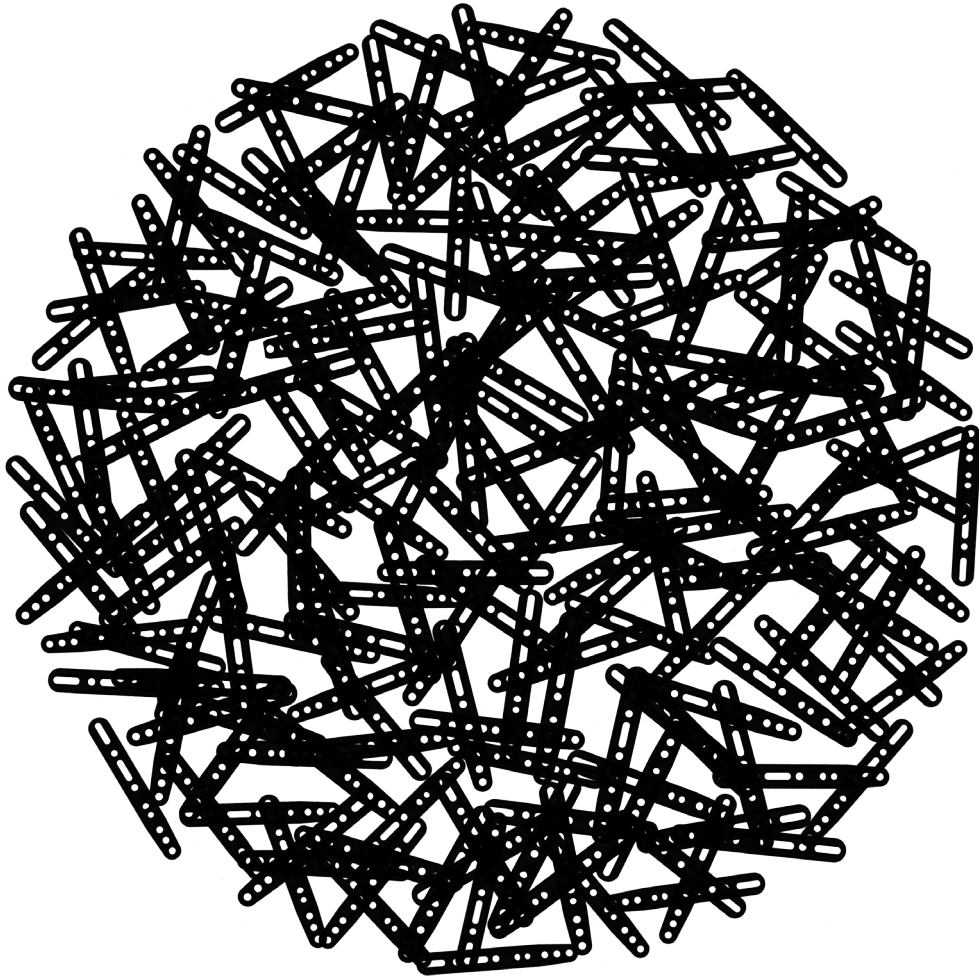


ITS.

Implants
trauma



UOL 2

Ulna Osteotomy Locking Plate 2

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



Hello!

◦ Preface

With the further developed, angularly stable ulna osteotomy plate, a plate system with angular stability and compression screws is available, which is specially adapted to the anatomical and biomechanical requirements after shortening osteotomy of the distal ulna.

The all-in-one solution allows a unique plane-parallel cross-section, with a rotation-stable shortening process and a compression option.

The resulting standardization of several operations in a “one-device-system” increases and ensures the quality of the operational sequence.

○ Screws

32271-XX Cortical Screw, D=2.7mm

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

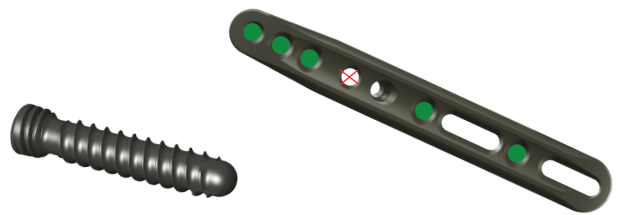
56095-70 Screwdriver, Torque, T9x70



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

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

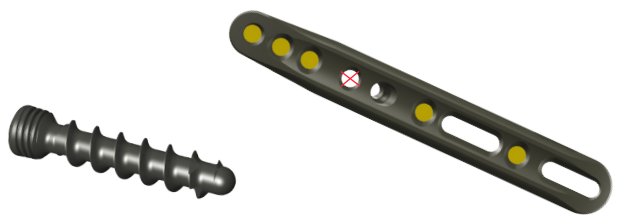
56095-70 Screwdriver, Torque, T9x70



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

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

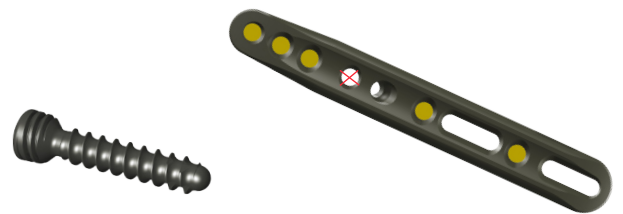
56095-70 Screwdriver, Torque, T9x70



37241-XX Stabilization Screw, D=2.4mm, RH

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

56095-70 Screwdriver, Torque, T9x70



Attention:

- The two oblong holes may only be used with the D= 2.7mm cortex screw (32271-XX).
- The threaded hole is used only for the attachment of the instrumentation and must not be filled with screws

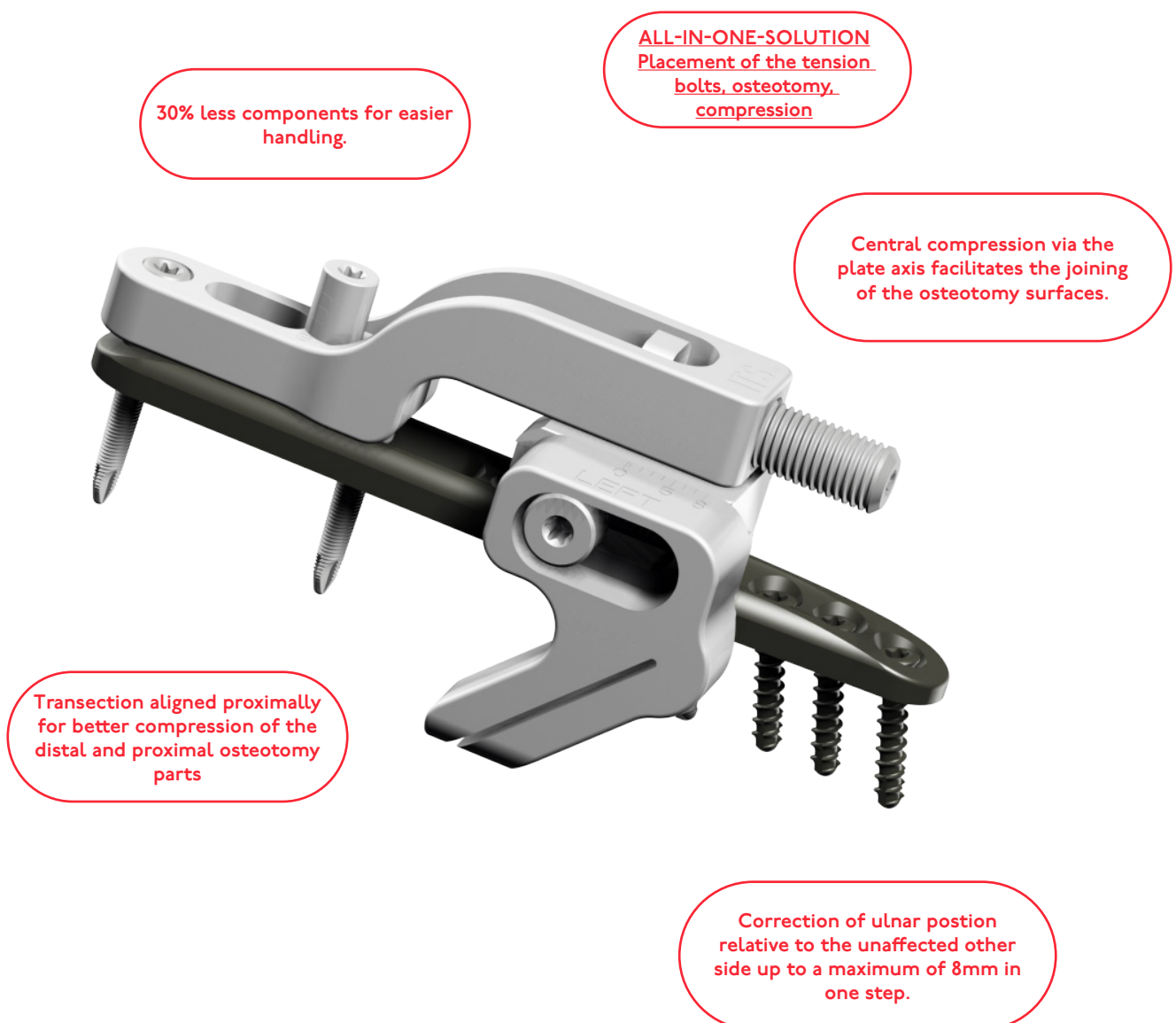
○ Properties

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
- ◆ Three holes distal of the osteotomy
- ◆ Fixation of the osteotomy by a screw perpendicular to the cutting surface



◦ Indications & Contraindications

Indications:

- ◆ Impaction syndrome of the ulnar wrist
- ◆ Symptomatic, post-traumatic ulnar malposition in the distal radio-ulnar joint (DRUJ)
- ◆ Degenerative ulnar wrist
- ◆ Correction of the ulnar position relative to the unaffected other side up to a maximum of 8mm in one step or 16mm in two steps

Extended Indications:

- ◆ Primary ulnar shortening in forearm fractures with insufficient reconstruction of the length of the radius
- ◆ Deformities
- ◆ Degenerative ulnar variant in conically shaped DRUJ according to Förstner

Contraindications:

- ◆ Severe osteoporosis
- ◆ Existing bone or soft tissue infections in the operation field
- ◆ In cases of skin and soft tissue problems
- ◆ Obesity
- ◆ Lack of patient compliance

Surgical Technique

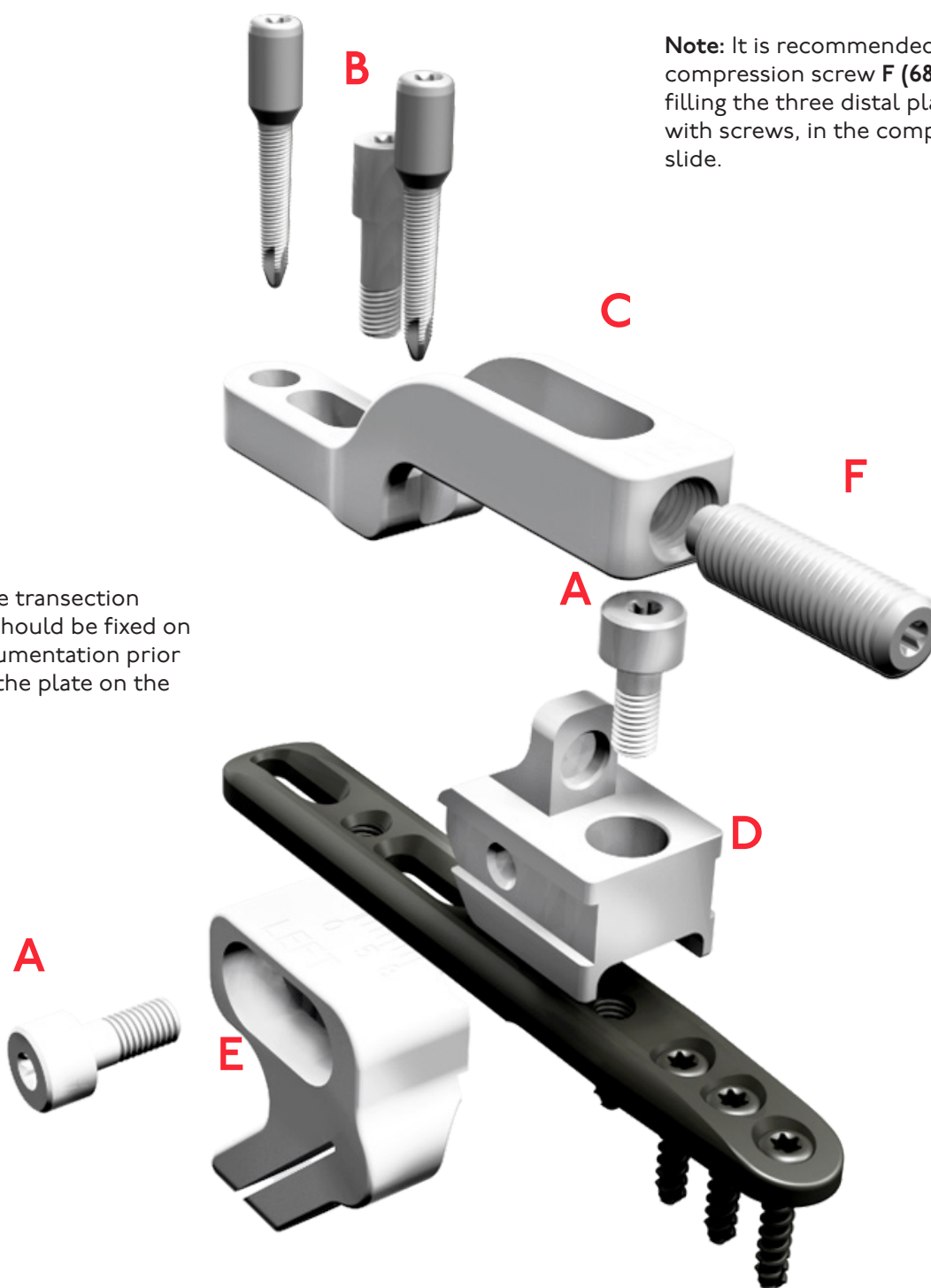
2.

○ Assembly of the instruments

- The mounting of the instruments for the application on the left and right ulnar bones differs only in the attachment of the transection gauge. The other components are identical for both sides.
- First, the jig **D (680870)** is fixed on the plate with the fixing screw **A (680871)**. The recess for the 45 ° hole points to proximal. The front flat side of the carrier unit must be aligned with the laser marking transverse to the plate axis, to enable an easier fixation.
- Afterwards, fix the compression slide **C (680876)** with the fixing screw **B (680872-2)** on the plate.
- Then, fix the transection gauge **E (680873 for the right side / 680874 for the left side)** with the screw **A (680871)** on the carrier unit.

Note: The transection gauge **E** should be fixed on the instrumentation prior to place the plate on the bone.

Note: It is recommended to use the compression screw **F (680875)**, after filling the three distal plate holes with screws, in the compressing slide.



○ Pre-operative patient preparation

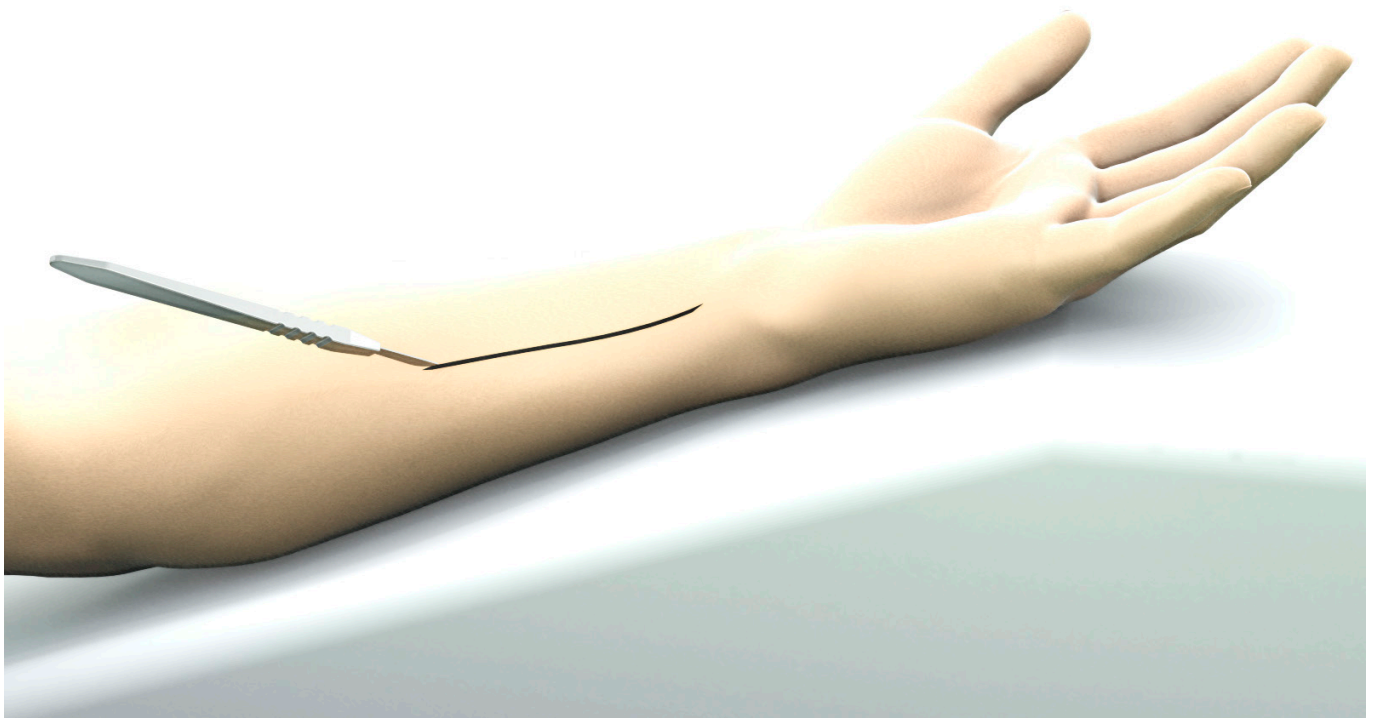
Place the patient in a supine position, cover the arm to be freely mobile and place it on an X-ray transparent table at a shoulder abduction of 90°. Perform the operation under regional or general anaesthesia with or without using a tourniquet on the upper arm.

The shape of the implant allows for palmar, ulnar or dorsal positioning of the plate. The plate should be completely fitted to the bone without protruding. As the distal palmar section of the ulna is usually curved, more proximal positioning of the plate or slightly pre-bending of the implant are recommended.

Attention: When bending the plate, make sure you bend the plate at the 3 distal bore holes only. If you bend the plate too much, it may happen that the “Locking” System doesn’t work due to deformation.

○ Exposure

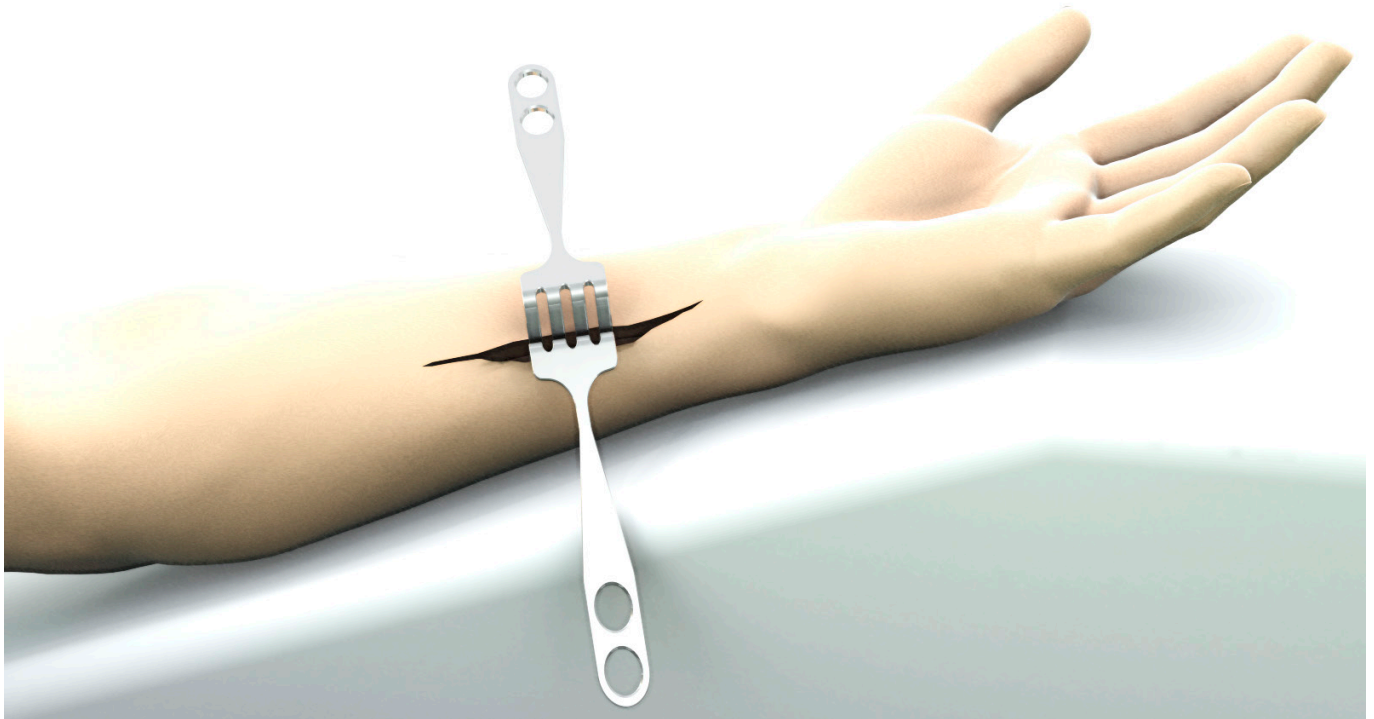
The upper extremity is rotated outwards, the elbow is bent, and the wrist is supported with a roll. Begin the incision of the skin approximately 2–3cm proximal of the evident ulna styloid process. It shall run 5mm palmar, parallel to the evident interosseous border approximately 7–8cm proximal. It is mandatory to pay attention to the dorsal branch of the ulnar nerve.



○ Plate insertion

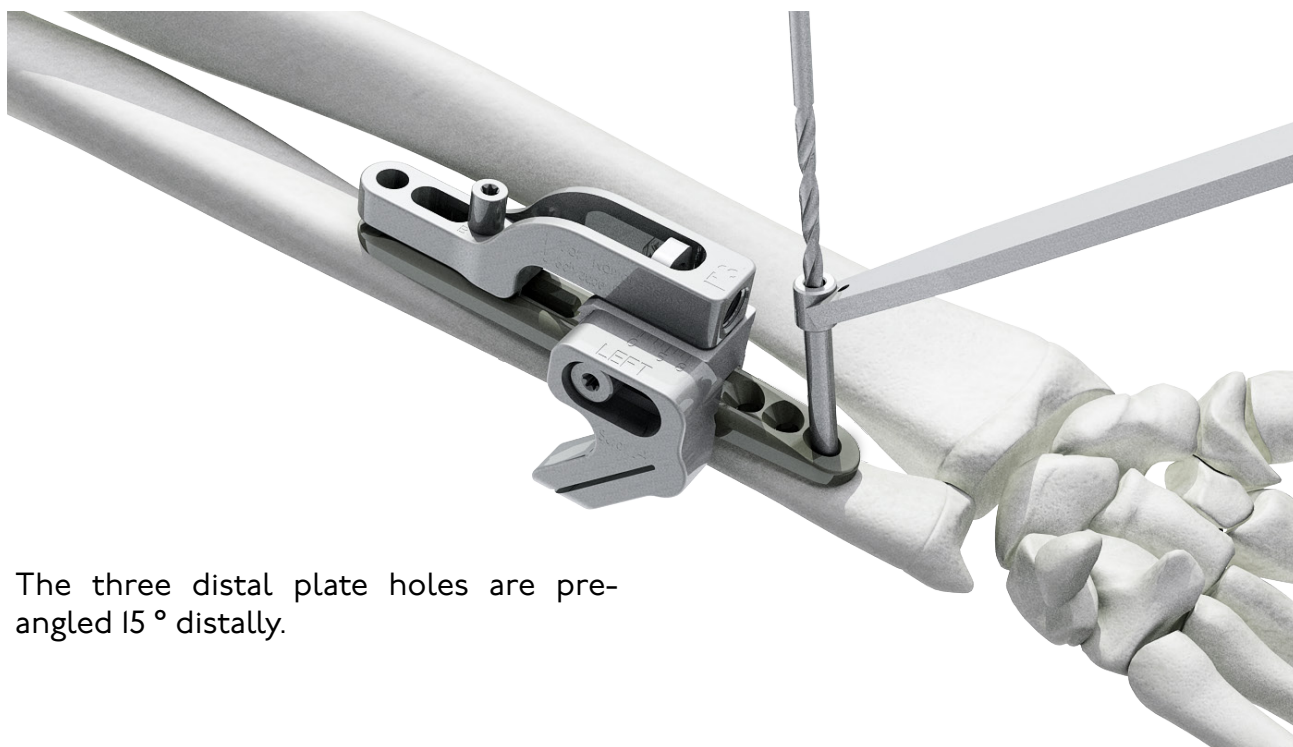
After opening the forearm fascia, mobilize bluntly the belly of the FCU (M. flexor carpi ulnaris) at its insertion point at the ulna and retract it medial using Hohmann retractors. Define the optimal position of the plate and incise the dorsal forearm fascia in the designated osteotomy area.

Note: The plate should be inserted with an already mounted instrument including the transection gauge.



○ Placement of the distal screws

At the beginning, the 3 distal plate holes are optionally filled with locking screws. Use the spiral drill and the drill guide (62221) for the three distal drillings (drill hole diameter depends on the screw selection - see page 6) and measure the corresponding length with the screw length gauge, PROlock II (59026).



The three distal plate holes are pre-angled 15° distally.

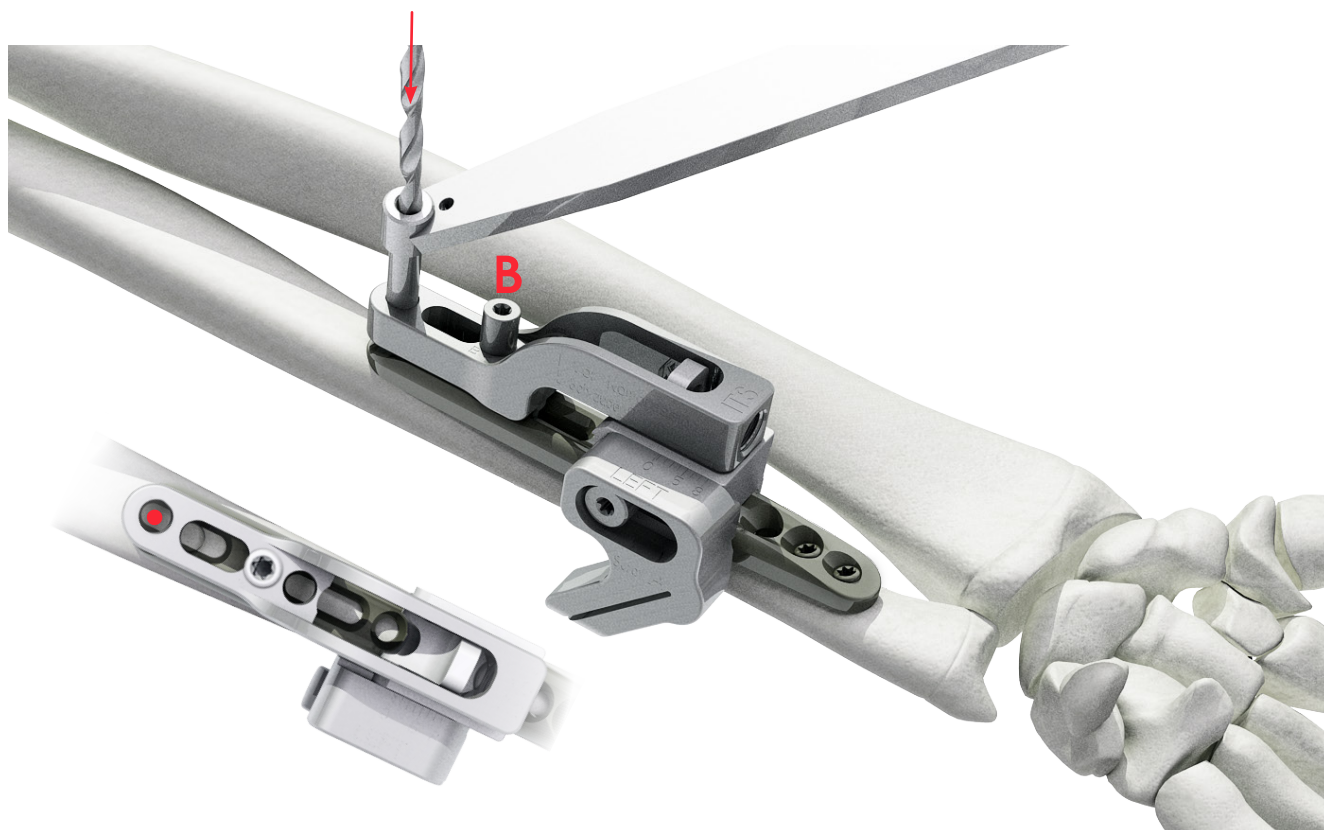


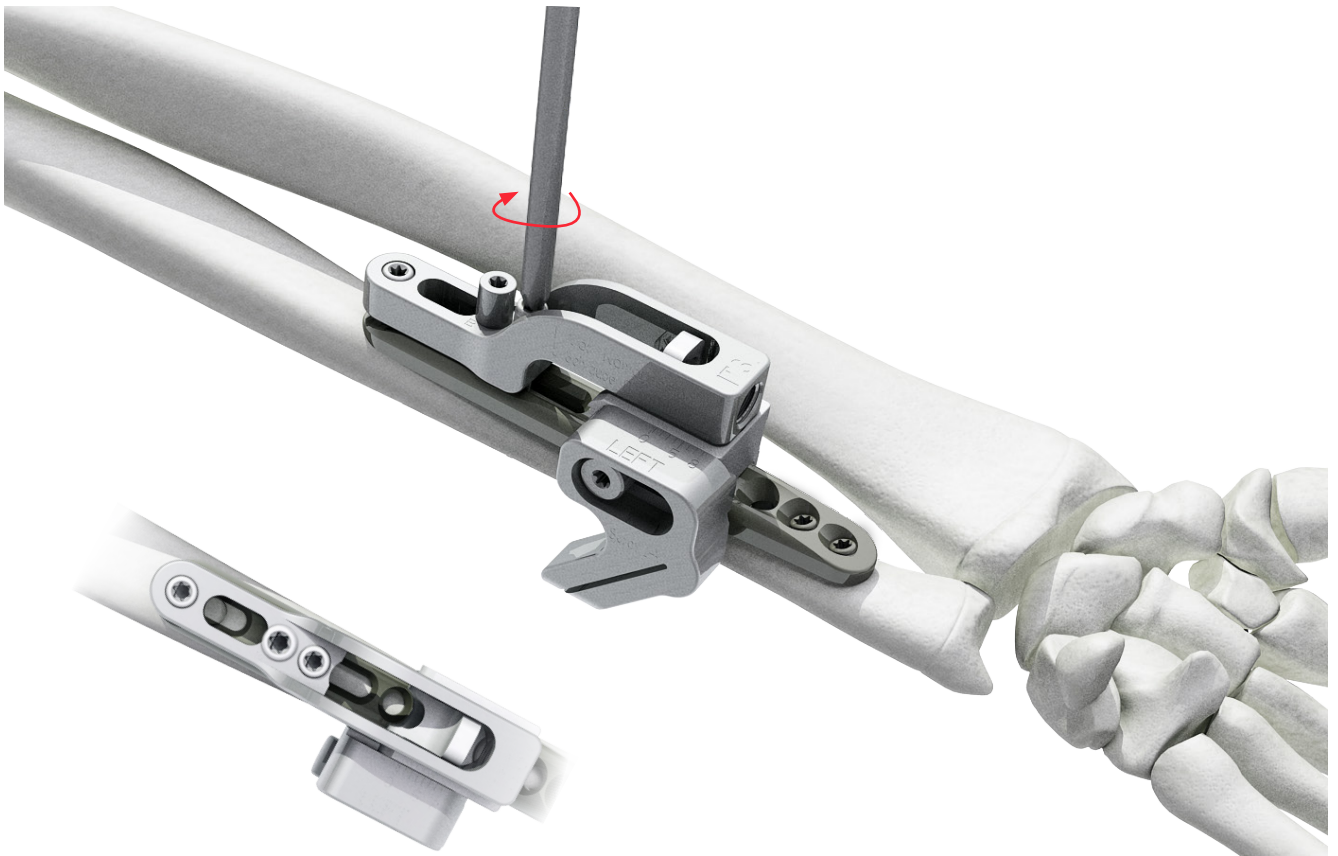
○ Placement of the tension bolts

For the placement of the tension bolts, the compression slide must be fixed with the fixing screw **B (680872-2)** on the plate.

Then the drill guide (**62221**) is inserted into the corresponding holes of the compression slide and drilled bi-cortically with the D=2.0mm spiral drill (**61203-100**).

Afterwards the tension bolts can be inserted with a T9 screwdriver (**56095-70**) through the compression slide.





Subsequent the fixing screw **B (680872-2)** can be removed and the compression screw (**680875**) can be screwed into the slide.

Remove fixing screw B

Insert compression screw

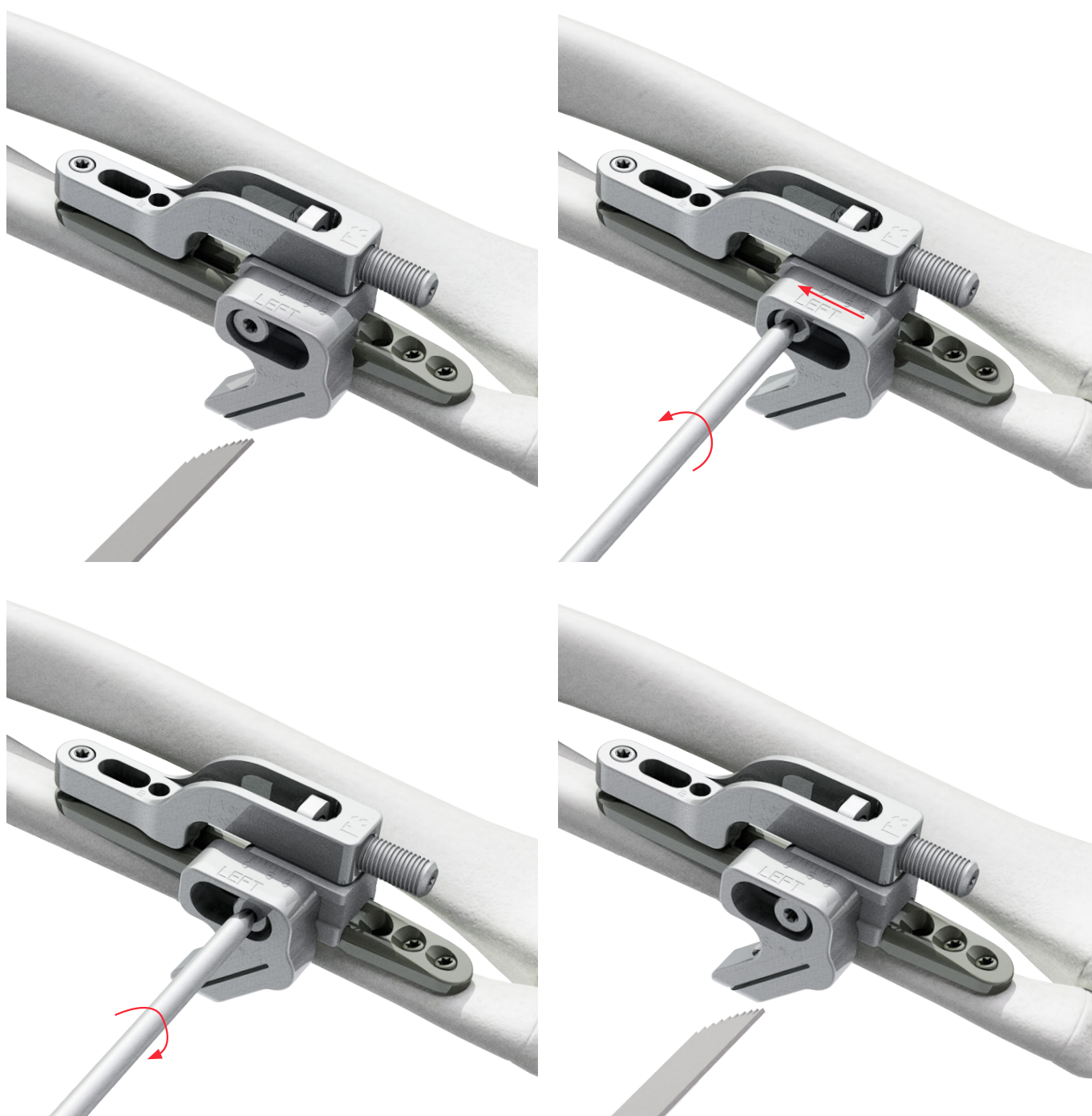


○ Shortening

Incise the periosteum at the osteotomy site and minimally retract it before starting. Using the transection gauge and producing as little heat as possible, make two atraumatic, parallel cuts according to the measured shortening.

The first cut must be performed at the cutting position „0“. The second incision at the desired osteotomy length (maximum 8 mm for the single-stage osteotomy or 16 mm for the two-stage osteotomy).

The thickness of the saw blade is a maximum of 0.7mm. We recommend a saw blade **0.5 - 0.7mm** in thickness, to achieve a precise cut.



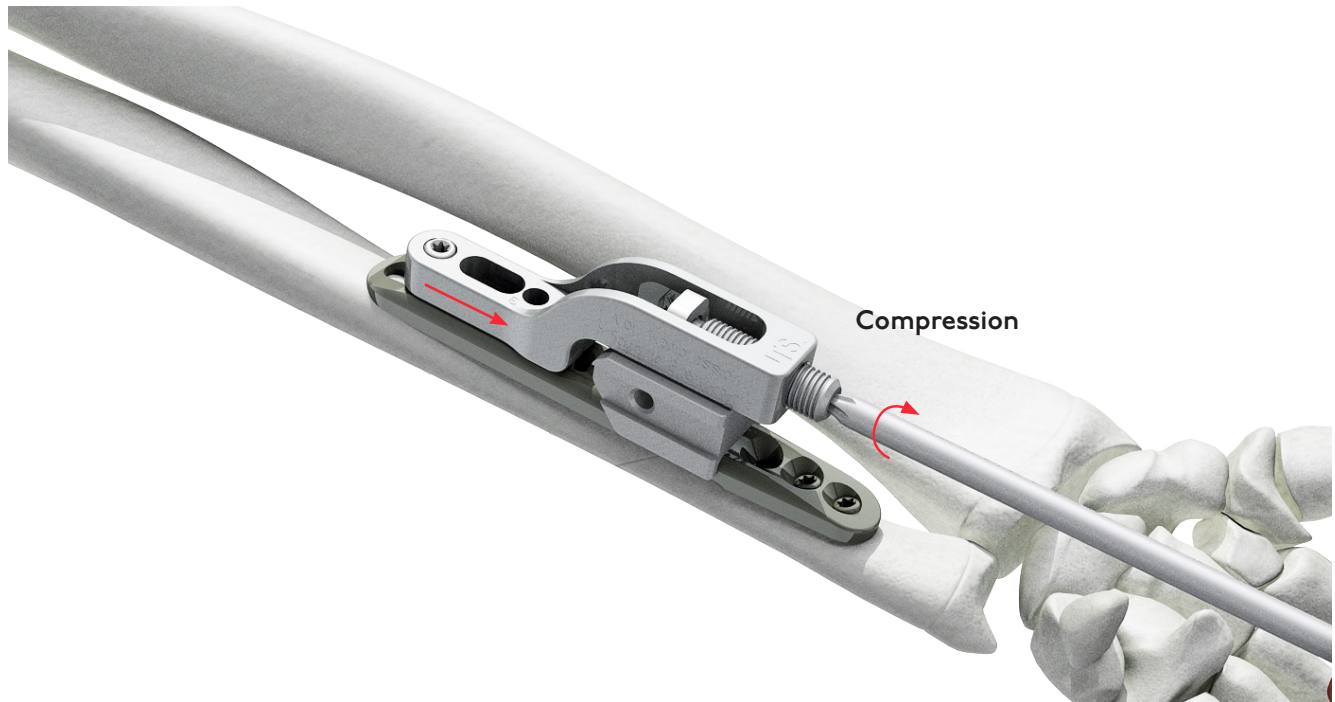
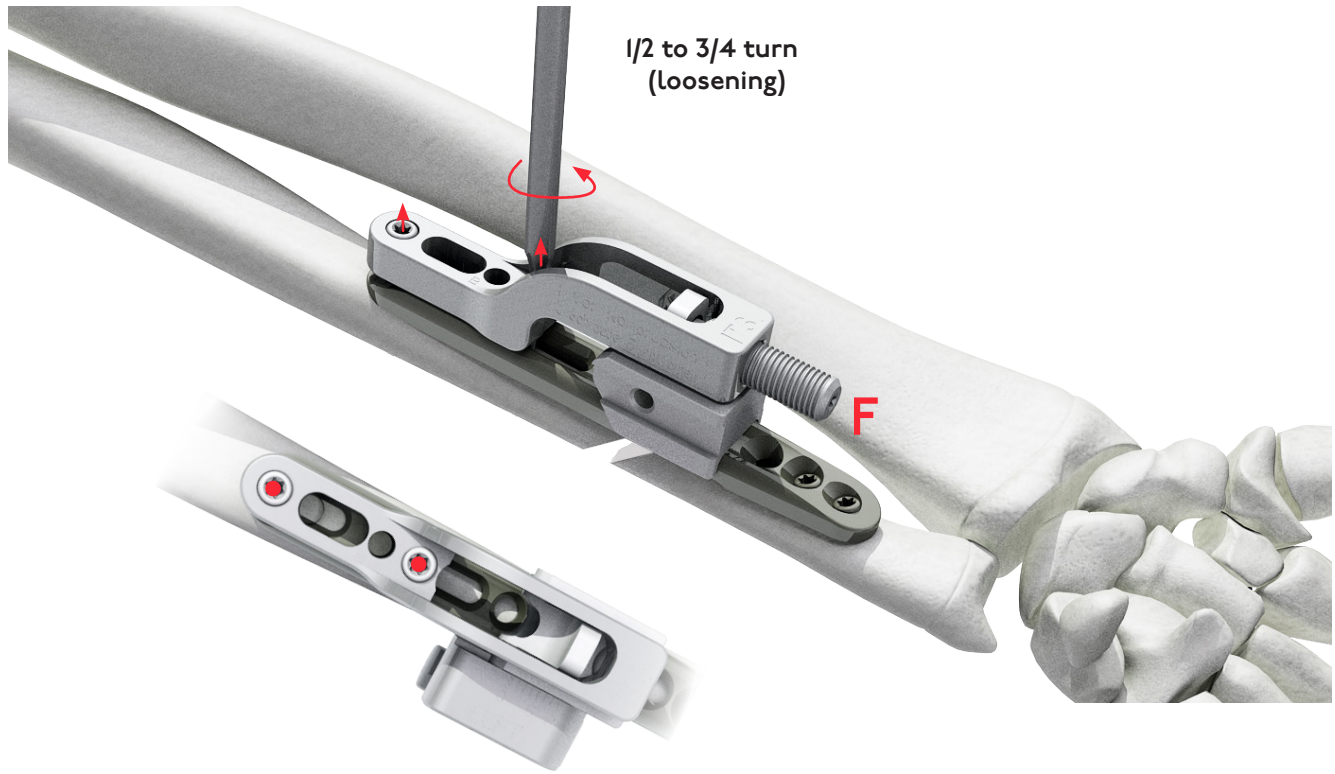
◦ Reduction

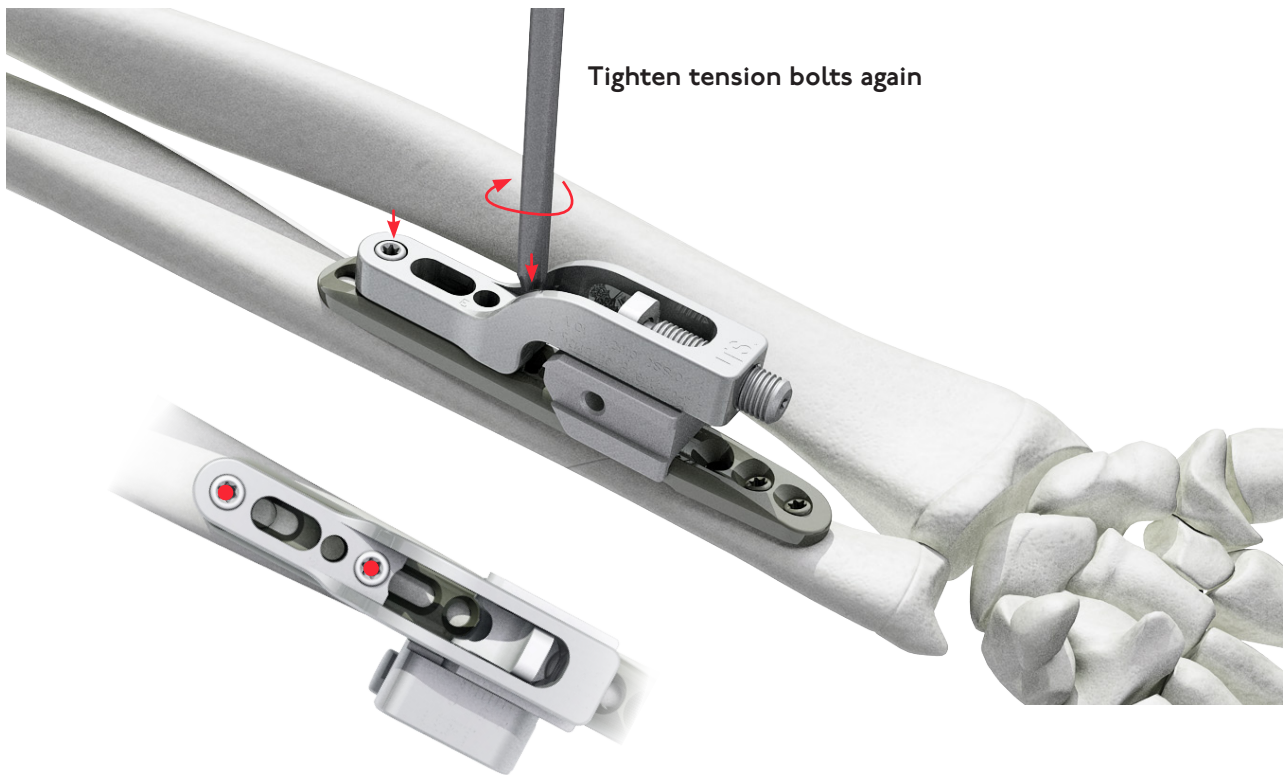
After removal of the dissection, the osteotomy surfaces must be cleaned meticulously of bone or soft tissue remnants. After loosening the tension bolts (1/2 to 3/4 turn), shortening is performed using the compression screw **F (680875)** and the compression slide **(680876)** which sits on the tension bolts.

If there are excessive tensions and shortening difficulties, this is usually the consequence of bone or soft tissue remnants.

After contact of the osteotomy surfaces, prior to a desired compression, the reduction may additionally be secured using holding forceps. Finally, tighten the tension bolts firmly.





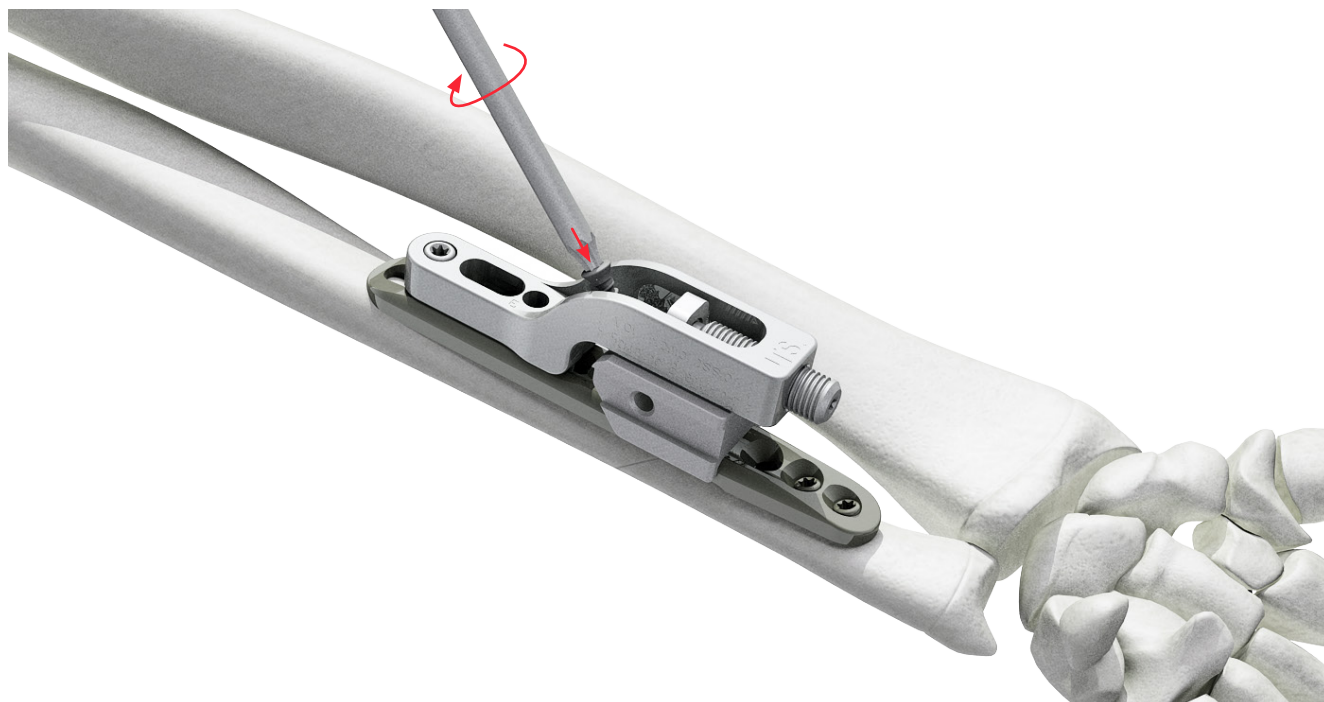


Tighten tension bolts again

○ Placement of the screws

The 45 ° drill hole is filled with a D=2.7mm cortical screw (**32271-xx**) as a fixing screw after drilling with the spiral drill, D=2.0mm, L=100mm, AO Connector (**61203-100**).

Note: The cortical screw can be optionally used as a tension screw (drilling of the cortical bone next to the plate with the spiral drill, D=2.4mm, L=100mm, AO Connector (**61243-100**)).



Note: In order to avoid a collision of the third distal screw with the transection screw (45 ° osteotomy fixing screw), the distal screw must be inserted with a 15° angle distally (depending on the diameter of the ulna bone). The drilling direction should be selected in such a way, that the opposite cortical bone is not weakened.

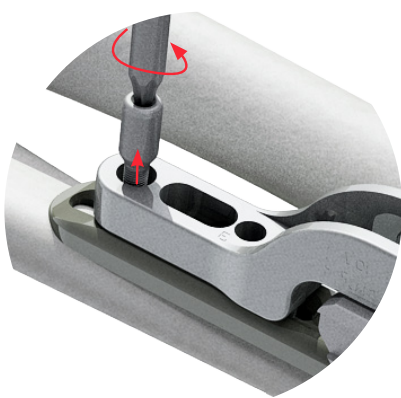
A monocortical insertion with a locking screw is possible as well.

It is possible to insert two screws - either locking or non-locking - in two holes proximal to the osteotomy without dismounting the compression slide.

Afterwards the pre-tension can be released, and the tension bolts can be replaced with a cortical screw D=2,7mm .

At first put out the proximal tension bolt and subsequently the tension bolt close to the osteotomy.

Attention: The fourth distal hole is just for the carrier unit assembly and must not be used for an implant screw.



○ Removal of the instruments

After replacing the tension bolts with cortical screws (32271-XX), the compression slide and the carrier unit can be removed.



Optionally, either locking or non-locking screws can be inserted into the remaining plate holes (Drilling diameter depends on screw selection - see page 6) Appropriate lengths can be determined previously with the screw depth gauge, PROlock II (59026).

The rearward periosteum is intended to cover the osteotomy area. After checking the rotation and radiological control of the osteotomy gap, plate position and screw length, the seam of the fascia and closure of the skin occurs.

Drainage as required.



Attention:

The threaded hole is used only for the attachment of the instrumentation and must not be filled with screws.

○ Postoperative treatment

Forearm splint for 3 weeks. Physical therapy aiming at freely closing the fist and bending/stretching of the elbow joint. During this period, rotation of the forearm should be restricted to R: 30/0/30. From the 5th postoperative week on, this is to be focused upon in accordance with the clinical and radiological follow-up examination results.

○ Explantation

If desired by the patient, the implant can be removed.

Removal should be performed at the earliest 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 25).

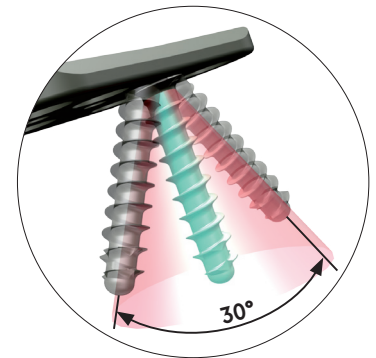
Information

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*

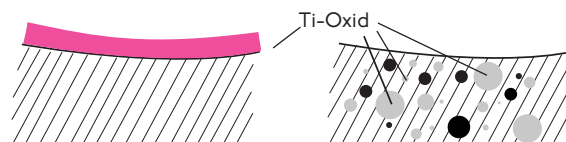
Type III anodization

- ◆ 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

Ulna Osteotomy Plate, 6-hole	21231-6	
Cancellous Stabilization Screw, D=3.0mm, L=10mm, RH	37303-10	
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, 10mm, RH	37241-10	
Stabilization Screw, D=2.4mm, 12mm, RH	37241-12	
Stabilization Screw, D=2.4mm, 14mm, RH	37241-14	
Stabilization Screw, D=2.4mm, 16mm, RH	37241-16	
Stabilization Screw, D=2.4mm, 18mm, RH	37241-18	
Stabilization Screw, D=2.4mm, 20mm, RH	37241-20	
Stabilization Screw, D=2.4mm, 22mm, RH	37241-22	
Stabilization Screw, D=2.4mm, 24mm, RH	37241-24	
Cortical Stabilization Screw, D=3.0mm, L= 10mm, RH	37304-10	
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=10mm	32271-10	
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	
Cortical Screw, D=2.7mm, L=26mm	32271-26	
Screwdriver, Torque, T9x70	56095-70	
Screwdriver, Torque, T9x150	56095-150	
Depth Gauge, PROlock II	59026	
Drill Guide, D=2.0/2.4mm	62221	
Spiral Drill, D=1.8mm, L=100mm, AO Connector	61183-100	
Spiral Drill, D=2.0mm, L=100mm, AO Connector	61203-100	
Spiral Drill, D=2.4mm, L=100mm, AO Connector	61243-100	

Instruments, Ulna Osteotomy Plate

Jig, Ulna Osteotomy Plate	680870	
Fixing Screw, Ulna Osteotomy Plate	680871	
Fixing Screw, Compression Slide, Ulna Osteotomy Plate	680872-2	
Transection, Right, Ulna Osteotomy Plate	680873	
Transection, Left, Ulna Osteotomy Plate	680874	
Compression Screw, Ulna Osteotomy Plate	680875	
Compression Slide, Ulna Osteotomy Plate	680876	
Tension Bolt, Ulna Osteotomy Plate	680877	
Sterilization Tray, Ulna Osteotomy Plate 6-hole	50267	

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



ITS. GmbH
Autal 28, 8301 Lassnitzhöhe, Austria
Tel.: +43 (0) 316 / 211 21 0
Fax: +43 (0) 316 / 211 21 20
office@its-implant.com
www.its-implant.com

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