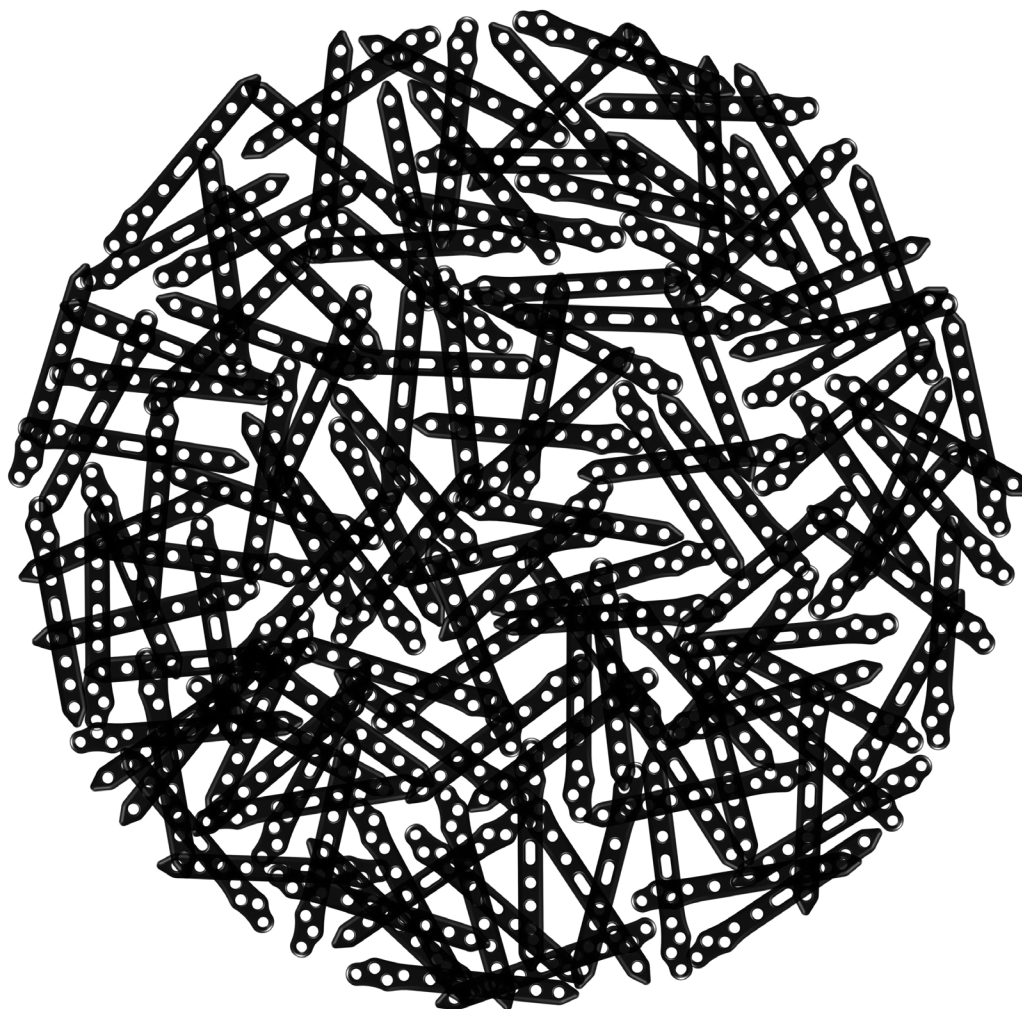


ITS.

Implants
trauma



FL

Fibula Locking Plate

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 Fibula Locking Plate is a proven osteosynthesis system for various distal fibula 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 oblong hole).

The free choice of screw angulation ($\pm 15^\circ$, see page 17) provides an advantage in fracture treatment, especially in the case of complex fractures.



○ Screws

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

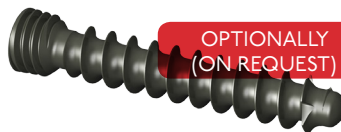
56252 Screwdriver, WS 2.5,
self-holding sleeve



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

61253-I80 Spiral Drill, D=2.5mm, L=180mm, AO Connector

56252 Screwdriver, WS 2.5,
self-holding sleeve



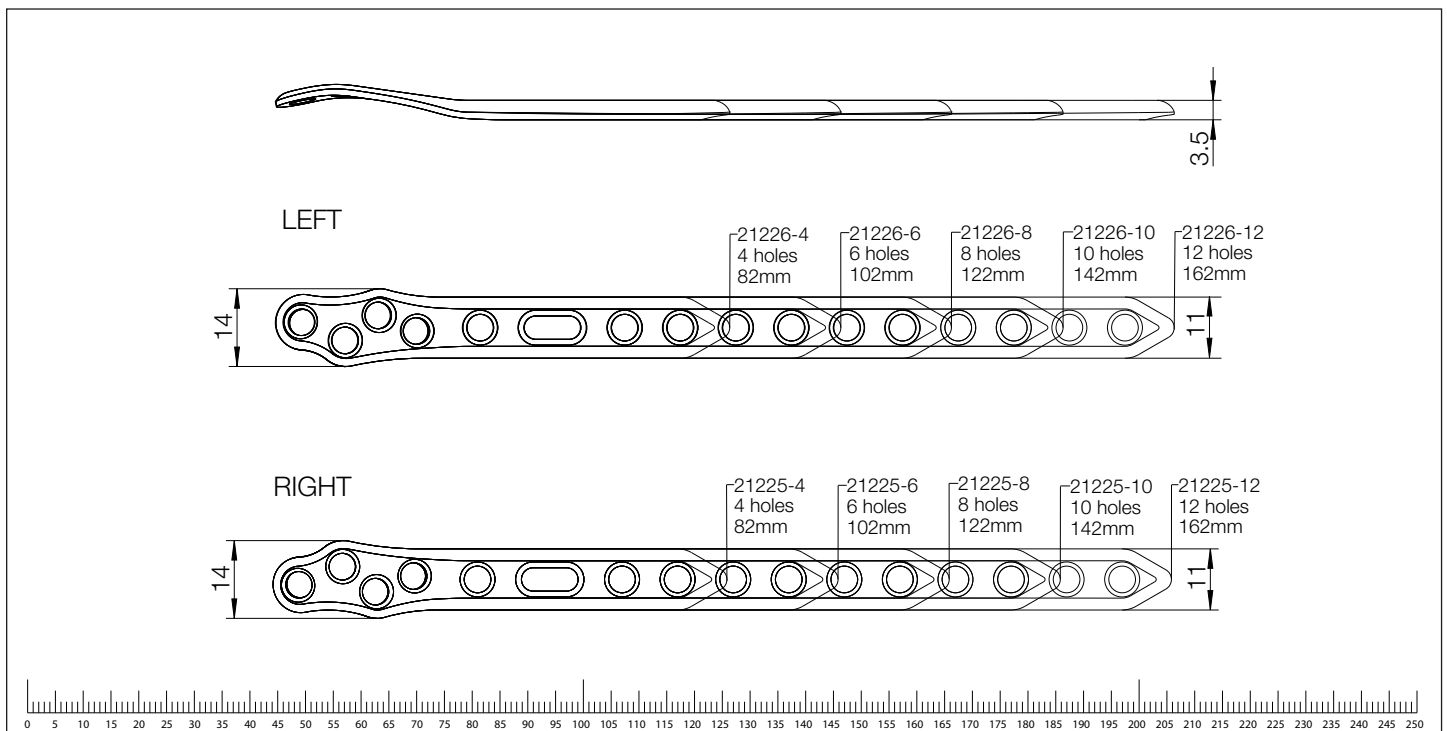
○ Properties

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
- Anatomically shaped
- Oblong hole for optimal positioning and alignment of the fibula length
- Pointed proximal plate end for percutaneous insertion
- Left/right version
- Plate lengths: 4, 6, 8, 10, 12-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
- ♦ With advanced osteoporosis
- ♦ In cases of skin and soft tissue problems that prevent a tension-free skin closure
- ♦ Obesity
- ♦ Lack of patient compliance

Time of operation:

- ♦ Immediately after injury
- ♦ After regression of the swelling

2.

○ Pre-operative patient preparation

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

○ Access

Lateral access:

- ♦ Skin incision above the center of the fibula
- ♦ The incision should be made 10-20mm away from the fracture so that the suture is not directly over the plate
- ♦ After incision of the inferior extensor retinaculum (cruciform ligament) directly in front of the fibula the toe extensors and the variable peroneus tertius are retracted forwards¹

○ Reduction

- ♦ Temporary fixation of the plate to the fibula shaft using forceps or temporary plate holder (**58164-I50**)
- ♦ Anatomical reduction of the fracture segments to the plate
- ♦ Subsequent control under fluoroscopy



○ Placement of the screws

With the spiral drill, D=2.7mm, L=100mm, AO Connector (**61273-100**), drill through the drill guide, D=2.7/2.0mm (**62202**) into the oblong hole.

Determine appropriate length using the depth gauge, solid small fragment screws (**59022**). Insert the D=3.5mm cortical screw (**3235I-XX**) with the screwdriver, WS 2.5, self-holding sleeve (**56252**).



Advice: For optimal alignment of the plate with fibula length, we recommend to first occupy the oblong hole.



Then using the spiral drill, D=2.7mm, L=100mm, AO Connector (**61273-100**) to drill through the drill guide, D=2.7/2.0mm (**62202**) into a distal plate hole. Determine appropriate length using the depth gauge, solid small fragment screws (**59022**). Insert the D=3.5mm locking cortical screw (**37351-XX-N**) with the screwdriver, WS 2.5, self-holding sleeve (**56252**).



Using the spiral drill, D=2.7mm, L=100mm, AO Connector (**61273-100**) drill through the drill guide, D=2.7/2.0mm (**62202**) into a shaft plate hole. Determine appropriate length using the depth gauge, solid small fragment screws (**59022**). Insert the D=3.5mm cortical locking (**37351-XX**) or non-locking screw (**32351-XX**) with the screwdriver, WS 2.5, self-holding sleeve (**56252**).



The remaining plate holes are then filled, with either locking or non-locking screws. Subsequent control of plate position under fluoroscopy.



○ Postoperative treatment

- Splinted shank for 2 weeks
- Physical therapy
- 6-8 weeks rest
- When a locking screw connection has been used, it is necessary to be aware that the diagnosis of non-union may be very delayed.

○ Explantation

If desired by the patient, the implant can be removed.

Removal should be performed at the earliest 6 months - 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).

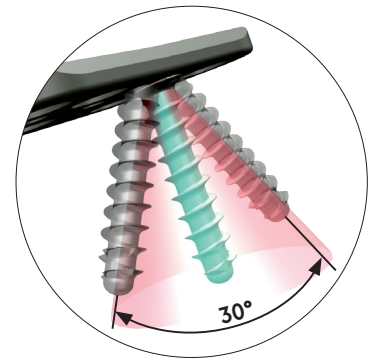
Information

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:

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

○ Dotize®

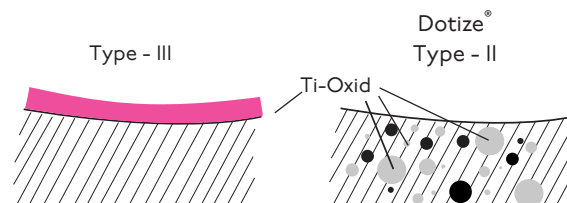
Chemical process - anodization in a strong alkaline solution*

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 3.5mm, Right, 4-hole	21225-4
Fibula Plate 3.5mm, Left, 4-hole	21226-4
Fibula Plate 3.5mm, Right, 6-hole	21225-6
Fibula Plate 3.5mm, Left, 6-hole	21226-6
Fibula Plate 3.5mm, Right, 8-hole	21225-8
Fibula Plate 3.5mm, Left, 8-hole	21226-8
Fibula Plate 3.5mm, Right, 10-hole	21225-10
Fibula Plate 3.5mm, Left, 10-hole	21226-10
Fibula Plate 3.5mm, Right, 12-hole	21225-12
Fibula Plate 3.5mm, Left, 12-hole	21226-12



Cortical Screw, D=3.5mm, L=10mm	32351-10
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=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



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



Screwdriver, WS 2.5, self-holding sleeve	56252
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Depth Gauge, Solid Small Fragment Screws	59022
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Drill Guide, D=2.0/2.7mm	62202
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Spiral Drill, D=2.7mm, L=100mm, AO Connector	61273-100
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Sterilization Tray, Fibula Plate 3.5mm	50242
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For detailed cleaning and sterilization instructions, please refer to package insert.

Optional (on request)

Cancellous Screw, locking, D=4.2mm, L=12mm, SH	37422-12-N
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



Spiral Drill, D=2.5mm, L=180mm, AO Connector	61253-180
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Temporary Plate Holder	58164-150
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I.T.S. USA
1778 Park Avenue N, Suite 200
Maitland, FL 32751

Tel.: 877 - 971 - 8054
Fax: 877 - 971 - 8056
info@its-implantusa.com
www.its-implantusa.com



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