

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 Distal Anterolateral Tibia Locking Plate is a proven osteosynthesis system for various distal tibia 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 (+/- I5°, see page I9) provides an advantage in fracture treatment, especially in the case of complex fractures.





3735I-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

3235I-XX Cortical Screw, D=3.5mm

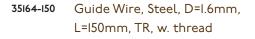
61273-100 Spiral Drill, D=2.7mm, L=100mm, AO Connector

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





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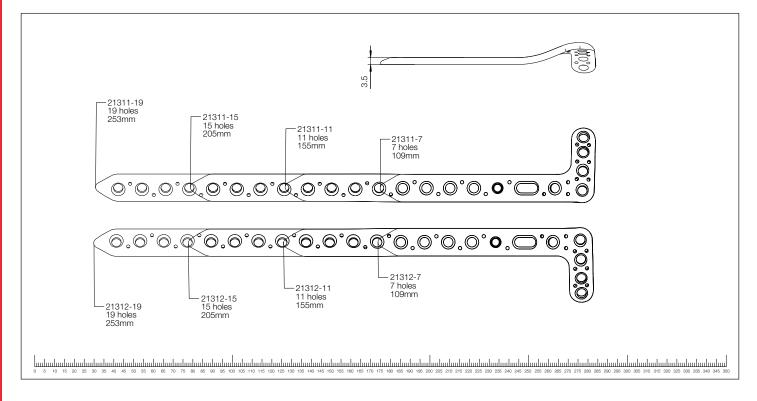
• Properties

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
- Torsion and contour of the plate shaft has been adapted to that of the distal tibia
- 4 distal plate holes for fixation close to joint
- Oblong hole for optimal positioning and alignment of the tibia length
- Pointed proximal plate end for percutaneous insertion
- Left/right version
- Plate lenghts: 7, 11, 15, 19-hole



Indications, Contraindications & Time of operation

Indications:

- Extra- and intra-articular fractures of the distal tibia
- Distal tibia fractures also in combination with diaphyseal fractures

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 trauma or delayed

Surgical Technique

• 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

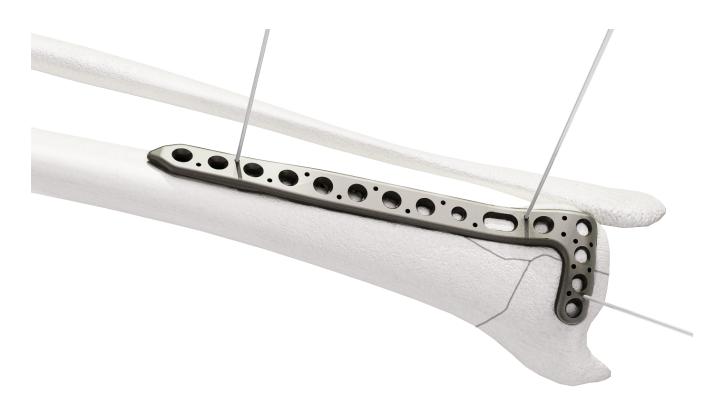
Anterior approach:

- Skin incision along the middle line of the upper ankle joint with the center over the joint
- The incision should be made I to 2cm away from the fracture to avoid suture placement directly above the plate
- Separation of the superficial and deep fascia giving due attention to the superficial peroneal nerve
- The tendon of the tibialis anterior muscle is held away medially, while the superficial peroneal nerve, the deep peroneal nerve, the anterior tibial artery and the tendons of the extensor muscle are held away laterally



• Reduction

- Temporary fixation of the plate to the tibial shaft 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 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 tibia length, we recommend to first fill the oblong hole.

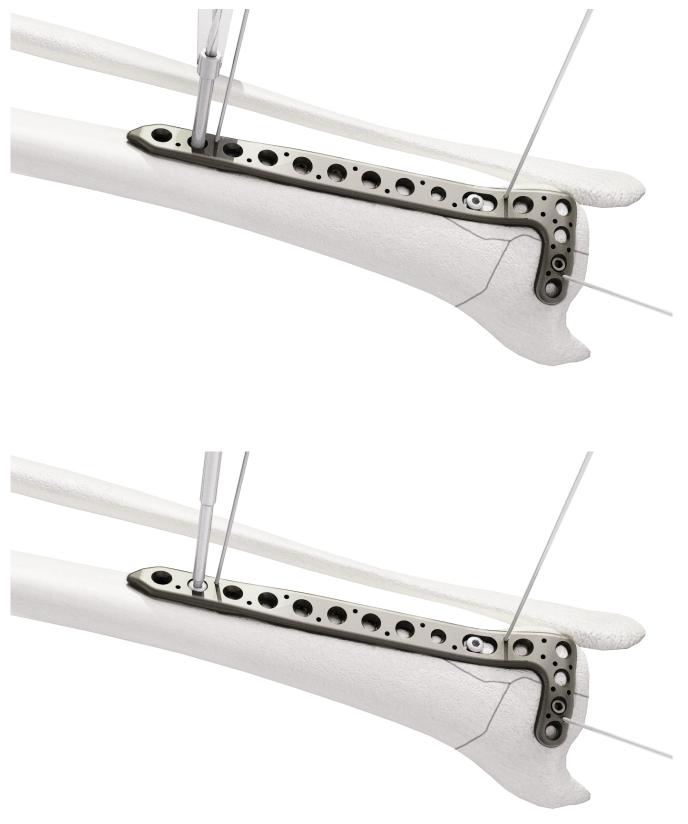


Then, using the spiral drill, D=2.5mm, L=100mm, AO Connector **(61253-100)**,drill through the drill guide, D=2.7/2.0mm **(62202)** into a distal plate hole.

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).



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 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

- 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): 10-15kg
- 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 the diagnosis of a non-union may be very delayed.

• 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 19).

• Notes

Information

• Locking

Locking works because of:

- Screw material (TiAlV) is slightly harder than plate material (Titanium Grade 2)
- Screw head **forms** thread into the plate (no cutting)

Benefits:

- ± I5° and Locking
- No pre threading
- No cold welding
- No debris
- You can re-set the screw up to 3 times



Chemical process - anodization in a strong alkaline solution*

Type III anodization

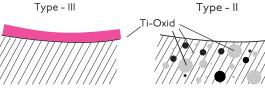
Dotize Type II anodization

Dotize®

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

Layer thickness 2000-10 000nm

- + Film becomes an interstitial part of the titanium
- No visible cosmetic effect



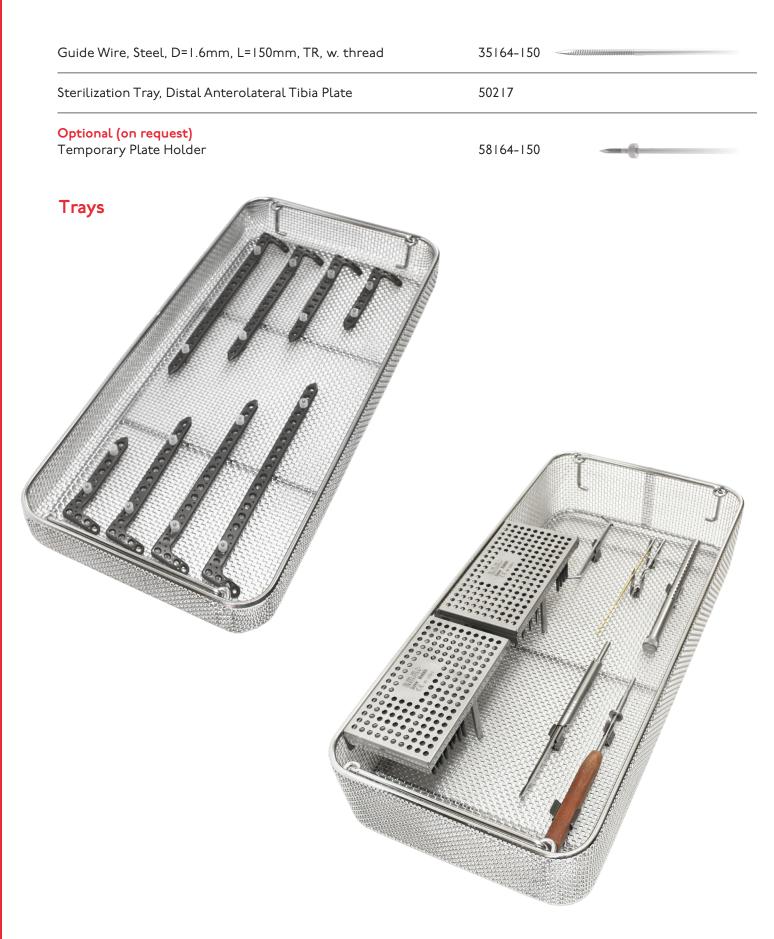
Anodization Type II leads to following benefits*

- 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



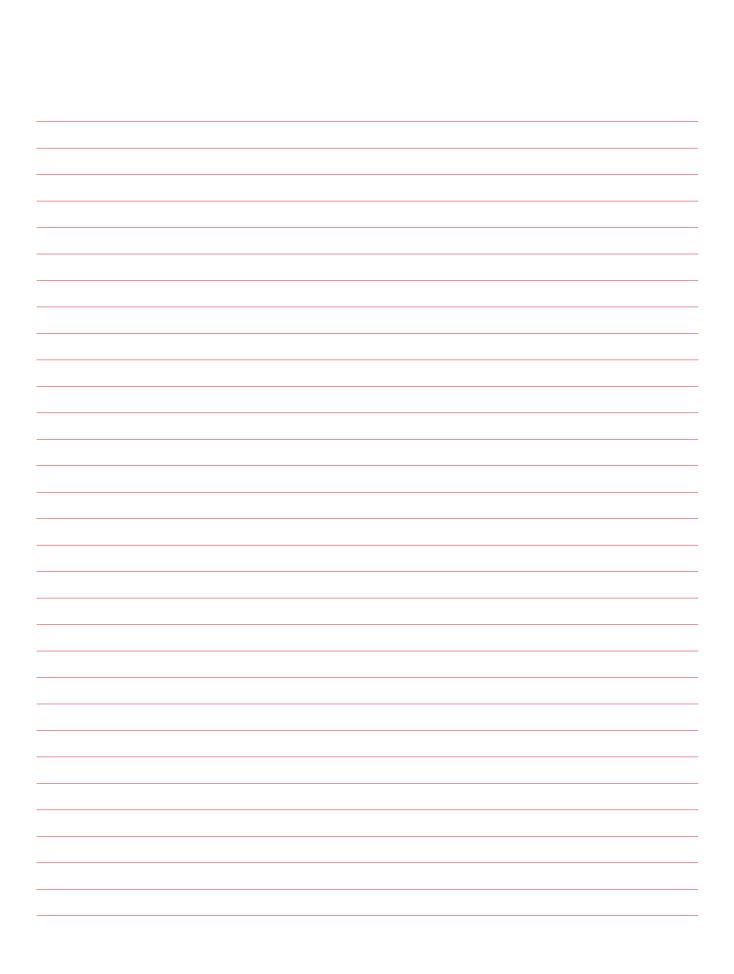
• Order list

Distal Anterolateral Tibia Plate, Right, 7-hole Distal Anterolateral Tibia Plate, Left, 7-hole Distal Anterolateral Tibia Plate, Right, 11-hole Distal Anterolateral Tibia Plate, Left, 11-hole Distal Anterolateral Tibia Plate, Right, 15-hole Distal Anterolateral Tibia Plate, Left, 15-hole Distal Anterolateral Tibia Plate, Right, 19-hole Distal Anterolateral Tibia Plate, Left, 19-hole	2 3 -7 2 3 2-7 2 3 -1 2 3 2-1 2 3 1-15 2 3 2-15 2 3 2-15 2 3 1-19 2 3 2-19	
Cortical Screw, D=3.5mm, L=24mm Cortical Screw, D=3.5mm, L=28mm Cortical Screw, D=3.5mm, L=32mm Cortical Screw, D=3.5mm, L=36mm Cortical Screw, D=3.5mm, L=40mm	32351-24 32351-28 32351-32 32351-36 32351-40	Juccesses
Cortical Screw, Locking, D=3.5mm, L=24mm, SH Cortical Screw, Locking, D=3.5mm, L=26mm, SH Cortical Screw, Locking, D=3.5mm, L=28mm, SH Cortical Screw, Locking, D=3.5mm, L=30mm, SH Cortical Screw, Locking, D=3.5mm, L=32mm, SH Cortical Screw, Locking, D=3.5mm, L=34mm, SH Cortical Screw, Locking, D=3.5mm, L=36mm, SH Cortical Screw, Locking, D=3.5mm, L=38mm, SH Cortical Screw, Locking, D=3.5mm, L=38mm, SH	37351-24-N 37351-26-N 37351-28-N 37351-30-N 37351-32-N 37351-34-N 37351-34-N 37351-36-N 37351-38-N 37351-40-N	
Cancellous Screw, Locking, D=4.2mm, L=18mm, SH Cancellous Screw, Locking, D=4.2mm, L=20mm, SH Cancellous Screw, Locking, D=4.2mm, L=22mm, SH Cancellous Screw, Locking, D=4.2mm, L=24mm, SH Cancellous Screw, Locking, D=4.2mm, L=26mm, SH Cancellous Screw, Locking, D=4.2mm, L=28mm, SH Cancellous Screw, Locking, D=4.2mm, L=30mm, SH Cancellous Screw, Locking, D=4.2mm, L=30mm, SH Cancellous Screw, Locking, D=4.2mm, L=34mm, SH Cancellous Screw, Locking, D=4.2mm, L=34mm, SH Cancellous Screw, Locking, D=4.2mm, L=36mm, SH Cancellous Screw, Locking, D=4.2mm, L=36mm, SH Cancellous Screw, Locking, D=4.2mm, L=36mm, SH Cancellous Screw, Locking, D=4.2mm, L=40mm, SH Cancellous Screw, Locking, D=4.2mm, L=40mm, SH Cancellous Screw, Locking, D=4.2mm, L=40mm, SH Cancellous Screw, Locking, D=4.2mm, L=44mm, SH Cancellous Screw, Locking, D=4.2mm, L=46mm, SH Cancellous Screw, Locking, D=4.2mm, L=46mm, SH Cancellous Screw, Locking, D=4.2mm, L=46mm, SH	37422-18-N 37422-20-N 37422-22-N 37422-24-N 37422-26-N 37422-28-N 37422-30-N 37422-30-N 37422-32-N 37422-34-N 37422-34-N 37422-40-N 37422-40-N 37422-40-N 37422-40-N 37422-40-N 37422-40-N 37422-40-N 37422-40-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 Spiral Drill, D=2.5mm, L=180mm, AO Connector	61273-100	



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





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