

# ITS.

Implants  
trauma



## CLS

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.

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# Introduction



## ○ 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 using a locking or non-locking screw).

The free choice of screw angulation ( $\pm 15^\circ$ , see page 21) provides an advantage in fracture treatment, especially in the case of complex fractures.



## ○ Screws

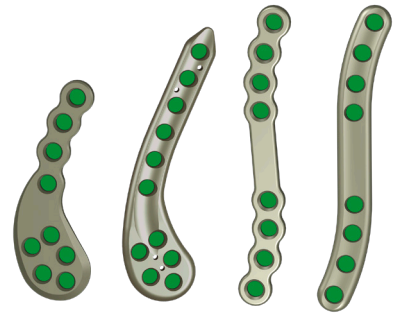
### Special advantages:

- ♦ Both 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)

3735I-XX-N Cortical Screw, locking, D=3.5mm, SH

61273-I00 Spiral Drill, D=2.7mm, L=100mm, AO Connector

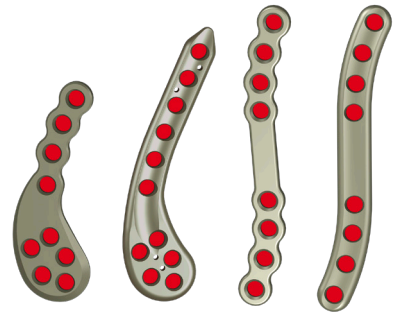
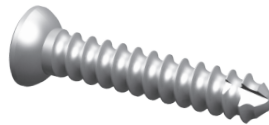
56252 Screwdriver, WS 2.5,  
self-holding sleeve



3235I-XX Cortical Screw, D=3.5mm

61273-I00 Spiral Drill, D=2.7mm, L=100mm, AO Connector

56252 Screwdriver, WS 2.5,  
self-holding sleeve



35164-228 Guide Wire, Steel, D=1.6mm,  
L=228mm, 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:

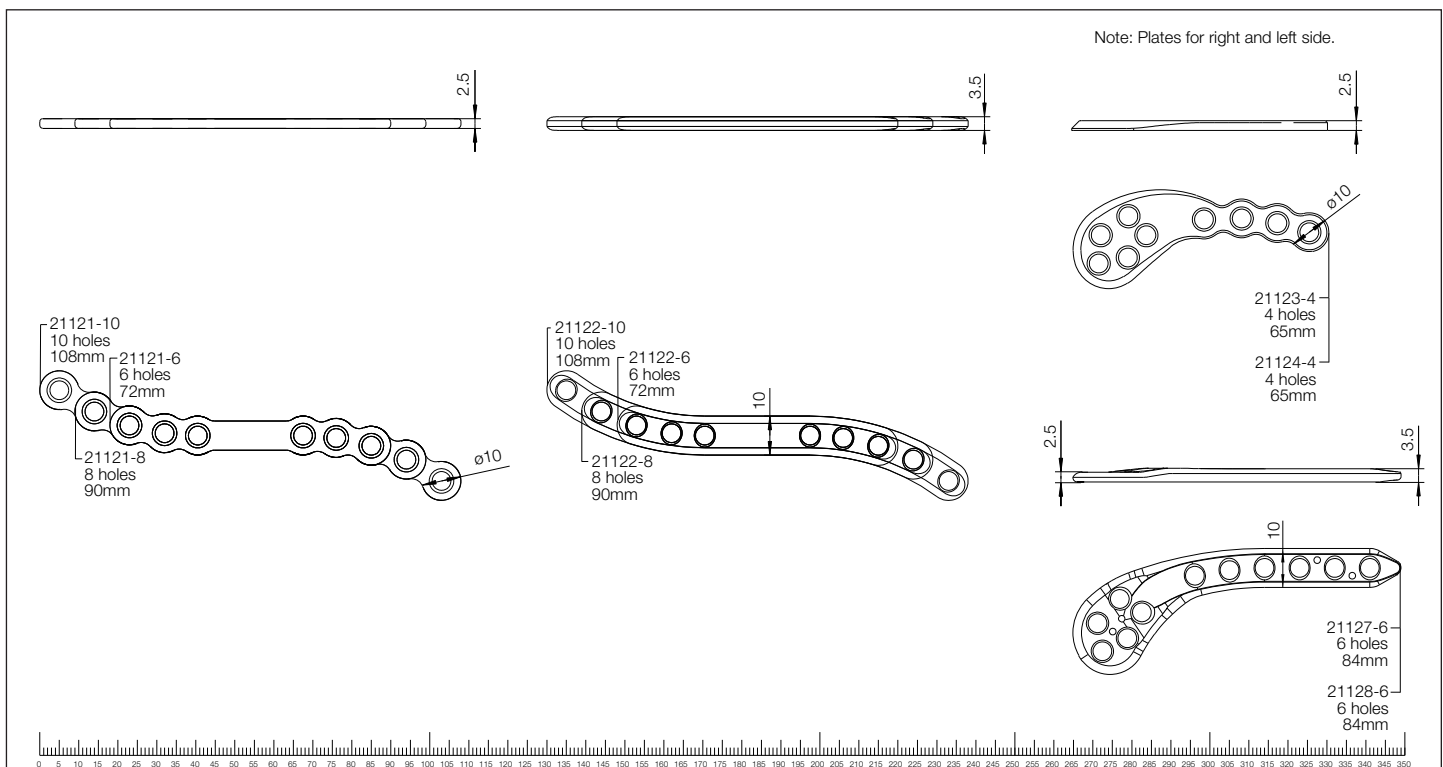
- Multi-directional locking
- Anatomical plate design

### Medial Clavicle Plate:

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

### Lateral Clavicle Plate:

- Version left/right
- 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.
- ♦ Hygienisation of pseudo-arthroses with or without spongiosal 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:

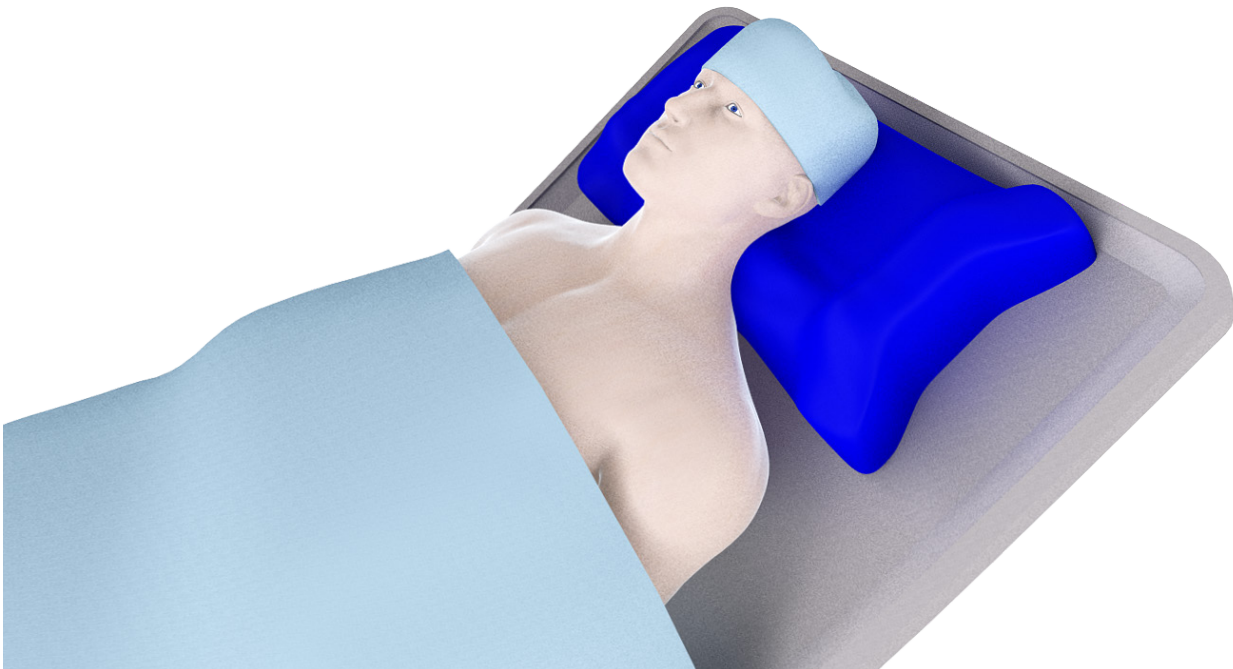
- ♦ Immediately after trauma or delayed
- ♦ After regression of swelling



# 2.

## ◦ Pre-operative patient preparation

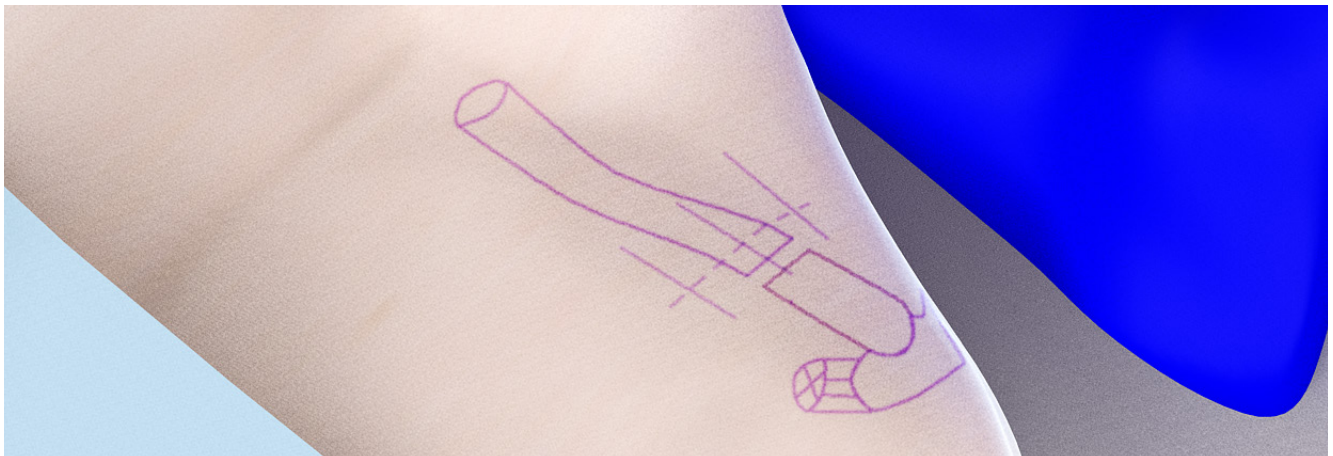
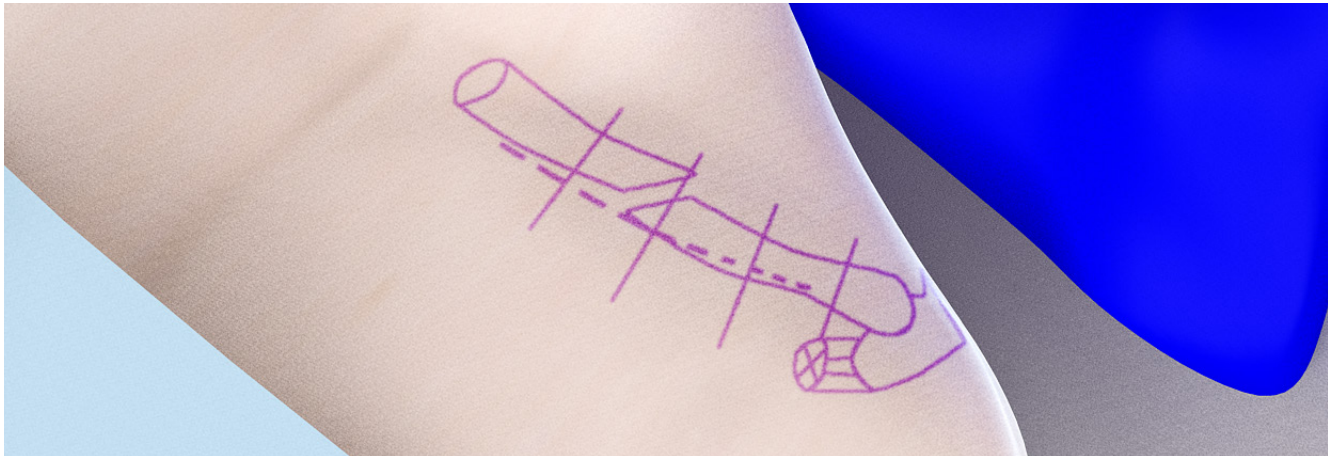
- Semi-sitting angle of about 30° - 40°, shoulder freely moveable (optional shoulder table)
- The arm should be freely moveable to allow fracture reduction
- General anaesthesia, regional anaesthesia or combination can be used



## ○ 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

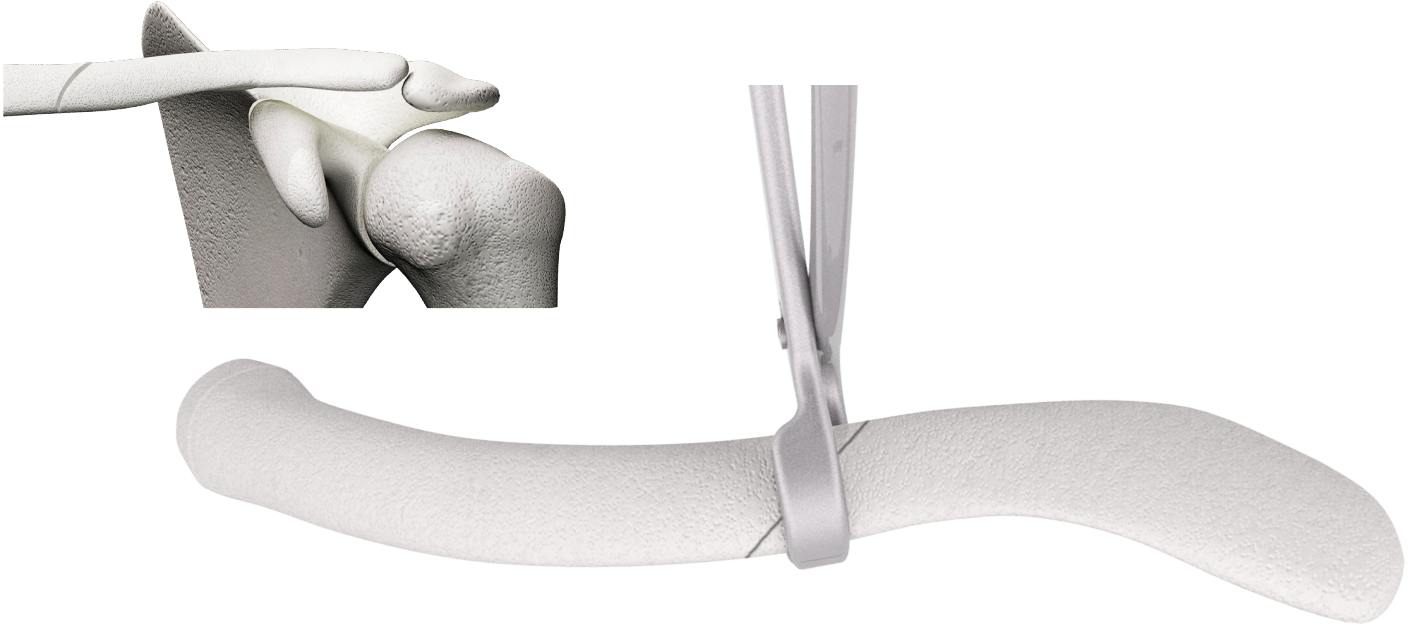
### Anterosuperior approach (sabre-cut incision)

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

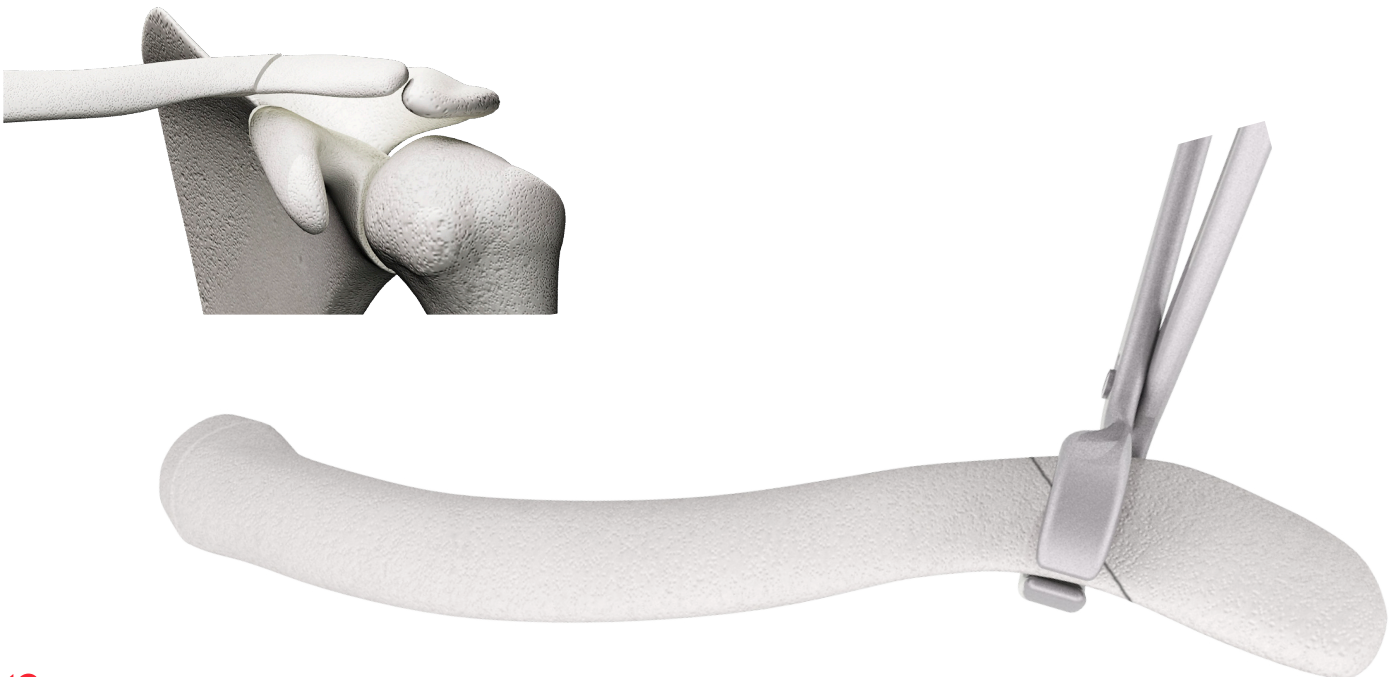
## ◦ Reduction

- ♦ Temporary fixation of the fracture segments 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 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 **(3235I-XX)** of appropriate lengths determined previously with the depth gauge, solid small fragment screws **(59022)**.



## Medial Clavicle Plate



## Lateral Clavicle Plate





Subsequently, place D=3.5mm locking cortical screws (**3735I-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 (**3735I-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 occurred.

Prompt rehabilitation and early functionality are brought about by the short immobilization time.

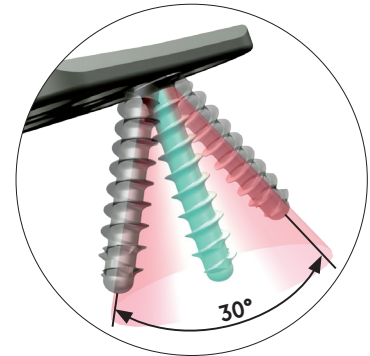
Information

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:

- $\pm 15^\circ$  and Locking
- No pre threading
- No cold welding
- No debris
- You can re-set the screw up to 3 times

## ○ Dotize®

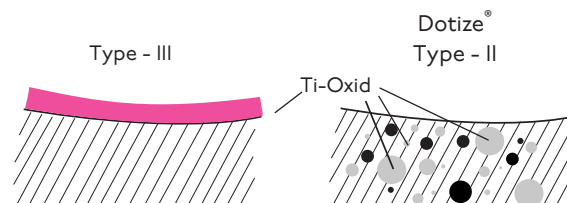
### Chemical process - anodization in a strong alkaline solution\*

#### 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

## 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	
Guide Wire, Steel, D=1.6mm, L=228mm, TR, w. Thrd.	35164-228	
Temporary Plate Holder	58164-150	
Sterilization Tray, Clavicle Plate System	50253	

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

## Notes



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