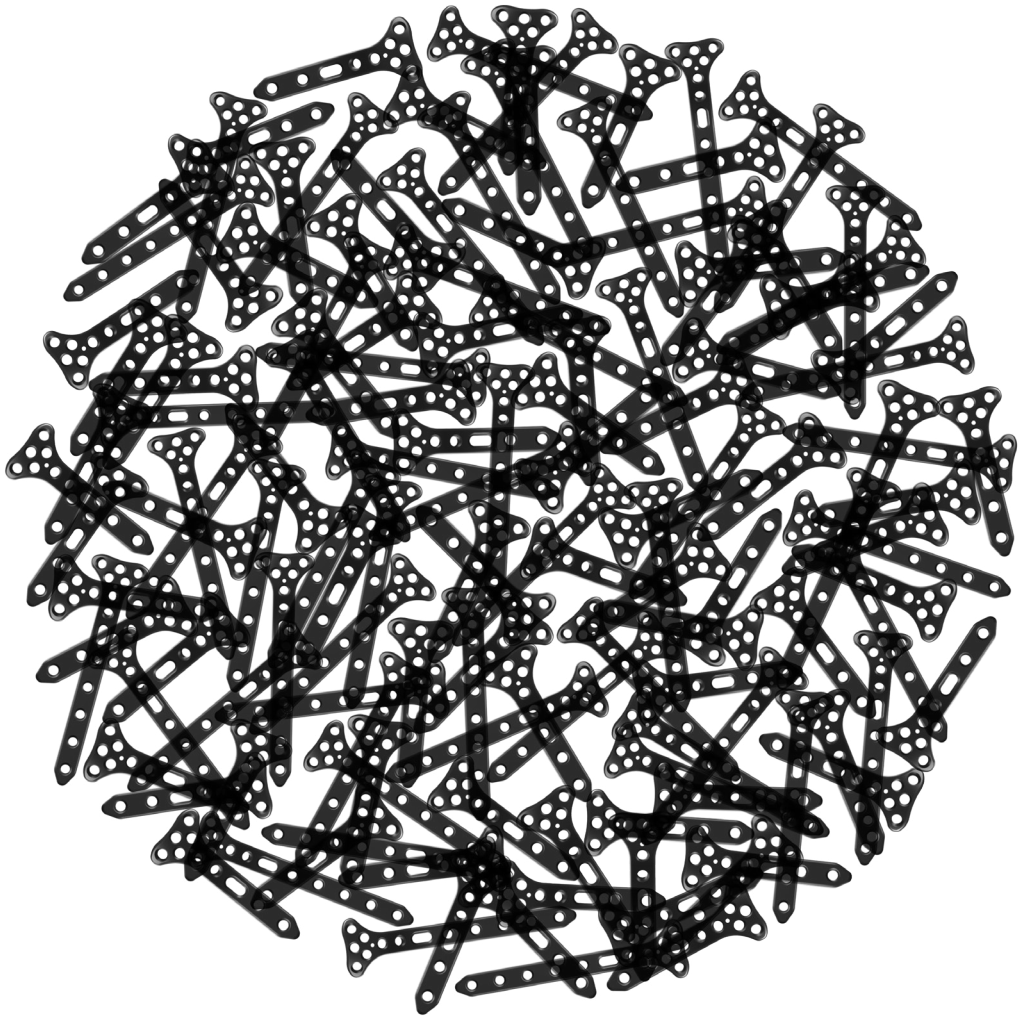
ITS.

Implants
trauma



PROMET

Proximal Medial Tibia 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

Preface

The Locking Proximal Medial Tibia Plate is an osteosynthesis system for various proximal tibia fractures, and can be used for complex C1 to C3 fractures in combination with the Proximal Lateral Tibia Plate.

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 (+/- 15°, see page 17) as well as the possibility to set several subchondral screws provides advantages especially in the case of complex fractures.

Screws

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

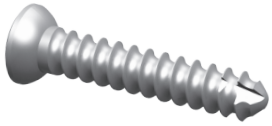
61273-220 Spiral Drill, D=2.7mm, L=220mm, AO Connector

56252 Screwdriver, WS 2.5, self-holding sleeve

32351-XX Cortical Screw, D=3.5mm

61273-220 Spiral Drill, D=2.7mm, L=220mm, AO Connector

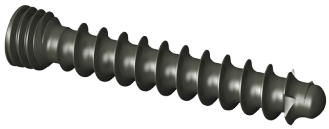
56252 Screwdriver, WS 2.5, self-holding sleeve



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

61253-220 Spiral Drill, D=2.5mm, L=220mm, AO Connector

56252 Screwdriver, WS 2.5, self-holding sleeve



35164-150 Guide Wire, Steel, D=1.6mm, L=150mm, TR, w. thread

Properties

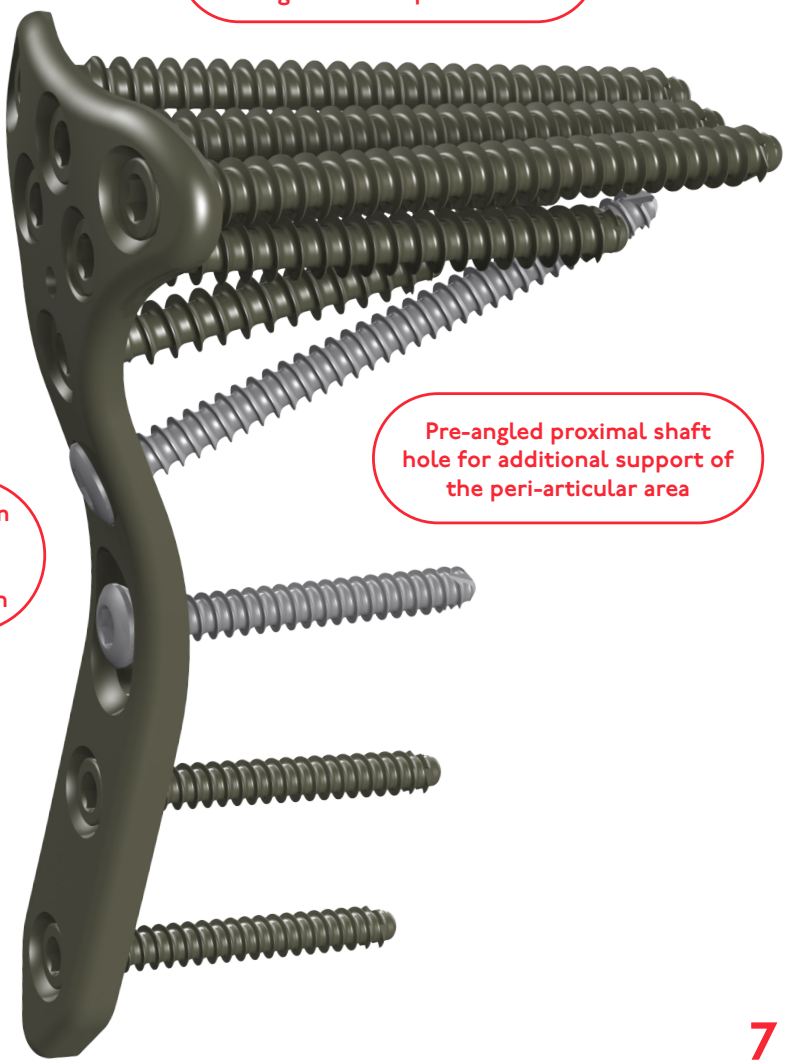
Properties of the material:

- 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
- 5 proximal plate holes for peri-articular fixation
- Oblong hole for optimal positioning and alignment of the tibia length
- Pointed distal plate end for percutaneous insertion

Lengths: 4, 7-hole

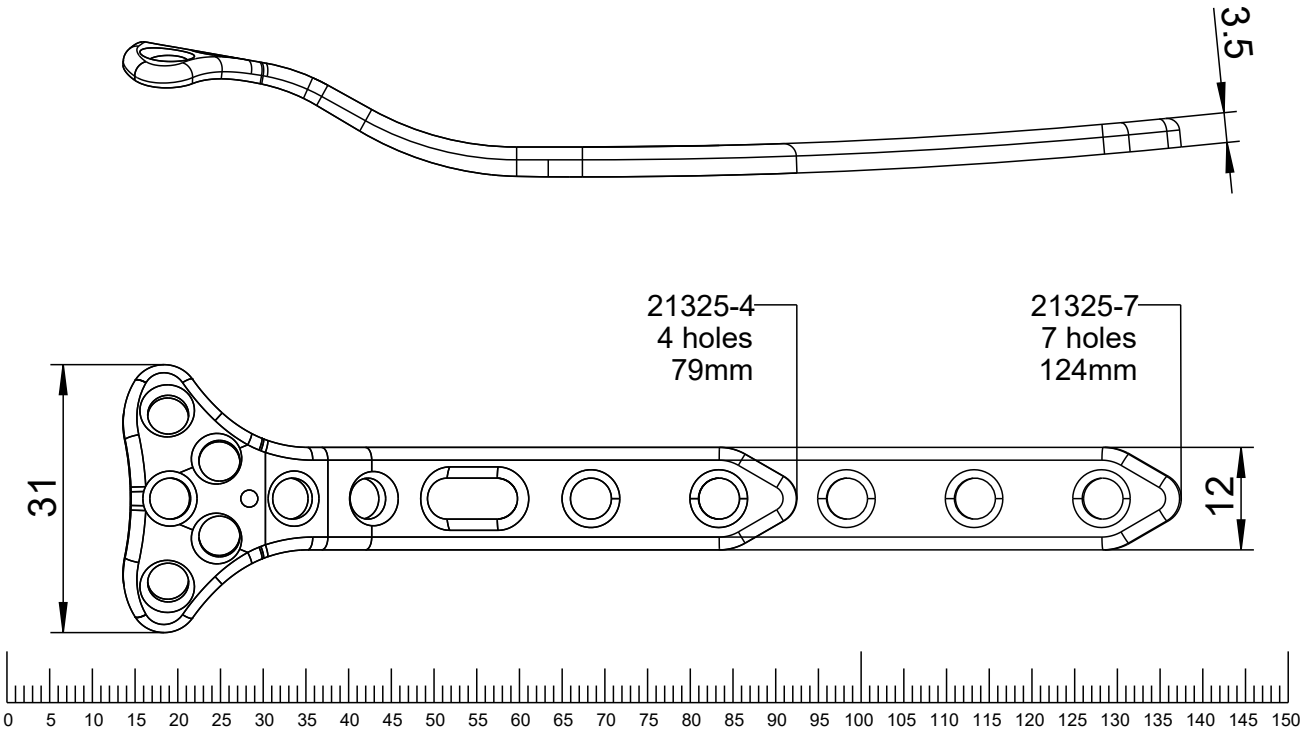


Locking screw placement parallel to joint to enable a rigid buttress platform

Pre-angled proximal shaft hole for additional support of the peri-articular area

Plate strength transition from 3.5mm to 2.0mm in the proximal part in order to minimize soft tissue irritation

Pre-operative planning



Indications, Contraindications

Indications:

- Buttress metapyhseal fractures of the medial tibia plateau
- Split fractures of the medial tibia plateau (with possible depressions)
- Stabilization of the proximal quarter of the tibia (medial and lateral)
- Complex CI-C3 fractures can be treated in combination with the PTL - Proximal Lateral Tibia Plate

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

Surgical Technique

2.

Time of operation

- Immediately after trauma or delayed

Pre-operative patient preparation

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

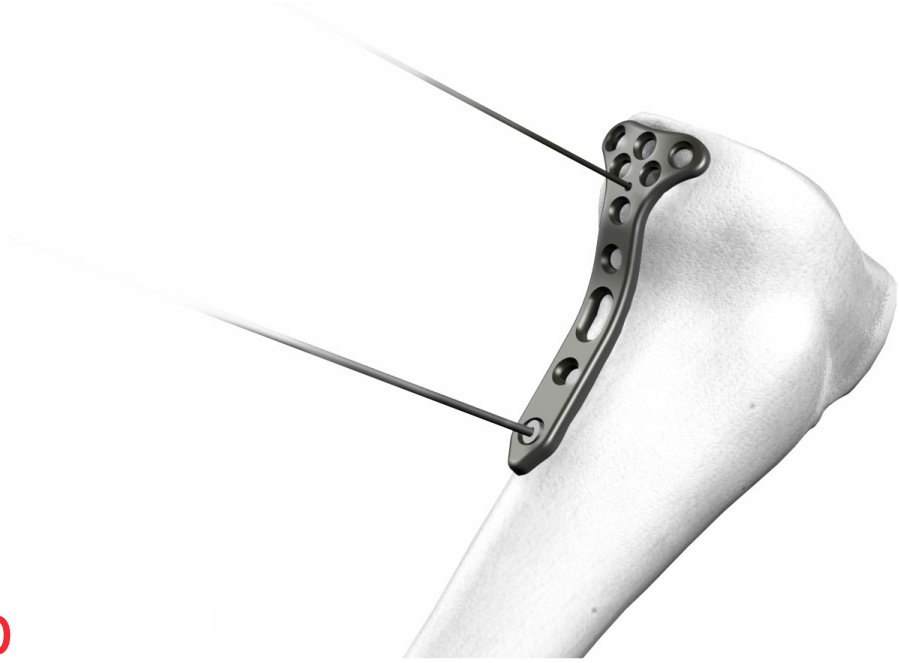
Access

Posteromedial incision:

- Straight or slightly curved incision between the hamstrings (pes ansernius) and gastrocnemius musle, running from the medial epicondyle towards the posteromedial edge of the tibia.

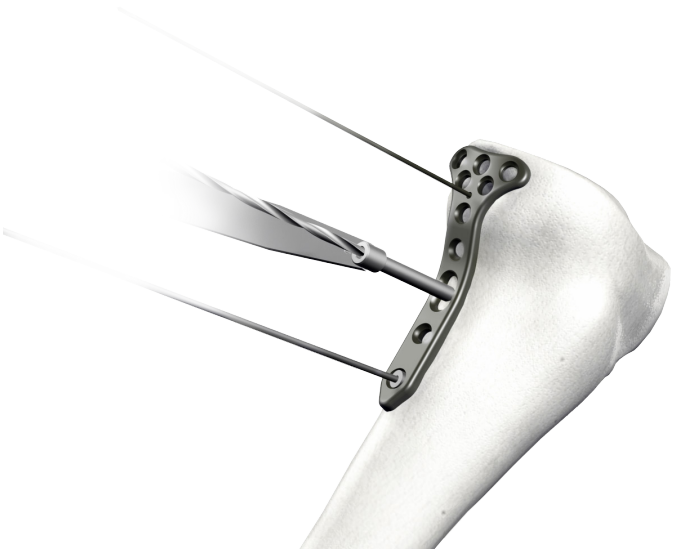
Reduction

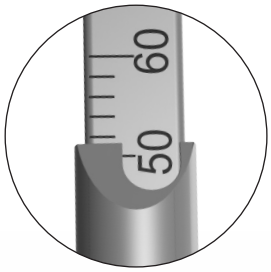
- Temporary fixation of the plate using guide wires or optionally available Temporary Plate Holder **(58164-150)**.
- Anatomical reduction of the articular block and fracture segments to the plate (varus/valgus, ante-/retroversion)
- Subsequent control under fluoroscopy

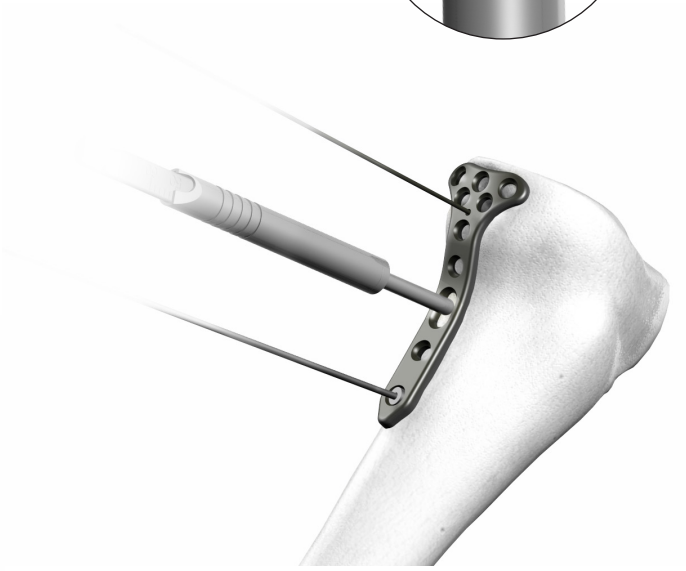


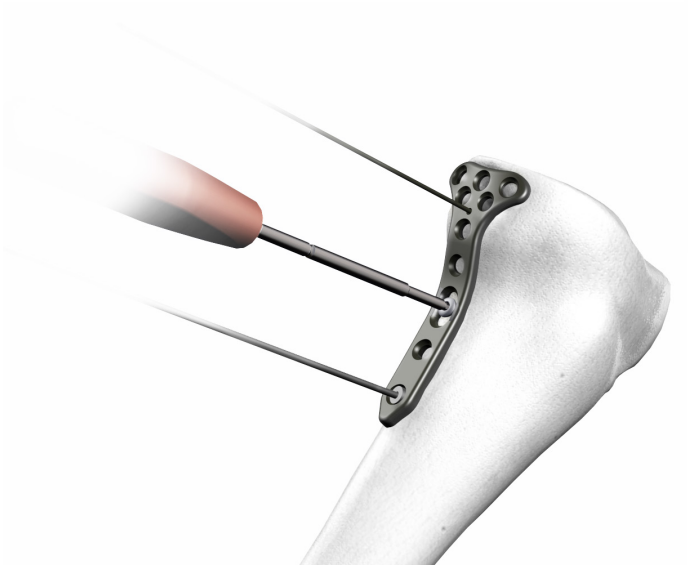
Placement of the screws

For optimal alignment of the length of reduction, we recommend to first fill the oblong hole.
With the spiral drill, D=2.7mm, L=220mm, AO Connector **(61273-220)**, 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 **(32351-XX)** with the screwdriver, WS 2.5, self-holding sleeve **(56252)**.

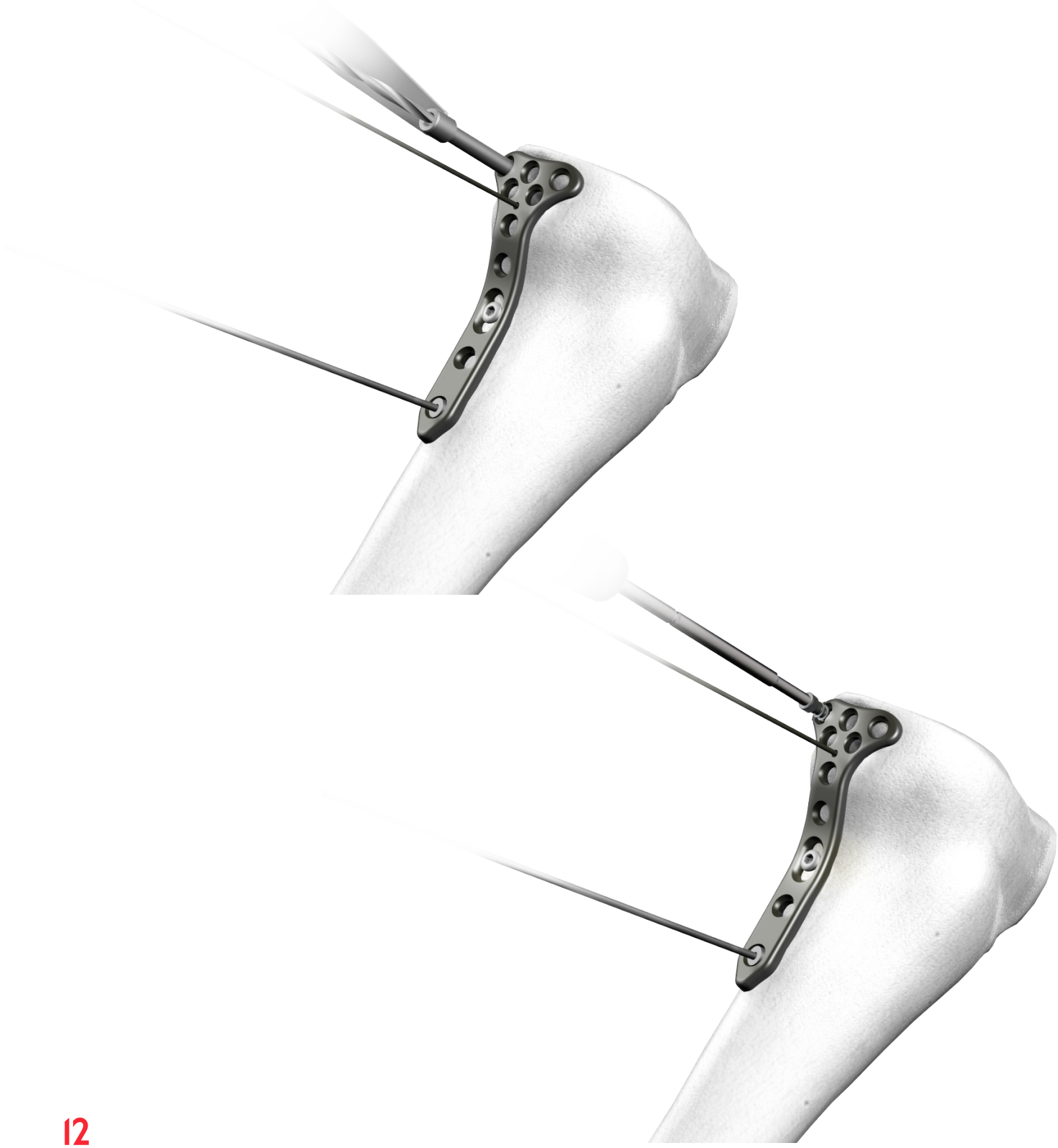




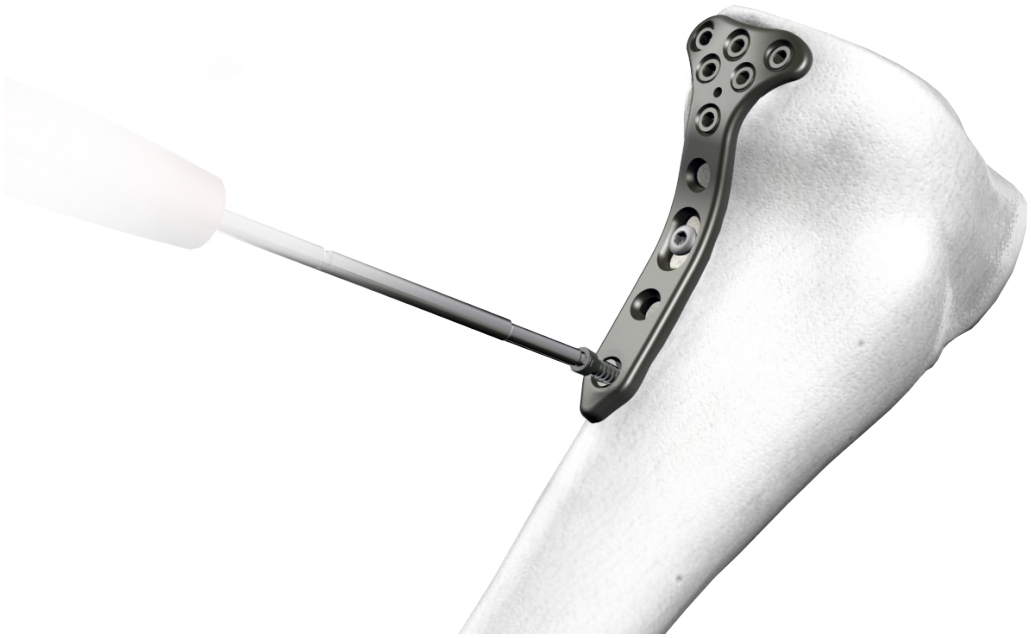




Then, using the spiral drill, D=2.5mm, L=220mm, AO Connector **(61253-220)**, drill through the drill guide, D=2.7/2.0mm **(62202)** into a proximal plate hole.
Determine appropriate length using the depth gauge, solid small fragment screws **(59022)**.
Insert the D=4.2mm locking cancellous screw **(37422-XX-N)** with the screwdriver, WS 2.5, self-holding sleeve **(56252)**.



Using the spiral drill, D=2.7mm, L=220mm, AO Connector **(61273-220)** 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, optionally locking **(32351-XX / 37351-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.

Postoperative treatment

- Keep leg raised for 2 to 5 days and take decongestant actions
- After reduction of swelling, beginning of the passive mobilization (CPM splint)
- No weight bearing in the treatment of articular fractures for a minimum of 10 to 12 weeks

- 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 17).

Information

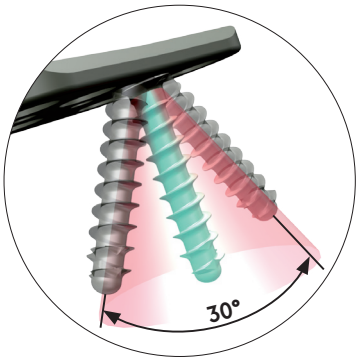
3.

Notes

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®

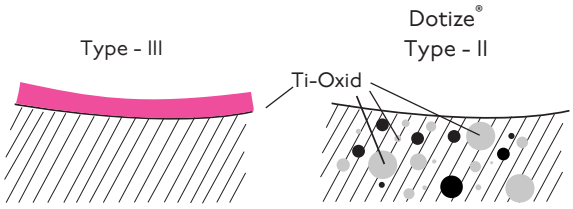
Chemical process - anodization in a strong alkaline solution*

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

Proximal Medial Tibia Plate, 4-Hole	21325-4
Proximal Medial Tibia Plate, 7-Hole	21325-7

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, 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, D=3.5mm, L=65mm	32351-65
Cortical Screw, D=3.5mm, L=70mm	32351-70
Cortical Screw, D=3.5mm, L=75mm	32351-75
Cortical Screw, D=3.5mm, L=80mm	32351-80
Cortical Screw, D=3.5mm, L=85mm	32351-85
Cortical Screw, D=3.5mm, L=90mm	32351-90

Cortical Screw, Locking, D=3.5mm, L=24mm, SH	37351-24-N
Cortical Screw, Locking, D=3.5mm, L=26mm, SH	37351-26-N
Cortical Screw, Locking, D=3.5mm, L=28mm, SH	37351-28-N
Cortical Screw, Locking, D=3.5mm, L=30mm, SH	37351-30-N
Cortical Screw, Locking, D=3.5mm, L=32mm, SH	37351-32-N
Cortical Screw, Locking, D=3.5mm, L=34mm, SH	37351-34-N
Cortical Screw, Locking, D=3.5mm, L=36mm, SH	37351-36-N
Cortical Screw, Locking, D=3.5mm, L=38mm, SH	37351-38-N
Cortical Screw, Locking, D=3.5mm, L=40mm, SH	37351-40-N
Cortical Screw, Locking, D=3.5mm, L=42mm, SH	37351-42-N
Cortical Screw, Locking, D=3.5mm, L=44mm, SH	37351-44-N
Cortical Screw, Locking, D=3.5mm, L=46mm, SH	37351-46-N
Cortical Screw, Locking, D=3.5mm, L=48mm, SH	37351-48-N
Cortical Screw, Locking, D=3.5mm, L=50mm, SH	37351-50-N
Cortical Screw, Locking, D=3.5mm, L=55mm, SH	37351-55-N
Cortical Screw, Locking, D=3.5mm, L=60mm, SH	37351-60-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
Cancellous Screw, Locking, D=4.2mm, L=55mm, SH	37422-55-N
Cancellous Screw, Locking, D=4.2mm, L=60mm, SH	37422-60-N
Cancellous Screw, Locking, D=4.2mm, L=65mm, SH	37422-65-N
Cancellous Screw, Locking, D=4.2mm, L=70mm, SH	37422-70-N
Cancellous Screw, Locking, D=4.2mm, L=75mm, SH	37422-75-N
Cancellous Screw, Locking, D=4.2mm, L=80mm, SH	37422-80-N
Cancellous Screw, Locking, D=4.2mm, L=85mm, SH	37422-85-N
Cancellous Screw, Locking, D=4.2mm, L=90mm, SH	37422-90-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=2.5mm, L=220mm, AO Connector	61253-220 
Spiral Drill, D=2.7mm, L=220mm, AO Connector	61273-220
Guide Wire, Steel, D=1.6mm, L=150mm, TR, w. Thread	35164-150
Sterilization Tray, Proximal Medial Tibia Plate	50280
Optionally (on request) Temporary Plate Holder	58164-150 

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

* All implants are available sterile-packed optionally.
Add „-S" to article number for sterile-packed implants (ex. 37304-12-S; 21031-3-S)
Delivery times, prices & minimum quantity vary from standard.

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