MARQUARDT
Medizintechnik

WINSTA-PH2 Percutaneous Proximal Humeral Plate System

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Note:

The surgical technique outlined below reflects the surgical procedure usually chosen by the clinical advisor. However, each surgeon must decide which surgical method and which approach is the most successful for his patient.

Introduction

System Characteristics:

- High stability with low implant dimensions.
- Anatomically adapted design with asymmetric dorsal widening for secure fixation of the tuberculum majus.
- Drill hole running in a distal direction in the transition zone for the stabilisation of fractures near the neck.
- 6 strongly rounded angled drill holes in the edge area of the proximal plate end for optimal suture fixation. The dorsal lateral localisation of the fixation holes permits the intoduction of the suture material after the osteosynthesis is completed.
- Diverging and converging screw arrangement in the proximal plate section increases stability in osteoporotic bone.
- Optimal fixation of complex fractures due to individually usable screw positions in the humerus head.
- Locking and conventional screws (Ø 3.5 mm), usable both in shaft and in head.
- Use of a torque key not required, due to the special surface treatment.
- Special surface treatment with type II anodisation of the plates.
- The screw design allows the use of one drill both for locking and for conventional screws.
- Simple instrument set with an easy overview.

Indications:

- 2-fragment, 3-fragment and simple slightly dislocated 4-fragment fractures
- Reconstructable fractures of the articular surface

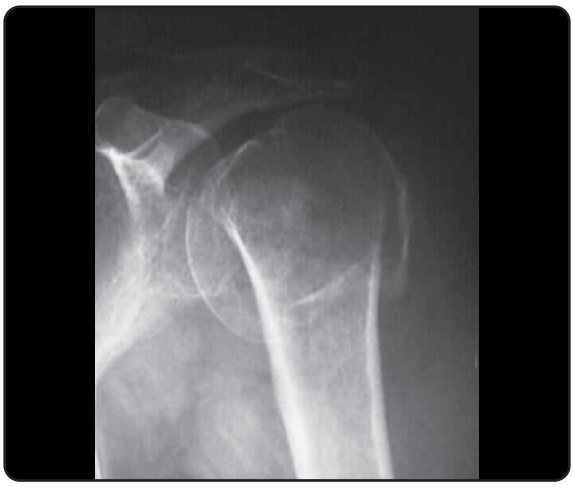
Surgical Technique

Patient Positioning and Access

- The surgery is done with the patient prone in the beach chair position.
- The shoulder receiving surgery is positioned so far out that in the intraoperative image transformer controls, both the a.p. and the axial x-rays can be done.
- Positioning on a special shoulder table has proven itself in this process.
- The deltoid pectoral access is suitable for complex reconstructions, particularly when an open repositioning procedure is required.

Repositioning the Fracture

- The preliminary repositioning of the main fragments takes place by placing the calotte fragment upright and folding in the tuberculum parts, using the image transformer.
- Temporary fixation of the repositioning results takes place by means of K-Wires, wherein care must be taken to ensure their proper positioning with regard to the plate length.

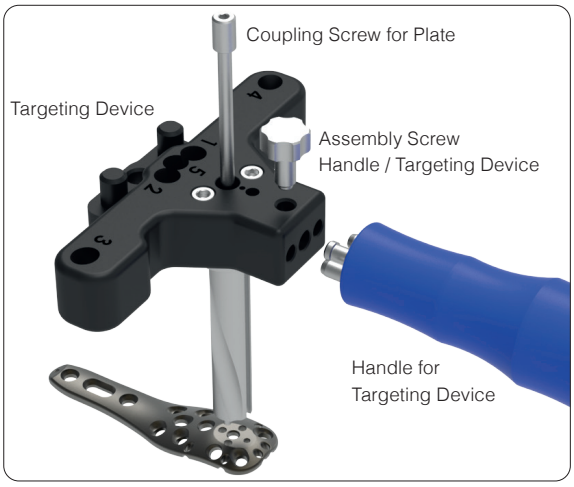


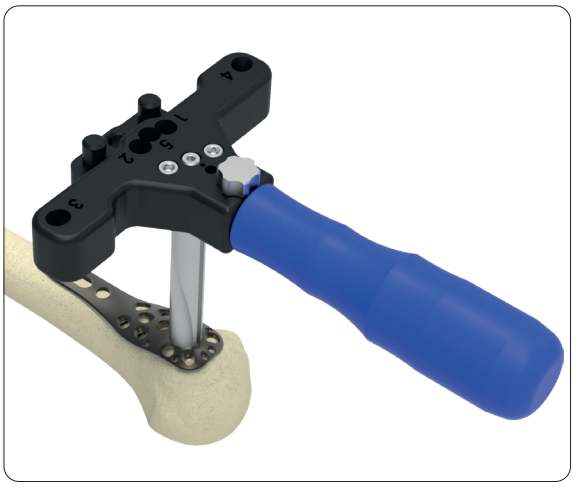
Assembly of the WINSTA-PH2 Targeting Device

Instruments

REF 14.20070.100	*Targeting Device*
REF 14.20060.013	*Assembly Screw Handle / Targeting Device*
REF 14.20070.130	*Coupling Screw for Plate*
REF 01.20202.006	*Handle for Targeting Device*

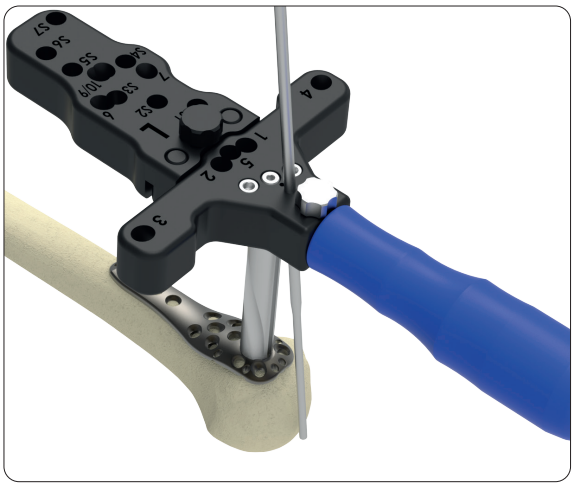
- The handle is inserted into the WINSTA-PH2 MIS Target Device.
- Then hand-tighten with the assembly screw.
- The planned WINSTA-PH2 plate is attached to the targeting device using the WINSTA-PH coupling screw.
- The corresponding right or left version of the plate must be selected in order to utilise the asymmetric part of the proximal plate end for better fixation of the tuberculum majus.





Positioning of the WINSTA-PH2

- Using the deltoid split approach, the plate is advanced superiosteally from the tuberculum majus on the bone to the proximal shaft area.
- The anatomical preforming of the plate simplifies the placement of the plate.
- The ideal position of the plate is just dorsally from the sulcus bicipitalis and approx. 6 to 8 mm below the rotator cuff base on the tuberculum majus.



Height determination of the WINSTA-PH2

Instruments

REF 14.20070.110/120	*Targeting Module right / left*
REF 14.20060.015	*Assembly Screw Targeting Device / Targeting Modules*
REF 14.20060.070	*Heigth Determination Device*

- After inserting the plate, the corresponding target module is connected to the target device using the assembly screw.
- Alternatively, the plate position can be determined with the height determination device by applying it to the proximal articular surface of the humeral head.

Fixation using K-Wire

Instruments

REF 11.90016.280	*K-wire Ø 1.6 mm*

- Temporary fixation of the plate is performed with a K-wire through the targeting device (proximal).
- Both the repositioning of the fracture and the precise position of the plate are now verified on 2 planes with the image transformer.

Plate Fixation in the Humeral Head

Instruments

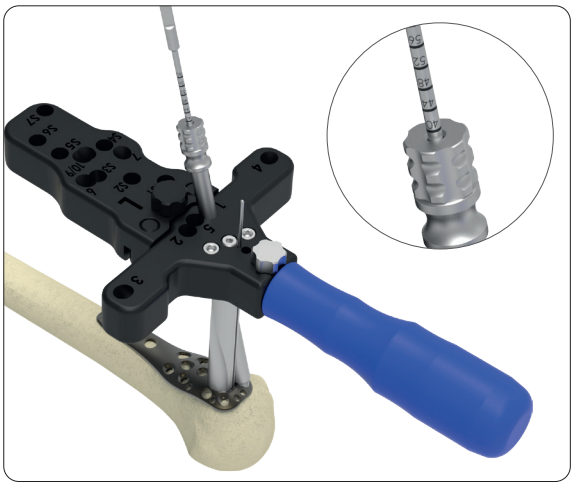
REF 14.20060.020	*Protection Sleeve Ø 6.0 mm*
REF 14.20070.140	*Drill Guide 2.5*
REF 14.20060.040	*Centering Sleeve for K-wire*
REF 14.20060.030	*Trocar Ø 1.6 mm*
REF 11.90016.280	*K-wire Ø 1.6 mm*

- The protection sleeve, the drill guide, the centering sleeve and the trocar, is advanced through the targeting device to the desired plate hole and screwed to the plate.
- The trocar is then removed and the expected screw position can be checked with the K-wire before drilling.

Instruments

REF 14.20010.125 *Drill Bit Ø 2.5 mm*

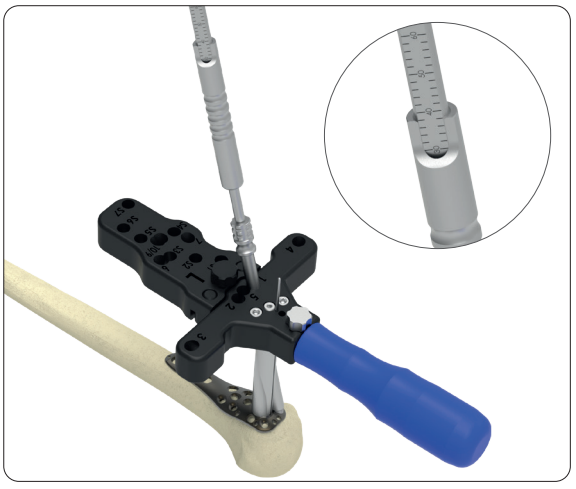
- Remove the K-wire and the centering sleeve.
- The screw hole is then drilled to just subchondral with the drill bit over the drill guide.



Instruments

REF 14.20060.060 *Length Determination Instrument for Screws up to 60 mm*

- After drilling, use the length determination instrument to measure the screw length over the drill guide.



Instruments

REF 14.20060.065 *Screwdriver, hex 2.5 mm*

- After removing the drill guide, the locking screw is screwed in through the protection sleeve with the screwdriver.
- After selecting the screw holes to be filled, the other screws are inserted one after the other in the humeral head. The procedure corresponds to the points described above.

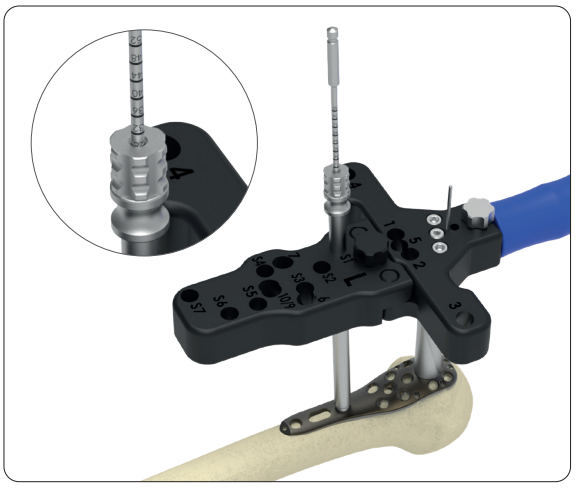
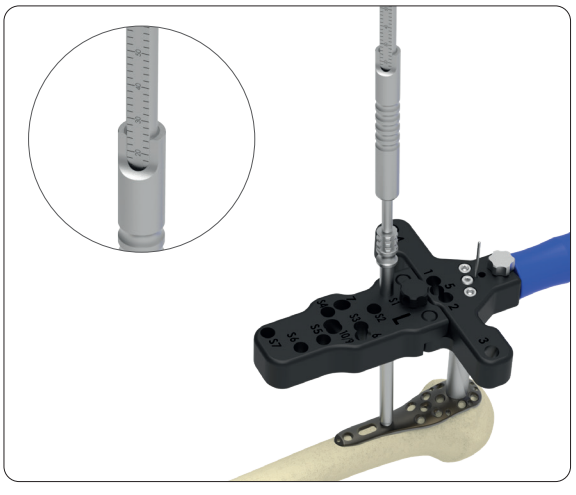


Plate fixation in the shaft region

Instruments

REF 14.20060.020 *Protection Sleeve Ø 6.0 mm*
REF 14.20070.140 *Drill Guide 2.5*
REF 14.20010.125 *Drill Bit Ø 2.5 mm*

- A stab incision is used to open access for plate fixation in the shaft region.
- The protection sleeve and the drill guide is advanced to the bone.
- Then pre-drill bicortically with the drill bit.



Instruments

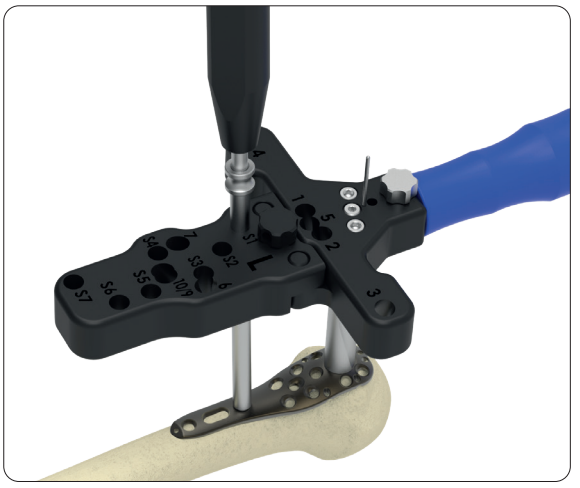
REF 14.20060.060 *Length Determination Instrument for Screws up to 60 mm*

- The length determination instrument is used to measure the screw length over the drill guide after drilling.

Instruments

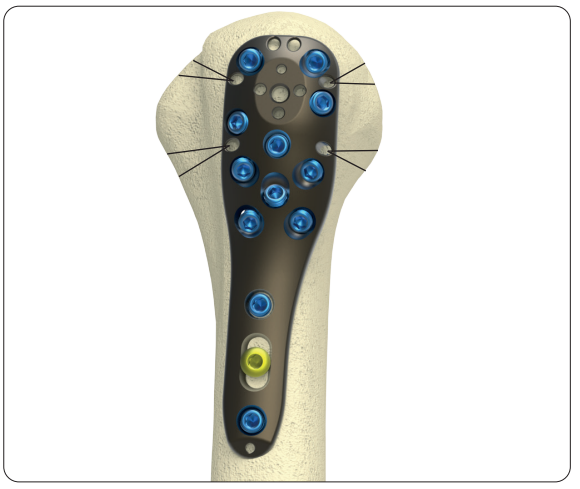
REF 14.20060.065 Screwdriver, hex 2.5 mm

- After removing the drill guide, the locking screw is screwed in through the protection sleeve with the screwdriver.
- After selecting the screw holes to be filled, the other screws are inserted one after the other in the humeral head. The procedure corresponds to the points described above.
- After all screws have been placed, a final image transformer check is performed in both planes.



Suture fixation of the rotator cuff

- To improve stability, dynamic fixation of the rotator cuff to the WINSTA-PH2 plate is possible.
- The special positioning of the drill holes permits suture fixation (generally with non-resorbable suture material) even after the osteosynthesis is completed.
- The fixation sutures of the rotator cuff can easily be threaded into the plate subsequently.
- Fixation holes are provided ventrally for the subscapularis tendon, cranially for the supraspinatus tendon, and dorsally for the infraspinatus tendon.
- Depending on the fracture, completion of the osteosynthesis can also take place with isolated fixation screws outside the plate.



Follow-up treatment

- Depending on the secure fixation of the fragments, particularly the tubercula, and the dynamic fixation of the rotator cuff, movement therapy can generally be initiated starting on the first post-op day.
- Here, we initially carry out passive movement therapy on the motor movement chair.
- The treatment is then complemented step by step with active and passive physiotherapeutic exercises without restriction of the range of movement, except for avoidance of outside rotation exercises in the four segment fracture.
- If applicable, however, the surgeon may specify further restrictions, depending on the stability of the osteosynthesis.

Material removal

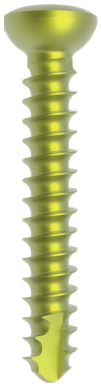
- Depending on the age of the patients receiving treatment and the function achieved, material removal may be useful.
- When removing the materials, all screws are first loosened.
- Only then they are turned out gradually.

Product Information

Implants

WINSTA-PH2
Proximal Humeral Plate

Article Number *	Number of holes in shaft with long hole	Length in mm	Orientation
14.11200.003	3	84,5	rigth
14.11200.005	5	105,5	rigth
14.11200.007	7	128,5	rigth
14.11200.010	10	170,5	rigth
14.11200.012	12	198,5	rigth
14.11200.014	14	226,5	rigth
14.11200.017S	17	268,5	rigth
14.11200.103	3	84,5	left
14.11200.105	5	105,5	left
14.11200.107	7	128,5	left
14.11200.110	10	170,5	left
14.11200.112	12	198,5	left
14.11200.114	14	226,5	left
14.11200.117S	17	268,5	left

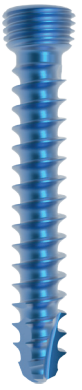


Cortical Screw ∅ 3.5 mm,
self-tapping

Article Number *	Length
03.03612.020	20 mm
03.03612.022	22 mm
03.03612.024	24 mm
03.03612.026	26 mm
03.03612.028	28 mm
03.03612.030	30 mm
03.03612.032	32 mm
03.03612.034	34 mm
03.03612.036	36 mm
03.03612.038	38 mm
03.03612.040	40 mm

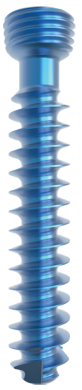
***** All implants are also available in sterile. Therefor, add suffix "S" to article number.

Locking Cortical Screw ∅ 3.5 mm, self-tapping



Article Number *	Length	Article Number *	Length
03.05612.020	20 mm	03.05612.042	42 mm
03.05612.022	22 mm	03.05612.044	44 mm
03.05612.024	24 mm	03.05612.046	46 mm
03.05612.026	26 mm	03.05612.048	48 mm
03.05612.028	28 mm	03.05612.050	50 mm
03.05612.030	30 mm	03.05612.052	52 mm
03.05612.032	32 mm	03.05612.054	54 mm
03.05612.034	34 mm	03.05612.056	56 mm
03.05612.036	36 mm	03.05612.058	58 mm
03.05612.038	38 mm	03.05612.060	60 mm
03.05612.040	40 mm		

Locking Cancellous Bone Screw ∅ 4.0 mm, self-tapping



Article Number	Length	Article Number	Length
03.05640.020S	20 mm	03.05640.042S	42 mm
03.05640.022S	22 mm	03.05640.044S	44 mm
03.05640.024S	24 mm	03.05640.046S	46 mm
03.05640.026S	26 mm	03.05640.048S	48 mm
03.05640.028S	28 mm	03.05640.050S	50 mm
03.05640.030S	30 mm	03.05640.052S	52 mm
03.05640.032S	32 mm	03.05640.054S	54 mm
03.05640.034S	34 mm	03.05640.056S	56 mm
03.05640.036S	36 mm	03.05640.058S	58 mm
03.05640.038S	38 mm	03.05640.060S	60 mm
03.05640.040S	40 mm		

***** All implants are also available in sterile. Therefor, add suffix "S" to article number.

Instruments

11.90016.280 Kirschner Wire Ø 1.6mm, trocar tip, L 280mm

14.20010.125 Drill Bit Ø 2.5 mm, scaled, AO Coupling, L 230/200mm

14.20060.020 WINSTA-PH MIS Protection Sleeve Ø 6.0

14.20070.140 WINSTA-PH2 MIS Drill Guide 2.5

14.20060.040 WINSTA-PH MIS Centering Sleeve for Kirschner Wire Ø 1.6mm

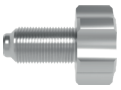
14.20060.030 WINSTA-PH MIS Trocar Ø 1.6mm

14.20060.060 WINSTA-PH MIS Length Determination Instrument, for Screws up to 60mm

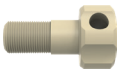
14.20060.090 WINSTA-PH MIS Length Determination Instrument, for K-Wires Ø 1.6mm x 280 mm

14.20060.070 WINSTA-PH MIS Height Determination Instrument

14.20060.013 WINSTA-PH MIS Assembling Screw for Handle / Targeting Device



14.20060.015 WINSTA-PH MIS Assembling Screw for Targeting Device / Targeting Modules



14.20070.130 WINSTA-PH2 MIS Coupling Screw for WINSTA-PH2 Plate

14.20060.065 Screwdriver, hex 2.5mm, L 244/134mm

03.20040.225 Torque Screwdriver, hex 2.5mm

14.20060.095 Screwdriver with Stop, hex 2.5mm, AO Coupling, L 150/115mm

01.20202.006 Handle for Targeting Device

14.20070.100 WINSTA-PH2 MIS Targeting Device

14.20070.110 WINSTA-PH2 MIS Targeting Module, right

14.20070.120 WINSTA-PH2 MIS Targeting Module, left

14.20060.014 WINSTA-PH MIS Pin Wrench Ø 4.0mm for REF 14.20060.015

14.20060.080 WINSTA-PH MIS Cover Pin for Targeting Module

MRI Safety Information

Non-clinical testing has demonstrated that the plates range from Marquardt Medizintechnik is MR Conditional in accordance with the ASTM F2503-20 standard definitions. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Cylindrical-bore
- Horizontal magnetic field (B_0)
- Spatial field gradient lower than or equal to
  - **1.5 T:** 23.45 T/m (2345 G/cm)
  - **3.0 T:** 11.75 T/m (1175 G/cm)
- Radiofrequency (RF) field exposure:
  - RF excitation: Circularly Polarized (CP)
  - RF transmit coil: whole-body transmit coil
  - RF receive coil type: whole-body receive coil
  - Maximum permitted whole-body averaged specific absorption rate (SAR): Normal Operating Mode, 2 W/kg.
  - Scan duration and wait time:

    1.5 T: 2 W/kg whole-body average SAR for **8min and 15s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **8min and 15s** if this limit is reached.

    3.0 T: 2 W/kg whole-body average SAR for **6min and 19s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **6min and 19s** if this limit is reached.
- The plates are expected to produce a maximum temperature rise of 8.5 °C at 1.5 T and 6.9 °C at 3 T both after the scanning periods presented above.
- The presence of this implant may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact. In non-clinical testing, the image artifact caused by the device extends approximately 83 mm from the device edge when imaged with a spin echo pulse sequence and 65 mm with a gradient echo, both at 1.5 T.
- Patients with uncompromised thermoregulation and under uncontrolled conditions or patients with compromised thermoregulation (all persons with impaired systemic or reduced local thermoregulation) and under controlled conditions (a medical doctor or a dedicated trained person can respond instantly to heat induced physiological stress).

Note:

Undergoing an MRI scan, there is a potential risk for patients with a metallic implant. The electromagnetic field created by an MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, or other undesirable effects.

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