

*instructions for use*

# OPENING WEDGE OSTEOTOMY

IMPLANTS ◦

INSTRUMENT SET 40.5350.600 ◦

SURGICAL TECHNIQUE ◦



# 21D

CE 0197  
ISO 9001  
ISO 13485

ChM®



<b>I. INTRODUCTION</b> .....	<b>4</b>
I.1. CLOSING METHOD OF OSTEOTOMY.....	5
I.2. OPENING METHOD OF OSTEOTOMY.....	5
<b>II. IMPLANTS</b> .....	<b>6</b>
II.1. WEDGE DISTANCE PLATES .....	6
II.2. CORTICAL SELF - TAPPING SCREW 4.5.....	7
II.3. CANCELLOUS SELF - TAPPING SCREW 6.5 .....	7
II.4. LOCKING PLATES FOR OSTEOTOMY.....	8
<b>III. INSTRUMENT SET</b> .....	<b>13</b>
<b>IV. SURGERY TECHNIQUE - TIBIA</b> .....	<b>15</b>
IV.1. INTRODUCTION .....	15
IV.2. INCISION TO ACCESS TIBIA .....	15
IV.3. ESTABLISHING THE CORRECTION ANGLE AND THE HEIGHT OF OPENING.....	15
IV.4. INSERTION OF GUIDE PIN WITH EYELET .....	16
IV.5. MOUNTING THE TARGETER FOR OSTEOTOMY ON THE GUIDE PIN.....	16
IV.6. INTRODUCTION OF GUIDE RODS .....	16
IV.7. PREPARATION FOR BONE INCISION .....	17
IV.8. PERFORMING THE INITIAL INCISION WITH THE SAW AND APPROPRIATE OSTEOTOME .....	17
IV.9. WEDGE OPENING WITH THE INSTRUMENT SET FOR OSTEOTOMY .....	18
IV.10. CONTROL OF CORRECTION ANGLE AND THE HEIGHT OF WEDGE BONE OPENING .....	18
IV.11. REMOVAL OF GRASPING PART OF THE SET AND CONTROL OF OPENING CORRECTNESS .....	18
IV.12. SELECTION AND INSERTION OF WEDGE DISTANCE PLATE .....	18
IV.13. INSERTION OF SCREWS USED FOR MOUNTING THE WEDGE DISTANCE PLATE .....	19
<b>V. SURGERY TECHNIQUE - FEMUR</b> .....	<b>22</b>
V.1. INTRODUCTION .....	22
V.2. INCISION TO ACCESS THE FEMUR.....	22
V.3. ESTABLISHING THE CORRECTION ANGLE AND THE HEIGHT OF OPENING.....	22
V.4. INTRODUCTION OF GUIDE PIN WITH EYELET .....	23
V.5. MOUNTING THE TARGETER FOR OSTEOTOMY ON THE GUIDE PIN.....	23
V.6. INTRODUCTION OF GUIDE RODS .....	23
V.7. PREPARATION FOR BONE INCISION .....	24
V.8. PERFORMING THE INITIAL INCISION WITH THE SAW AND APPROPRIATE OSTEOTOME .....	24
V.9. WEDGE OPENING WITH THE INSTRUMENT SET FOR OSTEOTOMY .....	25
V.10. CONTROL OF CORRECTION ANGLE AND THE HEIGHT OF WEDGE BONE OPENING .....	25
V.11. REMOVAL OF GRASPING PART OF THE SET AND CONTROL OF OPENING CORRECTNESS .....	25
V.12. SELECTION AND INSERTION OF WEDGE DISTANCE PLATE .....	25
V.13. INSERTION OF SCREWS USED FOR MOUNTING THE WEDGE DISTANCE PLATE .....	26
<b>VI. TABLES OF CORRECTION ANGLE</b> .....	<b>27</b>

## I. INTRODUCTION

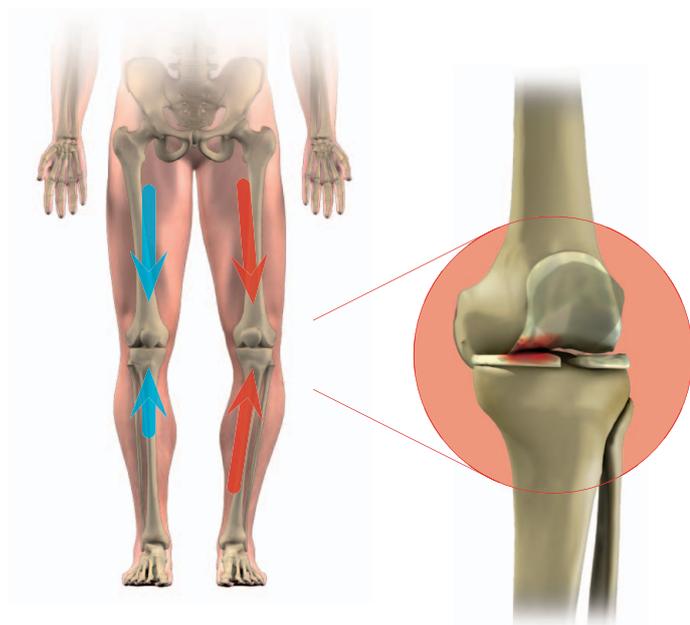
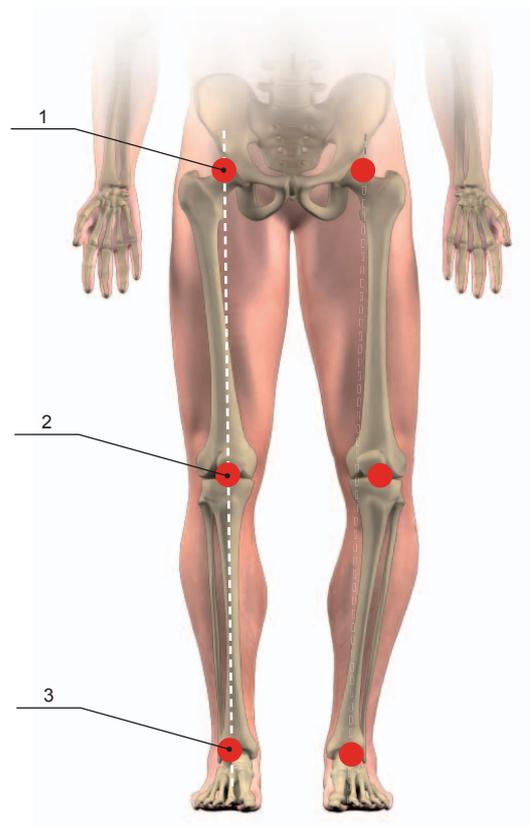
Instrument set for correcting the bone curvature with the wedge-shaped incision consists of:

- 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 correction is done by incising the bone curvature and insertion of wedge distance plate which keeps performed incision and required angle of correction.

Straightness of the lower limb is defined by the line that is presented by three characteristic points: center of the femoral head [1], the center of knee joint [2] and center of distal tibia head [3]. In the case if those 3 points are not connected by straight line, the lower limb is curved.

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



There are two ways of straightening the knee:

### 1. The closing method

The surgeon makes the transverse cut of the tibia, or lateral or anterior femur (*it depends on the limb curvature*), removes the wedge piece of the bone, connects the open edges and unites the bone with plate or clasps.

### 2. The opening method

The surgeon makes the transverse cut of the tibia, or lateral or anterior femur then wedge 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 cutting is called **osteotomy**.

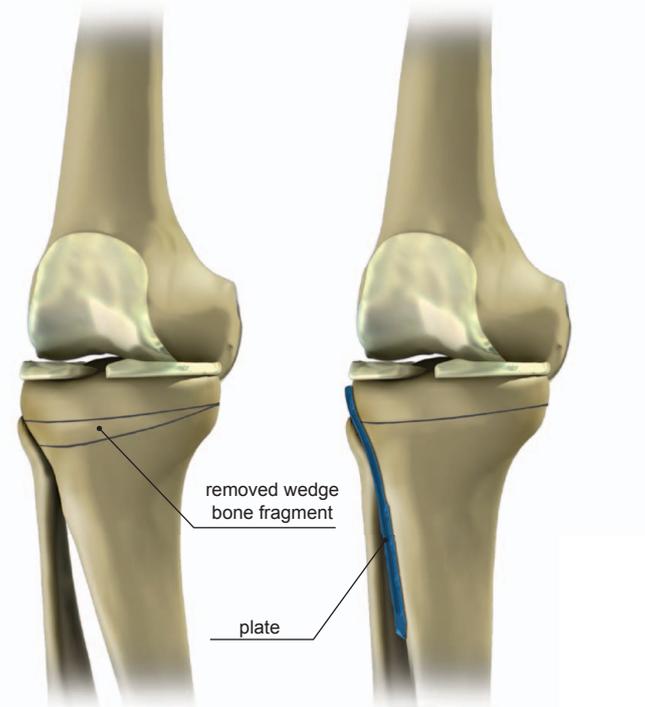
**I.1. CLOSING METHOD OF OSTEOTOMY**

The incision is made in the lateral or the anterior side of the knee. It allows to see the upper end of tibia or the lower end of the femur (*it depends which bone is being corrected*). Muscles, nerves and blood vessels which pass through the knee joint should be protected from damaging.

After exposing the bone there are two wedge shaped osteotomies made. Use the X-Rays or fluoroscopy to make sure the wedge is of proper size and is placed correctly.

Take out the wedge. Both sides of the bone cut are to be closed and kept in place with metal plate or clasps. It changes the bone angle and helps to restore the alignment of knee axis. After fixing both edges of the bone using plate or clasps, the skin is to be sutured. Then the leg is to be placed in the padded splint in order to protect the knee joint.

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



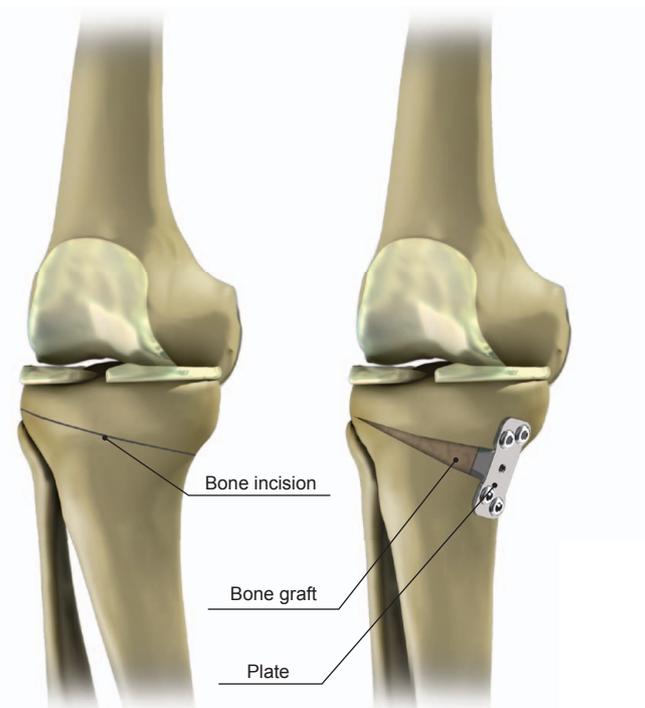
**I.2. OPENING METHOD OF OSTEOTOMY**

The opening method is performed on the lateral and the anterior side of the knee. Muscles, nerves and blood vessels which pass through the knee joint should be protected from damaging.

After exposing the bone, one incision is performed. Fluoroscopy or X-Ray is used to verify if the incision is done in the correct place.

Both sides of bone cut are separated in order to form the wedge-shaped opening. This opening is then filled with wedge distance plate of appropriate length or bone graft and distance plate without wedge to hold the wedge opening. Bone graft is usually taken from the pelvis. Bone graft is held in place by the metal plate, or clasps. Next, the skin is to be sutured and the leg placed in the padded splint in order to protect the knee joint.

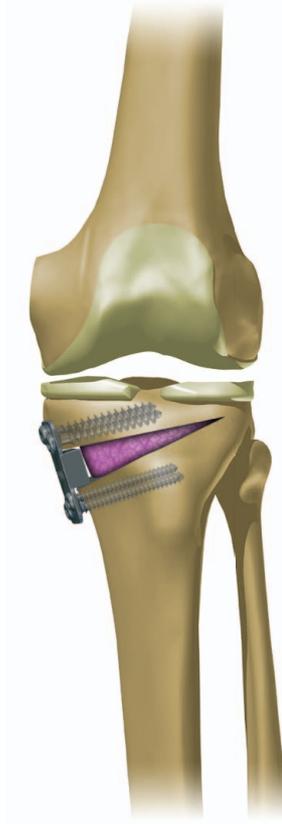
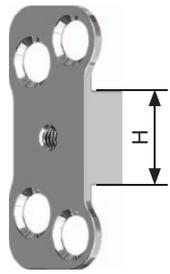
Surgical treatment should involve a minimum amount of pain and scarring.



## II. IMPLANTS

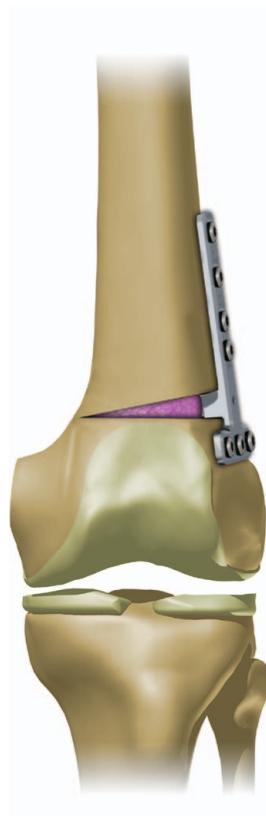
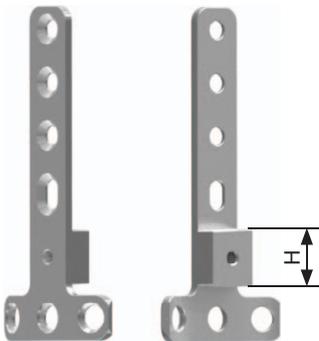
### II.1. WEDGE DISTANCE PLATES

#### Tibial



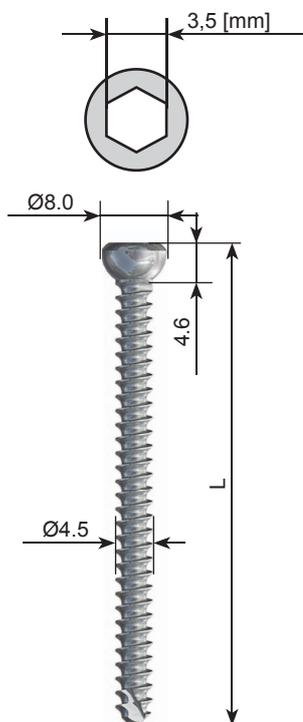
H [mm]	Catalogue no.	
	STEEL	TITANIUM
3.0	1.3541.030	3.3541.030
5.0	1.3541.050	3.3541.050
7.5	1.3541.075	3.3541.075
9.0	1.3541.090	3.3541.090
10.0	1.3541.100	3.3541.100
11.0	1.3541.110	3.3541.110
12.5	1.3541.125	3.3541.125
15.0	1.3541.150	3.3541.150
17.5	1.3541.175	3.3541.175

#### Femoral



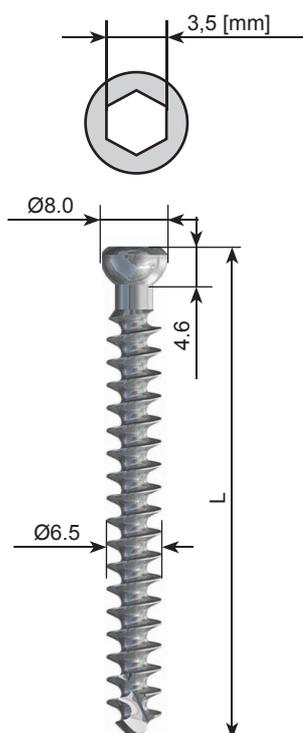
H [mm]	Catalogue no.	
	STEEL	TITANIUM
3.0	1.3542.030	3.3542.030
5.0	1.3542.050	3.3542.050
7.5	1.3542.075	3.3542.075
9.0	1.3542.090	3.3542.090
10.0	1.3542.100	3.3542.100
11.0	1.3542.110	3.3542.110
12.5	1.3542.125	3.3542.125
15.0	1.3542.150	3.3542.150
17.5	1.3542.175	3.3542.175

**II.2. CORTICAL SELF - TAPPING SCREW 4.5**



L [mm]	Catalogue no.	
	STEEL	TITANIUM
10	1.1443.010	3.1443.010
12	1.1443.012	3.1443.012
14	1.1443.014	3.1443.014
16	1.1443.016	3.1443.016
18	1.1443.018	3.1443.018
20	1.1443.020	3.1443.020
22	1.1443.022	3.1443.022
24	1.1443.024	3.1443.024
26	1.1443.026	3.1443.026
28	1.1443.028	3.1443.028
30	1.1443.030	3.1443.030
32	1.1443.032	3.1443.032
34	1.1443.034	3.1443.034
36	1.1443.036	3.1443.036
38	1.1443.038	3.1443.038
40	1.1443.040	3.1443.040
42	1.1443.042	3.1443.042
44	1.1443.044	3.1443.044
46	1.1443.046	3.1443.046
48	1.1443.048	3.1443.048
50	1.1443.050	3.1443.050
52	1.1443.052	3.1443.052
54	1.1443.054	3.1443.054
56	1.1443.056	3.1443.056
58	1.1443.058	3.1443.058
60	1.1443.060	3.1443.060
62	1.1443.062	3.1443.062
64	1.1443.064	3.1443.064
66	1.1443.066	3.1443.066
68	1.1443.068	3.1443.068
70	1.1443.070	3.1443.070
72	1.1443.072	3.1443.072
74	1.1443.074	3.1443.074
76	1.1443.076	3.1443.076
78	1.1443.078	3.1443.078
80	1.1443.080	3.1443.080
85	1.1443.085	3.1443.085
90	1.1443.090	3.1443.090
95	1.1443.095	3.1443.095
100	1.1443.100	3.1443.100
105	1.1443.105	3.1443.105
110	1.1443.110	3.1443.110
115	1.1443.115	3.1443.115
120	1.1443.120	3.1443.120
125	1.1443.125	3.1443.125
130	1.1443.130	3.1443.130
135	1.1443.135	3.1443.135
140	1.1443.140	3.1443.140

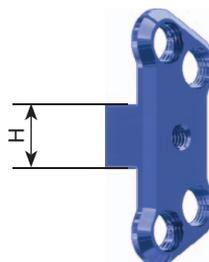
**II.3. CANCELLOUS SELF - TAPPING SCREW 6.5**



L [mm]	Catalogue no.	
	STEEL	TITANIUM
25	1.1611.025	3.1611.025
30	1.1611.030	3.1611.030
35	1.1611.035	3.1611.035
40	1.1611.040	3.1611.040
45	1.1611.045	3.1611.045
50	1.1611.050	3.1611.050
55	1.1611.055	3.1611.055
60	1.1611.060	3.1611.060
65	1.1611.065	3.1611.065
70	1.1611.070	3.1611.070
75	1.1611.075	3.1611.075
80	1.1611.080	3.1611.080
85	1.1611.085	3.1611.085
90	1.1611.090	3.1611.090
95	1.1611.095	3.1611.095
100	1.1611.100	3.1611.100
105	1.1611.105	3.1611.105
110	1.1611.110	3.1611.110
115	1.1611.115	3.1611.115
120	1.1611.120	3.1611.120
125	1.1611.125	3.1611.125
130	1.1611.130	3.1611.130
135	1.1611.135	3.1611.135
140	1.1611.140	3.1611.140

**7.0ChLP A/P tibial**

Catalogue no.	
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



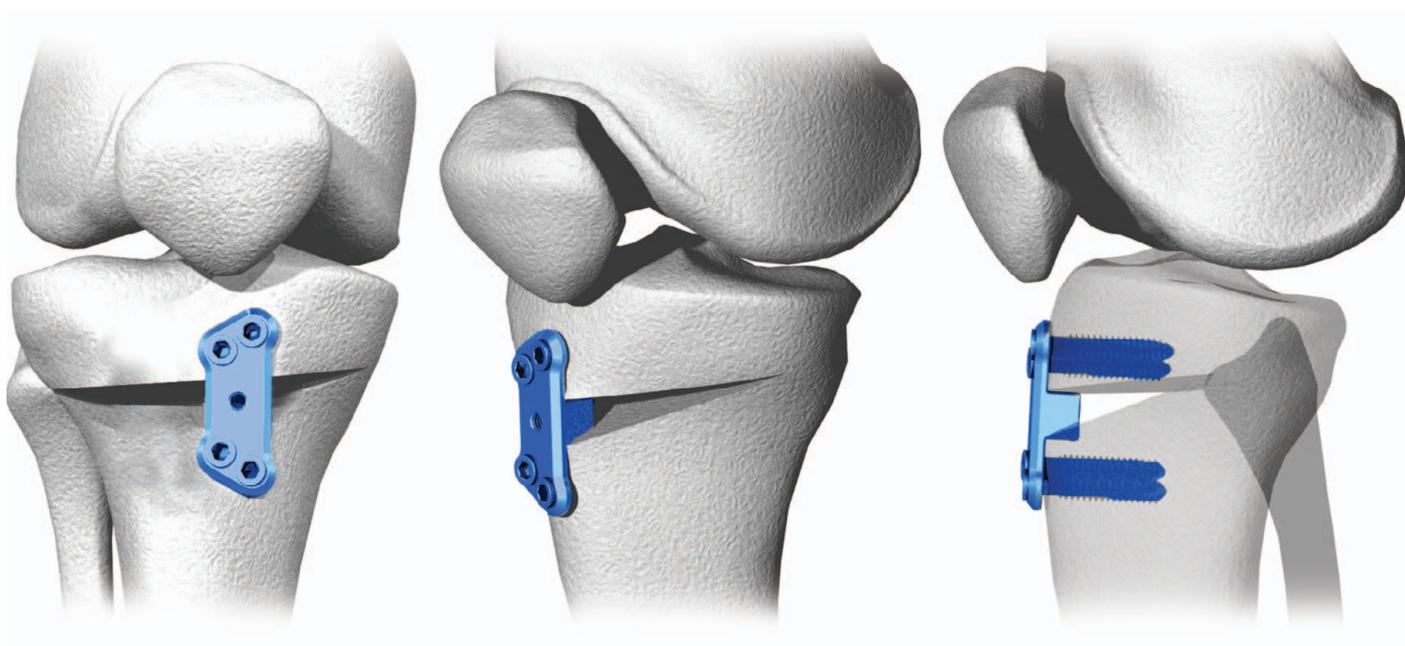
Titanium  
3.1380.030+090  
\* 3.5232.030+090



Titanium  
3.1448.016+110  
3.5210.016+110

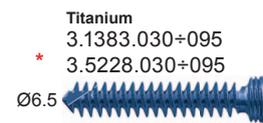
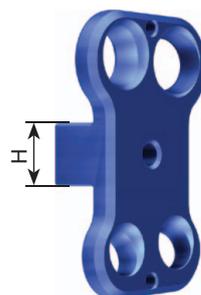


\*Cancellous

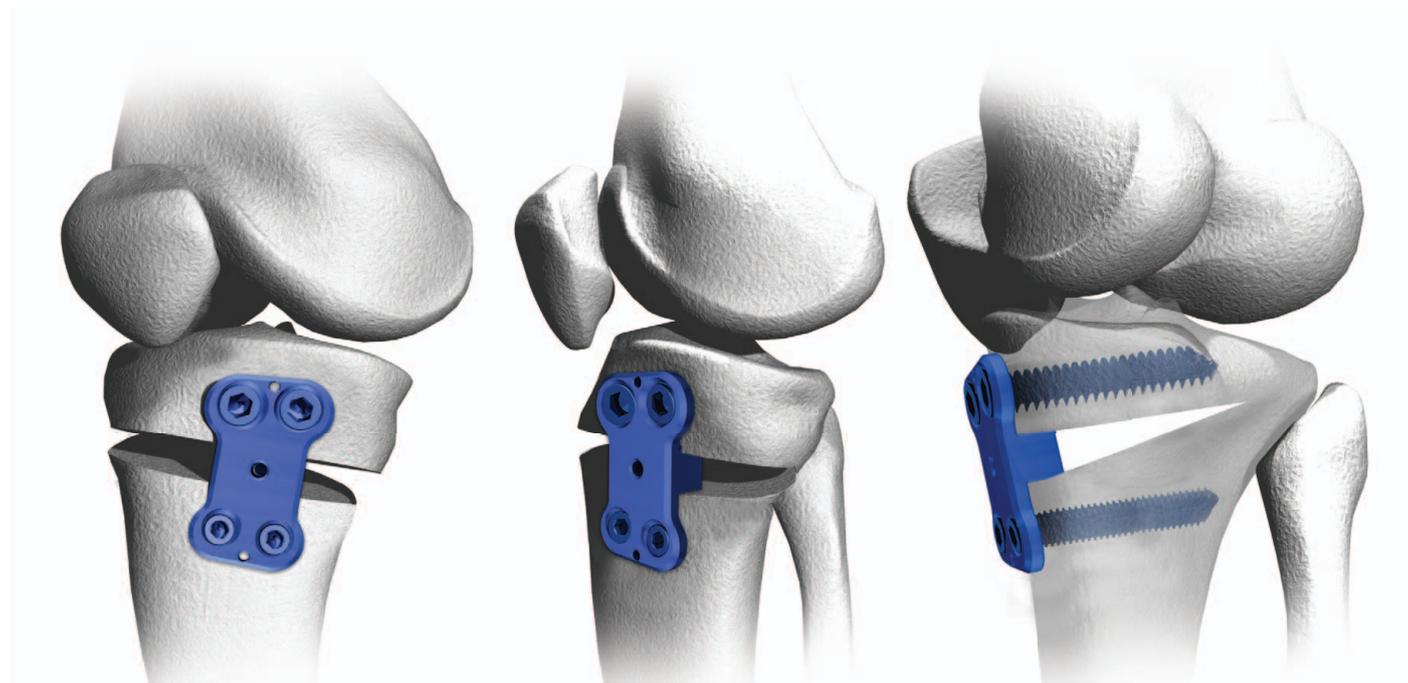


7.0ChLP Distance tibial plate

H [mm]	Left	Right
	Catalogue no.	
	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

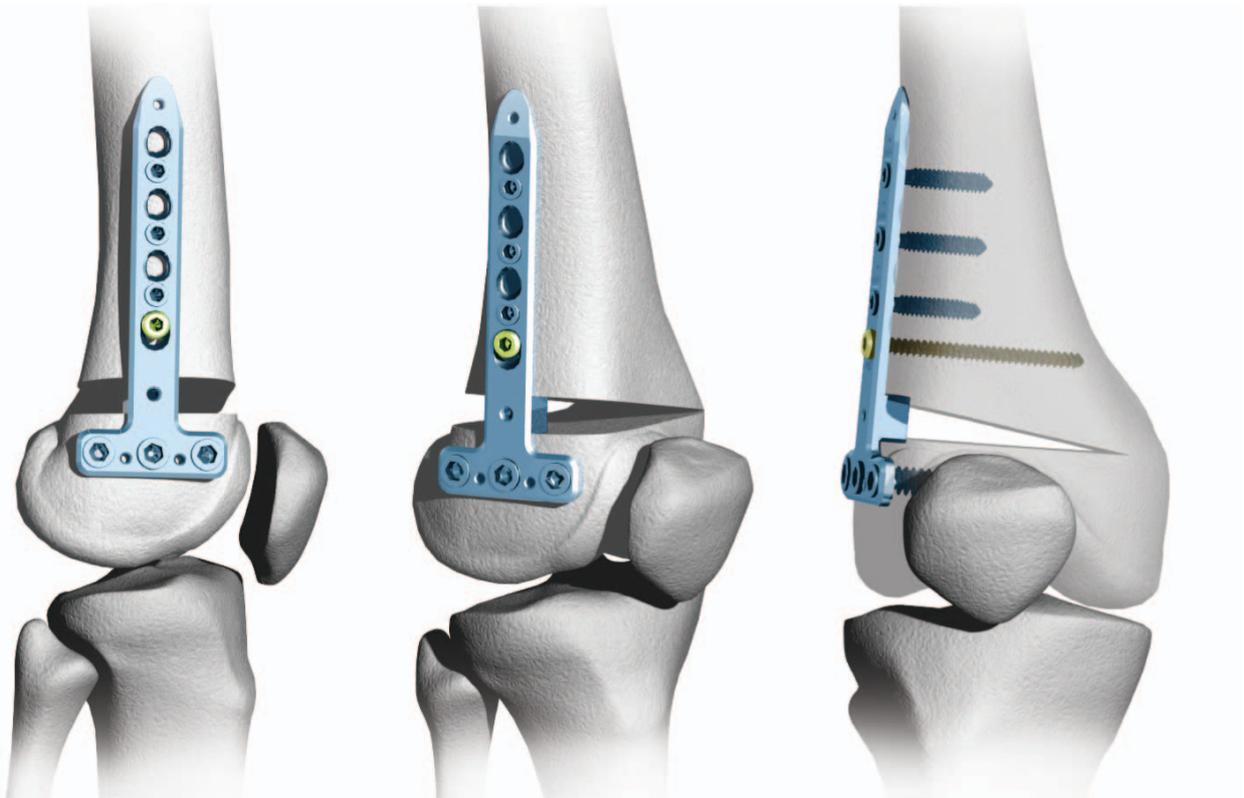
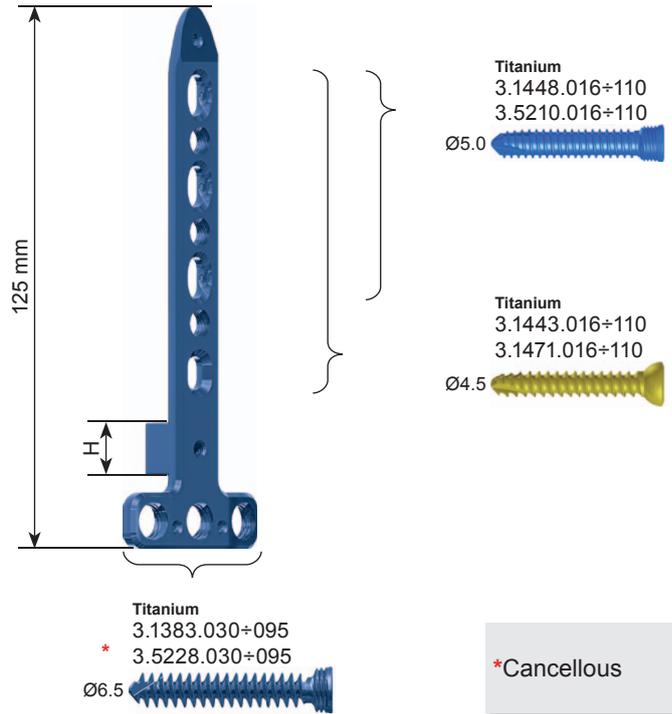


\*Cancellous

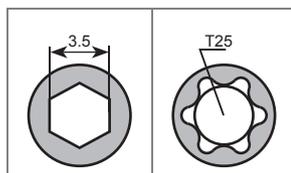
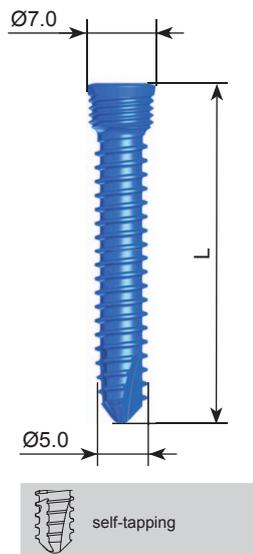


**7.0ChLP Distance femoral**

Catalogue no.	
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



7.0ChLP Screw 5.0

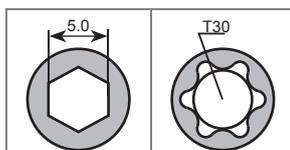
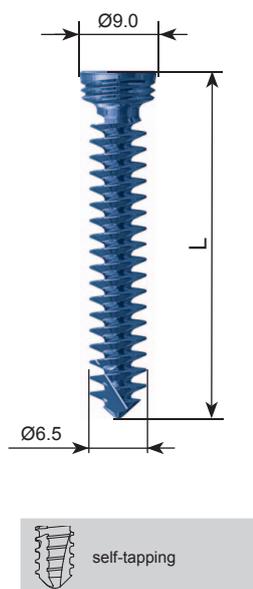


Catalogue no.

L [mm]	Titanium	
16	3.1448.016	3.5210.016
18	3.1448.018	3.5210.018
20	3.1448.020	3.5210.020
22	3.1448.022	3.5210.022
24	3.1448.024	3.5210.024
26	3.1448.026	3.5210.026
28	3.1448.028	3.5210.028
30	3.1448.030	3.5210.030
32	3.1448.032	3.5210.032
34	3.1448.034	3.5210.034
36	3.1448.036	3.5210.036
38	3.1448.038	3.5210.038
40	3.1448.040	3.5210.040
42	3.1448.042	3.5210.042
44	3.1448.044	3.5210.044
46	3.1448.046	3.5210.046
48	3.1448.048	3.5210.048
50	3.1448.050	3.5210.050
52	3.1448.052	3.5210.052
54	3.1448.054	3.5210.054
56	3.1448.056	3.5210.056
58	3.1448.058	3.5210.058
60	3.1448.060	3.5210.060
65	3.1448.065	3.5210.065
70	3.1448.070	3.5210.070
75	3.1448.075	3.5210.075
80	3.1448.080	3.5210.080
85	3.1448.085	3.5210.085
90	3.1448.090	3.5210.090
95	3.1448.095	3.5210.095
100	3.1448.100	3.5210.100
105	3.1448.105	3.5210.105
110	3.1448.110	3.5210.110

Ø core		4.0
Ø drill with scale	40.5651.222	4.0
guide sleeve	40.5705.740	7.0/4.0
screwdriver tip	40.5686.000	S3.5
screwdriver tip	40.5684.000	T25
tap	40.5646.000	5.0

7.0ChLP cancellous screw 6.5

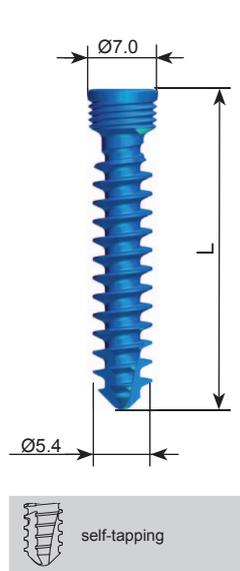


Catalogue no.

L [mm]	Titanium	
30	3.1383.030	3.5228.030
35	3.1383.035	3.5228.035
40	3.1383.040	3.5228.040
45	3.1383.045	3.5228.045
50	3.1383.050	3.5228.050
55	3.1383.055	3.5228.055
60	3.1383.060	3.5228.060
65	3.1383.065	3.5228.065
70	3.1383.070	3.5228.070
75	3.1383.075	3.5228.075
80	3.1383.080	3.5228.080
85	3.1383.085	3.5228.085
90	3.1383.090	3.5228.090
95	3.1383.095	3.5228.095

Ø core		3.0
Ø drill with scale	40.5650.222	3.2
guide sleeve	40.5707.732	3.2
screwdriver tip	40.5687.000	S5
screwdriver tip	40.5685.000	T30

## 7.0ChLP Cancellous screw 5,4



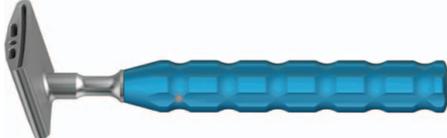
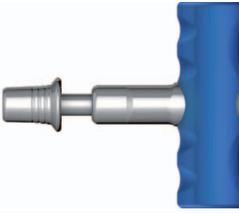
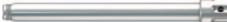
Catalogue no.			
L	Titanium		
[mm]			
30	3.1380.030	3.5232.030	
35	3.1380.035	3.5232.035	
40	3.1380.040	3.5232.040	
45	3.1380.045	3.5232.045	
50	3.1380.050	3.5232.050	
55	3.1380.055	3.5232.055	
60	3.1380.060	3.5232.060	
65	3.1380.065	3.5232.065	
70	3.1380.070	3.5232.070	
75	3.1380.075	3.5232.075	
80	3.1380.080	3.5232.080	
85	3.1380.085	3.5232.085	
90	3.1380.090	3.5232.090	

∅ core		3.2
∅ drill with scale	40.5650.222	3.2
guide sleeve	40.5707.732	3.2
screwdriver tip	40.5686.000	S3.5
screwdriver tip	40.5684.000	T25

**III. INSTRUMENT SET**

The Instrument Set [40.5350.600] – for correction of the bone curvature with the wedge-shaped incision.

The instrument set for the bone curvature correction by the wedge-shaped incision includes the following instruments:

No.		Name	Catalogue No.	Pcs
1		Guide pin with eyelet	40.3943.100	1
2		Osteotomy targeter	40.3974.200	1
3		Instrument set for osteotomy	40.5360.000	1
4		Reamer 20°	40.5357.020	2
5		Reamer 16°	40.5357.016	2
6		Depth measure	40.4639.700	1
7		Compression guide 3.2	40.4802.732	1
8		Kirschner wire 2.0/220	40.4815.220	2
9		Torque wrench	40.5270.400	1
10		Guide rod	40.5353.000	2
11		Osteotome 25	40.5361.000	1
12		Osteotome 35	40.5362.000	1
13		Applicator	40.5369.000	1
14		Drill with scale 3.2/220	40.5650.222	1
15		Drill with scale 4.0/220	40.5651.222	1
16		Screw length measure	40.5675.100	1
17		Screwdriver tip T25-1/4	40.5684.000	1
18		Cannulated screwdriver tip T30-1/4	40.5685.000	1
19		Screwdriver tip S3.5-1/4	40.5686.000	1
20		Cannulated screwdriver tip S5-1/4	40.5687.000	1
21		Guide sleeve 7.0/4.0	40.5705.740	1
22		Guide sleeve 9.0/3.2	40.5707.732	1

# INSTRUMENTS

No.		Name	Catalogue No.	Pcs
24		Stand for implants for osteotomy	<b>40.5358.000</b>	1
25		Stand for instrument set of osteotomy	<b>40.5359.600</b>	1
26		Lid perforated alu. 1/1 595x275x15mm Grey	<b>12.0750.200</b>	1
27		Container solid bottom 1/1 595x275x86mm	<b>12.0750.100</b>	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*).

## IV. SURGERY TECHNIQUE - TIBIA

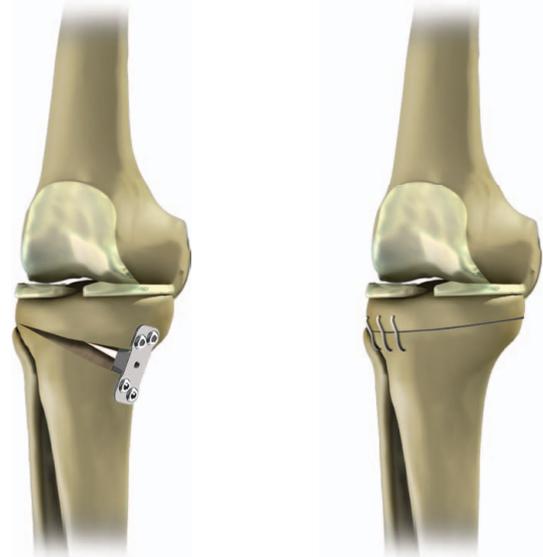
### IV.1. INTRODUCTION

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 [Fig. 2] are used for connecting the fragments of a cut bone in the opening method, while distal plates without wedge or clasps are used in the closing method.

The decision regarding the method of bone curvature correction and the manner of connecting the cut bone edges is to be taken by the surgeon on the basis of the size and type of curvature and the desired correction.

A procedure of tibia curvature correction by means of opening wedge incision with the use of distance plate for maintaining and connecting the cut bone is presented below.

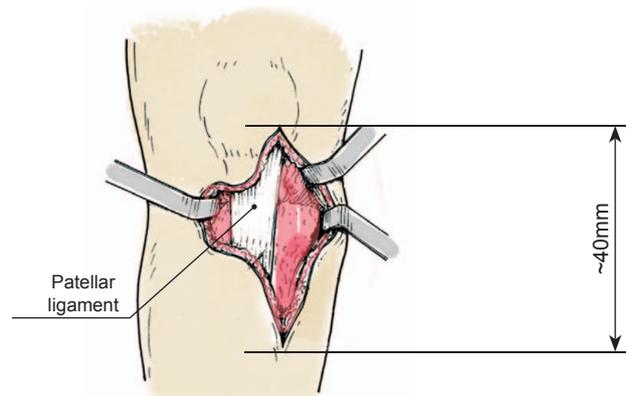


*Figure 1*  
Opening Method with wedge distance plate.

*Figure 2*  
Closing Method with clasps.

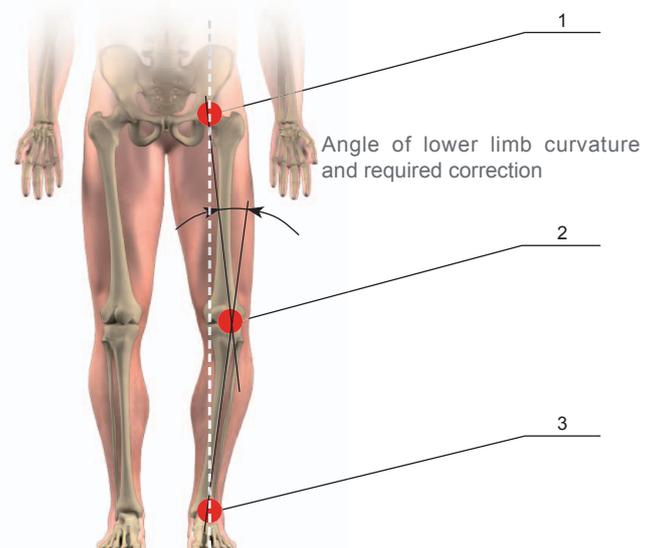
### IV.2. INCISION TO ACCESS TIBIA

Make the incision of the skin and tissue approximately 40mm of length in the median part of the knee, along the patellar ligament. It is necessary to act with due caution to not damage the nerves, tendons and blood vessels that run through the knee joint.



### IV.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.



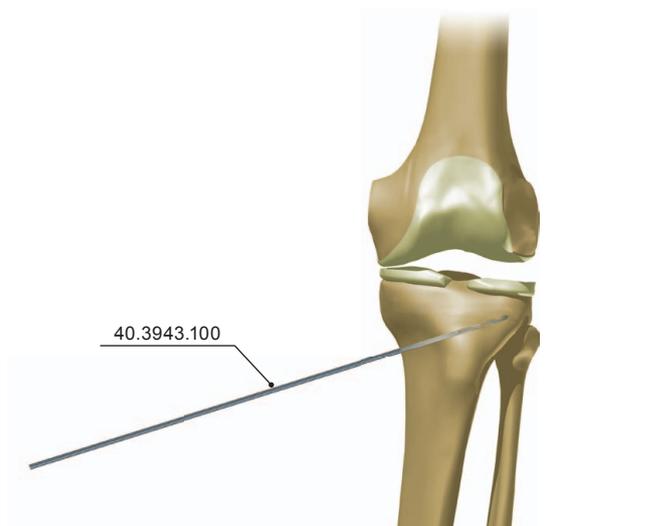
*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

## IV.4. INSERTION OF GUIDE PIN WITH EYELET

Insert the Guide Pin With Eyelet [40.3943] into exposed upper part of the tibia 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.



IV.4.



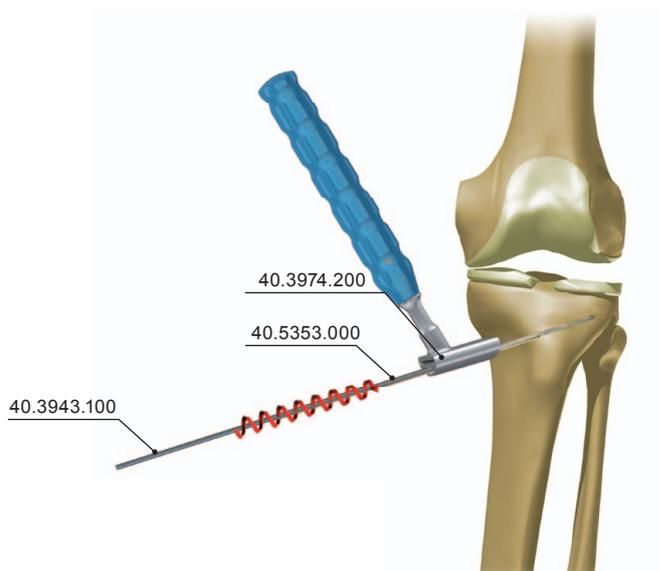
IV.5.

## IV.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.

## IV.6. INTRODUCTION OF GUIDE RODS

In order to establish the position of the targeter perpendicularly to the bone insert the guide rods [40.5353.000] through the holes of the targeter [40.3974.200] with the use of an electric drive.

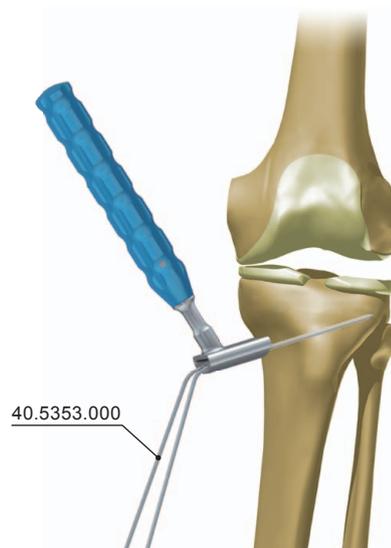


IV.6.

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

**IV.7. PREPARATION FOR BONE INCISION**

Remove the guide pin [40.3943.100] from the bone, then bend the guide rods [40.5353.000] so they do not hamper further procedures.

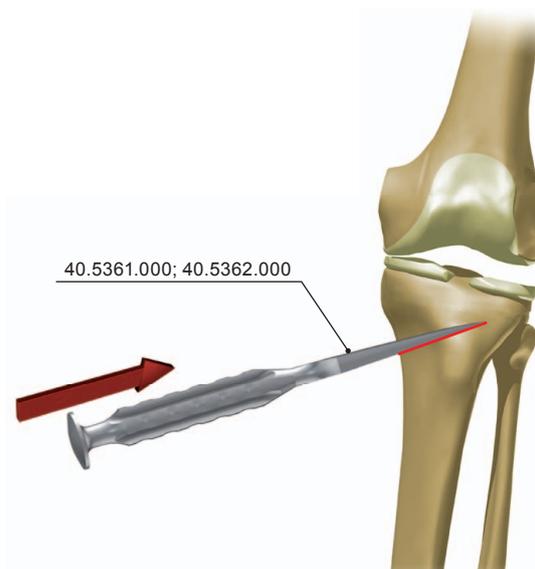


IV.7.

**IV.8. PERFORMING THE INITIAL INCISION WITH THE SAW AND APPROPRIATE 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 a saw, remove the targeter and guide rods. Then, with the use of osteotome with blade of appropriate width [40.5361.000; 40.5362.000] incise the bone. The osteotome should be carefully hit with a hammer, e.g. of Bergman type.



IV.8.

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

**IV.9. WEDGE OPENING WITH THE INSTRUMENT SET FOR OSTEOTOMY**

Use 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, oblique surface of the reamers. It is permitted to carefully hit the inserted instrument set for osteotomy with a hammer, e.g. of Bergman type.

**IV.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.

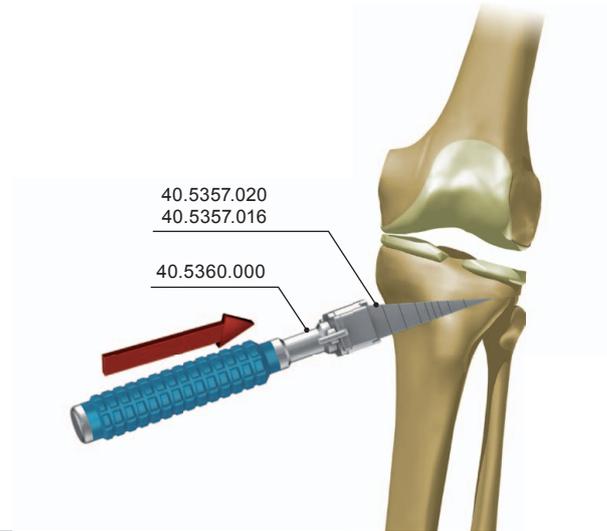
 **If the fluoroscope is used that casts the images on the fluorescent screen, it is recommended to repeatedly verify the consecutive steps of the surgery.**

**IV.11. REMOVAL OF GRASPING PART OF THE SET AND CONTROL OF OPENING CORRECTNESS**

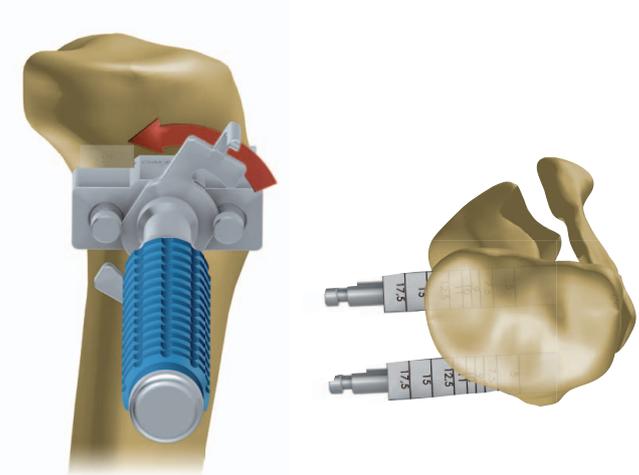
To allow access to the place where a plate of appropriate size is to be placed, it is necessary to dismantle the grasping part of the instrument set for osteotomy [40.5360.000] in such a manner that only two reamers remain in the bone, either [40.5357.020] or [40.5357.016].

**IV.12. SELECTION AND INSERTION OF WEDGE DISTANCE PLATE**

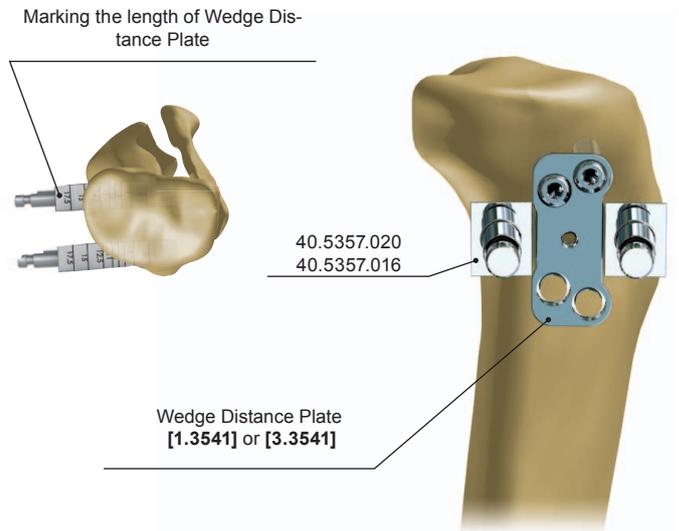
The height of distal part of the plate should be selected on the basis of values read from the upper, oblique surfaces of the reamers. After selecting the appropriate plate, place the plate in the wedge-shaped opening between the reamers with the help of an applicator [40.5369.000].



IV.9.



IV.11.

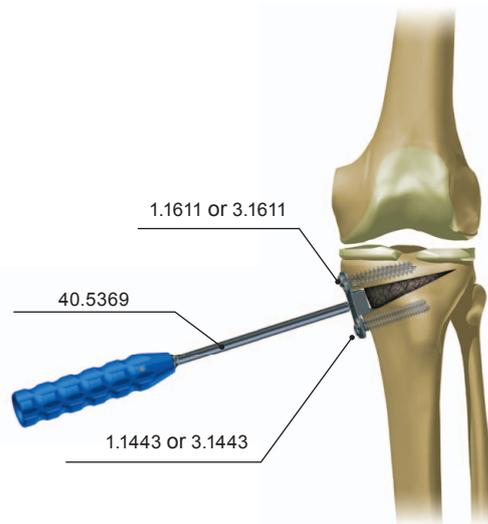


IV.12.

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

**IV.13. INSERTION OF SCREWS USED FOR MOUNTING THE WEDGE DISTANCE PLATE**

The upper part of the plate which is closer to the joint should be screwed in with the use of cancellous screws, then the reamers should be removed. The lower part of the plate which is further from the joint should be screwed in with the cortical screws. To mount the plate with the screws use the torque wrench [40.5270.400] with the screwdriver tip S3.5 [40.5686.000]. After mounting the plate, verify the correctness of the performed correction of bone curvature with the use of X-Ray or fluoroscopy. It should be possible to draw a straight line through previously mentioned three characteristic points.



IV.13.

**IV.13A. INSERTION OF SCREWS LOCKING THE WEDGE DISTANCE PLATE**

The upper part of the plate which is closer to the joint should be screwed in with the use of cancellous screws, then the reamers should be removed. The lower part of the plate which is further from the joint should be screwed in with the locking screws.



**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).**

**IV.13A.1. Insertion of a cancellous screw**

**Insertion of a guide sleeve**

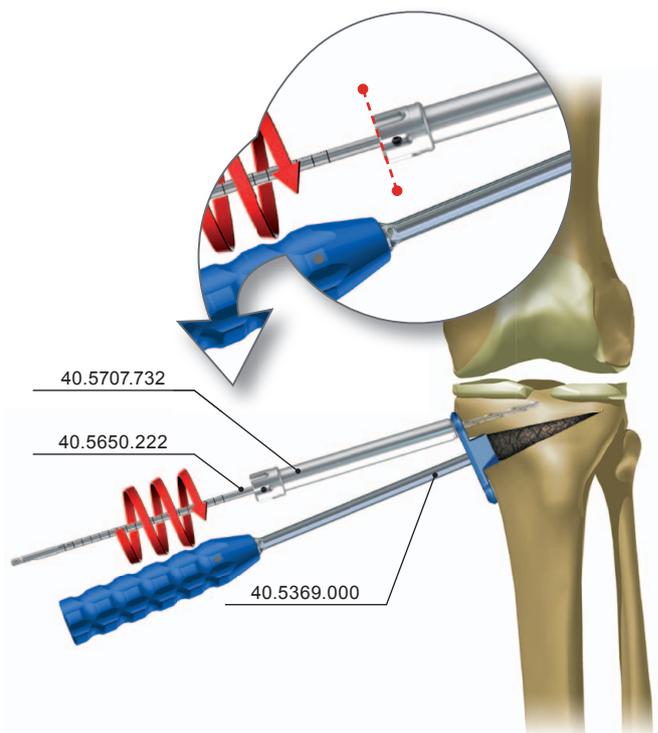
Insert the guide sleeve 9.0/3.2 [40.5707.732] into the plate.

**Hole drilling**

Drill a hole of a desired depth with the use of a drill with scale 3.2/220 [40.5650.222].

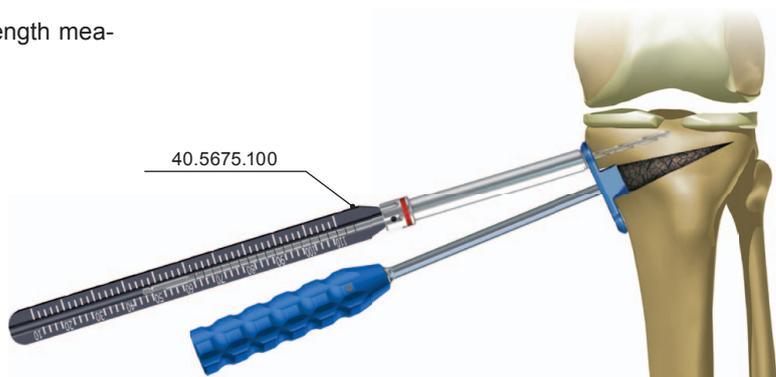
**Measurement of the hole depth**

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

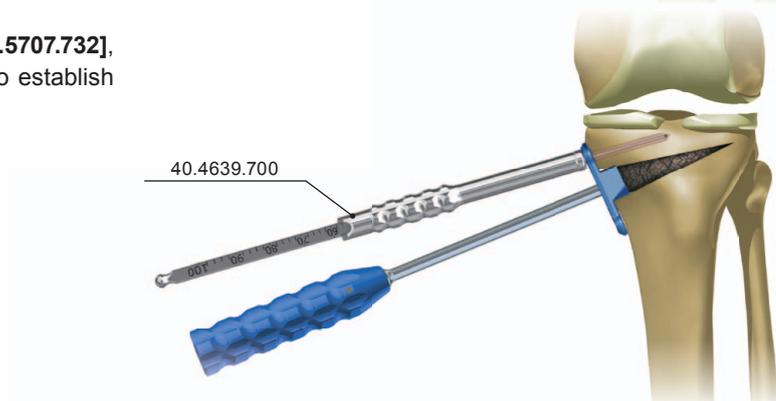


*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

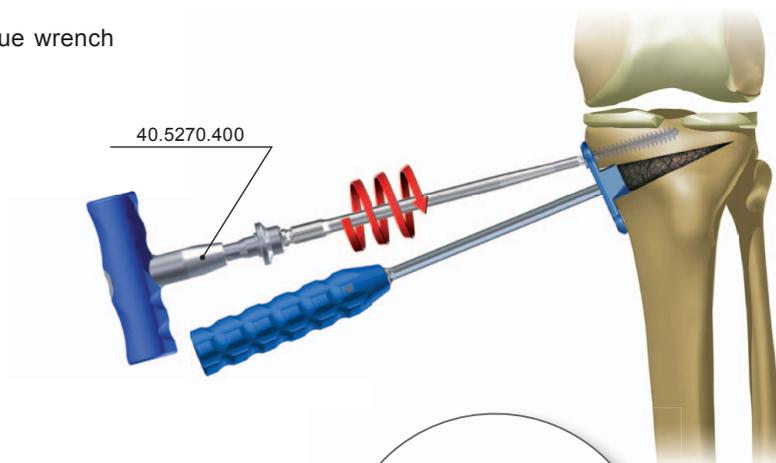
**OPTION II:** Check the value with the use of screw length measure [40.5675.100].



**OPTION III:** After removing the guide sleeve 9.0/3.2 [40.5707.732], use the depth measure [40.4639.700] to establish the length of the screw.



Insert the locking screw 5.0 with the use of a torque wrench [40.5270.400] and an appropriate screwdriver tip.



## IV.13A.2. Insertion of a cancellous screw 6.5

### Insertion of a guide sleeve

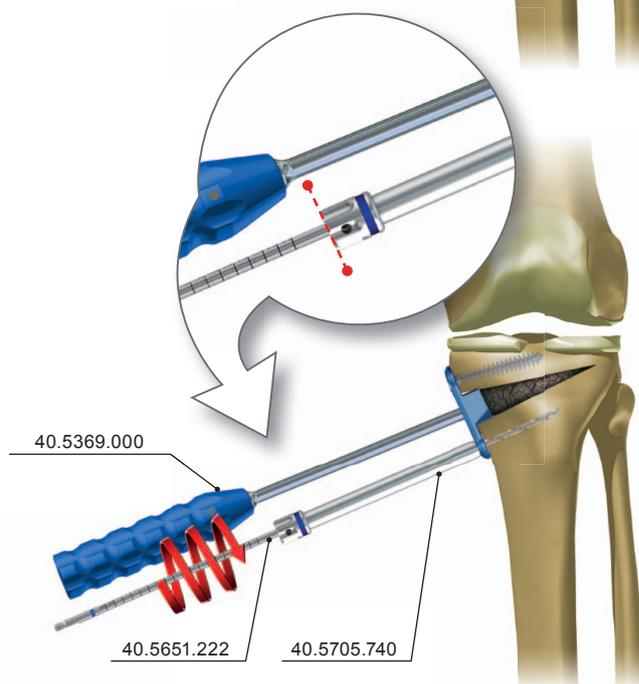
Insert the guide sleeve 7.0/4.0 [40.5705.740] into the plate.

### Hole drilling

Drill a hole of a desired depth with the use of a drill with scale 4.0/220 [40.5651.222].

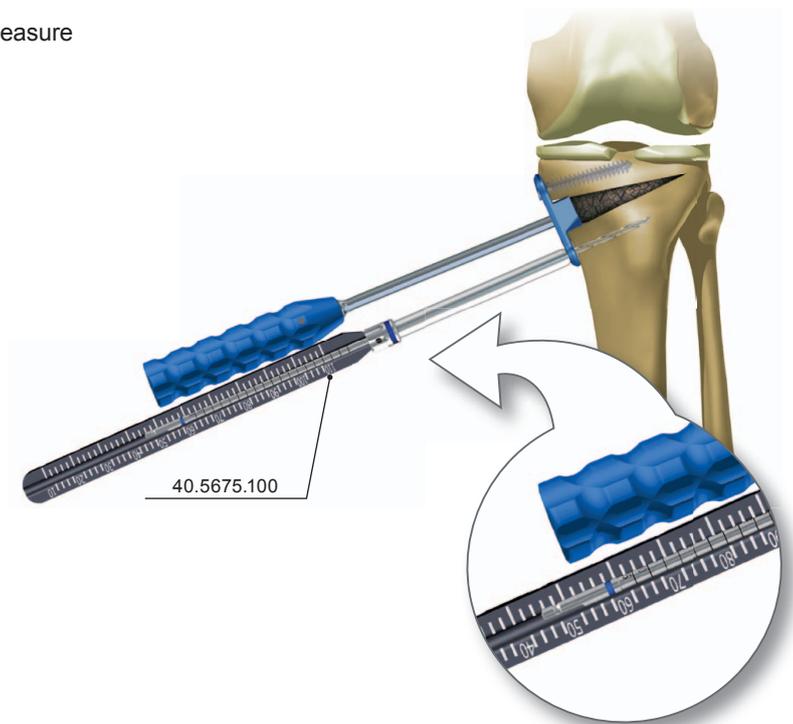
### Measurement of the hole depth

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

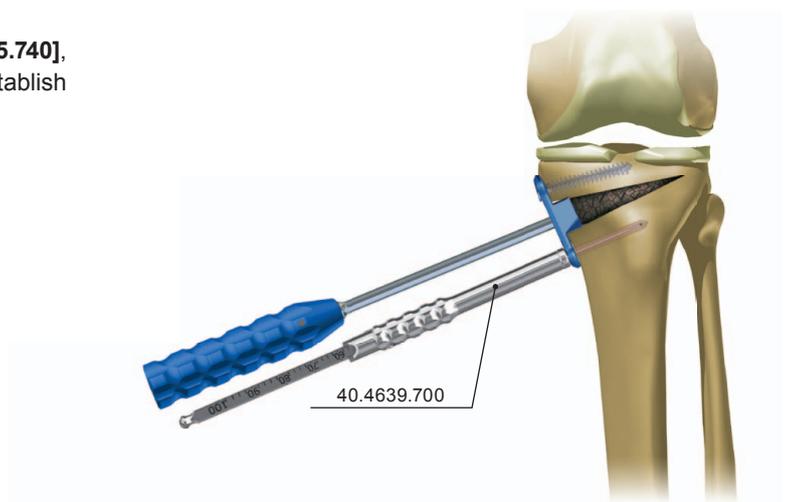


*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

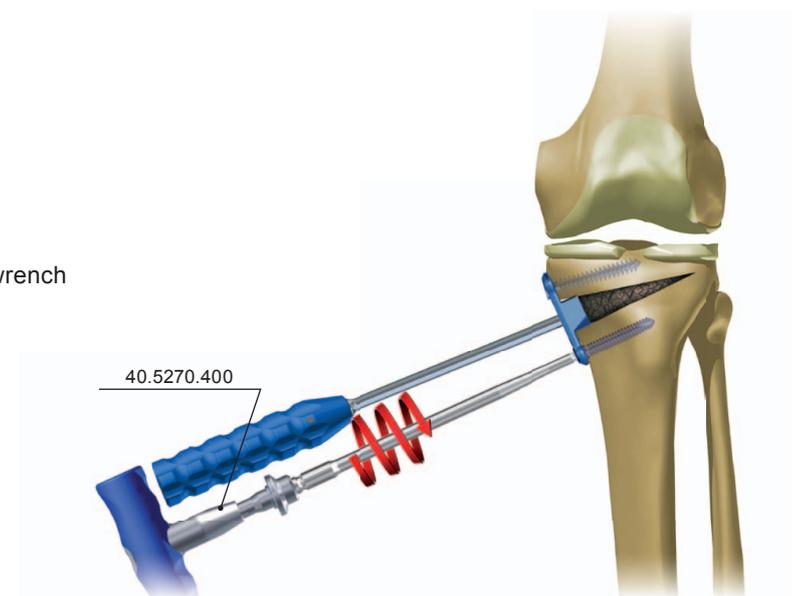
**OPTION II:** Check the value with the use of screw length measure [40.5675.100].



**OPTION III:** After removing the guide sleeve 7.0/4.0 [40.5705.740], use the depth measure [40.4639.700] to establish the length of the screw.



Insert the locking screw 5.0 with the use of a torque wrench [40.5270.400] and an appropriate screwdriver tip.



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

**V. SURGERY TECHNIQUE - FEMUR**

**V.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 [Fig. 2] are used for connecting the fragments of a cut bone in the opening method, while distal plates without wedge are used in the closing method.

The decision regarding the method of bone curvature correction and the manner of connecting the cut bone edges is to be taken by the surgeon on the basis of the size and type of curvature and the desired correction.

A procedure of femur curvature correction by means of opening wedge incision with the use of distance plate for maintaining and connecting the cut bone is presented below.

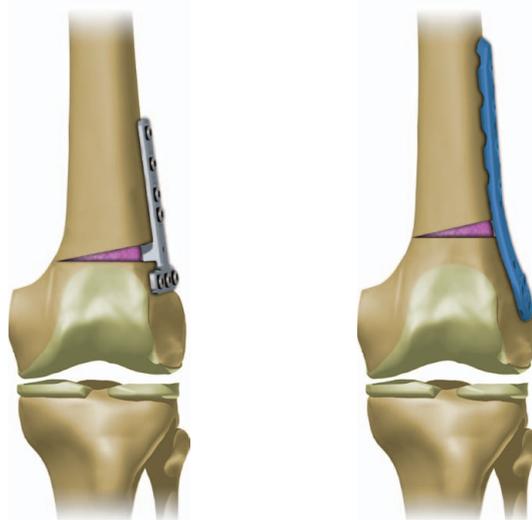


Figure 1  
The opening method with the wedge distance plate

Figure 2  
The opening method with the distance plate without wedge

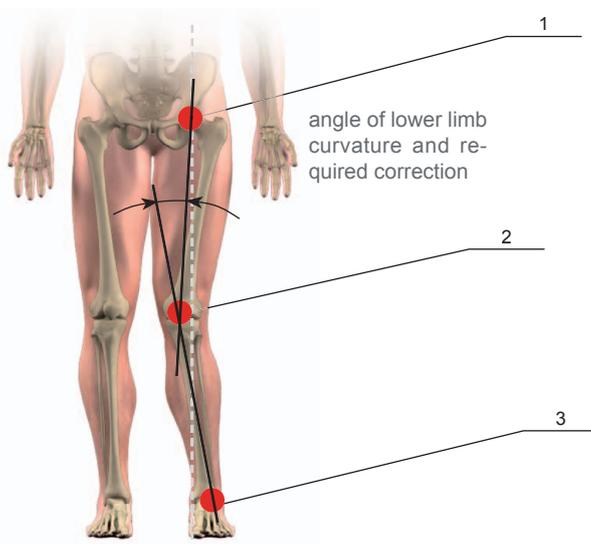
**V.2. INCISION TO ACCESS THE FEMUR**

Make the incision of the skin and tissue approximately 80mm of length (the exact length is to be chosen by the surgeon) on the fibular side, above the fibular collateral ligament (LCL). It is necessary to act with due caution to not damage the nerves, tendons and blood vessels that run through the knee joint.



**V.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.



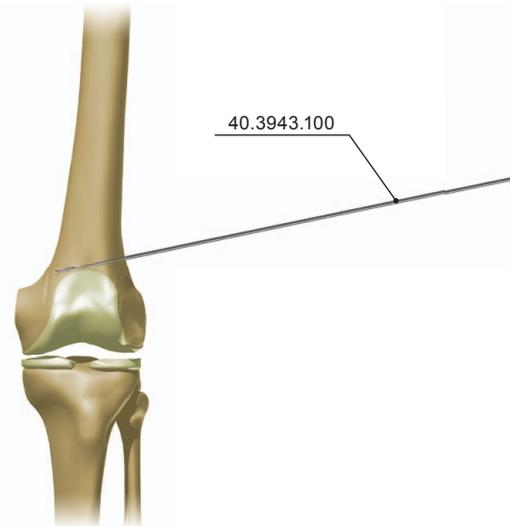
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

**V.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.



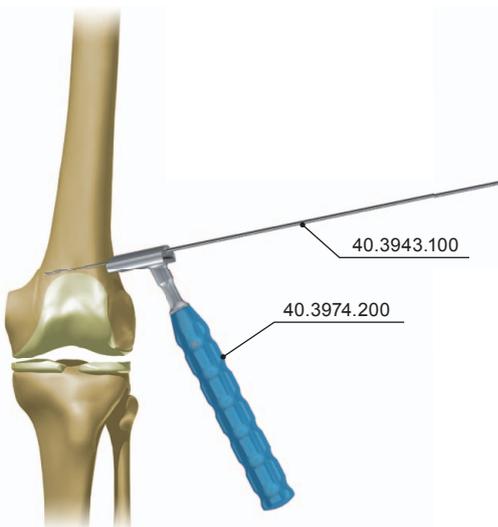
The blade of the guide pin **[40.3943.100]** should be placed about 10mm from the lateral cortex.



V.4.

**V.5. MOUNTING THE TARGETER FOR OSTEOTOMY ON THE GUIDE PIN**

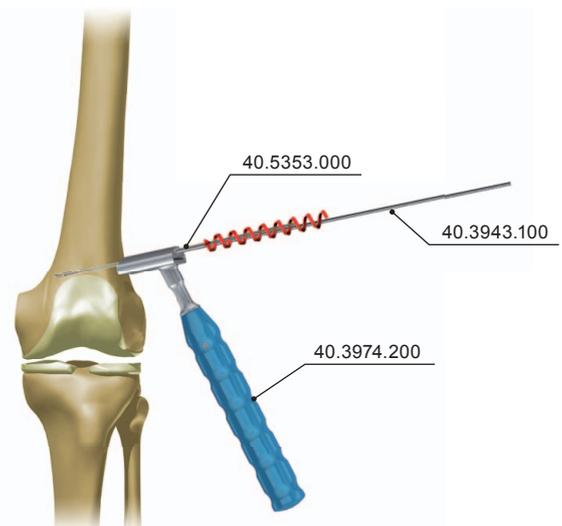
After inserting the guide pin **[40.3943.100]** mount the targeter for osteotomy **[40.3974.200]** on the pin. The manner of targeter positioning is to be chosen by the surgeon.



V.5.

**V.6. INTRODUCTION OF GUIDE RODS**

In order to establish the position of the targeter perpendicularly to the bone insert the guide rods **[40.5353.000]** through the holes of the targeter **[40.3974.200]** with the use of an electric drive.

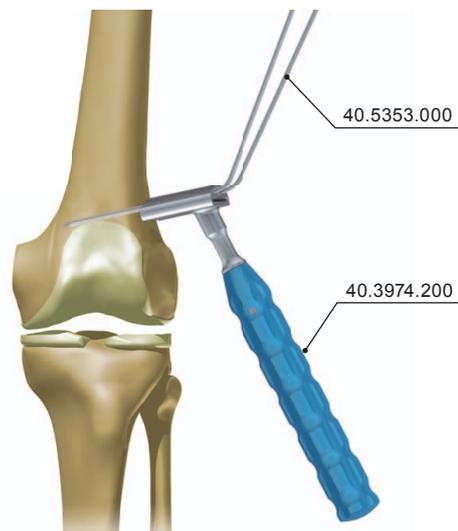


V.6.

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

## V.7. PREPARATION FOR BONE INCISION

Remove the guide pin [40.3943.100] from the bone, then bend the guide rods [40.5353.000] so they do not hamper further procedures.

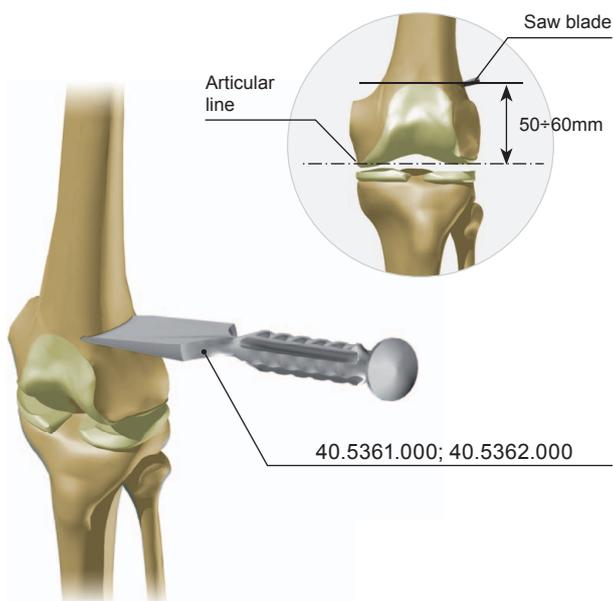


V.7.

## V.8. PERFORMING THE INITIAL INCISION WITH THE SAW AND APPROPRIATE 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 a saw, remove the targeter and guide rods. Then, with the use of osteotome with appropriate blade width [40.5361.000; 40.5362.000] incise the bone. The osteotome should be carefully hit with a hammer, e.g. of Bergman type.



V.9.

**V.9. WEDGE OPENING WITH THE INSTRUMENT SET FOR OSTEOTOMY**

Use 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, oblique surface of the reamers. It is permitted to carefully hit the inserted instrument set with a hammer, e.g. of Bergman type.

**V.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.



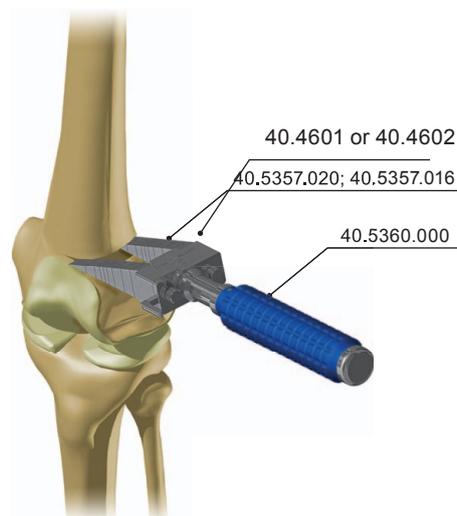
**If the fluoroscope is used that casts the images on the fluorescent screen, it is recommended to repeatedly verify the consecutive steps of the surgery.**

**V.11. REMOVAL OF GRASPING PART OF THE SET AND CONTROL OF OPENING CORRECTNESS**

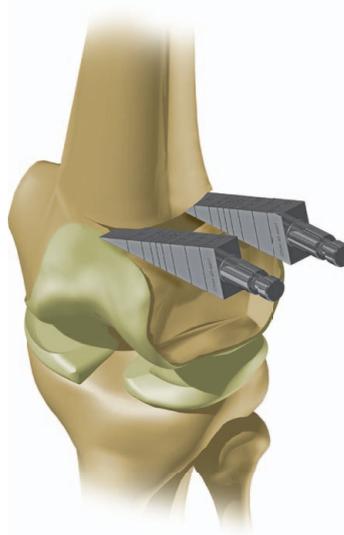
To allow access to the place where a plate of appropriate size is to be placed, it is necessary to dismantle the grasping part of the instrument set for osteotomy [40.5360.000] in such a manner that only two reamers remain in the bone, either [40.5357.020] or [40.5357.016].

**V.12. SELECTION AND INSERTION OF WEDGE DISTANCE PLATE**

The height of distal part of the plate should be selected on the basis of values read from the upper, oblique surfaces of the reamers. After selecting the appropriate plate it is to be placed in the wedge-shaped opening between the reamers with the help of an applicator [40.5369.000].



V.10.



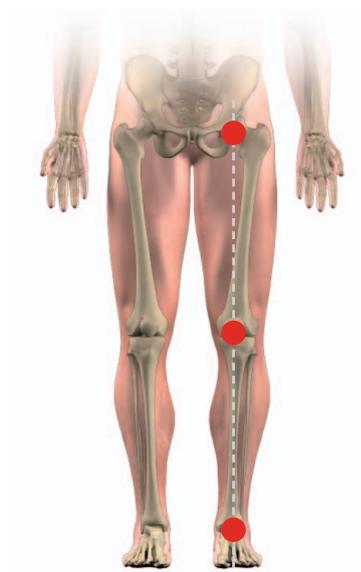
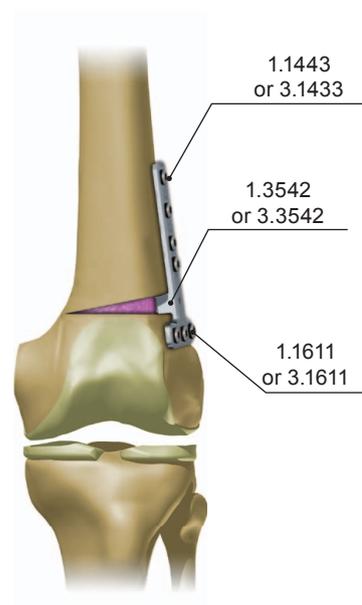
V.11.

### V.13. INSERTION OF SCREWS USED FOR MOUNTING THE WEDGE DISTANCE PLATE

The horizontal part of the plate which is closer to the joint should be screwed in with the use of cancellous screws, then the reamers should be removed. The vertical part of the plate which is further from the joint should be screwed in with the cortical screws. To mount the plate with the screws use the torque wrench [40.5270.400] with the screwdriver tip S3.5 [40.5686.000]. After mounting the plate, verify the correctness of the performed correction of bone curvature with the use of X-Ray or fluoroscopy. It should be possible to draw a straight line through previously mentioned three characteristic points.

### V.13A. INSERTION OF SCREWS LOCKING THE WEDGE DISTANCE PLATE

The horizontal part of the plate which is closer to the joint should be screwed in with the use of cancellous screws, then the reamers should be removed. The vertical part of the plate which is further from the joint should be screwed in with the locking screws.



#### CAUTION!

Further actions should be performed in accordance with the steps described in IV.13A.

**VI. TABLES OF CORRECTION ANGLE**

Table of correction angles [°] for plates 1.3535/3.3535; 1.7065/3.7065; 1.7066/3.7066; 1.3538/3.3538; 1.3539/3.3539; 1.3541/3.3541										
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

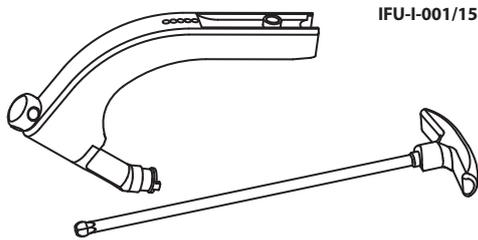
Table of correction angles [°] for plates 1.3536/3.3536; 1.3540/3.3540										
Length of Osteotomy [mm]	Height of opening [mm]									
	3	5	6	7	7.5	8	9	10	12.5	15
50	3.8	6.2	7.5	8.7	9.3	10	11.2	12.4	15.3	18.2
52	3.6	6	7.2	8.4	9	9.5	10.7	11.9	14.7	17.5
54	3.4	5.8	6.9	8	8.6	9.2	10.3	11.4	14.1	16.8
56	3.3	5.5	6.6	7.7	8.3	8.8	9.9	11	13.6	16.2
58	3.2	5.3	6.4	7.4	8	8.5	9.5	10.6	13.1	15.6
60	3.1	5.1	6.2	7.2	7.7	8.2	9.2	10.2	12.7	15.1
62	3	5	5.9	6.9	7.4	7.9	8.9	9.8	12.2	14.6
64	2.9	4.8	5.7	6.7	7.2	7.6	8.6	9.5	11.8	14.1
66	2.8	4.6	5.6	6.5	6.9	7.4	8.3	9.2	11.5	13.7
68	2.7	4.5	5.4	6.3	6.7	7.2	8.1	8.9	11.1	13.3
70	2.6	4.4	5.2	6.1	6.5	7	7.8	8.7	10.8	12.9

Table of correction angles [°] for plates 1.3542/3.3542										
Length of Osteotomy [mm]	Height of opening [mm]									
	3	5	7	7.5	9	10	11	12.5	15	17.5
50	3.9	6.5	9	9.7	11.6	12.8	14	15.9	18.8	21.7
52	3.7	6.2	8.7	9.3	11.1	12.3	13.5	15.2	18.1	20.8
54	3.6	5.9	8.3	8.9	10.6	11.8	12.9	14.6	17.4	20
56	3.4	5.7	8	8.5	10.2	11.3	12.4	14	16.7	19.3
58	3.3	5.5	7.7	8.2	9.8	10.9	11.9	13.5	16.1	18.6
60	3.2	5.3	7.4	7.9	9.5	10.5	11.5	13	15.5	18
62	3.1	5.1	7.1	7.6	9.1	10.1	11.1	12.6	15	17.4
64	3	4.9	6.9	7.4	8.8	9.8	10.7	12.2	14.5	16.8
66	2.9	4.8	6.6	7.1	8.5	9.5	10.4	11.8	14	16.3
68	2.8	4.6	6.4	6.9	8.3	9.2	10.1	11.4	13.6	15.8
70	2.7	4.5	6.2	6.7	8	8.9	9.8	11	13.2	15.3

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

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

Manufacturer: ChM sp. z o.o.  
Lewickie 3b, 16-061 Juchnowiec K., Poland  
tel.: +48 85 713-13-20 fax: +48 85 713-13-19  
e-mail: chm@chm.eu www.chm.eu



IFU-I-001/15



## INSTRUCTIONS FOR USE

## REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS



Instruments manufactured by ChM sp. z o.o. are made of steel, aluminium alloys and plastics according to ISO standards. Each medical instrument is exposed to occurrence of corrosion, stains and damage if not treated with special care and according to recommendations provided below.

## MATERIALS

Devices are produced of corrosion-resistant steel. The protective layer (*passive layer*) against corrosion is formed on the surface of the steel due to high content of chromium.

Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as handles of screwdrivers, awls or wrenches, etc. The protective oxide layer, which may be dyed or stay in natural colour (*silvery-grey*), is formed on the aluminium as an effect of electrochemical treatment on its surface.

Devices made of aluminium with processed layer have a good corrosion resistance. The contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference on the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: POM-C (*Polyoxymethylene Copolymer*), PEEK (*Polyetheretherketone*) and teflon (*PTFE*). The above mentioned materials can be processed (*washed, cleaned, sterilized*) at temperatures not higher than 140°C, they are stable in aqueous solution of washing-disinfecting agents with pH values from 4 to 9.5.

• If the material of the device cannot be specified, please contact ChM sp. z o.o. company representative.

## DISINFECTION AND CLEANING

Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quality of used detergent, the technique of cleaning (*manual/machine*), the correct rinsing and drying, the proper preparation of the instrument, the time, the temperature. Internal procedures of sterilization rooms, recommendations of cleaning and disinfecting agents, as well as recommendations for cleaning and sterilization in automatic machines shall be observed.

• Read and follow the instructions and restrictions specified by the manufacturers of the agents used for disinfection and cleaning procedures.

- Before the first use, the product has to be thoroughly washed in the warm water with washing-disinfecting detergent. It is important to follow the instructions and restrictions specified by the producer of those detergents. It is recommended to use water solutions of cleaning-disinfecting agents with a neutral pH.
- After use, for at least 10 minutes the product has to be immediately soaked in an aqueous disinfectant solution of enzyme detergent with a neutral pH (*with disinfecting properties*) normally used for reusable medical devices (*remember to prevent drying out of any organic remains on the product surface*). Follow all the instructions specified by the producer of those enzyme detergents.
- Carefully scrub/clean the surfaces and crevices of the product using a soft cloth without leaving threads, or brushes made of plastic, the nylon brushes are recommended. Do not use brushes made of metal, bristles or another damaging material as they can cause physical or chemical corrosion.
- Next, thoroughly rinse the instrument under the warm running water, paying particular attention to rinse the slots carefully. Use nylon brushes making multiple moves back and forth on the surface of the product. It is recommended to rinse under demineralized water, in order to avoid water stains and corrosion caused by chlorides, found in the ordinary water, and to avoid forming the stains on the surface (*e.g. acidized one*). During the rinsing, manually remove the adherent remains.
- Visually inspect the entire surface of the product to ensure that all contaminants are removed.

• If there are any residues of human tissue or any other contamination, repeat all stages of the cleaning process.

- Then, the instrument has to undergo a process of machine washing in the washer-disinfector (*use washing-disinfecting agents recommended for reusable medical devices and instruments*).

• Procedure of washing with the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and instructions for use prepared by the washing-disinfecting agents manufacturer.

**ATTENTION!** The manufacturer does not recommend using any preservatives on surgi-

cal and orthopedic devices.

## STERILIZATION

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds like residues after disinfection and sterilization processes, without structure damage (*cracks, fractures, bending, peeling*). Remember that sterilization is not a substitute for cleaning process!

• Devices manufactured out of plastics (PEEK, PTFE, POM-C) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.

Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards. It is recommended to sterilize in steam sterilizers where sterilizing agent is water vapour. Recommended parameters of the sterilization method:

- temperature: 134°C,
- pressure: 2 atm. of pressure above atmospheric (*overpressure*),
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

Validated sterilization methods are allowed. Durability and strength of instruments to a considerable degree depend on how they are used. Careful usage consistent with intended use of the product protects it against damage and prolongs its life.

If this instruction appears unclear, please contact the manufacturer, who shall provide all required explanations.

Updated INSTRUCTIONS FOR USE are available on the following website: [www.chm.eu](http://www.chm.eu)

IFU-I-001/15; Date of verification: January 2015

SYMBOL TRANSLATION - OBJASŇENIA SYMBOLŮ - ПОРЧЕННІЕ ОГОВНАЧЕНІЙ  
EXPLICACIÓN DE LOS SÍMBOLOS - SYMBOLERKLÄRUNG - SYMBOLY PŘEKLADY

Do not reuse Nie używać ponownie Не использовать повторно No reutilizar Nicht wiederverwenden Неповторно опакowanie	Do not resterilize Nie sterylizować ponownie Не стерилизовать повторно No reesterilizar Nicht reesterilisieren Неповторно стерилизация	Do not use if package is damaged Nie używać jeśli opakowanie jest uszkodzone Не использовать при поврежденной упаковке No utilizar si el empaque está dañado Nicht verwenden falls Verpackung beschädigt ist Неповреждете, pokud je obal poškozen
Sterilized using irradiation Sterylizowany przez napromienianie Радиационная стерилизация Esterilizado mediante radiación Sterilisiert durch Bestrahlung Sterilizovano zářením	Sterilized using hydrogen peroxide Sterylizowany nadkwasą wodorową Стерилизован перекисью водорода Esterilizado con peróxido de hidrógeno Sterilisiert mit Wasserstoffperoxid Sterilizovano s perovodom vodikom	Non-sterile Niesterylizy Не стерильно No estéril Unsteril Nesterilni
<b>STERILE R</b>	<b>STERILE VH202</b>	
Catalogue number Numer katalogowy Номер по каталогу Número de catálogo Katalognummer Katalogové číslo	Batch code Kód partii Код партии Código de lote Chargennummer Číslo šarže	Consult Instructions for Use Zapczy do instrukcji używania Обратитесь к инструкции по применению Consultar instrucciones de uso Siehe die Gebrauchsanweisung Rúče se návodom k použití
<b>REF</b>	<b>LOT</b>	
Material Materiał Материал Material Material Material	Quantity Ilość Количество Cantidad Menge Mnoštvi	Use by Użyj do Использовать по Usar antes de Verwenden bis Použiť do
<b>Mat:</b>	<b>Qty:</b>	
	Caution Ostrzeżenie Осторожно Advertencia Vorsicht Varoitus	

Manufacturer: ChM sp. z o.o.  
Lewickie 3b, 16-061 Juchnowiec K., Poland  
tel.: +48 85 713-13-20 fax: +48 85 713-13-19  
e-mail: chm@chm.eu www.chm.eu

# ChM®

**ChM sp. z o.o.**

**Lewickie 3b  
16-061 Juchnowiec K.  
Poland**

**tel. +48 85 713-13-20  
fax +48 85 713-13-19  
e-mail: chm@chm.eu**



- 4 INTRAMEDULLARY OSTEOSYNTHESIS OF HUMERUS
- 6 INTERMEDULLARY OSTEOSYNTHESIS OF FEMUR BY TROCHANTERIC NAILS
- 7 INTRAMEDULLARY OSTEOSYNTHESIS OF FIBULA AND FOREARM
- 8 DYNAMIC HIP (DSB) CONDYLAR (DSK) STABILIZER
- 9 SPINE STABILIZATION
- 10 EXTERNAL FIXATOR
- 15 TIBIAL AND FEMORAL ANGULAR SET BLOCK
- 17 INTRAMEDULLARY OSTEOSYNTHESIS OF FEMORAL AND TIBIA TELESCOPIC NAIL
- 20 RADIAL HEAD PROSTHESIS KPS
- 21 OPENING WEDGE OSTEOTOMY
- 22 LOCKING PLATES
- 23 OSTEOSYNTHESIS OF FEMUR REVERSED METHOD (condylar approach)
- 24 INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR
- 25 INTRAMEDULLARY OSTEOSYNTHESIS OF TIBIA
- 27 INTRAMEDULLARY OSTEOSYNTHESIS OF TIBIA (retrograde method)
- 28 INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR WITH TROCHANTERIC ChFN NAILS
- 29 CERVICAL LOCKING PLATE SYSTEM
- 30 PROXIMAL HUMERAL PLATE
- 31 THE FEMORAL PLATES
- 32 4.0 ChLP PLATES FOR DISTAL PART OF RADIAL BONE
- 34 INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR WITH ANATOMIC FEMUR NAILS
- 35 SPINE STABILIZATION
- 36 ChLP SCREWS REMOVING
- 37 STABILIZATION OF THE PUBIC SYMPHYSIS
- 38 INTRAMEDULLARY TIBIA OSTEOSYNTHESIS WITH CHARFIX2 NAILS
- 39 IDS SYSTEM
- 40 INTERVERTEBRAL CAGES PLIF PEEK CAGE
- 42 STERNO-COSTAL PLATE
- 43 INTRAMEDULLARY OSTEOSYNTHESIS OF HUMERUS
- 45 RECONSTRUCTION PLATES - PELVIS FIXATION
- 46 INTRAMEDULLARY OSTEOSYNTHESIS OF TIBIA (retrograde method)
- 47 LOCKING PLATES 5.0ChLP
- 48 LOCKING PLATES 7.0ChLP
- 49 INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR WITH CONDYLAR NAIL
- 52 INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR WITH TROCHANTERIC NAILS
- 54 ALIF PEEK INTERVERTEBRAL LOCKING CAGES
- 55 ELASTIC INTRAMEDULLARY NAIL FOR CHILDREN
- 56 TLIF PEEK INTERVERTEBRAL CAGES
- 57 5.0ChLP STRAIGHT LOCKING PLATE
- 58 7.0ChLP STRAIGHT LOCKING PLATE
- 59 DISTAL TIBIA TARGETER CHARFIX
- 60 DISTAL TIBIA TARGETER CHARFIX2

**SALES OFFICE**

**tel.: + 48 85 713-13-30 ÷ 38**

**fax: + 48 85 713-13-39**