HUMERUS PLATE WITH AIMING DEVICE

Surgical Instructions

VaWiKo proximal Humerus plate 4.0/3.5

Königsee
Implantate

Preface

Introduction

Many thanks for the trust you place in the VaWiKo proximal Humerus plate in combination with aiming device from Königsee Implantate.

This surgical instruction outlines the implantation procedure for the VaWiKo proximal Humerus plate with the use of the proximal aiming device.

In addition, the surgical instruction contains general information about how to handle instruments and implants. Both documents are available in a variety of languages at www.koenigsee-implantate.com.

You must carefully read through both the surgical instruction and instruction for use before using the Humerus plate and aiming device for the first time, and keep them in a safe place. We also advise that you receive instruction from an experienced surgeon to guarantee safe use of the instrument.

Qualification

To guarantee proper use, all of the instructions contained in this surgical instruction must be followed while taking into account any patient-specific requirements. In the Humerus plate system, all of the implants and instruments are coordinated with one another and can only be used in the area indicated.

We strongly discourage you from combining these products with other products which do not form part of the Königsee Implantate portfolio.

Safe use depends on faithful adherence to this surgical instruction and the surgeon's personal specialist knowledge, as well as proper handling of the implants and instruments. Königsee Implantate accepts no responsibility for injuries and/or damages caused by errors of judgement, improper use or failure to comply with the manuals. All of the warning notices and precautionary measures listed must be observed.

If you have any questions or suggestions with regard to our products, please contact your responsible contact in the Field Service team or our Product Training department.

Use

Our implants and instruments are delivered in a non-sterile state. Please refer to the instruction for use for recommendations on cleaning and sterilisation. Please check all of the products for damage before use. Implants are only suitable for single use. Information on MRI suitability can also be found in the instruction for use.

Contact

Königsee Implantate GmbH
OT Aschau | Am Sand 4
07426 Allendorf/Thuringia
Germany

Tel.: + 49 36738 498- 360
Fax: + 49 36738 498- 19

export@koenigsee-implantate.de
www.koenigsee-implantate.com

Table of contents

In detail

Goal of surgical instructions

Fig. 1

The proximal humeral fractures and humeral head fractures represent a particular challenge for osseous reconstruction due to the anatomical characteristics of the entirely soft tissue-controlled shoulder joint, as well as for an operational procedure that is as careful as possible with the soft tissue. Both can be achieved with the OP procedure described in the following.

Description and selection of the implant

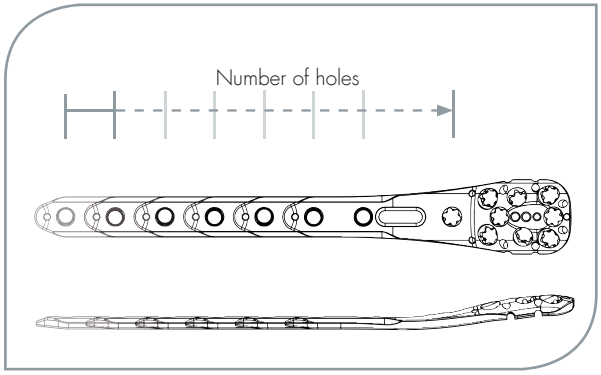


Fig. 2

Fig. 3

Humerus plate

- Item no. 5.07913.8X
- Anatomically formed and applicable on both the right and left sides
- VaWiKo head holes; WiKo shaft holes
- 3 - 8 shaft holes
- Plate thickness 3 mm
- Plate lengths: from 77 mm to 157 mm in 16 mm increments
- Titanium with TiOB®-optimised surface area
- Kirschner wire fixation holes
- Fixation holes for the rotator cuff
- A variable, angle-stable screw joint with conventional treatment possible
- Exclusively an angle-stable screw joint with minimally -invasive treatment

Aiming device

- Item no. 10.270.01; 10.270.02; 10.270.03
- Exclusively an angle-stable screw joint possible
- Carbon fibre reinforced PEEK (high durability)
- Protection of the nervus axillaris
- Straight-forward mounting and dismantling
- Clear allocation to the plate holes
- Optimized distance from the implant to the aiming device
- Specially adjusted instruments for the application of the aiming device
- Fixing possibilities for the retention stitches of the rotation cuffs

Introduction

The advantages of the VaWiKo proximal Humerus plate with aiming device

- In addition to the clearer anatomy with the repositioning, a essential advantage can be found in the low level of operative trauma to the soft tissue.
- The VaWiKo proximal Humerus plate is anatomically formed and applicable to both the right and left sides.
- Through the use of the aiming device system, a minimally-invasive treatment of the humeral fracture with the specially designed VaWiKo proximal Humerus plate (Item no. 5.07913.8X) is possible.
- As a result of the cranio-caudal line of sight and X-ray imaging, it is possible to achieve very good monitoring of the result of the realigning result.
- Good manipulability of the fragments by way of pre-positioned retention stitches.
- No additional hazard to the important ventromedial blood flow.
- Accessibility to the tuberculum majus that is frequently dislocated in the dorsocranial direction.
- Existing rotator cuff (partial-)ruptures can also be treated.
- Protection of the nervus axillaris.

Indications and contraindications

Indications

The indication for the VaWiKo proximal Humerus plate consists of 2 to 4 part fractures according to Neer, in which there is a sufficient amount of bone substance for a stable anchoring of the screws and from which it can be assumed from a retention of the medial periosteum that there is blood flow to the humeral head (caput humeri).

Contraindications

Contraindications include allergies to titanium and titanium alloys, plurifragmentary fractures of the joint surface of the humeral head (caput humeri), and if insufficient support of osteosynthesis in the calcar region is expected.

Warnings

- Every effort should be made to preserve the nervus axillaris during the entire preparation
- Manipulation of the shape and surface may weaken the implant thus causing product failure
- Compatibility of the aiming device and implant are no longer guaranteed after deformation
- A guarantee of compatibility only with application specific Königsee products
- It is extremely important to select the correct implant, the correct implant size and the insertion site so as to withstand the extreme physical stresses
- The implant's performance features will fully develop if the patient limits their physical activities

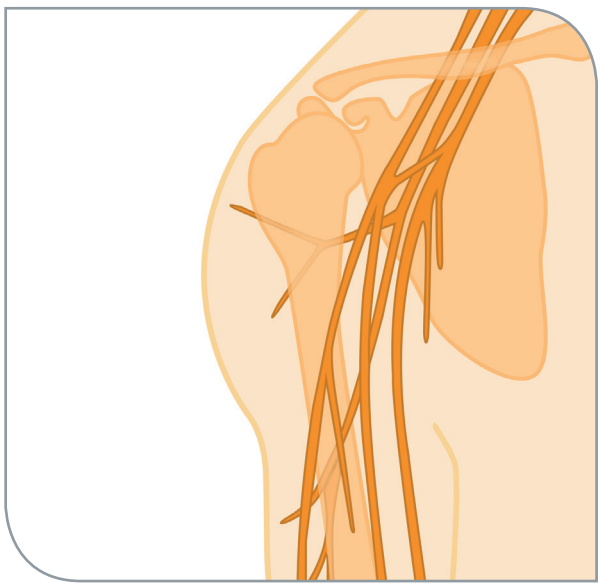


Fig. 4

Introduction

Target group

· The treatment with a humerus plate with aiming device is for adult patients.

Side effects

At the present time, this implant is not known to have any side effects. By way of precaution, we would like to point out that, as is the case with all osteosynthesis, material sensitivity or allergic reactions may occur.

Patient influence factors

A decisive factor for the success of the operation is the maintenance and restoration respectively of sufficient blood flow of the proximal bone fragments, especially the head fragment (caput humeri). In addition to a conservative operational procedure, secondary illnesses such as diabetes mellitus and its fine-tuning play a role, as well as possible nicotine consumption.

Any osteosynthesis on the proximal humerus as well as a prosthetic restoration depend significantly on the correct post-operative treatment and the compliance of the patient. Both the excessive demands and stresses of osteosynthesis at too early a point in time, and an overly long period of rest and recuperation for the shoulder endanger the post-operational functional result.

Explanation of the symbols and abbreviations

CE mark

Recognised notified body

Observe the usage information

Manufacturer

Products with the add-on "®" are registered trademarks of Königsee Implantate.

Products with the add-on "™" are trademarks of Königsee Implantate.

Documents with the add-on "©" are protected by copyright.

VaWiKo®	Variabel winkelstabile Kombination
WiKo®	Winkelstabile Kombination

In Germany the system names VaWiKo® and WiKo® are Registered Trade Marks. VaWiKo® is derived from the German designation "Variabel winkelstabile Kombination", which translates into English as "Variable Angle-Stable Combination". This system combines conventional plating technologies with stable locking at variable angles and angle-stable compression.

The system name WiKo® is derived from the German designation "Winkelstabile Kombination",which translates into English as "Angle-stable Combination". This is a plating technology which offers stable locking at a specified angle. It includes all the angle-stable plates both with and without compression.

In Germany, in the EU states, Switzerland an in the USA TiOB® is a Registered Trade Mark.

- Before beginning osteosynthesis the VaWiKo proximal Humerus plate should be assembled completely with aiming device in order to examine the function capability.
- The handle (Item no. 10.270.03) is fitted to the head of aiming device (Item no. 10.270.01) and by means of a fixation screw (Item no. 10.270.06) the head and handle are fixed together.

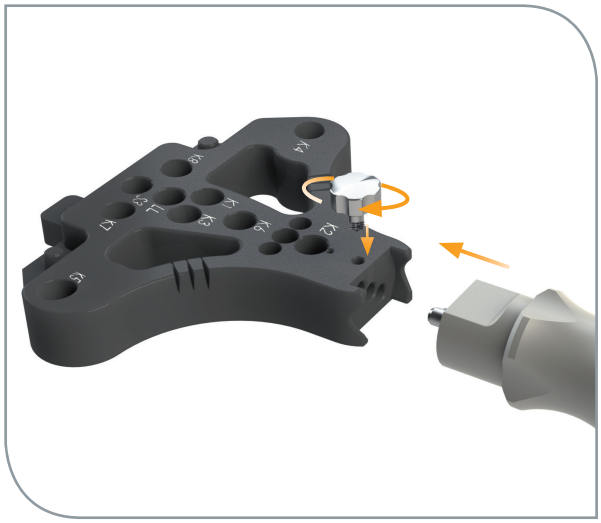


Fig. 5

- Finally, the mounting of the connecting rod (Item no. 10.270.10) for aiming device is done using two screws M3 x 17 (Item no. 10.179.15/17) on the head of aiming device.

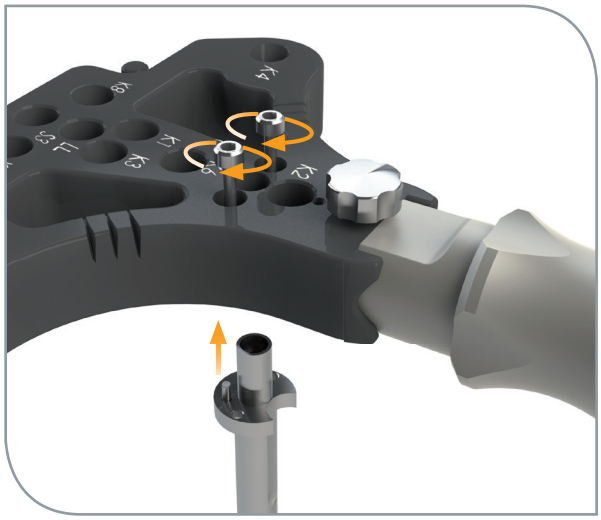


Fig. 6

- The implant (Item no. 5.07913.8X) is fixed with the fixing screw for connecting rod (Item no. 10.270.11), which is guided by the connecting rod for aiming device.

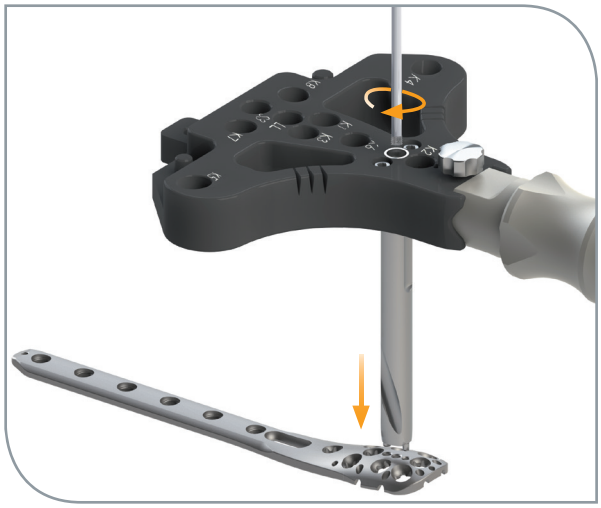


Fig. 7

Fitting the aiming device

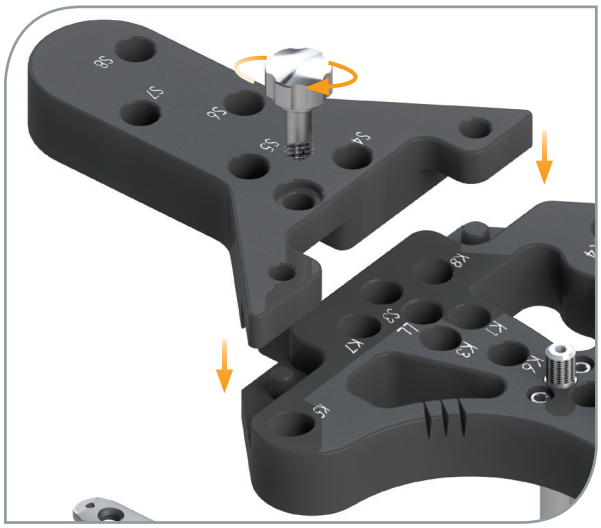


Fig. 8

- Now the shank for aiming device fitted (Item no. 10.270.02) to the head for aiming device using a connecting screw head-shank (Item no. 10.270.05).

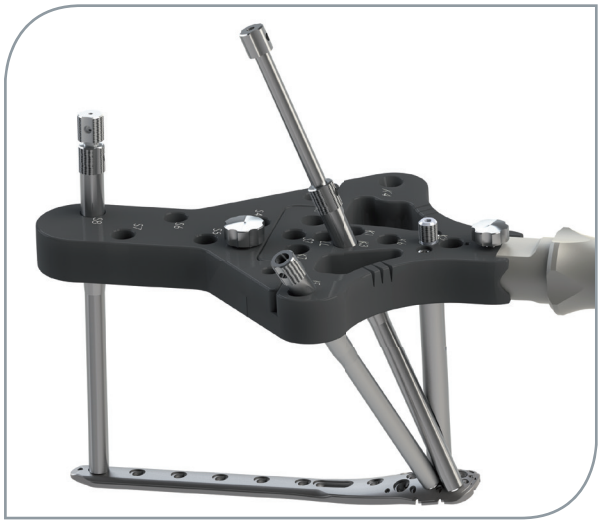


Fig. 9

- After the successful fitting of the aiming device the direction of all drill holes should be examined.
- This examination is conducted through the application of the tissue protection sleeves (Item no. 10.270.20) and screwing in the drill bushes for Ø 1.6 mm (Item no. 10.270.22) respectively the drill bushes for Ø 2.5 mm / Ø 3.0 mm (Item no. 10.270.30/31).

Positioning

- The patient should be placed in a beach chair position whereby it is to be ensured that both a cranio-caudal and a ventrodorsal fluoroscopy are possible without interruption.
- This is mostly successful when the back part of the OP table does not raise above 45° and the accompanying shoulder element of the OP table is removed.
- The affected arm is placed freely on an arm rest at approx. 20° external rotation, disinfected and covered.
- The preoperational single shot antibiosis is recommended.

Access

- A 6 cm anterolateral incision is made in the skin, beginning at the lateral acromial edge and over the middle of the humeral head.
- Finally, a blunt separation of the deltoid muscles in the direction of fibre and the opening of the bursa subacromialis takes place.
- Often the nervus axillaris can now be felt through the bursa on the caudal edge of the bursa.
- By means of retention stitches, individual tendons of the rotation cuffs are now gathered. 3 - 5 threads of strength 3 are preferred, organised in a u-form. It can be helpful to display the tendons using retraction sutures.
- Thereafter, the blunt preparation of the muscle tissue according to distal with the periosteal elevator.
- Insertion of the selected osteosynthesis plate with aiming device and creation of a second access.
- When attaching the plate it can be necessary to dismantle the shaft part of the aiming device.

Fig. 10

Reduction

- The plate is now removed and the fracture is resetting.
- In this regard it is helpful, after the humeral head (caput humeri) has, for example, been raised with an elevator, in order to cancel out the varus, to line if necessary, with cancellous bone or bonereplacement material.
- The humeral head (caput humeri) should overlap the upper edge of the tuberculum majus anatomically approx. 5 mm.
- With the retention stitches provided the tubercula fragments can then finally be integrated.

Surgical Instructions

Inserting and positioning the plate

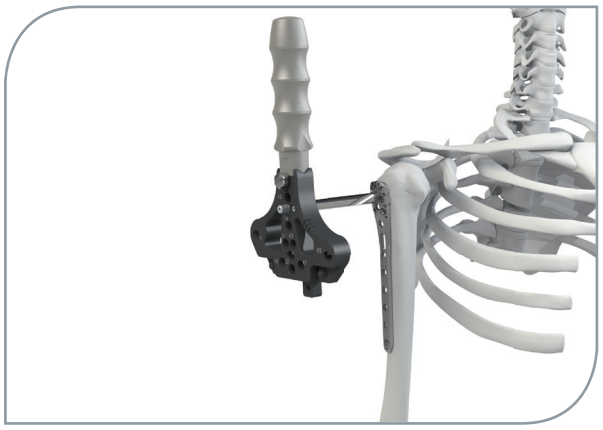


Fig. 11

- The plate is then re-inserted with the upper part of the aiming device.
- By maintaining the traction, the retention stitches can be clamped in the aiming device.
- The osteosynthesis plate should come to rest 2 mm below the upper edge of the tuberculum majus as a cranial limitation, on a straight extension from the tuberculum majus to the shaft in the cranial-caudal image.

Fixing the plate

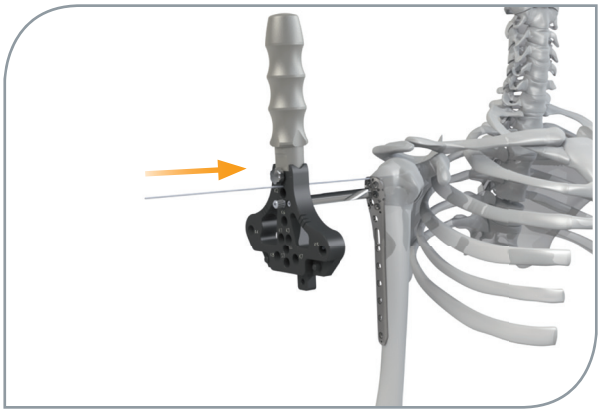


Fig. 12

- The first Kirschner wire (Item no. 6.061.16) is placed via the drilling hole positioned over the upper half of the K2 hole into the humeral head.
- Here in the ventrodorsal fluoroscopy, the correct vertebral height requires close attention.
- A perforation of the humeral head (caput humeri) must be avoided.

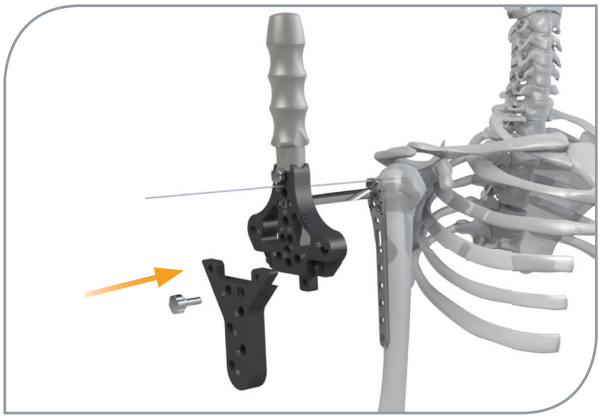


Fig. 13

- Now fully mount the aiming device.

· Insert the tissue protection sleeve (Item no. 10.270.20) at the distal plate hole.

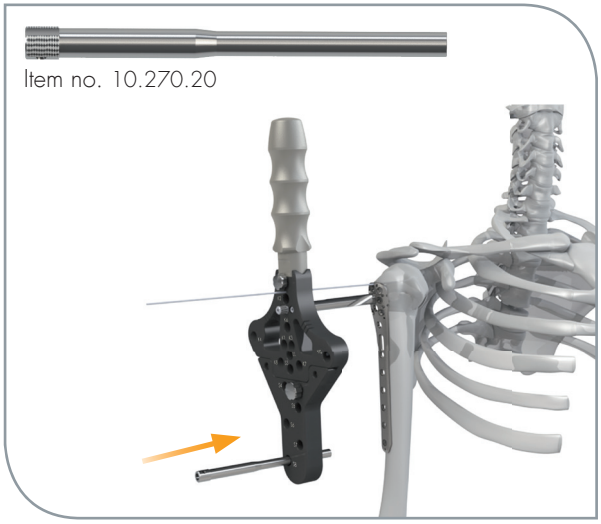


Fig. 14

· Screw in the drill bush for ∅ 1.6 mm (Item no. 10.270.22) for the Kirschner wire through the tissue protection sleeve.

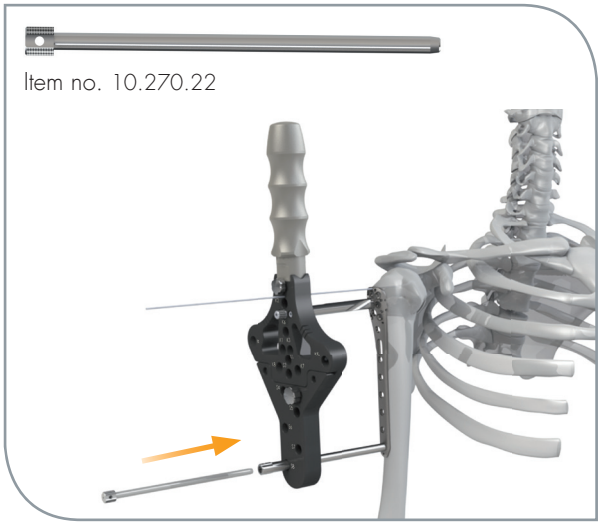


Fig. 15

· Insert the second Kirschner wire.

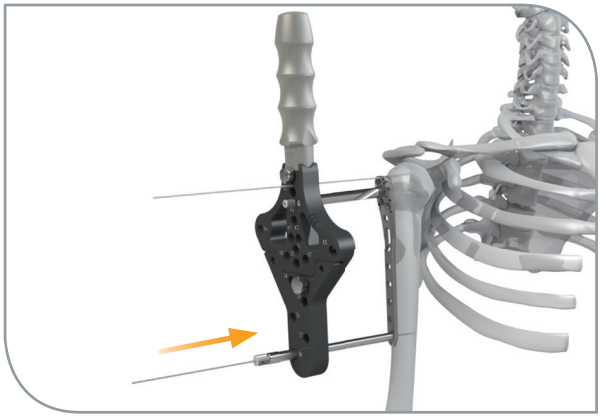


Fig. 16

Fitting the plate holes

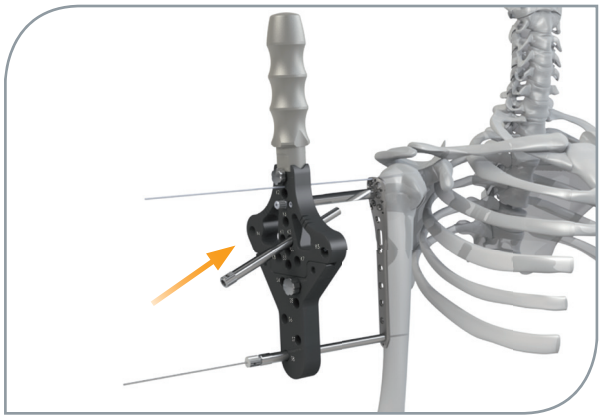


Fig. 17

- The allocation of the plate holes to the drilling holes in the aiming device are taken from the designation.
- The shaft hole S1 is not available with the use of the aiming device for the protection of the nervus axillaris.
- Insert a tissue protection sleeve at the selected plate hole.
- The order of use of the plate holes depends on the respective circumstances of the fracture.
- It often occurs that the humerus shaft subcapital to medial deviates from the plate.
- By placing the standard screws from caudal to cranial, the shaft can be gradually drawn onto the plate and set.

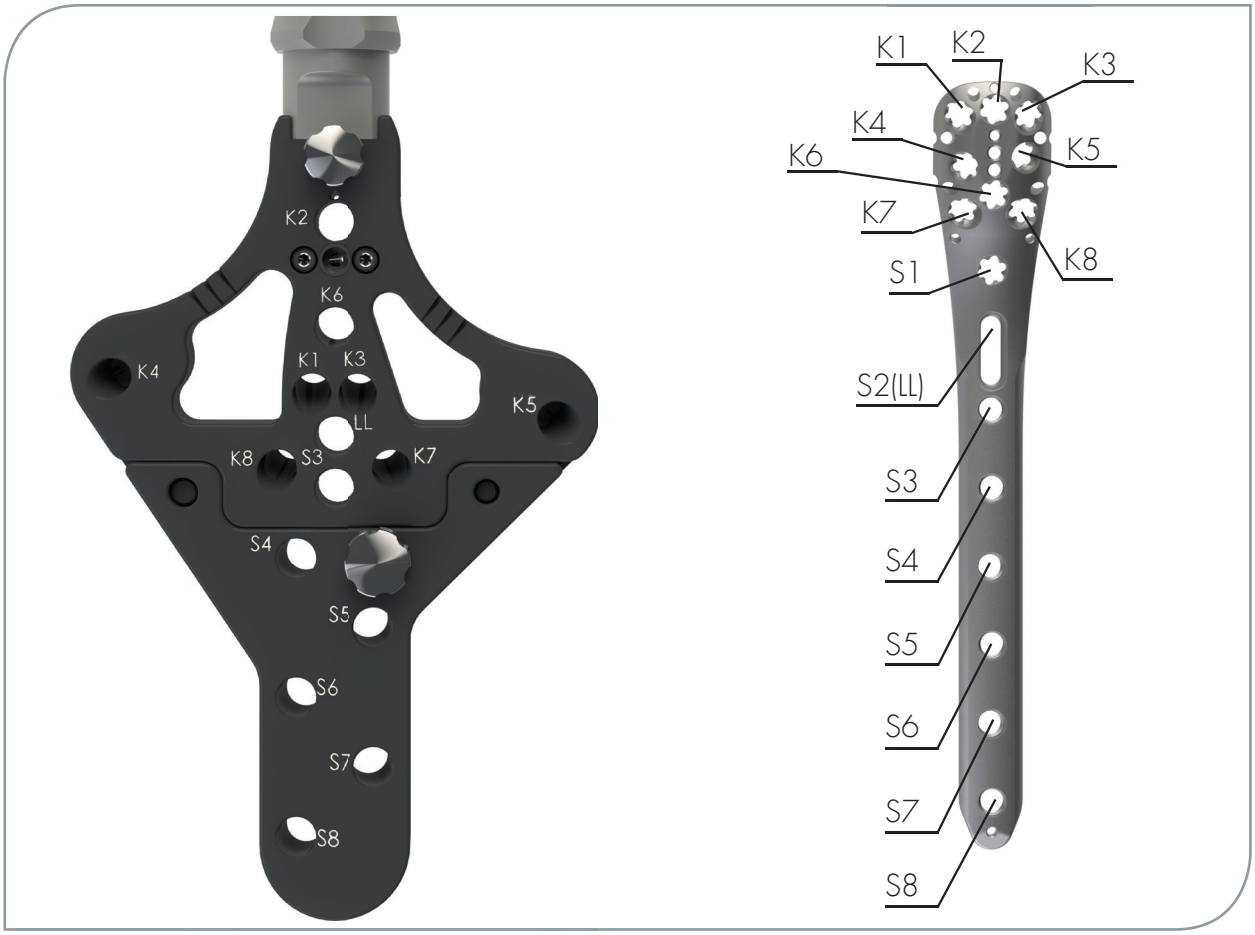


Fig. 18 Allocation of the plate holes to the aiming device

· Marking of further incision cuts on the skin surface using trocar (Item no. 10.270.21).

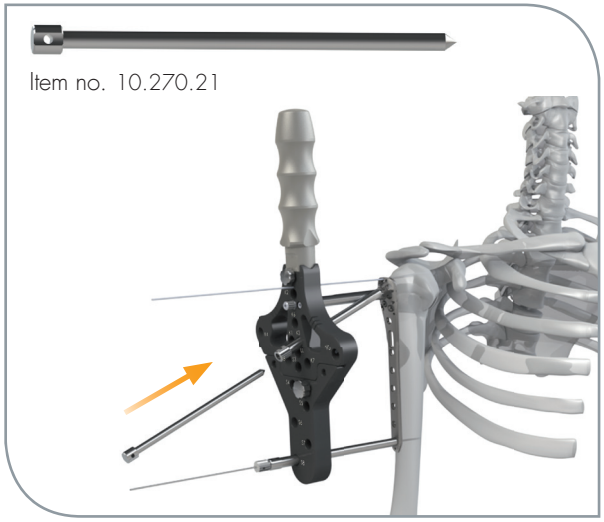


Fig. 19

· Screw in the drill bush for ∅ 2.5 mm (Item no. 10.270.23) through the protection sleeve.

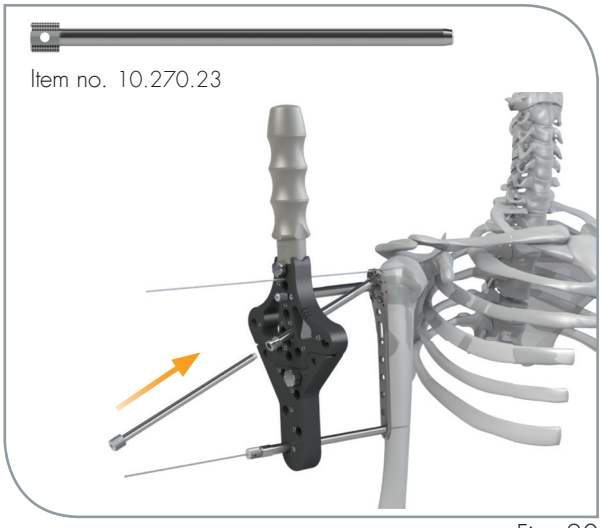


Fig. 20

· Pre-drill using the drill bit ∅ 2.5 mm (Item no. 10.270.30) for cortical screws ∅ 3.5 mm.
· A perforation of the humerus must be avoided in order to avoid an overlapping of the screws into the joint.
· The length of the screw to be used can be read directly using the scaling of the drill bit.

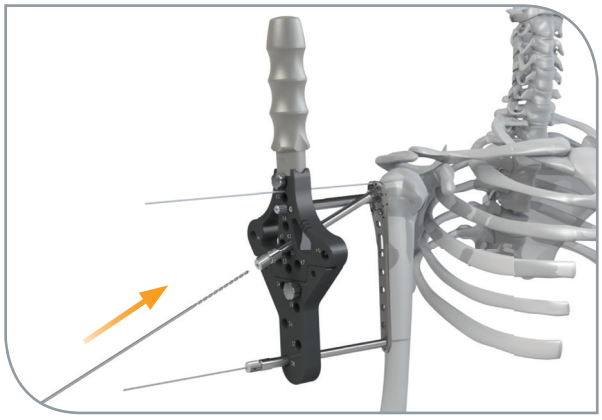


Fig. 21

Fitting the plate holes

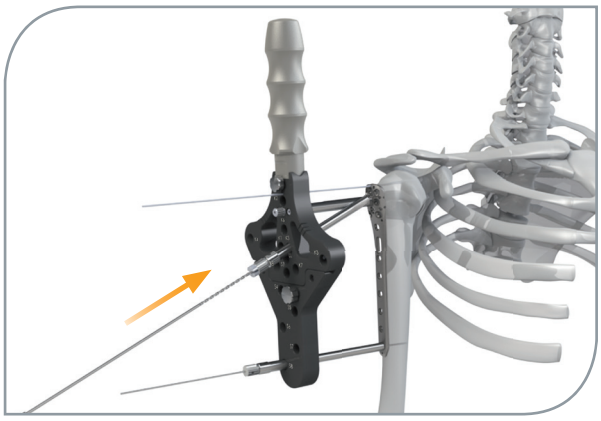


Fig. 22

- Using the measuring aid makes reading the scaling more convenient.

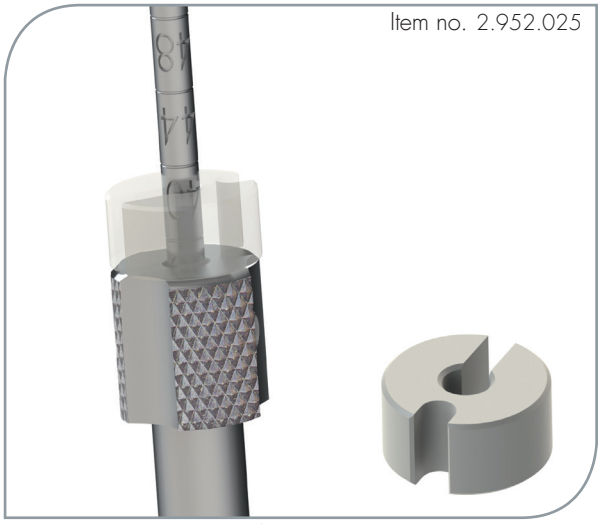


Fig. 23 Measuring aid

- To read the drilling depth using the measuring aid (Item no. 2.952.025) this is placed on the drill bit (Item no.10.270.30) so that it is lying on the drill bush.
- After reaching the desired drilling depth, the length measurement beneath the measuring aid (in the direction of drilling point) can be read.
- The registered value can hereby lie below the measuring aid.
- The length of screw to be selected corresponds to the registered value.

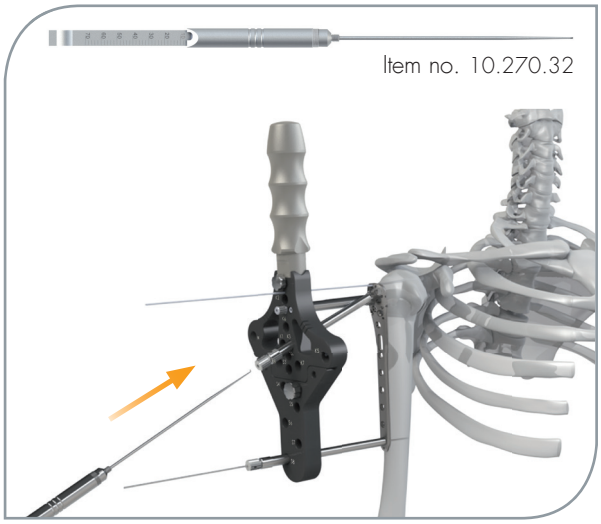


Fig. 24

- Alternatively, the length can also be determined with the gauge with hooks (Item no. 10.270.32).

Fitting the plate holes

- Remove the drill bush.

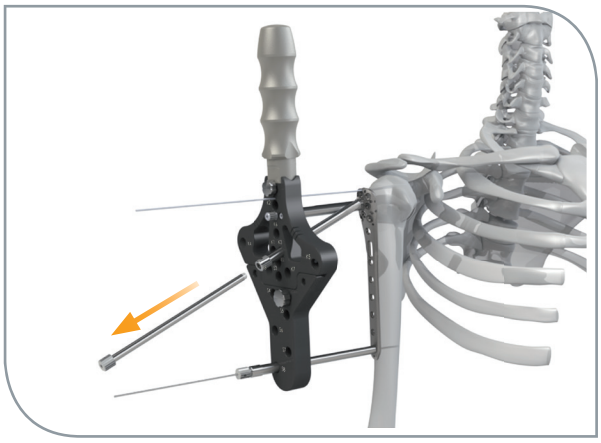


Fig. 25

- Insertion of the angle-stable screws through the tissue protection sleeve.
- In the LL position of the aiming device, only the use of the cortical screw is possible. This is positioned centrally in the elongated hole of the plate.
- Adopt this procedure for filling the remaining screws holes.
- In position K7 and K8 of the aiming device, the screws lie near to the calcar.

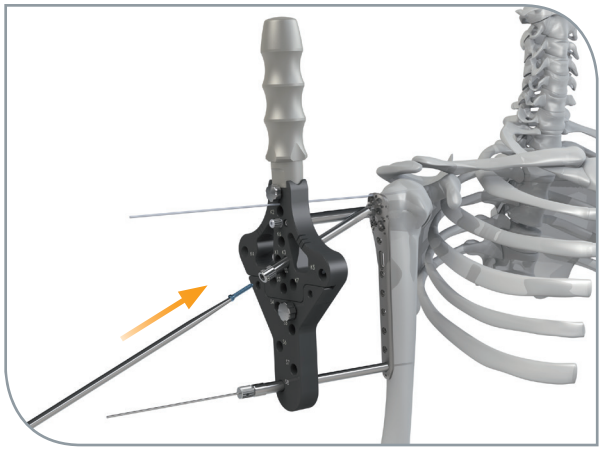


Fig. 26

Removing the aiming device

- The threads that remain clamped in the aiming device are freed.
- Kirschner wires, drill bushes and tissue protection sleeves are removed.

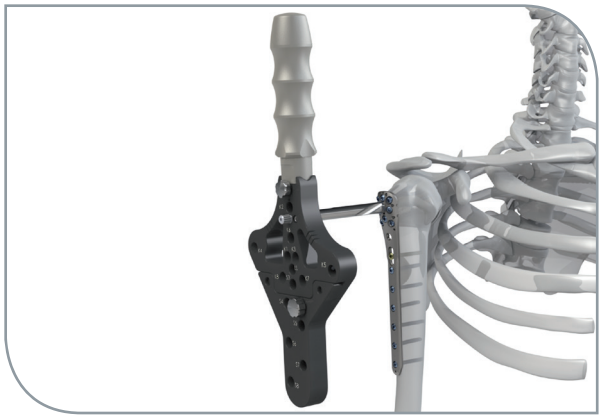


Fig. 27

Removing the aiming device

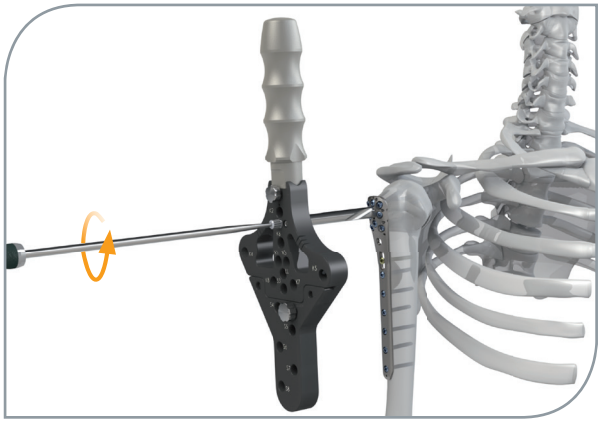


Fig. 28

· Loosening of the fixation screw for connecting rod.

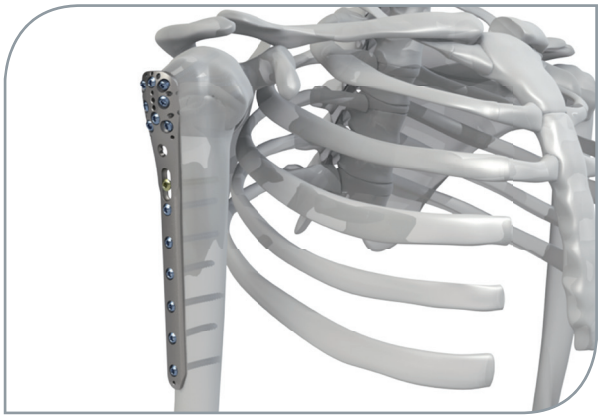


Fig. 29

· Removal of the aiming device with mounted connecting rod.
· Finally, the retention stitches of the rotation cuffs can be led through the fixation holes of the plate and knotted, through which the hold of the osteosynthesis is greatly improved.

Wound closure

· Suture of the musculus deltoidus.
· Subcutaneous suture and wound closure.

Sample cases

Pre-operative, sample case 1

- 90-year-old woman
- Subcapital humeral head fracture right
- Three fragment fracture
- Accompanying illnesses: dislocated subcortical humerus fracture right, non-dislocated radial head fracture right, as well as dislocated mandibular collum fracture left, diabetes mellitus, arterial hypertension, dizziness and insecure gait, anaemia

Fig. 30

Post-operative, sample case 1

- Functional post-treatment without load capacity for 6 weeks

Fig. 31

Sample cases

Pre-operative, sample case 2

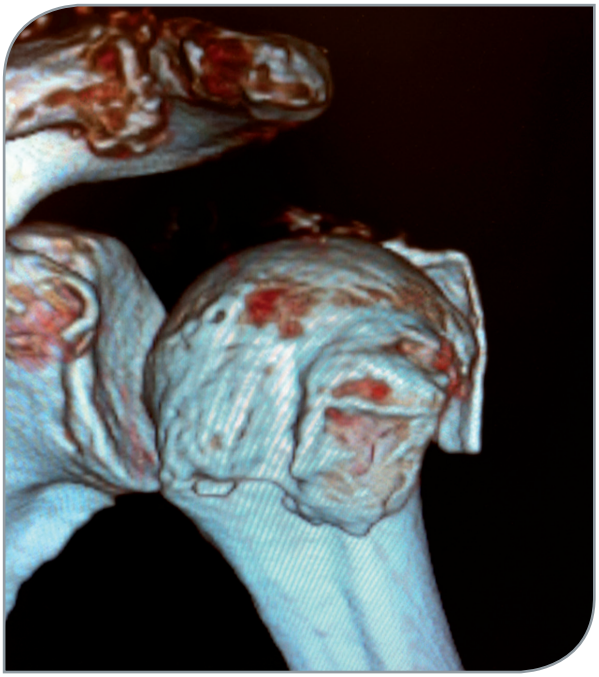


Fig. 32

- 66-year-old woman
- Trip over the pavement
- Proximal humerus head fracture left
- Accompanying illnesses: Hypertension, diabetes mellitus, psoriasis

Post-operative, sample case 2

Fig. 33

- Functional post-treatment without load capacity for 6 weeks

Pre-operative, sample case 3

- 67-year-old woman
- Fall in the house
- Subcapital humerus fracture left
- Accompanying illnesses: advanced dementia

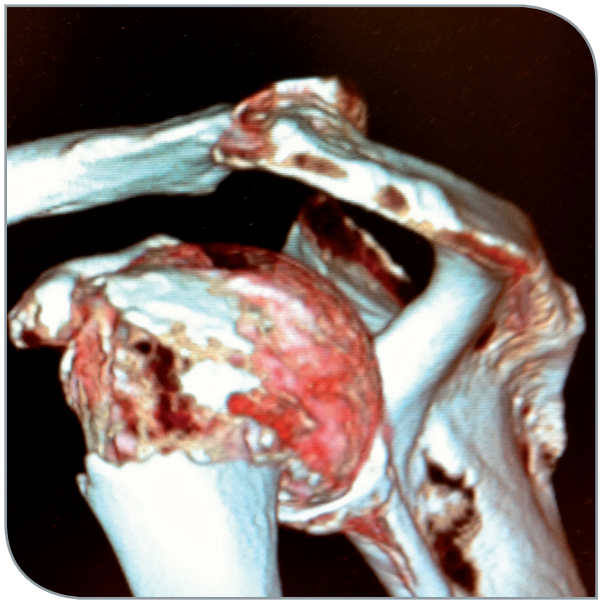


Fig. 34

Post-operative, sample case 3

- Immobilisation in the gilchrist for 2 weeks
- Functional movement exercises from the gilchrist without load capacity for 6 weeks

Fig. 35

Sample cases

Pre-operative, sample case 4

Fig. 36

- 64-year-old woman
- Fall
- Humerus head multiple fragment fracture left

Post-operative, sample case 4

Fig. 37

- Functional post-treatment without load capacity for 6 weeks

Pre-operative, sample case 5

- 43-year-old man
- Fall in the wet with his moped onto the left hand side of the body
- Moderate dislocation head to shaft
- Accompanying illnesses: Diabetes mellitus

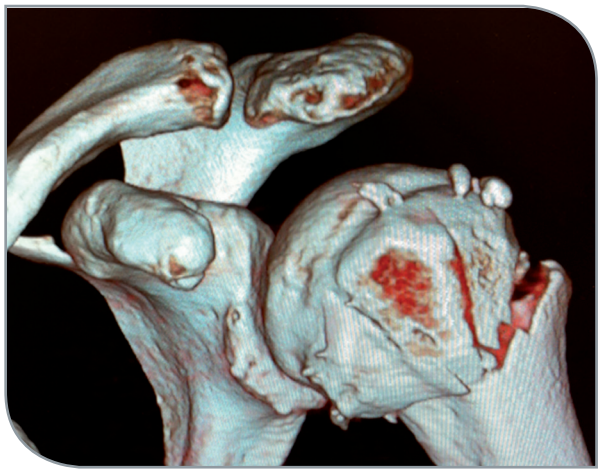


Fig. 38

Post-operative, sample case 5

- Functional post-treatment without load capacity for 6 weeks

Fig. 39

After-treatment

- Frequently, an exercise-stable osteosynthesis can be achieved in order that, post-operatively, movement exercises can be started with immediately.
- The post-operative lymphatic drain has also proven helpful for loosening the soft tissue.

Implant removal

- The removal of the implant is not necessary.
- After the complete consolidation of the fracture, it can be carried out with corresponding radiological procedural documentation.

References and picture credits

Images and photos

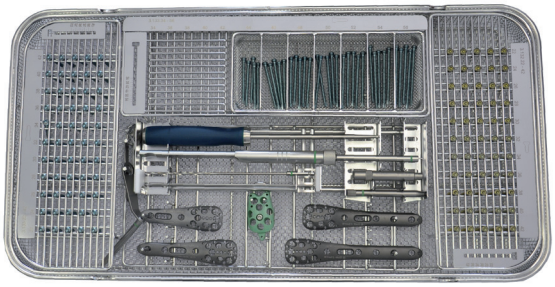
© Marcel Mende /www.foto-maxx.de

www.koenigsee-implantate.de

Dr. med. Stefan Hegermann

VaWiKo proximal Humerus plates 5.07913.8X; Ø 3.5 mm
Set-No. 19.3751.00

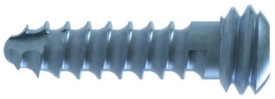
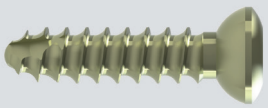
19.3751.00
VaWiKo proximal Humerus plates
5.07913.8X; Ø 3.5 mm



Item description	Item no.	Quantity	Figure
Implants - plates			
VaWiKo proximal Humerus plates 4.0/3.5 VaWiKo head holes; WiKo shank holes			
8 head holes; 3 shank holes; length 77 mm	5.07913.83	1	
8 head holes; 4 shank holes; length 93 mm	5.07913.84	1	
8 head holes; 5 shank holes; length 109 mm	5.07913.85	1	
8 head holes; 6 shank holes; length 125 mm	5.07913.86	1	
optional available			
8 head holes; 7 shank holes; length 141 mm	5.07913.87		
8 head holes; 8 shank holes; length 157 mm	5.07913.88		

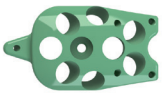
Ordering information

VaWiKo proximal Humerus plates 5.07913.8X; Ø 3.5 mm
Set-No. 19.3751.00

Item description	Item no.	Quantity	Figure
Implants - screws			
Angle-stable cortical screws Ø 3.5 mm; fully threaded; self tapping; titanium			
length 22	3.133.22	5	
length 24	3.133.24	5	
length 26	3.133.26	5	
length 28	3.133.28	5	
length 30	3.133.30	5	
length 32	3.133.32	5	
length 34	3.133.34	5	
length 36	3.133.36	5	
length 38	3.133.38	5	
length 40	3.133.40	5	
length 42	3.133.42	5	
length 44	3.133.44	5	
length 46	3.133.46	5	
length 48	3.133.48	5	
length 50	3.133.50	5	
length 52	3.133.52	5	
length 54	3.133.54	5	
length 56	3.133.56	5	
Cortical screws Ø 3.5 mm; fully threaded; self tapping; titanium			
length 22	3.132.22	5	
length 24	3.132.24	5	
length 26	3.132.26	5	
length 28	3.132.28	5	
length 30	3.132.30	5	
length 32	3.132.32	5	
length 34	3.132.34	5	
length 36	3.132.36	5	
length 38	3.132.38	5	
length 40	3.132.40	5	
length 42	3.132.42	5	

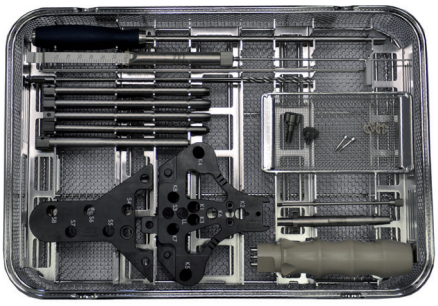
Ordering information

VaWiKo proximal Humerus plates 5.07913.8X; Ø 3.5 mm
Set-No. 19.3751.00

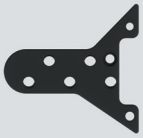
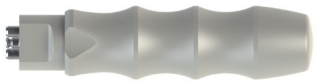
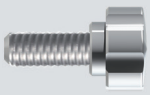
Item description	Item no.	Quantity	Figure
Instruments			
Drill bit for quick coupling; Ø 2.5 x 155 mm; spiral length 60 mm; double spiral	2.904.22	1	
Drill guide for angle stable screwing; length 68 mm; small fragment	2.977.04	2	
Hex screwdriver for Ø 2.7 mm up to Ø 4.0 mm; wrench size 2.5; conical; length 215 mm	2.9405.25	1	
Gauge with clasp for screws with conical head thread Ø 3.5/Ø 4.0 mm; measuring range 70 mm	2.953.70	1	
Aiming block for proximal humerus plates 5.07913.8X	10.179.15	1	
Sleeve for guide block for proximal small fragment humerus plates	10.173.01	1	
Screw forceps; self holding	2.954.01	1	
Drill guide with handle for variable angle stable screwing; small fragment; length 68 mm	2.977.09	1	
Container			
Perforated autoclavable container with inset for VaWiKo proximal Humerus plates 5.07913.8X; Ø 3.5 mm	19.3741.00	1	

Ordering information

Aiming device for VaWiKo proximal Humerus plate 5.07913.8X
Set-No. 19.375.00



19.375.00
Aiming device for
VaWiKo proximal humerus plate 5.07913.8X

Item description	Item no.	Quantity	Figure
Instruments			
Head for aiming device for proximal Humerus plates 5.07913.8X	10.270.01	1	
Shank for aiming device for proximal Humerus plates 5.07913.8X	10.270.02	1	
Handle for aiming device for proximal Humerus plates 5.07913.8X	10.270.03	1	
Connection screw head-shank for aiming device for proximal Humerus plates 5.07913.8X	10.270.05	1	
Fixing screw head-handle for aiming device for proximal Humerus plates 5.07913.8X	10.270.06	1	
Connecting rod for aiming device for proximal Humerus plates 5.07913.8X	10.270.10	1	
Fixing screw for connecting rod for aiming device for proximal Humerus plates 5.07913.8X	10.270.11	1	
Blind plug for aiming device for proximal Humerus plates 5.07913.8X	10.270.15	10	
Tissue protecting sleeve for aiming device for proximal Humerus plates 5.07913.8X; IØ 6 mm	10.270.20	3	
Trocar for aiming device for proximal Humerus plates 5.07913.8X; length 145 mm	10.270.21	3	

Ordering information

Aiming device for VaWiKo proximal humerus plate 5.07913.8X
Set-No. 19.375.00

Item description	Item no.	Quantity	Figure
Instruments			
Drill bush Ø 1.6 mm; Ø 10 x 145 mm; IØ 1.7 mm for aiming device for proximal Humerus plates 5.07913.8X	10.270.22	3	
Drill bush Ø 2.5 mm; Ø 10 x 145 mm; IØ 2.7 mm for aiming device for proximal Humerus plates 5.07913.8X	10.270.23	3	
Drill bush Ø 3.0; Ø10 x 145; IØ 3.2 mm for aiming device for proximal Humerus plates 5.07913.8X;	10.270.24	3	
Drill bit for quick coupling; Ø 2.5 x 250 mm; spiral length 60 mm; double spiral; with scaling	10.270.30	2	
Drill bit for quick coupling; Ø 3.0 x 250 mm; spiral length 60 mm; double spiral; with scaling	10.270.31	2	
Gauge for aiming device for proximal Humerus plates 5.07913.8X; measuring range 70 mm	10.270.32	1	
Hex screwdriver for Ø 3.5 mm and Ø 4.0 mm; wrench size 2.5; conical; length 315 mm	10.2705.40	1	
Measuring aid for drill Ø 2.5 mm	2.952.025	1	
Measuring aid for drill Ø 3.0 mm	2.952.030	1	
Screw head/connection rod for aiming device for proximal Humerus plates 5.07913.8X	10.179.15/17	2	
Wire			
Kirschner wire with Trokar point and round end; Ø 1.6 mm x 280 mm; stainless steel	6.061.16	5	
Container			
Perforated autoclavable container with inset for prox Humerus-guide frame instruments	19.374.00	1	

Königsee
Implantate

Königsee Implantate GmbH
OT Aschau | Am Sand 4
07426 Allendorf
Germany

Tel.: + 49 36738 498 - 360
Fax: + 49 36738 498 - 19

export@koenigsee-implantate.de
www.koenigsee-implantate.com

CE 1275

certified according to
EC directive 93/42/EEC
DIN EN ISO 13485

Surgical Instructions
with the friendly support of
Dr. med. Stefan Hegermann
Chief Physician
Accident and Joint Surgery
Städtische Kliniken Mönchengladbach

HUMERUS PLATE WITH AIMING DEVICE

VaWiKo proximal Humerus plate 4.0/3.5

Surgical Instructions