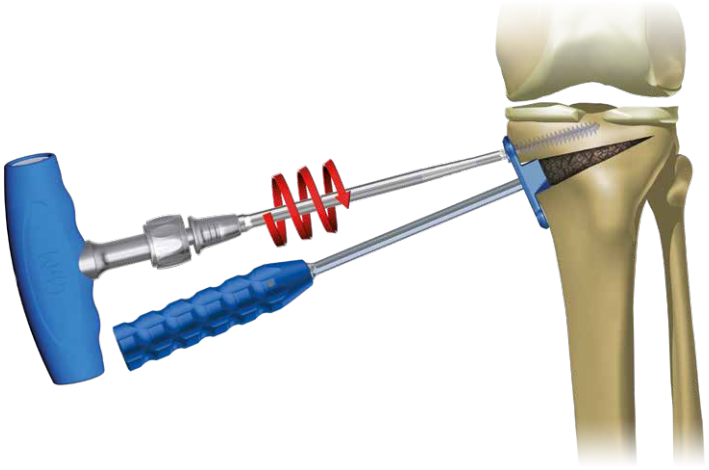

40.5707.832


40.4639.550



Insert the cancellous screw with the use of torque limiting ratchet handle T 4Nm [**40.6660.000**] and an appropriate screwdriver tip.


40.6660



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

4.12A.2. Insertion of 5.0 locking screw

Insertion of a guide sleeve

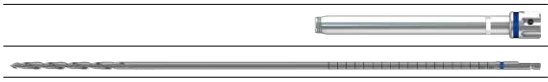
Insert the guide sleeve 7.0/4.0 [**40.5705.840**] into the plate.

Hole drilling

Drill a hole of a desired depth with the use of a drill with scale 4.0/210 [**40.5651.212**].

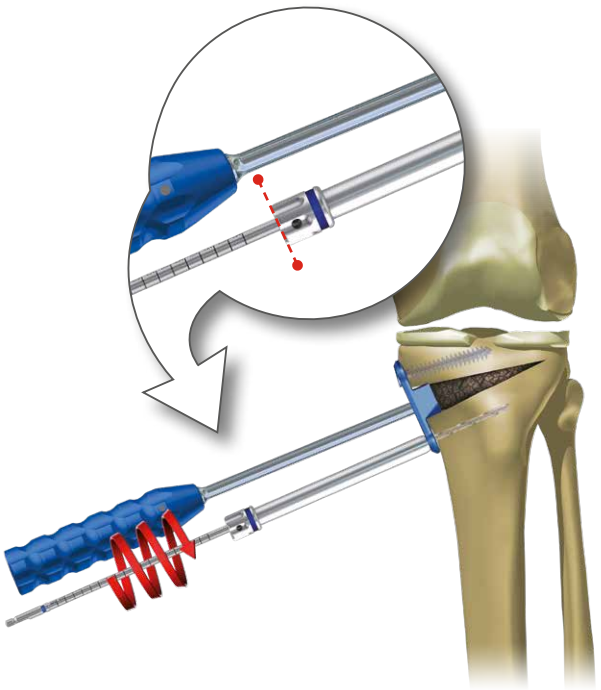
Measurement of the hole depth

OPTION I: Read the value from the scale on the drill [**40.5651.222**].

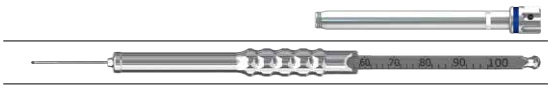


40.5705.840

40.5651.212

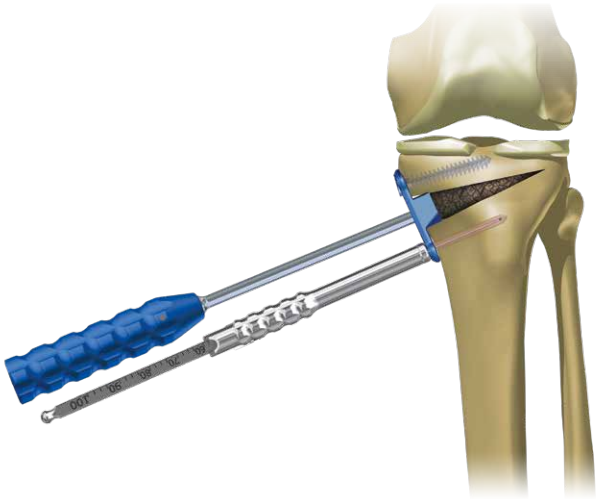


OPTION II: Remove the guide sleeve 7.0/4.0 [**40.5705.840**] and use the depth measure [**40.4639.550**] to determine the screw length.

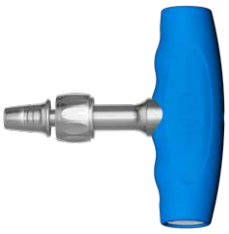


40.5705.840

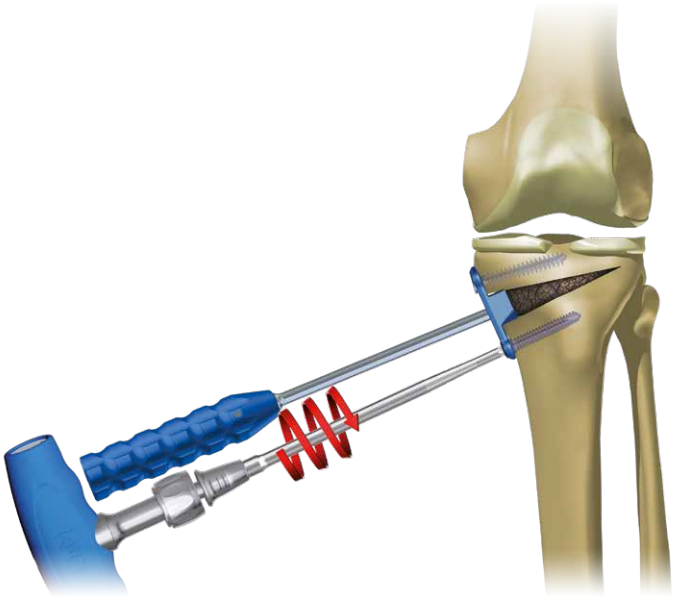
40.4639.550



Insert the locking screw 5.0 with the use of torque limiting ratchet handle T 4Nm [**40.6660.000**] and an appropriate screwdriver tip.



40.6660



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

5. SURGICAL TECHNIQUE - FEMUR

5.1. INTRODUCTION

Each procedure of bone curvature correction by means of wedge incision has to be carefully planned.

Wedge distance plates [**Fig.1**] or distance plates without wedge are used for connecting the incised bone in the opening method, while distance plates without wedge [**Fig. 2**] are used in the closing method.

The decision regarding the method of bone curvature correction and the implants to be used is taken by the surgeon on the basis of the size and type of curvature and the correction to be achieved.

A procedure of femur curvature correction by means of opening wedge osteotomy with use of wedge distance plate is presented below.

Figure 1
The opening wedge osteotomy with the wedge distance plate

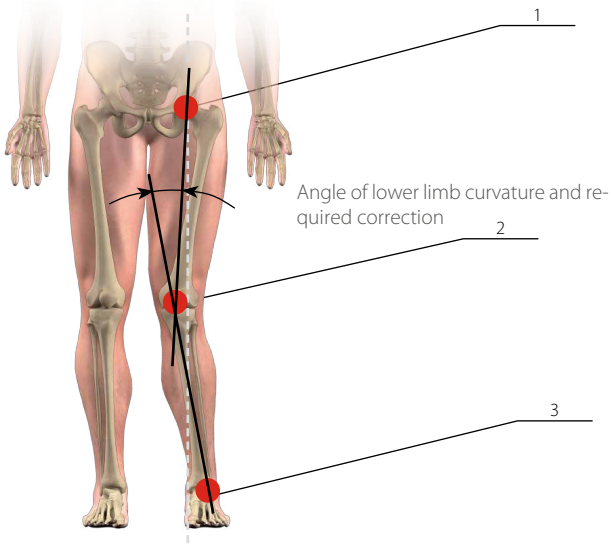
Figure 2
The opening wedge osteotomy with the distance plate without wedge

5.2. INCISION TO ACCESS THE FEMUR

Make the incision of the skin and tissues approximately 80mm in length on the fibular side, above the fibular collateral ligament (*LCL*). Make sure not to damage the nerves, tendons and blood vessels that run through the knee joint.

5.3. ESTABLISHING THE CORRECTION ANGLE AND THE HEIGHT OF OPENING

The lower limb curvature angle and the necessary height of opening for correction of the curvature are to be determined on the basis of the X-Ray or fluoroscopy images. The curvature angle of a lower limb should be established by drawing two straight lines: one passing through the center of the femur head [**1**] and the center of the knee joint [**2**], the other passing through the center of the distal epiphysis of tibia [**3**] and the center of the knee joint [**2**]. Curvature and correction angles should be measured between the intersecting lines, as presented in the picture below.



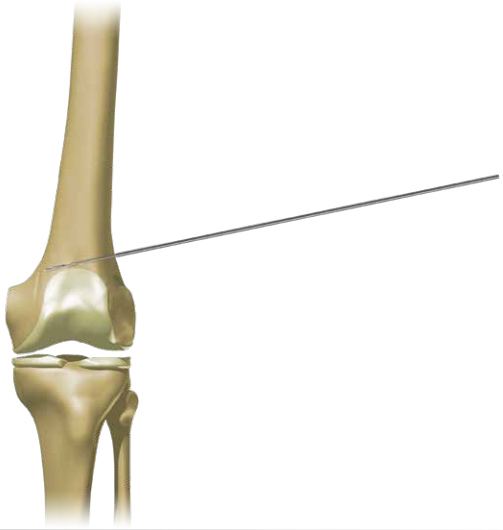
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

5.4. INTRODUCTION OF GUIDE PIN WITH EYELET

Insert the guide pin with eyelet [**40.3943.100**] into the exposed femur using the electric drive. The appropriate position of the pin is to be chosen by surgeon.

The blade of the guide pin [**40.3943.100**] should be placed about 10mm from the lateral cortex.

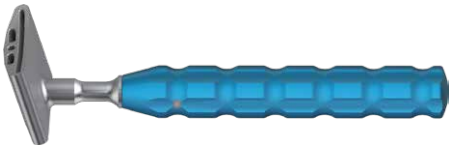
40.3943.100

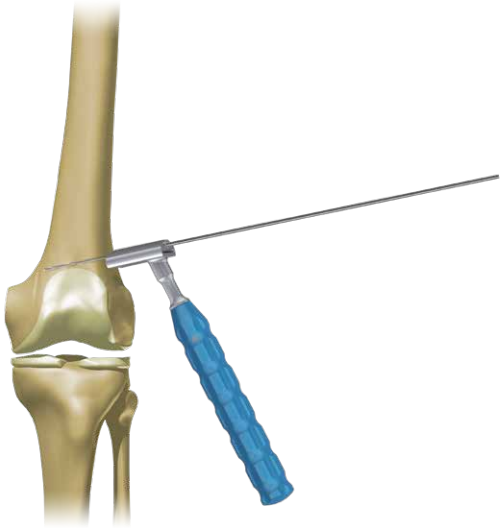

5.4.

5.5. MOUNTING THE TARGETER FOR OSTEOTOMY ON THE GUIDE PIN

After inserting the guide pin [**40.3943.100**], mount the targeter for osteotomy [**40.3974.200**] on the pin. The surgeon decides on the position of the targeter.

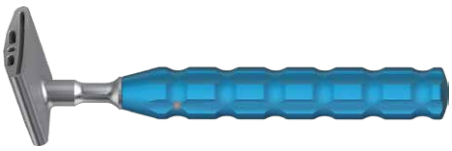
40.3943.100


40.3974.200

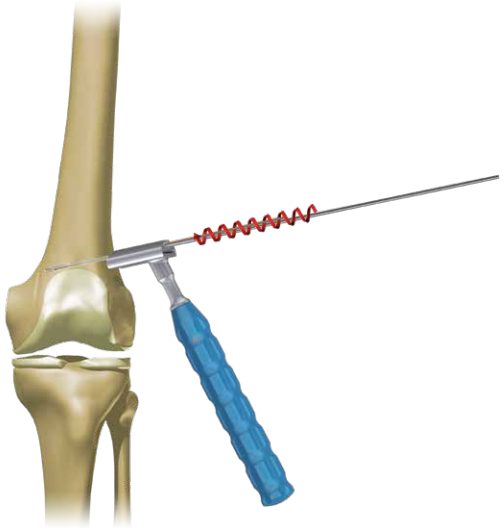

5.5.

5.6. INTRODUCTION OF KIRSCHNER WIRES

In order to establish the position of the targeter perpendicularly to the bone, insert the Kirscher wires [**40.4815.210**] through the holes of the targeter [**40.3974.200**] with the use of the electric drive.


40.3974.200

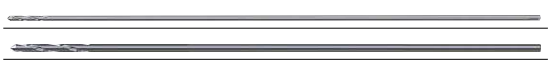
40.4815.210


5.6.

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

5.7. PREPARATION FOR BONE INCISION

Remove the guide pin [**40.3943.100**] from the bone, then bend the Kirscher wires [**40.4815.210**] so they do not hamper further procedures.


40.3943.100

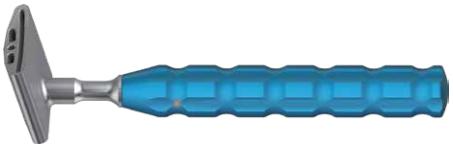
40.4815.210


5.7.

5.8. INITIAL INCISION WITH THE SAW AND FINAL WITH OSTEOTOME

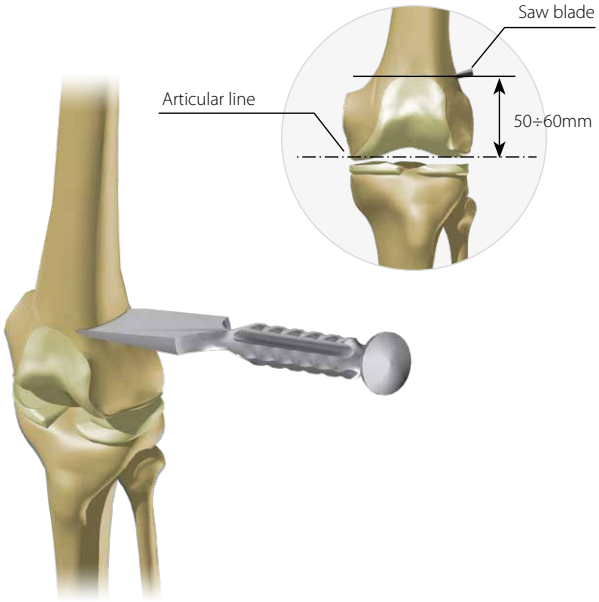
Perform the initial incision of the femur with the saw by utilizing the slit in the targeter [**40.3974.200**].

After performing the initial incision with the saw, remove the targeter and Kirscher wires.
Then use an osteotome with blade of appropriate width [**40.5361.000; 40.5362.000**] to incise the bone. The osteotome should be carefully hit with a hammer, e.g. of *Bergman* type.


40.3974.200


40.5361

40.5362



5.8.

5.9. WEDGE OPENING WITH THE INSTRUMENT SET FOR OSTEOTOMY

Enter the appropriate instrument set for osteotomy [**40.5360.000**] with correctly chosen bone reamer in the incision, as described below:

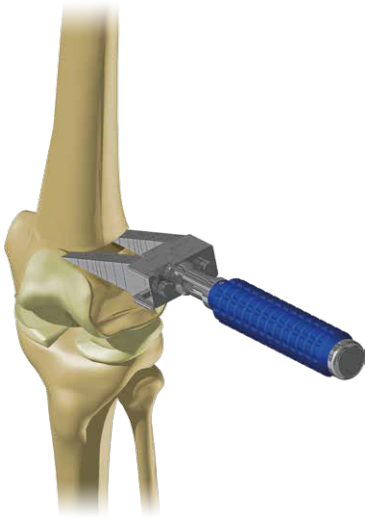
- [**40.5357.016**] - for smaller bones
- [**40.5357.020**] - for larger bones

at the length that matches the previously established height of the opening, which is marked on the upper, inclined surface of the reamers. It is permitted to carefully hit the inserted instrument set with a hammer, e.g. of *Bergman* type.

40.5360

40.5357.016

40.5357.020



5.9.

5.10. CONTROL OF CORRECTION ANGLE AND THE HEIGHT OF WEDGE BONE OPENING

In order to check the correction angle and related wedge opening, it is necessary to use X-Ray or fluoroscopy to assure the height of prepared wedge opening allows for achieving the selected correction angles and the height of the wedge bone opening.

If the fluoroscope is used that casts the images on the fluorescent screen, it is recommended to repeatedly verify the consecutive steps of the surgery.

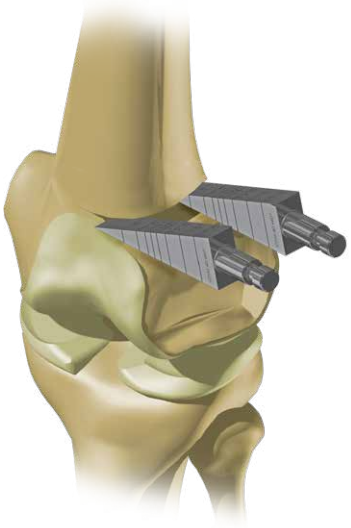
5.11. REMOVAL OF GRASPING PART OF THE SET AND CONTROL OF OPENING CORRECTNESS

To allow access to the place where a plate of appropriate size is to be placed, it is necessary to dismantle the grasping part of the instrument set for osteotomy [**40.5360.000**] in such a manner that only two reamers remain in the bone, either [**40.5357.020**] or [**40.5357.016**].

40.5360

40.5357.016

40.5357.020



5.11.

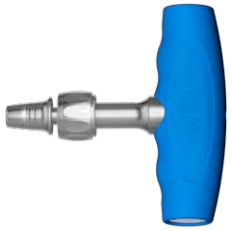
5.12. SELECTION AND INSERTION OF WEDGE DISTANCE PLATE

The height of the plate wedge should be selected on the basis of the values provided on the upper, inclined surfaces of the reamers. After selecting the plate, use the applicator [**40.5369.000**] to insert the wedge of the plate into the wedge opening in the bone, between the reamers.

40.5369

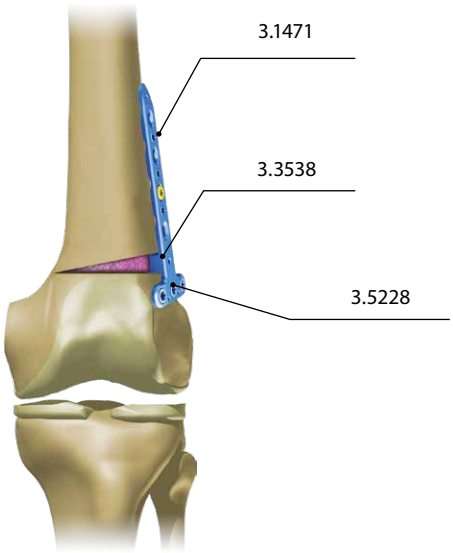
5.12A. INSERTION OF SCREWS USED FOR MOUNTING THE WEDGE DISTANCE PLATE

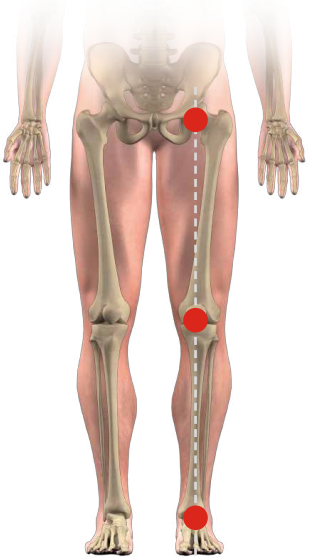
Use the cancellous screws to install the horizontal part of the plate (*which is closer to the joint*); remove the reamers. For the vertical part of the plate (*which is further from the joint*), use the locking screws. Torque limiting ratchet handle T 4Nm [**40.6660.000**] and screwdriver tip T 25-1/4 [**40.5684.200**] should be used for screws insertion. Afterwards, use X-Rays or a fluoroscope to verify the bone curvature correction. A straight line through the 3 characteristic points mentioned above should be possible to draw.



40.6660

40.5684.200





CAUTION!
Further actions should be performed in accordance with the steps described in 4.12B.

6. TABLES OF CORRECTION ANGLE

Table of correction angles for plates [°]
3.7065; 3.7066; 3.3538

Length of Osteotomy [mm]	Height of opening [mm]									
	3	**5**	**7**	**7.5**	**9**	**10**	**11**	**12.5**	**15**	**17.5**
50	4°	6.7°	9.2°	9.9°	11.8°	13.1°	14.3°	16.2°	19.2°	22.1°
52	3.8°	6.4°	8.8°	9.4°	11.4°	12.5°	13.75°	15.5°	18.4°	21.25°
54	3.7°	6.1°	8.5°	9.1°	10.8°	12°	13.2°	14.9°	17.7°	20.4°
56	3.5°	5.8°	8.1°	8.7°	10.4°	11.5°	12.7°	14.3°	17°	19.6°
58	3.3°	5.6°	7.8°	8.4°	10°	11.1°	12.2°	13.8°	16.4°	18.9°
60	3.25°	5.4°	7.5°	8.1°	9.7°	10.7°	11.7°	13.3°	15.8°	18.3°
62	3.1°	5.2°	7.25°	7.75°	9.3°	10.3°	11.3°	12.8°	15.25°	17.6°
64	3°	5°	7°	7.5°	9°	10°	10.9°	12.4°	14.75°	17.1°
66	2.9°	4.8°	6.75°	7.25°	8.7°	9.6°	10.6°	12°	14.3°	16.5°
68	2.8°	4.7°	6.5°	7°	8.4°	9.3°	10.2°	11.6°	13.8°	16°
70	2.75°	4.5°	6.3°	6.8°	8.1°	9°	9.9°	11.2°	13.4°	15.5°

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