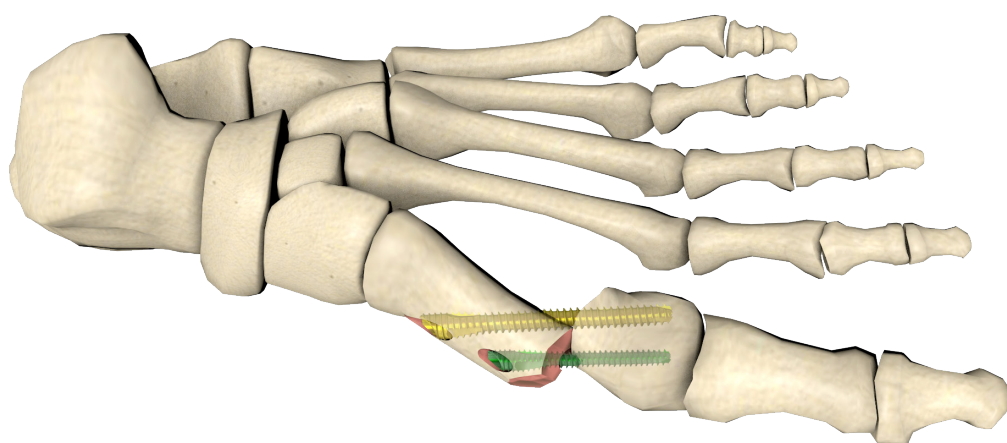















Cannulated screw
3.1480; 3.1481

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



SYMBOLS DESCRIPTION

	Titanium or titanium alloy		H length [mm]
	Cobalt		Angle
	Left		available lengths
	Right		Available number of holes
	Available versions: left/right		Thickness [mm]
	Length		Scale 1:1
	Torx drive		Number of threaded holes in the shaft part of the plate
	Torx drive cannulated		Number of locking holes in the plate
	Hexagonal drive		Variable angle
	Hexagonal drive cannulated		Cortical
	Cannulated		Cancellous
	Locking		Available in sterile/ non- sterile condition
	Diameter [mm]		Refer to surgical technique
	Caution - pay attention to a special procedure.		
	Perform the activity under X-Ray control.		
	Information about the next stages of a procedure.		
	Proceed to the next stage.		
	Return to the specified stage and repeat the activity.		
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.		
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.		

www.chm.eu

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Review date P-001-15.03.2021

The manufacturer reserves the right to introduce design changes.
Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu

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1. INTRODUCTION

This surgical technique applies to titanium cannulated screws intended for a minimally invasive technique of corrections, arthrodesis and fractures of foot bones.

The presented range of implants is made of materials in accordance with ISO 5832 standards.

The system includes:

- implants (*screws*),
- instrument set used in a surgery,
- surgical technique.

Indications

- hallux valgus,
- hallux varus,
- hallux rigidus,
- hammer finger,
- mallet finger,
- foot bones fractures,
- foot arthrodeses.

Implant selection

The implants are available in two sizes - 3.0 and 4.0mm and different lengths for optimal selection of a screw variant.



Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.

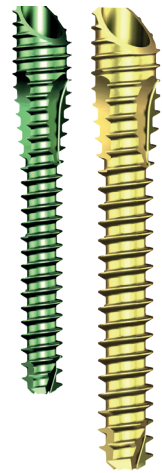


The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

2. IMPLANT DESCRIPTION

To facilitate their identification, the screws and compatible instruments are color coded:

- green - cannulated screw 3.0mm,
- yellow - cannulated screw 4.0mm.



• Wide range of implant sizes

- 3.0mm screws in the length range of 16 ÷ 60mm
- 4.0mm screws in the length range of 30 ÷ 60mm
- 2mm increments

• Designed for Minimally Invasive Technique

- easy percutaneous insertion
- small surgical approach
- improved operative procedure and better outcomes

• Comprehensive instrumentation

- colour-coded instruments - facilitated use
- full range of complementary devices
- ergonomic design of devices
- compact and transparent stand

• Beveled screw head

- the edge of the screw does not protrude above the bone surface, what significantly reduces irritation of peri-implant tissues
- bone contact along the entire length of the screw head - increased strength of the screw-to-bone connection

• Modified Torx drive

- control of the position of the beveled screw head in relation to the bone surface – pre-determined positioning of the screw in relation to the screwdriver
- excellent self-retaining feature
- improved torque transmission

• Sharp self-tapping flutes

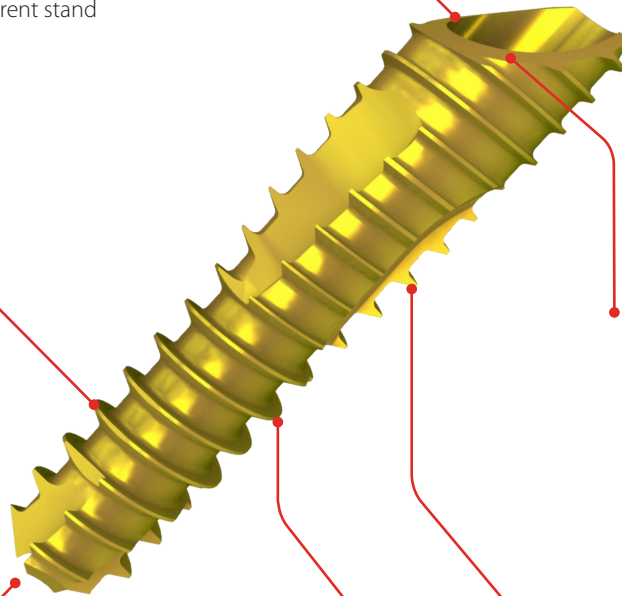
- facilitated screw insertion
- reduced operative time and efficient procedure

• Optimized thread profile

- insertion efficiency
- increased pullout resistance

• Guide hole

- precise implant insertion



3. SURGICAL TECHNIQUE

This surgical technique describes the treatment procedure for hallux valgus deformity using a minimally invasive method.

3.1. USE OF TARGETER 40.4989.000

3.1.1. PATIENT'S POSITIONING

The supine position with the heel resting against the edge of the operating table. Perform the procedure under fluoroscopy control (*preferably mini C-arm*).



Local tissue ischemia is not necessary.



3.1.2. SURGICAL APPROACH

Use fluoroscopic control (*AP position*) to navigate the place (*level*) of insertion of a cutter and subcapital first metatarsal osteotomy. Afterwards, perform a horizontal, several-mm-long medial incision of the first metatarsal.



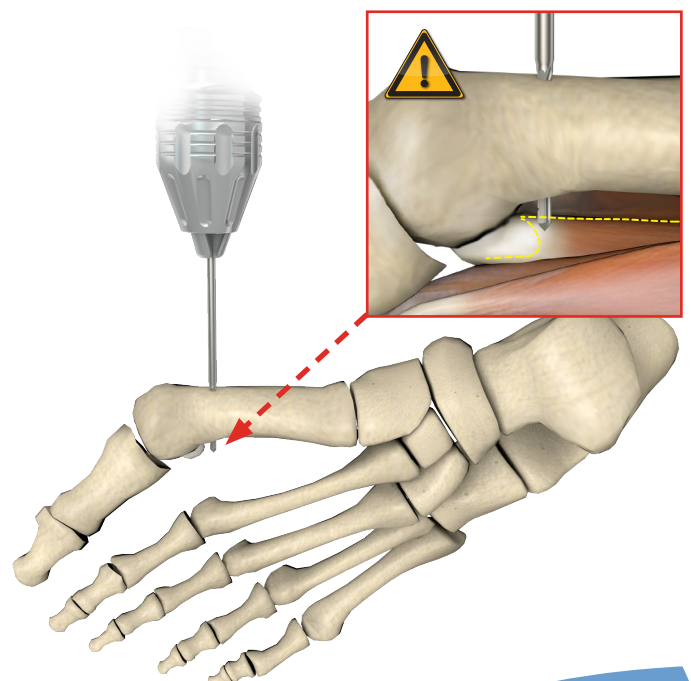
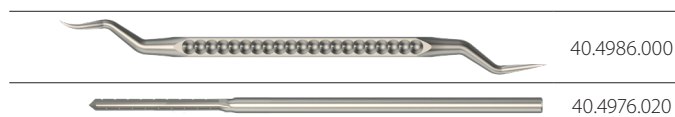
3.1.3. USE OF A CUTTER

Use elevator [40.4986.000] to uncover the periosteum and, under X-Ray control, insert the cutter 2.0/20 [40.4976.020] through both cortex layers. Insert the cutter in the direction of the planned subcapital first metatarsal osteotomy (*plantarization/ elevation, shortening/ lengthening of the 1st radius*).



The tip of the cutter should reach a line along the lateral edge of the lateral sesamoid and be below the proximal pole of the lateral sesamoid.

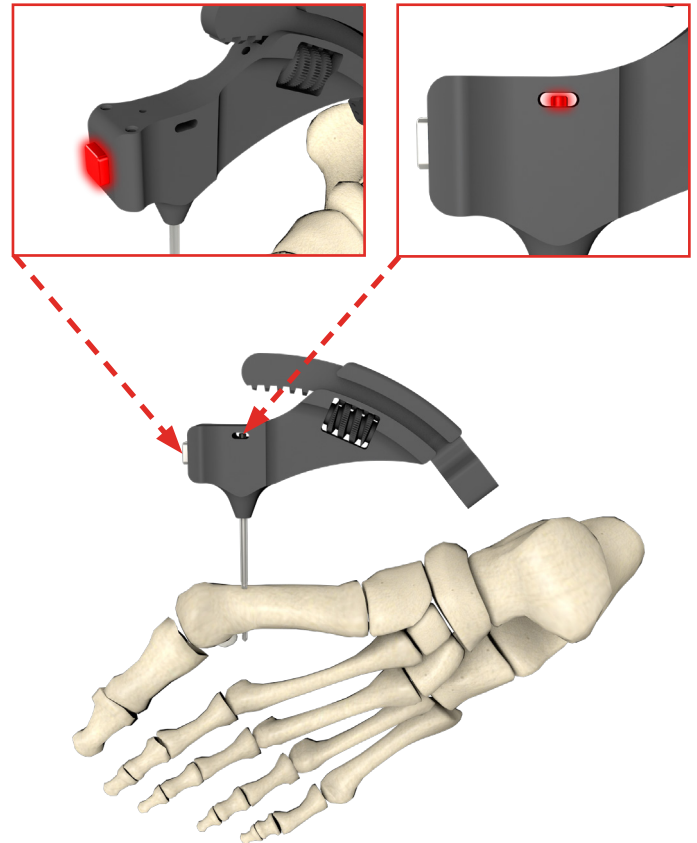
Leave the cutter in the bone.



3.1.4. TARGETER ASSEMBLY

3.1.4a. Targeter-to-cutter installation

Install the targeter **[40.4989.000]** on the inserted cutter. The end of the cutter visible in the targeter's window proves correct assembly.

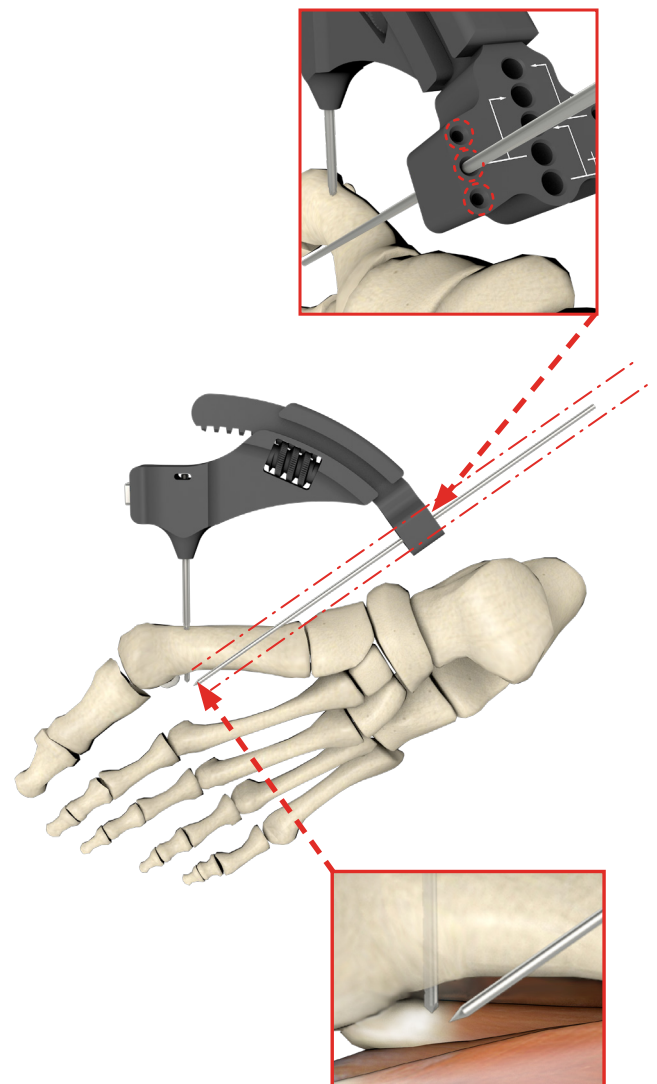
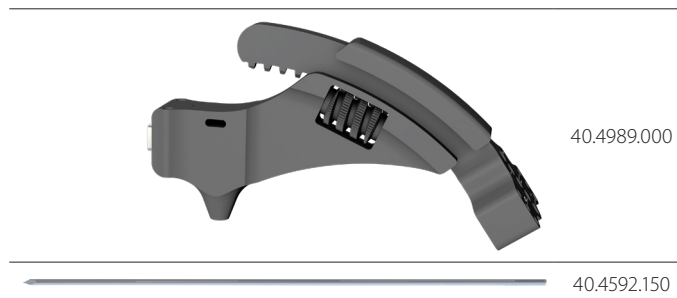


3.1.5. SETTING THE ANGLE AND DIRECTION OF THE SCREWS

Position the wire under fluoroscopy control in AP foot projection. Insert Kirschner wire 1.5/150 **[40.4592.150]** through one of the top three positioning holes on the targeter.



The wire should not pass through the first metatarsal bone but be located dorsally above the skin of the first metatarsal and indicate the direction of the proximal screw to be introduced.

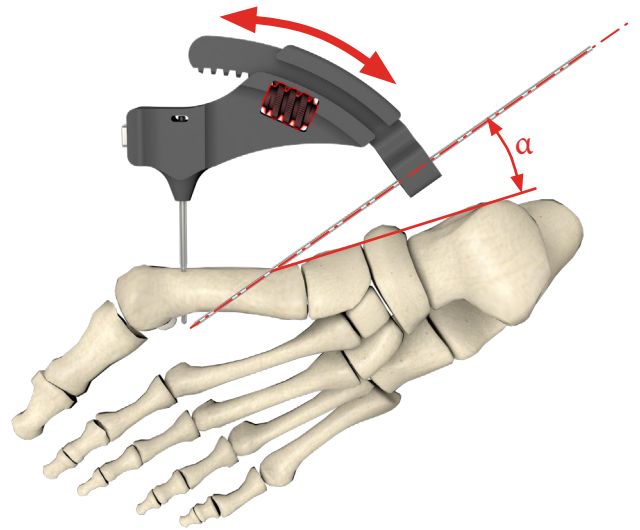


Set the screw insertion angle α using the rotating knob. Verify the correct setting by taking an X-Ray image from above



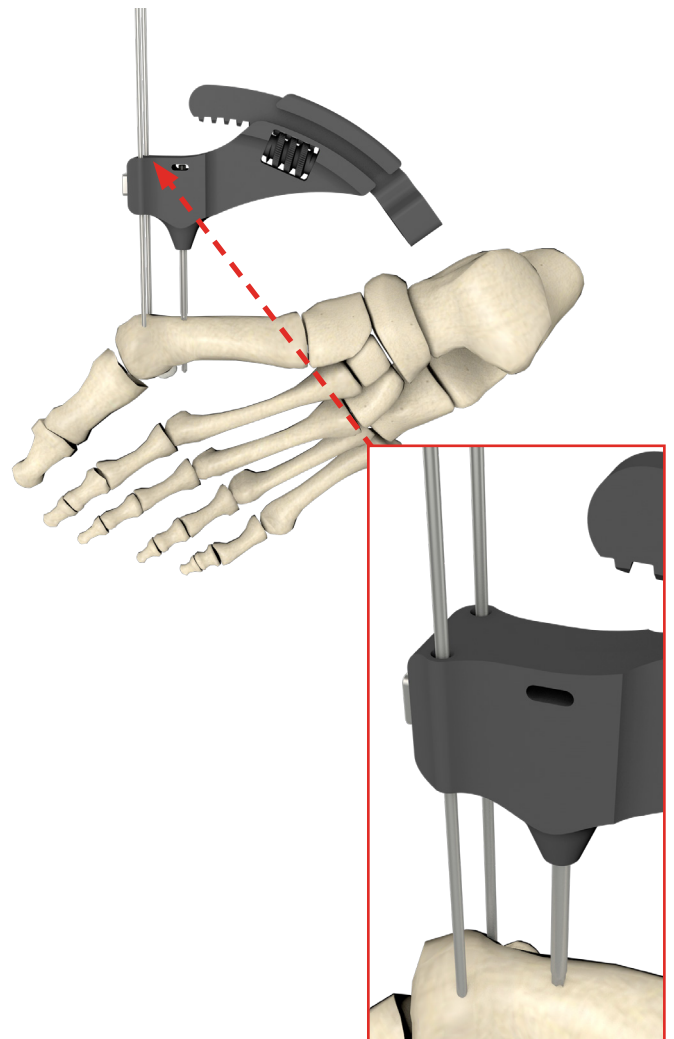
For proper bi-cortical fixation of the proximal screw, it is recommended to insert the screw close to the first cuneometatarsal joint, so the tip of the screw reaches the level of the side cortex at least 3-4 mm from the cutter.

Remove Kirschner wire 1.5/150 [40.4592.150].



3.1.6. KIRSCHNER WIRES INSERTION IN THE BONE HEAD

Set and verify the position of the targeter in the sagittal plane. Insert two Kirschner wires 1.5/150 [40.4592.150] into the bone head through the holes in the targeter.



3.1.7. FIRST KIRSCHNER WIRE 1.5/150 INSERTION

Insert the guide sleeve 1.5 **[40.4988.015]** through the central hole of the targeter **[40.4989.000]**. Make a several-mm-long horizontal incision of the skin and after securing and uncovering the soft tissue, move the sleeve to the bone.



The instrument set includes guide sleeves in two versions: long and short. Always use the short guide sleeve **[40.4988.110/115]** as proximal to the bone. However, the other, longer sleeve **[40.4988.010/015]** should be used as parallel instrument.



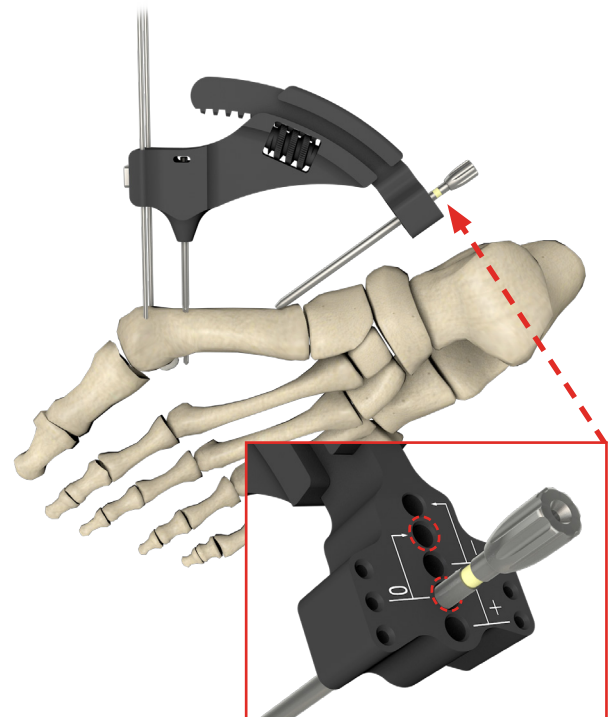
Insert the sleeve into the central hole corresponding to the positioning hole used in point 3.1.5 - SETTING THE ANGLE AND DIRECTION OF THE SCREWS.



40.4989.000

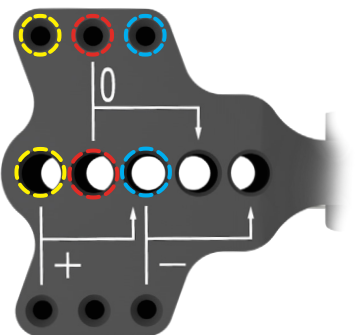


40.4988.115



positioning holes

central holes



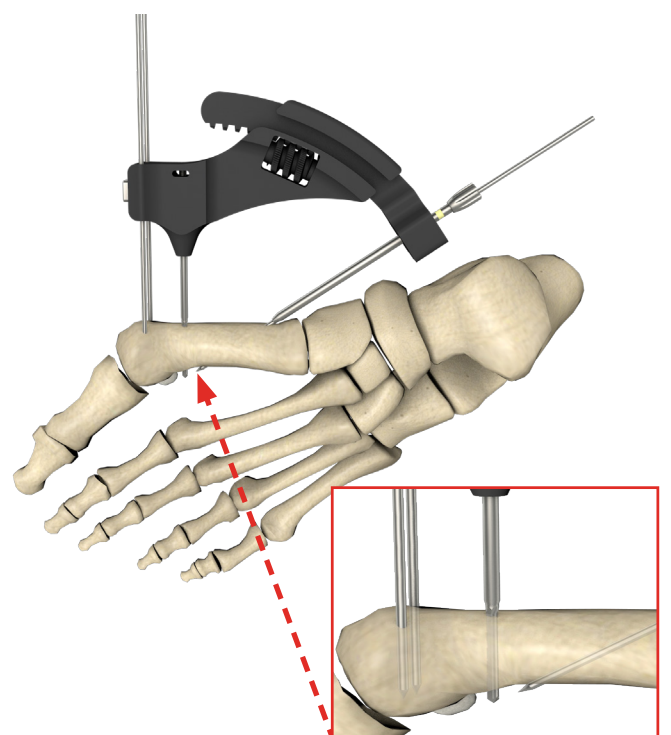
Use guide sleeve 1.5 **[40.4988.115]** to insert Kirschner wire 1.5/150 **[40.4592.150]** through both cortices.



Use fluoroscope to verify the position of the Kirschner wire in the AP and lateral projections.

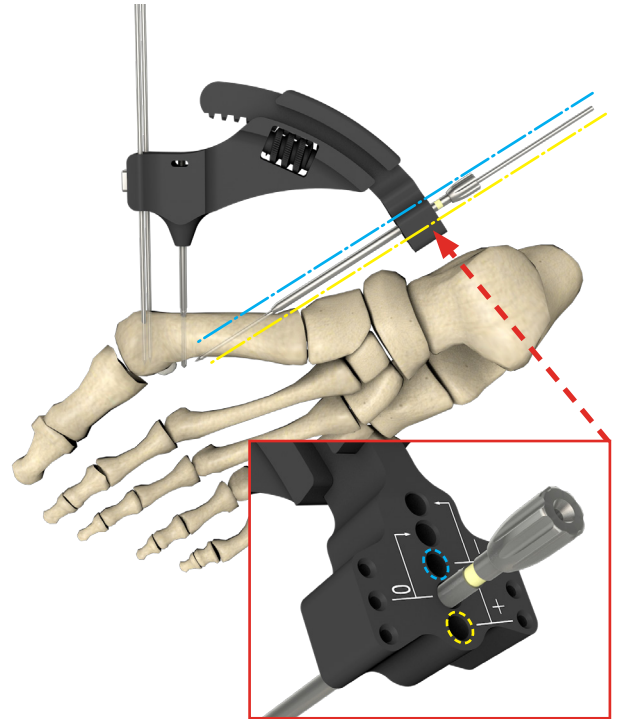


The correct positioning of Kirschner wire for the proximal screw determines the correct fixation. The proximal Kirschner wire should be positioned in accordance with the principles described above, axially in the sagittal plane with respect to the long axis of the first metatarsal bone (*a slight deflection is permissible, however, the tip of the screw should always be embedded in the distal osteotomy part after correction*).





If the position of the Kirschner wire (*for the proximal screw*) in the AP or lateral fluoroscopic inspection is incorrect, the targeter allows for a change in its setting by a use of additional holes. Should the wire be positioned incorrectly in the lateral projection, it may be necessary to remove the Kirschner wires locking the targeter in the head of the 1st metatarsal, correct the positioning of the targeter (*by rotation upwards or downwards*) and reattach the targeter to the head of the 1st metatarsal.

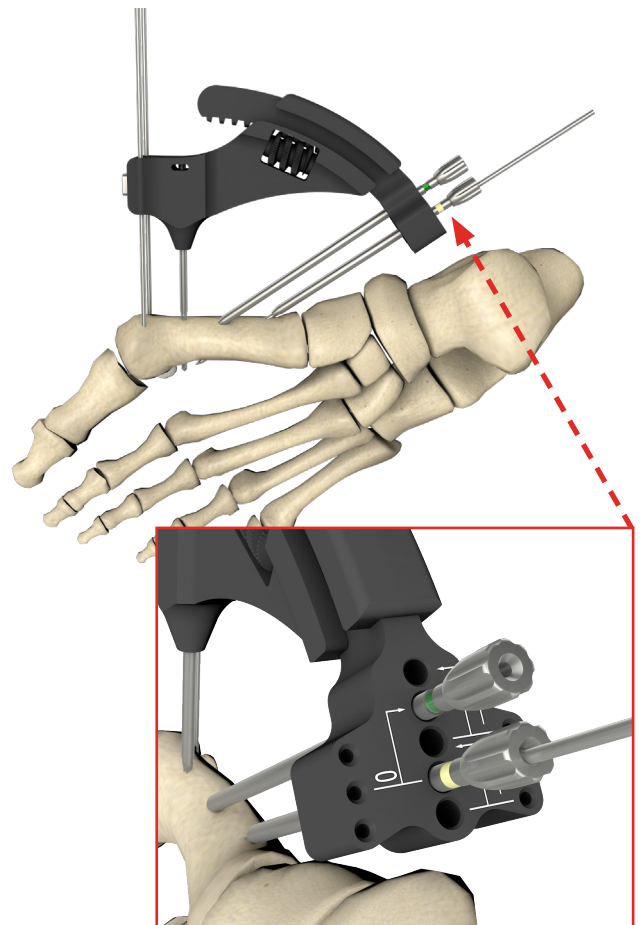
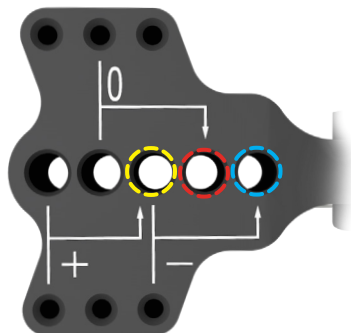


3.1.8. INSERTION OF THE OTHER KIRSCHNER WIRE 1.0/150

Insert the longer guide sleeve 1.0 **[40.4988.010]** through the central hole in the targeter indicated by the arrow. Make a several-mm-long horizontal incision of the skin and after securing and uncovering the soft tissue, move the sleeve to the bone.



central holes for guide
sleeve 1.0



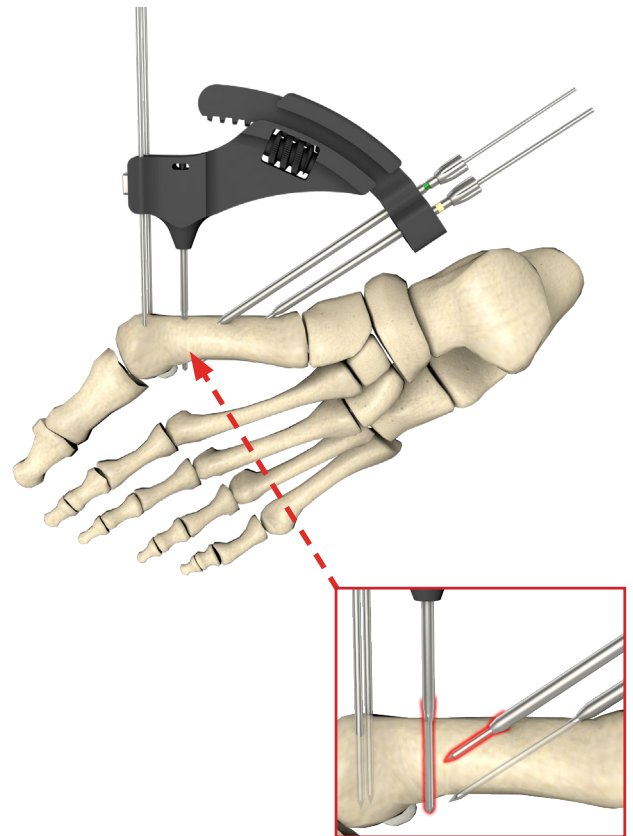
Use guide sleeve 1.0 **[40.4988.010]** to insert Kirschner wire 1.0/150 **[40.4814.150]** as close to the cutter as possible.



Use fluoroscope to verify the position of the Kirschner wire.



The presented surgical technique describes the introduction of cannulated screws with two diameters - 4.0 and 3.0mm. If two 4.0mm screws are to be inserted, use a 2.0mm wire with a dedicated sleeve:

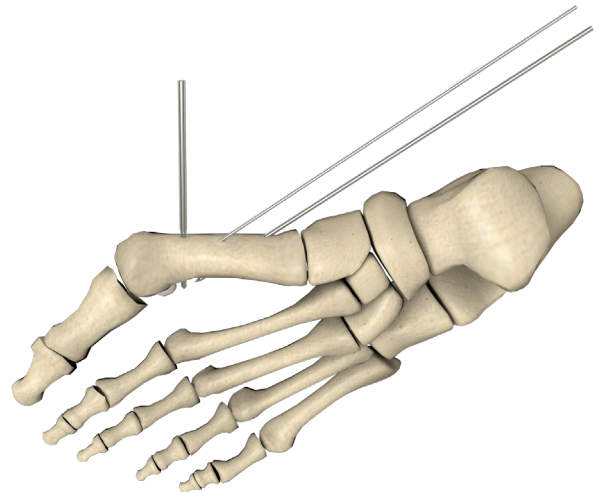


3.1.9. TARGETER DISASSEMBLY

Remove guide sleeves **[40.4988]**. Press the button and remove the targeter **[40.4989.000]**.



Kirschner wires 1.5/150 **[40.4592.150]** inserted into the head of the first metatarsal bone may be used for bone rotation or correction.



3.1.10. CORRECTION

3.1.10a. Osteotomy

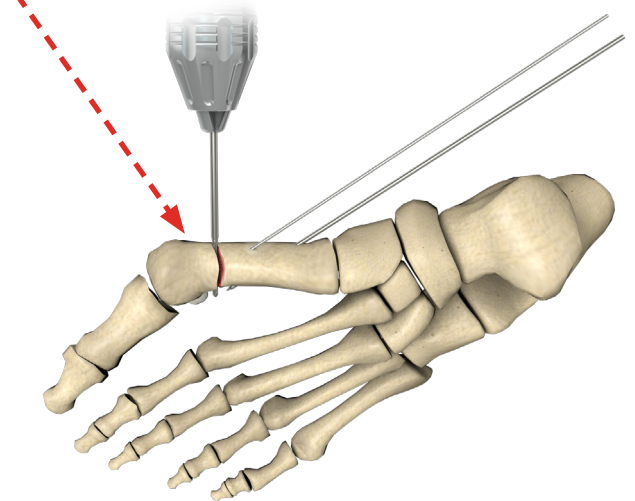
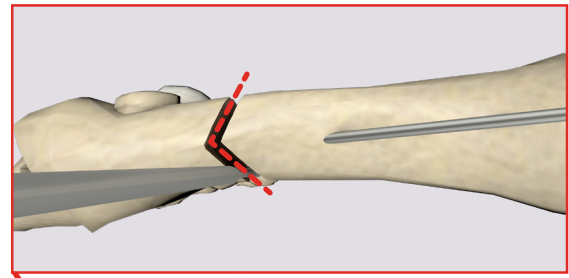
Install a drive on the cutter 2.0/ 20 **[40.4976.020]** and perform Chevron-type osteotomy.



Chevron-type distal osteotomy consists in subcapital cutting of the 1st metatarsal bone. The shape of the cutting lines resembles the "V" letter.



40.4976.020



3.1.10b. Bone head positioning

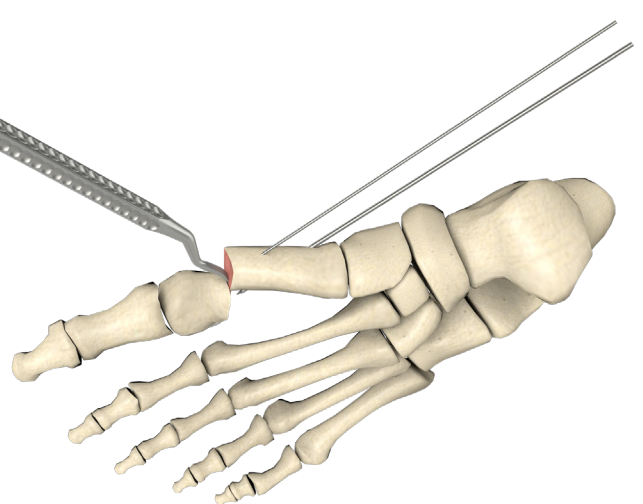
Use elevator **[40.4984.000; 40.4985.000]** for bone correction.



40.4984.000



40.4985.000



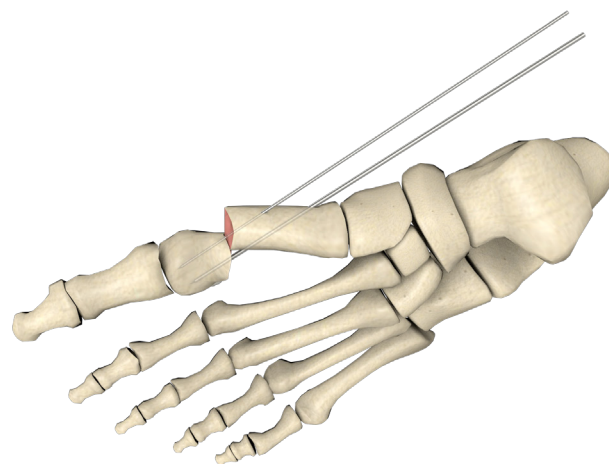
3.1.10c. Stabilization of the bone head

Insert Kirschner wires **[40.4592.150/40.4814.150]** further to the desired depth of screws implantation. Stabilize the performed correction.

	40.4814.150
	40.4592.150





Avoid penetration of the articular surface and MTP joint.

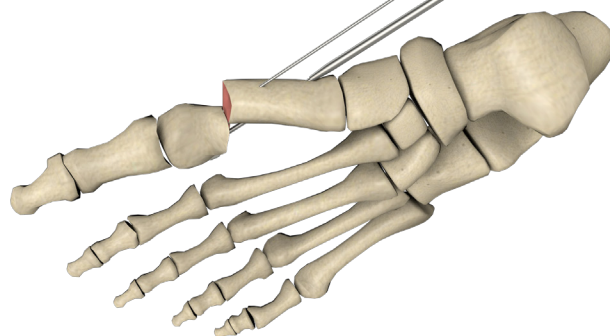
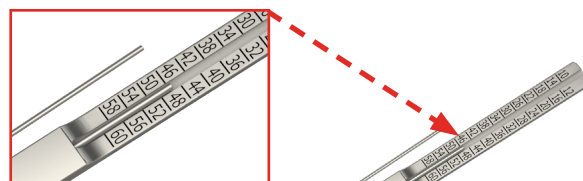


3.1.11. SCREWS LENGTH MEASUREMENT

3.1.11a. Cannulated screw 4.0mm measurement


Use Kirschner wire 1.5/150 **[40.4592.150]** to introduce the length measure **[40.4975.000]** until its end rests on the bone surface. Read the length of the screw 4.0 on the measure scale.

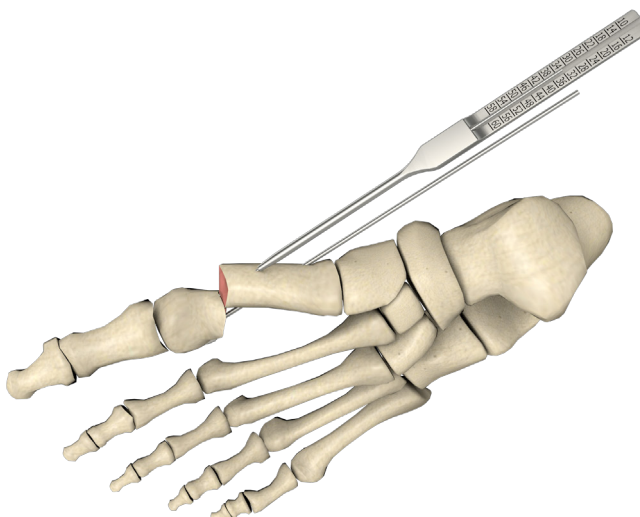
	40.4592.150
	40.4975.000



3.1.11b. Cannulated screw 3.0mm measurement

Use Kirschner wire 1.0/150 **[40.4814.150]** to introduce the length measure **[40.4975.000]** until its end rests on the bone surface. Read the length of the screw 3.0 on the measure scale.

	40.4814.150
	40.4975.000

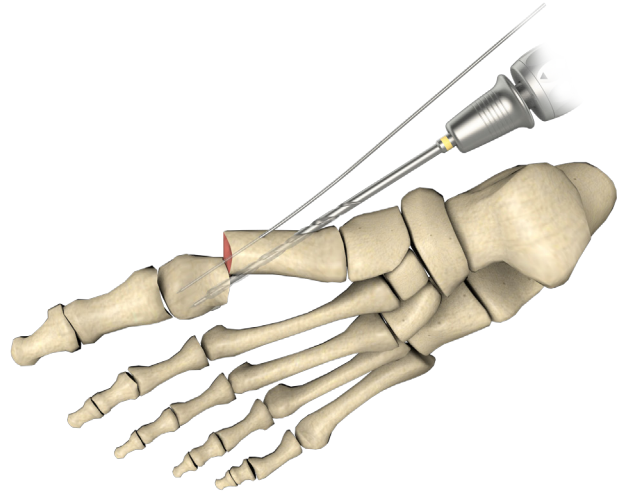


3.1.12. SCREWS INSERTION

3.1.12a. Screw 4.0mm insertion



Use Kirschner wire 1.5/150 **[40.4592.150]** and cannulated drill 3.2/1.5/120 **[40.4973.122]** to make, under X-Ray control, a hole. The drill shall also penetrate the lateral cortex of the proximal fragment.

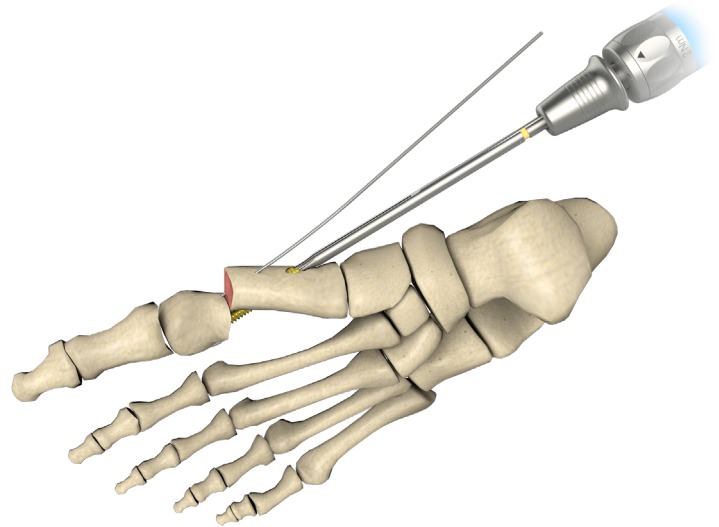
	40.4592.150
	40.4973.122



Use Kirshner wire 1.5/150 **[40.4592.150]** and cannulated screwdriver tip T15 **[40.4972.000]** to insert 4.0mm screw fully into the bone.

Remove Kirshner wire 1.5/150.

	40.4592.150
	40.4972.000



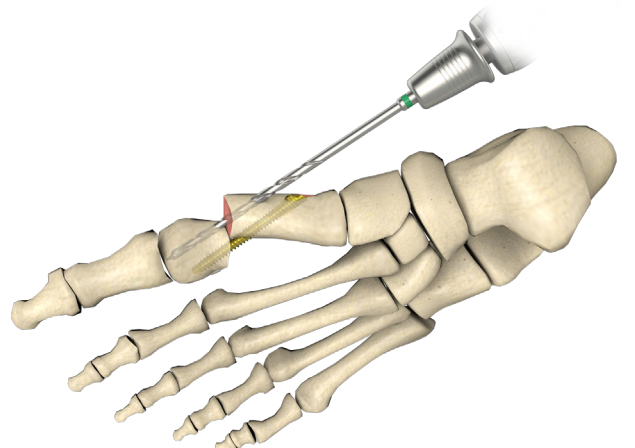
The screws have a special shape of the socket that is compatible with dedicated screwdriver tips. Only one position of the screw is possible, to ensure the later control of the position of the screw head with respect to the bone surface.



3.1.12b. Screw 3.0mm insertion

Use Kirschner wire 1.0/150 **[40.4814.150]** and cannulated drill 2.4/1.0/120 **[40.4974.122]** to make, under X-Ray control, a hole.

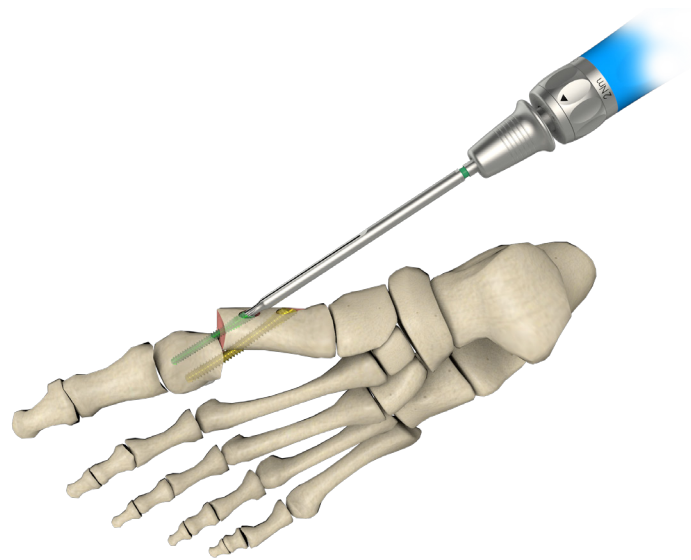
	40.4974.122
	40.4814.150





Use Kirshner wire 1.0/150 **[40.4814.150]** and cannulated screwdriver tip T10 **[40.4971.000]** to insert 3.0mm screw fully into the bone.

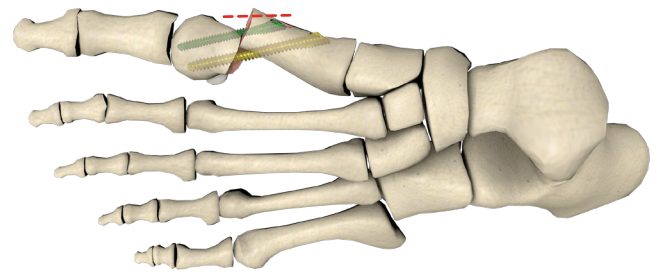
Remove Kirshner wire 1.0/150.

	40.4814.150
	40.4971.000

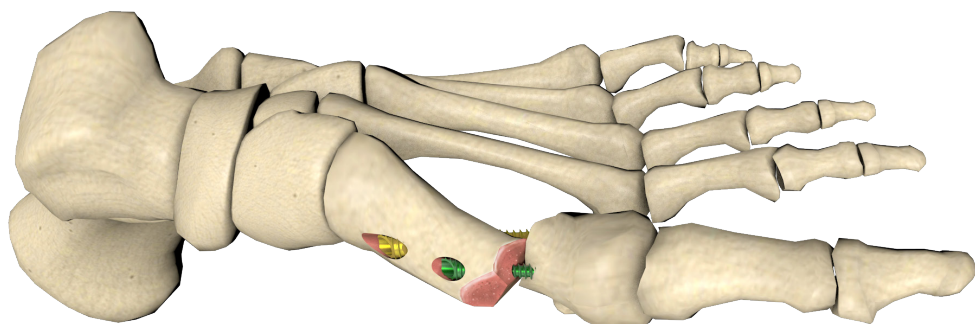


The presented surgical technique describes the introduction of cannulated screws with two diameters - 4.0 and 3.0mm. If two 4.0mm screws are to be inserted, use the following instruments:

	40.4592.150
	40.4973.122
	40.4972.000



If necessary, perform percutaneous resection of the bunion.



3.2. USE OF PARALLEL GUIDE 40.4987.000 ("FREE-HAND TECHNIQUE")

3.2.1. PATIENT'S POSITIONING

The supine position recommended. Ensure proper X-Ray control.



3.2.2. SURGICAL APPROACH

Perform a horizontal, several-mm-long medial subcapital incision of the first metatarsal.



3.2.3. OSTEOTOMY

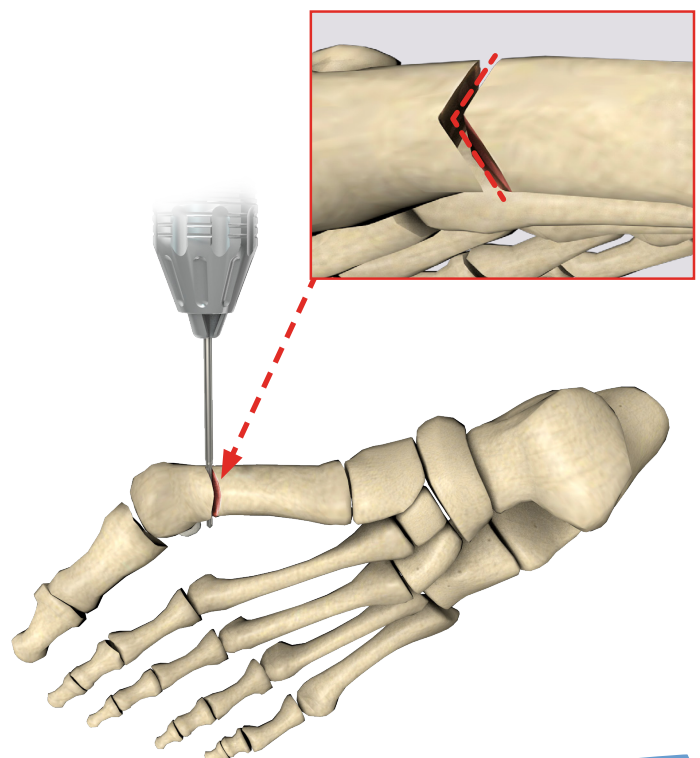
Use cutter 2.0/ 20 [40.4976.020] to perform Chevron-type osteotomy.



Chevron-type distal osteotomy consists in subcapital cutting of the 1st metatarsal bone. The shape of the cutting lines resembles the "V" letter.








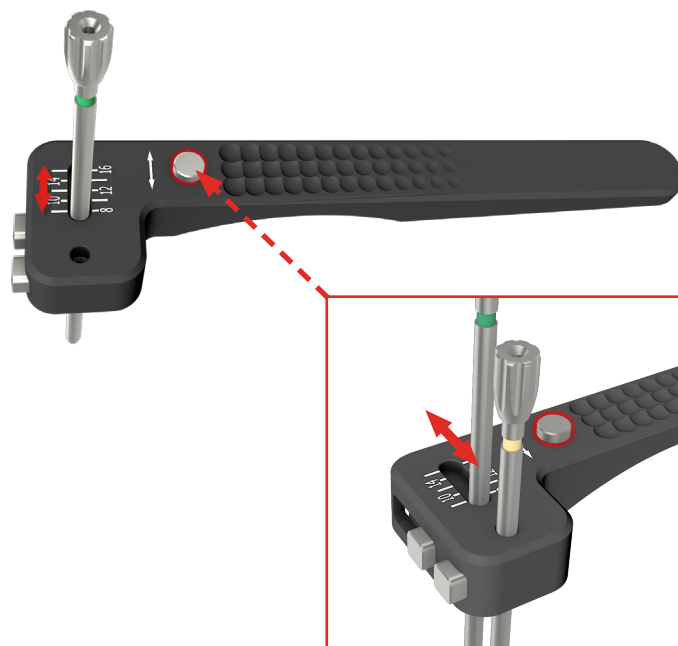
40.4976.020



3.2.4. PARALLEL GUIDE POSITIONING

Press the upper button of the parallel guide **[40.4987.000]** and set the desired screws spacing.

	40.4987.000
	40.4988.015
	40.4988.010
	40.4988.115
	40.4988.110

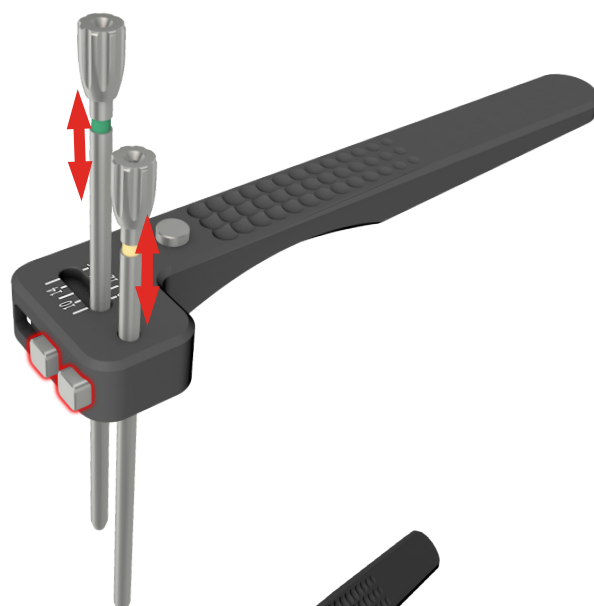


3.2.5. GUIDE SLEEVES ASSEMBLY

Press the side button on the parallel guide **[40.4987.000]** and insert the guide sleeve **[40.4988]**. Insert the other sleeve in the same way.



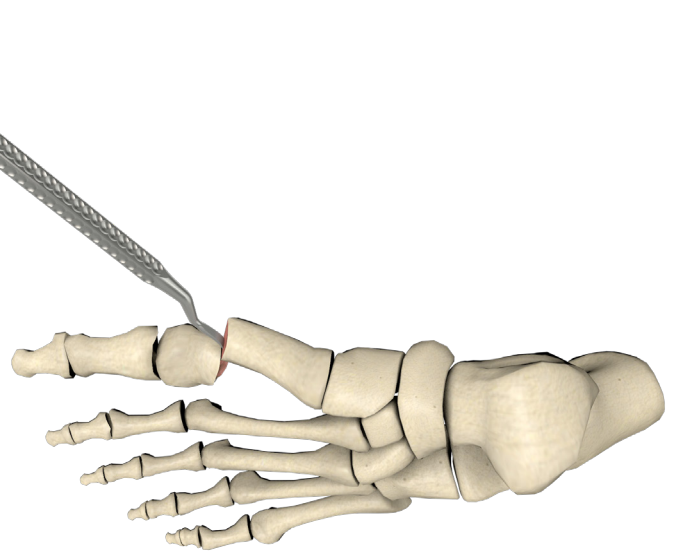
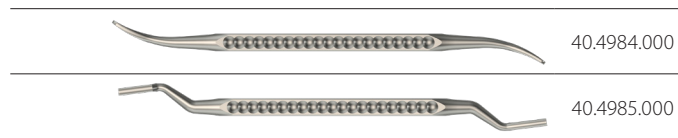
The instrument set includes guide sleeves in two versions: long and short. Always use the short guide sleeve **[40.4988.110/115]** as proximal to the bone. However, the other, longer sleeve should be used as parallel instrument **[40.4988.010/015]**.



3.2.6. CORRECTION

3.2.6a. Bone head positioning

Use elevator [40.4984.000; 40.4985.000] for bone correction.

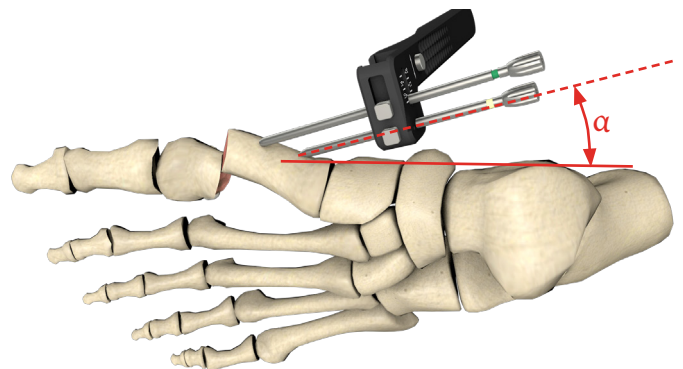
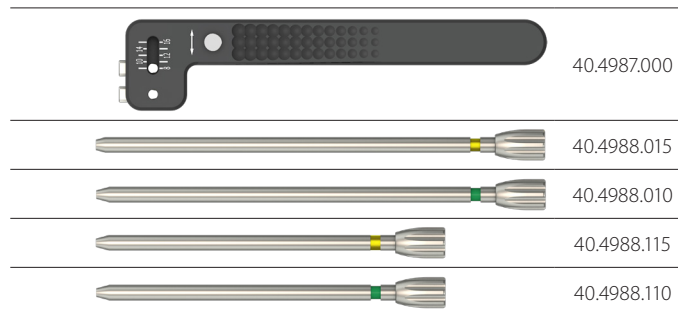


3.2.6b. Parallel guide positioning

Position the parallel guide [40.4987.000] with guide sleeves at a desired angle α .

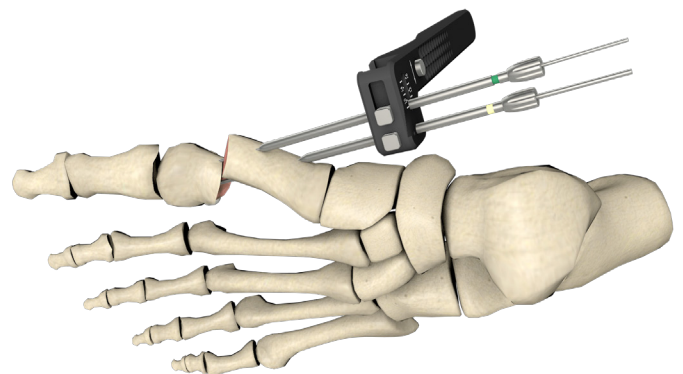


Verify the correct setting by taking an X-Ray image from above



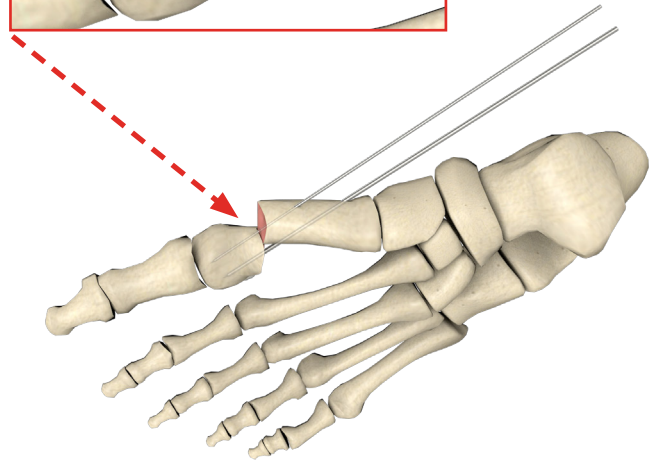
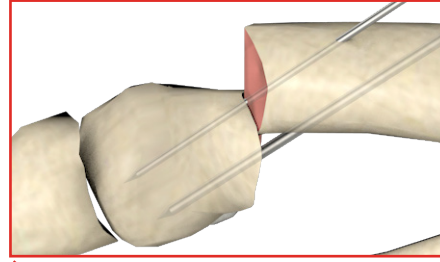
3.2.6c. Stabilization of the bone head

Use guide sleeves [40.4988] to insert Kirschner wires [40.4592.150/40.4814.150] through both bone fragments to the desired depth of screws implantation. Stabilize the performed correction.





Avoid penetration of the articular surface and MTP joint.



3.2.7. SCREWS LENGTH MEASUREMENT

3.2.7a. Cannulated screw 4.0mm measurement



See p. 3.1.11a „Cannulated screw 4.0mm measurement“.

3.2.7b. Cannulated screw 3.0mm measurement



See p. 3.1.11b „Cannulated screw 3.0mm measurement“.

3.2.8. SCREWS INSERTION

3.2.8a. Screw 4.0mm insertion



See p. 3.1.12a „Screw 4.0mm insertion“.

3.2.8b. Screw 3.0mm insertion



See p. 3.1.12b „Screw 3.0mm insertion“.

3.3. WOUND CLOSURE

Before closing the wound, take an X-Ray image in at least two projections to confirm implant position. Use appropriate surgical technique to close the wound.

4. POSTOPERATIVE PROCEDURE

Introduce appropriate postoperative treatment that is determined by the physician. In order to avoid patient's movement limitations, introduce exercises as soon after surgery as possible. However, make sure that the limb is not fully loaded before fragments osteosynthesis is complete.

5. IMPLANT REMOVAL

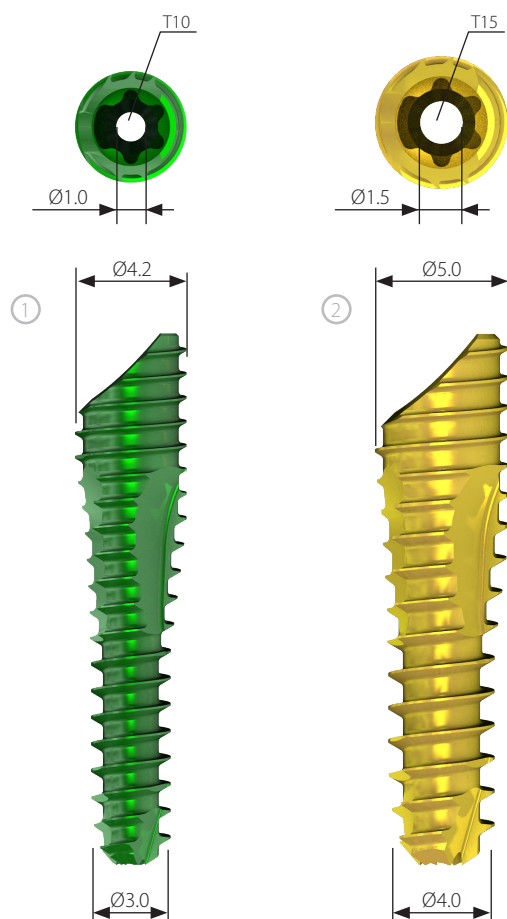
The physician decides about implant removal. In order to remove the implants from the body, use the following instruments:

screw 3.0mm - cannulated screwdriver tip T10 **[40.4971.000]**

screw 4.0mm - cannulated screwdriver tip T15 **[40.4972.000]**.

6. CATALOGUE PAGES

6a. Cannulated screws



Len

Ti

Cannulated screw 3.0

16	3.1480.016
18	3.1480.018
20	3.1480.020
22	3.1480.022
24	3.1480.024
26	3.1480.026
28	3.1480.028
30	3.1480.030
32	3.1480.032
34	3.1480.034
36	3.1480.036
38	3.1480.038
40	3.1480.040
42	3.1480.042
44	3.1480.044
46	3.1480.046
48	3.1480.048
50	3.1480.050
52	3.1480.052
54	3.1480.054
56	3.1480.056
58	3.1480.058
60	3.1480.060

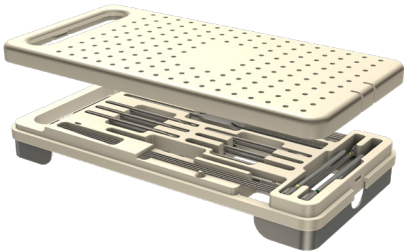
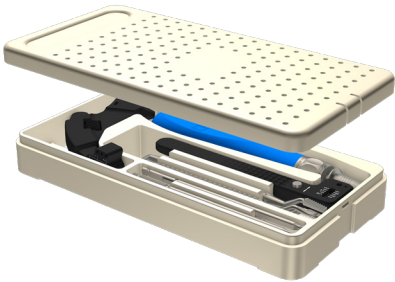
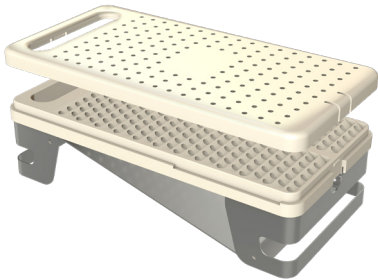


Cannulated screw 4.0

30	3.1481.030
32	3.1481.032
34	3.1481.034
36	3.1481.036
38	3.1481.038
40	3.1481.040
42	3.1481.042
44	3.1481.044
46	3.1481.046
48	3.1481.048
50	3.1481.050
52	3.1481.052
54	3.1481.054
56	3.1481.056
58	3.1481.058
60	3.1481.060

6b. INSTRUMENT SET
















Set for 3.1480/3.1481 4X4H

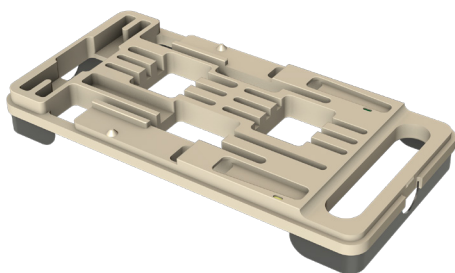
15.0102.001

No.		Name	Catalogue no.	Pcs
1		Instrument set for 3.1480/3.1481 4X2 1/2H	15.0102.202	1
2		Instrument set for 3.1480/3.1481 4X2 1/2H	15.0102.203	1
3		Stand for screws 3.1480/3.1481 4x2H	14.0102.401	1
4		Container for 3.1480/3.1481 4x4H	14.0102.103	1
5		Container lid for 3.1480/3.1481 4x4H	14.0102.104	1

Instrument set for 3.1480/3.1481 4X2 1/2H

15.0102.202

	Name	Catalogue no.	Pcs
	Kirschner wire 1.0/150	40.4814.150	4
	Kirschner wire 1.5/150	40.4592.150	4
	Cannulated drill 2.4/1.0/120	40.4974.122	2
	Cannulated drill 3.2/1.5/120	40.4973.122	2
	Length measure	40.4975.000	1
	Guide sleeve 1.0	40.4988.010	1
	Guide sleeve 1.0	40.4988.110	1
	Guide sleeve 1.5	40.4988.015	1
	Guide sleeve 1.5	40.4988.115	1
	Cutter 2.0/8	40.4977.008	2
	Cutter 2.0/12	40.4977.012	2
	Cutter 2.0/20	40.4976.020	2
	Cutter 3.1/13	40.4978.013	2
	Cutter 4.1/13	40.4979.013	2
	Cutter 5.1/15	40.4980.015	2












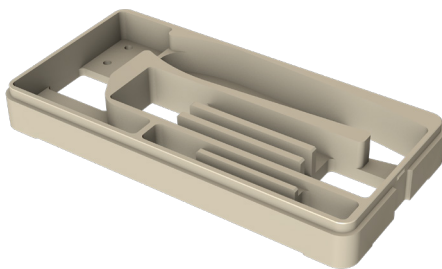
Stand for instrument set 3.1480/3.1481 4x2 1/2H

14.0102.202

1

Instrument set for 3.1480/3.1481 4X2 1/2H

15.0102.203

	Name	Catalogue no.	Pcs
	Cannulated screwdriver tip T10	40.4971.000	1
	Cannulated screwdriver tip T15	40.4972.000	1
	Bone rasp	40.4983.000	1
	Elevator	40.4984.000	1
	Elevator	40.4985.000	1
	Elevator	40.4986.000	1
	Targeter	40.4989.000	1
	Parallel guide	40.4987.000	1
	Handle ratchet device	40.6654.001	1
	Statyw na instrumentarium 3.1480/3.1481 4x2 1/2H	14.0102.203	1

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