

instruction

OPENING WEDGE OSTEOTOMY

IMPLANTS ◦
INSTRUMENT SET ◦
SURGICAL TECHNIQUE ◦



21B

CE 0197
ISO 9001
ISO 13485

ChM®

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I. INTRODUCTION

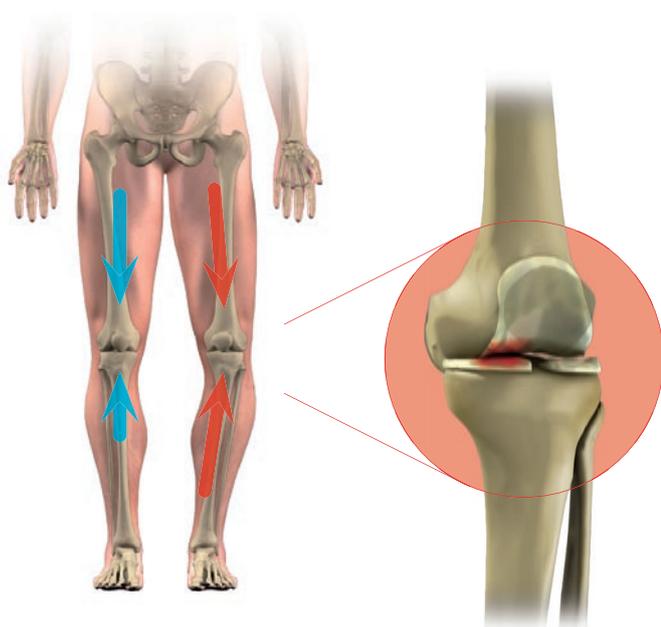
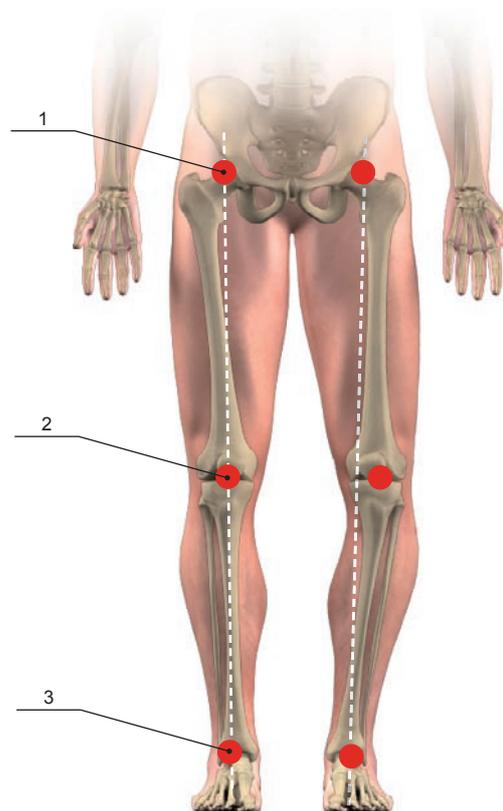
Instrument set for correcting the bone curvature with the wedge-shaped incision consists of:

- 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 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 causes 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 proximal femur (it depends on the limb curvature), removes the wedge piece of the bone, connects the open edges and unites the bones with plates or clasps.

2. The opening method

The surgeon makes the transverse cut of the tibia, or lateral or proximal 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**.

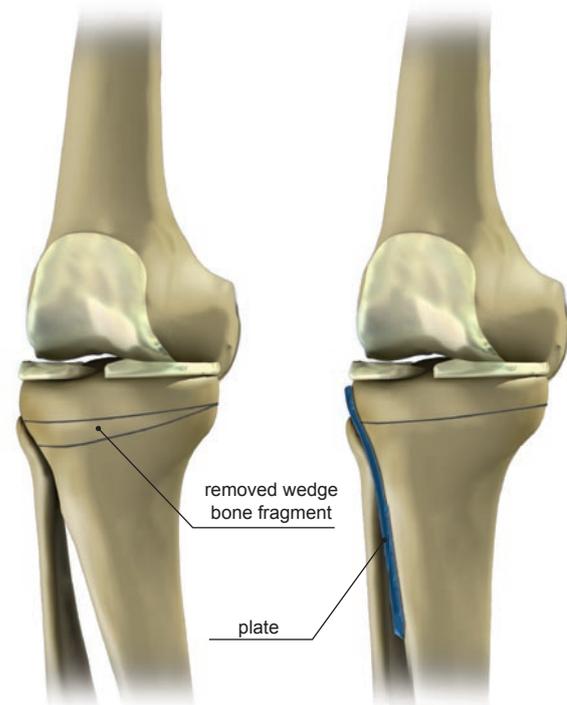
I.1. Closing method of osteotomy

The incision is made in the lateral or the proximal side of the knee. It allows to see the upper end of tibia or the lower end of the femur (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 has proper size and is placed correctly. The X-ray should view the images on the fluorescent screen.

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

Surgical treatment should have minimum amount of pain and scarring.



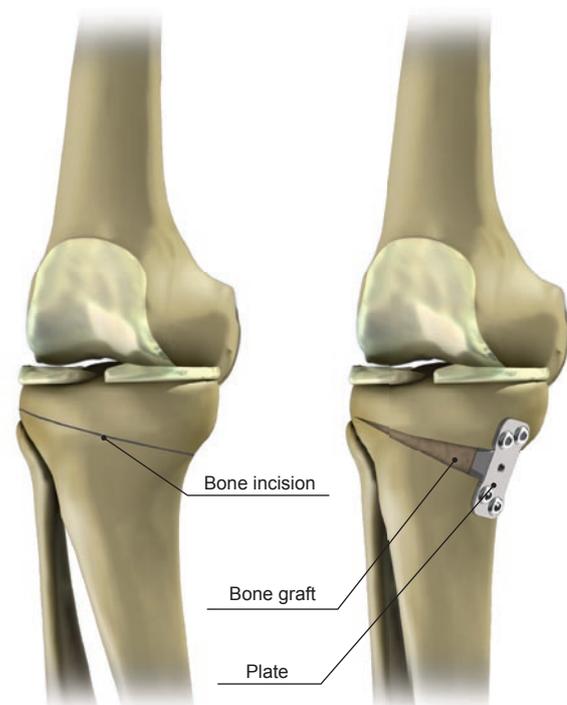
I.2. Opening method of osteotomy

The opening method is performed on the lateral and the proximal 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 carried. Used the Fluoroscopy or x-ray 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 the appropriate length of wedge distance plate 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 the place by the metal plate, or clasps. Next, the skin is to be sutured and the leg placed on the padded rail in order to protect the knee joint.

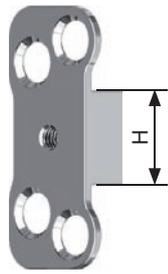
Surgical treatment should have a minimum amount of pain and scarring.



II. IMPLANTS

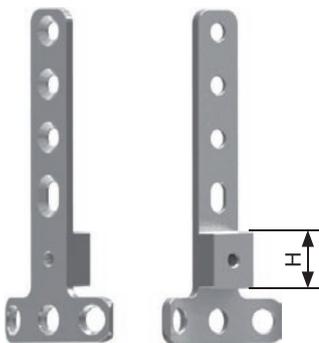
II.1. Wedge distance plates

Tibial



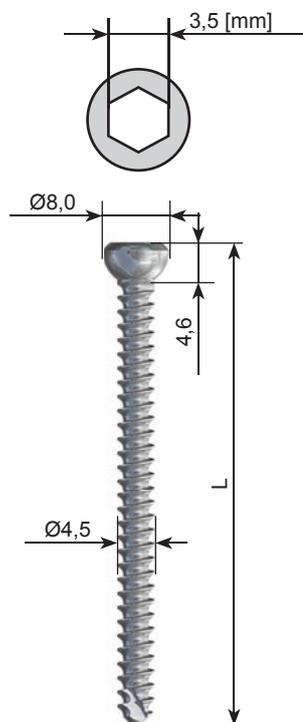
H [mm]	Catalogue no.	
	Steel	Titanium
3,0	1.3541.030	3.3541.030
5,0	1.3541.050	3.3541.050
7,5	1.3541.075	3.3541.075
9,0	1.3541.090	3.3541.090
10,0	1.3541.100	3.3541.100
11,0	1.3541.110	3.3541.110
12,5	1.3541.125	3.3541.125
15,0	1.3541.150	3.3541.150
17,5	1.3541.175	3.3541.175

Femoral



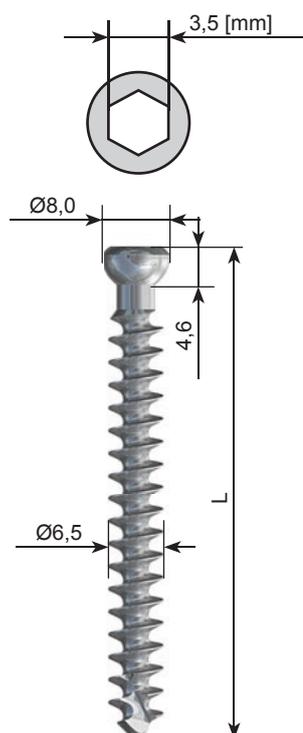
H [mm]	Catalogue no.	
	Steel	Titanium
3,0	1.3542.030	3.3542.030
5,0	1.3542.050	3.3542.050
7,5	1.3542.075	3.3542.075
9,0	1.3542.090	3.3542.090
10,0	1.3542.100	3.3542.100
11,0	1.3542.110	3.3542.110
12,5	1.3542.125	3.3542.125
15,0	1.3542.150	3.3542.150
17,5	1.3542.175	3.3542.175

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

III. INSTRUMENT SET

The Instrument Set **[40.5350.000]** – for correction of the bone curvature with the wedge-shaped incision.

The set of instrument is placed on the Stands **[40.5359]** with a lid to enable transport to the operating suite.

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

Lp.	Catalogue no.	Name	Qty.
1	40.3661.000	Drill guide Ø6,5/Ø2,8	2
2	40.3943.000	Guide pin with eyelet	1
3	40.3974.000	Osteotomy target	1
4	40.4601.000	Instrument set for osteotomy 10	1
5	40.4602.000	Instrument set for osteotomy 16	1
6	40.5351.000	Trocar	1
7	40.5353.000	Guide rod	2
8	40.5354.000	Guide gouge	1
9	40.5355.000	Universal osteotome	1
10	40.5356.010	Osteotome blade 10mm	1
11	40.5356.025	Osteotome blade 25mm	1
12	40.5356.035	Osteotome blade 35mm	1
13	40.5369.000	Applicator	1
14	40.0321.000	Hexagonal screwdriver S2.5	1
15	40.0320.000	Hexagonal screwdriver S3.5	1
16	40.5359.000	Stand	1

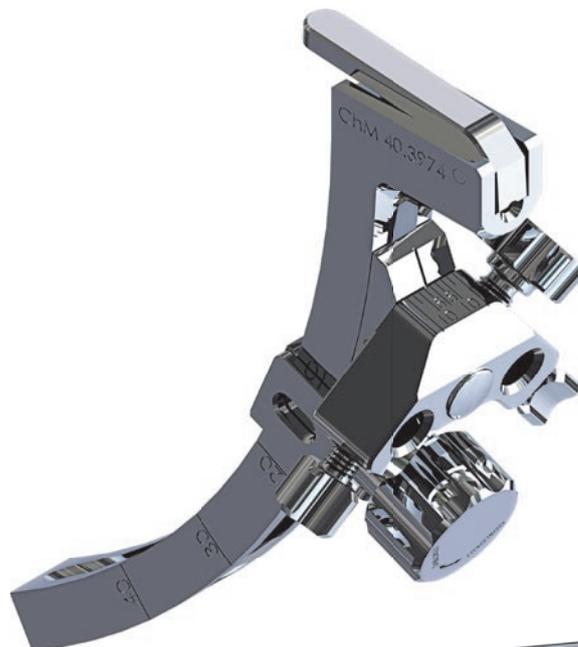
To carry out the surgery, some other basic devices are needed:

- the electric drive,
 - surgery hammers
- and other (pliers, a saw)

1. Drill guide Ø6,5/Ø2,8
[40.3661.000]



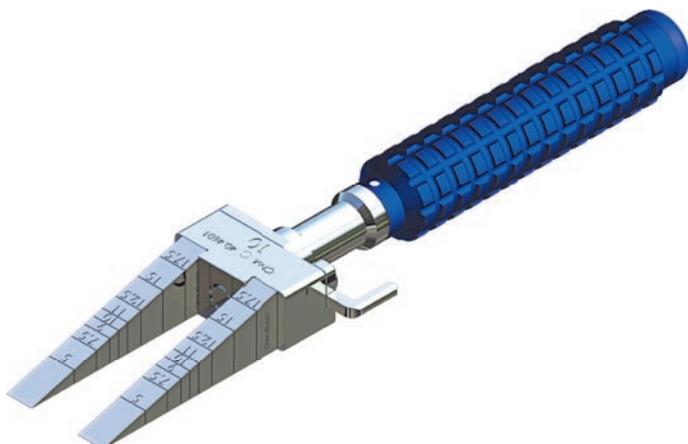
3. Osteotomy target
[40.3974.000]



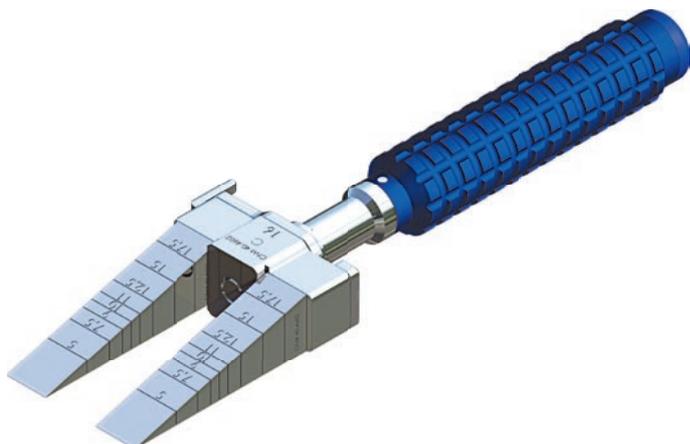
2. Guide pin with eyelet
[40.3943.000]



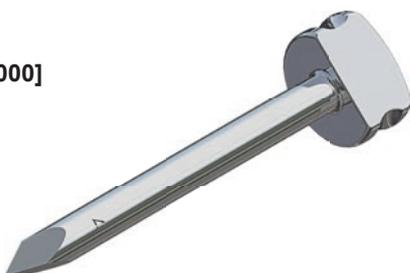
4. Instrument set for osteotomy „10”
[40.4601.000]



5. Instrument set for osteotomy „16”
[40.4602.000]



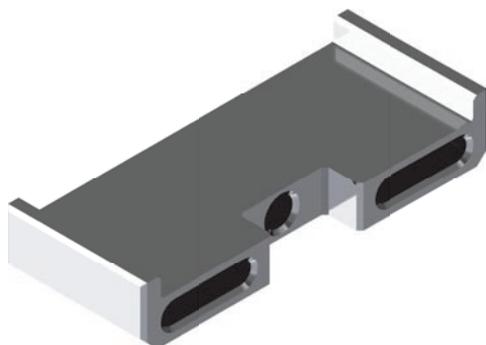
6. Trocar
[40.5351.000]



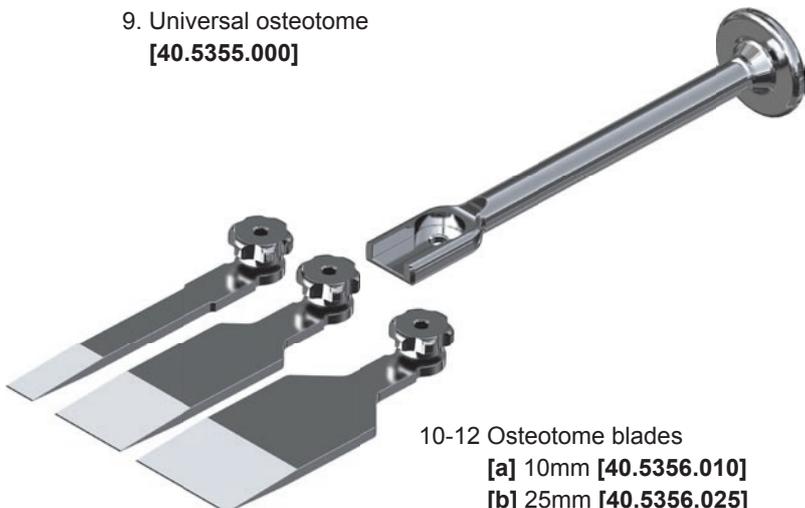
7. Guide rod
[40.5353.000]



8. Guide gouge
[40.5354.000]



9. Universal osteotome
[40.5355.000]



10-12 Osteotome blades
[a] 10mm [40.5356.010]
[b] 25mm [40.5356.025]
[c] 35mm [40.5356.035]

IV. SURGERY TECHNIQUE - TIBIA

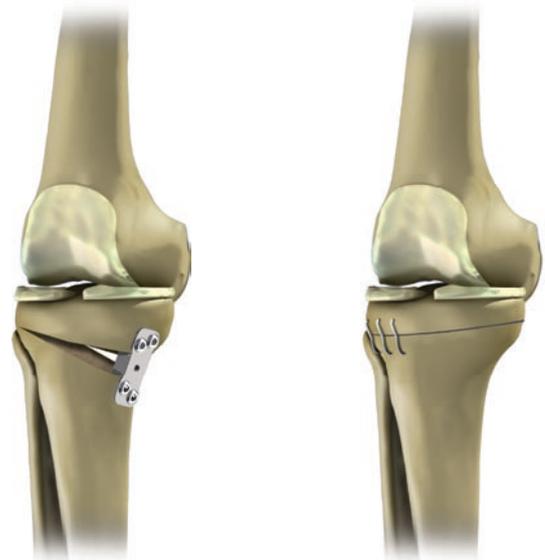
IV.1. Introduction

Any bone curvature correction is to be properly planned. In opening method (1) the wedge distance plates are used to connect the edges of the bone cut. Distance plates without wedge can also be used.

In closing method the clasps are used (2) to connect the edges of the bone cut. Distance plates without wedge can also be used.

Both, the method and the type of connection that based on the size and type of curvature should be chosen by the surgeon.

Below, the opening osteotomy of tibia.



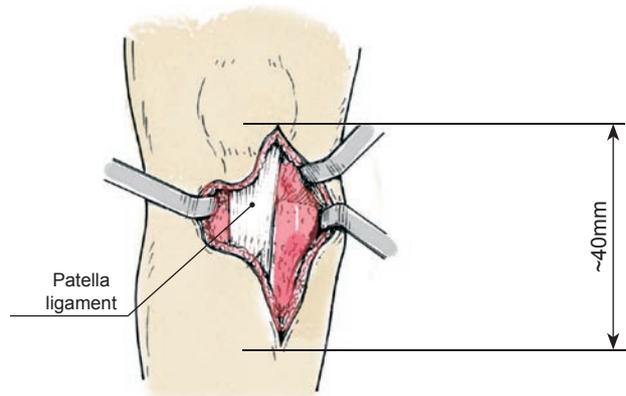
Picture 1
Opening Method with wedge distance plate.

Picture 2
Closing Method with clasps.

IV.2. Incision to access tibia

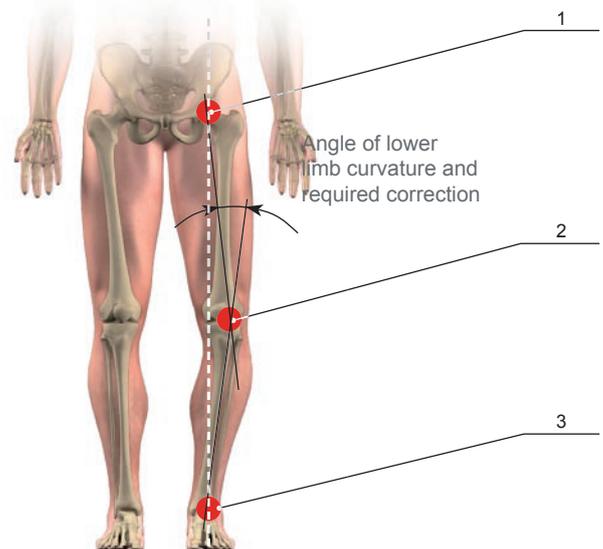
Make skin incision to the approx. length of 40mm in the middle of the knee, along the patella ligament. The approx. length of the cut should be decided by surgeon.

Nerves, tendons and blood vessels which pass through the knee joint should be protected from damaging.



IV.3. Angle correction and height of opening

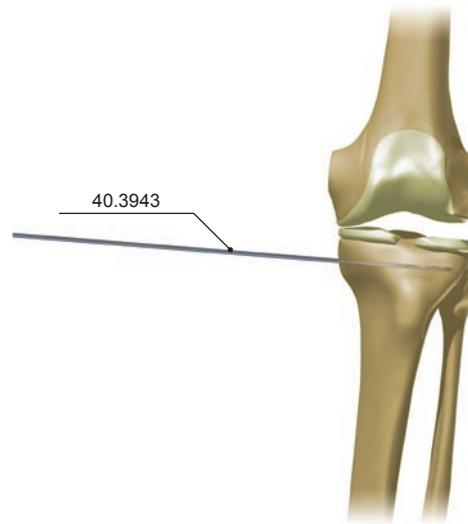
The angle of lower limb curvature and needed length of opening is to be examined by fluoroscopy. The bone angle is defined by drawing two straight lines. One line is drawn from the center of femoral head (1) to point of midway of knee joint (2). Another line is drawn from center of distal tibia head (3) to point of midway of knee joint(2). The angle formed by the intersection of these two line determines the degree of the correction. Look at the picture.



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

IV.4. Insertion of guide pin with eyelte

Insert the Guide Pin With Eyelte [40.3943] to exposed upper part of the tibia using the electric drive. The guide pin is to be perpendicularly positioned to the tibia. The appropriate position of the pin is to be chosen by surgeon.



IV.4.



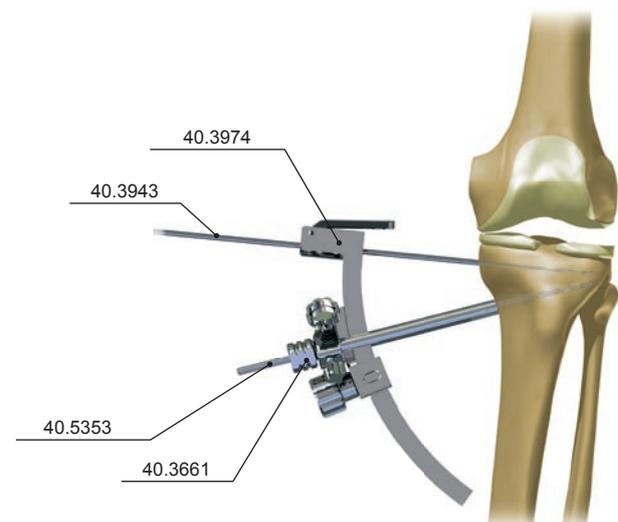
IV.5.

IV.5. Locating osteotomy target on pin

Insert the Osteotomy Target [40.3974] onto the Guide Pin With Eyelte [40.3943]. Distance from the osteotomy target to the tibia should be less than total length of the Drill Guide Ø6.5/Ø2.8 [40.3661].

IV.6. Introduction of drill guides and guide rods

Use attached Osteotomy Target [40.3974], to insert both Drill Guides [40.3661]. Insert the Guide Rods [40.5353] into the Drill Guide [40.3661] using the saw.



IV.6.

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

IV.7. Removal of osteotomy target and insertion of guide gouge

After rods are inserted, remove the Osteotomy Target [40.3974] and both Drill Guides [40.3661]. Then remove the Guide Pin With Eyelet [40.3943]. Next, insert the Guide Gouge [40.5354] onto the Guide Rods [40.5353].

The lateral walls of the guide gouge should be directed downward and the cut by the middle hole outside.



IV.7.



IV.8.

IV.8. Insertion of trocar and reduction of guide rods

Insert the Trocar [40.5351] into the guide gouge using the hammer (e.g. Bergman). Then reduce the Guide Rods [40.5353]. Use claws to cut the protruding guide rods part which could interfere with carrying out the surgery.

IV.9. Pre-incision and universal osteotome

Use the plane formed by the Guide Gouge [40.5354] to make pre-incision of the tibia using the saw.

The incision should be removed about 20 ÷ 25 mm from the articular line (The surgeon decides about the appropriate distance).

After pre-incision, using the Guide Gouge [40.5354] plane, make the tibia incision with the Universal Osteotome [40.5355] equipped with appropriate Osteotome Blades [40.5356.010; 40.5356.025; 40.5356.035]. Gently use the hammer (e.g. Bergman) to place the universal osteotome.



IV.9.

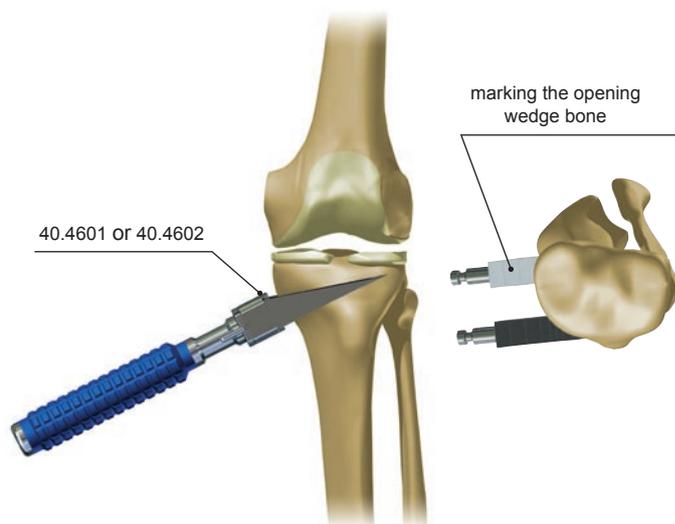
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.10. Implementation of opening osteotomy by using instrument set

After the incision, remove the Guide Rods [40.5353] and the Guide Gouge [40.5354]. Insert the instrument set for osteotomy into the incision of the bone:

- [40.4601] - instrument set for osteotomy "10"
- [40.4602] - instrument set for osteotomy "16"

Gently use the hammer (e.g. Bergman) to place the instrument set for osteotomy "10"/ "16".



IV.10.

IV.11. Controlling the angel of correction and the height of wedge opening

To control the correction angel and the height of the wedge opening use the x-ray or Fluoroscopy. Make sure that the desire degree of correction is maintain.



If the Fluoroscopy is used, all steps should be confirmed repeatedly.

IV.12. Removing handle part of instrument set and controlling wedge opening

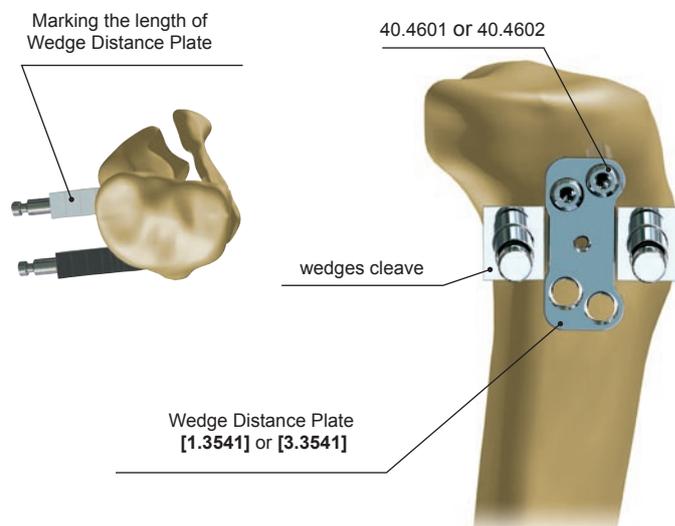
Remove the handle part of the Instrument Set [40.4601] or [40.4602] to access the place where the Wedge Distance Plate ([1.3541] steel or [3.3541] – titanium) will be inserted. Only two splitting wedges should remain in the bone.



IV.12.

IV.13. Selection and insertion of wedge distance plate

Selection of the length of the Wedge Distance Plate ([1.3541] steel or [3.3541] – titanium) should be based on the values read at the upper sloping surfaces of wedges cleave. Use the Applicator [40.5369] to insert selected wedge distance plate into wedge bone cut.



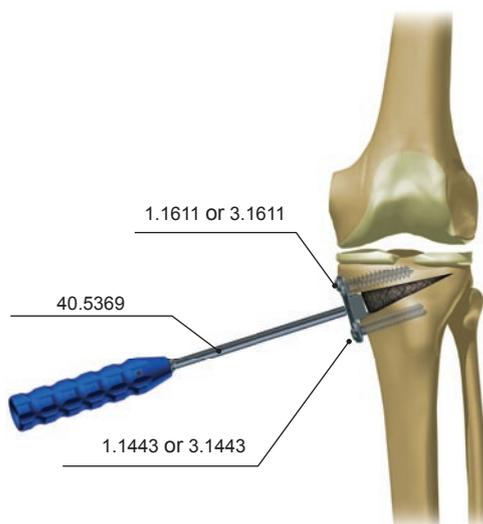
IV.13.

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

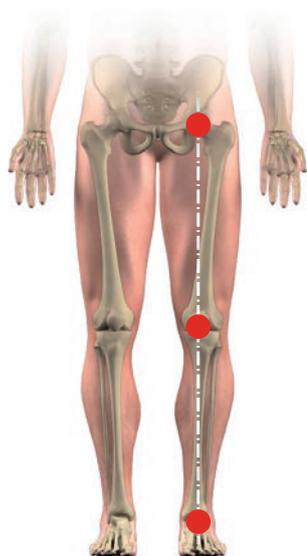
IV.14. Insertion of wedge distance plate screws

The upper part of the Wedge Distance Plate ([1.3541] steel or [3.3541] – titanium) that is placed closer to the joint, should be inserted using cancellous screws ([1.1611] – steel or [3.1611] – titanium). The splitting wedges should be removed. The lower part of Wedge Distance Plate ([1.3541] steel or [3.3541] – titanium); that is placed further from the joint; should be inserted using the Corical Screws ([1.1443] – steel, or [3.1443] – titanium). Insert the screws into the plate using the Hexagonal Screwdriver S3.5 [40.0320]. After placing the plate and screws, use the x-ray or Fluoroscopy to make sure that desire degree of correction is maintain.

3 points that are mentioned in the Introduction, should be now connected by the straight line.



IV.14.



V. SURGERY TECHNIQUE - FEMUR

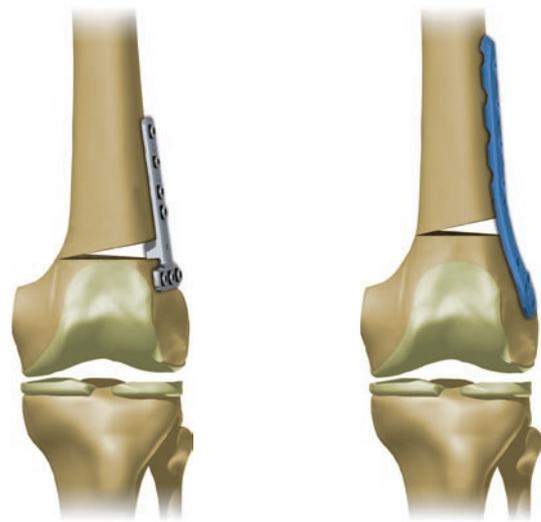
V.1. Introduction

Any correction of bone curvature by incision is to be properly planned.

In opening wedge method, the wedge distance plates are used [1]. Distance plates without wedge can also be used. In closing method, the distance plates without wedge are used [2].

Both, the method and the type of connection, that based on the size and type of curvature, should be chosen by the surgeon.

Below, opening wedge osteotomy of femur.



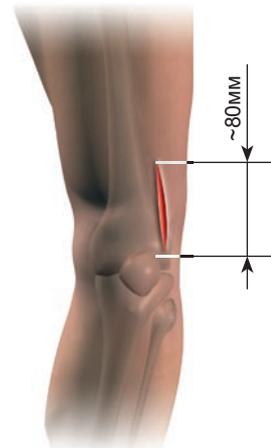
Picture 1
The opening method with the wedge distance plates

Picture 2
The closing method with the distance plates without wedge

V.2. Incision to access the femur

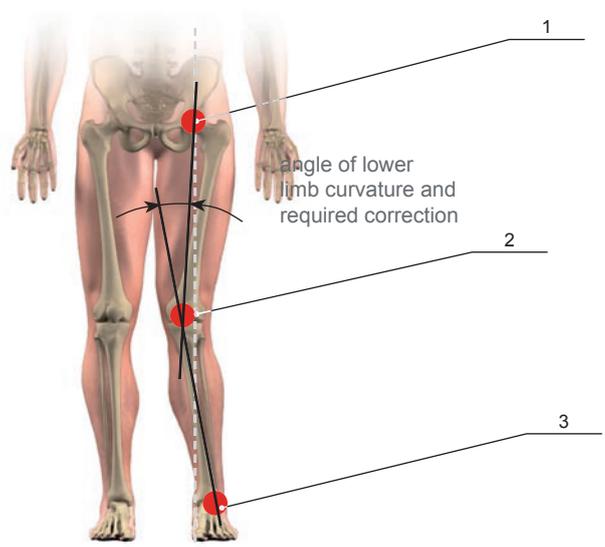
Make the incision of the skin and tissue to an approx. length of 80mm in the middle of the femur, below the minor ligament of tibia (LCL). The surgeon decides about the approx. length of the cut.

Nerves, tendons and blood vessels which pass through the knee joint should be protected from damaging.



V.3. Angle correction and height of opening

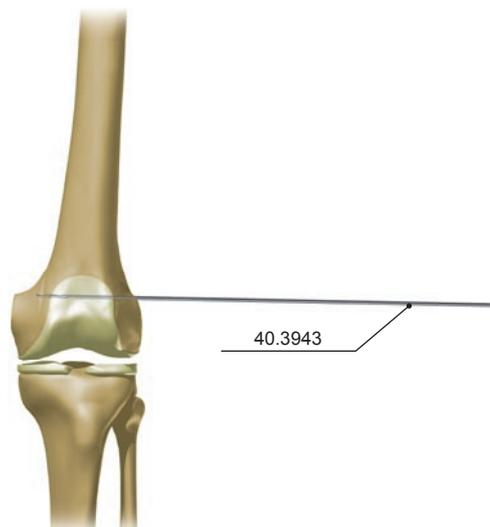
The angle of lower limb curvature and required height of the opening is to be examined by fluoroscopy. The bone angle is defined by drawing two straight lines. One line is drawn from the center of femoral head [1] to point of midway of the knee joint [2]. Another line is drawn from center of distal tibia head [3] to point of midway of the knee joint [2]. The intersection of these two line determines the degree of the correction. Look at 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 eyelte

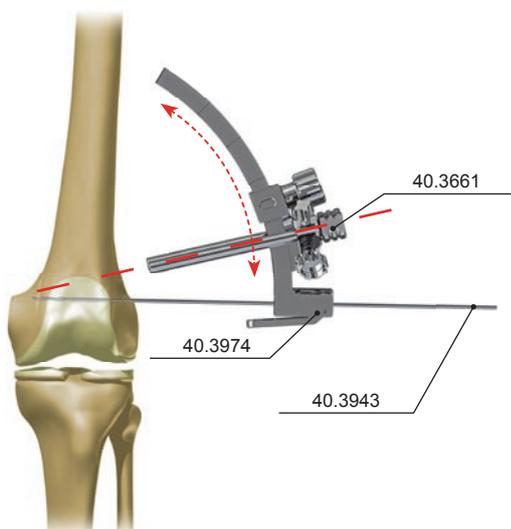
Insert the Guide Pin with Eyelte [40.3943] into the exposed femur using the electric drive. The guide pin is to be perpendicularly position to the femur. The appropriate position of the pin is to be chosen by surgeon.



V.4.

V.5. Locating osteotomy target onto pin

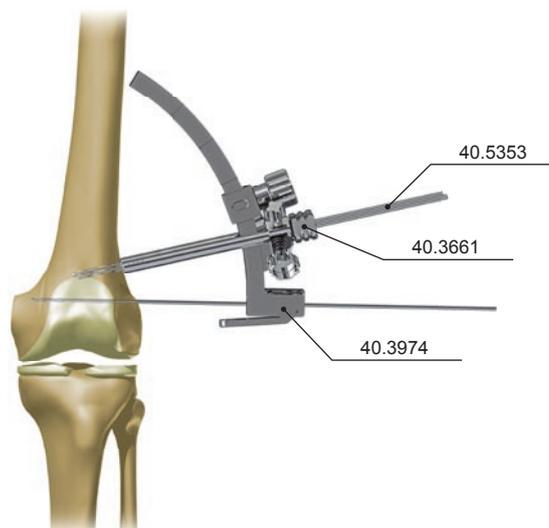
Insert the Osteotomy Target [40.3974] onto the Guide Pin with Eyelte [40.3943]. Distance from the osteotomy target to the femur should be less than total length of the Drill Guide [40.3661].



V.5.

V.6. Introduction of drill guides and guide rods

Use the attached Osteotomy Target [40.3974] to insert both Drill Guides [40.3661]. Use the drill to insert the Guide Rods [40.5353] into the Drill Guide [40.3661].

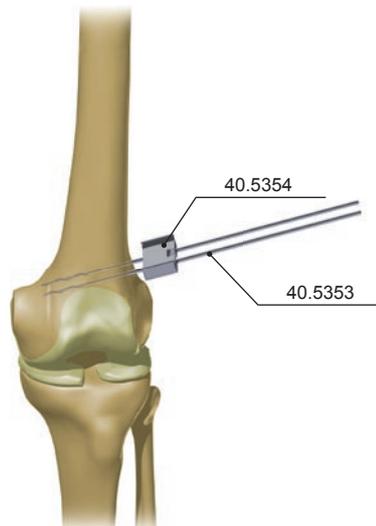


V.6.

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

V.7. Removal of osteotomy target and insertion of guide gouge

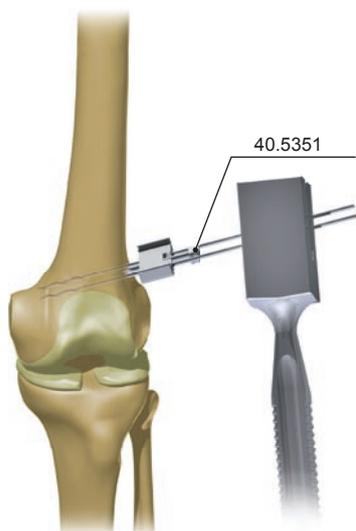
After drill rods are inserted, remove the Osteotomy Target [40.3974] and both Drill Guides [40.3661]. Then remove the Guide Pin With Eyelet [40.3943]. Next, insert the Guide Gouge [40.53543] onto the Guide Rods [40.5353]. The lateral walls of the Guide Gouge should be directed downward and the cutting by the middle hole outside.



V.7.

V.8. Insertion of trocar and reduction of guide rods

Use the hammer (e.g. Bergman) to insert the Trocar [40.5351] into the Guide Gouge [40.5354]. Then reduce the Guide Rods [40.5353]. Use claws to cut the protruding guide rods part which could interfere while carrying out the operation.



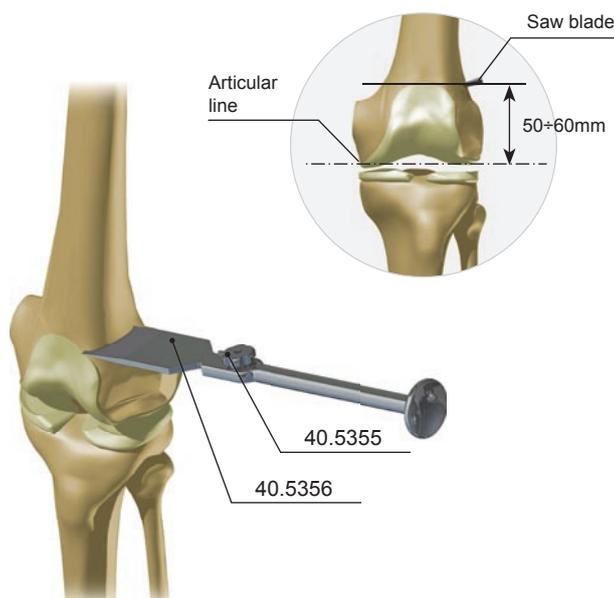
V.8.

V.9. Pre-incision and universal osteotome

Use the plane formed by the Guide Gouge [40.5354] to make pre-incision of the femur with the saw.

The incision should be removed about 50 ÷ 60 mm from the articular line (The surgeon decides about the appropriate distance).

After the pre-incision, using the plane of the Guide Gouge [40.5354], make the femur incision using the Universal Osteotome [40.5355] equipped with appropriate the Osteotome Blades [40.5356.010; 40.5356.025; 40.5356.035]. Gently use the hammer (e.g. Bergman) to place the universal osteotome.



V.9.

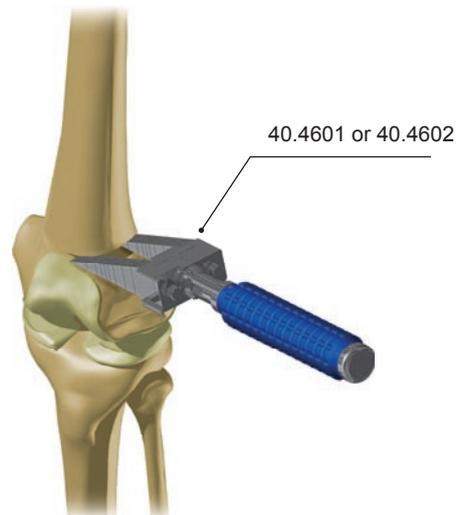
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

V.10. Implementation of opening osteotomy by using instrument set

After the incision, remove the Guide Rods [40.5353] and the Guide Gouge [40.5354]. Insert the instrument set for the osteotomy into the incision of the bone:

- [40.4601] - Instrument Set for osteotomy "10"
 - [40.4602] - Instrument Set for osteotomy "16"
- at a distance corresponding to the determined height of the opening, which is marked on the upper sloping surfaces of wedges.

Gently use the hammer (e.g. Bergman) to place the instrument set for osteotomy "10"/ "16"



V.10.

V.11. Controlling the angel of correction and the height of wedge opening

To control the angle of correction and the height of the wedge opening use the x-ray or Fluoroscopy. Make sure that the desire degree of correction is maintain.



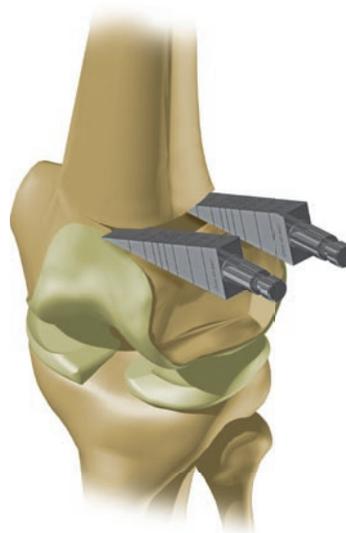
If the Fluoroscopy is used, all steps should be confirmed repeatedly.

V.12. Removing handle part of instrument set and controlling wedge opening

Remove handle part of the Instrument Set for Osteotomy [40.4601] or [40.4602] to access the place where the wedge distance plate ([1.3541] steel or [3.3541] – titanium) will be inserted. Only two splitting wedges should remain in the bone.

V.13. Selection and insertion of wedge distance plate

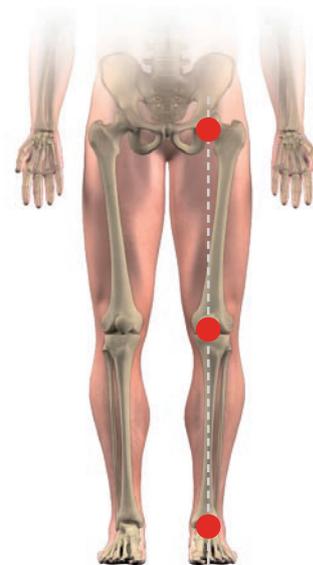
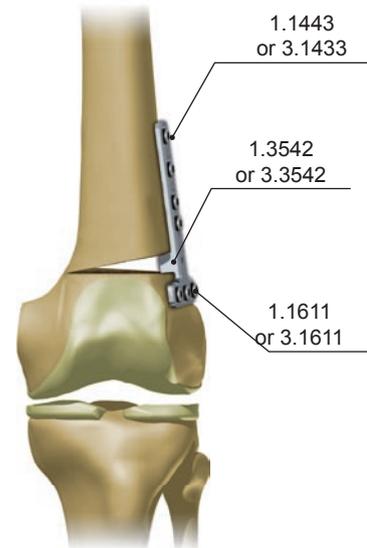
Selection of the Wedge Distance Plate ([1.3541] steel or [3.3541] – titanium) should base on the values read at the upper sloping surfaces of wedges cleave. Use the Applicator [40.5369] to insert selected wedge distance plate into the wedge bone cut.



V.12.

V.14. Insertion of wedge distance plate screws

The horizontal part of the Wedge Distance Plate ([1.3541] steel or [3.3541] – titanium) that is placed closer to the joint, should be inserted using the Cancellous Screws ([1.1611] – steel or [3.1611] - titanium). Then remove the splitting wedges. The vertical part of the Wedge Distance Plate ([1.3541] steel one or [3.3541] – titanium one); that is placed further from the joint; should be inserted using the Cortical Screws ([1.1443] – steel, or [3.1443] - titanium). Use the Hexagonal Screwdriver S3,5 [40.0320] to insert the screws into the plate. After placing the plate and screws, use the x-ray or Fluoroscopy to make sure that desire degree of correction is maintain. 3 points that are mentioned in the Introduction, should now be connected by straight line.



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

VI. CONVERSION TABLE OF ANGLE CORRECTION

Table of angle correction [°] for plates 1.3535/3.3535; 1.3537/3.3537; 1.3538/3.3538; 1.3539/3.3539 i 1.3541/3.3541										
Length of Osteotomy [mm]	Height of Osteotomy [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 angle correction [°] for plates 1.3536/3.3536 i 1.3540/3.3540										
Length of Osteotomy [mm]	Height of Osteotomy [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 angle correction [°] for plates 1.3542/3.3542										
Length of Osteotomy [mm]	Height of Osteotomy [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.



REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

ChM[®]

Instruments manufactured by ChM Ltd. are made of stainless steel, aluminium alloys and plastics which according to obligatory procedures are used in medicine. Each medical instrument is exposed to occurrence of corrosion, stains and damage, if not treated with special care and recommendations below.

1. Materials

Devices are produced of corrosion-resistant steels. Thanks to high content of chromium, the protective layer (passive layer) against corrosion is formed on the surface of the stainless steel.

Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as handles of screwdriver, awl or wrench, 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 surface 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 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-disinfection with pH values from 4 to 9.5.



If the material of the device cannot be specified, please contact ChM Ltd. company representative.

2. 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 sterilizers, recommendations of cleaning and disinfection agents, as well as recommendations for cleaning and sterilizing automatic machines shall be observed.



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

1. 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 detergent. It is recommended to use water solutions of cleaning-disinfection agents with a neutral pH.
2. 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 a disinfection properties) normally used for reusable medical devices (remember to prevent drying out any organic remains on the product surface). Follow all the instructions specified by the producer of those enzyme detergents.
3. Carefully scrub/clean the surfaces and crevices of the product using a soft cloth without leaving threads, or brushes made of plastic, only the nylon brushes are recommended. Do not use brushes made of metal, bristles or damaging material as they can cause physical or chemical corrosion.
4. Next, thoroughly rinse the instrument under the warm running water, paying particular attention for carefully rinsing the slots. Use nylon brushes making multiple moves back and forth on the surface of the product. It is recommended to rinse in 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 such as anodized. During the rinsing manually remove the adherent remains.
5. Visually inspect the entire surface of the product to ensure that all contaminations are removed.



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

6. 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-disinfection agents manufacturer.

3. Sterilization

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds as residues after disinfection and sterilization processes, without structure damages (cracks, fractures, bending, peeling). Remember that sterilization is not 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 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 min. 134°C, pressure of 2 atm.



The above given parameters of sterilization are to be absolutely observed.

Validated sterilization methods are allowed. Durability and strength of instruments highly depend on their usage. Careful usage consistent with intended application of the product, prevents product damaging and prolongs its life.

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- 4G Intramedullary osteosynthesis of humerus**
- 7C Intramedullary osteosynthesis of fibula and forearm**
- 6D Intermedullary osteosynthesis of femur by trochanteric nails**
- 8E Dynamic Hip (DSB)/ Condylar (DSK) stabilizer**
- 9D Spine stabilization CHARSPINE**
- 15B Tibial and femoral angular set block**
- 20B Radial Head Prosthesis KPS**
- 22C Locking plates**
- 23C Intramedullary osteosynthesis of femur (reversed method) 40.3660**
- 24E Intramedullary osteosynthesis of femur 40.5060.000**
- 25C Intramedullary osteosynthesis of tibia 40.5370.500**
- 28D Intramedullary osteosynthesis of femur by trochanteric nail - ChFN**
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