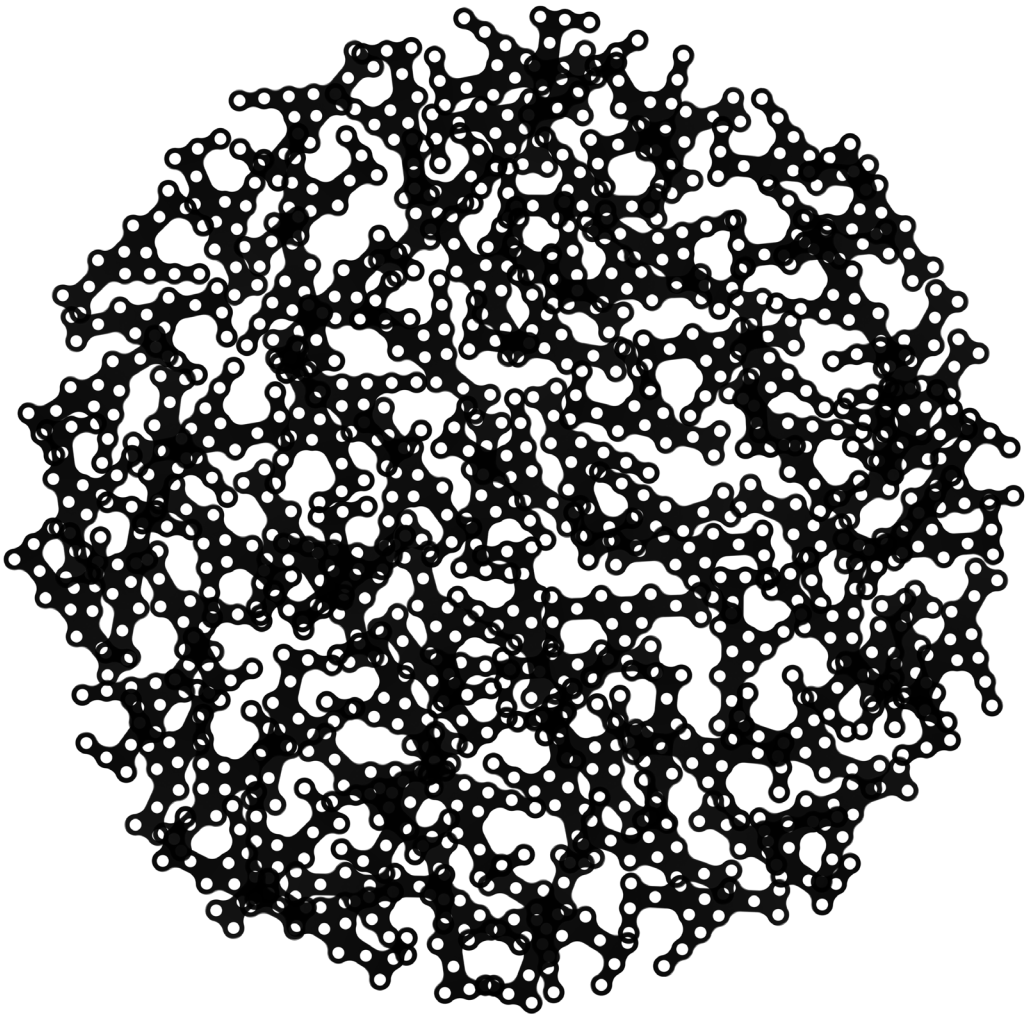
ITS.

Implants
trauma



CAL

Calcaneus 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.

Contents

1. Introduction

2. Surgical Technique

3. Information

Introduction

1.

Preface

The Locking Calcaneus Plate is a proven osteosynthesis system for various calcaneus 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).

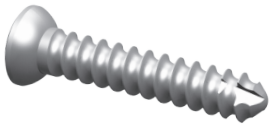
The free choice of screw angulation (+/- 15°, see page 15) provides an advantage in fracture treatment, especially in the case of complex fractures.

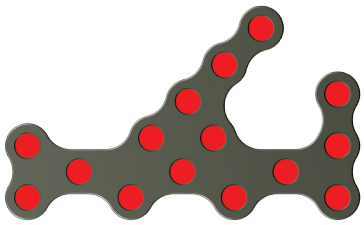
Screws

32351-XX Cortical Screw, D=3.5mm

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

56252 Screwdriver, WS 2.5,
with self-holding sleeve

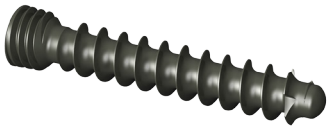


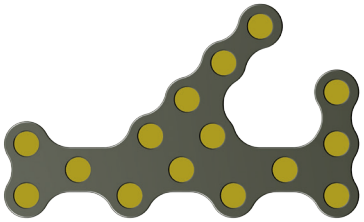


37422-XX-N Cancellous Screw, locking, D=4.2mm, SH

61253-110 Spiral Drill, D=2.5mm, L=110mm, AO Connector

56252 Screwdriver, WS 2.5,
with self-holding sleeve



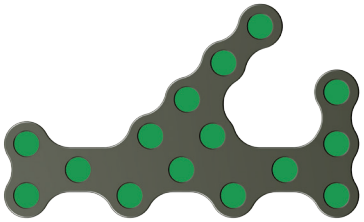


37351-XX Cortical Screw, Locking, D=3.5mm

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

56252 Screwdriver, WS 2.5,
with self-holding sleeve

OPTIONAL
(ON REQUEST)



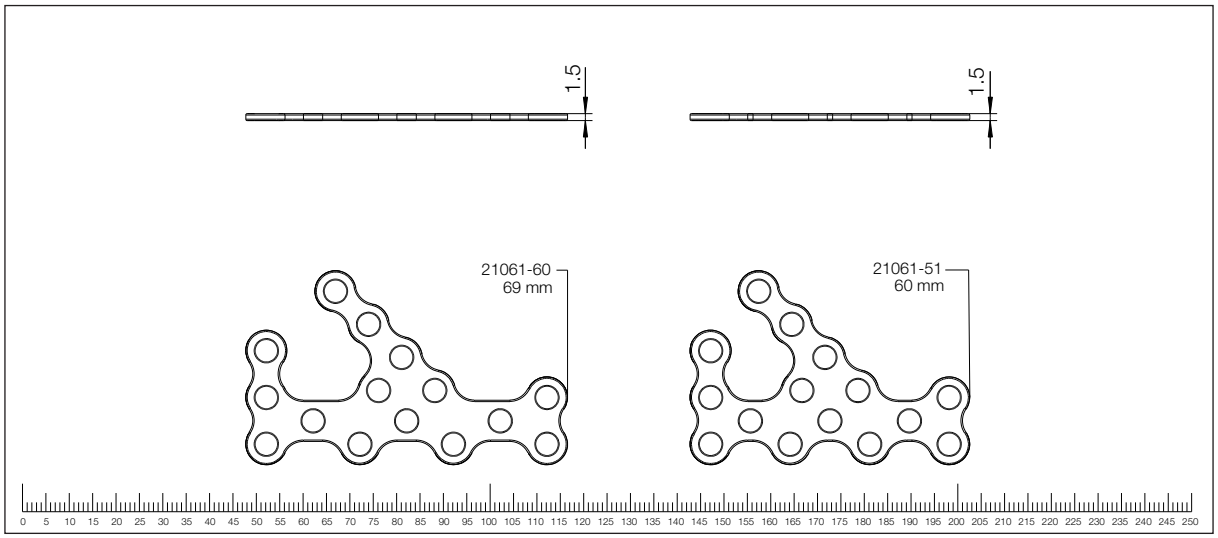
Properties

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
- Short and long version



Indications, Contraindications & Time of operation

Indications:

- Complex fractures of the calcaneus
- All intra-articular fractures with relevant joint distortion and a comminution zone in which a semi-operative procedure (screws, drill wires) does not raise expectations of exact repositioning

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:

- After regression of the swelling

Surgical Technique

2.

Pre-operative patient preparation

- Supine position or lateral position
- Blood arrest

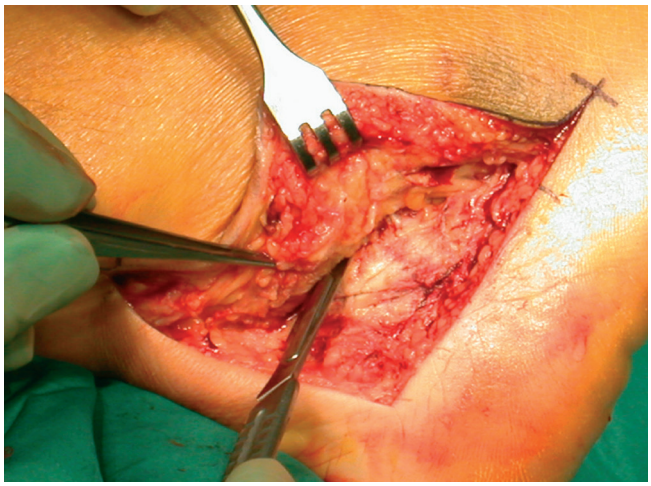
Diagnosis

Standard X-ray of the calcaneus, axial and coronet CT with reconstructions.

Access

Expanded lateral approach:

- Subperiostal single layered lifting of a lateral skin-soft tissue flap
- Hold away the flap by using bent guide wires

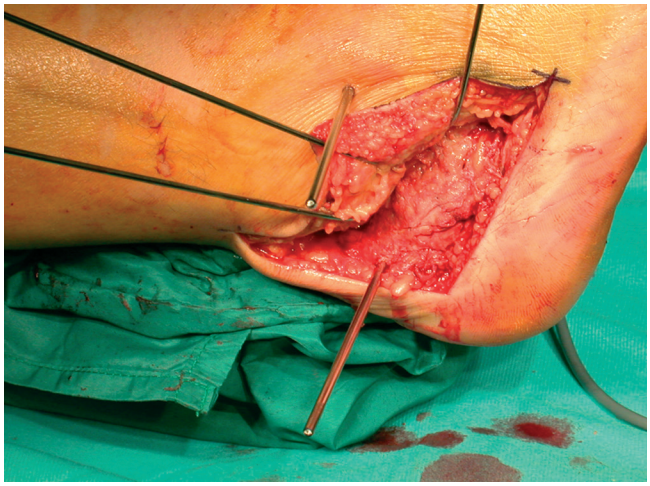


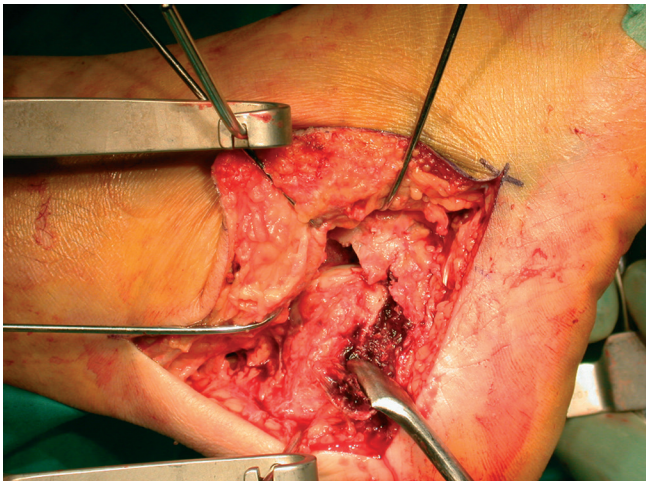
Reduction

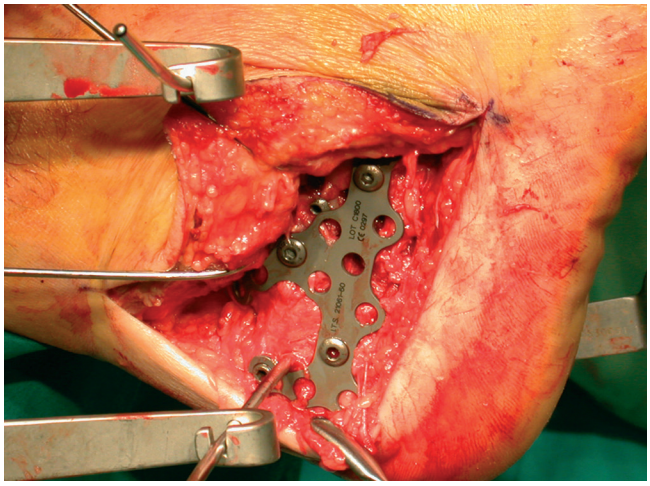
- Open reduction under view by mean of Schanz screw, Steinmann nails, guide wires
- Padding of comminuted zones with bone replacement

Fixation

- Temporarily by guide wires, eventually by cancellous screws
- Forming the locking plate for calcaneus
- Fixation with the cancellous screws in the main fragments
- Finishing with locking screws







Postoperative treatment

- Plastex cast of the lower leg for 2 weeks until healing
- Physical therapy
- Mobilization by crutches
- Relief of the strain for 8-12 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 15).

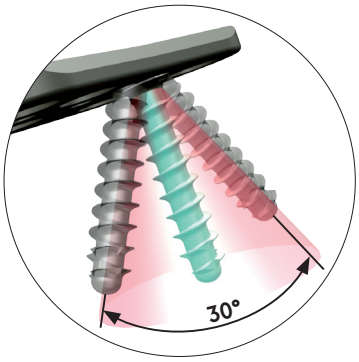
Information

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®

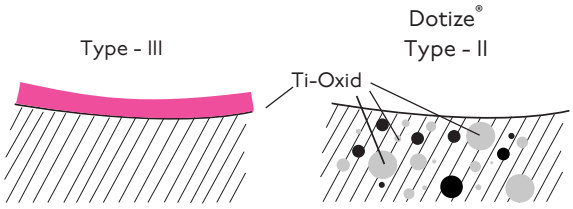
Chemical process - anodization in a strong alkaline solution*

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

Calcaneus Plate, Short	21061-51
Calcaneus Plate, Long	21061-60

Cancellous Screw, Locking, D=4.2mm, L=26mm, SH	37422-26-N
Cancellous Screw, Locking, D=4.2mm, L=28mm, SH	37422-28-N
Cancellous Screw, Locking, D=4.2mm, L=30mm, SH	37422-30-N
Cancellous Screw, Locking, D=4.2mm, L=32mm, SH	37422-32-N
Cancellous Screw, Locking, D=4.2mm, L=34mm, SH	37422-34-N
Cancellous Screw, Locking, D=4.2mm, L=36mm, SH	37422-36-N
Cancellous Screw, Locking, D=4.2mm, L=38mm, SH	37422-38-N
Cancellous Screw, Locking, D=4.2mm, L=40mm, SH	37422-40-N
Cancellous Screw, Locking, D=4.2mm, L=42mm, SH	37422-42-N
Cancellous Screw, Locking, D=4.2mm, L=44mm, SH	37422-44-N
Cancellous Screw, Locking, D=4.2mm, L=46mm, SH	37422-46-N
Cancellous Screw, Locking, D=4.2mm, L=48mm, SH	37422-48-N
Cancellous Screw, Locking, D=4.2mm, L=50mm, SH	37422-50-N

Cortical Screw, D=3.5mm, L=26mm	32351-26
Cortical Screw, D=3.5mm, L=28mm	32351-28
Cortical Screw, D=3.5mm, L=30mm	32351-30
Cortical Screw, D=3.5mm, L=32mm	32351-32
Cortical Screw, D=3.5mm, L=34mm	32351-34
Cortical Screw, D=3.5mm, L=36mm	32351-36
Cortical Screw, D=3.5mm, L=38mm	32351-38
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

Screwdriver, WS 2.5, with self-holding sleeve	56252

Depth Gauge, Solid Small Fragment Screws	59022

Drill Guide, D=2.0/2.7mm	62202

Spiral Drill, D=2.5mm, L=110mm, AO Connector	61253-110
Spiral Drill, D=2.7mm, L=100mm, AO Connector	61273-100

Sterilization Tray, Calcaneus Plate	50171

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

Special sizes & instruments optional on request *

Cortical Screw, Locking, D=3.5mm, L=26mm, SH	32351-26
Cortical Screw, Locking, D=3.5mm, L=28mm, SH	32351-28
Cortical Screw, Locking, D=3.5mm, L=30mm, SH	32351-30
Cortical Screw, Locking, D=3.5mm, L=32mm, SH	32351-32
Cortical Screw, Locking, D=3.5mm, L=34mm, SH	32351-34
Cortical Screw, Locking, D=3.5mm, L=36mm, SH	32351-36
Cortical Screw, Locking, D=3.5mm, L=38mm, SH	32351-38
Cortical Screw, Locking, D=3.5mm, L=40mm, SH	32351-40
Cortical Screw, Locking, D=3.5mm, L=42mm, SH	32351-42
Cortical Screw, Locking, D=3.5mm, L=44mm, SH	32351-44
Cortical Screw, Locking, D=3.5mm, L=46mm, SH	32351-46
Cortical Screw, Locking, D=3.5mm, L=48mm, SH	32351-48
Cortical Screw, Locking, D=3.5mm, L=50mm, SH	32351-50

Tray Setting

* Delivery times, prices & minimum quantities may vary from standard

Notes

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