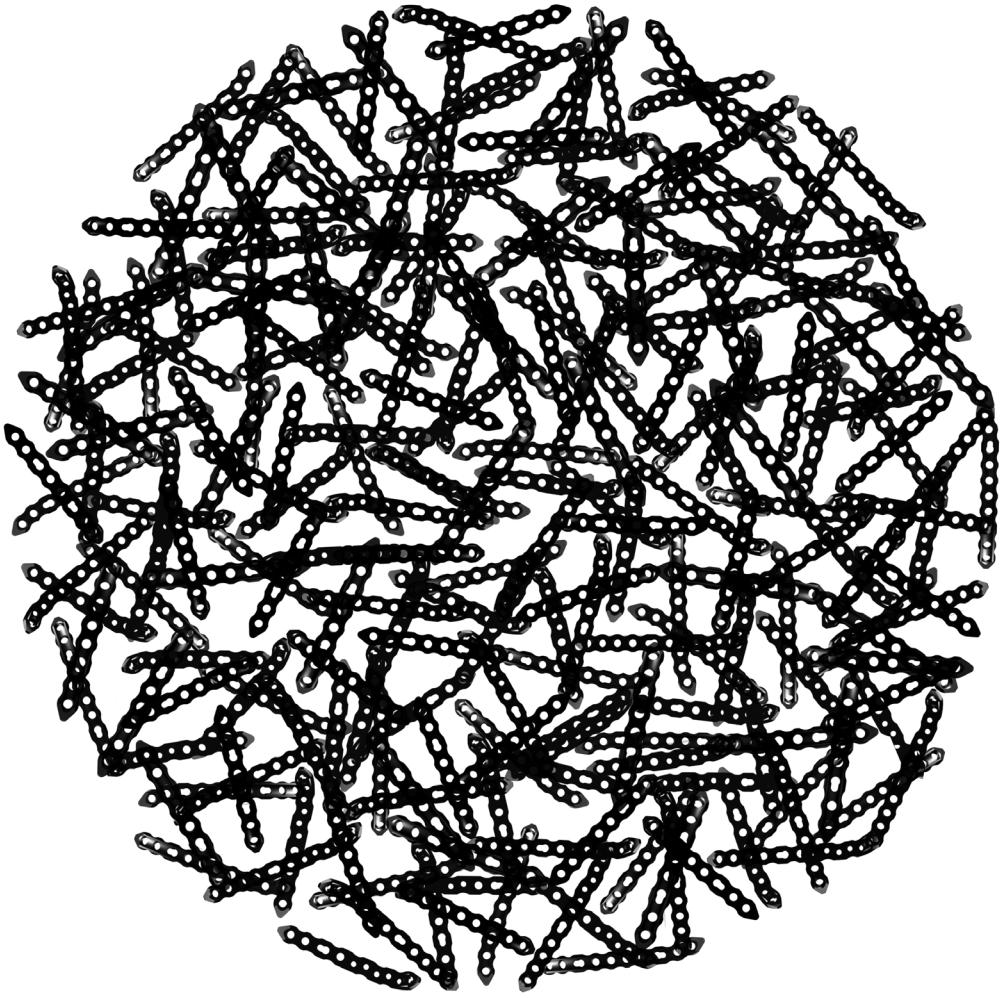
ITS.

Implants
trauma



ACLS

Anterior Clavicle Locking Plates System

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.

Contents

1. Introduction

2. Surgical Technique

3. Information

Introduction

1.

Preface

The Locking Anterior Clavicle Plate System is a proven osteosynthesis system for various clavicle fractures.

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, either locking or non-locking screw (except compression hole).

In particular the anatomical plate design as well as the pre-angled plate holes of the lateral plate version provide an optimal fixation in the very lateral area of the clavicle.

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

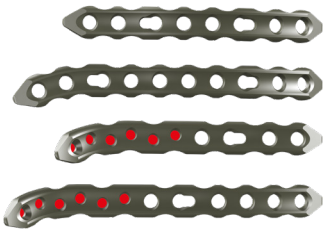
61273-100 Spiral Drill D=2.7mm, L=100mm, AO Connector

56252 Screwdriver, WS 2.5, self-holding sleeve

32271-XX Cortical Screw, D=2.7mm

61203-100 Spiral Drill D=2.0mm, L=100mm, AO Connector

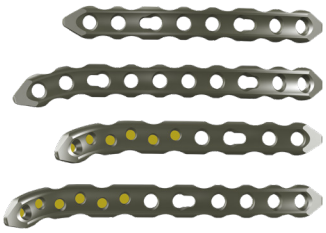
56095-70 Screwdriver, Torque, T9x70



37303-XX Cancellous Stabilization Screw, D=3.0mm, RH

61203-100 Spiral Drill D=2.0mm, L=100mm, AO Connector

56095-70 Screwdriver, Torque, T9x70



M= medial versions;
L= lateral versions

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 pre-contoured plate design
- Anterior plate position minimizes the risk of injuries of the subclavian artery and lung perforation
- Medial and lateral version
- 3.5mm cortical screws in the shaft (optionally locking)
- 2.7mm cortical screws and 3.0mm locking cancellous screws in the lateral area

Tapered plate ends and edges minimizes soft tissue irritations

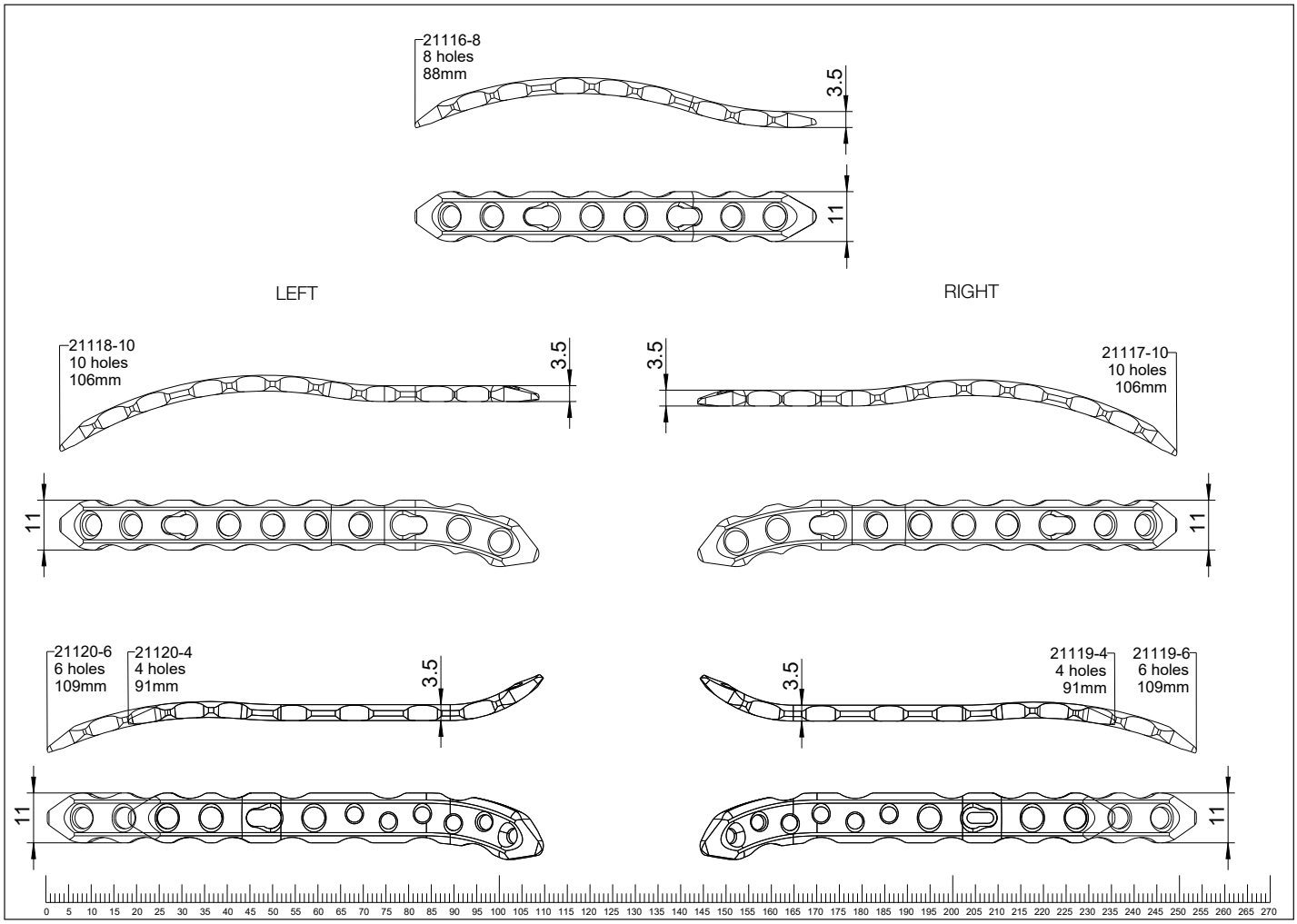
Sliding hole with compression option up to 7mm

10-hole and lateral plate version are adapted to the anatomy of the lateral clavicle in the horizontal and vertical plane.

Recon Design facilitates individual contouring

Staggered & pre-angled plate holes for optimal fixation in the flat lateral area

Pre-operative planning



Indications

Indications:

- All fractures of the clavicle in metaphyseal and diaphyseal areas.
- Hygienisation of pseudo-arthroses with or without spongiosal graft.
- Corrective osteotomy.
- Open and closed fractures

Contraindications, Time of operation

Contraindications:

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

Time of operation:

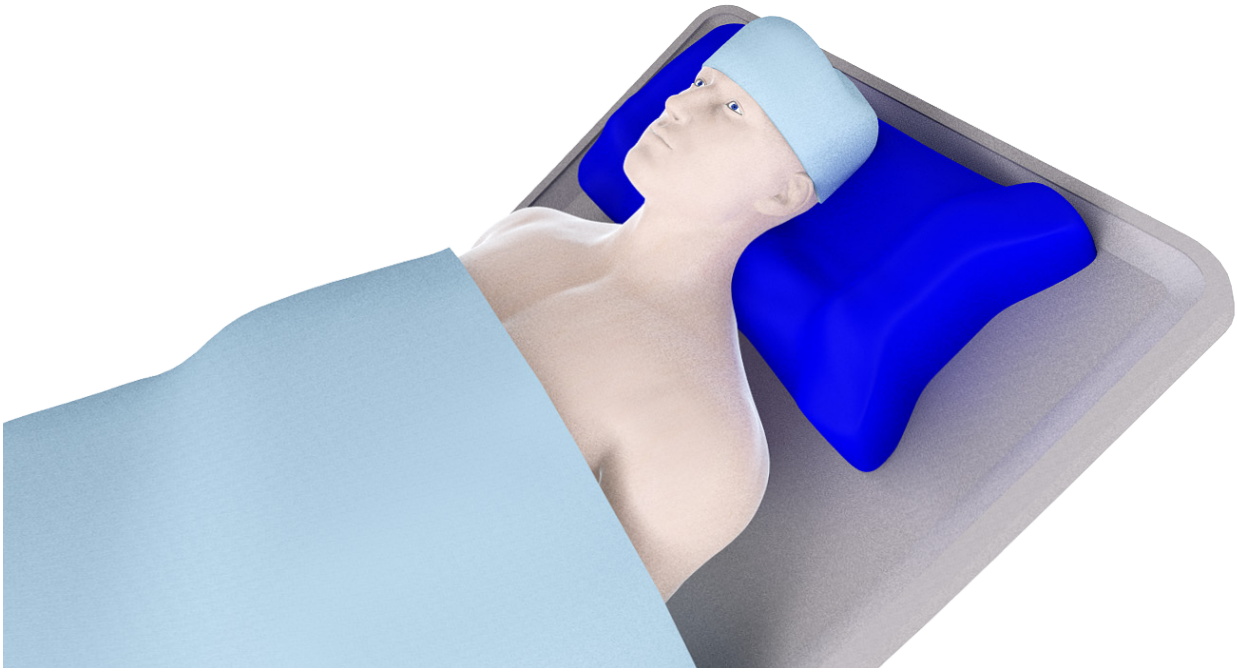
- Immediately after trauma or delayed
- After regression of swelling

Surgical Technique

2.

Pre-operative patient preparation

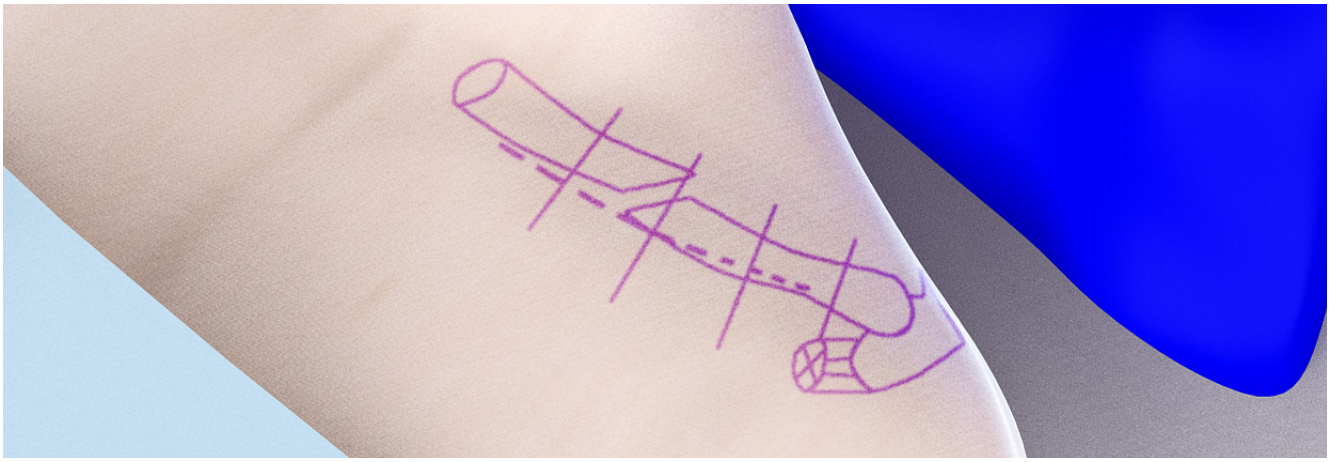
- Semi-sitting angle of about 30° - 40°, shoulder freely moveable (optional shoulder table)
- The arm should be freely moveable to allow fracture reduction
- General anaesthesia, regional anaesthesia or combination can be used

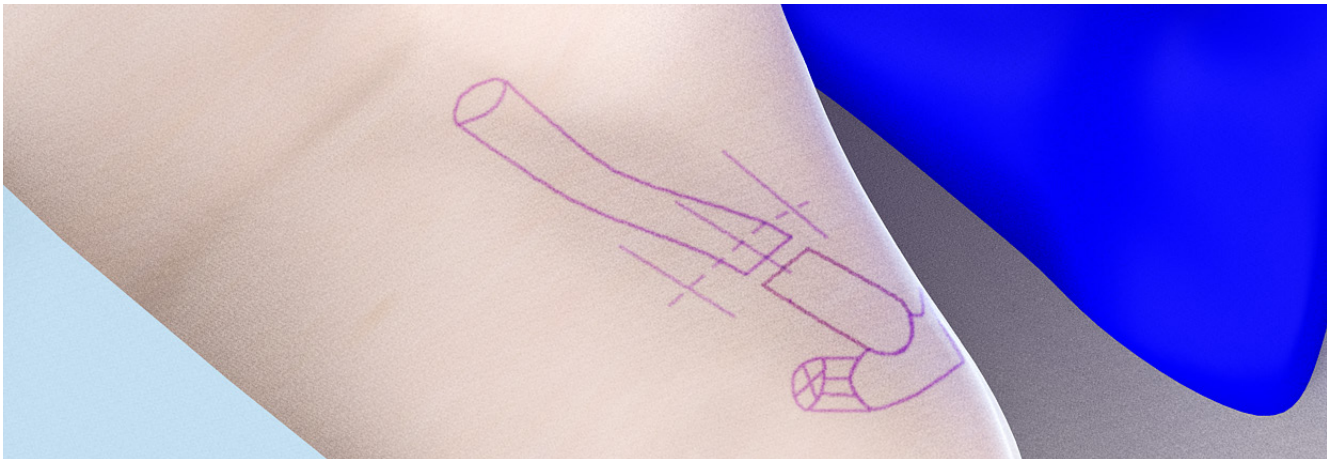


Access

Outline the fracture and draw incision line on the skin. A horizontal dashed line marks the place for the skin incision. Vertical marks show the position for a tension free suture.

The incision should be made 1-2cm away from the fracture line to avoid placement of the suture directly over the plate.





Exposure

Transverse approach (medial to lateral)

- Transverse incision parallel to the long axis of the clavicle.

Anterosuperior approach (sabre-cut incision)

- Make a half-moon shaped incision over the middle of the clavicle with short dorsal branch

Reduction

- Temporary fixation of the fracture parts using forceps
- Seek compression of the fracture
- Control under fluoroscopy

Plate insertion

Insert the plate from lateral to medial under a bone holding forceps and additionally fix in place with two clamps.

Optionally, the plate can be stabilized using the ITS. Temporary Plate Holder **(58164-150)**.

Confirmation of correct plate position under fluoroscopy.

Placement of the ⌀ 2.7/3.0mm screws

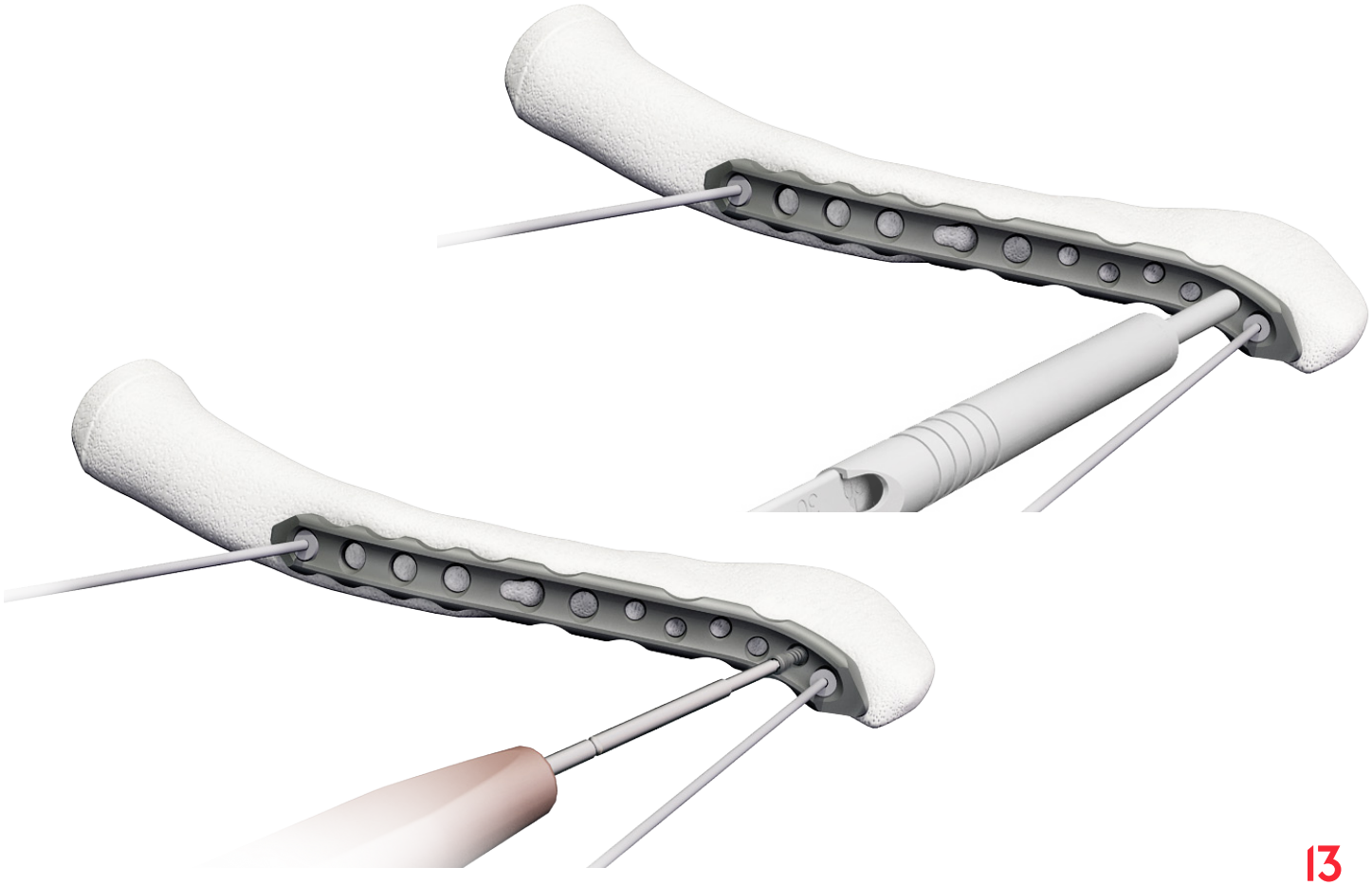
Lateral Anterior Clavicle Plate (21119-X; 21120-X)

The cross section of the clavicle changes from a tube in the medial area to a flat ellipse in the lateral area. To gain proper fixation in the lateral area, the hole dimension of the outer plate holes were adjusted. These holes can be filled with either D=2.7mm cortical screws or D=3.0mm cancellous stabilization screws.

Use the drill guide, D=2.0/2.7mm **(62202)** to bore holes with the spiral drill D=2.0mm, L=100mm, AO Connector **(61203-100)** into the lateral plate holes.

Attention: It is recommend to drill oscillating, to avoid injuries of the artery subclavia and/or the brachial plexus. Do not use locking screws close to the fracture.

Use the screwdriver, T9x70 **(56095-70**) to insert either D=2.7mm cortical screws **(32271-XX)** or D=3.0mm cancellous stabilization screws **(37303-XX)** of appropriate lengths determined previously with the depth gauge, solid small fragment screws **(59022)**.



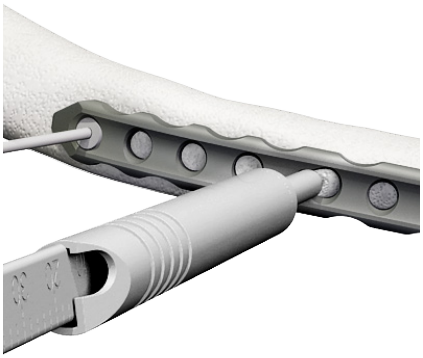
Placement of the Ø 3.5mm screws

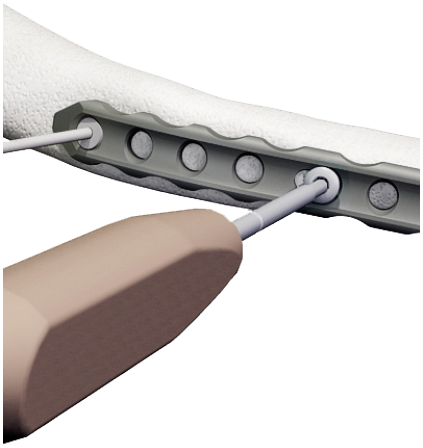
If compression should be achieved, a D=3.5mm cortical screw has to be inserted in the narrow area of the compression hole.

Note: A compression up to 3.5mm can be achieved per each compression hole.

Use the drill guide, D=2.0/2.7mm **(62202)** to bore holes with the spiral drill D=2.7mm, L=100mm, AO Connector **(61273-100)** into the narrow area of the compression hole.

Attention: It is recommend to drill oscillating, to avoid injuries of the artery subclavia and/or the brachial plexus. Do not use locking screws close to the fracture.





Use the screwdriver, WS 2.5, self-holding sleeve **(56252)** to insert D=3.5mm cortical screws **(32351-XX)** of appropriate lengths determined previously with the depth gauge, solid small fragment screws **(59022)**.

Advice: Angled drill holes avoid cortical bone giving way in the case of any fissures (fracture ridges).

The remaining plate holes are then filled, with either locking or non-locking D=3.5mm screws **(37351-XX-N / 32351-XX)** respectively D=2.7mm cortical screws **(32271-XX)** or D=3.0mm cancellous stabilization screws **(37303-XX)** at the lateral plate versions - suitable drills see page 6.

Attention: It is recommend to drill oscillating, to avoid injuries of the artery subclavia and/or the brachial plexus. Do not use locking screws close to the fracture.

Subsequent control of plate position under fluoroscopy.

Medial Anterior Clavicle Plate

Lateral Anterior Clavicle Plate

Postoperative treatment

- Shoulder-arm dressing until wound healing (approx. 2 weeks)
- Physical therapy
- Full exertion after fracture healing (approx. 5-7 weeks)

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 17).

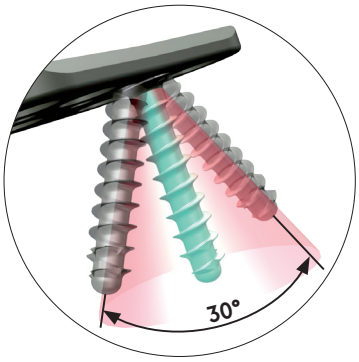
Information

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®

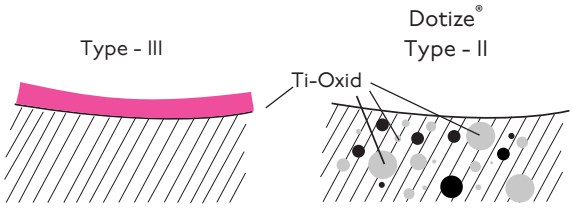
Chemical process - anodization in a strong alkaline solution*

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

Anterior Clavicle Plate, Medial, 8-Hole	21116-8
Anterior Clavicle Plate, Medial, 10-Hole, Right	21117-10
Anterior Clavicle Plate, Medial, 10-Hole, Left	21118-10

Anterior Clavicle Plate, Lateral, 4-Hole, Right	21119-4
Anterior Clavicle Plate, Lateral, 4-Hole, Left	21120-4
Anterior Clavicle Plate, Lateral, 6-Hole, Right	21119-6
Anterior Clavicle Plate, Lateral, 6-Hole, Left	21120-6

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, 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

Cancellous Stabilization Screw, D=3.0mm, L=10mm, RH	37303-10
Cancellous Stabilization Screw, D=3.0mm, L=12mm, RH	37303-12
Cancellous Stabilization Screw, D=3.0mm, L=14mm, RH	37303-14
Cancellous Stabilization Screw, D=3.0mm, L=16mm, RH	37303-16
Cancellous Stabilization Screw, D=3.0mm, L=18mm, RH	37303-18
Cancellous Stabilization Screw, D=3.0mm, L=20mm, RH	37303-20
Cancellous Stabilization Screw, D=3.0mm, L=22mm, RH	37303-22
Cancellous Stabilization Screw, D=3.0mm, L=24mm, RH	37303-24
Cancellous Stabilization Screw, D=3.0mm, L=26mm, RH	37303-26
Cancellous Stabilization Screw, D=3.0mm, L=28mm, RH	37303-28
Cancellous Stabilization Screw, D=3.0mm, L=30mm, RH	37303-30

Cortical Screw, D=2.7mm, L=10mm	32271-10
Cortical Screw, D=2.7mm, L=12mm	32271-12
Cortical Screw, D=2.7mm, L=14mm	32271-14
Cortical Screw, D=2.7mm, L=16mm	32271-16
Cortical Screw, D=2.7mm, L=18mm	32271-18
Cortical Screw, D=2.7mm, L=20mm	32271-20
Cortical Screw, D=2.7mm, L=22mm	32271-22
Cortical Screw, D=2.7mm, L=24mm	32271-24
Cortical Screw, D=2.7mm, L=26mm	32271-26

Screwdriver, WS 2.5, self-holding sleeve	56252

Screwdriver, Torque, T9x70	56095-70	
Depth Gauge, Solid Small Fragment Screws	59022	
Drill Guide, D=2.0/2.7mm	62202	
Spiral Drill D=2.7mm, L=100mm, AO Connector	61273-100	
Spiral Drill D=2.0mm, L=100mm, AO Connector	61203-100	
Temporary Plate Holder	58164-150	
Sterilization Tray, Anterior Clavicle Plate System	50279	

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

* All implants are available sterile-packed optionally.
Add „-S" to article number for sterile-packed implants (ex. 37304-12-S; 21031-3-S)
Delivery times, prices & minimum quantity vary from standard.

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