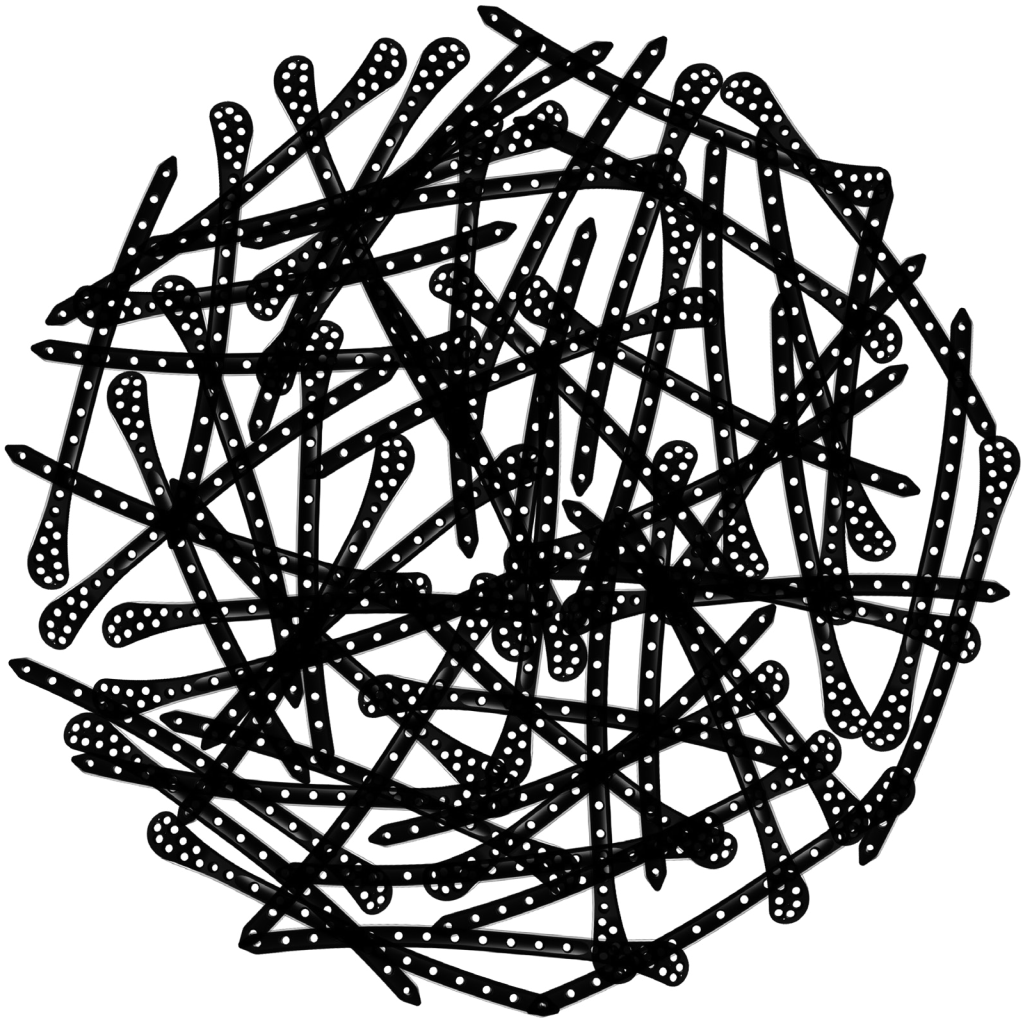
ITS.

Implants
trauma



DFL

Distal Femur 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

1.

Preface

The newly developed LRS System - Locking Reconstruction System - enables the medical treatment of fractures in the joint area with an optional less invasive method.

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.

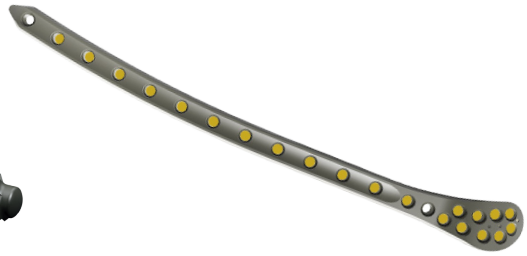
The system provides the opportunity to operate with or without a drill block in the joint area.
Especially with complex fractures the free choice of screw angle (+/- 15°, see page 23) has advantages in the fracture treatment.

Screws

37592-XX Cancellous Screw, locking, D=5.9mm

61354-280 Spiral Drill, D=3.5mm, L=280mm, AO Connector

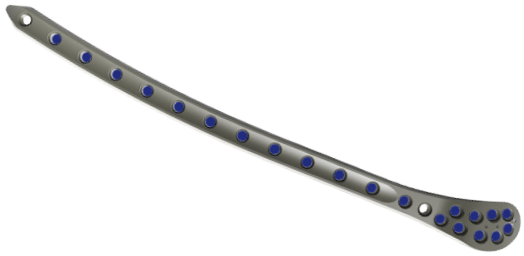
54353-230SH Screwdriver Shank, PRS, Solid, WS 3.5, L=230mm, AO Connector



30591-XX Cancellous Screw, D=5.9mm

61354-280 Spiral Drill, D=3.5mm, L=280mm, AO Connector

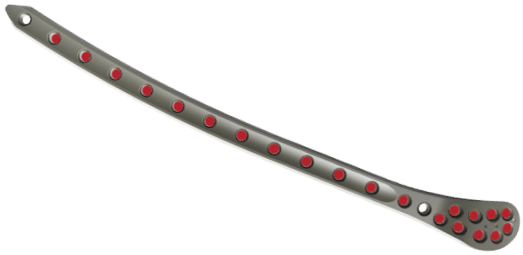
54353-230SH Screwdriver Shank, PRS, Solid, WS 3.5, L=230mm, AO Connector



32455-XX Cortical Screw, D=4.5mm

61324-280 Spiral Drill, D=3.2mm, L=280mm, AO Connector

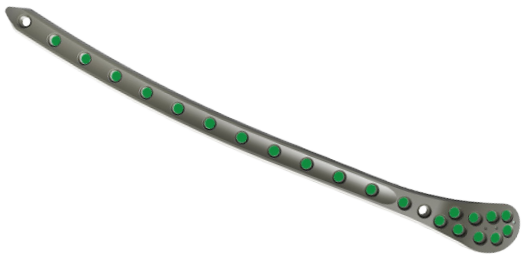
54353-230SH Screwdriver Shank, PRS, Solid, WS 3.5, L=230mm, AO Connector



37455-XX Cortical Screw, locking, D=4.5mm

61324-280 Spiral Drill, D=3.2mm, L=280mm, AO Connector

54353-230SH Screwdriver Shank, PRS, Solid, WS 3.5, L=230mm, AO Connector



Note: The threaded holes are primary for mounting the insertion guide. If desired by the surgeon, these holes can be filled with screws. ITS. recommends the use of locking screws, inserted 90° to the plate axis.

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
- Left/right version
- Plate lenghts: 5, 9, 13-hole

Less invasive method:

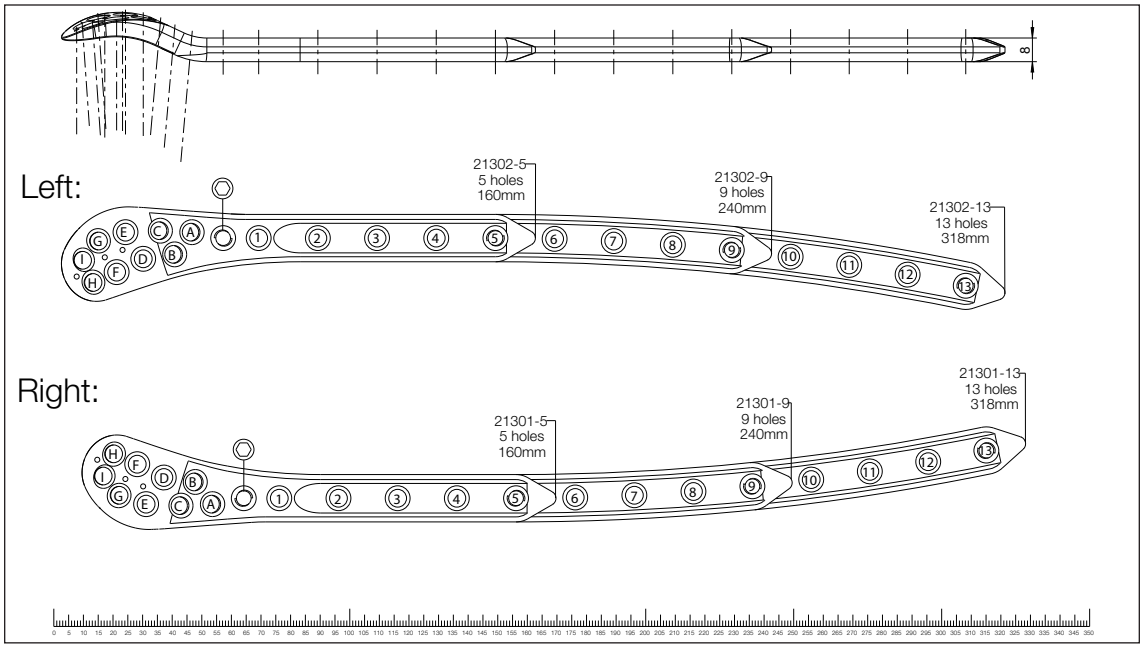
- Radiolucent handle and drill block close to joint
- Reduction instrument for easier reduction

Preoperative identification of screw length

- Preparing a x-ray with a 50mm calibration plate
- Measure the length of the calibration plate **(CPL)** on the x-ray
- Measure the width of the bone **(WB)** on the x-ray
- True width of the bone **(TWB)** is calculated as shown beside: $\mathbf{TWB = \frac{50}{CPL} \cdot WB}$

- Example: **CPL = 55mm; WB = 88mm**

$\mathbf{TWB = \frac{50}{55} \cdot 88mm}$ **TWB = 80mm** The true width of the bone equals 80mm.



Indications, Contraindications & Time of operation

Indications:

For the stabilization of fractures of the distal femur

- Distal shaft fractures
- Supracondylar fractures
- Intra-articular fractures

Contraindications:

- With advanced osteoporosis
- In cases of skin and soft tissue problems above the lateral epicondylus
- Obesity
- Lack of patient compliance

Time of operation:

- Primary: Within the first hours after trauma
- Secondary: After swelling subsides, intermediate fixation with external fixation or extension

Surgical Technique

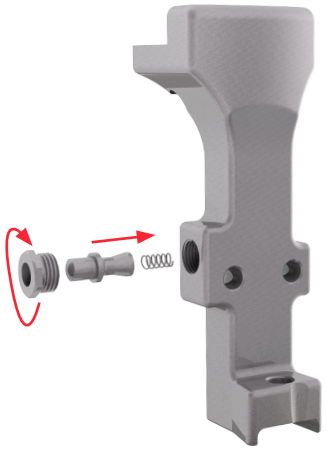
2.

Pre-operative patient preparation

- Position the patient supine on a radiolucent table
- Leg freely movable
- In patients with very short distal fragments, flex the lower leg to approximately 60°

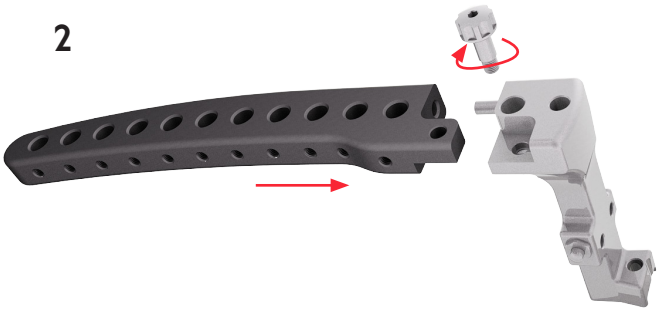
Assembly of the insertion guide

1

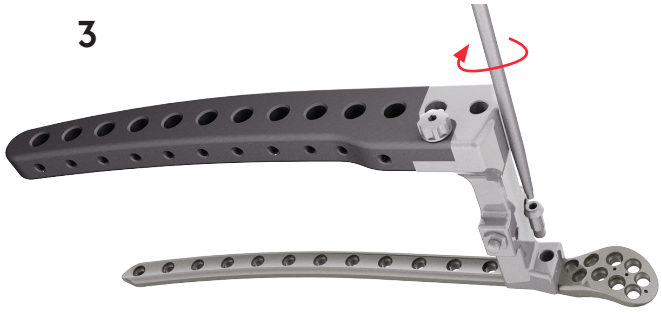


Assemble the clamping bolt with flat wrench, WS II **(70011)**

2



3

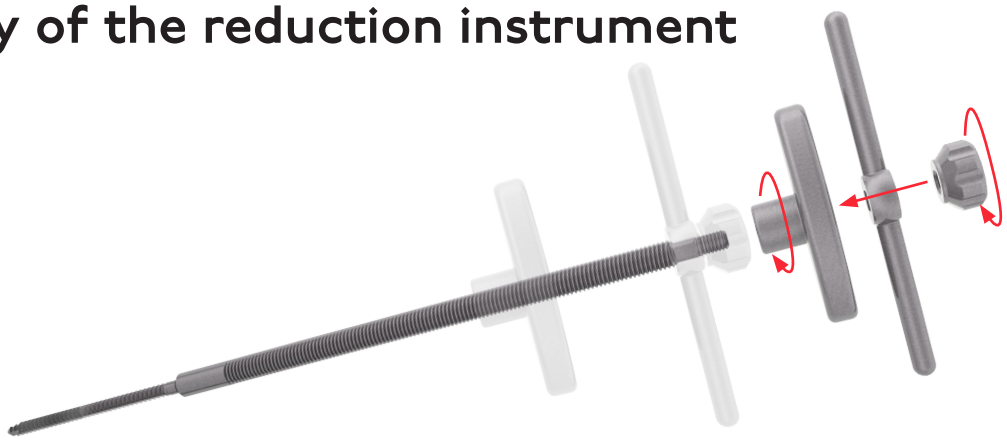


Assemble the insertion guide on the plate with the fixation screw **(118003-7)**

4

5

Assembly of the reduction instrument



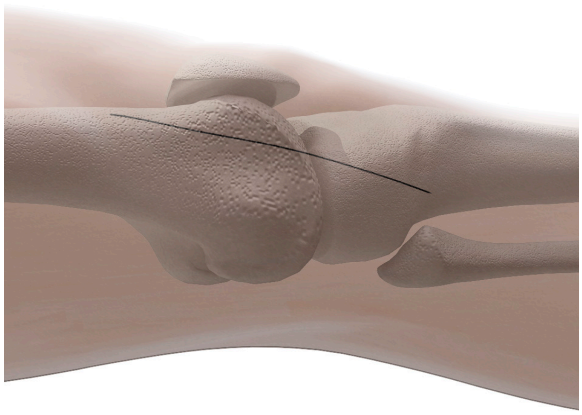
Reduction

- Anatomic reduction of the fracture
- In intra-articular fractures reconstruct and stabilize the whole joint
- Possible temporary fixation with K-Wires
- Following x-ray control

Access

Extra-articular fractures:

- Skin incision from lateral over the femoral condyle
- Split the iliotibial tract in direction of the fibers
- Open the space between the lateral vastus muscle and the periosteum
- Insert the plate between the periosteum and the muscle



Intra-articular fractures:

- Anterolateral arthrotomy providing good control of the reduction

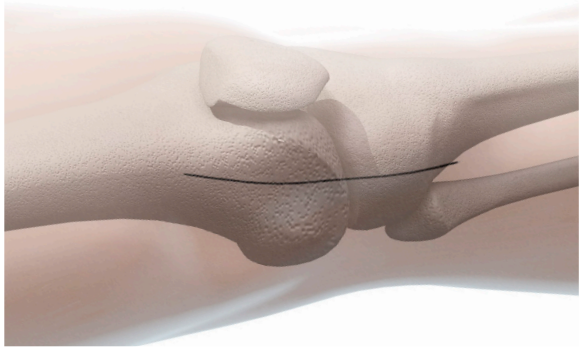
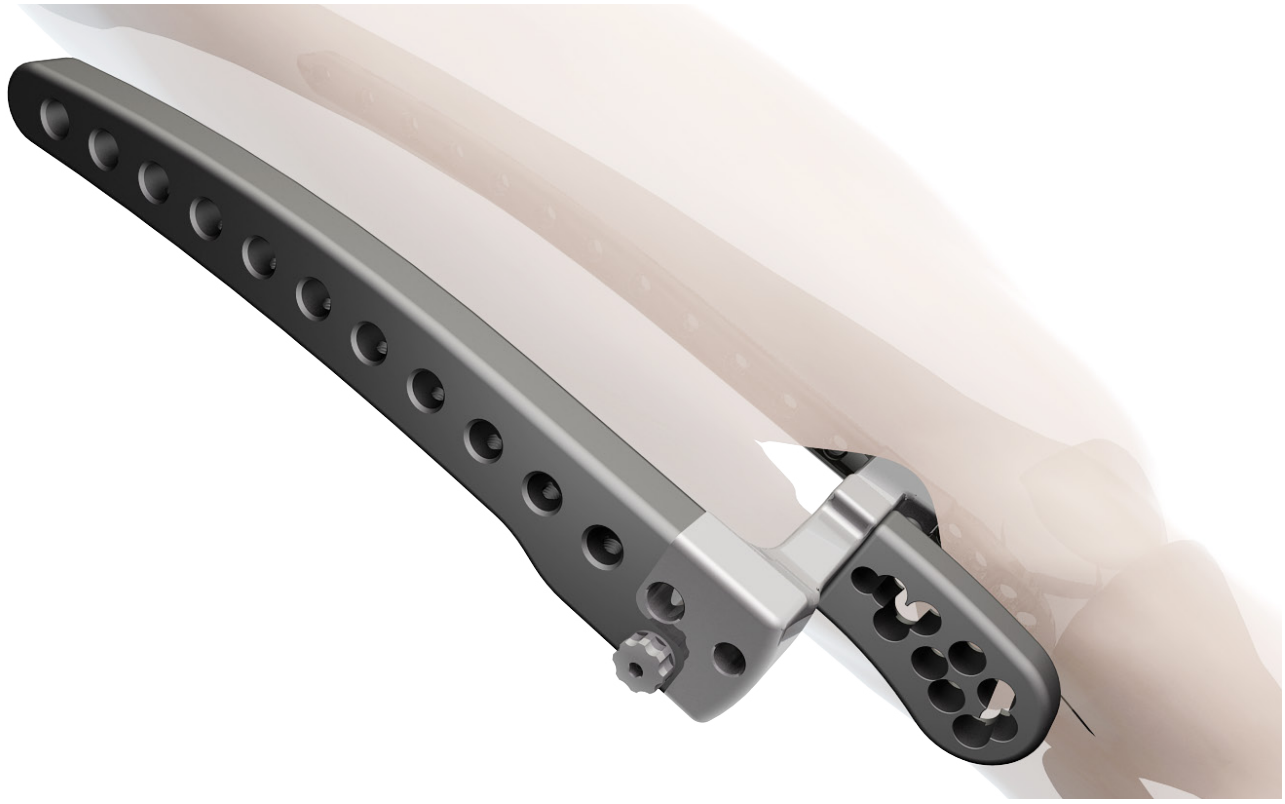


Plate insertion

- Insert the plate, assembled on the insertion guide, between the vastus muscle and periost
- Proximal end of the plate should remain in constant contact with the bone
- Position the distal end of the plate against the lateral condyle (plate must lie flat up against the condyle. If it's problematic to find the correct position, enlarge the incision)
- Verify the correct plate position under fluoroscopy and temporarily secure it with the tissue protection sleeve **(118003-11)**, drill sleeve, D=1.7/3.6mm **(118003-9/118003-10)** and the inserted guide wire, steel, D=1.6/3.2mm, L=260mm, TR w. Thrd. **(35164-260/35324-260)** into one of the distal holes (D, E, F - figure page 7) of the drill block
- Verify the correct plate position

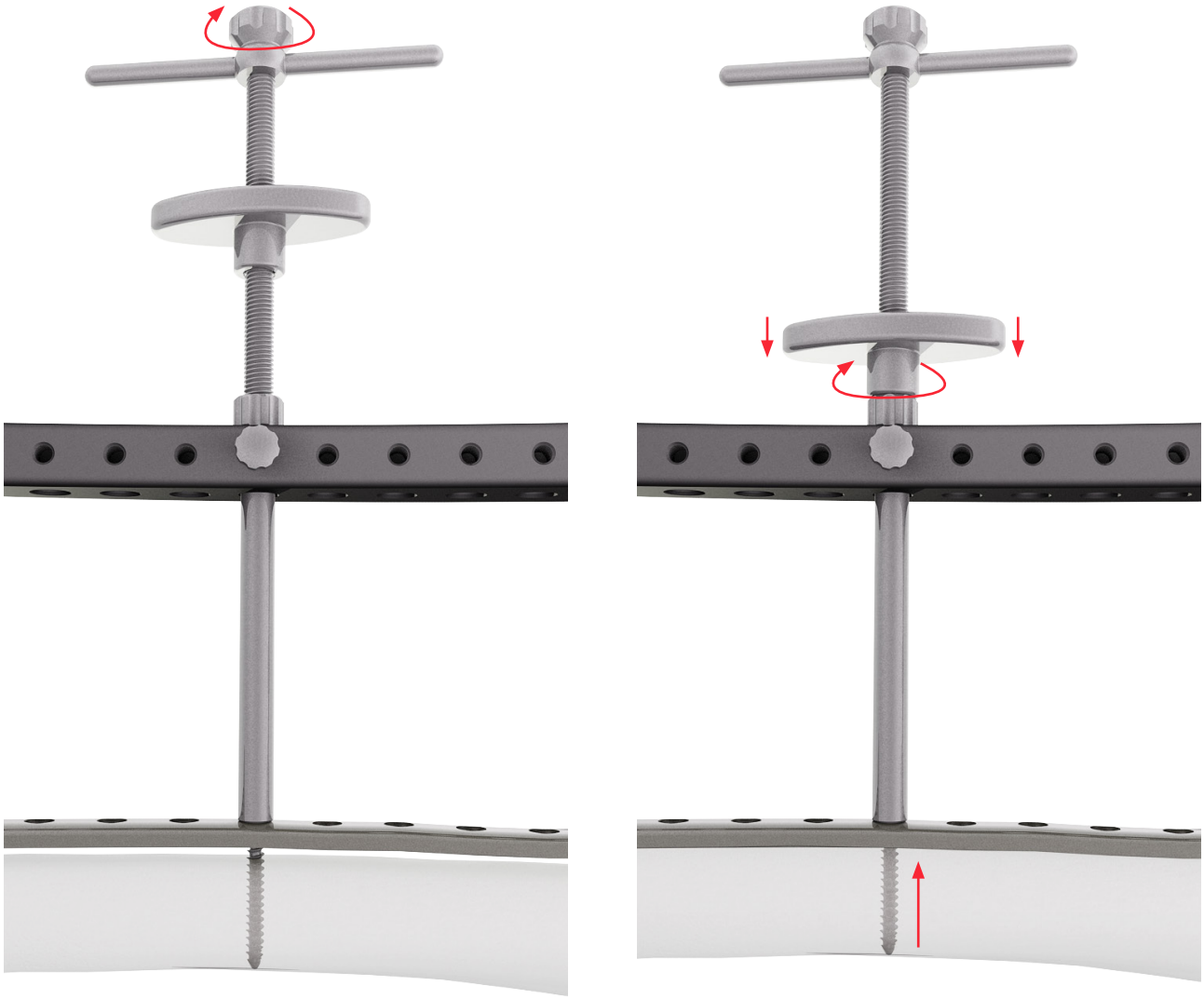


Temporary fixation with K-Wires

Fixation with K-Wires passed through tissue protection sleeves **(118003-11)** and inserted drill sleeve D=1.7/3.6mm **(118003-9/118003-10)** can be performed as soon as plate and bone have been optimally aligned. Proximal fixation follows after distal fixation. Insert trocar **(57042)** through the tissue protection sleeve **(118003-11)** in the most proximal hole of the plate (guiding instrument) and advance to the plate after stab incision. Then, insert the retaining sleeve **(118003-16)**, screw it onto the plate and place the D=1.6mm guide wire **(35164-260)** through the retaining sleeve **(118003-16)**. Fix the retaining sleeve with the clamping screw **(118003-12)** at the insertion guide. Then check placement under fluoroscopy.

Reduction instrument

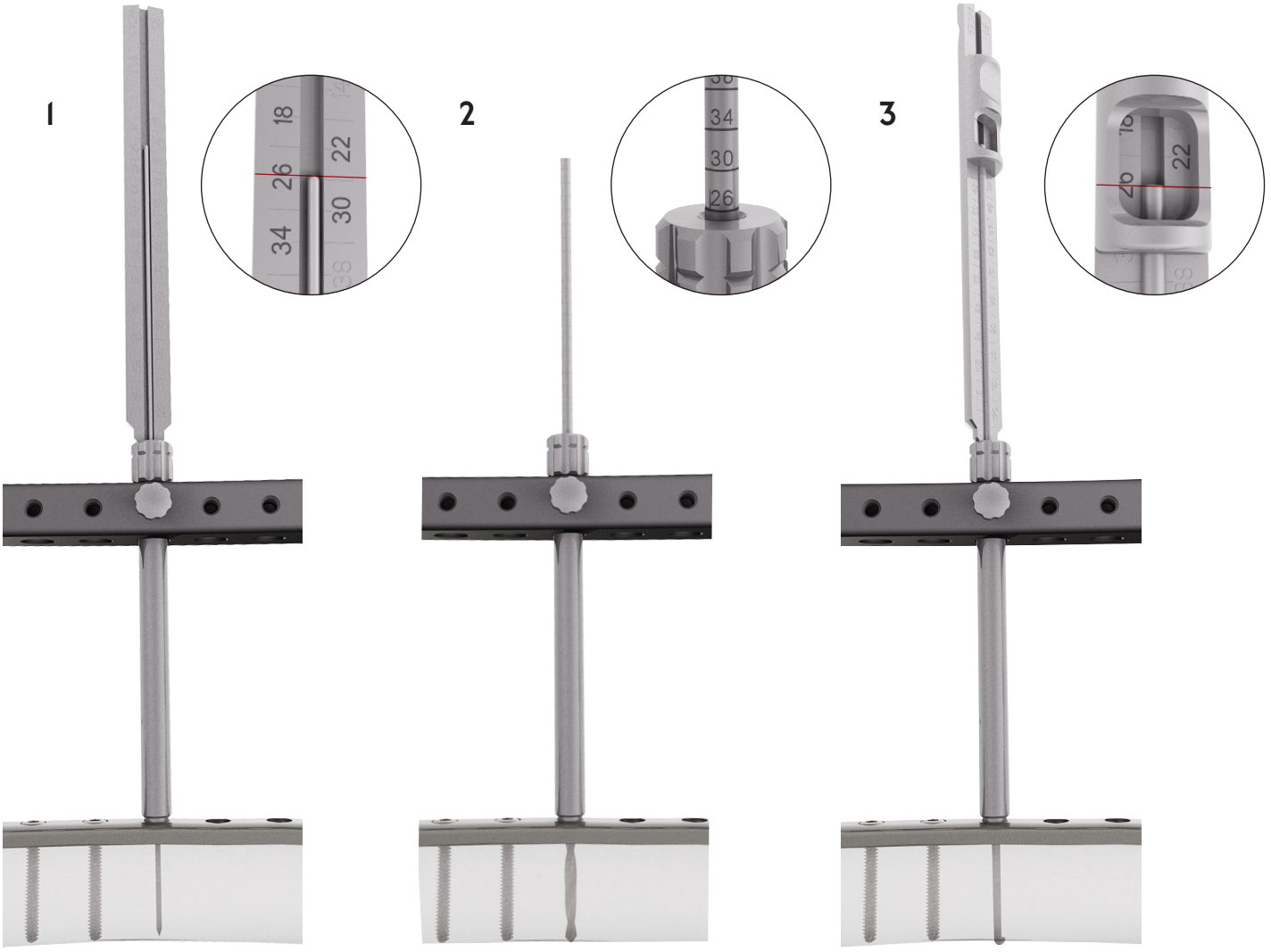
Use a D=3.2mm spiral drill **(61324-280)** to create a hole for the insertion of the reduction instrument **(62700)** through the tissue protection sleeve **(118003-11)** and the D=3.6mm drill sleeve **(118003-10)**.
Following removal of the drill sleeve, screw in the extraction instrument through the tissue protection sleeve into the bone. As soon as fixed in the bone, a reposition can be made by rotating the oval spindle nut while holding the T-handpiece. Turn in a screw through one of the adjacent plate holes to maintain reposition.
Then, the reduction instrument can be removed.



Intraoperative identification of screw length

1. Insert the guide wire D=1.6/3.2mm **(35164-260/35324-260)** under fluoroscopy monitoring through the far cortices of the plate. Then, position the depth gauge, 2 parts **(59324)** and read off the required screw length at the end of the calibrated K-Wire.
2. Drill screw holes under fluoroscopy guidance through the far cortices of the plate. Then, read off the required screw length at the calibrated D=3.2/3.5mm spiral drill **(61324-280/61354-280)**.
3. Insert the depth gauge, 2 parts **(59324)** after drilling screw holes. After hooking into the far cortices of the plate, position the length gauge at the drill sleeve and read off the required screw length at the end of the calibrated measuring wire.

Note: In the distal area, the screw length may also be determined using the standard depth gauge, solid small fragment screws **(59022)**.

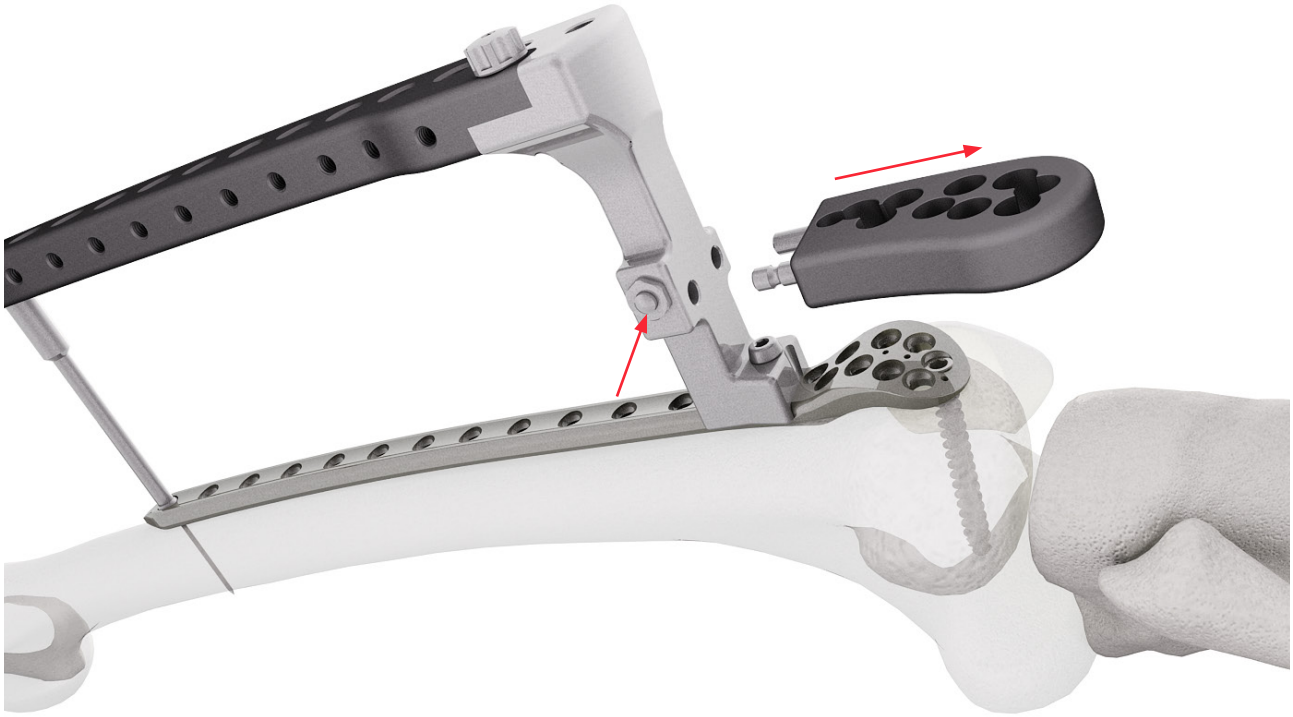


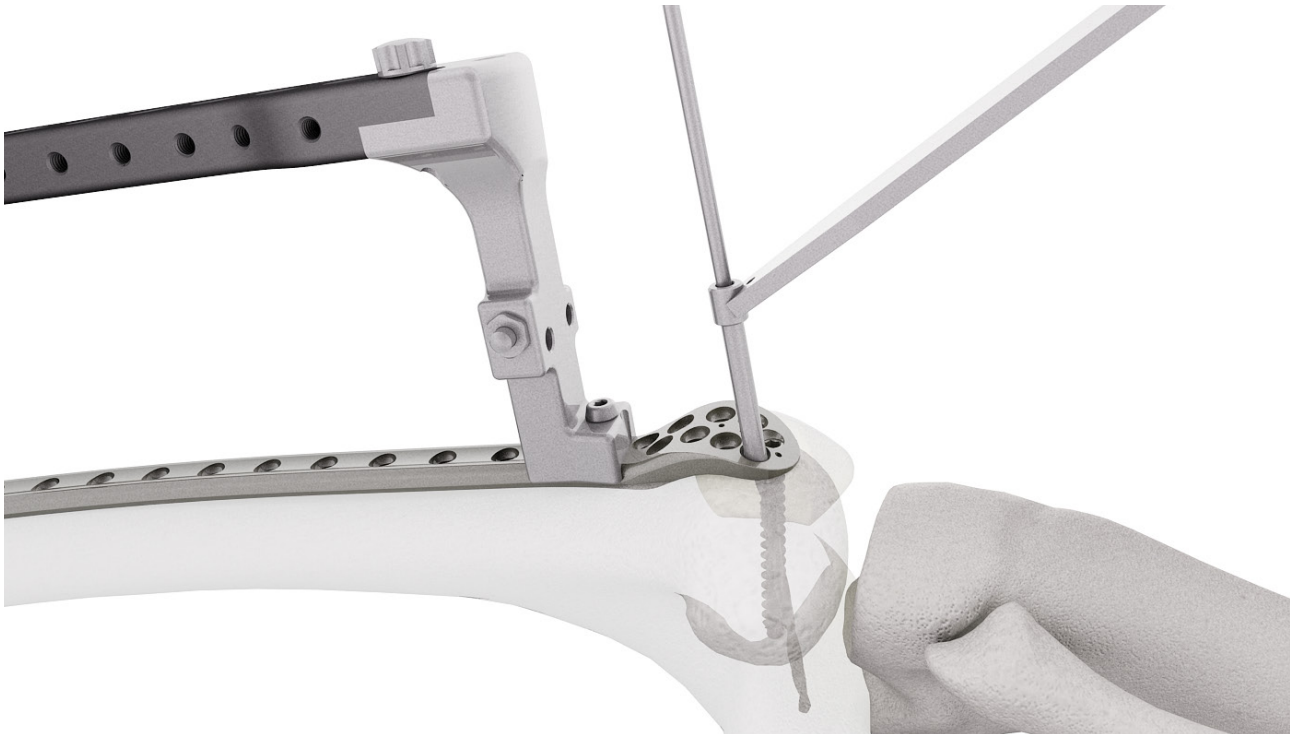
Placement of the screws

After temporary fixation with K-Wires, 2-3 D=5.9mm locking cancellous screws **(37592-XX)** in accordance with the measured length are now placed distally.
The D=3.5mm spiral drill **(61354-280)** is used to pre-drill holes for the D=5.9mm locking cancellous screws. Drilling is performed through the D=3.6mm drill sleeve **(118003-10)** that was placed in the tissue protection sleeve **(118003-11)**. Then, the drill sleeve is removed and the screw (appropriate length measured before) is inserted through the tissue protection sleeve.

Drilling optionally

The distal screws can be fitted, having a free choice of screw angle (+/- 15°), without the drill block.
To loosen the drill block **(118003-5/118003-6)** push the clamping bolt **(118003-13)** along the side.
Use the D=3.5mm spiral drill **(61354-280)** and the drill guide D=2.5/3.5mm **(62252)** to insert a D=5.9mm cancellous screw, locking **(37592-XX)**.





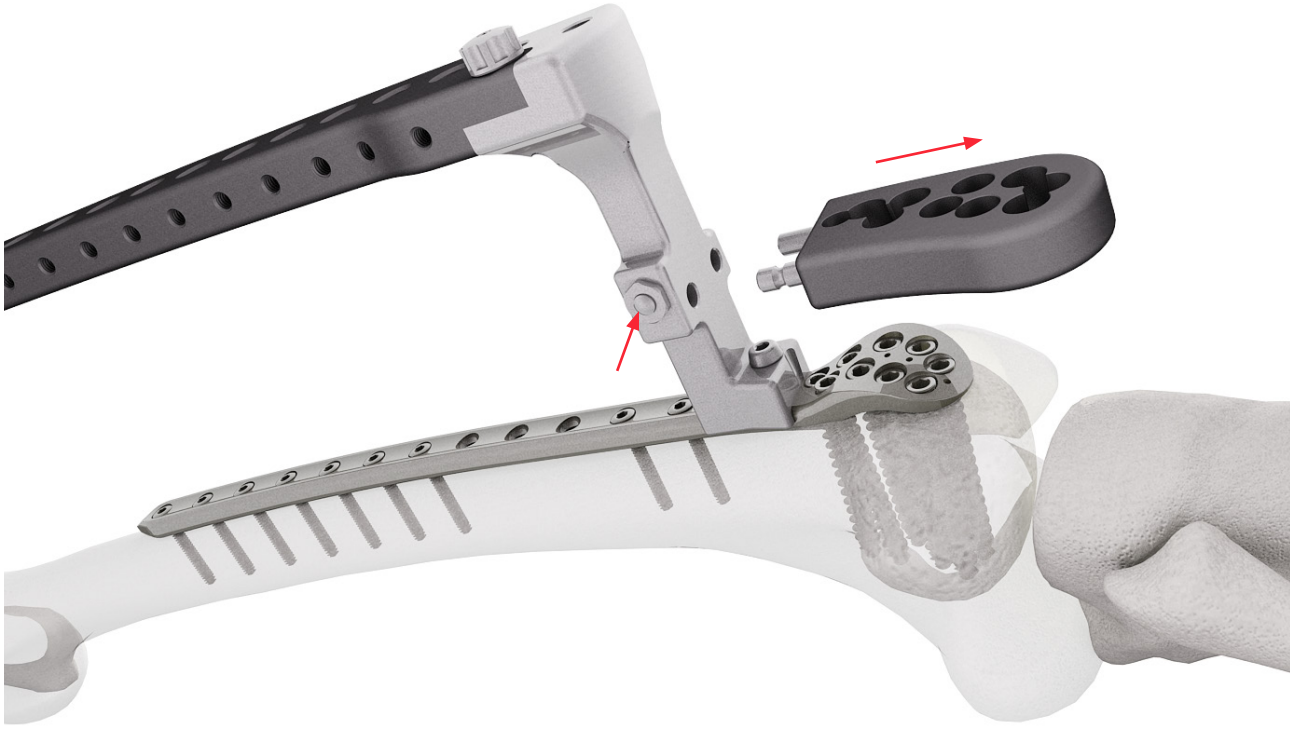
Placement of the screws

After that, 2-3 D=4.5mm cortical screws, either non-locking or locking **(32455-XX/37455-XX),** are placed proximally in the shaft. For that reason the D=3.2mm spiral drill **(61324-280)** is used. Drilling is again performed through the D=3.6mm drill sleeve **(118003-10)** that was placed in the tissue protection sleeve **(118003-11)**. Then, the drill sleeve is removed and the screw (appropriate length measured before) is inserted through the tissue protection sleeve.

Afterwards, fill all distal holes with screws and then all shaft holes. Pay attention not to place screws in the region of the fracture and the adjacent plate holes (that would lead to problems of the fracture healing).

Disassembling of the insertion guide

To release the drill block **(118003-5/118003-6)** push the clamping bolt **(118003-13)** along the side.



To remove the entire guiding instrument, loosen the fixation screw **(118003-7)**.

Postoperative treatment

- Position the patient in a slight knee bend and bedrest
- After reduction of swelling, beginning of the passive mobilization (CPM Splint)
- Partial weight-bearing sole contact - Week 0-6: 33 lbs
  - Week 6-10: 66 lbs
- Full weight-bearing - Week 10-12 after fracture has healed
  - Week 16-20 at C-fractures after fracture has healed

Explantation

- Removal is possible, if desired by the patient. This is facilitated by the fact that cold welding never occurs.
- Implant removal is performed 6 months post-operative and if the fracture has healed
- Vice versa of implantation
- Skin incision following the old scar
- Assemble the insertion guide onto the plate
- Stab incision and remove the screw with the screwdriver WS 3.5mm **(5301l with 54353-230SH)**
- The problem of cold welding was resolved by using a special surface treatment (for further information see page 23).

Summary

The newly developed LRS System - Locking Reconstruction System - enables the medical treatment of fractures in the joint area with a less invasive method.
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.

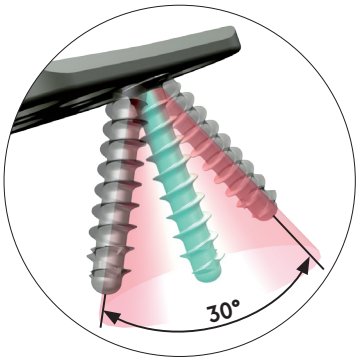
Information

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:

- ± 15° and Locking
- No pre threading
- No cold welding
- No debris
- You can re-set the screw up to 3 times

Dotize®

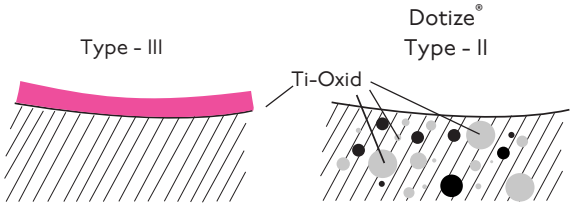
Chemical process - anodization in a strong alkaline solution*

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

Distal Femur Plate, 5-hole, Right	21301-5
Distal Femur Plate, 5-hole, Left	21302-5
Distal Femur Plate, 9-hole, Right	21301-9
Distal Femur Plate, 9-hole, Left	21302-9
Distal Femur Plate, 13-hole, Right	21301-13
Distal Femur Plate, 13-hole, Left	21302-13

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
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=16mm, Threaded	30591-16
Cancellous Screw, D=5.9mm, L=20mm, Threaded	30591-20
Cancellous Screw, D=5.9mm, L=24mm, Threaded	30591-24
Cancellous Screw, D=5.9mm, L=28mm, Threaded	30591-28
Cancellous Screw, D=5.9mm, L=32mm, Threaded	30591-32
Cancellous Screw, D=5.9mm, L=36mm, Threaded	30591-36
Cancellous Screw, D=5.9mm, L=40mm, Threaded	30591-40
Cancellous Screw, D=5.9mm, L=44mm, Threaded	30591-44
Cancellous Screw, D=5.9mm, L=48mm, Threaded	30591-48
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
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

Cortical Screw, D=4.5mm, L=16mm, Cort. Thread	32455-16
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Cortical Screw, D=4.5mm, L=28mm, Cort. Thread	32455-28
Cortical Screw, D=4.5mm, L=32mm, Cort. Thread	32455-32
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Cortical Screw, D=4.5mm, L=52mm, Cort. Thread	32455-52
Cortical Screw, D=4.5mm, L=56mm, Cort. Thread	32455-56
Cortical Screw, D=4.5mm, L=60mm, Cort. Thread	32455-60
Cortical Screw, D=4.5mm, L=65mm, Cort. Thread	32455-65
Cortical Screw, D=4.5mm, L=70mm, Cort. Thread	32455-70
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Cortical Screw, D=4.5mm, L=120mm, Cort. Thread	32455-120

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
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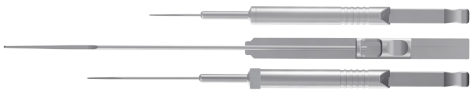
Cortical Screw, locking, D=4.5mm, L=52mm	37455-52
Cortical Screw, locking, D=4.5mm, L=56mm	37455-56
Cortical Screw, locking, D=4.5mm, L=60mm	37455-60
Cortical Screw, locking, D=4.5mm, L=65mm	37455-65
Cortical Screw, locking, D=4.5mm, L=70mm	37455-70
Cortical Screw, locking, D=4.5mm, L=75mm	37455-75
Cortical 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
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

Order list

5x Guide Wire, Steel, D=1.6mm, L=260mm, TR, w. thread	35164-260	
5x Guide Wire, Steel, D=3.2mm, L=260mm, TR, w. thread	35324-260	
Handle, 25mm, AO Connector	53011	
2x Screwdriver Shank, PRS, Solid, WS 3.5mm, L=230mm, AO Connector	54353-230SH	
Reduction Instrument	62700	
Spiral Drill, D=3.2mm, L=280mm, AO Connector	61324-280	
Spiral Drill, D=3.5mm, L=280mm, AO Connector	61354-280	
Depth Gauge, Solid Small Fragment Screws	59022	
Depth Gauge, 2 Parts for D=3.2mm Wire	59324	
Depth Gauge, 110mm, for longer screws	KG.400.06	
Drill Guide, D=2.5/3.5mm	62252	
Trochar LRS	57042	
Screw Tweezers, SH 8cm	33.839.09	
Flat Wrench, WS 11	70011	
Insertion Guide Distal Femur Plate	118003	
Sterilization Tray, Distal Femur Plate	50206	

Spare Parts List Insertion Guide / Optional (on request)

Jig, Right	118003-1	
Jig, Left	118003-2	
Handle, Right	118003-3	
Handle, Left	118003-4	
Drill Block, Right	118003-5	
Drill Block, Left	118003-6	
Fixation Screw	118003-7	

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

Retaining Screw	118003-8	
Drill Sleeve, D=1.7mm	118003-9	
Drill Sleeve, D=3.6mm	118003-10	
Tissue Protection Sleeve	118003-11	
Clamping Screw	118003-12	
Clamping Bolt	118003-13	
Nut f. Clamping Bolt	118003-14	
Coil Spring f. Clamping Bolt	118003-15	
Retaining Sleeve	118003-16	

Special sizes & instruments optional on request *

Cancellous Screw, Locking, D=5.9mm, L=18mm	37592-18
Cancellous Screw, Locking, D=5.9mm, L=22mm	37592-22
Cancellous Screw, Locking, D=5.9mm, L=26mm	37592-26
Cancellous Screw, Locking, D=5.9mm, L=30mm	37592-30
Cancellous Screw, Locking, D=5.9mm, L=34mm	37592-34
Cancellous Screw, Locking, D=5.9mm, L=38mm	37592-38
Cancellous Screw, Locking, D=5.9mm, L=42mm	37592-42
Cancellous Screw, Locking, D=5.9mm, L=46mm	37592-46
Cancellous Screw, Locking, D=5.9mm, L=50mm	37592-50
Cancellous Screw, Locking, D=5.9mm, L=54mm	37592-54
Cancellous Screw, Locking, D=5.9mm, L=58mm	37592-58

Cancellous Screw, D=5.9mm, L=18mm	30591-18
Cancellous Screw, D=5.9mm, L=22mm	30591-22
Cancellous Screw, D=5.9mm, L=26mm	30591-26
Cancellous Screw, D=5.9mm, L=30mm	30591-30
Cancellous Screw, D=5.9mm, L=34mm	30591-34
Cancellous Screw, D=5.9mm, L=38mm	30591-38
Cancellous Screw, D=5.9mm, L=42mm	30591-42
Cancellous Screw, D=5.9mm, L=46mm	30591-46
Cancellous Screw, D=5.9mm, L=50mm	30591-50
Cancellous Screw, D=5.9mm, L=54mm	30591-54
Cancellous Screw, D=5.9mm, L=58mm	30591-58

Cortical Screw, D=4.5mm, L=18mm, Cort. Thread	32455-18
Cortical Screw, D=4.5mm, L=22mm, Cort. Thread	32455-22
Cortical Screw, D=4.5mm, L=26mm, Cort. Thread	32455-26
Cortical Screw, D=4.5mm, L=30mm, Cort. Thread	32455-30
Cortical Screw, D=4.5mm, L=34mm, Cort. Thread	32455-34
Cortical Screw, D=4.5mm, L=38mm, Cort. Thread	32455-38

* Delivery times, prices & minimum quantities may vary from standard

Order list

Cortical Screw, D=4.5mm, L=42mm, Cort. Thread	32455-42
Cortical Screw, D=4.5mm, L=46mm, Cort. Thread	32455-46
Cortical Screw, D=4.5mm, L=50mm, Cort. Thread	32455-50
Cortical Screw, D=4.5mm, L=54mm, Cort. Thread	32455-54
Cortical Screw, D=4.5mm, L=58mm, Cort. Thread	32455-58

Cortical Screw, Locking, D=4.5mm, L=18mm	37455-18
Cortical Screw, Locking, D=4.5mm, L=22mm	37455-22
Cortical Screw, Locking, D=4.5mm, L=26mm	37455-26
Cortical Screw, Locking, D=4.5mm, L=30mm	37455-30
Cortical Screw, Locking, D=4.5mm, L=34mm	37455-34
Cortical Screw, Locking, D=4.5mm, L=38mm	37455-38
Cortical Screw, Locking, D=4.5mm, L=42mm	37455-42
Cortical Screw, Locking, D=4.5mm, L=46mm	37455-46
Cortical Screw, Locking, D=4.5mm, L=50mm	37455-50
Cortical Screw, Locking, D=4.5mm, L=54mm	37455-54
Cortical Screw, Locking, D=4.5mm, L=58mm	37455-58

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Notes

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