ITS.

Implants
trauma

CLS

Clavicle Locking Plates System

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 Locking 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).

The free choice of screw angulation (+/- 15°, see page 21) provides an advantage in fracture treatment, especially in the case of complex fractures.

Screws

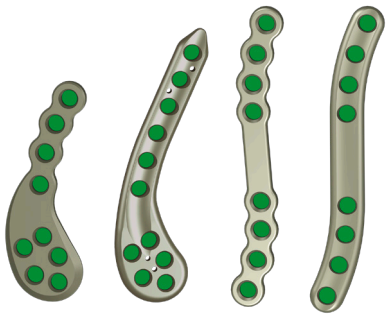
Special advantages:

- All three screw types can be used in each plate hole
- Four different plate variants allow surgical treatment for numerous types of clavicle fractures
- For taking over forces - direct contact between plate and bone is not necessary (principle of Fixateur Interne)

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

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

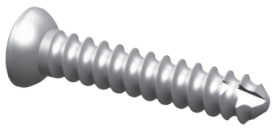
56252 Screwdriver, WS 2.5, self-holding sleeve

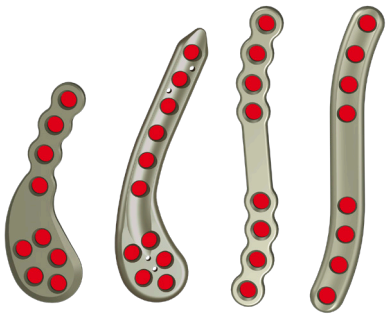


32351-XX Cortical Screw, D=3.5mm

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

56252 Screwdriver, WS 2.5, self-holding sleeve

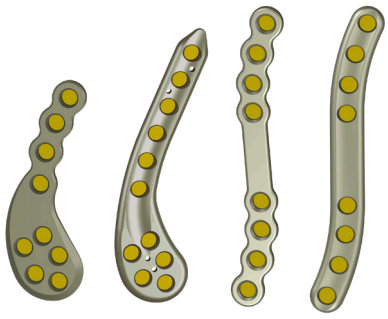




37352-XX-N Cancellous Screw, locking, D=3.5mm, SH

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

56252 Screwdriver, WS 2.5, self-holding sleeve



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:

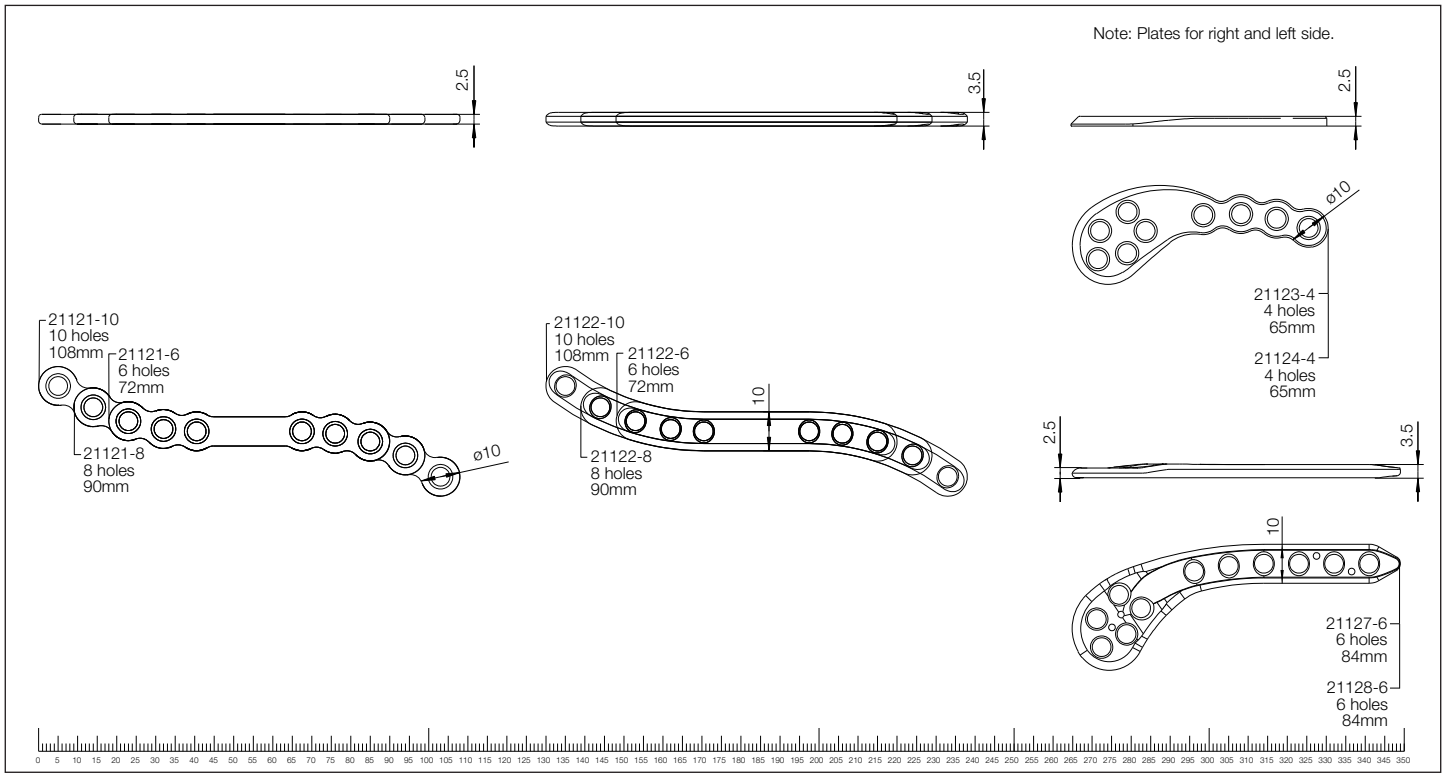
- Multi-directional Locking
- Anatomical plate design

Medial Clavicle Plate:

- Turn 180° for right and left version
- Plate lengths: 6, 8, 10-hole
- Plate strenghts: 2.5mm and 3.5mm

Lateral Clavicle Plate:

- Left/right version
- Plate length: 4-hole,
  Plate strength: 2.5mm
- Plate length: 6-hole,
  Plate strength: 3.5mm



Indications, Contraindications & Time of operation

Indications:

- All fractures of the clavicle in metaphyseal and diaphyseal areas
- Fixation of non-unions with or without cancellous graft
- Corrective osteotomy
- Open and closed fractures

Contraindications:

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

Time of operation:

- Immediately after trauma or delayed
- After regression of swelling

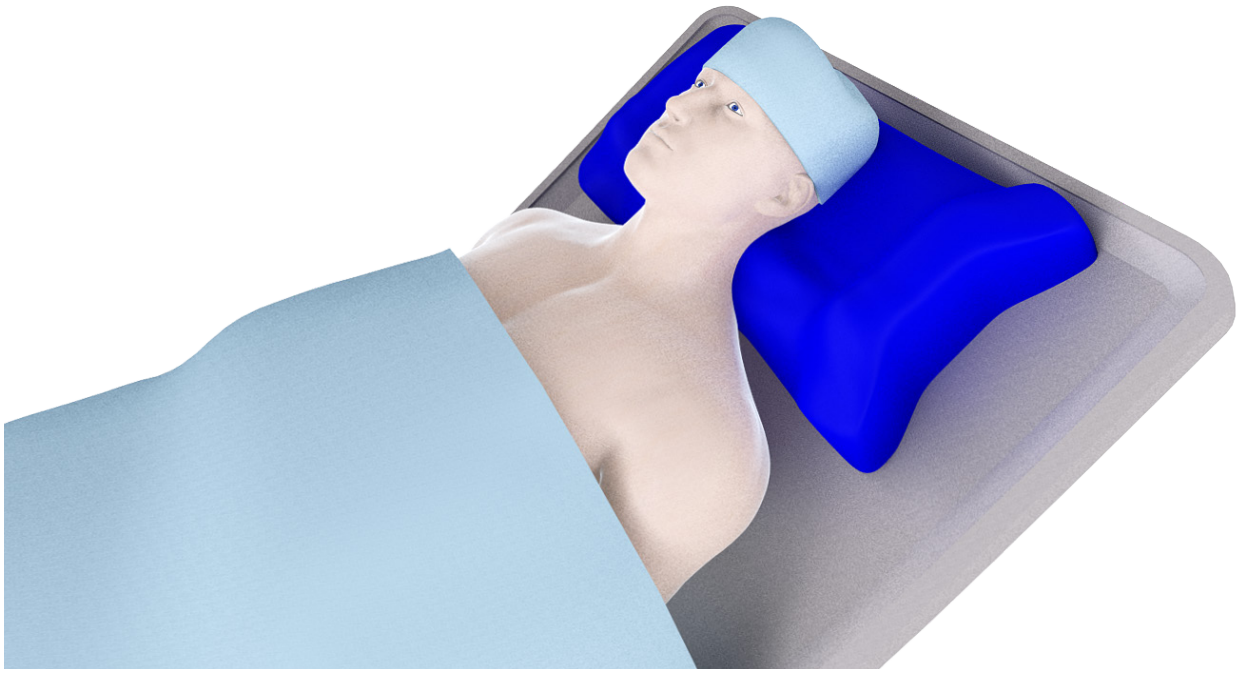
Intended purpose
The plates, screw implants (non-locking and locking screws) and the instrumentation required for the Clavicle Plate System are used for temporary stabilisation of bone segments of the clavicle until bony consolidation is achieved.

Surgical Technique

2.

Pre-operative patient preparation

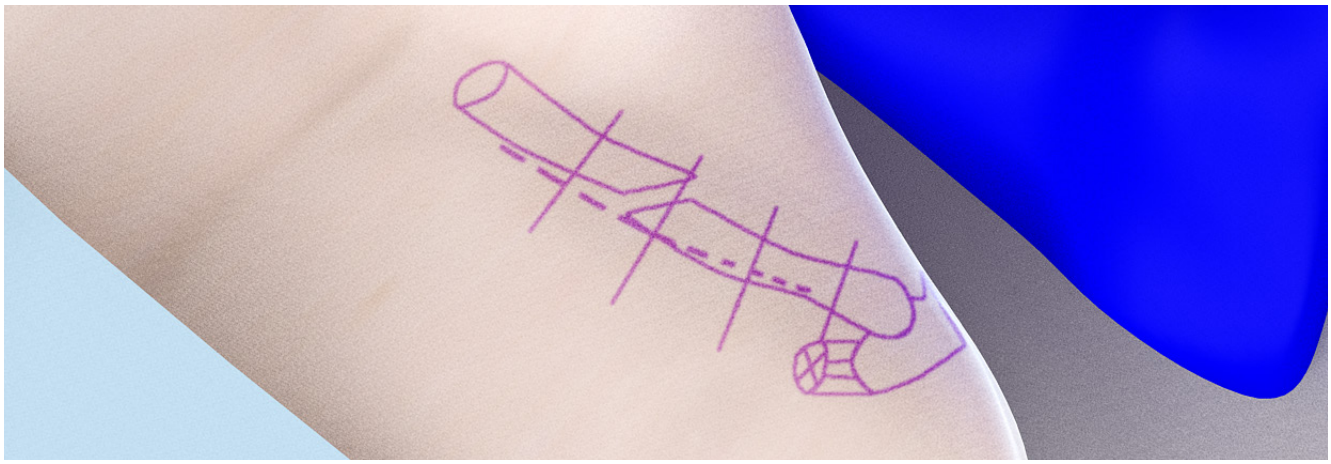
- Semi-sitting angle of about 30° - 40°, shoulder freely moveable (optional shoulder table)
- The arm should be freely moveable to allow fracture reduction
- General anaesthesia, regional anaesthesia or combination can be used

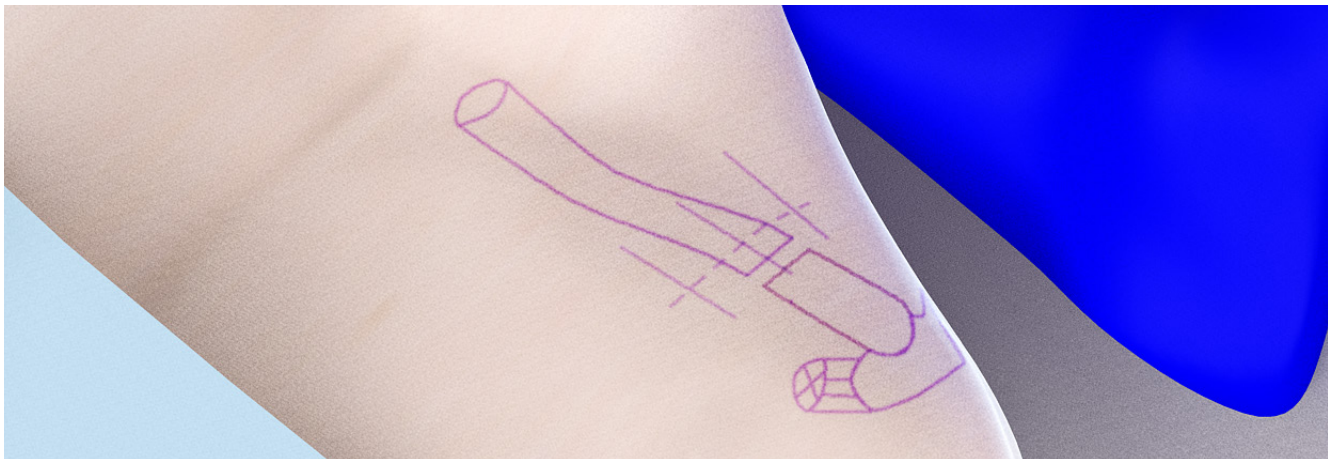


Access

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

Supraclavicular approach:

- Make a skin incision parallel to the clavicle in the supraclavicular fossa above the portion of the clavicle which is to be exposed

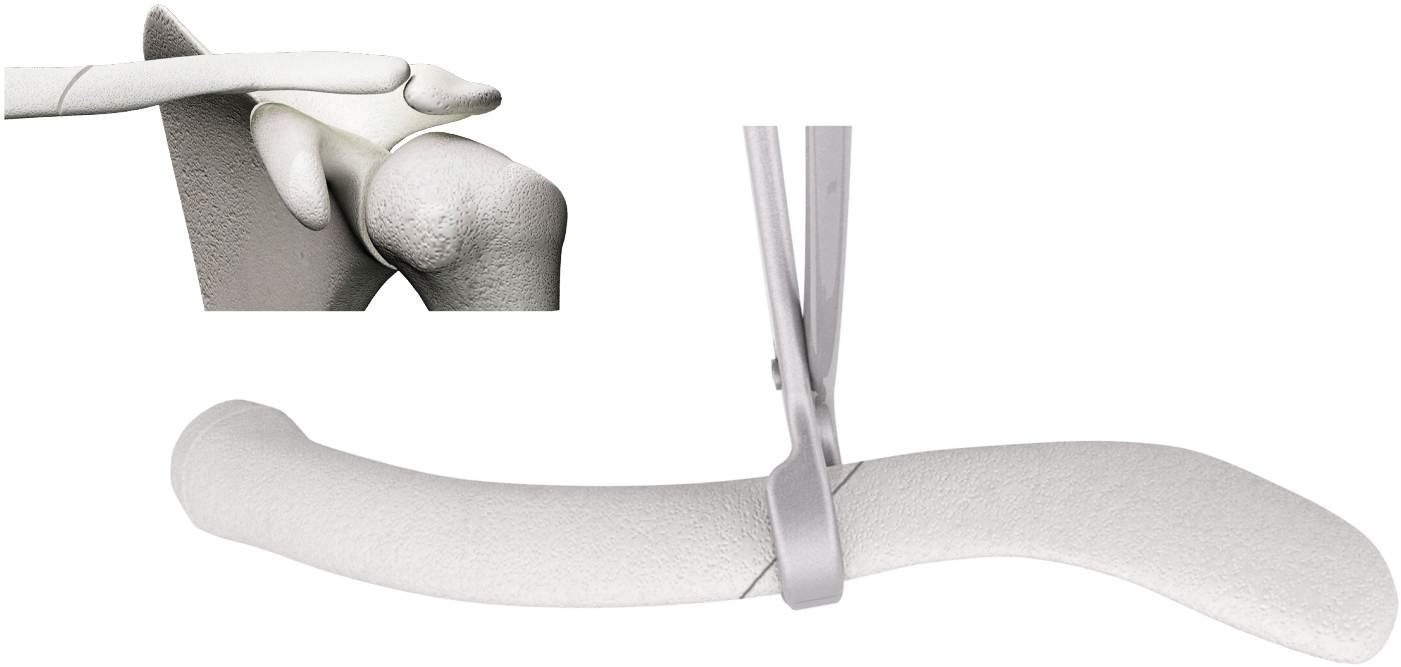
Anterosuperior approach (sabre-cut incision)

- 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

Medial Clavicle Plate



Lateral Clavicle Plate

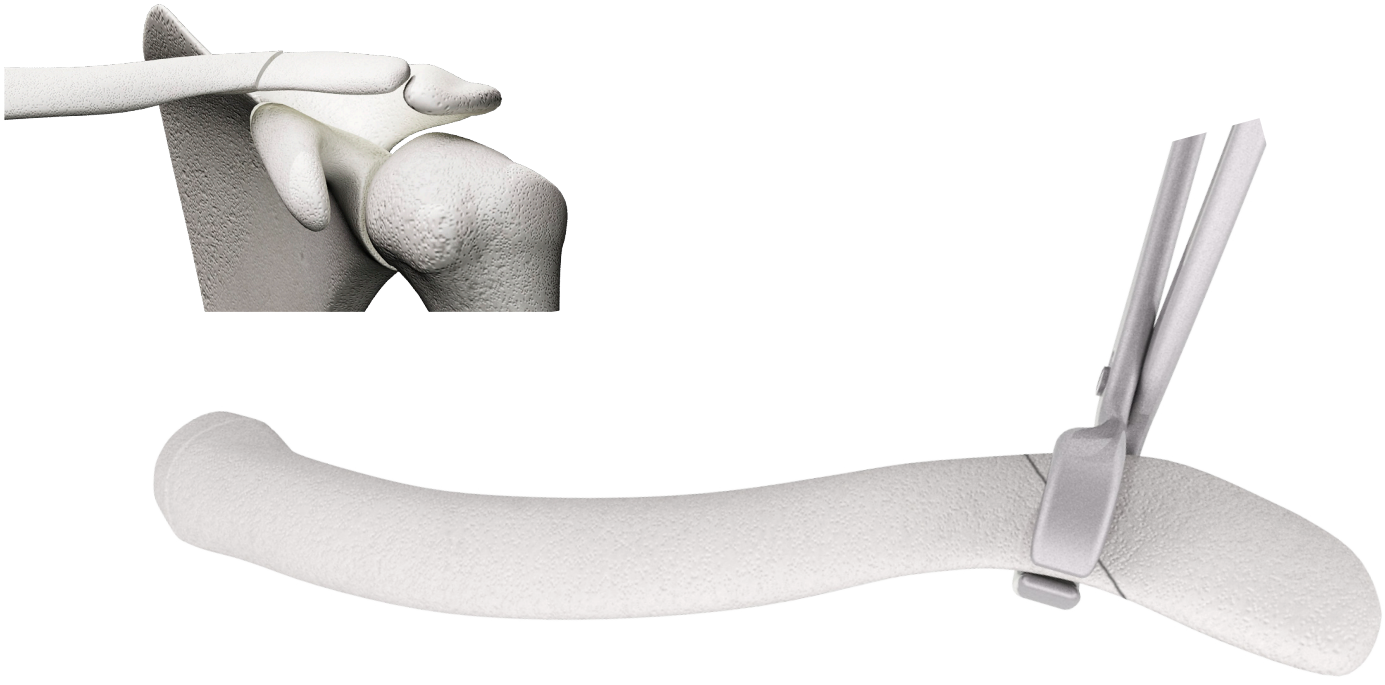


Plate insertion

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

Confirmation of correct plate position under fluoroscopy (optional).

Placement of the screws

Use the drill guide, D=2.7/2.0mm **(62202)** to bore holes with the spiral drill D=2.7mm, L=100mm, AO Connector **(61273-100)** into the two plate holes closest to the fracture.

Attention: To avoid disruption of soft tissue, nerves and/or blood vessels place a Hohmann retractor under the clavicle during drilling (or drill oscillating). It is recommended that locking screws are not used 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).

Then drill holes into the adjacent plate holes using the drill guide, D=2.7/2.0mm **(62202)** to bore holes with the spiral drill D=2.7mm, L=100mm, AO Connector **(61273-100)**.

Attention: To avoid disruption of soft tissue, nerves and/or blood vessels place a Hohmann retractor under the clavicle during drilling (or drill oscillating). It is recommended that locking screws are not used 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)**.

Medial Clavicle Plate

Lateral Clavicle Plate

Subsequently, place either D=3.5mm locking cortical or cancellous screws **(37351-XX-N/37352-XX-N)** in plate holes far from fracture.
Use the drill guide, D=2.7/2.0mm **(62202)** to bore holes with the spiral drill D=2.0mm or D=2.7mm, L=100mm, AO Connector **(61203-100/61273-100)** into plate holes far from fracture.

Attention: To avoid disruption of soft tissue, nerves and/or blood vessels place a Hohmann retractor under the clavicle during drilling (or drill oscillating). It is recommended that locking screws are not used close to the fracture.

Use the screwdriver, WS 2.5, self-holding sleeve **(56252)** to insert D=3.5mm locking cortical screws **(37351-XX-N)** or D=3.5mm locking cancellous screws **(37352-XX-N)** of appropriate lengths determined previously with the depth gauge, solid small fragment screws **(59022)**.

Finally, control plate position under fluoroscopy.

Medial Clavicle Plate

Lateral 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 21).

Summary

The Locking Clavicle Plate System is a proven osteosynthesis system for various clavicle fractures. Using this technology, an anatomic reduction is achieved and held in place until healing has occured.
Prompt rehabilitation and early functionality are brought about by the short immobilization time.

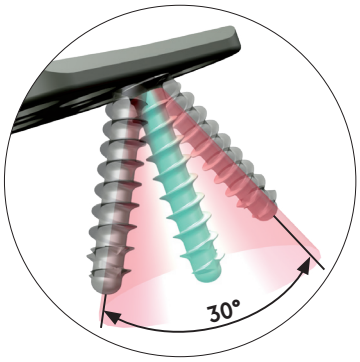
Information

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®

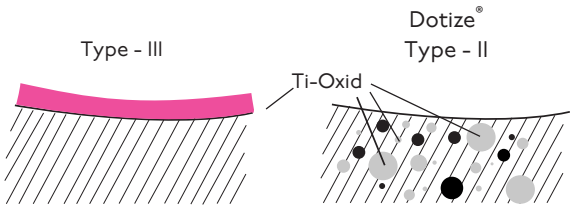
Chemical process - anodization in a strong alkaline solution*

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

Clavicle Plate, 6-hole	21121-6
Clavicle Plate, 8-hole	21121-8
Clavicle Plate, 10-hole	21121-10

Clavicle Plate, 3.5 mm, 6-hole	21122-6
Clavicle Plate, 3.5 mm, 8-hole	21122-8
Clavicle Plate, 3.5 mm, 10-hole	21122-10

Clavicle Plate, Lateral, 4-hole, Right	21123-4
Clavicle Plate, Lateral, 4-hole, Left	21124-4

Clavicle Plate, Lateral, 6-hole, Right	21127-6
Clavicle Plate, Lateral, 6-hole, Left	21128-6

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

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=2.7mm, L=100mm, AO Connector	61273-100
Spiral Drill, D=2.0mm, L=100mm, AO Connector	61203-100

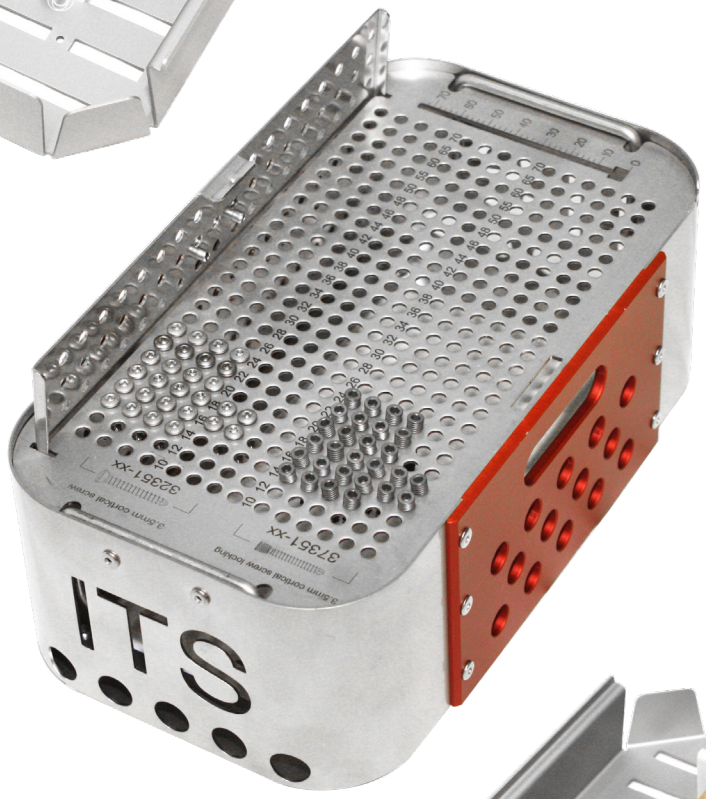
Sterilization Tray, Clavicle Plate System	50253

Optional (on request)

Temporary Plate Holder	58164-150

Cancellous Screw, Locking, D=3.5mm, L=14mm, SH	37352-14-N
Cancellous Screw, Locking, D=3.5mm, L=16mm, SH	37352-16-N
Cancellous Screw, Locking, D=3.5mm, L=18mm, SH	37352-18-N
Cancellous Screw, Locking, D=3.5mm, L=20mm, SH	37352-20-N
Cancellous Screw, Locking, D=3.5mm, L=22mm, SH	37352-22-N
Cancellous Screw, Locking, D=3.5mm, L=24mm, SH	37352-24-N

Trays



Notes

ITS. GmbH
Autal 28, 8301 Lassnitzhöhe, Austria
Tel.: +43 (0) 316 / 211 21 0
Fax: +43 (0) 316 / 211 21 20
office@its-implant.com
www.its-implant.com

CE 0297

Order No. CLS-OP-0723-EN
Edition: July/2023