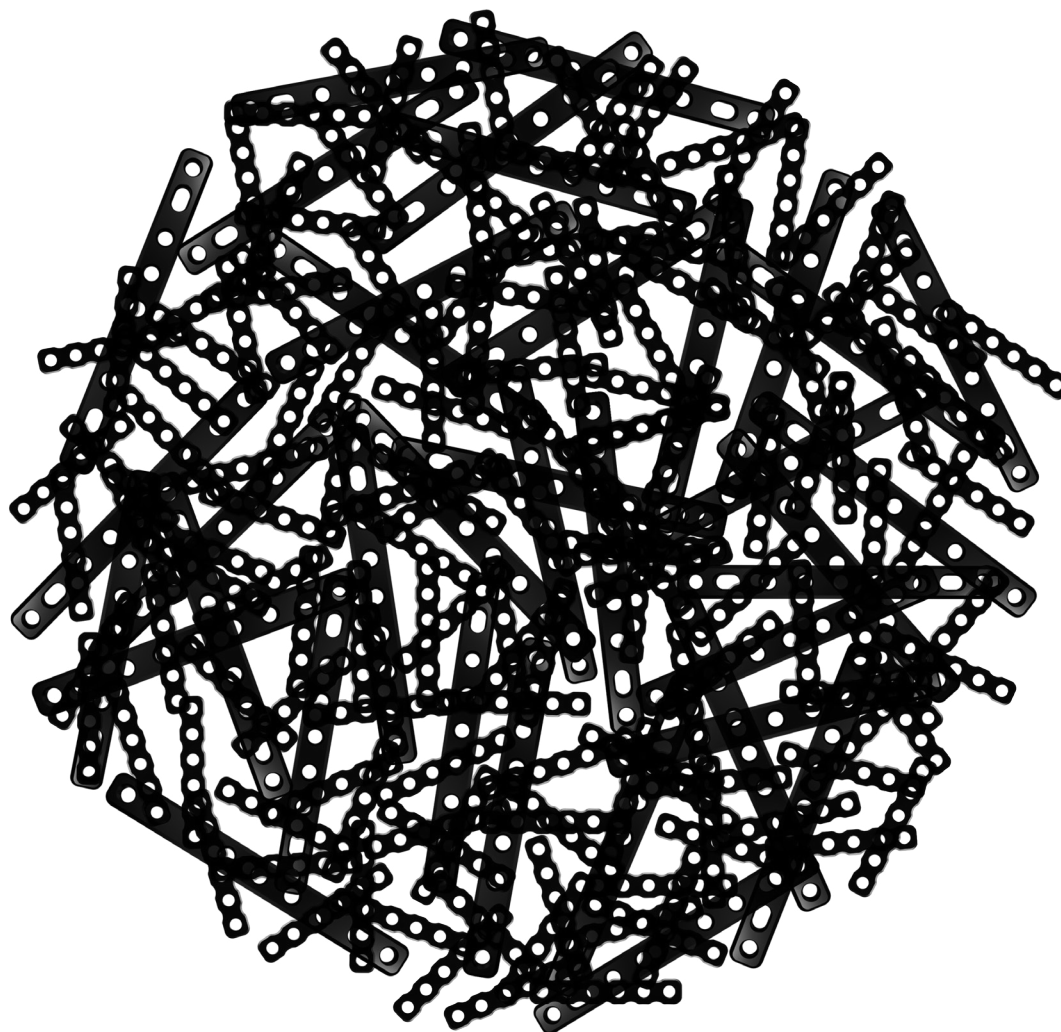


ITS.

Implants
trauma



SLS

Straight 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. 5 Preface
- P. 6 Screws
- P. 7 Properties
- P. 8 Time of operation

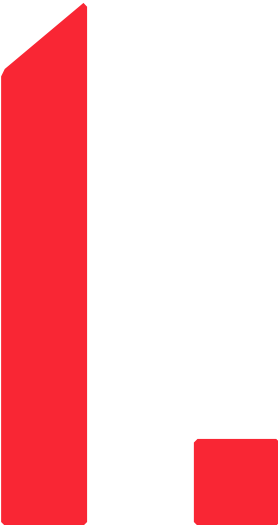
2. Surgical Technique

- P. 8 Pre-operative patient preparation
- P. 8 Exposure
- P. 10 Straight Locking Plate 1.5mm
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Introduction

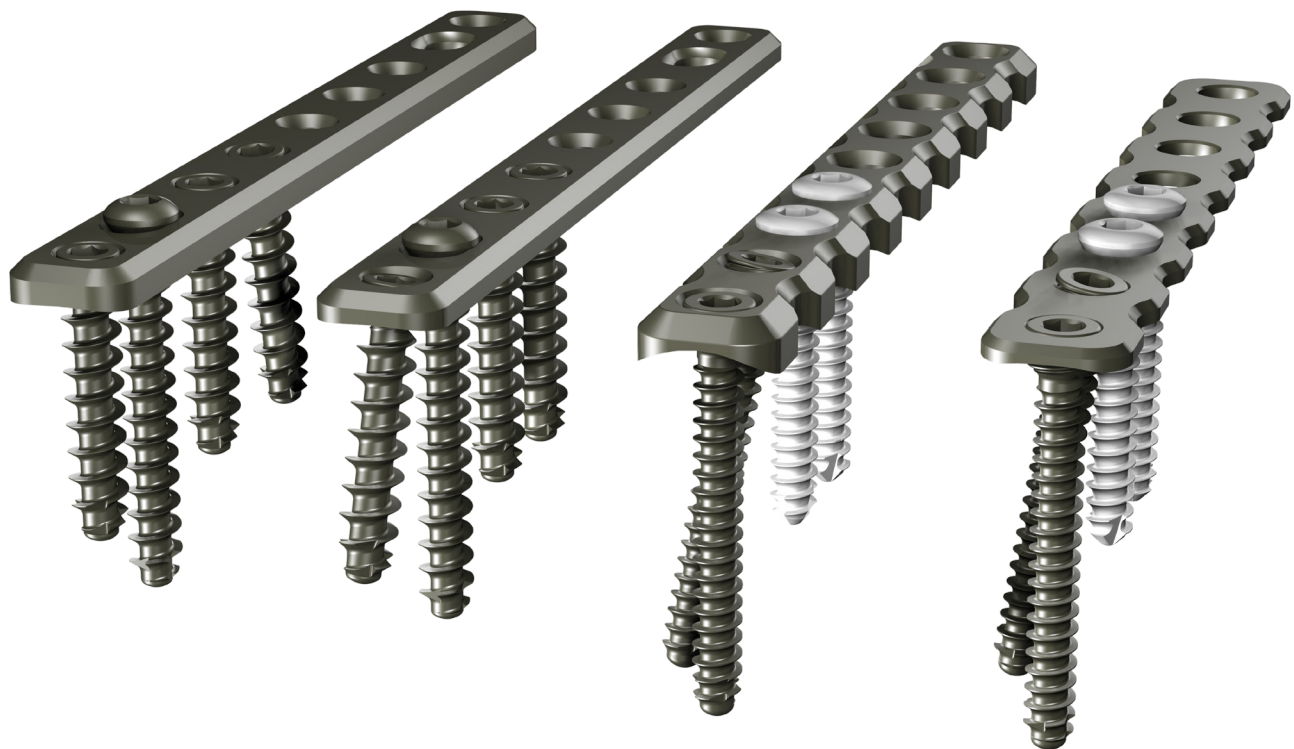


○ Preface

ITS. provides various Straight Locking Plates with different plate strengths and lengths covering a wide range of indications for shaft fractures.

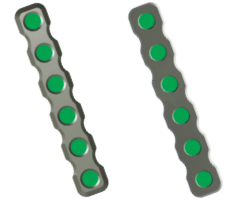
The special feature of these implants is the free choice of screw placement. The user is able to set any desired screw in any hole either locking or non-locking screw (except long hole).

The free choice of screw angulation ($\pm 15^\circ$, see page 17) provides an advantage in fracture treatment, especially in the case of complex fractures.

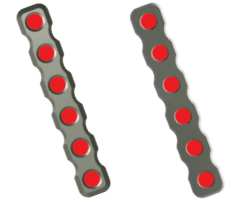


○ Screws Straight Locking Plate 1.5/2.0mm

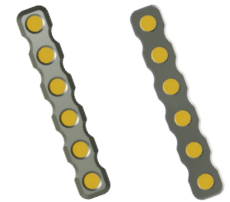
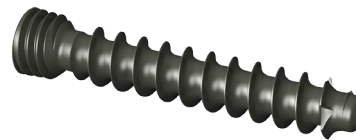
- 37351-XX-N Cortical Screw, locking, D=3.5mm, SH
- 61273-100 Spiral Drill, D=2.7mm, L=100mm, AO Connector
- 56252 Screwdriver, WS 2.5, self-holding sleeve



- 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

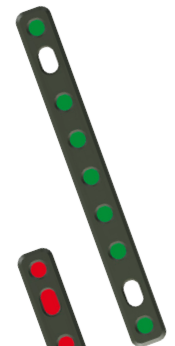


- 37422-XX-N Cancellous Screw, locking, D=4.2mm, SH
- 61253-110 Spiral Drill, D=2.5mm, L=110mm, AO Connector
- 56252 Screwdriver, WS 2.5, self-holding sleeve

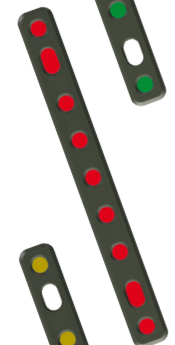


○ Screws Straight Locking Plate 3.5/4.5mm

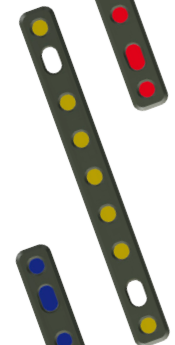
- 37455-XX Cortical Screw, locking, D=4.5mm
- 61323-145 Spiral Drill, D=3.2mm, L=145mm, AO Connector
- 56352-SH Screwdriver, WS 3.5, conic, self-holding



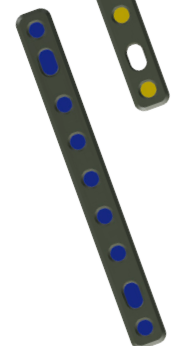
- 32455-XX Cortical Screw, D=4.5mm
- 61323-145 Spiral Drill, D=3.2mm, L=145mm, AO Connector
- 56352-SH Screwdriver, WS 3.5, conic, self-holding



- 37592-XX Cancellous Screw, locking, D=5.9mm
- 61353-110 Spiral Drill, D=3.5mm, L=110mm, AO Connector
- 56352-SH Screwdriver, WS 3.5, conic, self-holding



- 30591-XX Cancellous Screw, D=5.9mm
- 61353-110 Spiral Drill, D=3.5mm, L=110mm, AO Connector
- 56352-SH Screwdriver, WS 3.5, conic, self-holding



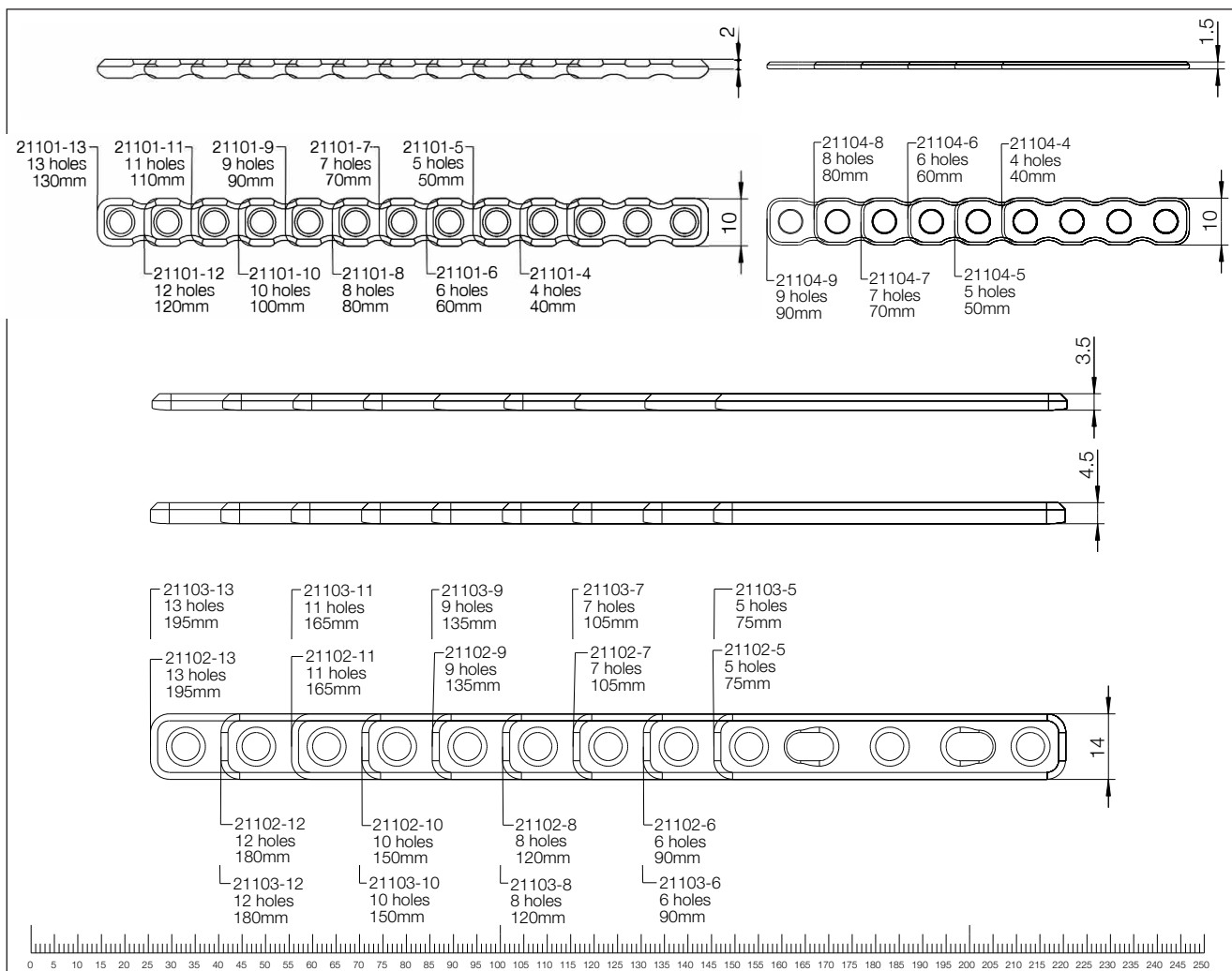
○ Properties

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
- ◆ Accurate fitting of the plate on the bone
- ◆ Plate lengths, 1.5mm: 4, 5, 6, 7, 8, 9-hole
- ◆ Plate lengths, 2.0mm: 4, 5, 6, 7, 8, 9, 11, 13-hole
- ◆ Plate lengths, 3.5/4.5mm: 5, 6, 7, 8, 9, 10, 11, 12, 13-hole
- ◆ Straight Plate 3.5/4.5mm: Fracture gap compression up to 8mm



◦ Time of operation

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

◦ Pre-operative patient preparation

- ◆ General anaesthesia, regional anaesthesia or combined can be used
- ◆ Tourniquet/partial deprivation of the blood supply

◦ Exposure

- ◆ Intra-operative x-ray fluoroscopy observation is required during the entire procedure
- ◆ Incision to the limb subchondral bone fracture site
- ◆ Transection of musculature if possible along the course of muscle fibers

Surgical Technique

2.

◦ Straight Locking Plate 1.5mm

Indications:

- ◆ The plate should primarily be used to reconstruct an anatomic situation
- ◆ Corrective osteotomies

Contraindications:

- ◆ The plate is not intended for shaft fractures of large bones such as humerus, femur and tibia
- ◆ Advanced osteoporosis
- ◆ In case of skin and soft tissue problems
- ◆ Existing infections
- ◆ Obesity
- ◆ Lack of patient compliance

◦ Plate insertion

- ◆ Anatomical reduction of the fracture segments
- ◆ Temporary fixation of the plate using guide wires
- ◆ Subsequent control under fluoroscopy
- ◆ Optionally, the plate can be stabilized using the ITS. Temporary Plate Holder (**58164-150**)



○ Placement of the screws

Use the drill guide, D=2.7/2.0mm (**62202**) to bore with the spiral drill, D=2.7mm, L=100mm, AO Connector (**61273-100**) into the plate holes closest to the fracture.

Use the screwdriver, WS 2.5, self-holding sleeve (**56252**) to insert D=3.5mm cortical screws (**3235I-XX**) of appropriate lengths determined previously with the depth gauge, solid small fragment screws (**59022**).

Attention: It is recommended that locking screws are not used close to the fracture.



Subsequently, place either D=3.5mm cortical or locking cortical screws (**3235I-XX/3735I-XX-N**) in plate holes far from the fracture.

Finally, control plate position under fluoroscopy.



◦ Straight Locking Plate 2.0mm

Indications:

- ◆ The plate should primarily be used to reconstruct an anatomic situation
- ◆ Corrective osteotomies

Contraindications:

- ◆ The plate is not intended for shaft fractures of large bones such as humerus, femur and tibia
- ◆ Advanced osteoporosis
- ◆ In case of skin and soft tissue problems
- ◆ Existing infections
- ◆ Obesity
- ◆ Lack of patient compliance

◦ Plate insertion

- ◆ Anatomical reduction of the fracture segments
- ◆ Temporary fixation of the plate using guide wires
- ◆ Subsequent control under fluoroscopy
- ◆ Optionally, the plate can be stabilized using the ITS. Temporary Plate Holder (**58164-150**)

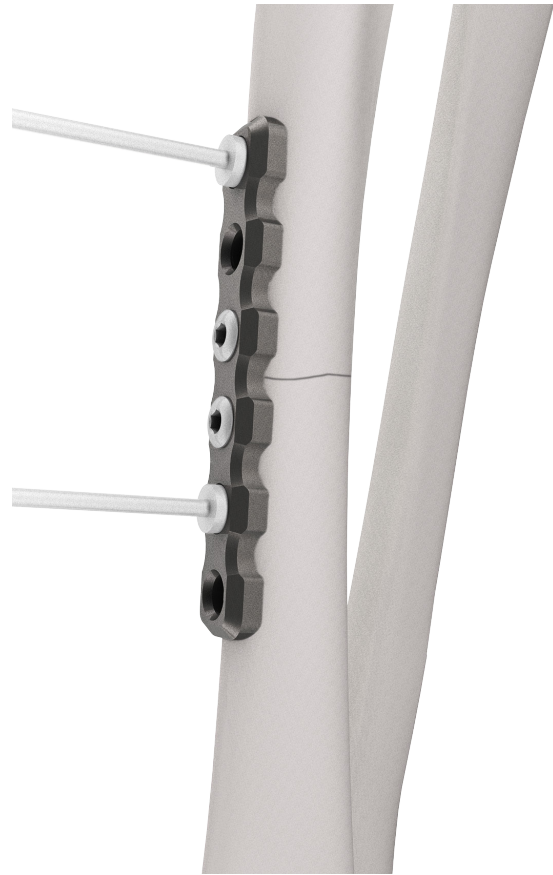


○ Placement of the screws

Use the drill guide, D=2.7/2.0mm (**62202**) to bore with the spiral drill, D=2.7mm, L=100mm, AO Connector (**61273-100**) into the plate holes closest to the fracture.

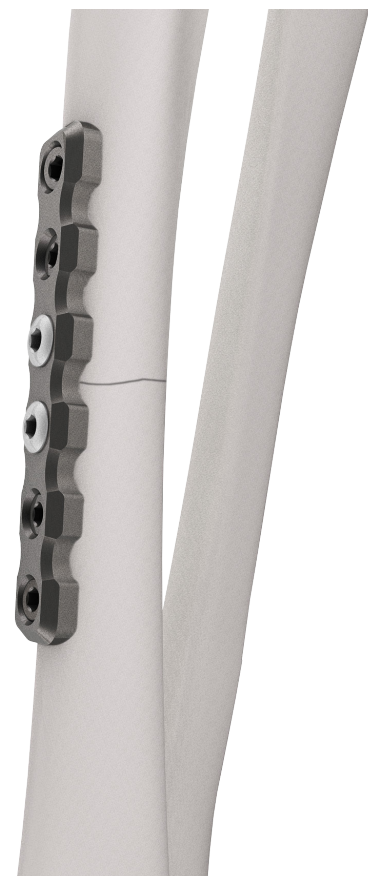
Use the screwdriver, WS 2.5, self-holding sleeve (**56252**) to insert D=3.5mm cortical screws (**3235I-XX**) of appropriate lengths determined previously with the depth gauge, solid small fragment screws (**59022**).

Attention: It is recommended that locking screws are not used close to the fracture.



Subsequently, place either D=3.5mm cortical or locking cortical screws (**3235I-XX/3735I-XX-N**) in plate holes far from the fracture.

Finally, control plate position under fluoroscopy.



○ Straight Locking Plate 3.5/4.5mm

Indications:

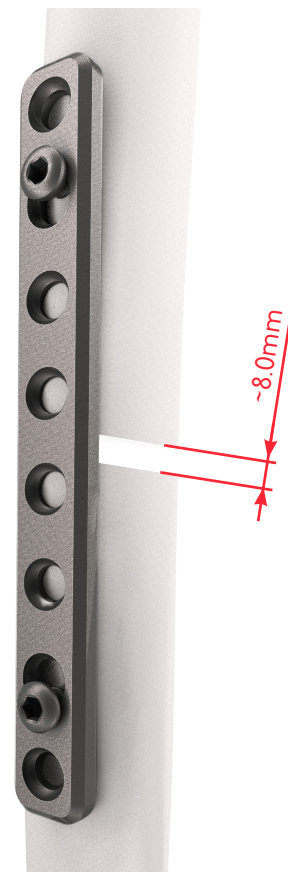
- ◆ All diaphyseal fractures, especially when compression for fracture treatment is needed
- ◆ Corrective osteotomies

Contraindications:

- ◆ Advanced osteoporosis
- ◆ In case of skin and soft tissue problems
- ◆ Existing infections
- ◆ Obesity
- ◆ Lack of patient compliance

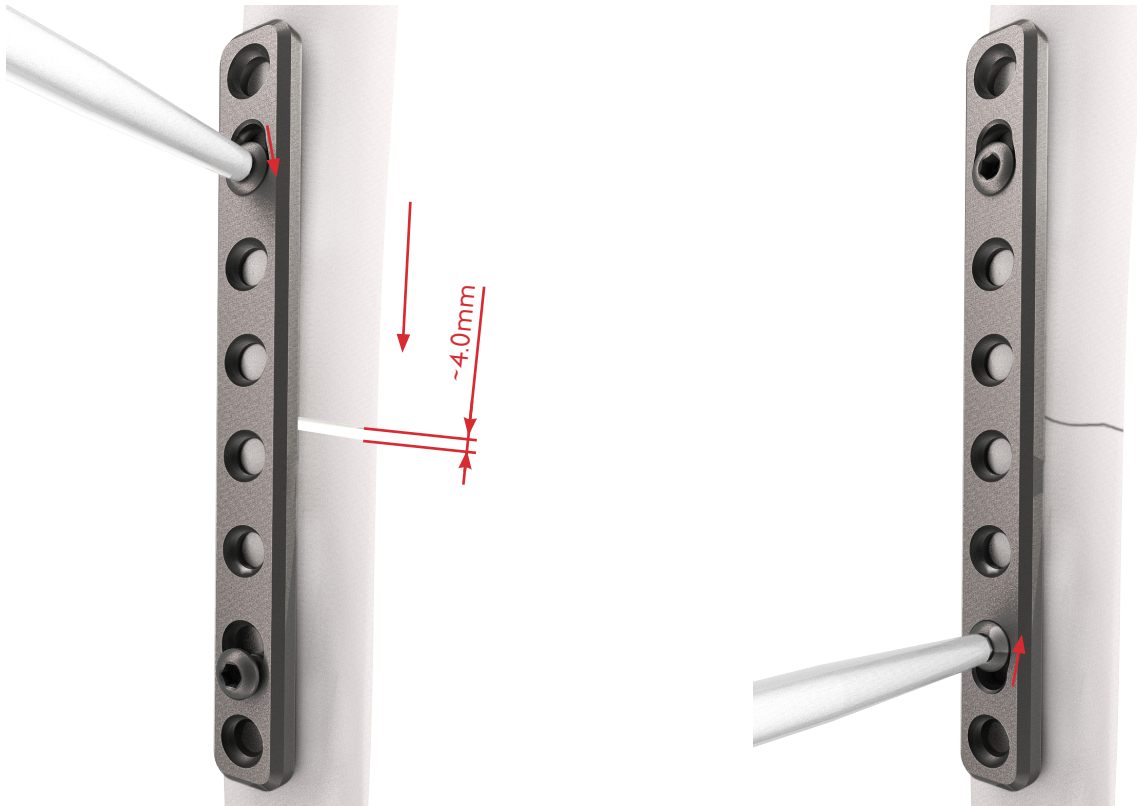
○ Plate insertion

- ◆ Anatomical reduction of the fracture parts
- ◆ Temporary fixation of the plate using forceps
- ◆ Subsequent control under fluoroscopy



○ Placement of the screws

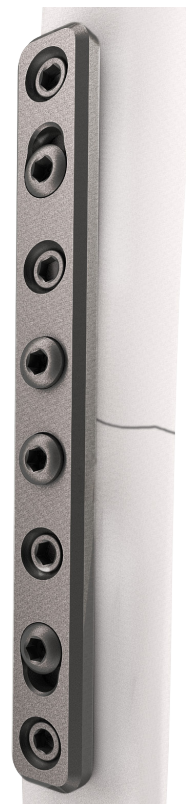
For compression up to 8mm the D=4.5mm cortical screws or D=5.9mm cancellous screws (32455-XX/30591-XX) are used at both sides of the fracture for compression.



Subsequently, place screws in the remaining plate holes.

Attention: It is recommended that locking screws are not used close to the fracture.

Finally, control plate position under fluoroscopy.



○ Postoperative treatment

- ◆ Drainage is recommended for 12-24 hours to prevent postoperative hematoma
- ◆ Proper bandage dressing for 2 weeks (until the wound heals)
- ◆ Physical therapy for 5-7 weeks

- ◆ 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).

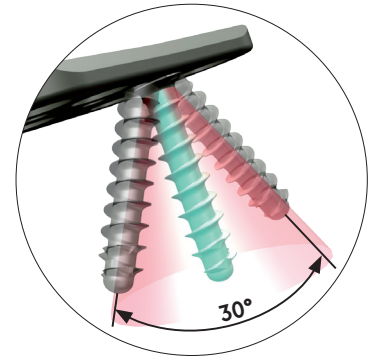
Information



○ 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®

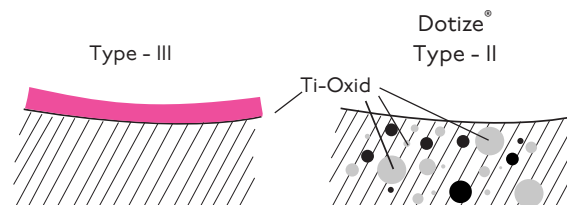
Chemical process - anodization in a strong alkaline solution*

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, Straight Locking Plate 1.5/2.0mm

Straight Plate, 1.5mm, 4-hole	21104-4
Straight Plate, 1.5mm, 5-hole	21104-5
Straight Plate, 1.5mm, 6-hole	21104-6
Straight Plate, 1.5mm, 7-hole	21104-7
Straight Plate, 1.5mm, 8-hole	21104-8
Straight Plate, 1.5mm, 9-hole	21104-9



Straight Plate, 2.0mm, 4-hole	21101-4
Straight Plate, 2.0mm, 5-hole	21101-5
Straight Plate, 2.0mm, 6-hole	21101-6
Straight Plate, 2.0mm, 7-hole	21101-7
Straight Plate, 2.0mm, 8-hole	21101-8
Straight Plate, 2.0mm, 9-hole	21101-9
Straight Plate, 2.0mm, 11-hole	21101-11
Straight Plate, 2.0mm, 13-hole	21101-13



Instruments and Screws, Straight Plate 1.5/2.0mm

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, D=3.5mm, L=26mm	32351-26
Cortical Screw, D=3.5mm, L=28mm	32351-28
Cortical Screw, D=3.5mm, L=30mm	32351-30
Cortical Screw, D=3.5mm, L=32mm	32351-32
Cortical Screw, D=3.5mm, L=34mm	32351-34
Cortical Screw, D=3.5mm, L=36mm	32351-36
Cortical Screw, D=3.5mm, L=38mm	32351-38
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, 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
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=4.2mm, L=14mm, SH	37422-14-N
Cortical Screw, Locking, D=4.2mm, L=16mm, SH	37422-16-N
Cortical Screw, Locking, D=4.2mm, L=18mm, SH	37422-18-N
Cortical Screw, Locking, D=4.2mm, L=20mm, SH	37422-20-N
Cortical Screw, Locking, D=4.2mm, L=22mm, SH	37422-22-N
Cortical Screw, Locking, D=4.2mm, L=24mm, SH	37422-24-N
Cortical Screw, Locking, D=4.2mm, L=26mm, SH	37422-26-N
Cortical Screw, Locking, D=4.2mm, L=28mm, SH	37422-28-N
Cortical Screw, Locking, D=4.2mm, L=30mm, SH	37422-30-N
Cortical Screw, Locking, D=4.2mm, L=32mm, SH	37422-32-N
Cortical Screw, Locking, D=4.2mm, L=34mm, SH	37422-34-N
Cortical Screw, Locking, D=4.2mm, L=36mm, SH	37422-36-N
Cortical Screw, Locking, D=4.2mm, L=38mm, SH	37422-38-N
Cortical Screw, Locking, D=4.2mm, L=40mm, SH	37422-40-N
Cortical Screw, Locking, D=4.2mm, L=42mm, SH	37422-42-N
Cortical Screw, Locking, D=4.2mm, L=44mm, SH	37422-44-N
Cortical Screw, Locking, D=4.2mm, L=46mm, SH	37422-46-N
Cortical Screw, Locking, D=4.2mm, L=48mm, SH	37422-48-N
Cortical Screw, Locking, D=4.2mm, L=50mm, SH	37422-50-N
Cortical Screw, Locking, D=4.2mm, L=55mm, SH	37422-55-N
Cortical Screw, Locking, D=4.2mm, L=60mm, SH	37422-60-N



Screwdriver, WS 2.5, self-holding sleeve	56252
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Spiral Drill, D=2.7mm, L=100mm, AO Connector	61273-100
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Depth Gauge, Solid Small Fragment Screws	59022
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Drill Guide, D=2.7/2.0mm	62202
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Temporary Plate Holder	58164-150
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Sterilization Tray, Straight Plate 1.5mm	50166
Sterilization Tray, Straight Plate 2.0mm	50166

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

Order list, Straight Locking Plate 3.5/4.5mm

Straight Plate, 3.5mm, 5-hole	21102-5
Straight Plate, 3.5mm, 6-hole	21102-6
Straight Plate, 3.5mm, 7-hole	21102-7
Straight Plate, 3.5mm, 8-hole	21102-8
Straight Plate, 3.5mm, 9-hole	21102-9
Straight Plate, 3.5mm, 10-hole	21102-10
Straight Plate, 3.5mm, 11-hole	21102-11
Straight Plate, 3.5mm, 12-hole	21102-12
Straight Plate, 3.5mm, 13-hole	21102-13



Straight Plate, 4.5mm, 5-hole	21103-5
Straight Plate, 4.5mm, 6-hole	21103-6
Straight Plate, 4.5mm, 7-hole	21103-7
Straight Plate, 4.5mm, 8-hole	21103-8
Straight Plate, 4.5mm, 9-hole	21103-9
Straight Plate, 4.5mm, 10-hole	21103-10
Straight Plate, 4.5mm, 11-hole	21103-11
Straight Plate, 4.5mm, 12-hole	21103-12
Straight Plate, 4.5mm, 13-hole	21103-13



Cortical Screw, D=4.5mm, L=16mm	32455-16
Cortical Screw, D=4.5mm, L=20mm	32455-20
Cortical Screw, D=4.5mm, L=24mm	32455-24
Cortical Screw, D=4.5mm, L=28mm	32455-28
Cortical Screw, D=4.5mm, L=32mm	32455-32
Cortical Screw, D=4.5mm, L=36mm	32455-36
Cortical Screw, D=4.5mm, L=40mm	32455-40
Cortical Screw, D=4.5mm, L=44mm	32455-44
Cortical Screw, D=4.5mm, L=48mm	32455-48
Cortical Screw, D=4.5mm, L=52mm	32455-52
Cortical Screw, D=4.5mm, L=56mm	32455-56
Cortical Screw, D=4.5mm, L=60mm	32455-60
Cortical Screw, D=4.5mm, L=65mm	32455-65
Cortical Screw, D=4.5mm, L=70mm	32455-70
Cortical Screw, D=4.5mm, L=75mm	32455-75
Cortical Screw, D=4.5mm, L=80mm	32455-80
Cortical Screw, D=4.5mm, L=85mm	32455-85
Cortical Screw, D=4.5mm, L=90mm	32455-90



Cortical Screw, Locking, D=4.5mm, L=16mm	37455-16
Cortical Screw, Locking, D=4.5mm, L=20mm	37455-20
Cortical Screw, Locking, D=4.5mm, L=24mm	37455-24
Cortical Screw, Locking, D=4.5mm, L=28mm	37455-28
Cortical Screw, Locking, D=4.5mm, L=32mm	37455-32
Cortical Screw, Locking, D=4.5mm, L=36mm	37455-36
Cortical Screw, Locking, D=4.5mm, L=40mm	37455-40
Cortical Screw, Locking, D=4.5mm, L=44mm	37455-44
Cortical Screw, Locking, D=4.5mm, L=48mm	37455-48
Cortical Screw, Locking, D=4.5mm, L=52mm	37455-52
Cortical Screw, Locking, D=4.5mm, L=56mm	37455-56
Cortical Screw, Locking, D=4.5mm, L=60mm	37455-60
Cortical Screw, Locking, D=4.5mm, L=65mm	37455-65



Cortical Screw, Locking, D=4.5mm, L=70mm	37455-70
Cortical Screw, Locking, D=4.5mm, L=75mm	37455-75
Cortical Screw, Locking, D=4.5mm, L=80mm	37455-80
Cortical Screw, Locking, D=4.5mm, L=85mm	37455-85
Cortical Screw, Locking, D=4.5mm, L=90mm	37455-90

Cancellous Screw, Locking, D=5.9mm, L=16mm	37592-16
Cancellous Screw, Locking, D=5.9mm, L=20mm	37592-20
Cancellous Screw, Locking, D=5.9mm, L=24mm	37592-24
Cancellous Screw, Locking, D=5.9mm, L=28mm	37592-28
Cancellous Screw, Locking, D=5.9mm, L=32mm	37592-32
Cancellous Screw, Locking, D=5.9mm, L=36mm	37592-36
Cancellous Screw, Locking, D=5.9mm, L=40mm	37592-40
Cancellous Screw, Locking, D=5.9mm, L=44mm	37592-44
Cancellous Screw, Locking, D=5.9mm, L=48mm	37592-48
Cancellous Screw, Locking, D=5.9mm, L=52mm	37592-52
Cancellous Screw, Locking, D=5.9mm, L=56mm	37592-56
Cancellous Screw, Locking, D=5.9mm, L=60mm	37592-60
Cancellous Screw, Locking, D=5.9mm, L=65mm	37592-65
Cancellous Screw, Locking, D=5.9mm, L=70mm	37592-70
Cancellous Screw, Locking, D=5.9mm, L=75mm	37592-75
Cancellous Screw, Locking, D=5.9mm, L=80mm	37592-80
Cancellous Screw, Locking, D=5.9mm, L=85mm	37592-85
Cancellous Screw, Locking, D=5.9mm, L=90mm	37592-90



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Cancellous Screw, D=5.9mm, L=44mm, Threaded	30591-44
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Cancellous Screw, D=5.9mm, L=52mm, Threaded	30591-52
Cancellous Screw, D=5.9mm, L=56mm, Threaded	30591-56
Cancellous Screw, D=5.9mm, L=60mm, Threaded	30591-60
Cancellous Screw, D=5.9mm, L=65mm, Threaded	30591-65
Cancellous Screw, D=5.9mm, L=70mm, Threaded	30591-70
Cancellous Screw, D=5.9mm, L=75mm, Threaded	30591-75
Cancellous Screw, D=5.9mm, L=80mm, Threaded	30591-80
Cancellous Screw, D=5.9mm, L=85mm, Threaded	30591-85
Cancellous Screw, D=5.9mm, L=90mm, Threaded	30591-90



Screwdriver, WS 3.5, Conic, Self-holding	56352-SH
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Spiral Drill, D=3.2mm, L=145mm, AO Connector	61323-145
Spiral Drill, D=3.5mm, L=110mm, AO Connector	61353-110



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

Depth Gauge, Solid Small Fragment Screws 59022 

Drill Guide, D=2.5/3.5mm 62252 

Sterilization Tray, Straight Plate 3.5/4.5mm 50223

Optional (on request)*

Cortical Screw, D=4.5mm, L=95mm 32455-95
Cortical Screw, D=4.5mm, L=100mm 32455-100
Cortical Screw, D=4.5mm, L=105mm 32455-105
Cortical Screw, D=4.5mm, L=110mm 32455-110
Cortical Screw, D=4.5mm, L=115mm 32455-115
Cortical Screw, D=4.5mm, L=120mm 32455-120



Cortical Screw, Locking, D=4.5mm, L=95mm 37455-95
Cortical Screw, Locking, D=4.5mm, L=100mm 37455-100
Cortical Screw, Locking, D=4.5mm, L=105mm 37455-105
Cortical Screw, Locking, D=4.5mm, L=110mm 37455-110
Cortical Screw, Locking, D=4.5mm, L=115mm 37455-115
Cortical Screw, Locking, D=4.5mm, L=120mm 37455-120



Cancellous Screw, Locking, D=5.9mm, L=95mm 37592-95
Cancellous Screw, Locking, D=5.9mm, L=100mm 37592-100
Cancellous Screw, Locking, D=5.9mm, L=105mm 37592-105
Cancellous Screw, Locking, D=5.9mm, L=110mm 37592-110
Cancellous Screw, Locking, D=5.9mm, L=115mm 37592-115
Cancellous Screw, Locking, D=5.9mm, L=120mm 37592-120



Cancellous Screw, D=5.9mm, L=95mm, Threaded 30591-95
Cancellous Screw, D=5.9mm, L=100mm, Threaded 30591-100
Cancellous Screw, D=5.9mm, L=105mm, Threaded 30591-105
Cancellous Screw, D=5.9mm, L=110mm, Threaded 30591-110
Cancellous Screw, D=5.9mm, L=115mm, Threaded 30591-115
Cancellous Screw, D=5.9mm, L=120mm, Threaded 30591-120



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



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