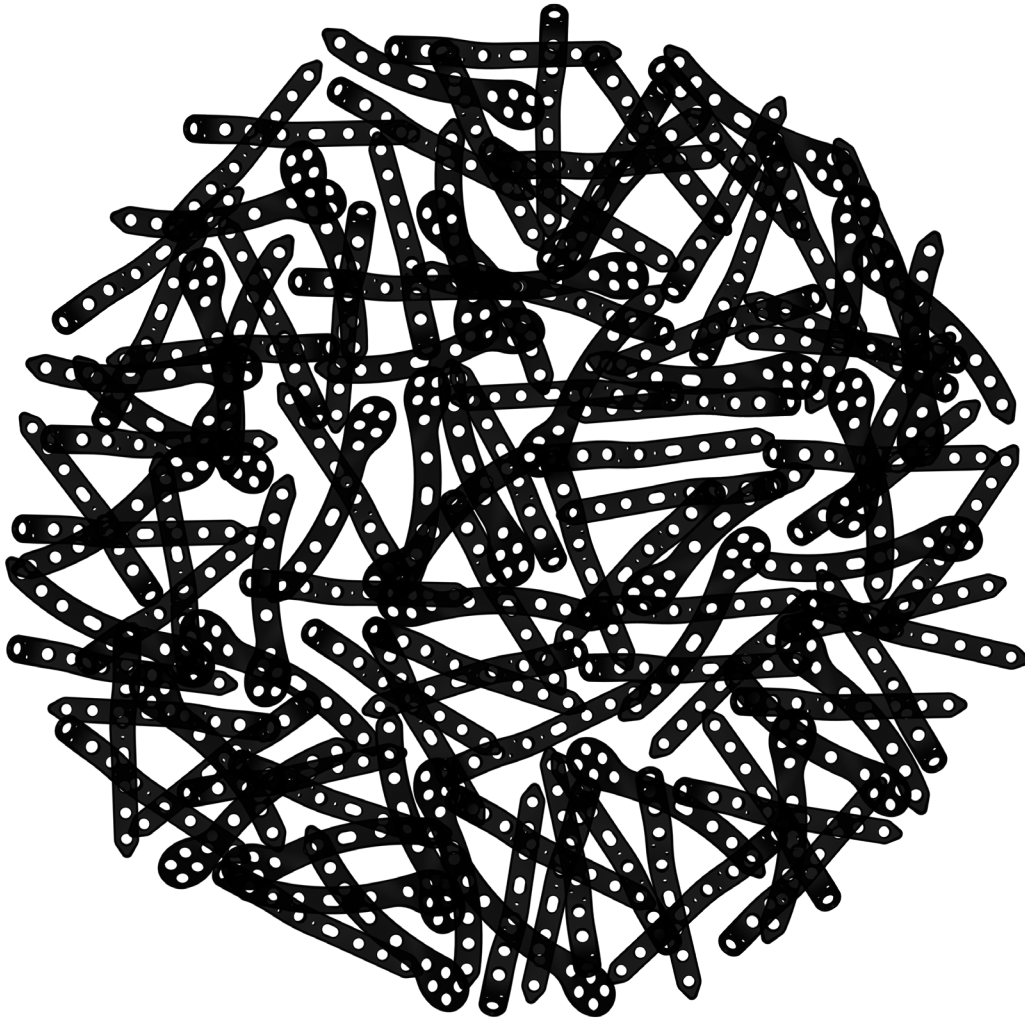


ITS.

Implants
trauma



DHL

Distal Humeral Locking Plates

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 Distal Humeral Locking Plates are a proven osteosynthesis system for various fractures of the distal humerus.

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 sliding 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

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

61273-I00 Spiral Drill, D=2.7mm, L=100mm, AO Connector

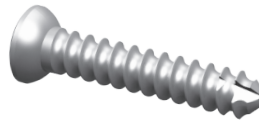
56252 Screwdriver, WS 2.5,
self-holding sleeve



32351-XX Cortical Screw, D=3.5mm

61273-I00 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-I80 Spiral Drill, D=2.5mm, L=180mm, AO Connector

56252 Screwdriver, WS 2.5,
self-holding sleeve



35164-I50 Guide Wire, Steel, D=1.6mm,
L=150mm, TR, with thread



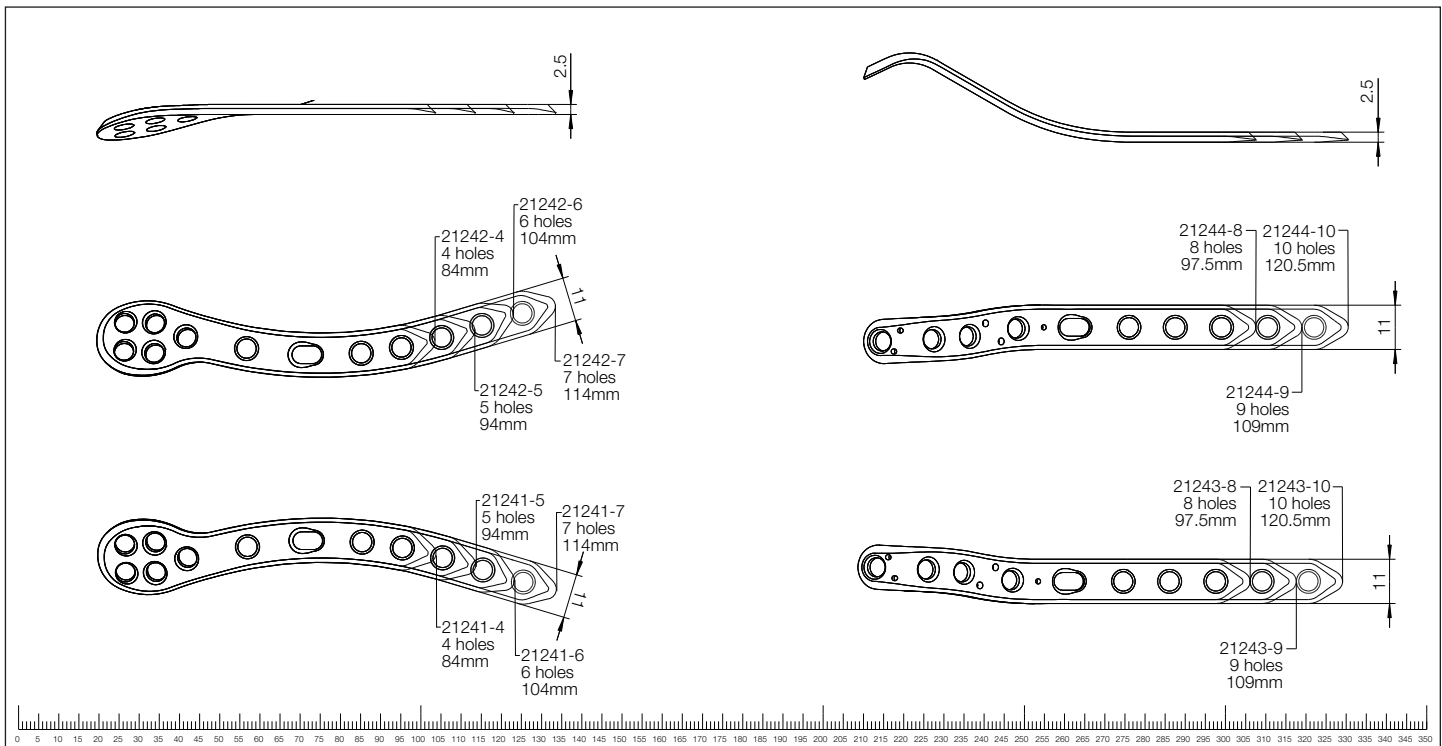
○ Properties

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
- Sliding hole with compression option up to 4mm
- Pointed proximal plate end for percutaneous insertion
- Left/right version
- Lengths, dorsolateral: 4, 5, 6, 7-hole
- Lengths, medial: 8, 9, 10-hole



◦ Indications, Contraindications & Time of operation

Indications:

- ♦ Supra- and diacondylar upper-arm fractures

Contraindications:

- ♦ Severe osteoporosis
- ♦ Existing infections in the area of the fracture
- ♦ Strongly reduced general conditions
- ♦ Obesity
- ♦ Lack of patient compliance

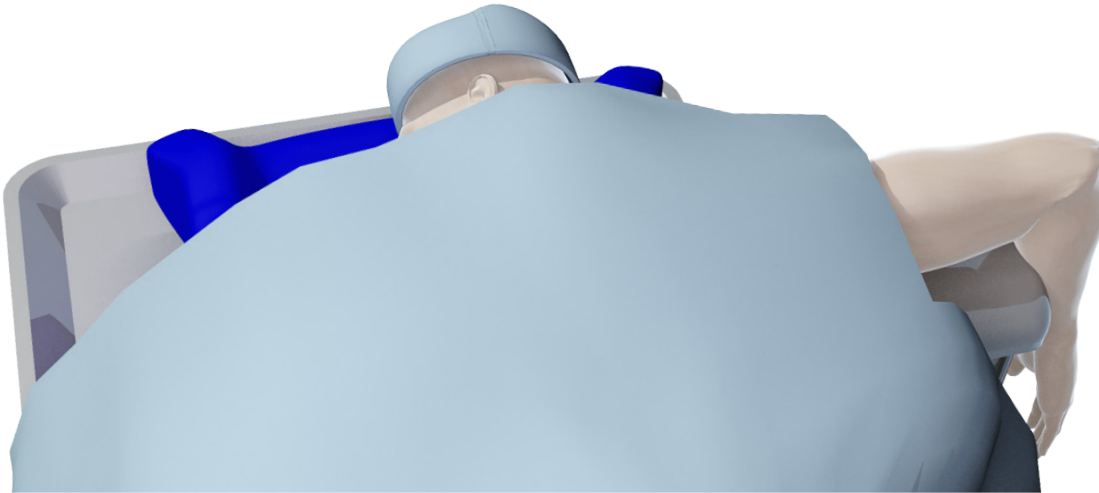
Time of operation:

- ♦ Within the first hours of the trauma or in the following days
- ♦ If the operation is not primary, arm should be immobilized in a splint

2.

○ Pre-operative patient preparation

- ◆ General or regional anaesthesia or combination can be used
- ◆ Tourniquet
- ◆ Prone position



○ Access

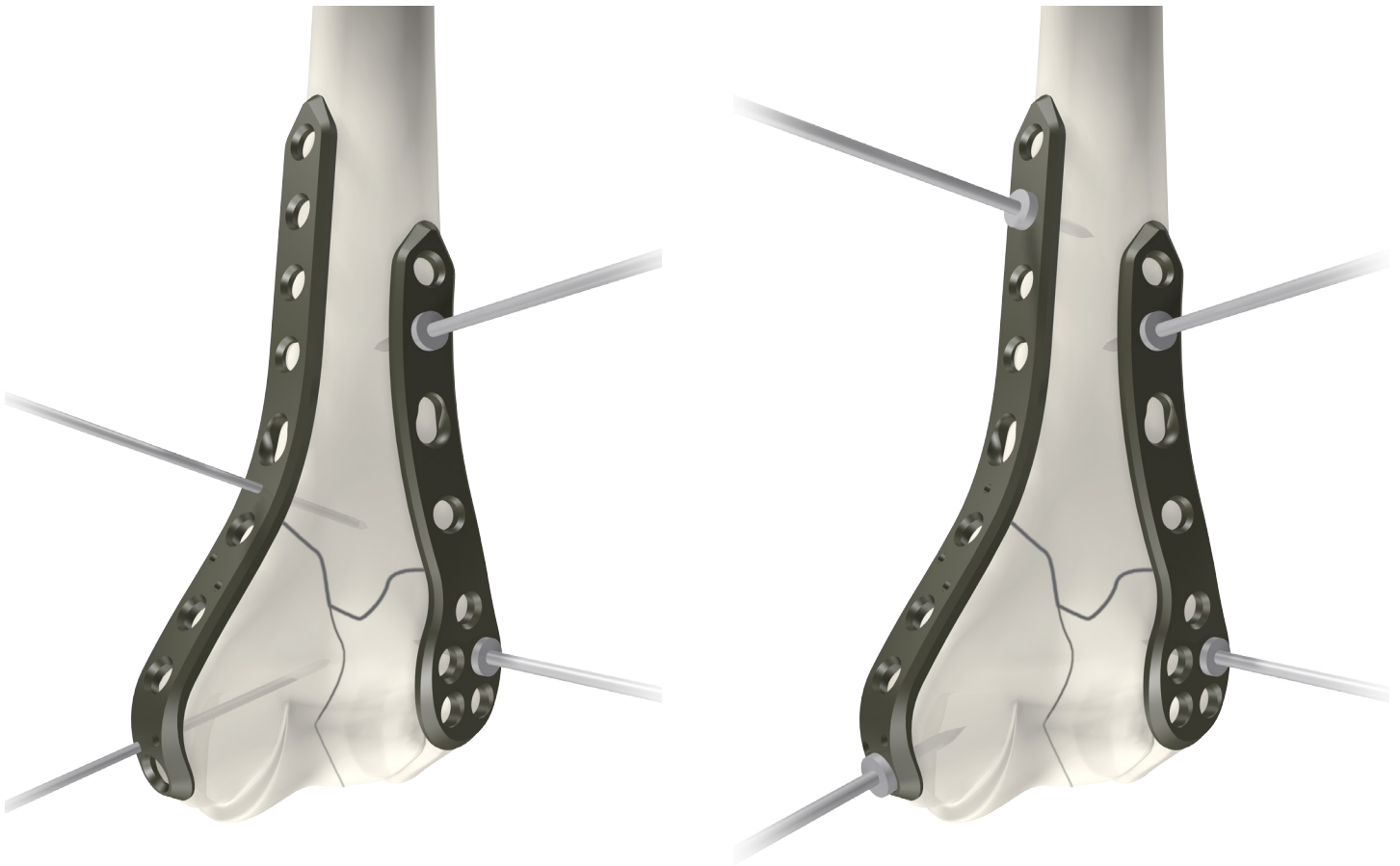
Posterior approach:

- ◆ Median incision in the ulnar rim on the distal upper arm above the olecranon
- ◆ Exposure and retraction of the ulnar nerve
- ◆ Depending on the type of fracture, olecranon osteotomy and retraction of the triceps
- ◆ In the case of supracondylar fractures, it is possible to approach from the ulnar and radial side adjacent to the brachial triceps tendon



◦ Reduction

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



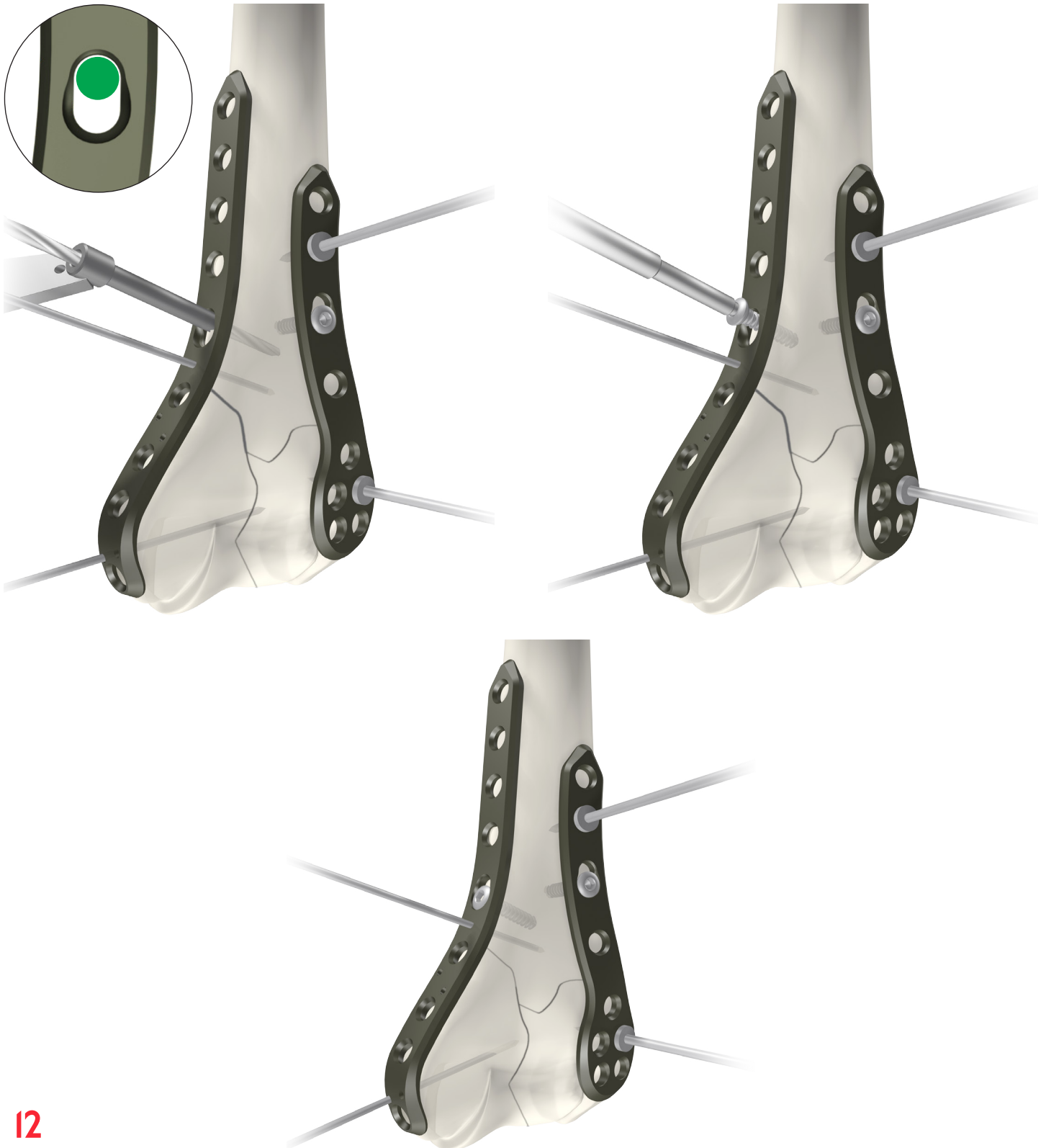
Optionally, the plate can be stabilized using the ITS. Temporary Plate Holder (58164-150).



○ Placement of the screws

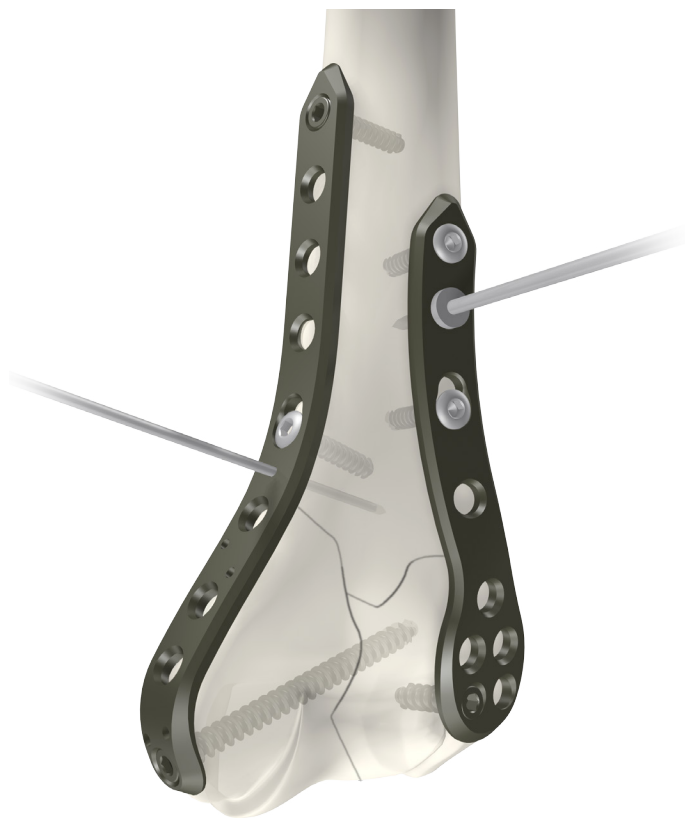
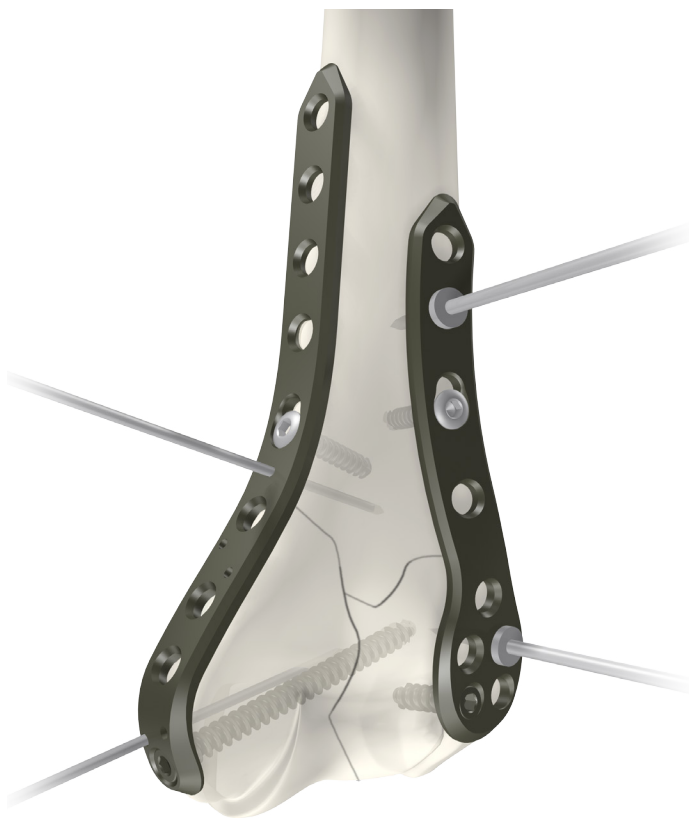
Use the drill guide, D=2.7/2.0mm (**62202**) to bore holes with the spiral drill D=2.7mm, L=100mm, AO Connector (**61273-100**) into the compression hole.

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**).



Then, drill holes into a distal and proximal plate hole using the drill guide, D=2.7/2.0mm **(62202)** to bore holes with the spiral drill D=2.5mm, L=180mm resp. D=2.7mm, L=100mm, AO Connector **(61253-180/61273-100)**.

Use the screwdriver, WS 2.5, self-holding sleeve **(56252)** to insert the D=4.2mm cancellous screw **(37422-XX-N)** or D=3.5mm cortical screw, optionally locking **(32351-XX/37351-XX-N)** of appropriate lengths determined previously with the depth gauge, solid small fragment screws **(59022)**.



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
- In case of poor bone quality or insecure fixation, movement fixator for a maximum of 6 weeks or upper-arm plaster cast for a maximum of 3 weeks
- When a locking screw connection has been used, it is necessary to be aware that the 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).

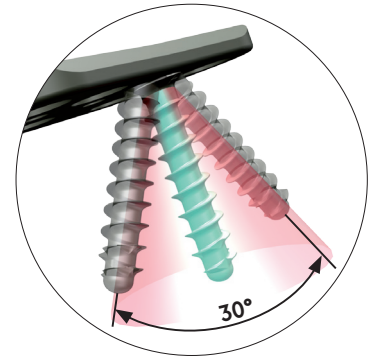
Information

3.

○ 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:

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

○ Dotize®

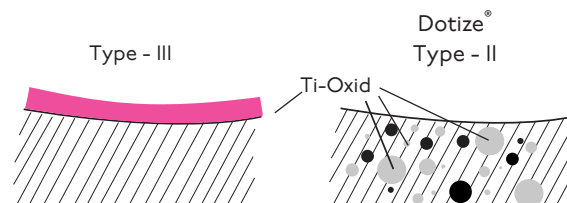
Chemical process - anodization in a strong alkaline solution*

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

Humeral Plate, Distal, 5-hole, Left, Dorsolateral
 Humeral Plate, Distal, 5-hole, Right, Dorsolateral
 Humeral Plate, Distal, 7-hole, Left, Dorsolateral
 Humeral Plate, Distal, 7-hole, Right, Dorsolateral

21242-5
 21241-5
 21242-7
 21241-7



Humeral Plate, Distal, 8-hole, Left, Medial
 Humeral Plate, Distal, 8-hole, Right, Medial
 Humeral Plate, Distal, 10-hole, Left, Medial
 Humeral Plate, Distal, 10-hole, Right, Medial

21244-8
 21243-8
 21244-10
 21243-10



Cortical Screw, locking, D=3.5mm, L=12mm, SH
 Cortical Screw, locking, D=3.5mm, L=14mm, SH
 Cortical Screw, locking, D=3.5mm, L=16mm, SH
 Cortical Screw, locking, D=3.5mm, L=18mm, SH
 Cortical Screw, locking, D=3.5mm, L=20mm, SH
 Cortical Screw, locking, D=3.5mm, L=22mm, SH
 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=40mm, SH

37351-12-N
 37351-14-N
 37351-16-N
 37351-18-N
 37351-20-N
 37351-22-N
 37351-24-N
 37351-26-N
 37351-28-N
 37351-30-N
 37351-32-N
 37351-34-N
 37351-36-N
 37351-38-N
 37351-40-N



Cortical Screw, D=3.5mm, L=12mm
 Cortical Screw, D=3.5mm, L=14mm
 Cortical Screw, D=3.5mm, L=16mm
 Cortical Screw, D=3.5mm, L=18mm
 Cortical Screw, D=3.5mm, L=20mm
 Cortical Screw, D=3.5mm, L=22mm
 Cortical Screw, D=3.5mm, L=24mm
 Cortical Screw, D=3.5mm, L=26mm
 Cortical Screw, D=3.5mm, L=28mm
 Cortical Screw, D=3.5mm, L=30mm
 Cortical Screw, D=3.5mm, L=32mm
 Cortical Screw, D=3.5mm, L=34mm
 Cortical Screw, D=3.5mm, L=36mm
 Cortical Screw, D=3.5mm, L=38mm
 Cortical Screw, D=3.5mm, L=40mm
 Cortical Screw, D=3.5mm, L=42mm
 Cortical Screw, D=3.5mm, L=44mm
 Cortical Screw, D=3.5mm, L=46mm
 Cortical Screw, D=3.5mm, L=48mm
 Cortical Screw, D=3.5mm, L=50mm
 Cortical Screw, D=3.5mm, L=52mm
 Cortical Screw, D=3.5mm, L=54mm
 Cortical Screw, D=3.5mm, L=56mm
 Cortical Screw, D=3.5mm, L=58mm
 Cortical Screw, D=3.5mm, L=60mm

32351-12
 32351-14
 32351-16
 32351-18
 32351-20
 32351-22
 32351-24
 32351-26
 32351-28
 32351-30
 32351-32
 32351-34
 32351-36
 32351-38
 32351-40
 32351-42
 32351-44
 32351-46
 32351-48
 32351-50
 32351-52
 32351-54
 32351-56
 32351-58
 32351-60



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
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



Screwdriver, WS 2.5, self-holding sleeve	56252
--	-------



Depth Gauge, Solid Small Fragment Screws	59022
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Drill Guide, D=2.0/2.7mm	62202
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Spiral Drill, D=2.7mm, L=100mm, AO Connector	61273-100
Spiral Drill, D=2.5mm, L=180mm, AO Connector	61253-180



Guide Wire, Steel, D=1.6mm, L=150mm, TR, w. thread	35164-150
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Temporary Plate Holder	58164-150
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Sterilization Tray, Humeral Plate, Distal	50216
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For detailed cleaning and sterilization instructions, please refer to package insert.

Optional (on request)

Humeral Plate, Distal, 4-hole, Left, Dorsolateral	21242-4
Humeral Plate, Distal, 4-hole, Right, Dorsolateral	21241-4
Humeral Plate, Distal, 6-hole, Left, Dorsolateral	21242-6
Humeral Plate, Distal, 6-hole, Right, Dorsolateral	21241-6

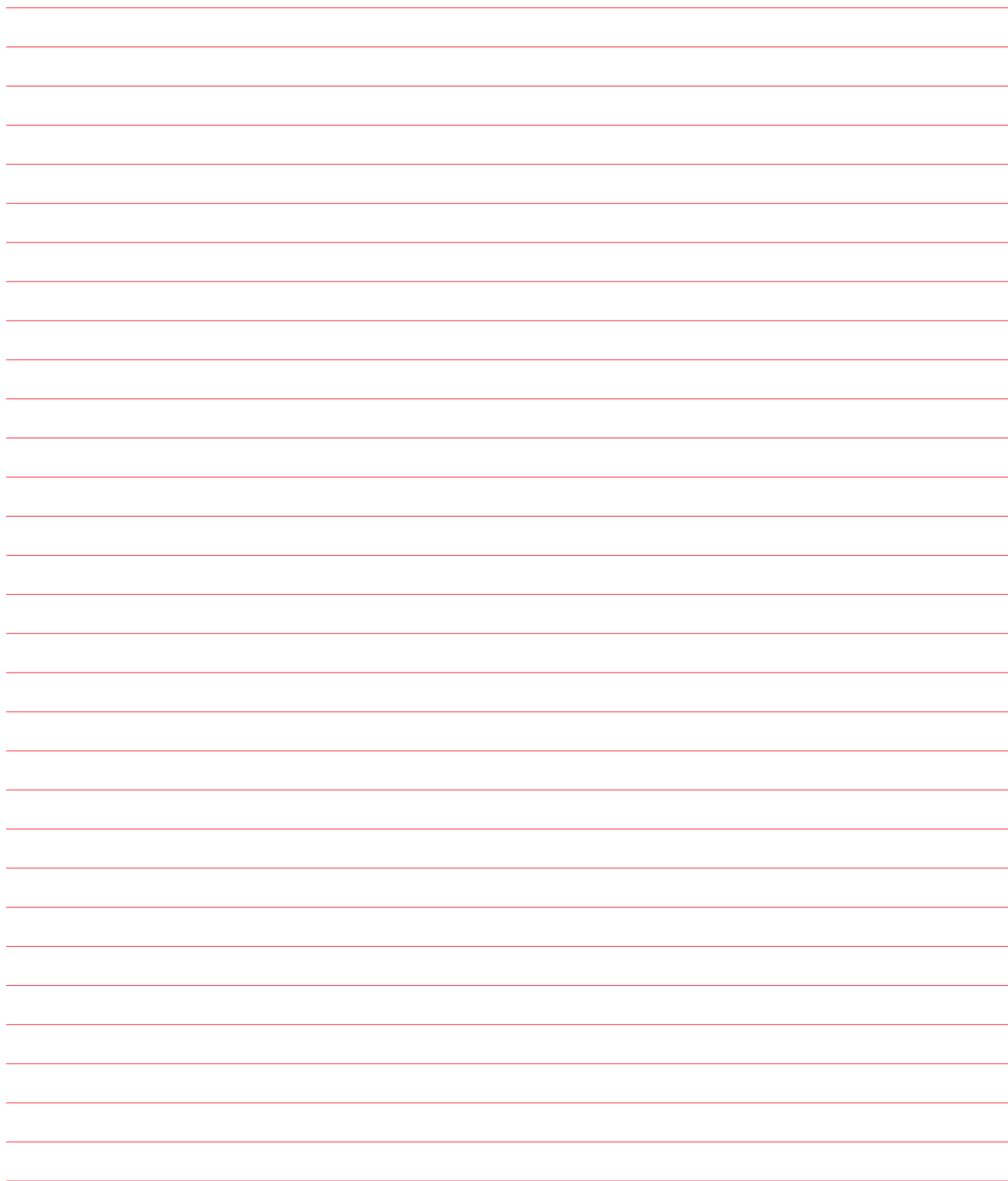


Humeral Plate, Distal, 9-hole, Left, Medial	21244-9
Humeral Plate, Distal, 9-hole, Right, Medial	21243-9



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

Notes



A blank sheet of lined paper with horizontal ruling lines and a vertical margin line on the right side. The paper is white with light blue horizontal lines and a single vertical blue margin line on the right. The lines are evenly spaced and extend across the width of the page.

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