ITS.

Implants
trauma

PLS

Pilon 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.

Contents

1. Introduction

P. 5 Preface
P. 6 Screws
P. 7 Properties
P. 8 Indications & Contraindications
P. 8 Time of operation

2. Surgical Technique

P. 10 Pre-operative patient preparation
P. 10 Access
P. 11 Reduction
P. 12 Placement of the screws
P. 15 Postoperative treatment
P. 15 Explantation

3. Information

P. 17 Locking
P. 17 Dotize®
P. 18 Order list

Introduction

1.

Preface

The Pilon Locking Plate is a proven osteosynthesis system for various fractures of the pilon.

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 17) provides an advantage in fracture treatment, especially in the case of complex fractures.

Screws

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

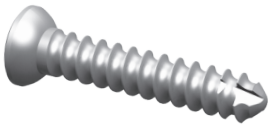
61273-100 Spiral Drill, D=2.7mm, L=100mm, AO Connector

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

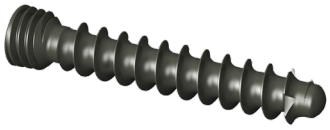
56252 Screwdriver, WS 2.5, self-holding sleeve

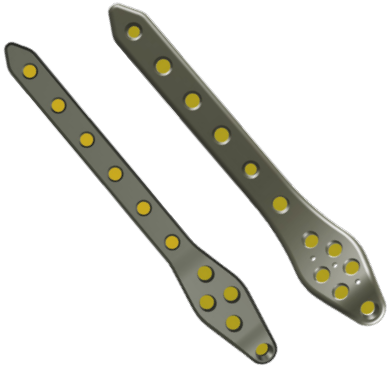


37422-XX-N Cancellous Screw, locking, D=4.2mm, SH

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

56252 Screwdriver, WS 2.5, self-holding sleeve





Note: The threaded holes are primary for mounting the insertion guide. If desired by the surgeon, these holes can be filled with screws. ITS. recommends the use of locking screws, inserted 90° to the plate axis.

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:

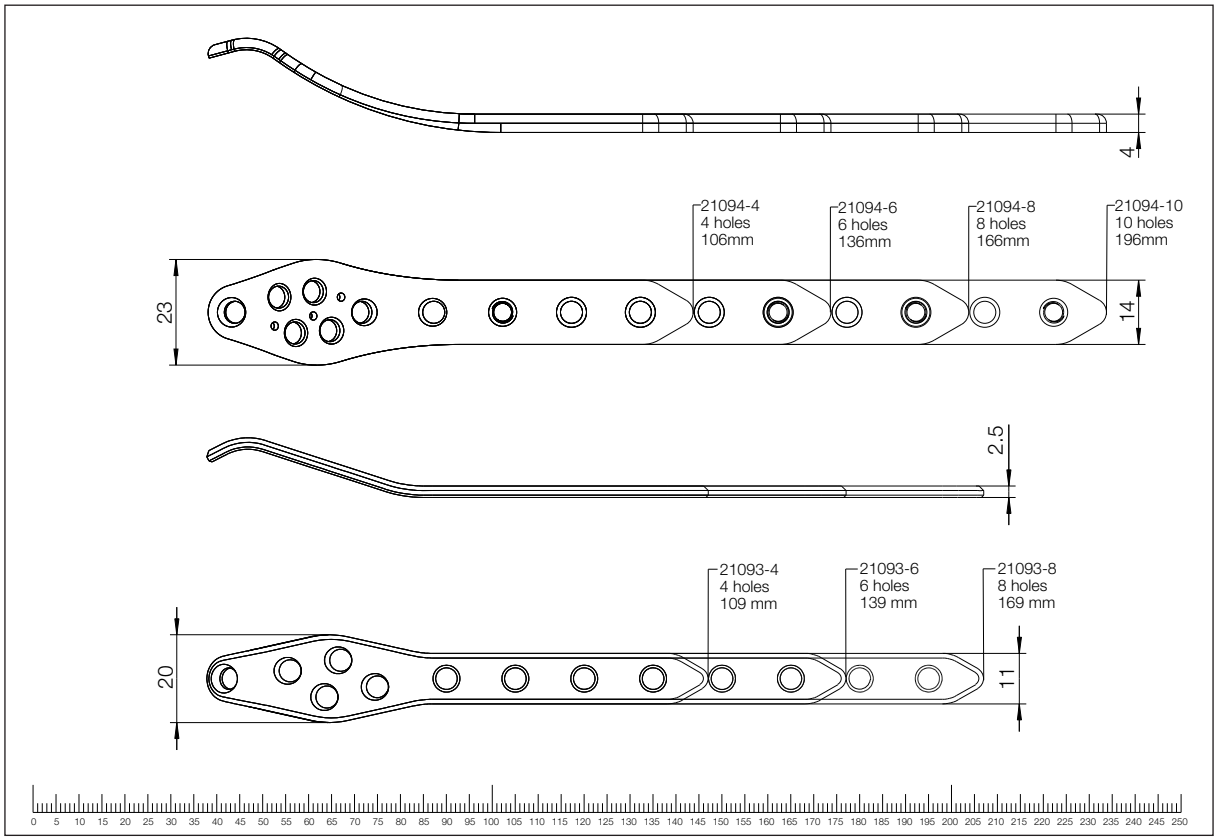
- Multi-directional locking
- Anatomically shaped
- 5 resp. 6 distal plate holes for fixation close to joint
- Pointed proximal plate end for percutaneous insertion

Pilon Plate small:

- 5 distal plate holes for optimal fixation close to joint
- Lengths: 4, 6, 8-hole
- Strength: 2.5mm

Pilon Plate:

- 6 distal plate holes for optimal fixation close to joint
- K-Wire holes for preliminary plate fixation
- Lengths: 4, 6, 8, 10-hole
- Strength: 4.0mm



Indications, Contraindications & Time of operation

Indications:

- Fractures of the tibial pilon of AO classification A3, especially groups C2 and C3

Contraindications:

- Very advanced osteoporosis with very soft bones.
- Skin and soft-tissue problems which prevent a tension-free closure of the skin

Time of operation:

- Primarily in the first hours after trauma
- Secondarily after swelling has subsided. Intermediate fixation by means of a external fixator or by means of extension.

Surgical Technique

2.

Pre-operative patient preparation

- General anaesthesia, local anaesthesia or combination can be used
- The patient is in the supine position with the leg raised slightly on a pedestal
- Application of a tourniquet

Access

Medial Access:

- Skin incision is made via the inner side of the ankle
- The incision should be made 1-2cm away from the fracture so that the suture is not directly over the plate.
- If necessary, the flexor retinaculum (laciniate ligament) can be severed.
- Remove the tendon of the tibialis posterior muscle and the flexor tendons from their compartments and hold aside in the same way as the vessel-nerve cord. [1]

[1] Cf. Detlef von Torklus, Atlas orthopädisch-chirurgischer Zugangswege, page 256

Reduction

- Temporary fixation of the plate to the pilon using guide wires
- Anatomical reduction of the articular block and fracture segments to the plate (varus/valgus, ante-/retroversion)
- Subsequent control under fluoroscopy

Optionally, the plate can be stabilized using the ITS. Temporary Plate Holder **(58164-150)**.

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 a proximal plate hole.
Determine appropriate length using the depth gauge, solid small fragment screws **(59022)**.
Insert the D=3.5mm cortical screw **(32351-XX)** with the screwdriver, WS 2.5, self-holding sleeve **(56252)**.

Then using the spiral drill, D=2.5mm, L=100mm, AO Connector **(61253-100)** 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=4.2mm locking cancellous screw **(37422-XX-N)** 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.

Pilon Plate

Pilon Plate small

Postoperative treatment

- Keep leg raised for 2 to 5 days and take decongestant actions
- Physical therapy immediately following surgery (no immobilization required)
- Partial toe touch weight-bearing - at week 6-8 (depends on wound healing): 33-66 lbs
- Full weight-bearing - after about 3 months (depends on consolidation of the joint)
- When a locking screw connection has been used, it is necessary to be aware that a 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).

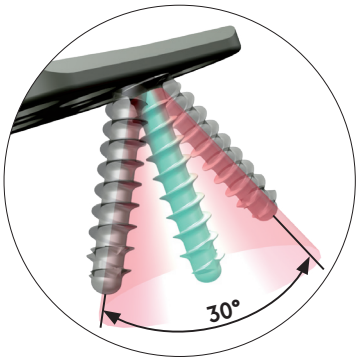
Information

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:

- ± 15° and Locking
- No pre threading
- No cold welding
- No debris
- You can re-set the screw up to 3 times

Type II Anodization

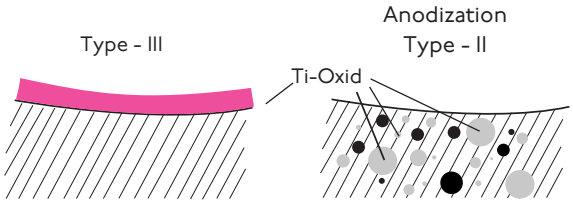
Chemical process - anodization in a strong alkaline solution*

Type III anodization

- Layer thickness 60-200nm
  - \+ Different colors
  - \- Implant surface remains sensitive to:
    Chipping
    Peeling
    Discoloration

Type II anodization

- Layer thickness 1000-2000nm
  - \+ 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

Pilon Plate 4mm, 4-hole	21094-4
Pilon Plate 4mm, 6-hole	21094-6
Pilon Plate 4mm, 8-hole	21094-8
Pilon Plate 4mm, 10-hole	21094-10

Pilon Plate, Small, 4-hole	21093-4
Pilon Plate, Small, 6-hole	21093-6
Pilon Plate, Small, 8-hole	21093-8

Cortical Screw, D=3.5mm, L=24mm	32351-24
Cortical Screw, D=3.5mm, L=28mm	32351-28
Cortical Screw, D=3.5mm, L=32mm	32351-32
Cortical Screw, D=3.5mm, L=36mm	32351-36
Cortical Screw, D=3.5mm, L=40mm	32351-40

Cortical Screw, Locking, D=3.5mm, L=24mm, SH	37351-24-N
Cortical Screw, Locking, D=3.5mm, L=28mm, SH	37351-28-N
Cortical Screw, Locking, D=3.5mm, L=32mm, SH	37351-32-N
Cortical Screw, Locking, D=3.5mm, L=36mm, SH	37351-36-N
Cortical Screw, Locking, D=3.5mm, L=40mm, SH	37351-40-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
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

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=2.5mm, L=180mm, AO Connector	61253-180	
Guide Wire, Steel, D=1.6mm, L=150mm, TR, w. Thrd.	35164-150	
Sterilization Tray, Pilon Plate	50187	
Optional (on request) Temporary Plate Holder	58164-150	

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

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

CE 0297

Order No. PLS-OP-0725-US
Edition: July/2025

© ITS. GmbH Graz/Austria 2025.
Subject to technical alterations, errors and misprints excepted.