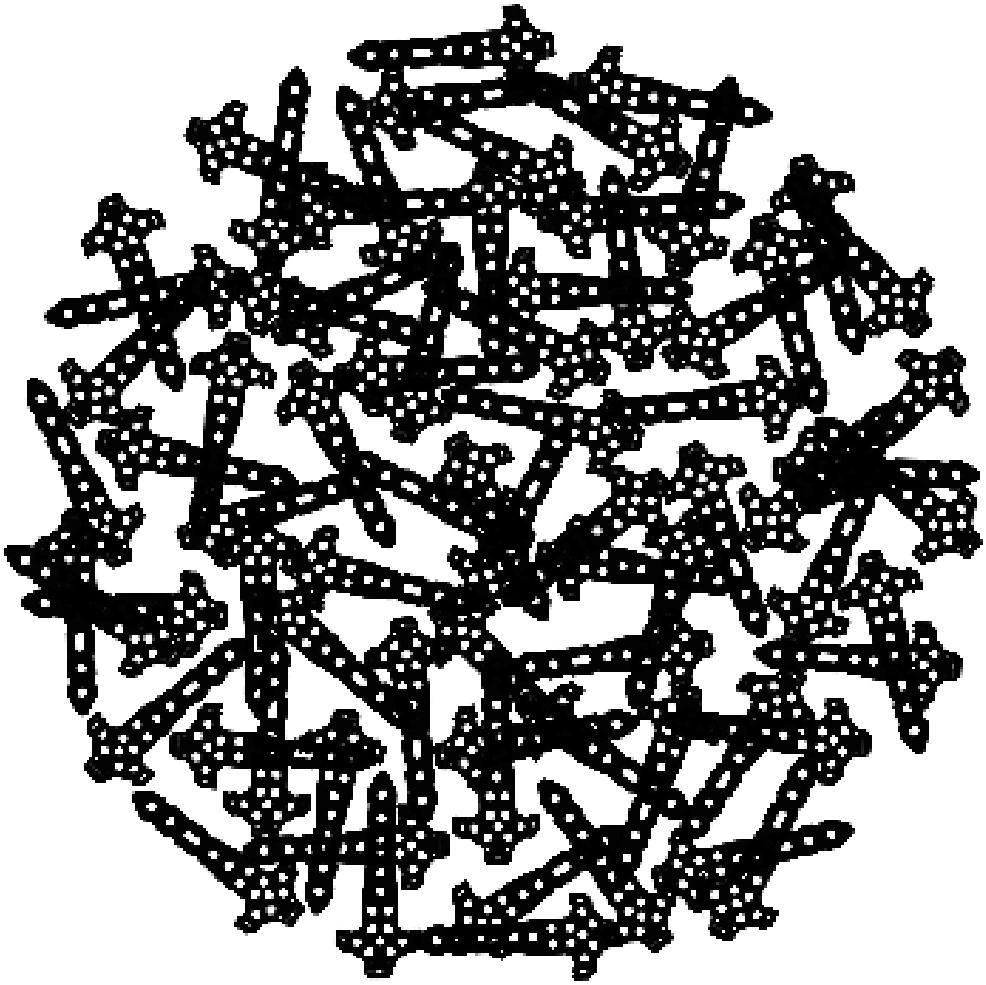
ITS.

Implants
trauma



PHL 2

Proximal Humeral Locking Plate 2

All ITS plates are preformed anatomically as a matter of principle. If adjustment of the plate to the shape of the bone is required, this is possible by carefully bending gently in one direction once. Particular care is required when bending in the region of a plate hole, as deformation of the plate may lead to a failure of the locking mechanism. The plate must not be buckled or bent several times. This is particularly important in the case of titanium implants, to prevent material fatigue and subsequent failure. The method of bending is the conscious responsibility of the operating doctor; I.T.S. GmbH can accept no liability whatsoever for this.

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Introduction

1.

Preface

The newly developed Proximal Humeral Locking Plate 2 enables the surgical treatment of various fractures of the proximal humerus.

This implant includes multiple versions of the proximal part with contourable flanges to enable a proper fixation of the entire humeral head - especially of the greater and lesser tuberosity.

An additonal feature is the free choice of screw placement. The user is able to set any desired screw in any hole (except oblong hole).

Especially with complex fractures the free choice of screw angle (+/- 15°, see page 19) has advantages in the fracture treatment. Even with poor bone quality, the plates support and cradle the humeral head in desired position.

Screws

37351-XX-N Cortical Screw, locking, D=3.5mm, SH

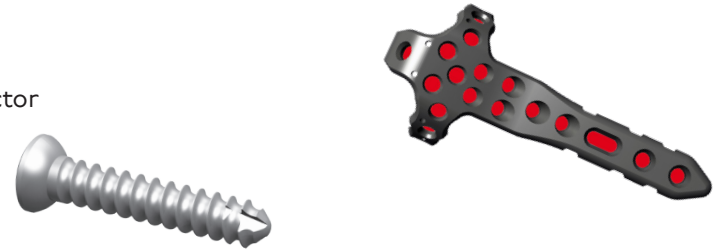
61273-100 Spiral Drill, D=2.7mm, L=100mm, AO Connector

56252-150 Screwdriver, WS 2.5, self-holding

32351-XX Cortical Screw, D=3.5mm

61273-100 Spiral Drill, D=2.7mm, L=100mm, AO Connector

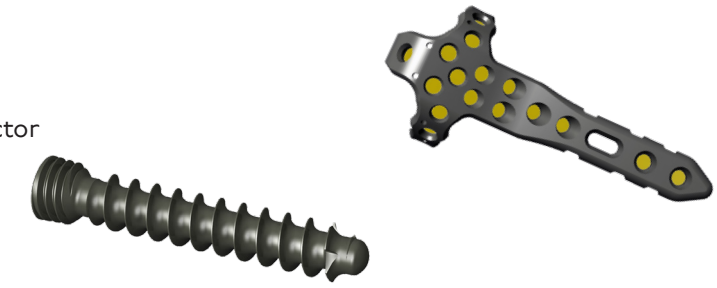
56252-150 Screwdriver, WS 2.5, self-holding



37422-XX-N Cancellous Screw, locking, D=4.2mm, SH

61253-180 Spiral Drill, D=2.5mm, L=180mm, AO Connector

56252-150 Screwdriver, WS 2.5, self-holding



35164-260 Guide Wire, Steel, D=1.6mm, L=260mm, TR, w. thread

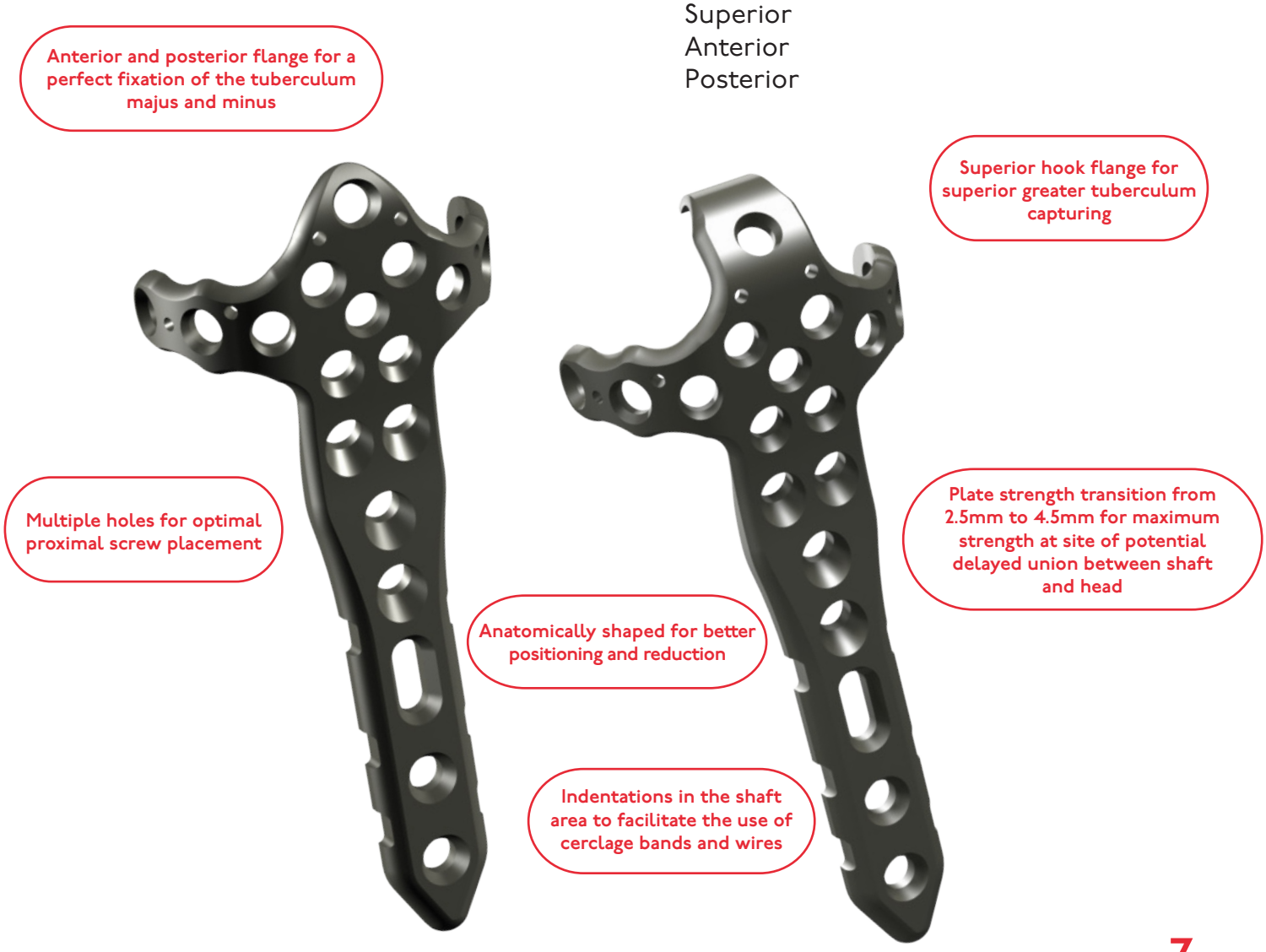
Properties

Properties of the material:

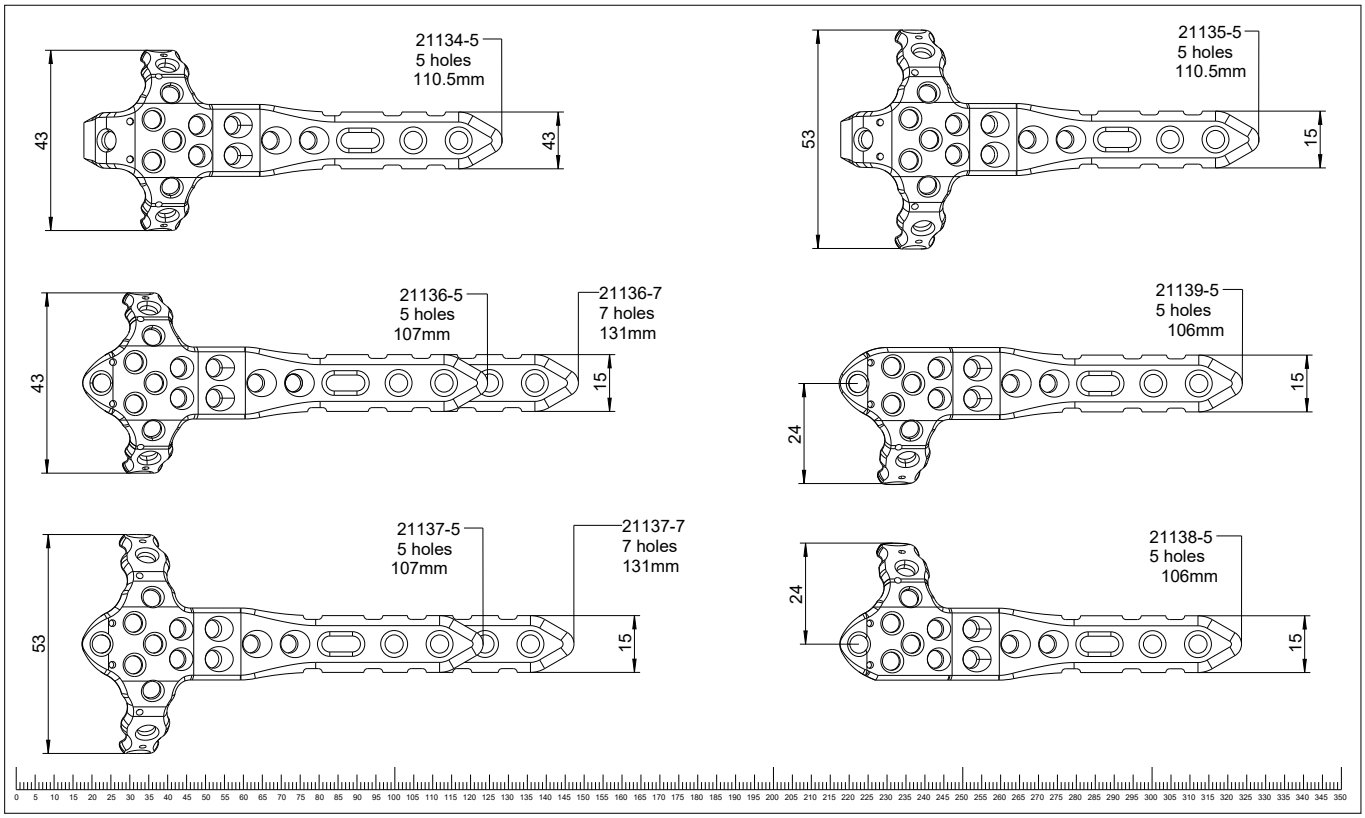
- Plate material: Titanium
- Material of screws: TiAl6V4 ELI
- Easier removal of the implant after the fracture has healed
- Improved fatigue strength of the implant
- Reduced risk of cold welding
- Reduced risk of inflammation and allergy

Properties of the implant:

- Multi-directional locking
- Anatomical plate design
- Anterior, superior and posterior flanges for tuberosity fixation
- Oblong hole for optimal positioning and adjustment of the humeral length
- Flanges are contourable in situ, for optimal adjustment to the individual anatomy
- K-Wire holes for preliminary plate fixation
- Pointed distal plate end for percutaneous insertion
- Lengths: 5, 7-hole
- Sizes: small, large
- Flanges:
  Superior
  Anterior
  Posterior



Pre-operative planning



Indications

The I.T.S. Humeral Plate with Angular Stability is used to stabilize fracture(s) of the proximal humerus bone in the shoulder.

- All stable and unstable humerus fractures with or without shaft involvement
- Fractures of the greater or lesser tuberosities.
- Repair of the greater tuberosity following prior fixation failure or tuberosity “escape”.
- Delayed or nonunion of the proximal humerus.
- Fixation following osteotomy of proximal humeral malunion.
- Displaced two, three and four part fracture of the proximal humerus.
- Displaced anterior and posterior fractures of the proximal humerus and greater tuberosity.
- Nonunion of two, three and four part fractures of the proximal humerus.
- Nonunion of anterior and posterior fracture-dislocations of the proximal humerus and greater tuberosity.

Contraindications & Time of operation

Contraindications:

- Severe osteoporosis
- Existing infections in the area of the fracture
- In cases of skin and soft tissue problems
- Obesity
- Lack of patient compliance

Time of operation:

- Primary as well as secondary after swelling subsides and after temporary fixation

Surgical Technique

2.

Pre-operative patient preparation

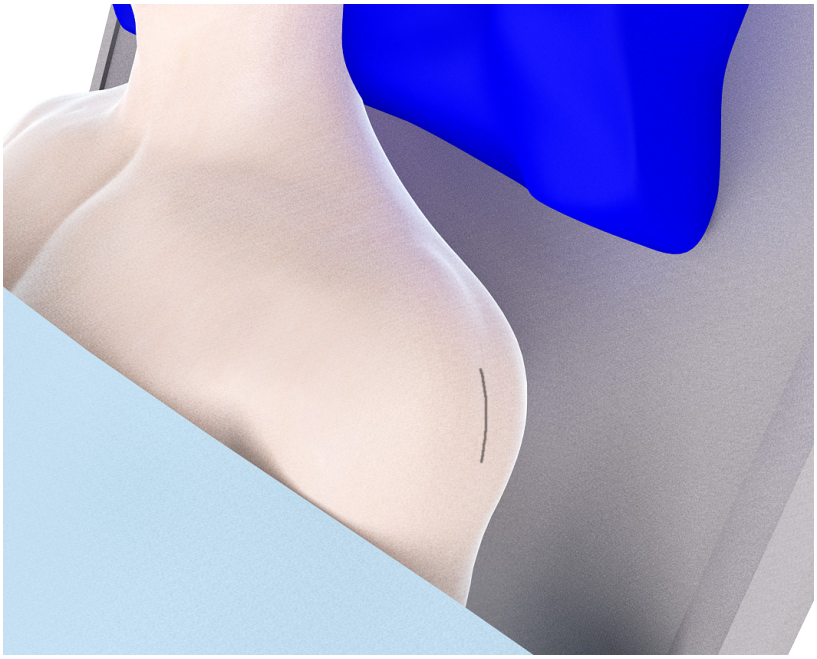
- Positioning on a radiolucent surgical table
- Semi-sitting angle of about 30° - 40°, shoulder should be freely moveable (optional shoulder table)
- The arm should be freely moveable to allow fracture reduction
- General anaesthesia, regional anaesthesia or combination can be used

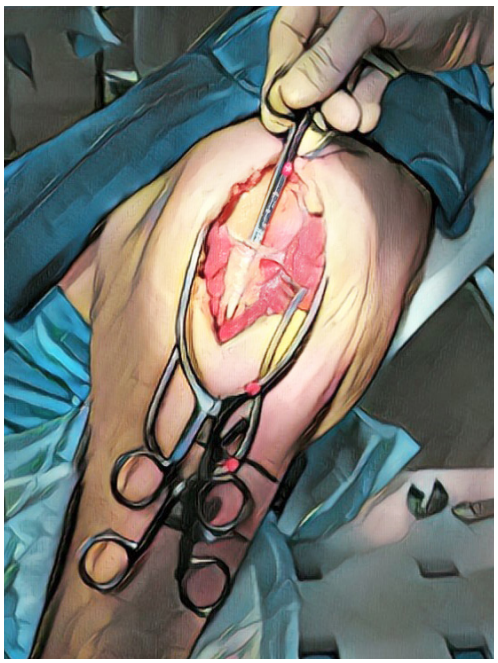
Exposure

I.) Anterolateral access:

- Skin incision parallel to the anterior acromion and extension 5cm distally in fiber direction of the M. deltoideus.
- Detachment of the pars acromialis of the M. deltoideus.

ATTENTION: The axillary nerve exits the lateral armpit dorsally and moves around the surgical neck (collum chirurgicum) of the humerus.



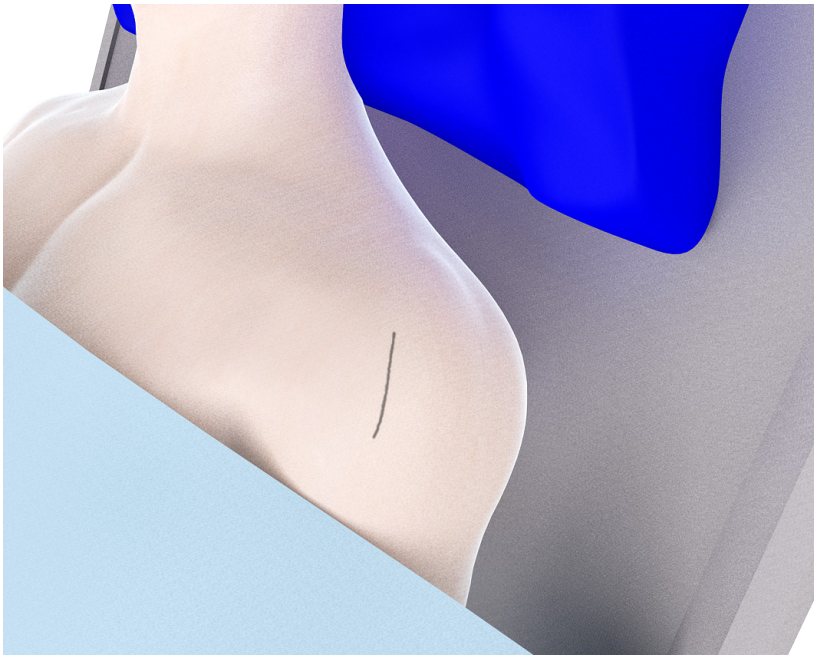


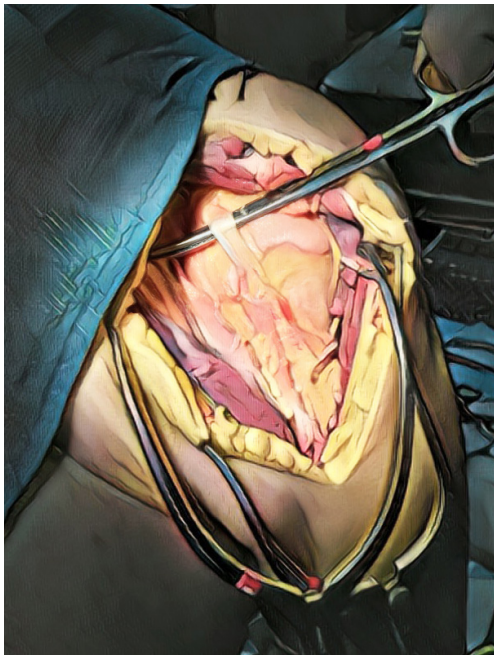
The illustration shows identification of the axillary nerve, a useful landmark.

2.) Deltoid-pectoral approach:

- Skin incision parallel to the delto- pectoral groove.
- Identify the cephalic vein and develop the delto- pectoral interval.
- The first of the conjoint tendon can be released to improve exposure.

ATTENTION: The axillary nerve exits the lateral armpit dorsally and moves around the surgical neck (collum chirurgicum) of the humerus.





The illustration shows identification of the biceps tendon, a useful landmark.

Plate selecton and insertion

Plate selection:

- Select the appropriate plate size 1.) small or large, 2.) 5- or 7-hole, 3.) flange pattern.
- The flanges are contourable with the plate in situ, so that some adjustment is possible after the application.
- Use the flange arrangement that best stabilizes the fracture pattern.
- The extended superior hooked plate is ideal for displaced or retracted tuberculum majus fragments and the anterior flange is indicated for tuberculum minus fragments for capture and fixation.
- All three flanges enable the plate to cradle and support the humeral head without relying soley a screw fixation.

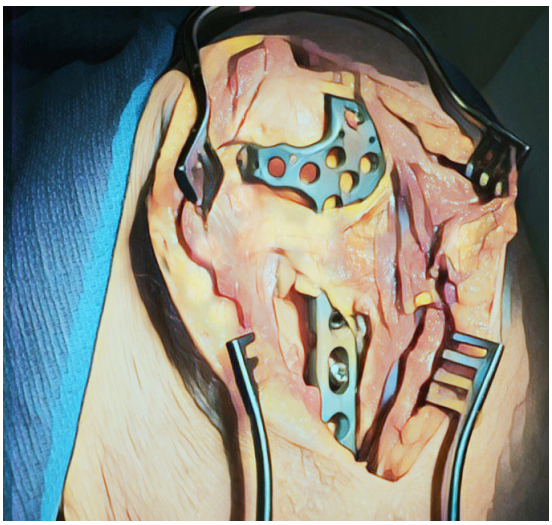
Note: The type of plate used will vary with the indications, i.e. for simple two part fractures a “standard” plate without the superior hook will be ideal, to maximize fixation and minimize the potential for impingement.

For more complex fractures with a greater tuberosity fragment the plate with the superior hook will be required.

Insertion:

- Insert the plate.
- Remain plate in constant contact with the bone and slide distally.
- Align the proximal end of the plate on the tuberculum majus.
- Verify the correct plate position. Optionally temporary fixation with guide wires, steel, D=1.6mm, L=260mm, TR, w. thread (35164-260) into proximal guide wire holes.

ATTENTION: Take care to avoid injuring the axillary nerve when inserting the plate.



Alternate open insertion:

- Apply the plate to reduced fracture.
- Keep the plate in central with the bone and center the humeral head inside the flanges of the plate: This prevents coronal translational malreduction of the head.
- Additionally, after the hook is engaged at the tuberosity - cuff junction, the plate can be manually translated distally to ensure reduction of the tuberosity, impacting the hook and minimizing the risk of impignement.

Fixation

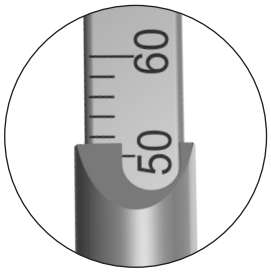
1. The greater tuberculum fragment is mobilized and running locked sutures of #2 nonabsorbable material are placed.

2. The sutures are used to pull the greater tuberculum fragment into place. Additionally, manual pressure can be applied!

3. The hook portion of the plate is applied to the junction of the tuberosity rotator cuff.

4. For optimal alignment of the plate to the humeral length, we recommend to first fill the oblong hole. With the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)**, drill through the drill guide, D=2.7/2.0mm **(62202)** into the oblong hole.
Determine appropriate length using the depth gauge, solid small fragment screws **(59022)**. Insert the D=3.5mm cortical screw **(32351-XX)** with the screwdriver, WS 2.5, self-holding sleeve **(56252-150)**.

5. A superior screw (non-locking), is injected to compress the greater tuberculum fragment and secure the superior portion of the plate to the bone. Use the spiral drill (suitable drills see page 6) and drill through the drill guide, D=2.7/2.0mm **(62202)** into superior plate hole. Determine appropriate length using the depth gauge, solid small fragment screws **(59022)**. Insert a D=3.5mm cortical screw **(32351-XX)** with the screwdriver, WS 2.5, self-holding sleeve **(56252-150)**.



6. The running locked stitches are then tied to the plate or even a bone bridge to augment fixation of the tuberosity fragment.

7. The remaining screws are inserted as per “plate application”.

Plate Application

Application A:

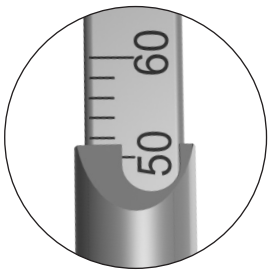
1.) Following provisional reduction, the superior hook screw is inserted in non-locking mode to compress and centre the plate on the humeral head.

Application B:

1.) The superior hook can be gently impacted into the greater tuberculum. If required, the superior hook screw can be removed and replaced with a locking screw.

2.) Following provisional reduction, the plate is applied to the shaft in compression mode with a locking or non-locking screw. The flanges can be adjusted to fit the bone with the in situ contouring tool **(66261, 66262, 66263)**.

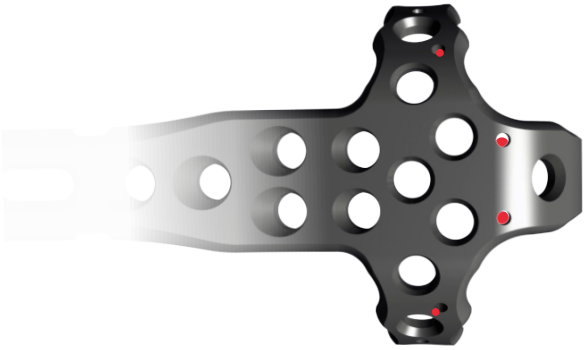
3.) Following plate application and checking of reduction, the important calcar screws are inserted in locking mode (2 screws). The remaining plate holes are then filled with either locking or non-locking screws. Subsequent control of plate position under fluoroscopy .



Radiographs reveal placement of the implant. For clarity, only the most critical screws are shown, including the tuberosity, calcar, and oblong hole screws.

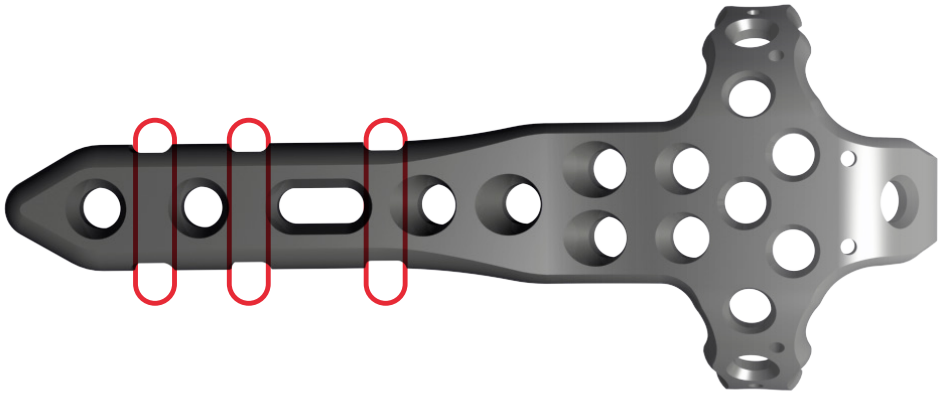
Optional fixation of soft tissue

Soft tissue can be sutured to the marginal holes in the proximal area of the plate with special suture material (see picture below - red marked).



Optional fixation in the shaft area with cerclage

Millings in the shaft area of the plate facilitate the optional use of cerclage wire (see picture below - red marked).



Postoperative treatment

As a rule, physical therapy immediately after surgery (passive motion exercices). Active motion exercices after 3-9 weeks. In case of poor bone quality or insecure fixation, immobilization for a maximum of 3 weeks.

Explantation

- Removal is possible, if desired by the patient. This is facilitated by the fact that cold welding never occurs. The problem of cold welding was resolved by using a special surface treatment (for further information see page 19)
- Implant removal is performed 18 months or after an fluoroscopy verification of the healed bone
- Vice versa of implantation
- Skin incision following the old scar
- Remove the screws with the screwdriver, WS 2.5 **(56252-150)**

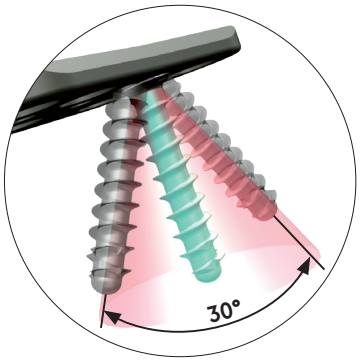
Information

3.

Locking

Locking works because:

- Screw material (TiAlV) is slightly harder than plate material (Titanium Grade 2)
- Screw head **forms** thread into the plate (no cutting)



Benefits:

- ± 15° and Locking
- No pre threading
- No cold welding
- No debris
- You can re-set the screw up to 3 times

Dotize®

Chemical process - anodization in a strong alkaline solution*

Type III anodization

- Layer thickness 60-200nm

  \+ Different colors

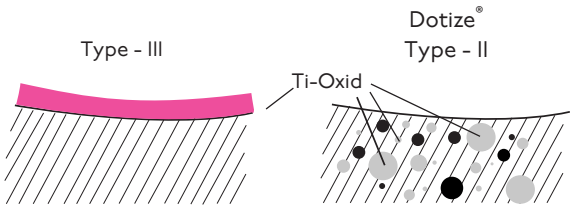
  \- Implant surface remains sensitive to:
  Chipping
  Peeling
  Discoloration

Dotize
Type II anodization

- Layer thickness 2000-10 000nm

  \+ Film becomes an interstitial part of the titanium

  \- No visible cosmetic effect



Anodization Type II leads to following benefits*

- Oxygen and silicon absorbing conversion layer
- Decrease in protein adsorption
- Closing of micro pores and micro cracks
- Reduced risk of inflammation and allergy
- Hardened titanium surface
- Reduced tendency of cold welding of titanium implants
- Increased fatigue resistance of implants
- Improved wear and friction characteristics

* White Paper: Ti6Al4V with Anodization Type II: Biological Behavior and Biomechanical Effects; Axel Baumann, Nils Zander

Order list

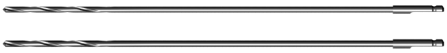
Proximal Humeral Plate, SAP Flange, Small, 5-hole	21134-5
Proximal Humeral Plate, SAP Flange, Large, 5-hole	21135-5
Proximal Humeral Plate, AP Flange, Small, 5-hole	21136-5
Proximal Humeral Plate, AP Flange, Small, 7-hole	21136-7
Proximal Humeral Plate, AP Flange, Large, 5-hole	21137-5
Proximal Humeral Plate, AP Flange, Large, 7-hole	21137-7
Proximal Humeral Plate, Flange, Right, 5-hole	21138-5
Proximal Humeral Plate, Flange, Left, 5-hole	21139-5

Cortical Screw, Locking, D=3.5mm, L=18mm, SH	37351-18-N
Cortical Screw, Locking, D=3.5mm, L=20mm, SH	37351-20-N
Cortical Screw, Locking, D=3.5mm, L=22mm, SH	37351-22-N
Cortical Screw, Locking, D=3.5mm, L=24mm, SH	37351-24-N
Cortical Screw, Locking, D=3.5mm, L=26mm, SH	37351-26-N
Cortical Screw, Locking, D=3.5mm, L=28mm, SH	37351-28-N
Cortical Screw, Locking, D=3.5mm, L=30mm, SH	37351-30-N
Cortical Screw, Locking, D=3.5mm, L=32mm, SH	37351-32-N
Cortical Screw, Locking, D=3.5mm, L=34mm, SH	37351-34-N
Cortical Screw, Locking, D=3.5mm, L=36mm, SH	37351-36-N
Cortical Screw, Locking, D=3.5mm, L=38mm, SH	37351-38-N
Cortical Screw, Locking, D=3.5mm, L=40mm, SH	37351-40-N

Cortical Screw, D=3.5mm, L=18mm	32351-18
Cortical Screw, D=3.5mm, L=20mm	32351-20
Cortical Screw, D=3.5mm, L=22mm	32351-22
Cortical Screw, D=3.5mm, L=24mm	32351-24
Cortical Screw, D=3.5mm, L=26mm	32351-26
Cortical Screw, D=3.5mm, L=28mm	32351-28
Cortical Screw, D=3.5mm, L=30mm	32351-30
Cortical Screw, D=3.5mm, L=32mm	32351-32
Cortical Screw, D=3.5mm, L=34mm	32351-34
Cortical Screw, D=3.5mm, L=36mm	32351-36
Cortical Screw, D=3.5mm, L=38mm	32351-38
Cortical Screw, D=3.5mm, L=40mm	32351-40
Cortical Screw, D=3.5mm, L=42mm	32351-42
Cortical Screw, D=3.5mm, L=44mm	32351-44
Cortical Screw, D=3.5mm, L=46mm	32351-46
Cortical Screw, D=3.5mm, L=48mm	32351-48
Cortical Screw, D=3.5mm, L=50mm	32351-50
Cortical Screw, D=3.5mm, L=55mm	32351-55
Cortical Screw, D=3.5mm, L=60mm	32351-60

Cancellous Screw, Locking, D=4.2mm, L=24mm, SH	37422-24-N
Cancellous Screw, Locking, D=4.2mm, L=26mm, SH	37422-26-N
Cancellous Screw, Locking, D=4.2mm, L=28mm, SH	37422-28-N
Cancellous Screw, Locking, D=4.2mm, L=30mm, SH	37422-30-N
Cancellous Screw, Locking, D=4.2mm, L=32mm, SH	37422-32-N
Cancellous Screw, Locking, D=4.2mm, L=34mm, SH	37422-34-N
Cancellous Screw, Locking, D=4.2mm, L=36mm, SH	37422-36-N
Cancellous Screw, Locking, D=4.2mm, L=38mm, SH	37422-38-N
Cancellous Screw, Locking, D=4.2mm, L=40mm, SH	37422-40-N
Cancellous Screw, Locking, D=4.2mm, L=42mm, SH	37422-42-N
Cancellous Screw, Locking, D=4.2mm, L=44mm, SH	37422-44-N

Cancellous Screw, Locking, D=4.2mm, L=46mm, SH	37422-46-N
Cancellous Screw, Locking, D=4.2mm, L=48mm, SH	37422-48-N
Cancellous Screw, Locking, D=4.2mm, L=50mm, SH	37422-50-N
Cancellous Screw, Locking, D=4.2mm, L=55mm, SH	37422-55-N
Cancellous Screw, Locking, D=4.2mm, L=60mm, SH	37422-60-N
Screwdriver, WS 2.5, conical head	56252-150
Depth Gauge, Solid Small Fragment Screws	59022
Drill Guide, D=2.0/2.7mm	62202
Spiral Drill, D=2.5mm, L=220mm, AO Connector	61253-220
Spiral Drill, D=2.7mm, L=220mm, AO Connector	61273-220
Guide Wire, Steel, D=1.6mm, L=260mm, TR, w. thread	35164-260
In-Situ Bending Iron, D=4.8mm, Straight	66261
In-Situ Bending Iron, D=4.8mm, Oblique	66262
In-Situ Bending Iron, D=4.8mm, 90°	66263
Sterilization Tray	50292



For detailed cleaning and sterilization instructions, please refer to package insert.

Notes

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