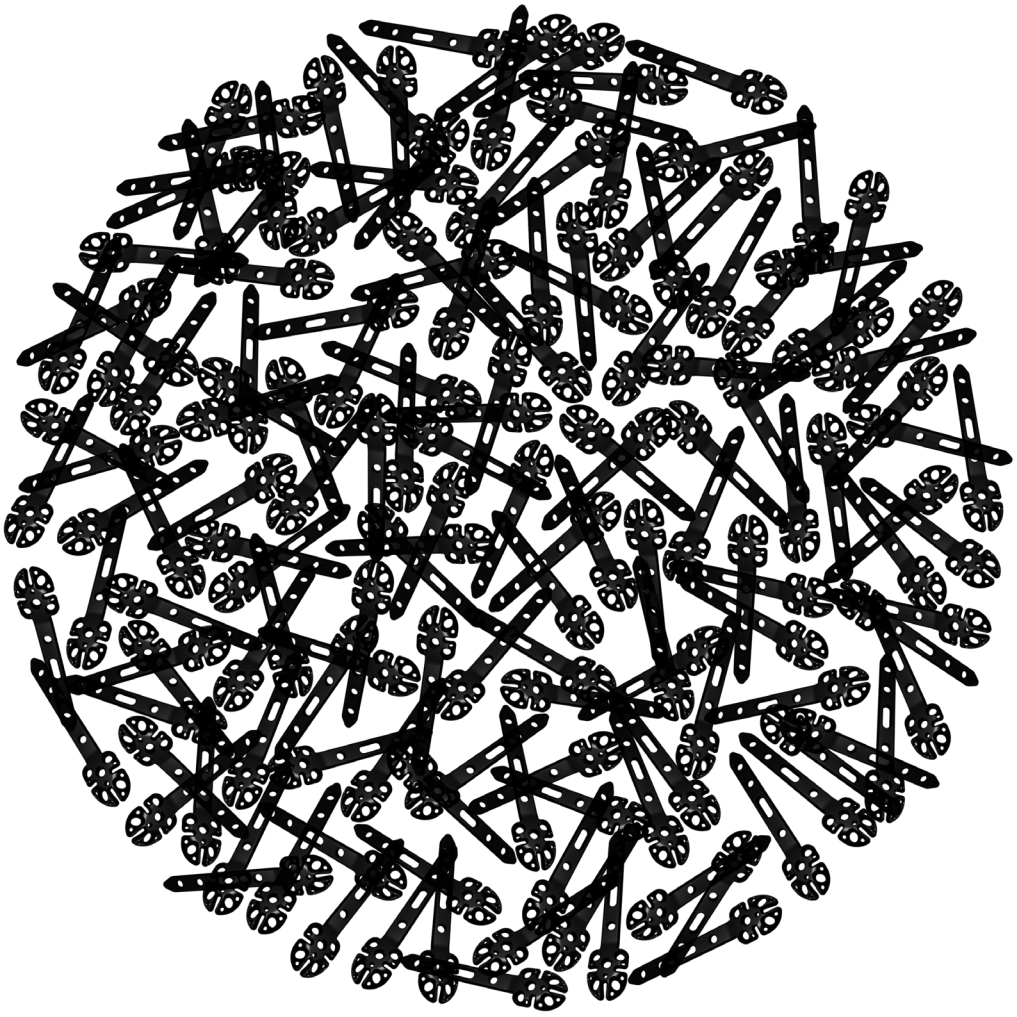
ITS.

Implants
trauma



PHLs

Proximal Humeral Locking Plate Small

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

WARNING: If there is no sufficient bone healing, wrong or incomplete postoperative care, plate might break.

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 Proximal Humeral Locking Plate Small enables the medical treatment of fractures in the joint area.

The special feature of this implant 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 13) has advantages in the fracture treatment.

Screws

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

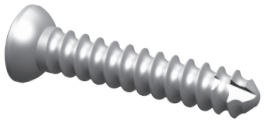
61273-100 Spiral Drill, D=2.7mm, L=100mm, AO Connector

56252 Screwdriver, WS 2.5, self-holding sleeve

32351-XX Cortical Screw, D=3.5mm

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

56252 Screwdriver, WS 2.5, self-holding sleeve



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

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

56252 Screwdriver, WS 2.5, self-holding sleeve

35204-228 Guide Wire, Steel, D=2.0mm, L=228mm, TR

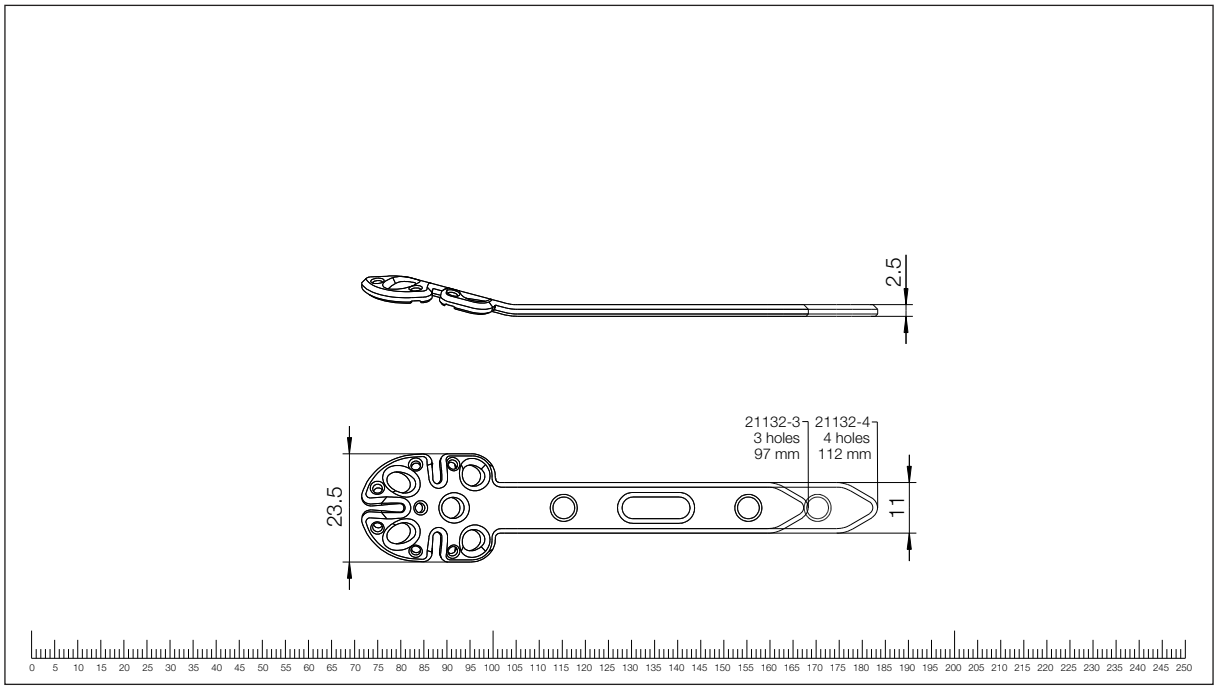
Properties

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
- Optimal reconstruction of the joint
- Easy adjustment due to oblong hole
- Plate lengths: 3, 4-hole



Indications & Contraindications

Indications:

- Disclocated, unstable 2, 3 and 4-segment fractures
- Valgus-impacted 4-segment fractures
- Pseudoarthroses of the head of the humerus

Contraindications:

- Diaphyseal fractures of the humeral head
- Existing infections in the fracture zone and operation area
- Common situations that do not allow osteosynthesis
- Obesity
- Lack of patient compliance

Proximal Humeral Locking Plate Small

Fractures of the humeral head amount to 5% of all fractures and at least 45% of all humerus fractures. Whereas severe injuries with considerable trauma predominate in younger patients, the humeral head can often fracture on slight trauma with increasing age due to reduced bone quality in the case of osteoporosis.

Frequent complications in the case of multiple-fragment fractures of the humeral head after osteosynthesis include redislocation of the fracture and necrosis of the humeral head.The incidence of necrosis of the humeral head amounts to 3-14% in the case of 3-segment fractures and 26-75% in the case of dislocated 4-fragment fractures. Full or partial necrosis of the humeral head usually means a deterioration of the prognosis.

However, it is not rare to achieve an acceptable functional result.

If necrosis of the head should occur in the case of malpositioning, this leads to a significant deterioration of prognosis. Therefore the therapeutic aim is to achieve a correct position of the tubercule by means of the most stable osteosynthesis.

The trend indicates that operative techniques conserving the humeral head using implants with the highest possible angular stability make sense.

Biomechanically angle-stable osteosynthesis are especially advantageous in the case of osteoporotic bones.

Surgical Technique

2.

Pre-operative patient preparation

- Beachchair position
- Adjustable accesory table to support arm position
- Fluoroscopy from the head end

Surgical Technique

- Deltopectoral access
- Raising the calotte fragment with reduction onto the shaft fragment (fig.1)
- Temporary fixation of the reduction using drill wires (fig.2)
- Position the humeral plate 5mm distal to the proximal end of the tuberculum majus and 10mm dorsal to the posterior edge of the intertubercular groove and fixation of the humeral head plate by means of a cortical screw in the sliding hole
- Fixation of the humeral head plate by means of a second cortical screw in the shaft
- Screw down the humeral head using locking screws
- Optional refixation of the tuberculum majus fragment using a frame suture
- Optional screw fixation of the tuberosity minus fragment
- Step by step closure of the wound

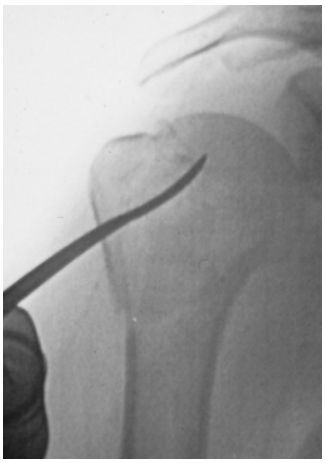


Fig.1

Fig.2

Postoperative treatment

- Functionally as early as possible
- If bone quality is bad, shoulder bandage for a maximum of 4 weeks
- Passively and actively guided movement exercises

Explantation

If desired by the patient, the implant can be removed.
Removal should be performed at the earliest 1 1/2 years later or after radiographic verification of the healed bone.

The problem of cold welding was resolved by using a special surface treatment (for further information see page 13).

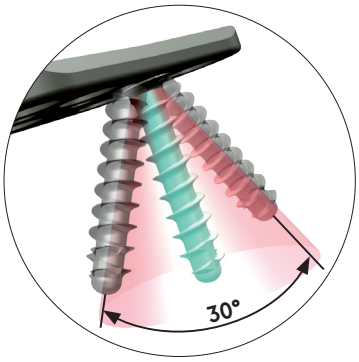
Information

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®

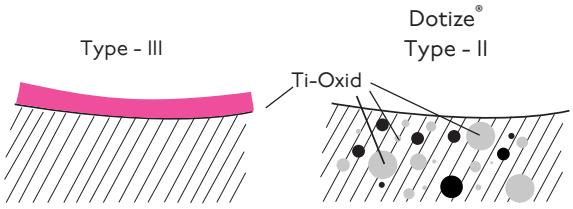
Chemical process - anodization in a strong alkaline solution*

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

Humeral Head Plate, Small, 3-hole	21132-3
Humeral Head Plate, Small, 4-hole	21132-4

Cancellous Screw, locking, D=4.2mm, L=14mm, SH	37422-14-N
Cancellous Screw, locking, D=4.2mm, L=16mm, SH	37422-16-N
Cancellous Screw, locking, D=4.2mm, L=18mm, SH	37422-18-N
Cancellous Screw, locking, D=4.2mm, L=20mm, SH	37422-20-N
Cancellous Screw, locking, D=4.2mm, L=22mm, SH	37422-22-N
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

Cortical Screw, locking, D=3.5mm, L=12mm, SH	37351-12-N
Cortical Screw, locking, D=3.5mm, L=14mm, SH	37351-14-N
Cortical Screw, locking, D=3.5mm, L=16mm, SH	37351-16-N
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=28mm, SH	37351-28-N
Cortical Screw, locking, D=3.5mm, L=32mm, SH	37351-32-N
Cortical Screw, locking, D=3.5mm, L=36mm, SH	37351-36-N
Cortical Screw, locking, D=3.5mm, L=40mm, SH	37351-40-N

Cortical Screw, D=3.5mm, L=12mm	32351-12
Cortical Screw, D=3.5mm, L=14mm	32351-14
Cortical Screw, D=3.5mm, L=16mm	32351-16
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
Screwdriver, WS 2.5, self-holding sleeve	56252
Depth Gauge, Solid Small Fragment Screws	59022
Drill Guide, D=2.0/2.7mm	62202
Spiral Drill, D=2.5mm, L=180mm, AO Connector	61253-180
Spiral Drill, D=2.7mm, L=100mm, AO Connector	61273-100
Guide Wire, Steel, D=2.0mm, L=228mm, TR	35204-228
Sterilization Tray, Humeral Head Plate	50186

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

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