ITS.

Implants for Trauma Surgery

SURGICAL TECHNIQUE

# Ulna Osteotomy Locking Plate II

ITS.
Implants for Trauma Surgery

# THE ART of TRAUMA SURGERY

*The Art of Trauma Surgery* is a collaborative project between I.T.S. and Austrian artist Oskar Stocker that celebrates the skill, perseverance, and artistry of surgeons and engineers who work tirelessly to improve outcomes for trauma patients.

At I.T.S., we stand for long-term, trusting relationships with our customers, suppliers, and development partners. Through our devotion to innovation and development, we continuously seek to improve and optimize products and techniques in the field of traumatology.

We believe that the success of our mission lies in the combination of the technical expertise, compassion and dedication of surgeons and engineers to help patients regain their health and well-being. Join us in celebrating these remarkable individuals and *The Art of Trauma Surgery!*

## About the Artist

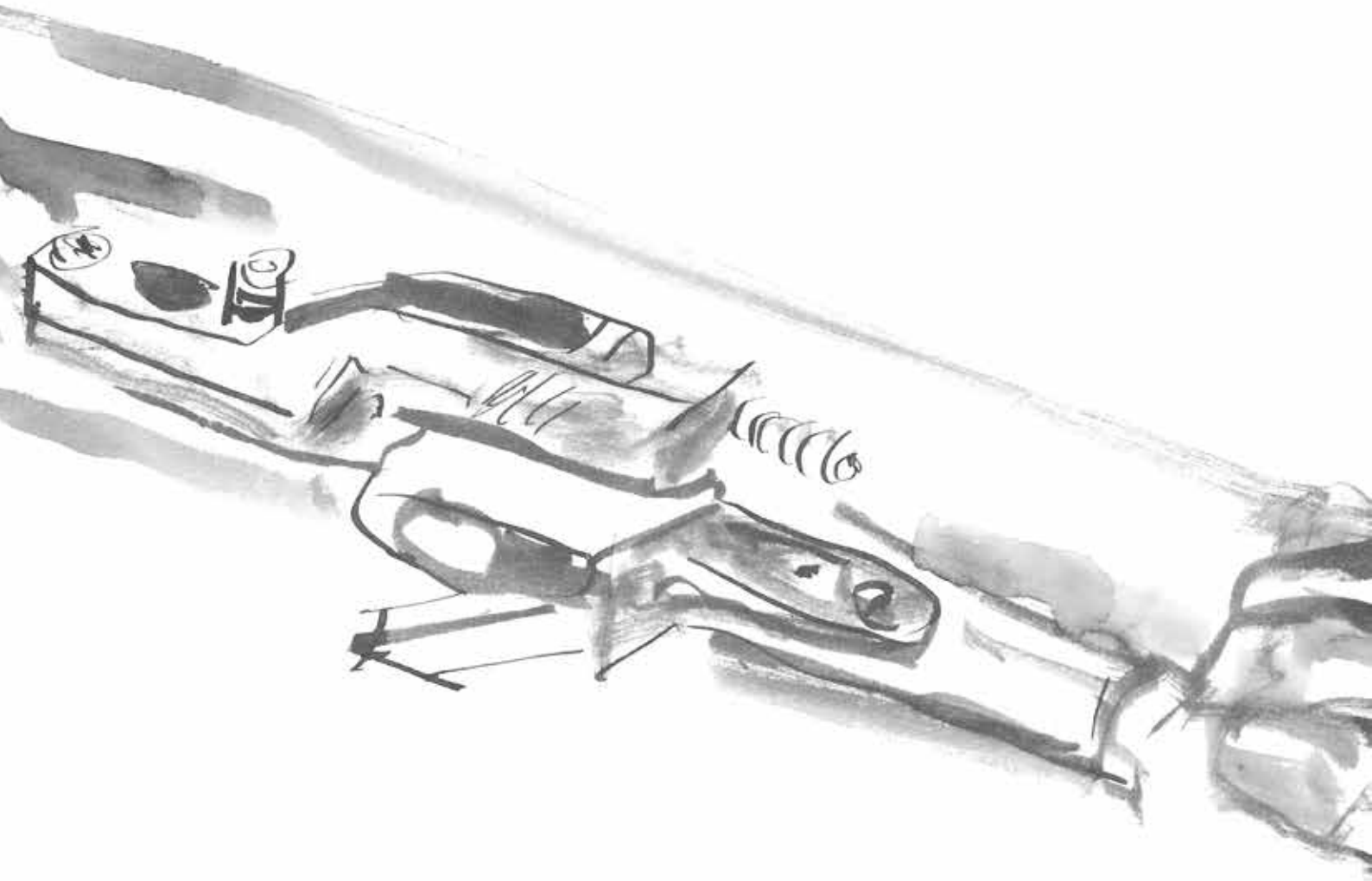
The Austrian artist Oskar Stocker (b. 1956) lives and works in Graz, Austria. He has become known internationally through the exhibition Facing Nations, which consists of portraits of more than 120 people of various nationalities living in Graz; it was shown first in Graz itself, then in Vienna, and later culminated in 2010 with its display at the UN Headquarters in New York City.

In addition to the portraits of individual people, he devotes himself to the depiction of landscapes and objects, down to the smallest detail.

11v

All I.T.S. 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.

# Table of Contents



# Introduction

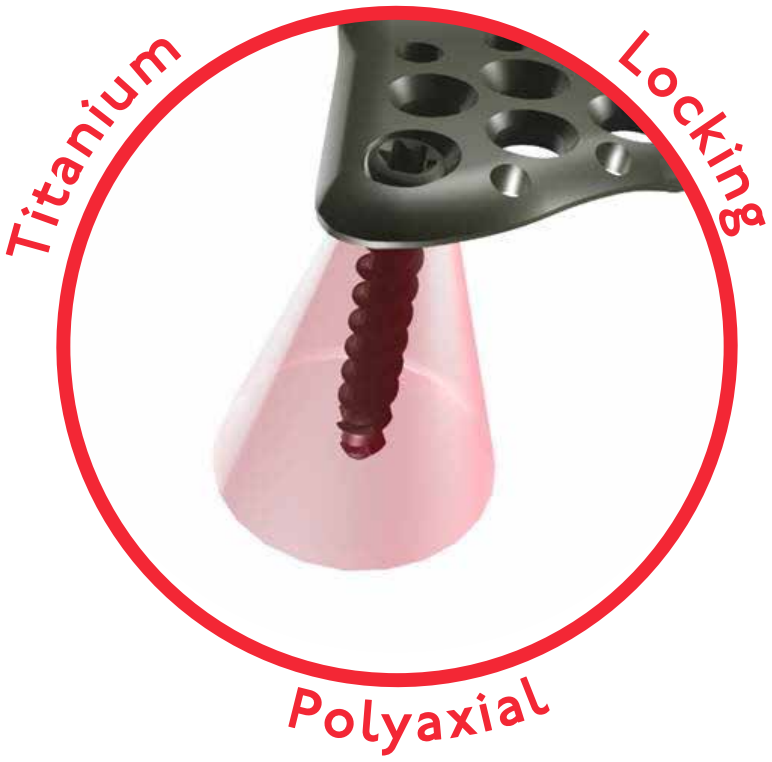
1.

# Plate Technology

At ITS., we stand for long-term, trusting relationships with our customers, suppliers and development partners. Through our dedication to innovation and development, we continuously seek to improve and optimize products and techniques for trauma surgery.

## ONE Technology for all implants

All ITS. plates are made from Titanium Grade 2, whereas the screws are made of a harder titanium-alloy. This allows the plates to have only non-threaded holes, which all (with the exception of oblong holes) accept both non-locking and locking screws.




When a locking screw is inserted, it forms threads into the plate. There is no cutting and thus no debris created. Each locking screw can be locked at a free placement within a cone of angulation up to ± 15°, and can be re-positioned up to three times.

# System Overview



With the advanced ITS. Ulna Osteotomy Locking Plate II, a plating system equipped with locking and compression screws is available, specifically tailored to the anatomical and biomechanical requirements following a shortening osteotomy of the distal ulna.

This all-in-one solution allows for a unique plane-parallel cross-section through the simplified device setup, with a rotationally stable shortening process and compression option.

The resulting standardization of multiple surgical procedures within a single device system enhances and ensures the quality of the surgical process.

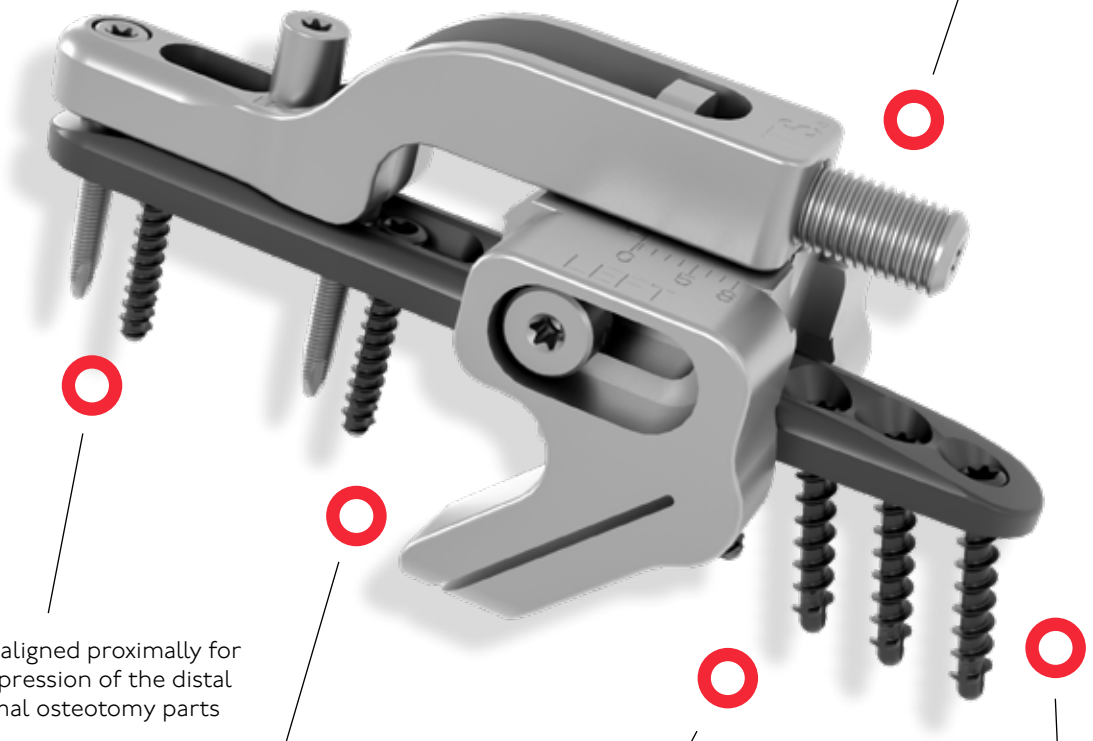
# Properties

**ALL-IN-ONE-SOLUTION**
**Placement of the tension bolts, osteotomy, compression**

Reduction of components by 30% compared to the first version for easier handling

Three holes distal of the osteotomy

Central compression via the plate axis facilitates the joining of the osteotomy surfaces.



Transection aligned proximally for better compression of the distal and proximal osteotomy parts

Fixation of the osteotomy by a screw perpendicular to the cutting surface

Anatomical plate design

Correction of ulnar position relative to the Surgical Technique - unaffected other side up to a maximum of 8mm in one step.

# Screws



**32271-xx** **NON-LOCKING**
Cortical Screw, D=2.7mm
Spiral Drill, D=2.0mm
Torque, T9

**37241-xx** **LOCKING**
Stabilization Screw, D=2.4mm
Spiral Drill, D=1.8mm
Torque, T9

**37303-xx** **LOCKING**
Cancellous Stabilization Screw, D=3.0mm
Spiral Drill, D=2.0mm
Torque, T9

**37304** **LOCKING**
Cortical Stabilization Screw, D=3.0mm
Spiral Drill, D=2.4mm
Torque, T9

# 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

Intended Purpose

The Ulna Plate System is used for impaction syndrome of the ulnar wrist, for symptomatic, post-traumatic ulnar plus misalignments in the distal radioulnar joint, for degenerative ulnar plus variants, as well as for correcting the relative ulna plus position to the healthy opposite side.

# Surgical Technique

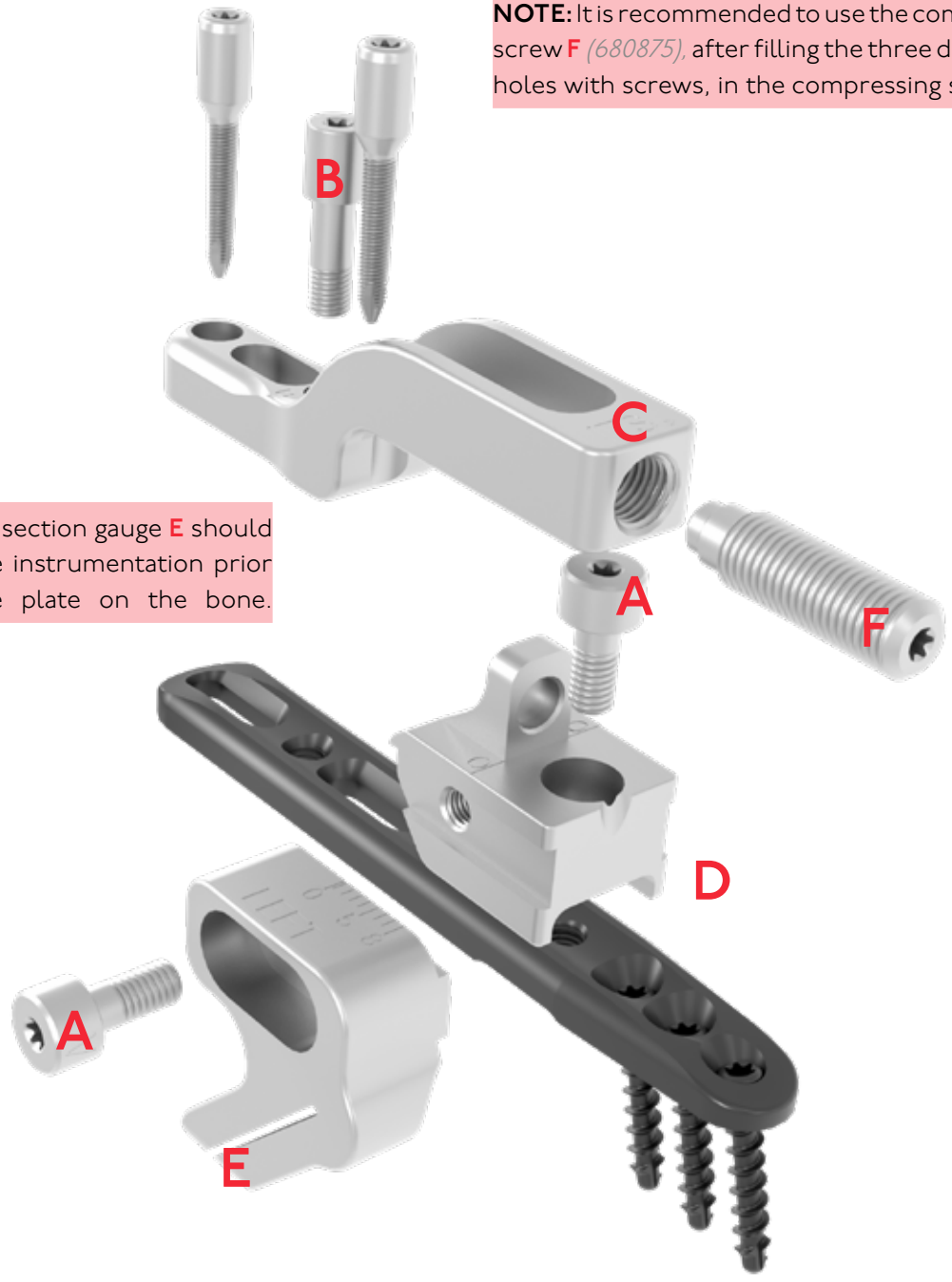
# 2.

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

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



# Pre-operative Patient Preparation

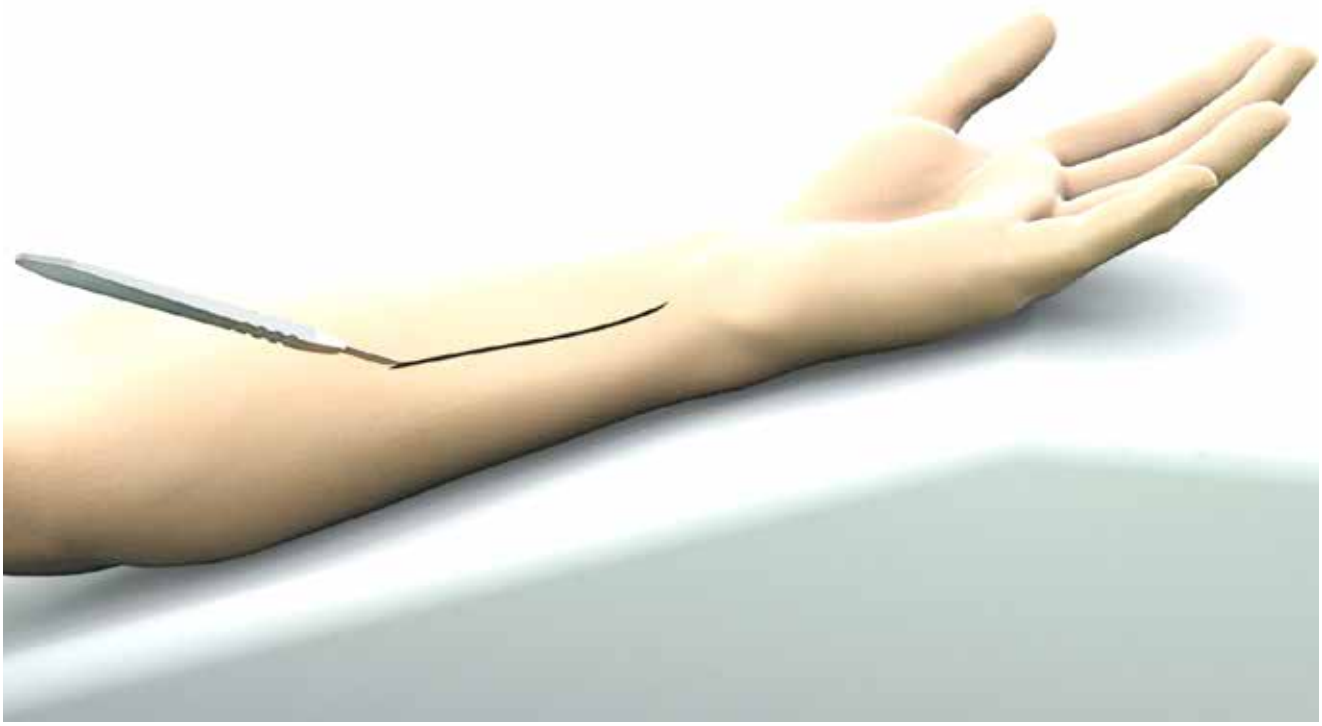
- Place the patient in a supine position, drape the arm to be freely mobile and place it on a radiolucent table at a shoulder abduction of 90°. Perform the operation under regional or general anaesthesia with or without using a tourniquet on the upper arm.
- The shape of the implant allows for palmar, 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.

**IMPORTANT**: 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.

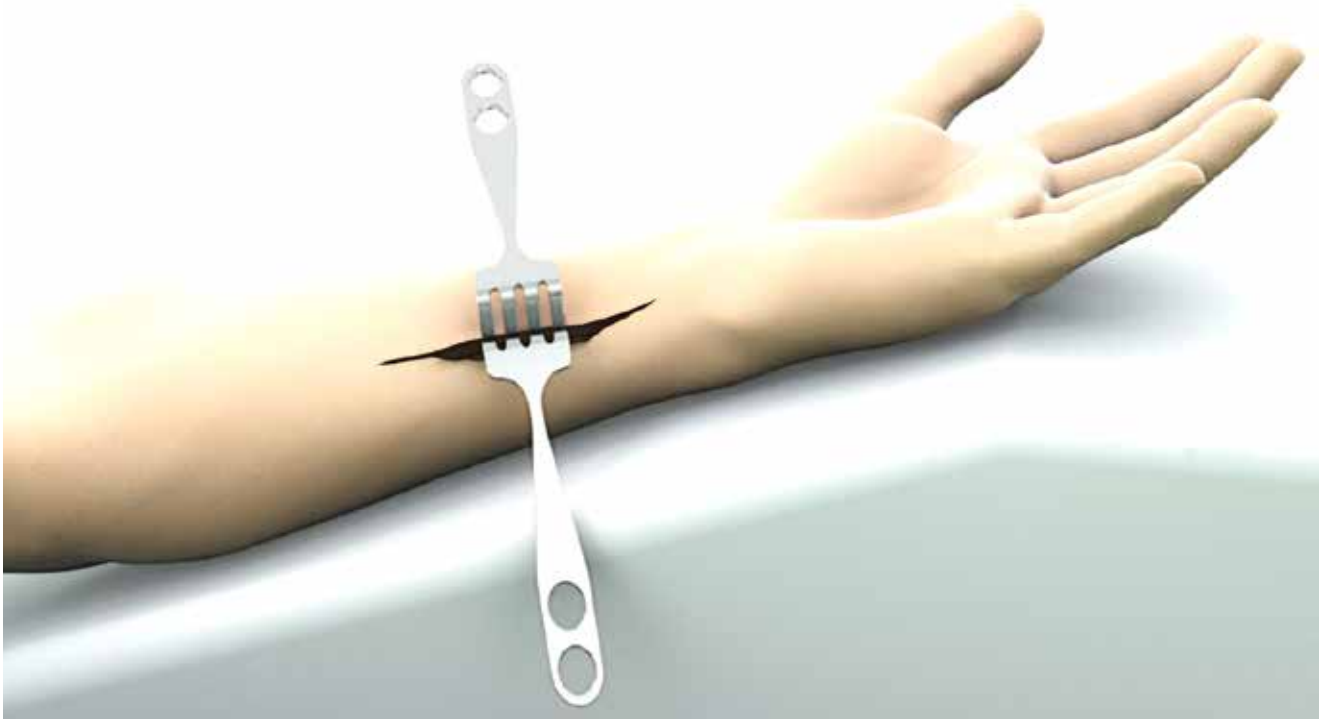
**IMPORTANT**: It is mandatory to pay attention to the dorsal branch of the ulnar nerve.



# 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 medially using Hohmann retractors. Define the optimal position of the plate and incise the dorsal forearm fascia in the designated osteotomy area.

**IMPORTANT**: 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.

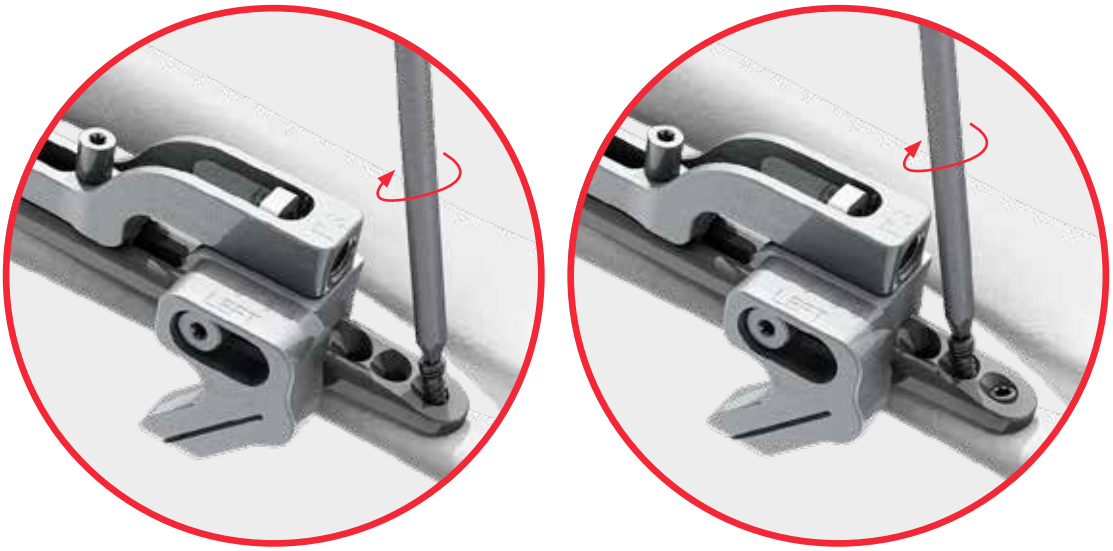


# Placement of distal Screws

- 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) and measure the corresponding length with the depth gauge, PROlock II *(59026)*.

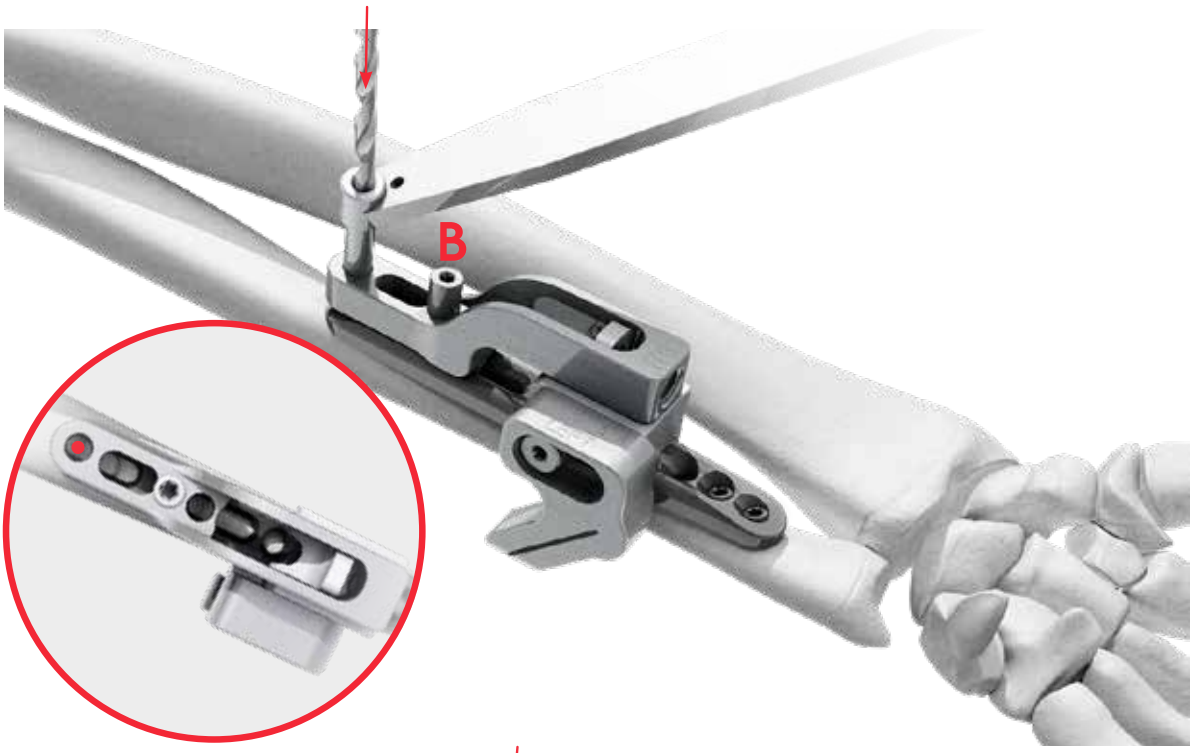
**NOTE**: The three distal plate holes are pre-angled 15° distally.

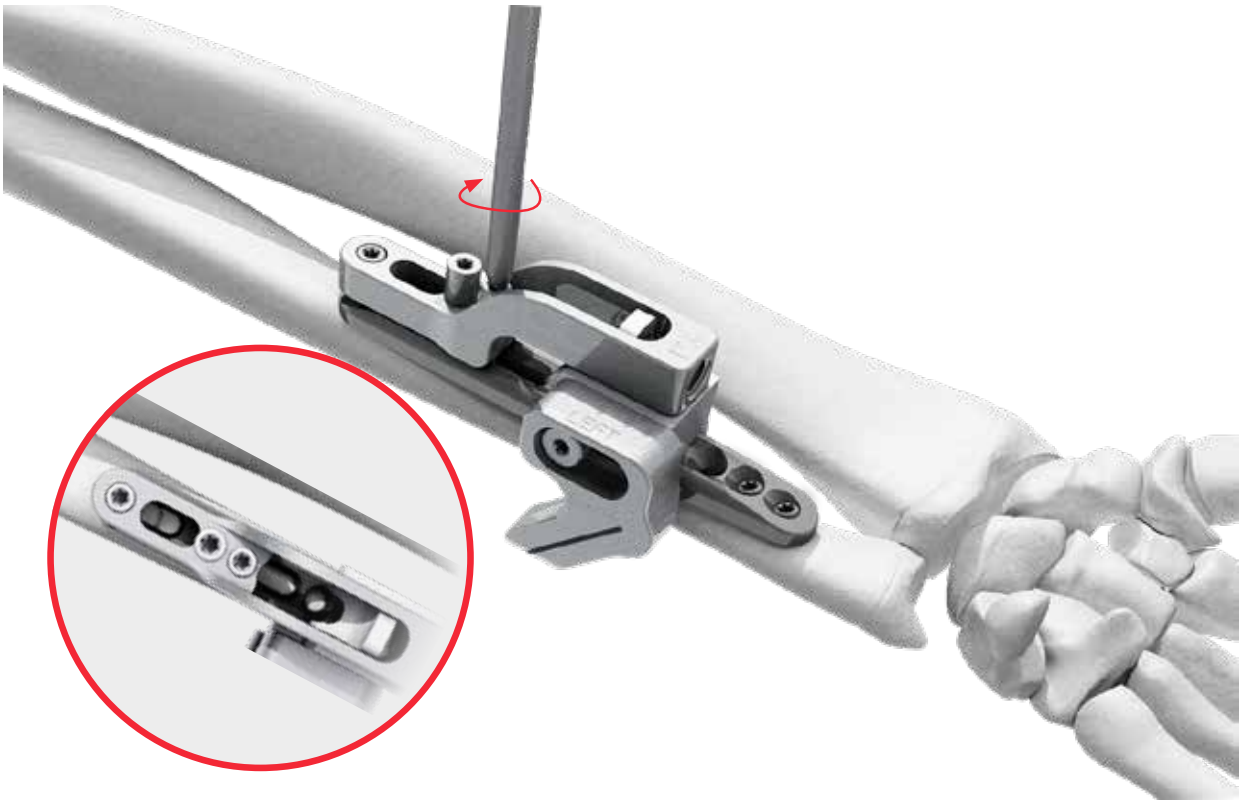
**TIP:** If necessary, use a non-locking D=2.7mm cortical screw in the middle distal plate hole to adjust the proximal plate position.



# Placement of 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 *(6222I)* is inserted into the corresponding holes of the compression slide and drilled bi- cortically with the D=2.0mm spiral drill *(6I203-I00)*.
- Afterwards the tension bolts can be inserted with a screwdriver T9x70 *(56095-70)* through the compression slide.

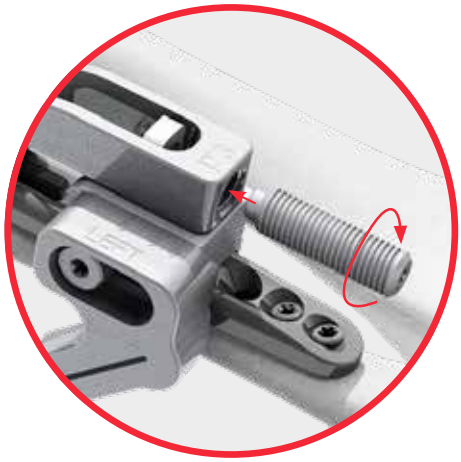


- Subsequently the fixing screw **B** *(680872-2)* can be removed and the compression screw *(680875)* can be screwed into the slide.

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 8mm for the single-stage osteotomy or 16mm for the two-stage osteotomy).

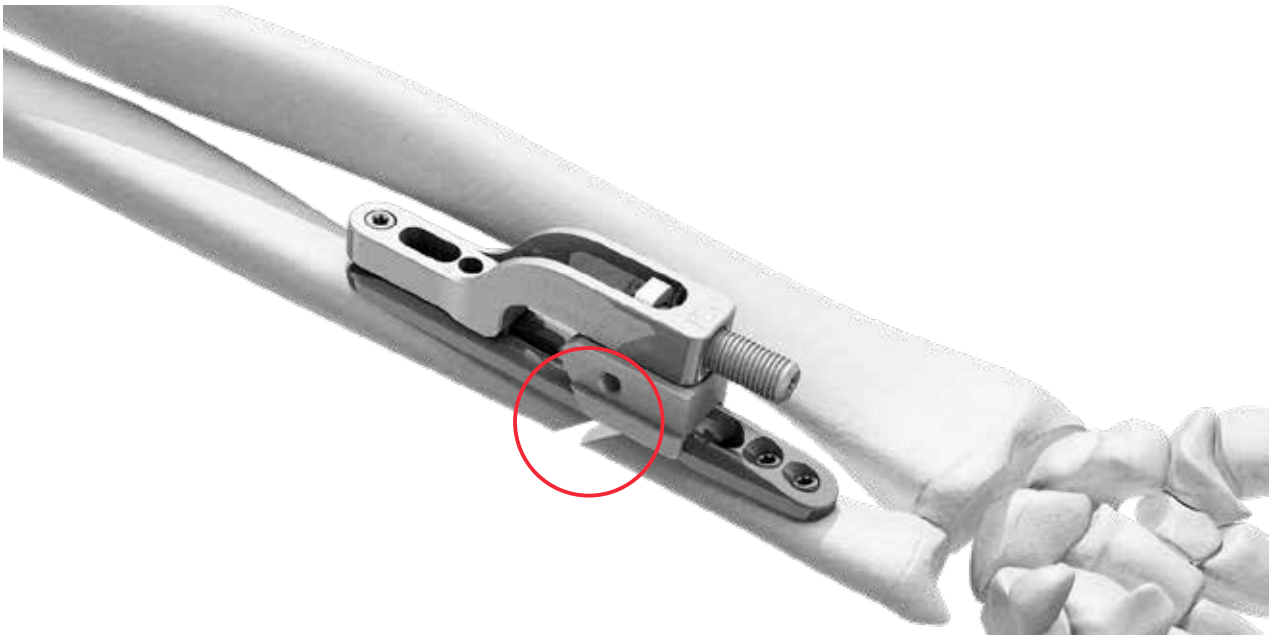
**TIP**: The thickness of the saw blade is a maximum of 0.7mm. We recommend a saw blade 0.5 – 0.7mm in thickness, to achieve a precise cut.

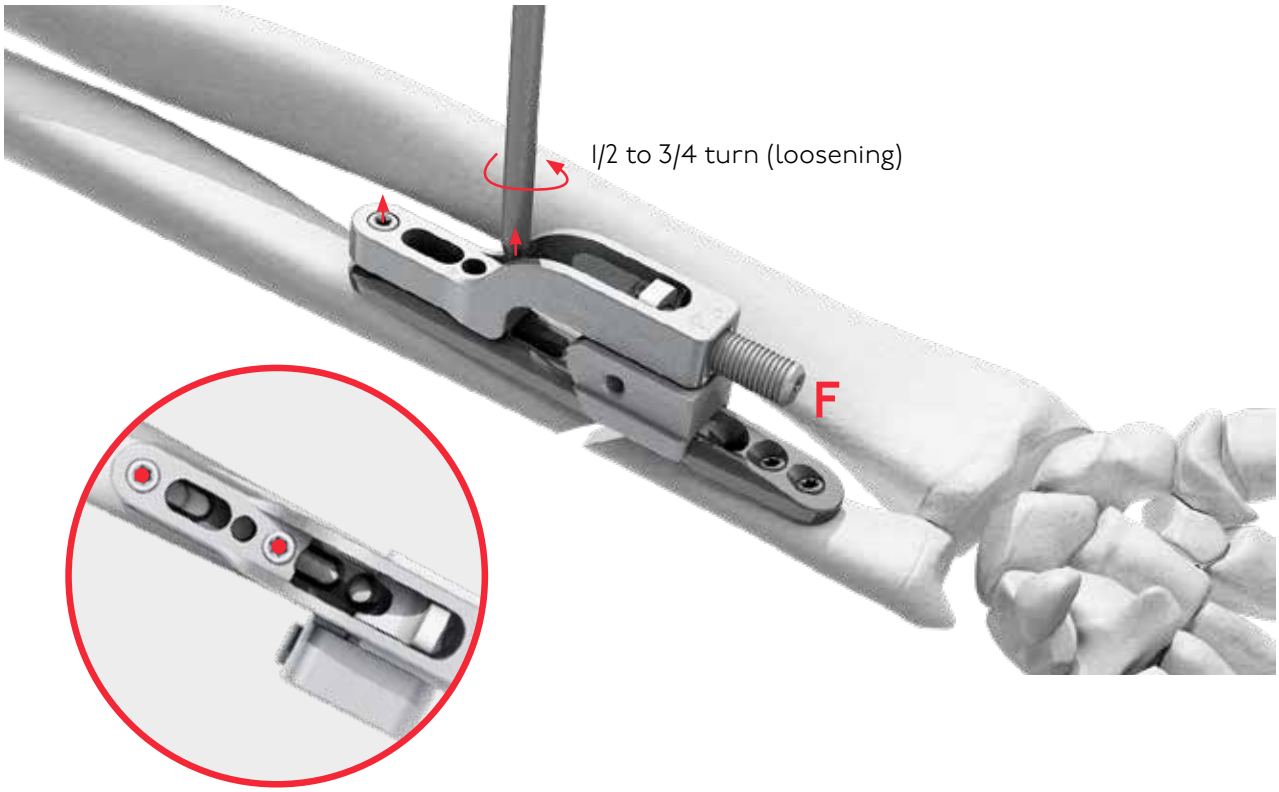
# Reduction

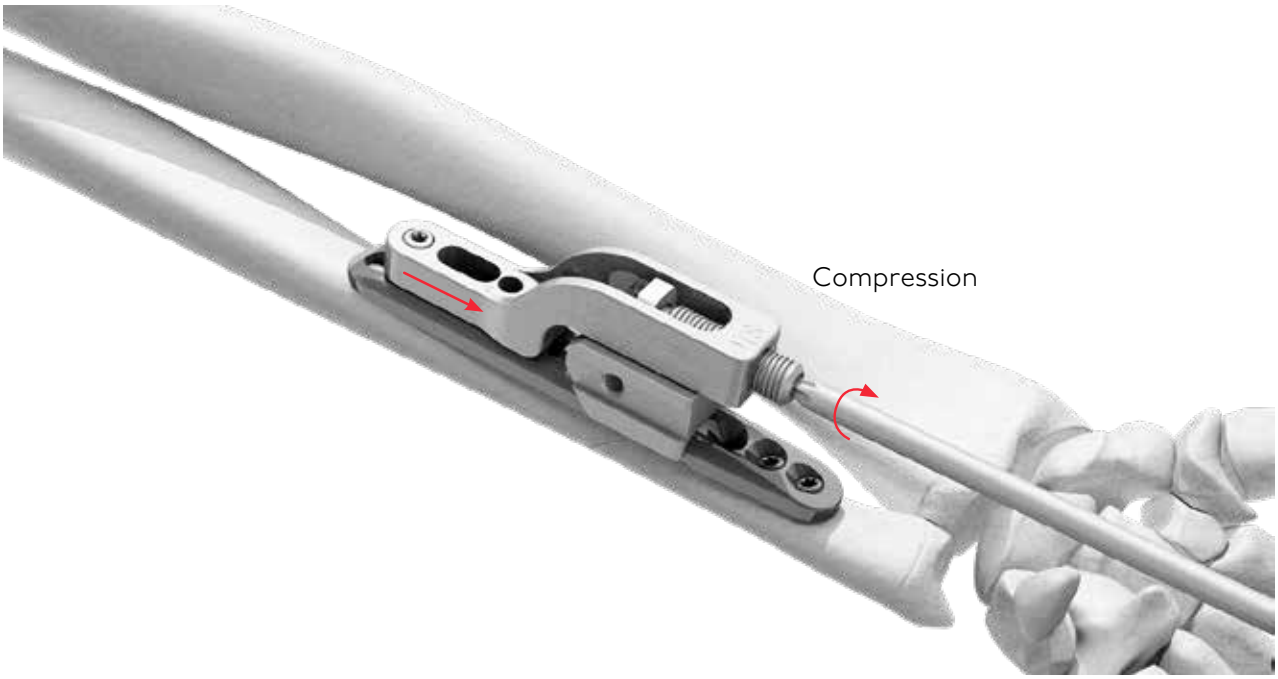
- After removal of the dissection, the osteotomy surfaces must be cleaned meticulously of bone or soft tissue remnants. After loosening the tension bolts (1/2 to 3/4 turn), shortening is performed using the compression screw **F** *(680875)* and the compression slide *(680876)* which sits on the tension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

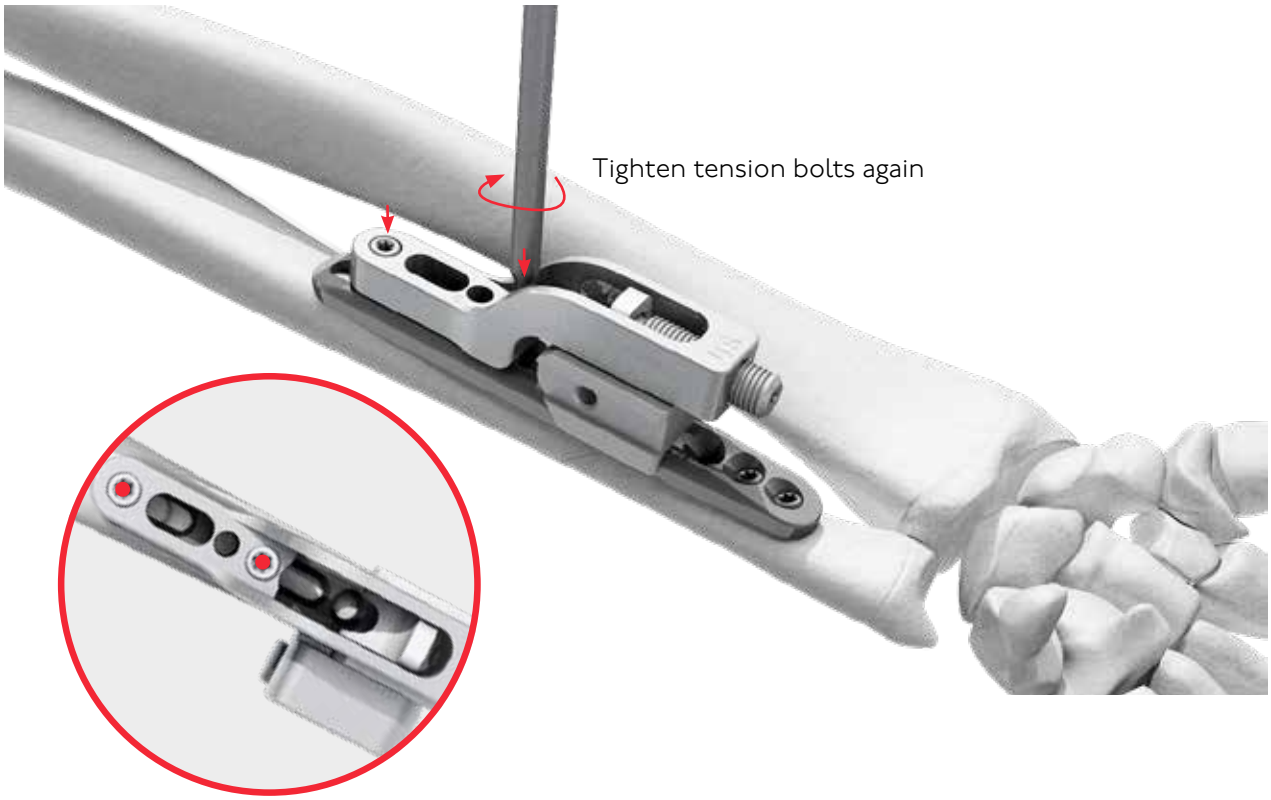
  **IMPORTANT**: If there are excessive tensions and shortening difficulties, this is usually the consequence of bone or soft tissue remnants.

- After the osteotomy surfaces are in contact, the reduction may additionally be secured using holding forceps prior to compression. Finally, tighten the tension bolts firmly.




1/2 to 3/4 turn (loosening)
F

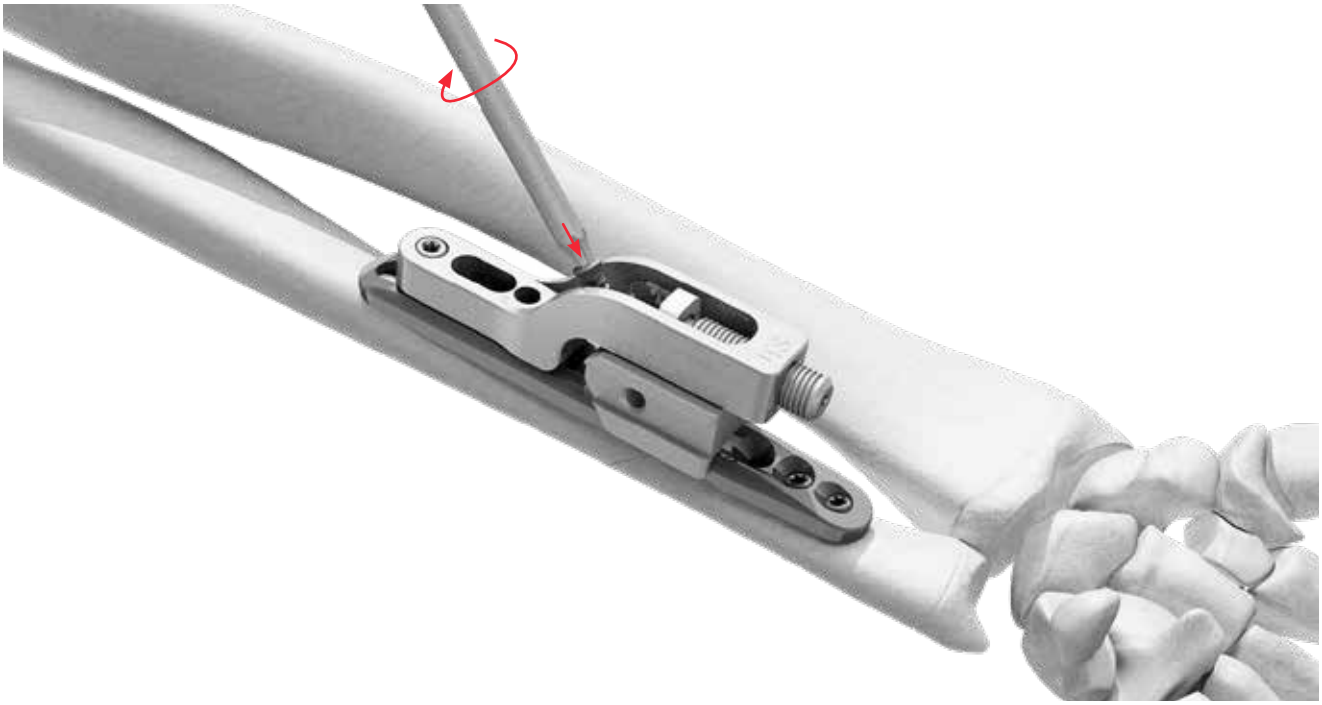

Compression


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)*.

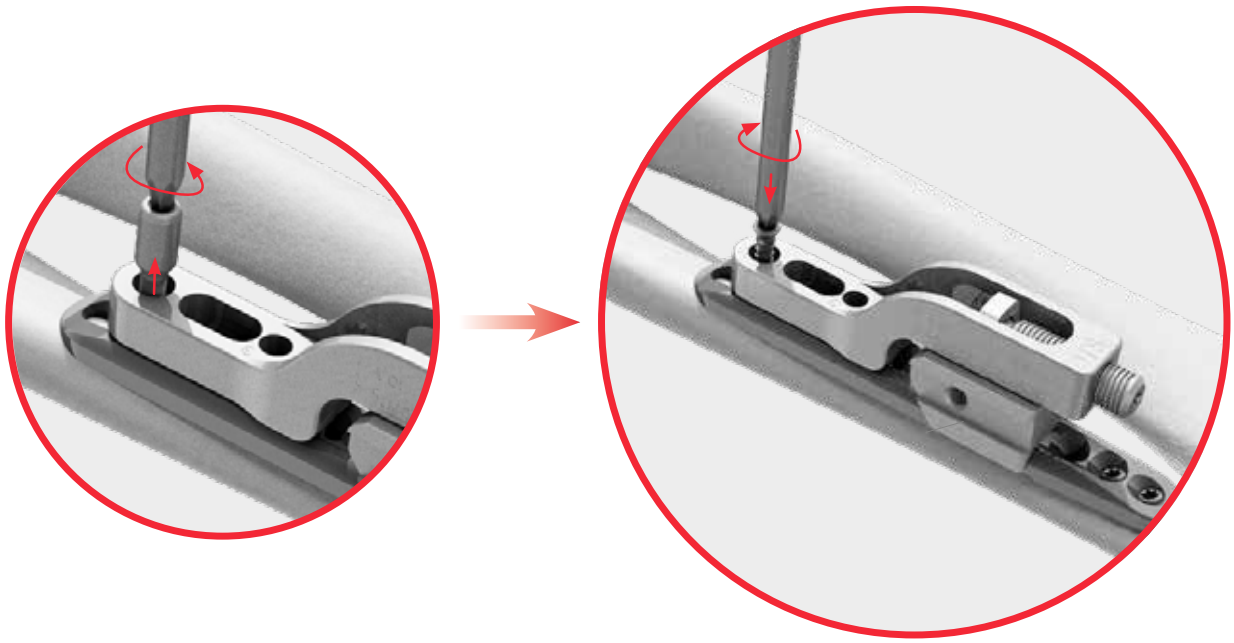
**TIPP**: The cortical screw can be optionally used as a tension screw (drilling of the cortical bone next to the plate with the spiral drill, D=2.4mm, L=100mm, AO-Connector *(61243-100)*).

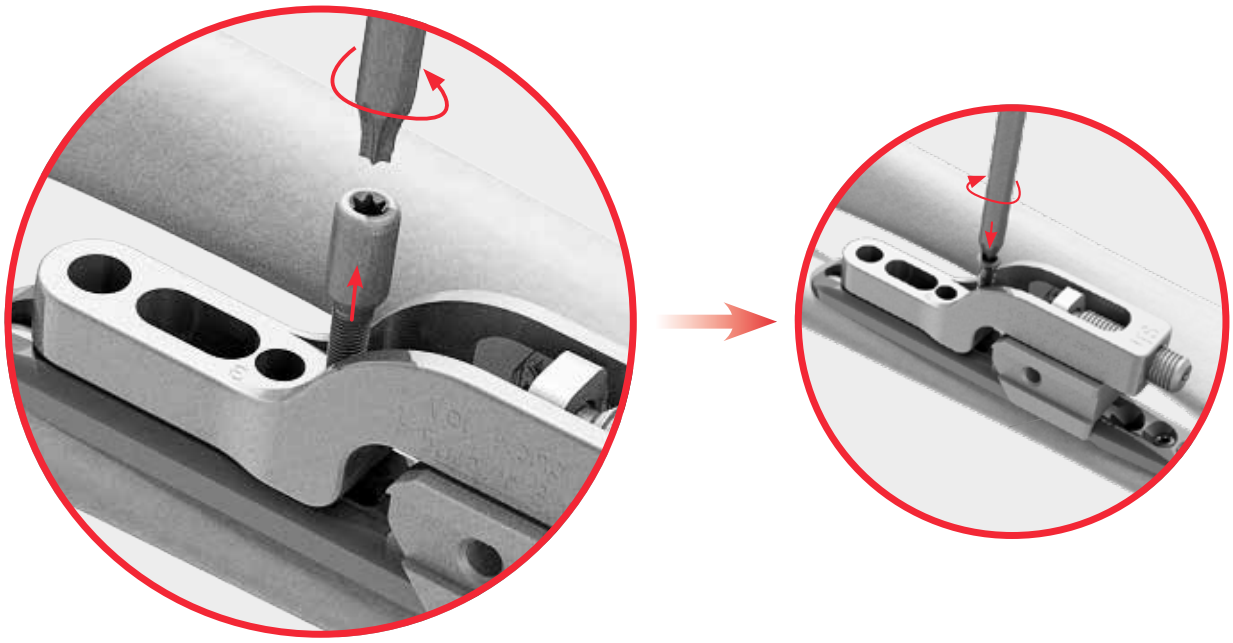


**NOTE:** In order to avoid a collision of the third distal screw with the transection screw (45° osteotomy fixing screw), the distal screw must be inserted with a 15° angle distally (depending on the diameter of the ulna bone). The drilling direction should be selected in such a way, that the opposite 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 *(3227I-XX)*. At first remove the proximal tension bolt and subsequently the tension bolt close to the osteotomy.

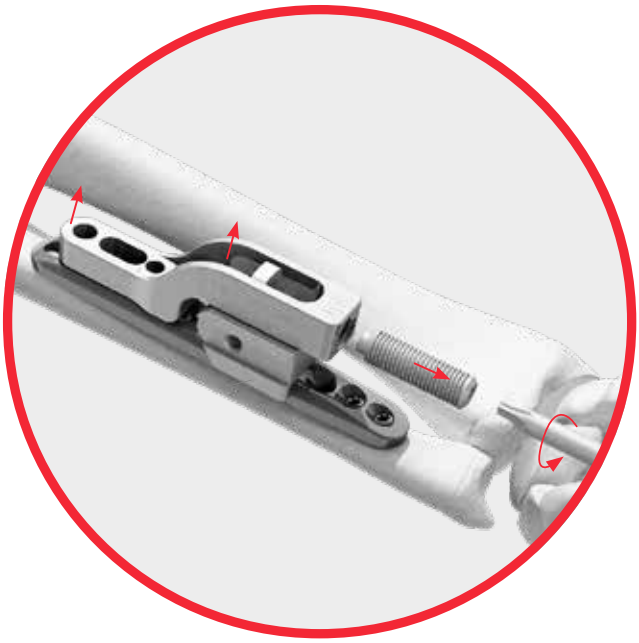
**ATTENTION**: The fourth distal hole is just for the carrier unit assembly and must not be used for an implant screw.

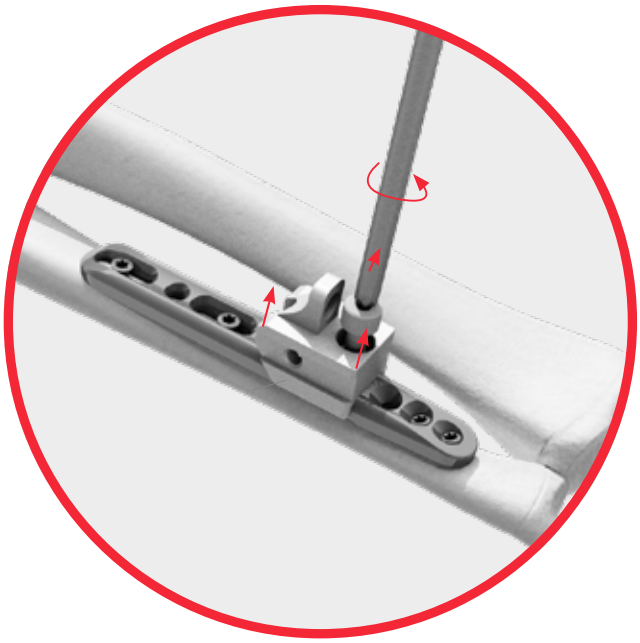




# Removal of Instruments

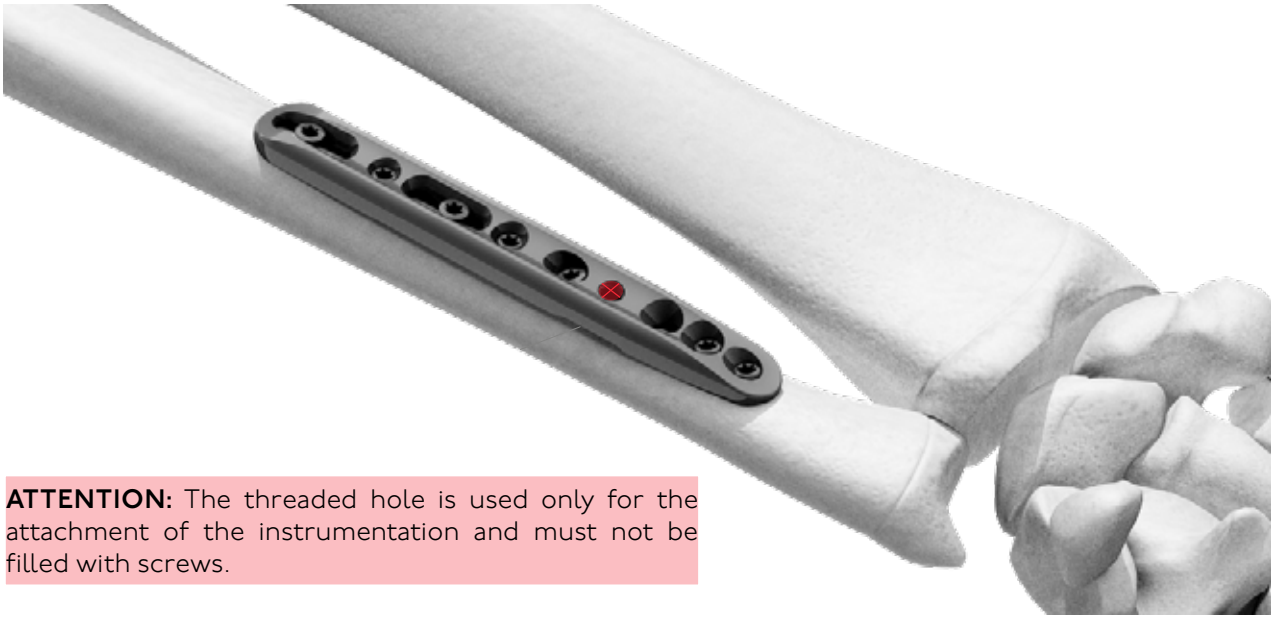
- After replacing the tension bolts with cortical screws *(32271-XX)*, the compression slide and the carrier unit can be removed.





**NOTE:** If the most proximal distal plate hole has not yet been used, remove the compression slide and place the drill guide on the countersink of the jig (15° distal pre-angled). Make sure that there is no contact with the 45° lag screw!

- Optionally, either locking or non-locking screws can be inserted into the remaining plate holes (Drilling diameter depends on screw selection) 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 verification of the rotation and radiological control of the osteotomy gap, plate position and screw length, closure of the fascia and skin is performed.
- Drainage as required.



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

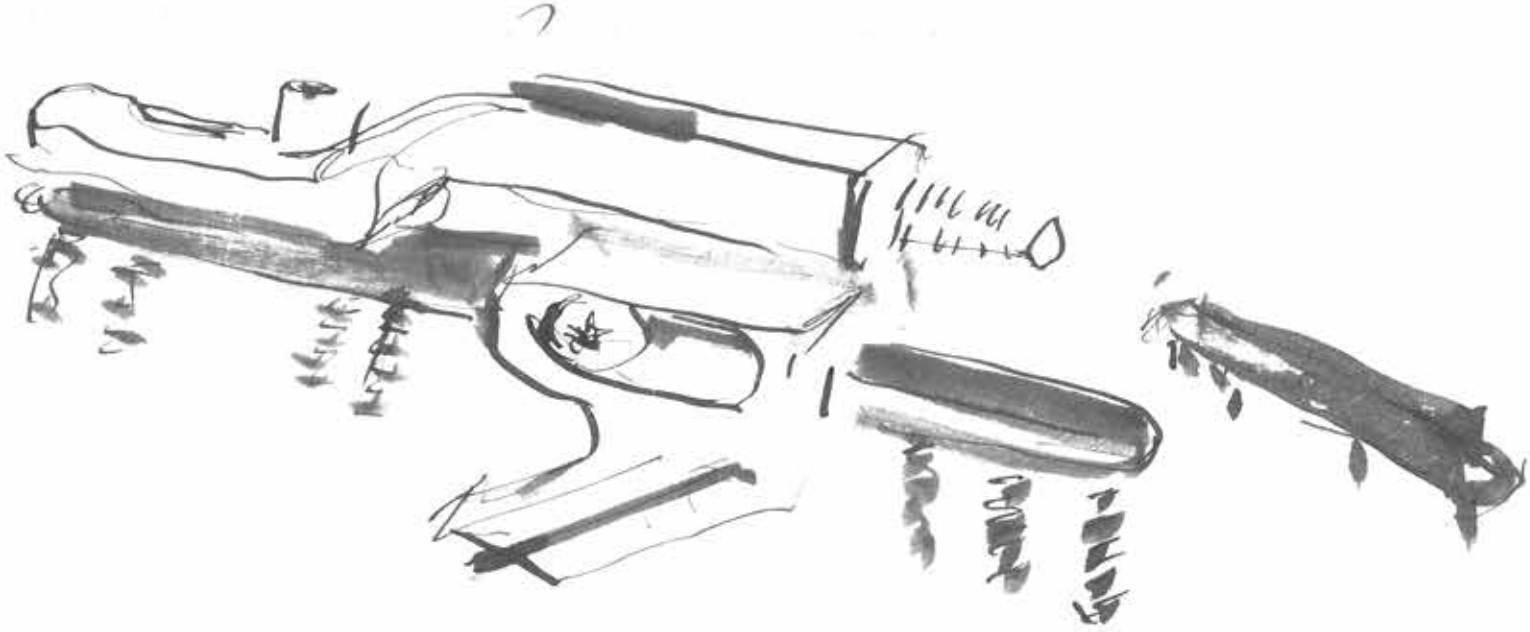
# Postoperative Treatment

- 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.

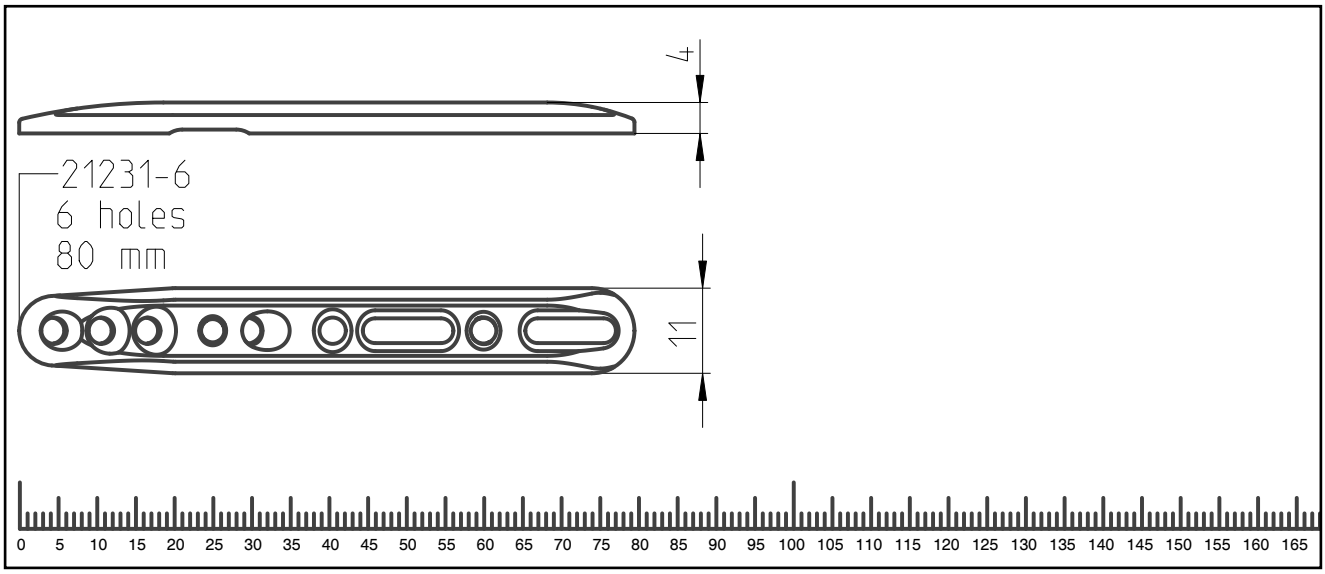
The ITS. Type II anodization surface treatment reduces the risk of cold welding of titanium implants (for more information, see page 31).



# Information

# 3.

# Technical Information




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

Not true to scale

# Type II Anodization

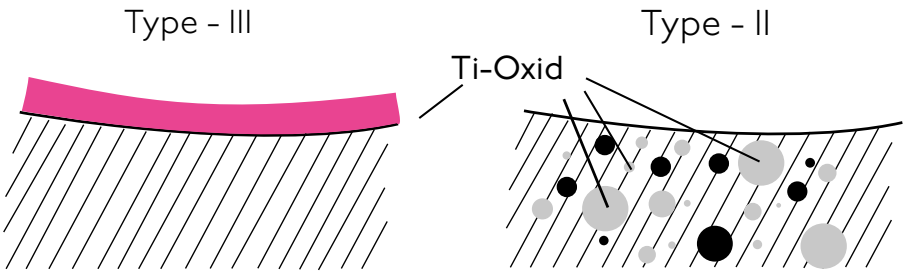
Chemical process - anodization in a strong alkaline solution*

## Type III anodization

- Layer thickness 60-200nm
  - \+ Different colors
  - \- Implant surface remains sensitive to:
    - Chipping
    - Peeling
    - Discoloration

## 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 the 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

# Ordering Information

## Ulna Osteotomy Plate

| Description | Holes | Article Number |
|---|---|---|
| Ulna Osteotomy Plate | 6 | 21231-6 |

## Screws

| Cortical Screw D=2.7mm | Length | Article Number |
|---|---|---|
| Non-Locking | 10 | 32271-10 |
|  | 12 | 32271-12 |
| | 14 | 32271-14 |
| | 16 | 32271-16 |
| | 18 | 32271-18 |
| | 20 | 32271-20 |
| | 22 | 32271-22 |
| | 24 | 32271-24 |
| | 26 | 32271-26 |

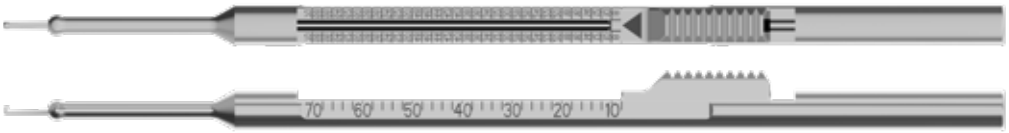
| Stabilization Screw D=2.4mm | Length | Article Number |
|---|---|---|
| Locking | 10 | 37241-10 |
|  | 12 | 37241-12 |
| | 14 | 37241-14 |
| | 16 | 37241-16 |
| | 18 | 37241-18 |
| | 20 | 37241-20 |
| | 22 | 37241-22 |
| | 24 | 37241-24 |

| Spongiosa Stabilization Screw, D=3.0mm | Length | Article Number |
|---|---|---|
| Locking | 10 | 37303-10 |
|  | 12 | 37303-12 |
| | 14 | 37303-14 |
| | 16 | 37303-16 |
| | 18 | 37303-18 |
| | 20 | 37303-20 |
| | 22 | 37303-22 |
| | 24 | 37303-24 |

| Cortical Stabilization Screw, D=3.0mm | Length | Article Number |
|---|---|---|
| Locking | 10 | 37304-10 |
|  | 12 | 37304-12 |
| | 14 | 37304-14 |
| | 16 | 37304-16 |
| | 18 | 37304-18 |
| | 20 | 37304-20 |
| | 22 | 37304-22 |
| | 24 | 37304-24 |

# Instruments

## Depth Gauge




59026

| Description | Article Number |
|---|---|
| Depth Gauge, PROlock II | 59026 |

## Drill

61183-100

61203-100

61243-100

| Description | Article Number |
|---|---|
| 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 |

## Drill Guide

62221

| Description | Article Number |
|---|---|
| Drill Guide, D=2.0/2.4mm | 62221 |

## Screwdriver

56095-70

T9

56095-150

T9

| Description | Article Number |
|---|---|
| Screwdriver , Torque, T9x70 | 56095-70 |
| Screwdriver , Torque, T9x150 | 56095-150 |

# Targeting Device

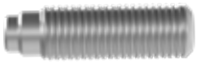

680870


680871


680872-2


680873


680874


680875


680875


680877

| Description | Article Number |
|---|---|
| Jig, Ulna Osteotomy Plate | 680870 |
| Fixing Screw, Ulna Osteotomy Plate | 680871 |
| Fixing Screw, Compression Slide, Ulna Osteotomy Plate | 680872-2 |
| Transection Gauge, Right, Ulna Osteotomy Plate | 680873 |
| Transection Gauge, Left, Ulna Osteotomy Plate | 680874 |
| Compression Screw, Ulna Osteotomy Plate | 680875 |
| Compression Slide, Ulna Osteotomy Plate | 680876 |
| Tension Bolt, Ulna Osteotomy Plate | 680877 |

Disclaimer:

The intended users are limited to medical personnel with appropriate product training by the medical product consultants or knowledge of the surgical procedure to be applied. The medical staff must ensure that the use of I.T.S. GmbH medical devices is appropriate, taking into account the medical condition and medical history of the patient. Prior to product use, medical personnel must refer to complete information on product label and in IFU, including, but not limited to, indications, contraindications, warnings and preventative measures, and cleaning and sterilization instructions. Product availability is dependent on country registrations and clearances. For more information, please visit www.its-implant.com or contact us at office@its-implant.com. All information herein is the intellectual property of I.T.S. GmbH.

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