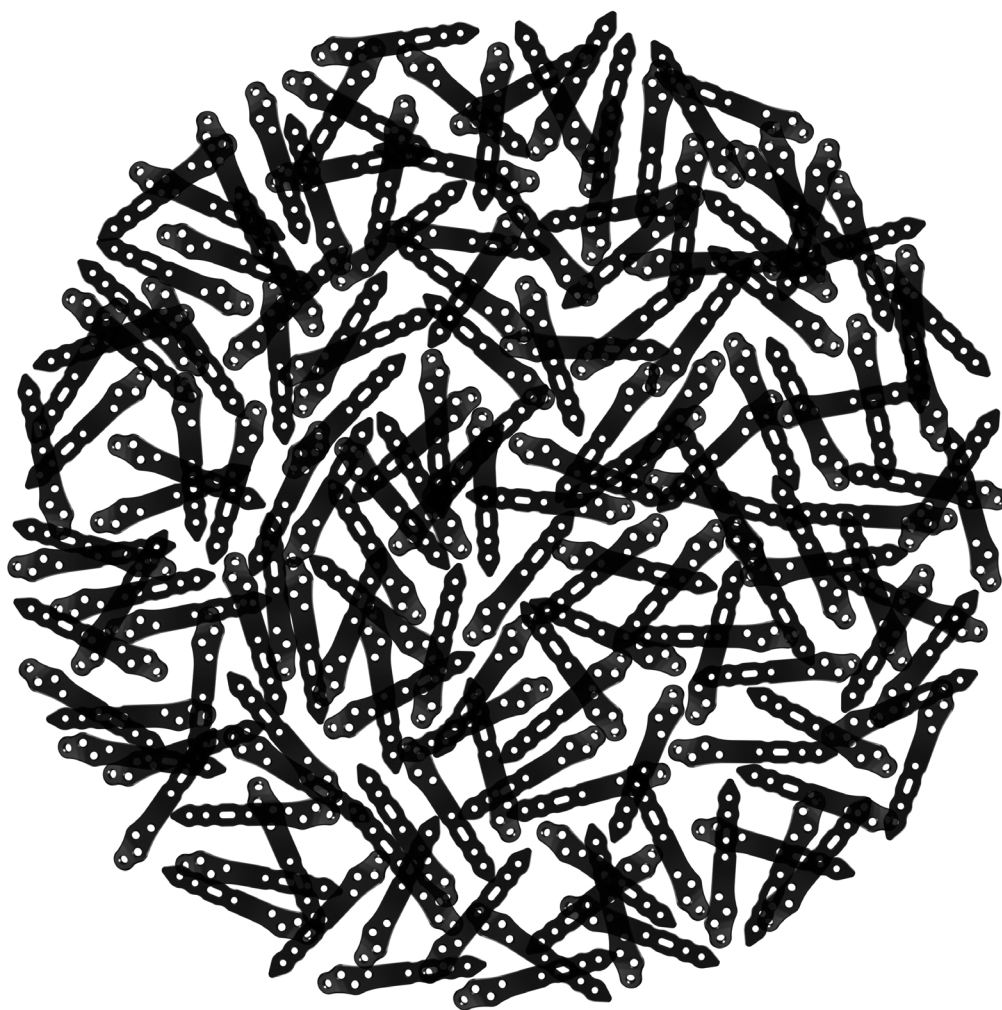


ITS.

Implants
trauma



PFL

PROlock Fibula Locking Plate

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 PROlock Fibula Locking Plate is a proven osteosynthesis system for various fractures of the distal fibula.

The special feature of this implant is the free choice of screw placement in the distal area (either locking or non-locking).

The free choice of screw angulation ($\pm 15^\circ$, see page 13) provides an advantage in fracture treatment, especially in the case of complex fractures.



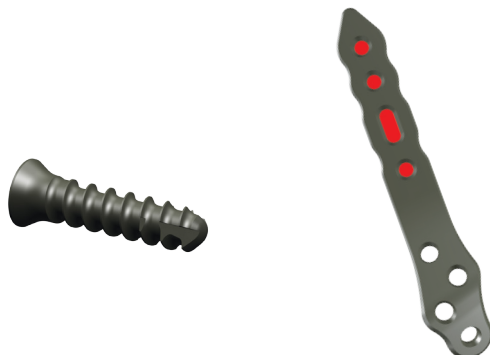
○ Screws

3227I-XX Cortical Screw, D=2.7mm

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

56095-70 Screwdriver, Torque, T9x70

56095-70-2 Self-holding sleeve, Screwdriver, Torque 9

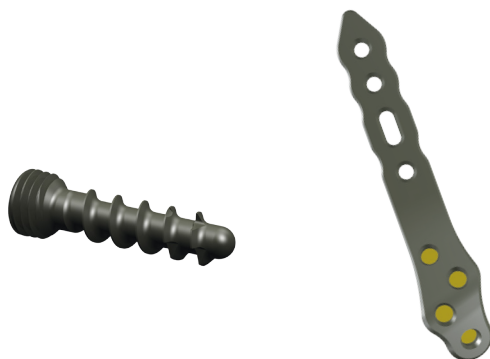


37302-XX Cancellous Screw, locking, D=3.0mm

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

56095-70 Screwdriver, Torque, T9x70

56095-70-2 Self-holding sleeve, Screwdriver, Torque 9



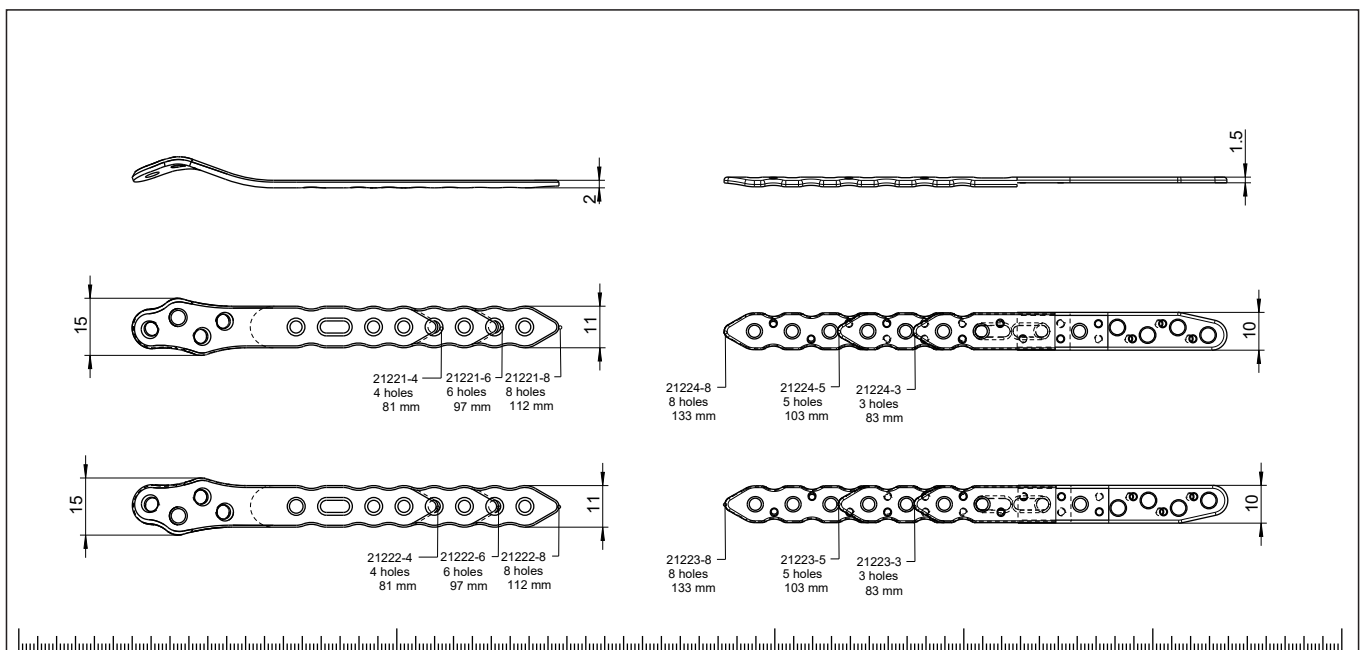
○ Properties

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
- ◆ Ideal positioning due to oblong hole
- ◆ Left/right version
- ◆ Plate lengths: 4, 6, 8-hole



◦ Indications, Contraindications & Time of operation

Indications:

- ♦ Dislocated ankle-fractures group B+C according to Weber (with or without comminuted zones)

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 injury
- ♦ After regression of the swelling

Surgical Technique

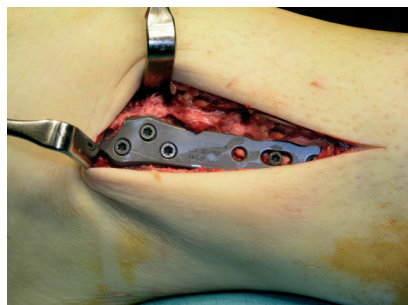
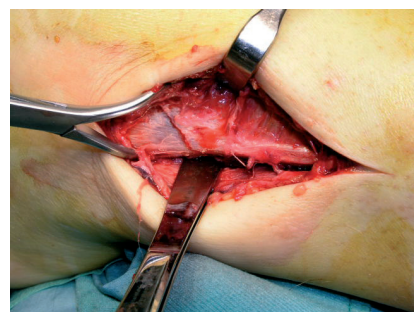
2.

○ Pre-operative patient preparation

- ◆ Supine position
- ◆ Primary Tourniquet
- ◆ General or regional anesthesia

○ Implantation

- ◆ Sterile washing and covering
- ◆ Typical distal fibula approach (lateral incision)
- ◆ Uncovering and cleaning of the fracture
- ◆ Open reduction and temporary fixation with clamps
- ◆ Temporary fixation with a lag screw possible
- ◆ Positioning of the anatomically formed fibula plate (left/right) to the reduced distal fibula and fixation with a D=2.7mm Cortical Screw through the oblong hole
- ◆ Fluoroscopic control of the reduction and plate position in a/p and lateral view
- ◆ Fill distal plate holes with D=3.0mm locking Cancellous Screws
- ◆ Insertion of another 2-3 D=2.7mm Cortical Screws in the shaft holes
- ◆ In case of instability of the syndesmosis the syndesmosis can be closed and an adjusting screw can be inserted through the longhole into the tibia after removal of the Cortical Screw
- ◆ Loosening of Tourniquet
- ◆ Wound closure



○ Postoperative treatment

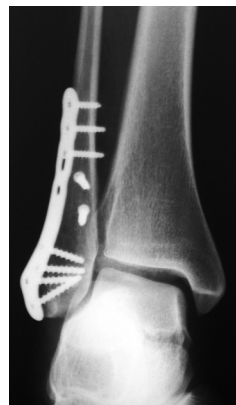
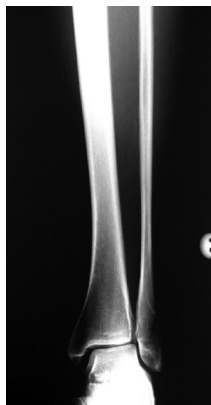
- ◆ Splinted shank for 2 weeks
- ◆ Physical therapy
- ◆ 6-8 weeks rest

○ 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 I3).

○ Case studies



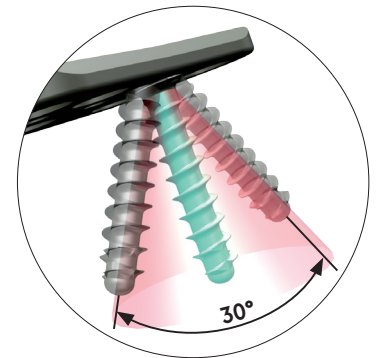
Information

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*

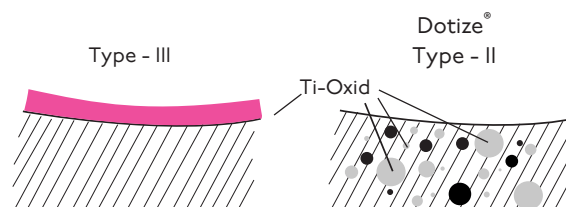
Type III anodization

- ♦ 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

Fibula Plate PROlock, 4-hole, Right	21221-4	
Fibula Plate PROlock, 4-hole, Left	21222-4	
Fibula Plate PROlock, 6-hole, Right	21221-6	
Fibula Plate PROlock, 6-hole, Left	21222-6	
Fibula Plate PROlock, 8-hole, Right	21221-8	
Fibula Plate PROlock, 8-hole, Left	21222-8	
<hr/>		
Cancellous Screw, Locking, D=3.0mm, L=10mm	37302-10	
Cancellous Screw, Locking, D=3.0mm, L=12mm	37302-12	
Cancellous Screw, Locking, D=3.0mm, L=14mm	37302-14	
Cancellous Screw, Locking, D=3.0mm, L=16mm	37302-16	
Cancellous Screw, Locking, D=3.0mm, L=18mm	37302-18	
Cancellous Screw, Locking, D=3.0mm, L=20mm	37302-20	
<hr/>		
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	
<hr/>		
Screwdriver Torque, T9x70	56095-70	
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Self-holding sleeve Screwdriver, Torque 9	56095-70-2	
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Depth Gauge, PROlock	59023	
<hr/>		
Drill Guide, D=2.0/2.7mm	62202	
<hr/>		
Spiral Drill, D=2.0mm, L=100mm, AO Connector	61203-100	
<hr/>		
Sterilization Tray, Fibula Plate PROlock	50170	

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

Tray





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