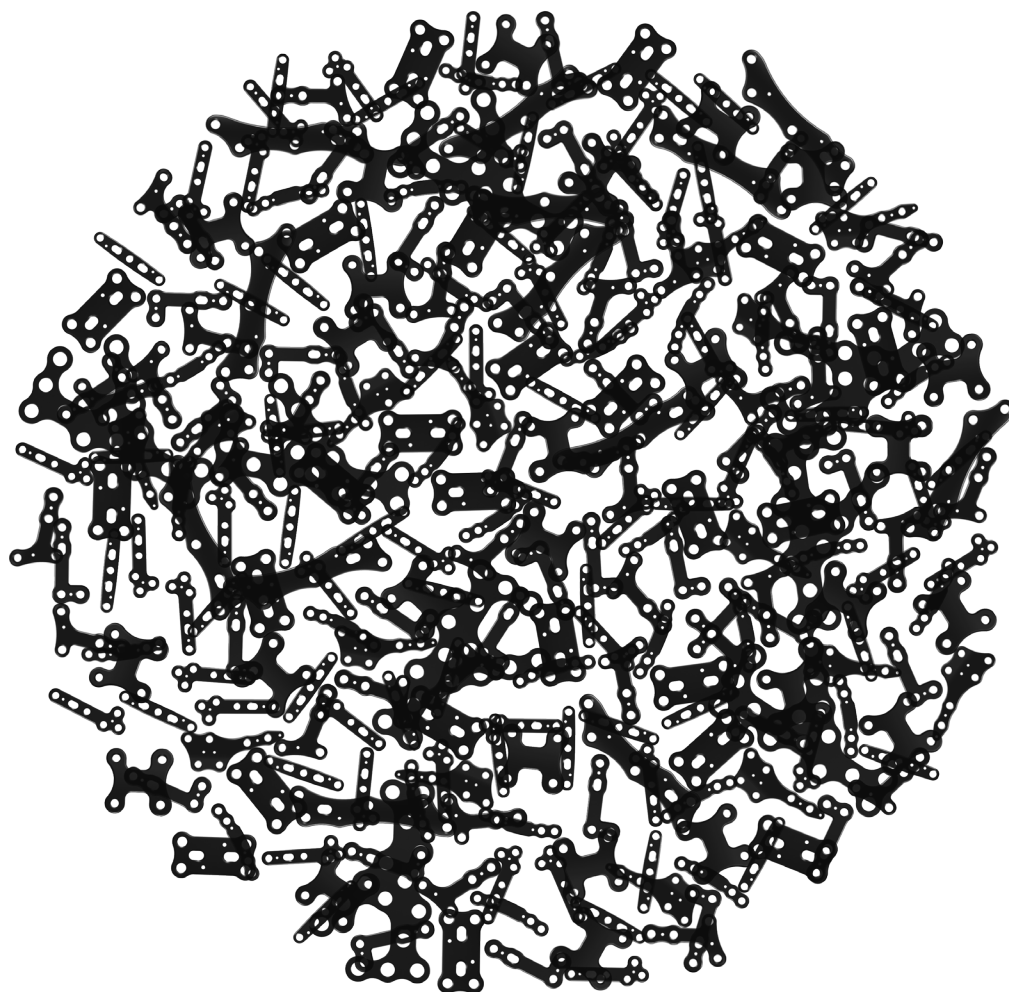


ITS.

Implants
trauma



FLS

Foot 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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Introduction



○ Preface

The FLS - Foot Locking System from I.T.S. is a proven osteosynthesis system with various plate types covering a wide range of indications for fractures of the foot.

The special feature of these implants 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 in the compression 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 - Foot Locking Plates System

3227I-XX Cortical Screw, D=2.7mm

61203-100 Spiral Drill, D=2.0mm, L=100mm, AO Connector

54095-100 Torque-Shank, T9x100, AO Connector

37304-XX Cortical Stabilization Screw, D=3.0mm, RH

61243-100 Spiral Drill, D=2.4mm, L=100mm, AO Connector

54095-100 Torque-Shank, T9x100, AO Connector

37303-XX Cancellous Stabilization Screw, D=3.0mm, RH

61203-100 Spiral Drill, D=2.0mm, L=100mm, AO Connector

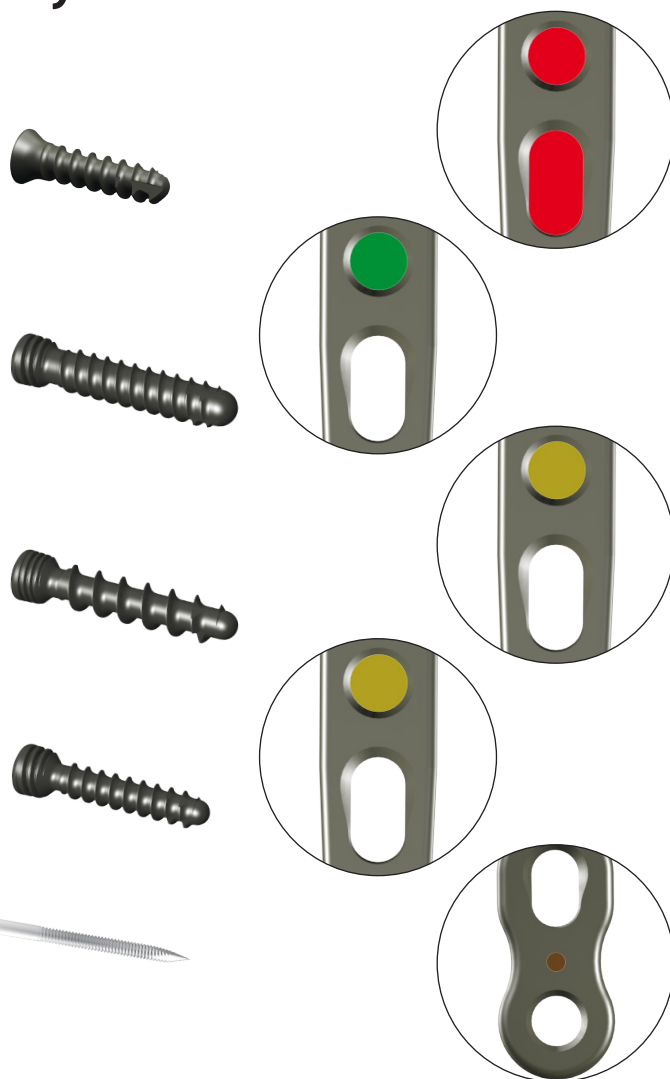
54095-100 Torque-Shank, T9x100, AO Connector

3724I-XX Stabilization Screw, D=2.4mm, RH

61183-100 Spiral Drill, D=1.8mm, L=100mm, AO Connector

54095-100 Torque-Shank, T9x100, AO Connector

35124-180 Guide Wire, Steel, D=1.2mm,
L=180mm, TR, w. thread



○ Screws - Calcaneus Locking Plate

3235I-XX Cortical Screw, D=3.5mm

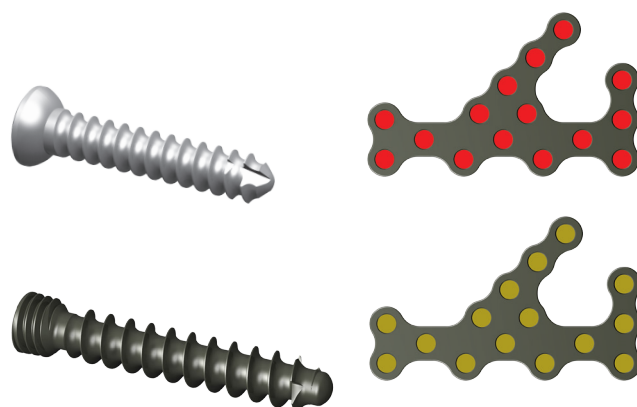
61273-100 Spiral Drill, D=2.7mm, L=100mm, AO Connector

54253-100 Hexagon-Shank, WS 2.5, L=100mm, AO Connector

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

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

54253-100 Hexagon-Shank, WS 2.5, L=100mm, AO Connector



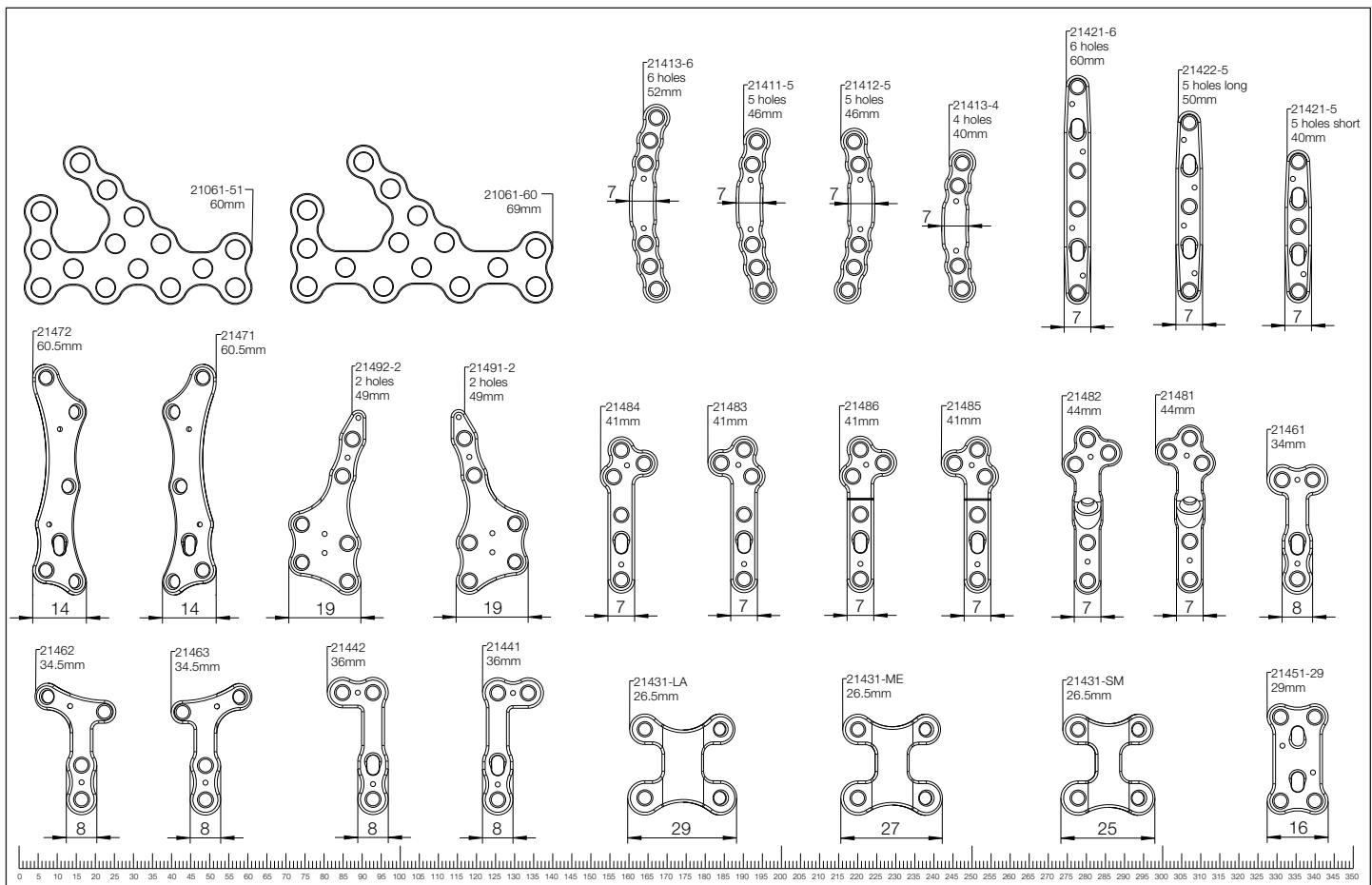
○ Properties

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:

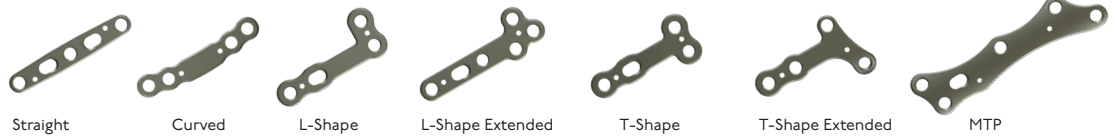
- Multi-directional locking
- Anatomical plate design
- Minimization of soft tissue irritation due to anatomical plate design
- K-Wire holes for preliminary plate fixation
- FLS Plate Straight, Square, L-Shape, L-Shape Extended, L-Shape Extended Imm Step, MTP, T-Shape: Sliding hole with compression option (to create tension)
- Plate strength: 1.5mm



Indications & Contraindications

Indications:

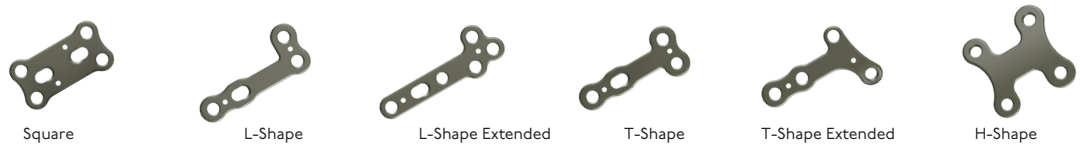
Metatarsal Fractures:



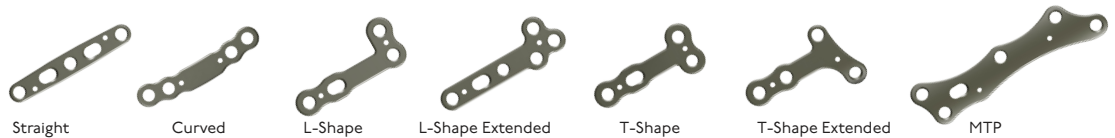
TMT I Arthrodesis:



TMT II-V Arthrodesis:



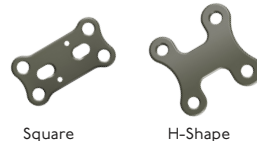
MTP I Arthrodesis:



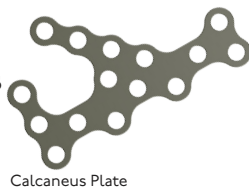
MTP II-V Arthrodesis:



TN, CC Arthrodesis:



Complex fractures of the Calcaneus



Corrective Osteotomies

Contraindications:

- Existing infections in the fracture zone and operation area
- Common situations that do not allow osteosynthesis
- With advanced osteoporosis
- Skin and soft-tissue problems which prevent a tension-free closure of the skin
- Obesity
- Lack of patient compliance

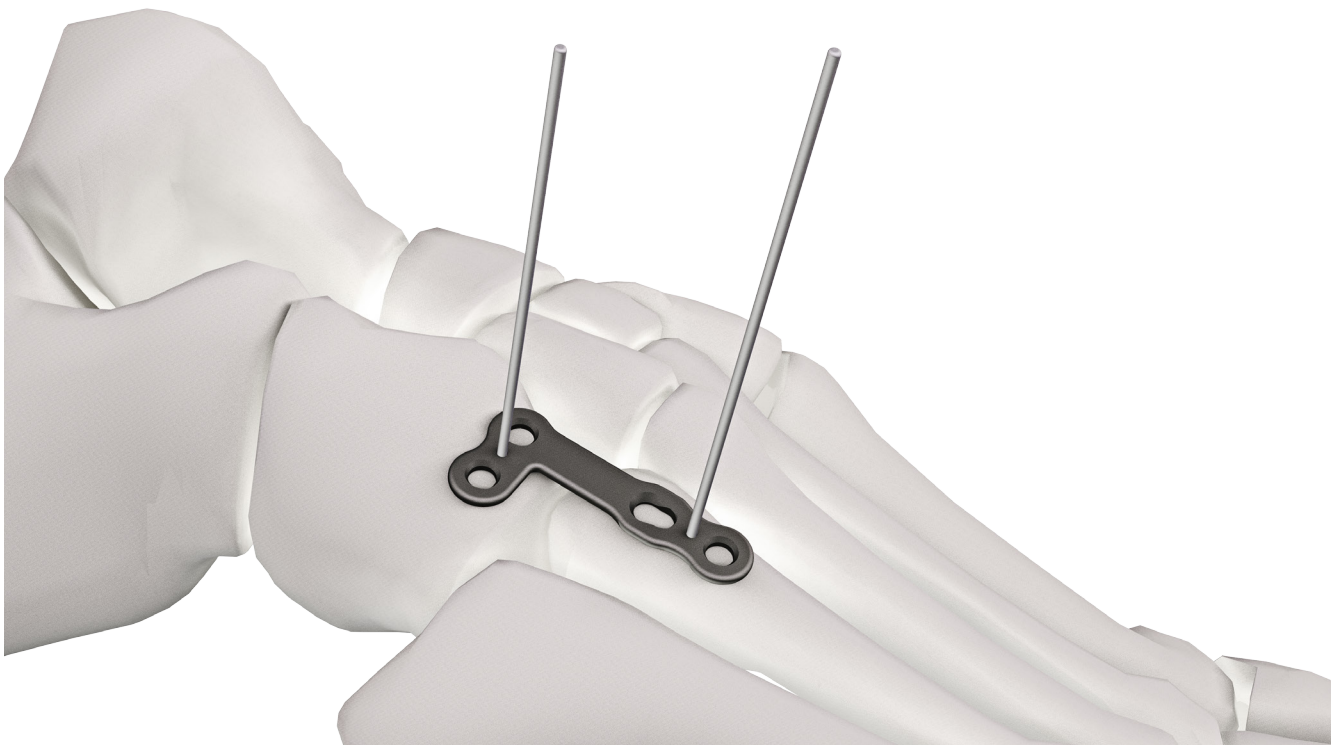
2.

◦ FLS Plate L-Shape

Example of use of a FLS Plate L-Shape at a tarsometatarsal joint IV arthrodesis.

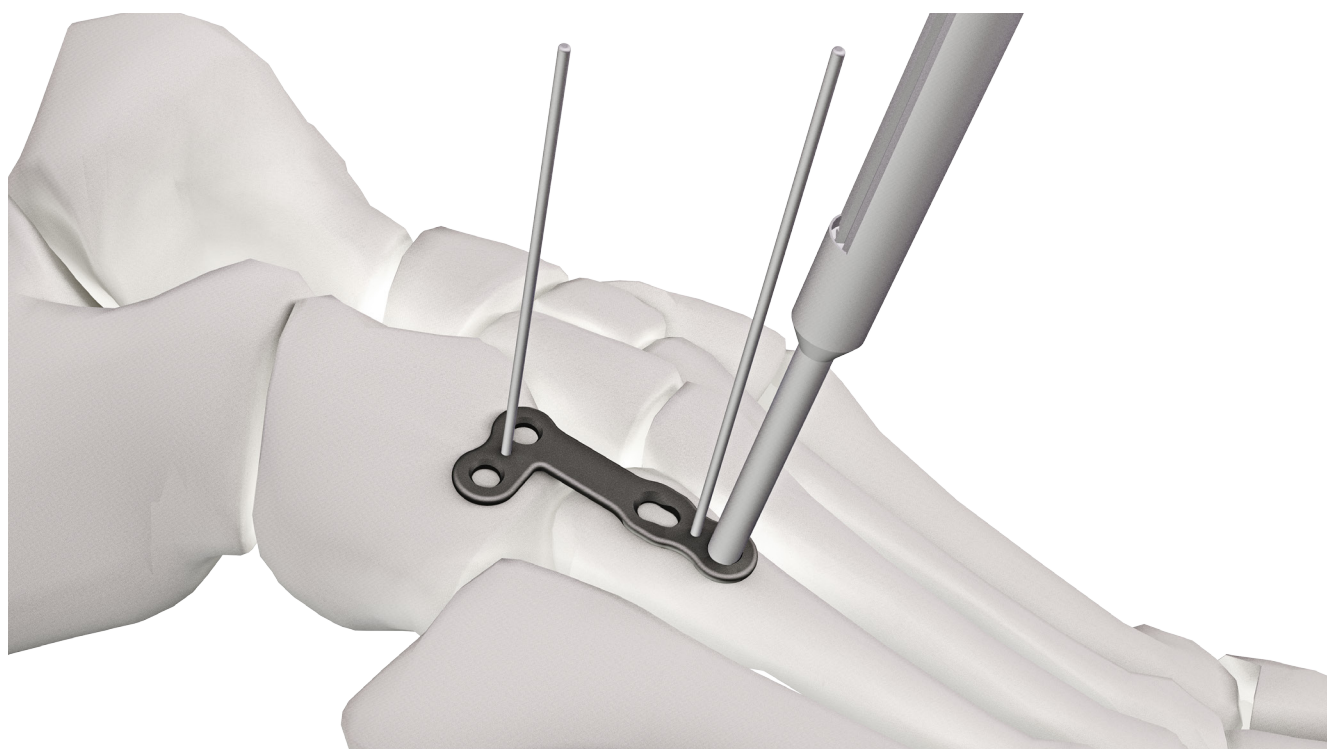
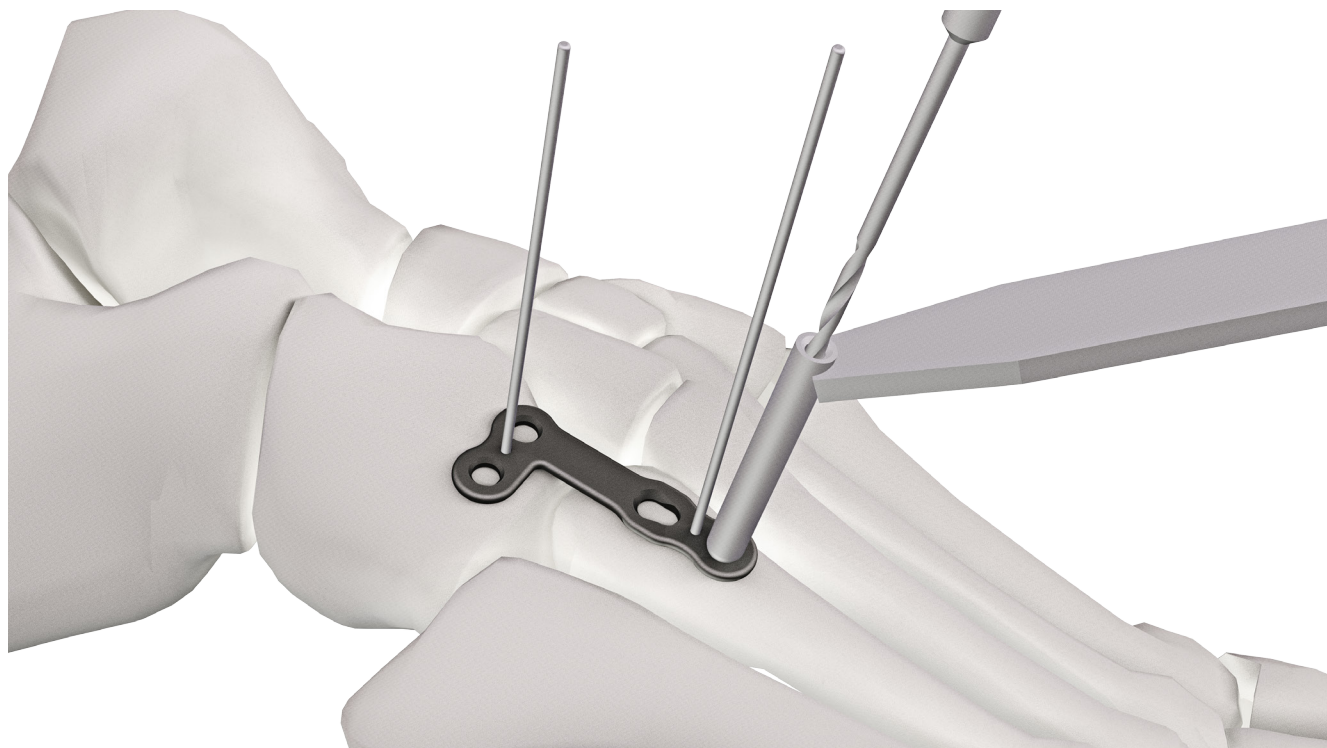
◦ Temporary fixation with K-Wires

- After an anatomical reduction of the fracture segments is achieved, the implant is chosen and if required, its shape can be further contoured
- Temporary fixation of the plate using guide wires, Steel, D=1.2mm, L=180mm, TR, w. thread (**35124-180**)
- Subsequent control under fluoroscopy

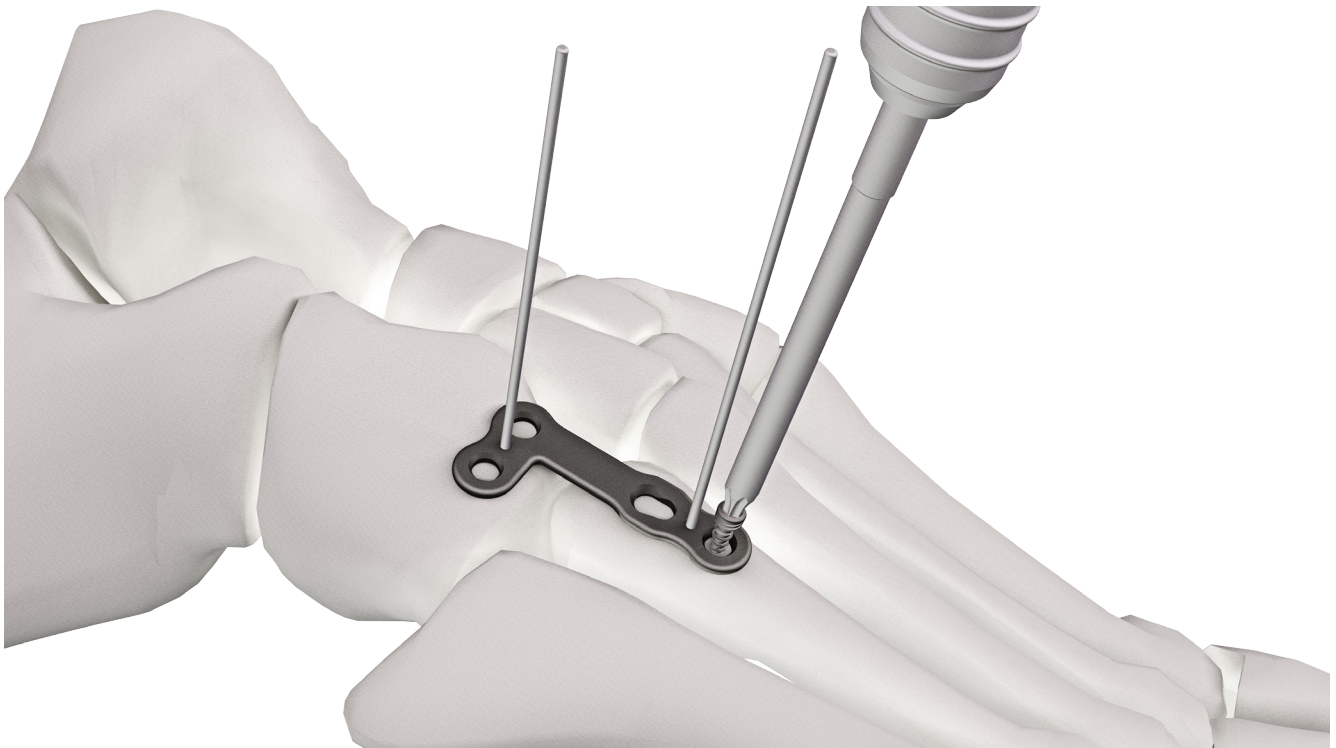


○ Placement of the screws

Use the spiral drill to drill through the drill guide, D=2.0/2.4mm **(62215)** (bore diameter depends on the choice of screw, for more information see page 6). Determine appropriate length using the depth gauge, PROlock II **(59026)**.



Then insert one of the four screwtypes with the Torque-Shank screwdriver, T9x100, AO Connector (**54095-100**).



Afterwards the remaining plate holes are filled, with either locking or non-locking screws. Subsequent control of plate position under fluoroscopy.



◦ Postoperative treatment

- Elevation and preventative edema measures on the day of the operation
- Mobilization with forefoot relief shoe
- Free weightbearing according to symptoms and stipulations of the operating surgeon

◦ Explantation

- Removal is possible, if desired by the patient. This is facilitated by the fact that cold welding never occurs.
- Implant removal is performed after radiographic verification, vice versa of implantation
- Skin incision following the old scar
- Remove the screws with the Torque-Shank screwdriver, T9xI00 **(54095-I00)**
- The problem of cold welding was resolved by using a special surface treatment (for further information see page I5)

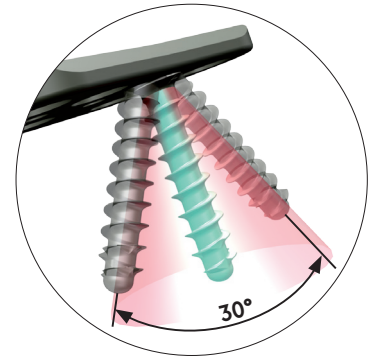
Information

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®

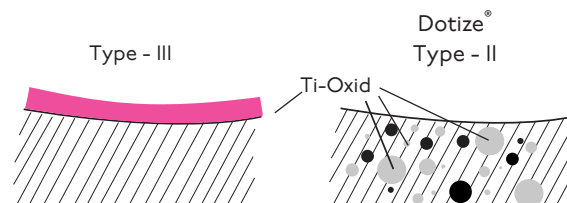
Chemical process - anodization in a strong alkaline solution*

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

FLS Plate, MTP, Right	21471	
FLS Plate, MTP, Left	21472	
FLS Plate, Curved, 4-hole	21413-4	
FLS Plate, Curved, 5-hole, Right	21411-5	
FLS Plate, Curved, 5-hole, Left	21412-5	
FLS Plate, Curved, 6-hole	21413-6	
FLS Plate, Straight, 5-hole, Short	21421-5	
FLS Plate, Straight, 5-hole, Long	21422-5	
FLS Plate, Straight, 6-hole	21421-6	
FLS Plate, H-Shape, Small	21431-SM	
FLS Plate, H-Shape, Medium	21431-ME	
FLS Plate, H-Shape, Large	21431-LA	
FLS Plate, Square	21451-29	
FLS Plate, L-Shape, Right	21441	
FLS Plate, L-Shape, Left	21442	
FLS Plate, L-Shape Extended, Right	21483	
FLS Plate, L-Shape Extended, Left	21484	
FLS Plate, L-Shape Extended, 1mm Step, Right	21485	
FLS Plate, L-Shape Extended, 1mm Step, Left	21486	
FLS Plate, L-Shape Extended, 45°, Right	21481	
FLS Plate, L-Shape Extended, 45°, Left	21482	
FLS Plate, T-Shape	21461	
FLS Plate, T-Shape Extended, Right	21463	
FLS Plate, T-Shape Extended, Left	21462	
FLS Plate, TMT, Right	21491-2	
FLS Plate, TMT, Left	21492-2	
Calcaneus Plate, Short	21061-51	
Calcaneus Plate, Long	21061-60	

Cancellous Stabilization Screw, D=3.0mm, L=8mm, RH	37303-8
Cancellous Stabilization Screw, D=3.0mm, L=9mm, RH	37303-9
Cancellous Stabilization Screw, D=3.0mm, L=10mm, RH	37303-10
Cancellous Stabilization Screw, D=3.0mm, L=11mm, RH	37303-11
Cancellous Stabilization Screw, D=3.0mm, L=12mm, RH	37303-12
Cancellous Stabilization Screw, D=3.0mm, L=14mm, RH	37303-14
Cancellous Stabilization Screw, D=3.0mm, L=16mm, RH	37303-16
Cancellous Stabilization Screw, D=3.0mm, L=18mm, RH	37303-18
Cancellous Stabilization Screw, D=3.0mm, L=20mm, RH	37303-20
Cancellous Stabilization Screw, D=3.0mm, L=22mm, RH	37303-22
Cancellous Stabilization Screw, D=3.0mm, L=24mm, RH	37303-24



Stabilization Screw, D=2.4mm, L=8mm, RH	37241-8
Stabilization Screw, D=2.4mm, L=10mm, RH	37241-10
Stabilization Screw, D=2.4mm, L=12mm, RH	37241-12
Stabilization Screw, D=2.4mm, L=14mm, RH	37241-14
Stabilization Screw, D=2.4mm, L=16mm, RH	37241-16
Stabilization Screw, D=2.4mm, L=18mm, RH	37241-18
Stabilization Screw, D=2.4mm, L=20mm, RH	37241-20
Stabilization Screw, D=2.4mm, L=22mm, RH	37241-22
Stabilization Screw, D=2.4mm, L=24mm, RH	37241-24



Cortical Stabilization Screw, D=3.0mm, L=8mm, RH	37304-8
Cortical Stabilization Screw, D=3.0mm, L=9mm, RH	37304-9
Cortical Stabilization Screw, D=3.0mm, L=10mm, RH	37304-10
Cortical Stabilization Screw, D=3.0mm, L=11mm, RH	37304-11
Cortical Stabilization Screw, D=3.0mm, L=12mm, RH	37304-12
Cortical Stabilization Screw, D=3.0mm, L=14mm, RH	37304-14
Cortical Stabilization Screw, D=3.0mm, L=16mm, RH	37304-16
Cortical Stabilization Screw, D=3.0mm, L=18mm, RH	37304-18
Cortical Stabilization Screw, D=3.0mm, L=20mm, RH	37304-20
Cortical Stabilization Screw, D=3.0mm, L=22mm, RH	37304-22
Cortical Stabilization Screw, D=3.0mm, L=24mm, RH	37304-24



Cortical Screw, D=2.7mm, L=8mm	32271-8
Cortical Screw, D=2.7mm, L=9mm	32271-9
Cortical Screw, D=2.7mm, L=10mm	32271-10
Cortical Screw, D=2.7mm, L=11mm	32271-11
Cortical Screw, D=2.7mm, L=12mm	32271-12
Cortical Screw, D=2.7mm, L=14mm	32271-14
Cortical Screw, D=2.7mm, L=16mm	32271-16
Cortical Screw, D=2.7mm, L=18mm	32271-18
Cortical Screw, D=2.7mm, L=20mm	32271-20
Cortical Screw, D=2.7mm, L=22mm	32271-22
Cortical Screw, D=2.7mm, L=24mm	32271-24



Order list

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	3235I-26
Cortical Screw, D=3.5mm, L=28mm	3235I-28
Cortical Screw, D=3.5mm, L=30mm	3235I-30
Cortical Screw, D=3.5mm, L=32mm	3235I-32
Cortical Screw, D=3.5mm, L=34mm	3235I-34
Cortical Screw, D=3.5mm, L=36mm	3235I-36
Cortical Screw, D=3.5mm, L=38mm	3235I-38
Cortical Screw, D=3.5mm, L=40mm	3235I-40
Cortical Screw, D=3.5mm, L=42mm	3235I-42
Cortical Screw, D=3.5mm, L=44mm	3235I-44
Cortical Screw, D=3.5mm, L=46mm	3235I-46
Cortical Screw, D=3.5mm, L=48mm	3235I-48
Cortical Screw, D=3.5mm, L=50mm	3235I-50



Guide Wire, Steel, D=1.2mm, L=180mm, TR, w. thread	35I24-180
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Drill Guide, D=2.0/2.4mm	622I5
Drill Guide, D=2.7/2.0mm	62202



Spiral Drill, D=1.8mm, L=100mm, AO Connector	61I83-100
Spiral Drill, D=2.0mm, L=100mm, AO Connector	61203-100
Spiral Drill, D=2.4mm, L=100mm, AO Connector	61243-100
Spiral Drill, D=2.5mm, L=110mm, AO Connector	61253-110
Spiral Drill, D=2.7mm, L=100mm, AO Connector	61273-100








Depth Gauge, PROlock II	59026
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AO Handle	530I3
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Torque-Shank, T9x100, AO Connector	54095-100	
Hexagon-Shank, WS 2.5, L=100mm, AO Connector	54253-100	
Mill for FLS Plate L-Shape Extended 45°, AO Connector	63602	
Cortical Counter Sink, AO Connector	63404-80	
Sterilization Tray, FLS	50235	
Optional (on request)*		
Depth Gauge, PROlock	59023	

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



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Order No. FLS-OP-0218-USA
Edition: February/2018

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Subject to technical alterations, errors and misprints excepted.