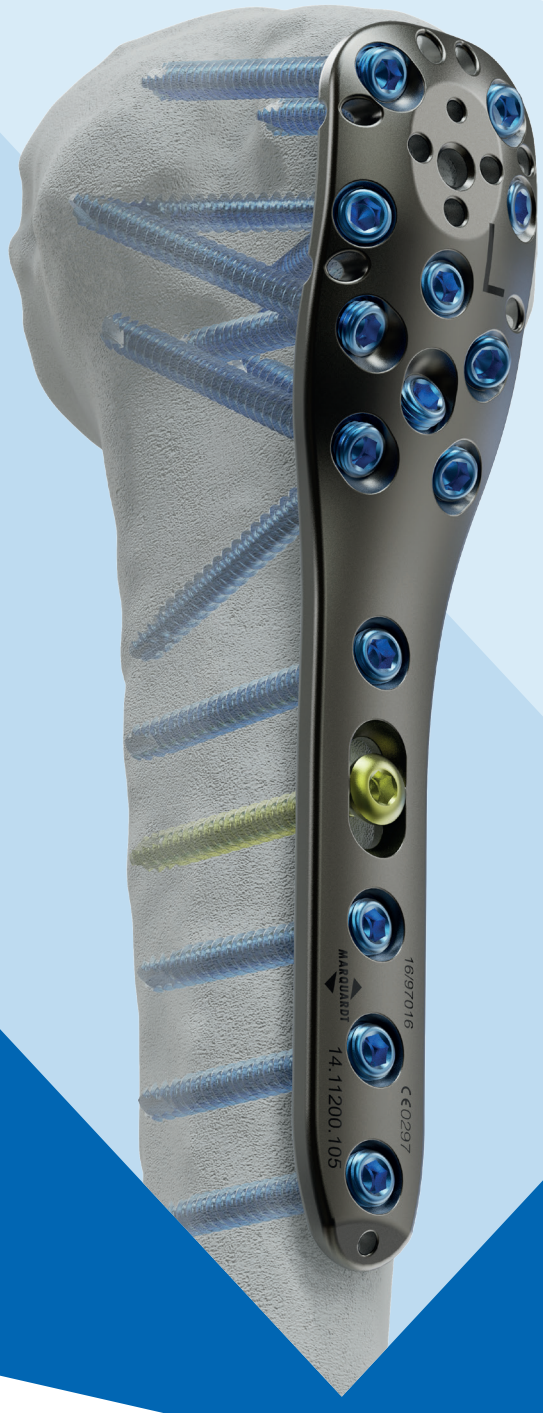
MARQUARDT
Medizintechnik




# WINSTA-PH
# Proximal Humeral Plate System

## Table of Contents



**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, 3 and 4 fragment fractures
- Reconstructable calotte fractures
- Pathological fractures
- Special indications such as pseudarthrosis and correcting osteotomy

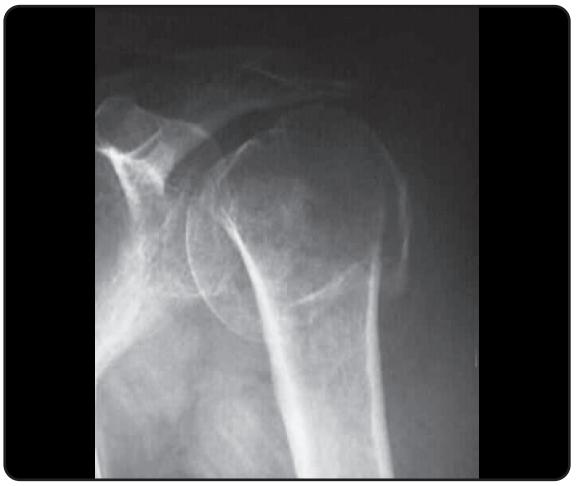
## Surgical Technique

### Positioning the patient

- 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

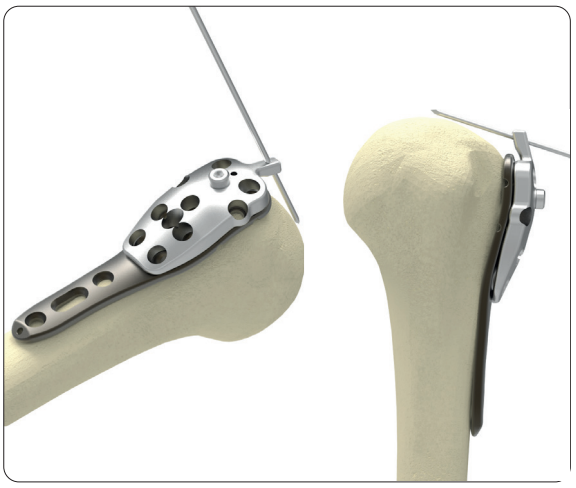
- The preliminary repositioning of the main fragments takes place by placing the calotte fragment upright and folding in the tuberculum parts, using the image transformer.
- Temporary fixation of the repositioning results takes place by means of K-Wires, wherein care must be taken to ensure their proper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



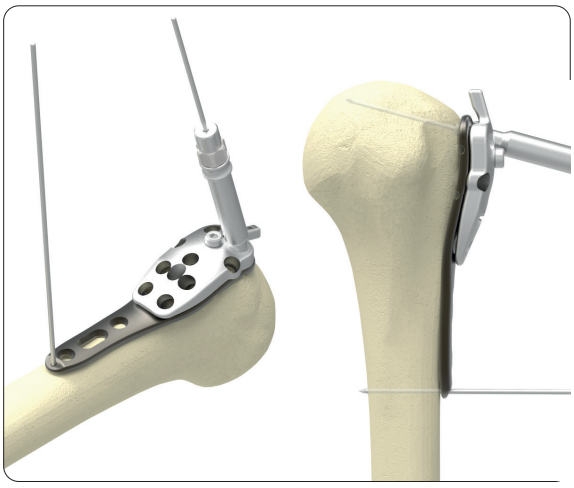
### Implant selection and positioning the plate over the guiding block

**Instruments**

| | |
|---|---|
| *REF 14.20010.041* | *Assembling Screw for Guiding Block* |
| *REF 14.20010.040* | *Guiding Block* |
| *REF 11.90016.150* | *K-Wire Ø 1.6 mm, L 150 mm* |



- 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.
- The anatomical pre-forming simplifies the placement of the plate. 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.
- After screwing in the screw for the guiding block, the guiding block is screwed onto the plate.
- Now the right plate position can be determined using a K-Wire.
- For this purpose, the K-wire is pushed through the proximal hole in the guiding block.
- The correct height of the plate is reached when the K-wire lies against the humerus head.



### Fixation of the plate using K-Wires

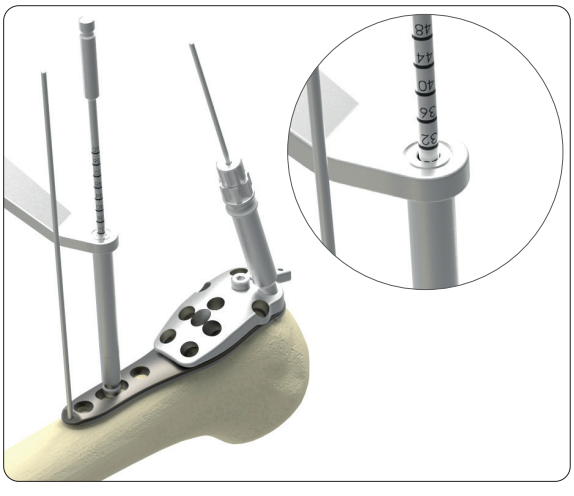
**Instruments**

| | |
|---|---|
| *REF 14.20010.020* | *Centering Sleeve for K-Wire* |
| *REF 14.20010.070* | *Guide Sleeve Ø 5.0* |
| *REF 14.20010.010* | *Drill Guide 2.5 mm* |

- After inserting the drill guide 2.5 into the guide sleeve Ø 5.0, screw in the assembled sleeves through the guiding block into the selected plate hole.
- Subsequently, inserting the guide sleeve for K-wire into the drill guide 2.5.
- Initial fixation of the plate (generally takes place proximally) with a K-wire.
- Then, after orienting the distal plate end on the upper arm shaft, distal fixation of the plate end takes place with another K-wire.
- Both the repositioning of the fracture and the precise position of the plate are now verified on 2 planes with the image transformer.

**Note:**

Depending on the extent of the fracture, the corresponding plate length should be selected for the osteosynthesis.



### Screw positioning

**Instruments**

| | |
|---|---|
| *REF 03.20010.425* | *Drill Bit Ø 2.5 mm* |
| *REF 14.20010.030* | *Drill Guide 2.5* |

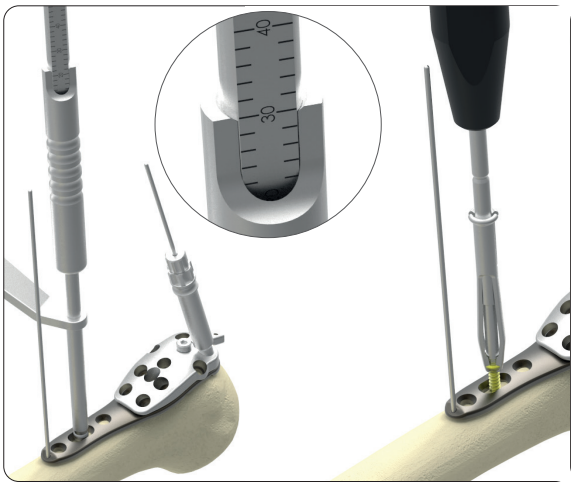
- The plate hole that is first occupied depends on the fracture type.
- Generally, the oval plate hole in the shaft region is occupied first, since it is then still possible to shift the plate in its longitudinal direction.
- For this purpose, the guide sleeve is placed on the long hole, and the screw hole is bi-cortically pre-drilled with the drill bit.

### Length measurement

**Instruments**

*REF 03.20040.025* *Screwdriver, hex 2.5 mm*
*REF 14.20100.060* *Length Determination Instrument, for Screws up to 60 mm*

- The suitable screw length is measured using the length determination instrument through the drill guide.
- Then, a Ø 3.5 mm self-tapping cortical screw is turned in with the screwdriver.

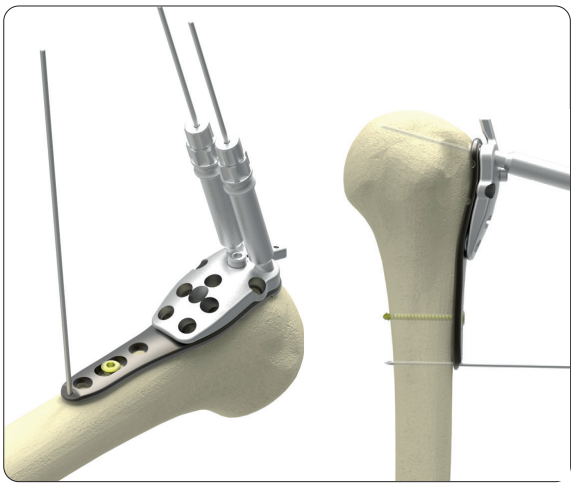



### Humerus head screws

**Instruments**

*REF 14.20010.020* *Centering Sleeve for K-Wire*
*REF 14.20010.070* *Guide Sleeve Ø 5.0*
*REF 14.20010.010* *Drill Guide 2.5 mm*

- The screw holes that are occupied in the humerus head region depend on the fracture type. Assemble the drill guide 2.5 with the guide sleeve Ø 5.0.
- Afterwards, screw in the assembled sleeves through the guiding block into the selected plate hole.
- Prior to pre-drilling, the expected screw position can be verified with the K-wire. For this purpose, the centering sleeve for K-Wire is pushed into the drill guide 2.5.
- Then the K-wire is placed in the humerus head through the guide sleeve.

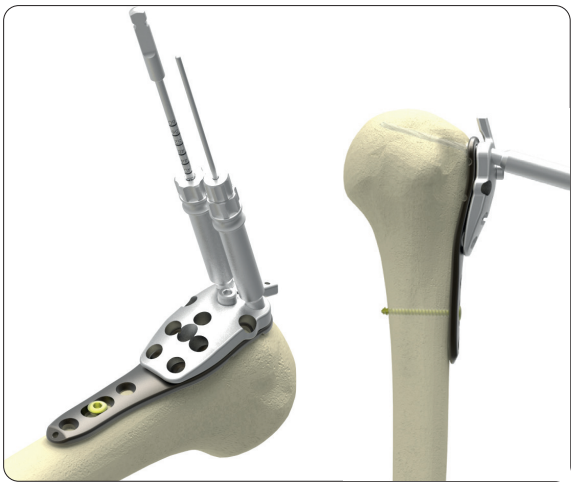


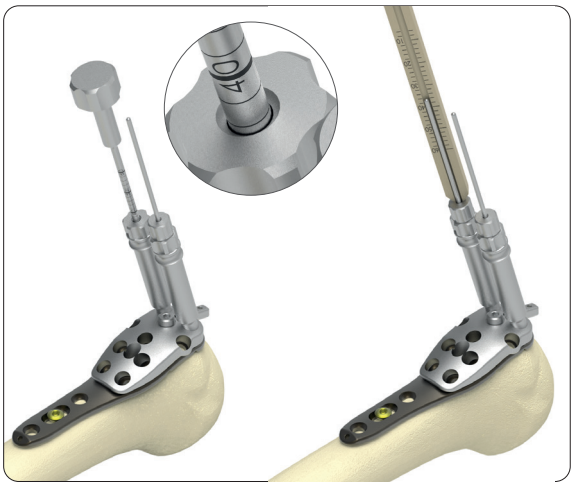
### Drilling the screw hole

**Instruments**

*REF 03.20010.425* *Drill Bit Ø 2.5 mm*

- After the removal of the K-wire and the guide sleeve, the screw hole is drilled with the drill bit through the drill guide barely to the subchondral area.



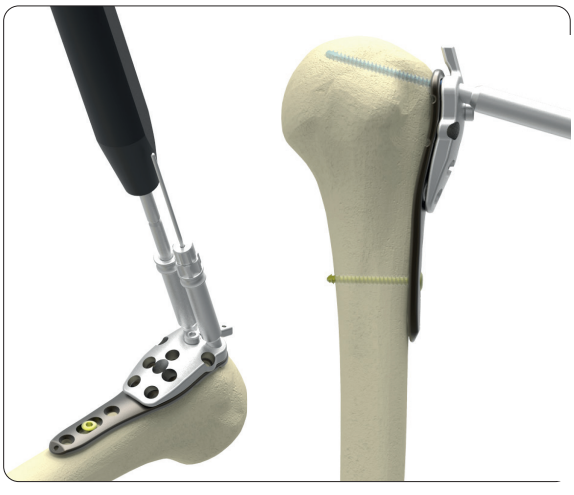


### Determination of the screw length

**Instruments**

| | |
|---|---|
| *REF 14.20010.060* | *Length Determination Device, for Screws up to 60 mm* |
| *REF 14.20010.050* | *Length Determination Instrument, for K-Wire Ø 1.6 mm x 150 mm* |

- Subsequently, the screw length is determined.
- This is measured using the length determination device via the drill guide.
- In order to avoid perforating the joint cartilage of the humerus head fragment, approx. 2 mm should be subtracted from the measured value.
- Alternatively, the screw length can also be determined via the K-wire which has already been placed.
- For this purpose, the length determination instrument is used and placed directly onto the centering sleeve for K-wires.
- The placed K-wire is guided into the groove of length determination instrument and the screw length can be determined by reading from proximal end of the K-wire.



### Insertion of the locking screw

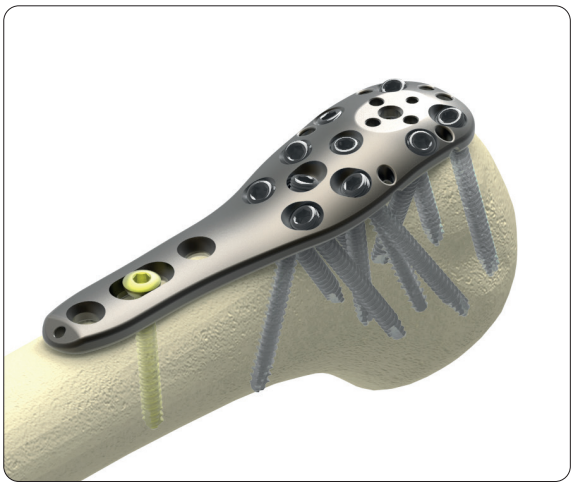
**Instruments**

| | |
|---|---|
| *REF 03.20040.025* | *Screwdriver, hex 2.5mm* |

- After the removal of the drill guide 2.5, the first locking screw is screwed in through the drill sleeve Ø 5.0 using the screwdriver.
- The direction of the screws, which can be placed partly diverging, partly converging as well as upwards or downwards, increases the stability of the angle-stable construction. .
- In the upper arm head area, 10 different locking screws can be inserted.
- It is recommended to place at least 5 - 6 locking screws.

### Insertion of further screws

- After selecting the screw holes to be occupied, further screws are introduced into the humerus head one at a time.
- The procedure is to be followed according to the previously described steps.



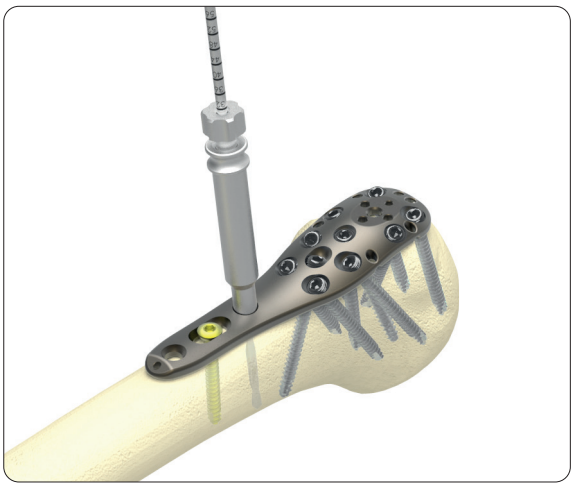
### Plate fixation in the shaft region

- After the osteosynthesis is completed in the humerus head region, loosening the Ø 3.5 mm cortical screw in the shaft will allow shifting of the plate as well as correction / optimisation of the height of the humerus head.
- After tightening the Ø 3.5 mm cortical screw, fixation to the proximal humerus shaft optionally takes place with locking screws or with conventional cortical screws.

### Drilling for shaft screws

**Instruments**

| | |
|---|---|
| *REF 14.20010.070* | *Guide Sleeve Ø 5.0* |
| *REF 14.20010.010* | *Drill Guide 2.5* |
| *REF 03.20010.425* | *Drill Bit Ø 2.5 mm* |

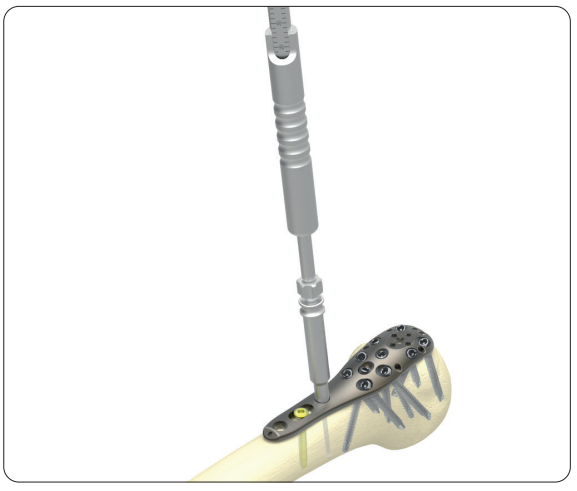


- Initially, the drill guide is inserted into the guide sleeve Ø 5.0.
- Subsequently, the drill guide is screwed into the preselected plate hole.
- The screw hole is bi-cortically pre-drilled through the drill guide 2.5 with the drill bit.

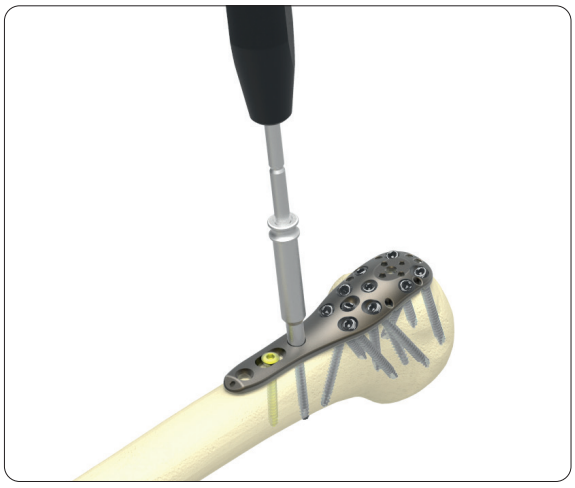
### Determination of the screw length

**Instruments**

| | |
|---|---|
| *REF 14.20100.060* | *Length Determination Instrument, for Screws up to 60 mm* |



- Subsequently, the screw length is determined via the drill guide, using the length determination instrument.

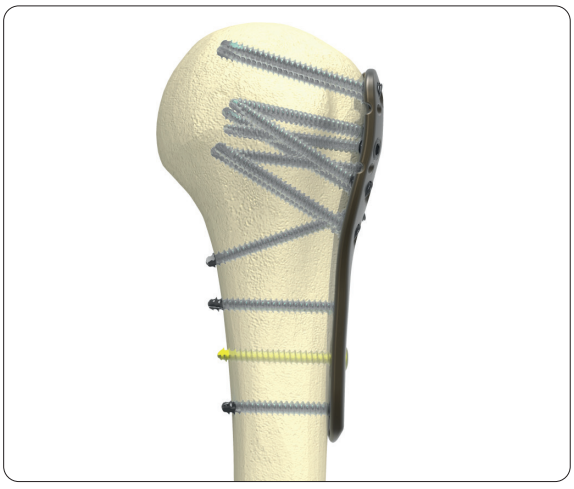


### Insertion of the screw

**Instruments**

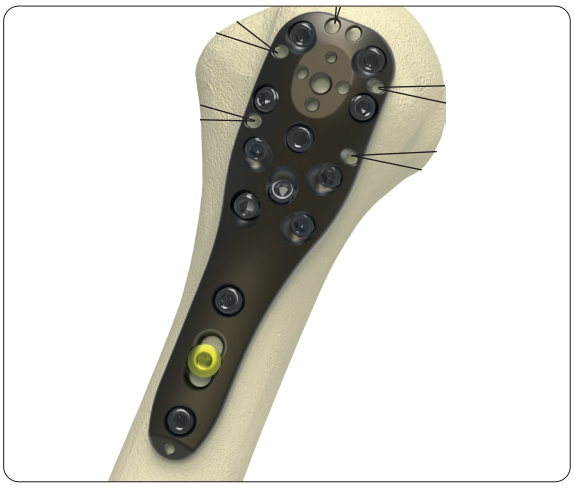
*REF 03.20040.025* *Screwdriver, hex 2.5mm*

- Now the selected screw is turned into the bone shaft with the screwdriver via the guide sleeve Ø 5.0.



### Insertion of further screws

- Subsequently, further screws are turned into the bone shaft.
- The procedure is to be followed according to the previously described steps.
- It is the surgeon´s preference regarding which type of screw is used to fill the screw holes.



### Suture fixation of the rotator cuff

- To improve stability, dynamic fixation of the rotator cuff to the WINSTA-PH 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

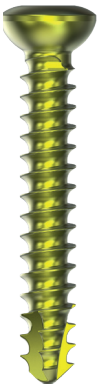
**WINSTA-PH**
**Proximal Humeral Plate**

| Article Number * | Number of Shaft Holes incl. Long Hole | Length | Orientation |
|---|---|---|---|
| 14.11133.003 | 3 | 85 mm | right |
| 14.11133.005 | 5 | 106 mm | right |
| 14.11133.007 | 7 | 127 mm | right |
| 14.11133.010 | 10 | 169 mm | right |
| 14.11133.012 | 12 | 197 mm | right |
| 14.11133.014 | 14 | 225 mm | right |
| 14.11133.017S | 17 | 267 mm | right |
| | | | |
| 14.11133.103 | 3 | 85 mm | left |
| 14.11133.105 | 5 | 106 mm | left |
| 14.11133.107 | 7 | 127 mm | left |
| 14.11133.110 | 10 | 169 mm | left |
| 14.11133.112 | 12 | 197 mm | left |
| 14.11133.114 | 14 | 225 mm | left |
| 14.11133.117S | 17 | 267 mm | left |

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

| 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 |

## Cortical Screw ∅ 3.5 mm, self-tapping



| Article Number* | Length | Article Number * | Length |
|---|---|---|---|
| 14.03355.020 | 20 mm | 14.03355.042 | 42 mm |
| 14.03355.022 | 22 mm | 14.03355.044 | 44 mm |
| 14.03355.024 | 24 mm | 14.03355.046 | 46 mm |
| 14.03355.026 | 26 mm | 14.03355.048 | 48 mm |
| 14.03355.028 | 28 mm | 14.03355.050 | 50 mm |
| 14.03355.030 | 30 mm | 14.03355.052 | 52 mm |
| 14.03355.032 | 32 mm | 14.03355.054 | 54 mm |
| 14.03355.034 | 34 mm | 14.03355.056 | 56 mm |
| 14.03355.036 | 36 mm | 14.03355.058 | 58 mm |
| 14.03355.038 | 38 mm | 14.03355.060 | 60 mm |
| 14.03355.040 | 40 mm | | |

## Locking Cortical Screw ∅ 3.5 mm, self-tapping

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

## Instruments

11.90016.150 Kirschner Wire Ø 1.6 mm, trocar tip, L 150 mm



03.20010.425 Drill Bit Ø 2.5 mm, 2-flute, scaled, AO Coupling, L 160/130 mm


14.20010.020 WINSTA-PH Centering Sleeve for Kirschner Wire Ø 1.6 mm

14.20010.070 WINSTA-PH Guide Sleeve Ø 5.0

14.20010.010 WINSTA-PH Drill Guide 2.5, for Locking Plates

14.20010.030 Drill Guide 2.5

14.20010.040 WINSTA-PH Guiding Block

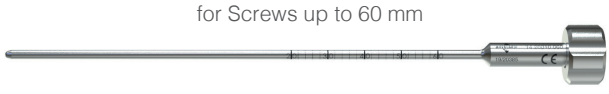

14.20010.041 WINSTA-PH Assembling Screw for Guiding Block

03.20040.025 Screwdriver, hex 2.5 mm, L 200/85 mm

02.20120.015 Screw Forceps, self-holding

03.20040.026 Holding Sleeve for Screws Ø 2.5 - 4.0 mm

14.20010.060 WINSTA-PH Length Determination Device, for Screws up to 60 mm



14.20100.060 WINSTA-PH Length Dtermination Instrument, for Screws up to 60 mm

## Optional

14.20010.050 WINSTA-PH Length Determination Instrument for Kirschner Wire Ø 1.6 mm x 150 mm

## MRI Safety Information

Non-clinical testing has demonstrated that the plates range from Marquardt Medizintechnik is MR Conditional in accordance with the ASTM F2503 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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MARQUARDT
Medizintechnik

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