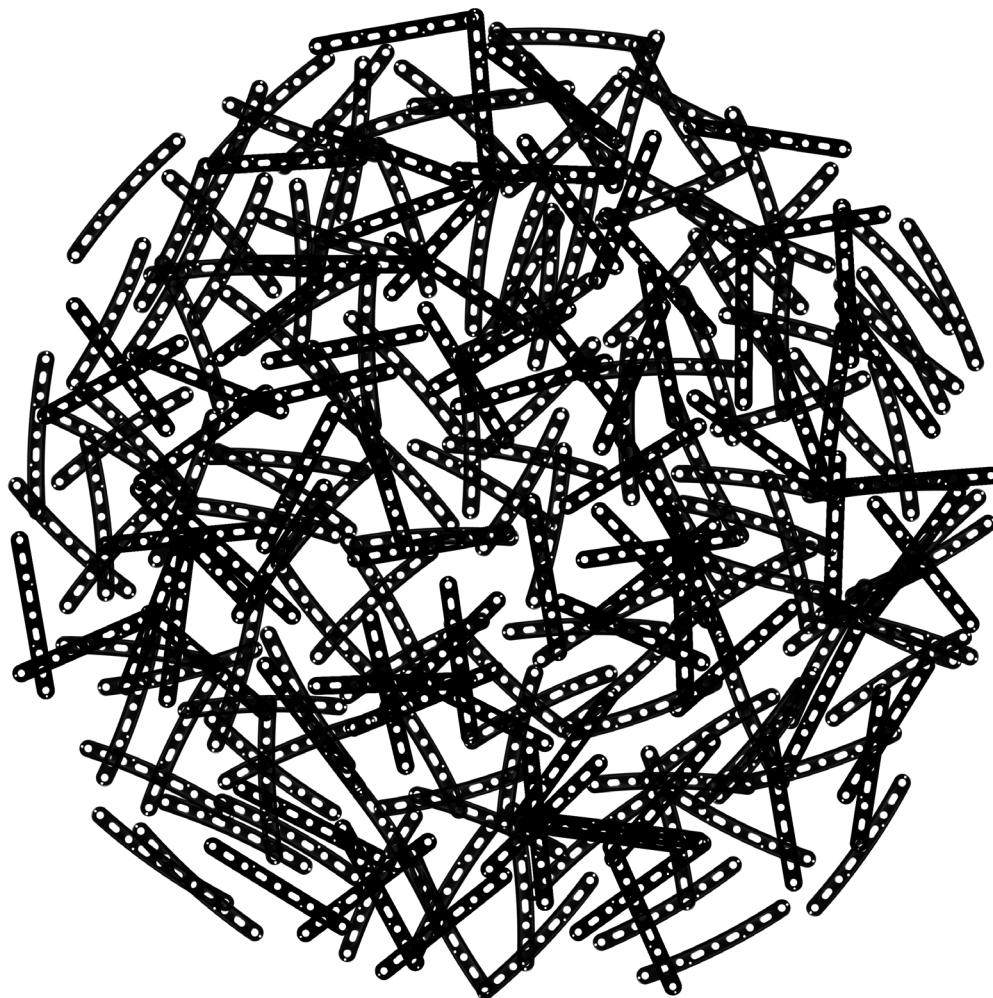


ITS.

Implants
trauma



UFS

Universal Forearm 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.

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- P. 8 Indications & Contraindications
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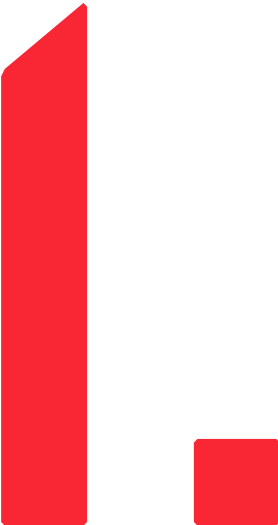
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Introduction



○ Preface

The Universal Forearm Locking Plates System is an osteosynthesis system for various forearm shaft 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 15) provides an advantage in fracture treatment, especially in the case of complex fractures.



○ Screws

3735I-XX-N Cortical Screw, Locking, D=3.5mm, SH

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

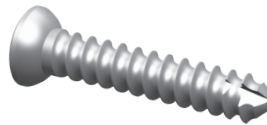
56252 Screwdriver, WS 2.5,
self-holding sleeve



3235I-XX Cortical Screw, D=3.5mm

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

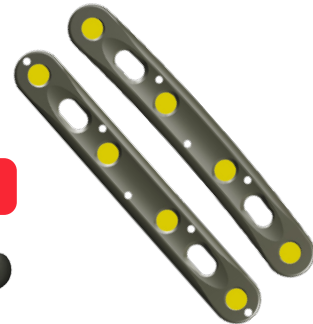
56252 Screwdriver, WS 2.5,
self-holding sleeve



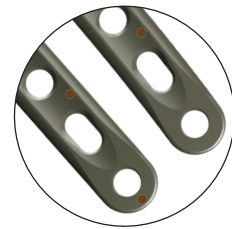
37422-XX-N Cancellous Screw, locking, D=4.2mm, SH

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

56252 Screwdriver, WS 2.5,
self-holding sleeve



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



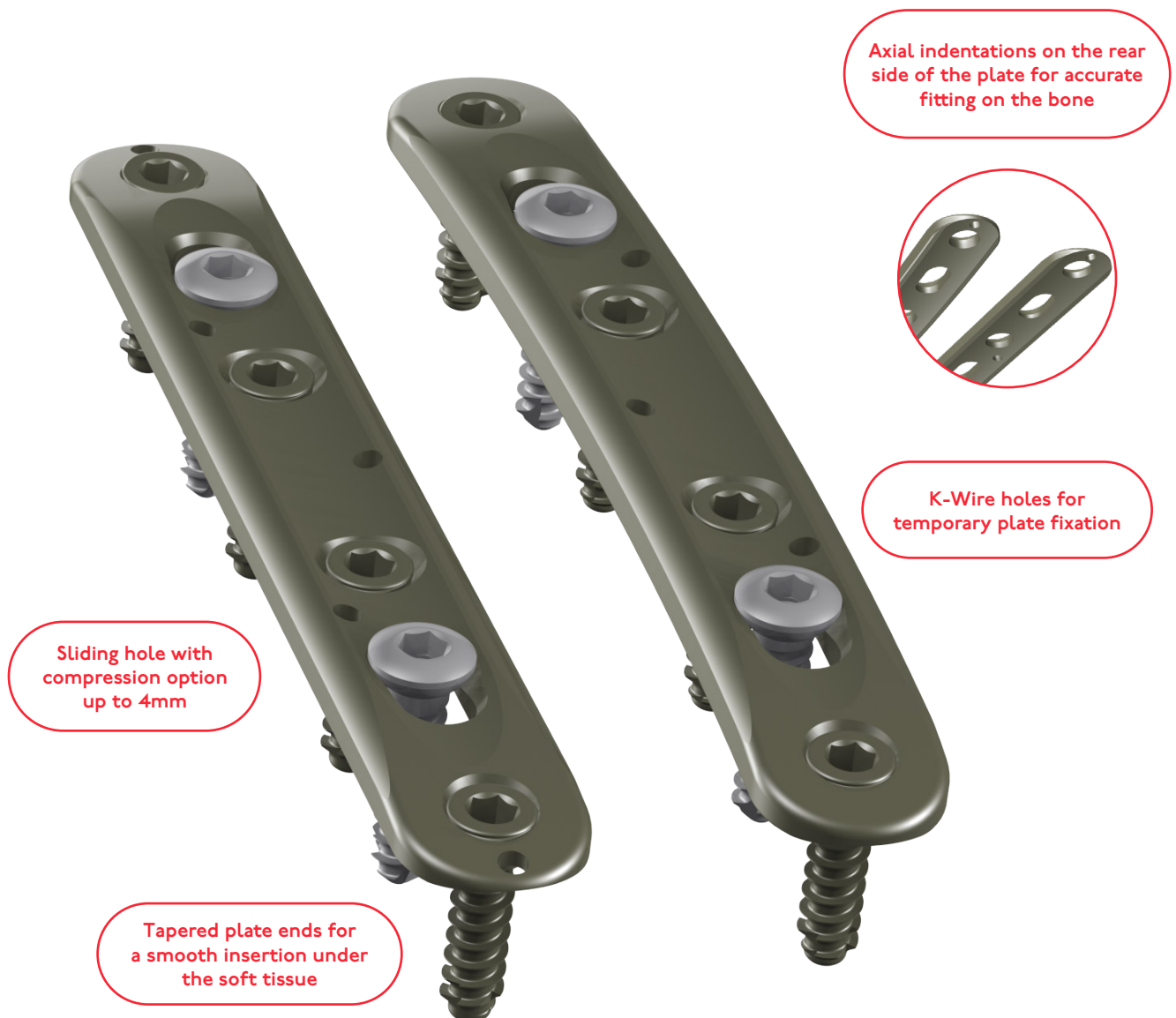
○ Properties

Properties of the material:

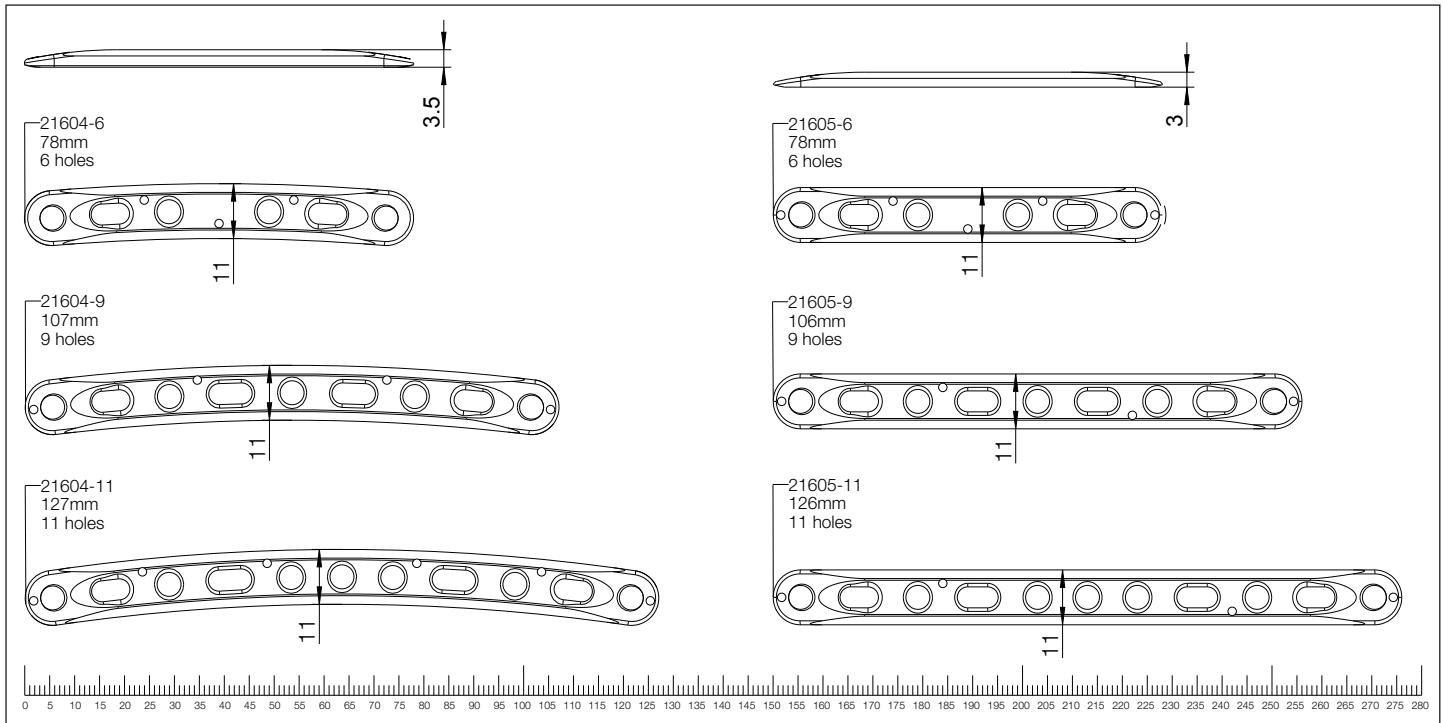
- ◆ Plate material: Titanium
- ◆ Material of screws: TiAl6V4 ELI
- ◆ Easier removal of the implant after the fracture has healed
- ◆ Improved fatigue strength of the implant
- ◆ Reduced risk of cold welding
- ◆ Reduced risk of inflammation and allergy

Properties of the implant:

- ◆ Multi-directional Locking
- ◆ Low-profile design
- ◆ Free choice of plate position (volar, dorsal, radial, ulnar)
- ◆ Straight and curved version adapted to the forearm anatomy
- ◆ Plate lengths: 6, 9, 11-hole
- ◆ Plate strength straight: 3.0mm
- ◆ Plate strength curved: 3.5mm



○ Pre-operative planning



○ Indications, Contraindications & Time of operation

Indications:

- ◆ For treatment of fractures, osteotomies and degenerative transformations.
Primary: radius, ulna; secondary: fibula
- ◆ Pediatric humeral and tibia fractures
- ◆ Comminuted fractures, supercondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, nonunions, and malunions. And as well, a fracture or osteotomy of the tibia, fibula, femoral, condyle, acetabulum, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; hip arthrodesis, and provisional hole fixation.

Contraindications:

- ◆ The plates are not intended for shaft fractures of large bones such as humerus, femur and tibia (except pediatric humeral and tibia fractures)
- ◆ 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

Contraindications:

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Time of operation:

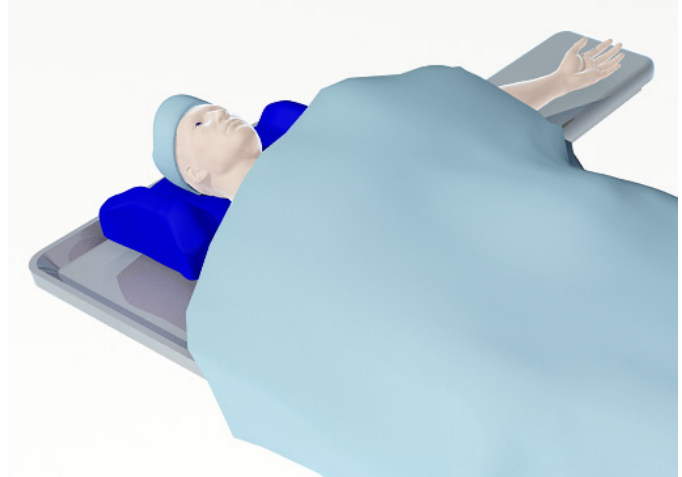
- ◆ Immediately after trauma or delayed
- ◆ After regression of swelling

Surgical Technique

2.

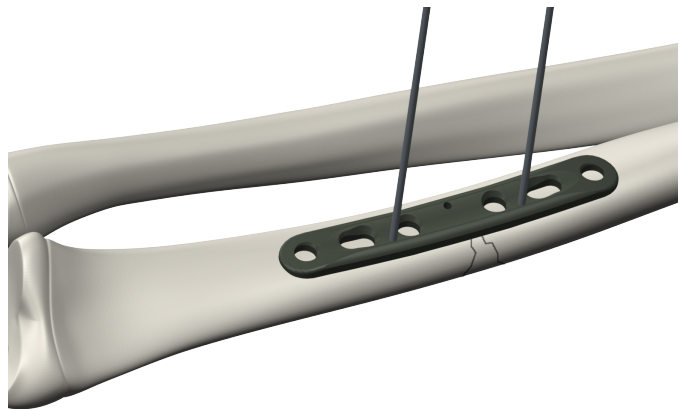
○ Pre-operative patient preparation

- ◆ The patient is placed in the supine position with pneumatic deprivation of blood supply
- ◆ The arm is positioned on a radiolucent surgical table

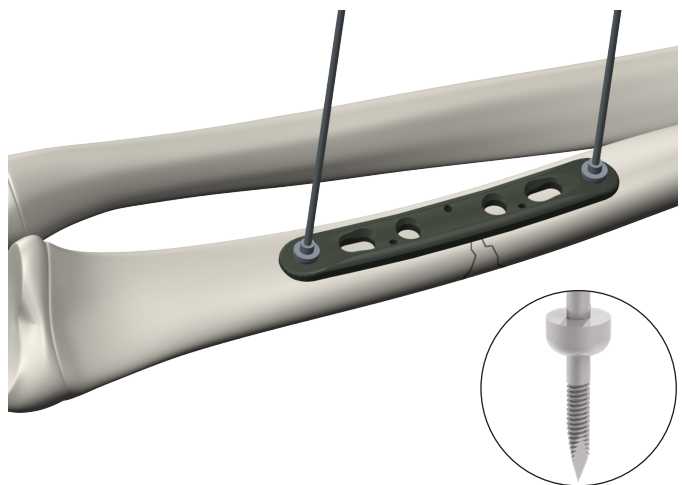


○ Reduction

- ◆ Temporary fixation of the plate using guide wires
- ◆ Anatomical reduction of the fracture segments to the plate
- ◆ Subsequent control under fluoroscopy



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

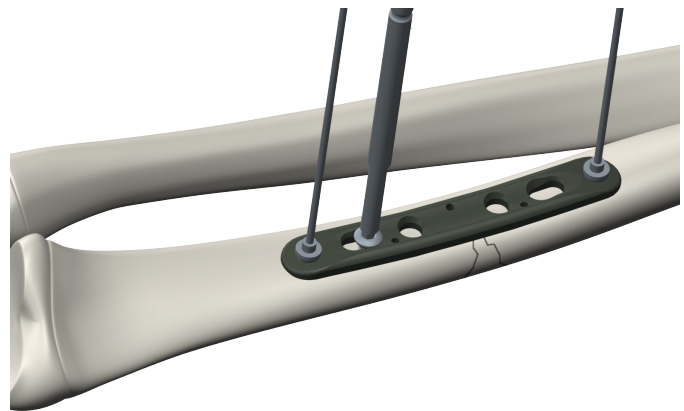
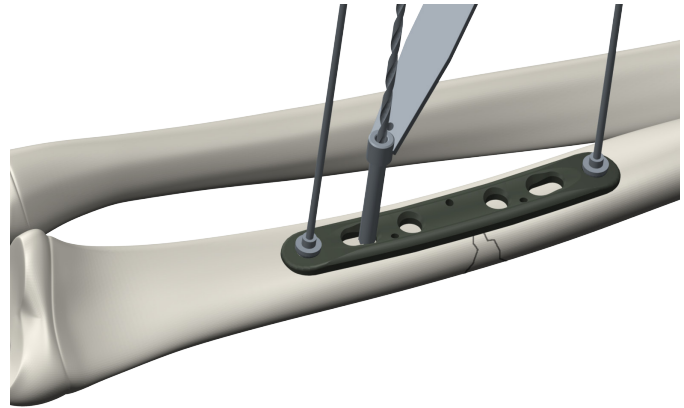


○ Placement of the screws

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 distal compression hole.

Determine appropriate length using the depth gauge, solid small fragment screws (**59022**).

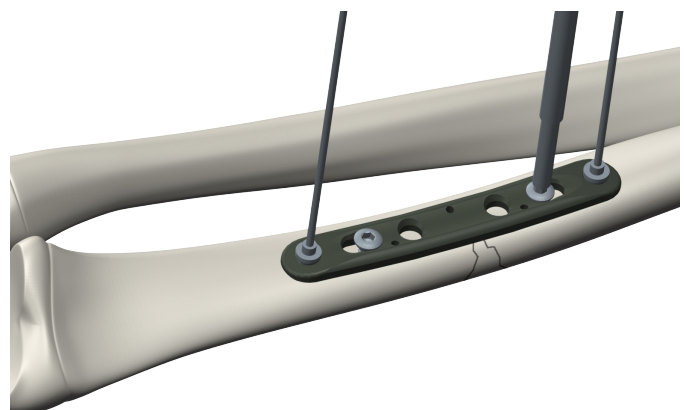
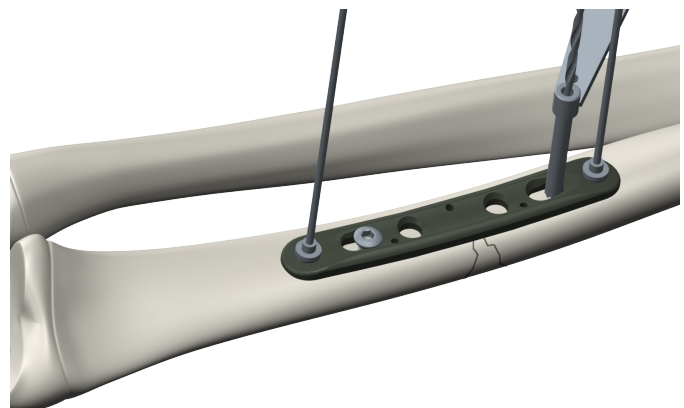
Insert the D=3.5mm cortical screw (**3235I-XX**) with the screwdriver, WS 2.5, self-holding sleeve (**56252**).



Then, 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 the proximal compression hole.

Determine appropriate length using the depth gauge, solid small fragment screws (**59022**).

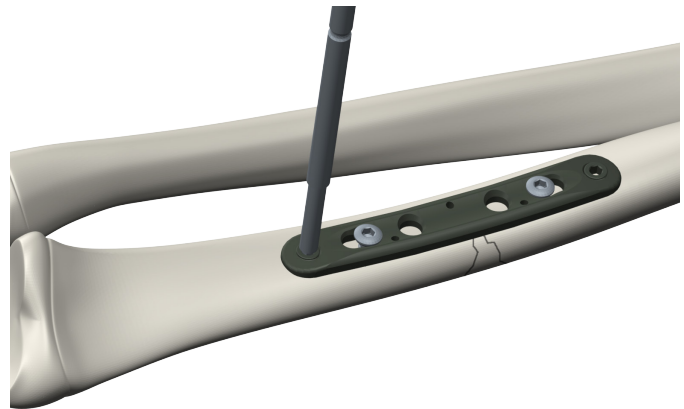
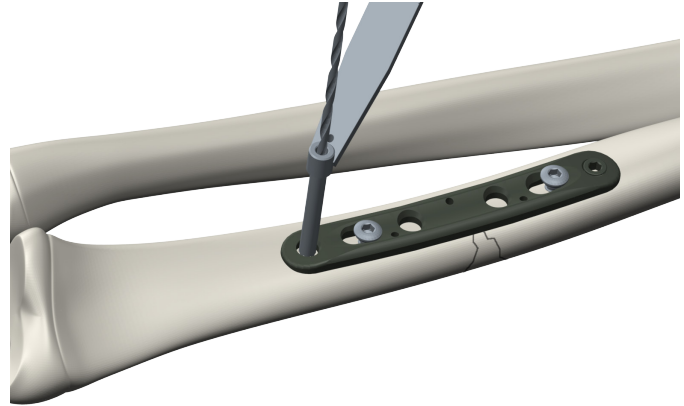
Insert the D=3.5mm cortical screw (**3235I-XX**) with the screwdriver, WS 2.5, self-holding sleeve (**56252**).



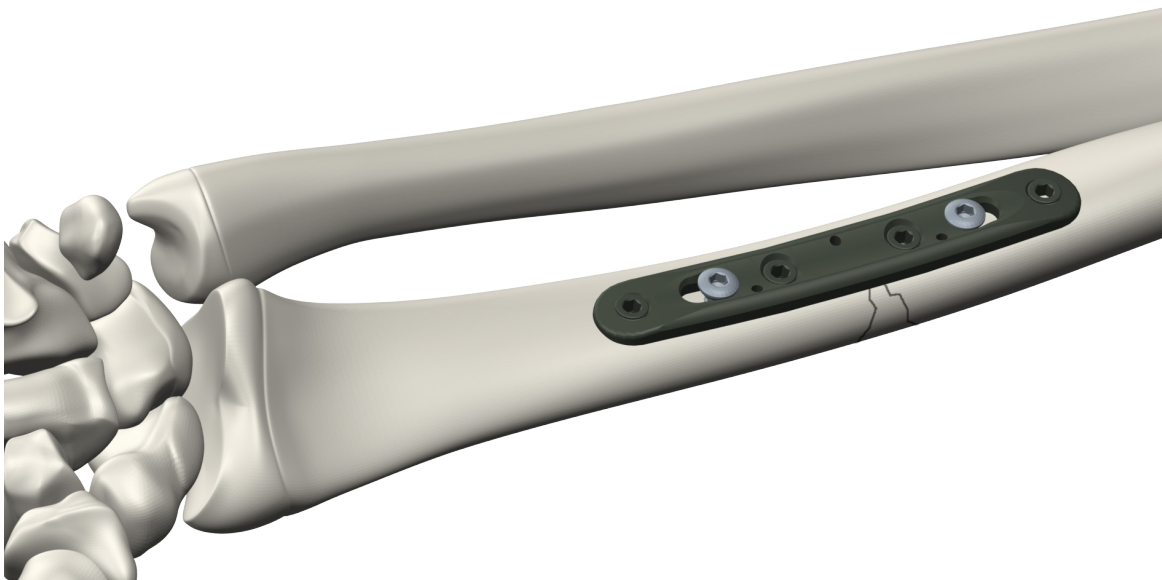
Using the spiral drill, D=2.7mm, L=100mm, AO Connector (**61273-100**) drill through the drill guide, D=2.7/2.0mm (**62202**) into the most distal plate hole.

Determine appropriate length using the depth gauge, solid small fragment screws (**59022**).

Insert the D=3.5mm cortical screw (**3235I-XX**) or the D=3.5mm locking cortical screw (**3735I-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

- Physical therapy immediately following surgery (no immobilization required)
- In case of poor bone quality or insecure fixation, movement fixator for a maximum of 6 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 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 15).

Information

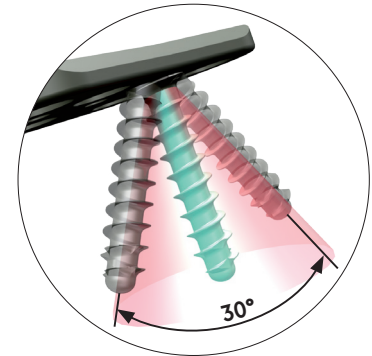
3.



○ 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:

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

○ Dotize®

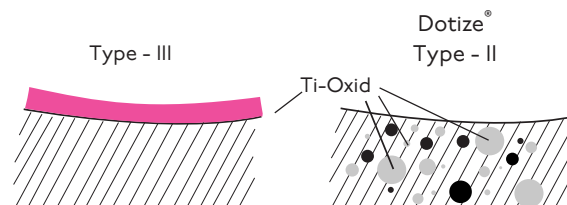
Chemical process - anodization in a strong alkaline solution*

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

Forearm Plate, Curved, 6-Hole	21604-6	
Forearm Plate, Curved, 9-Hole	21604-9	
Forearm Plate, Curved, 11-Hole	21604-11	
Forearm Plate, Straight, 6-Hole	21605-6	
Forearm Plate, Straight, 9-Hole	21605-9	
Forearm Plate, Straight, 11-Hole	21605-11	
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=22mm	32351-22	
Cortical Screw, D=3.5mm, L=24mm	32351-24	
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	
Cortical Screw, Locking, D=3.5mm, L=22mm, SH	37351-22-N	
Cortical Screw, Locking, D=3.5mm, L=24mm, SH	37351-24-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	
Guide Wire, Steel, D=1.6mm, L=150mm, TR, w. thread	35164-150	
Sterilization Tray, Forearm Plates System		

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	

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

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

61253-180



Temporary Plate Holder

58164-150





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