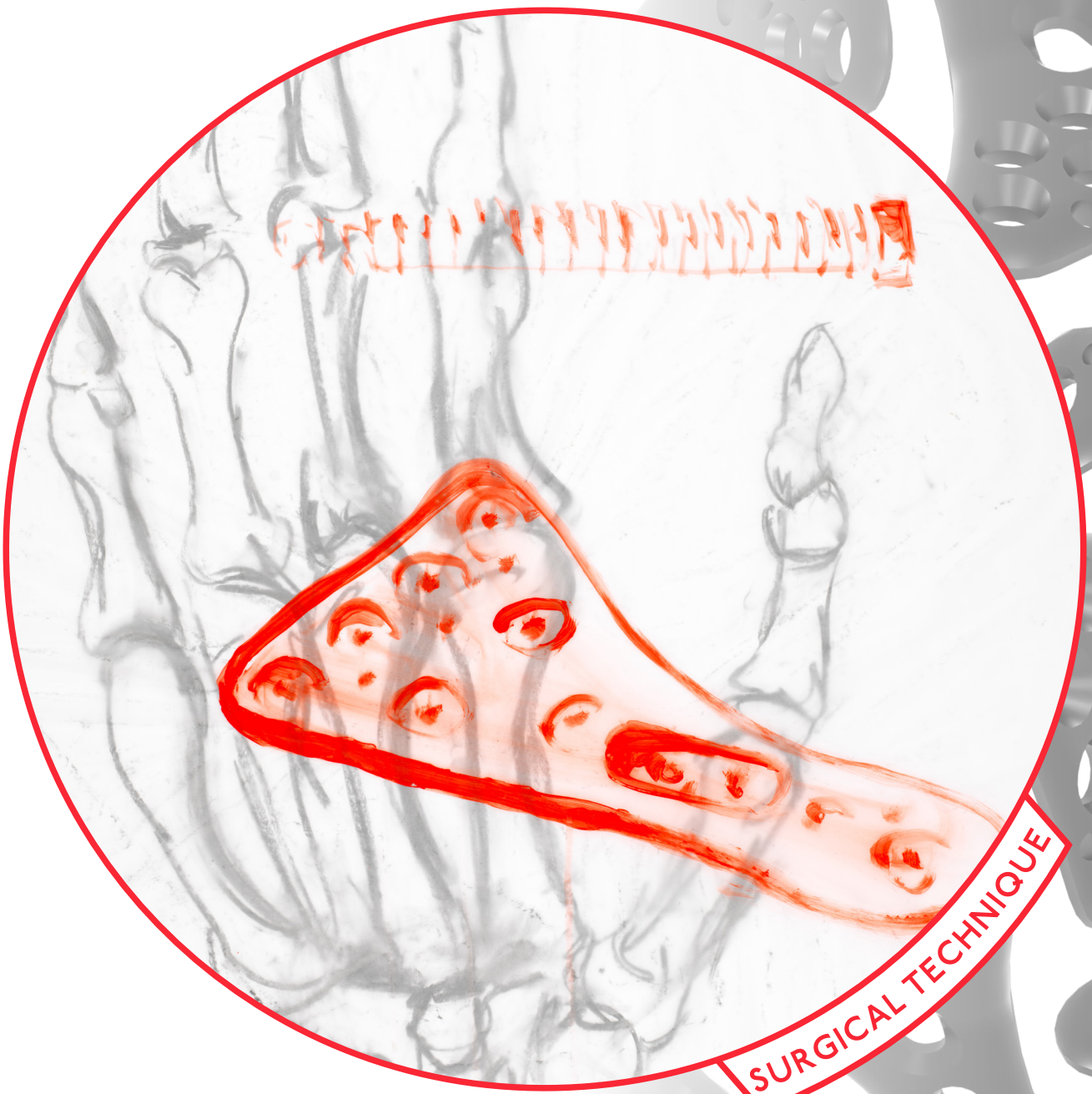
ITS.

Implants for Trauma Surgery



SURGICAL TECHNIQUE

PROlock Radius 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.

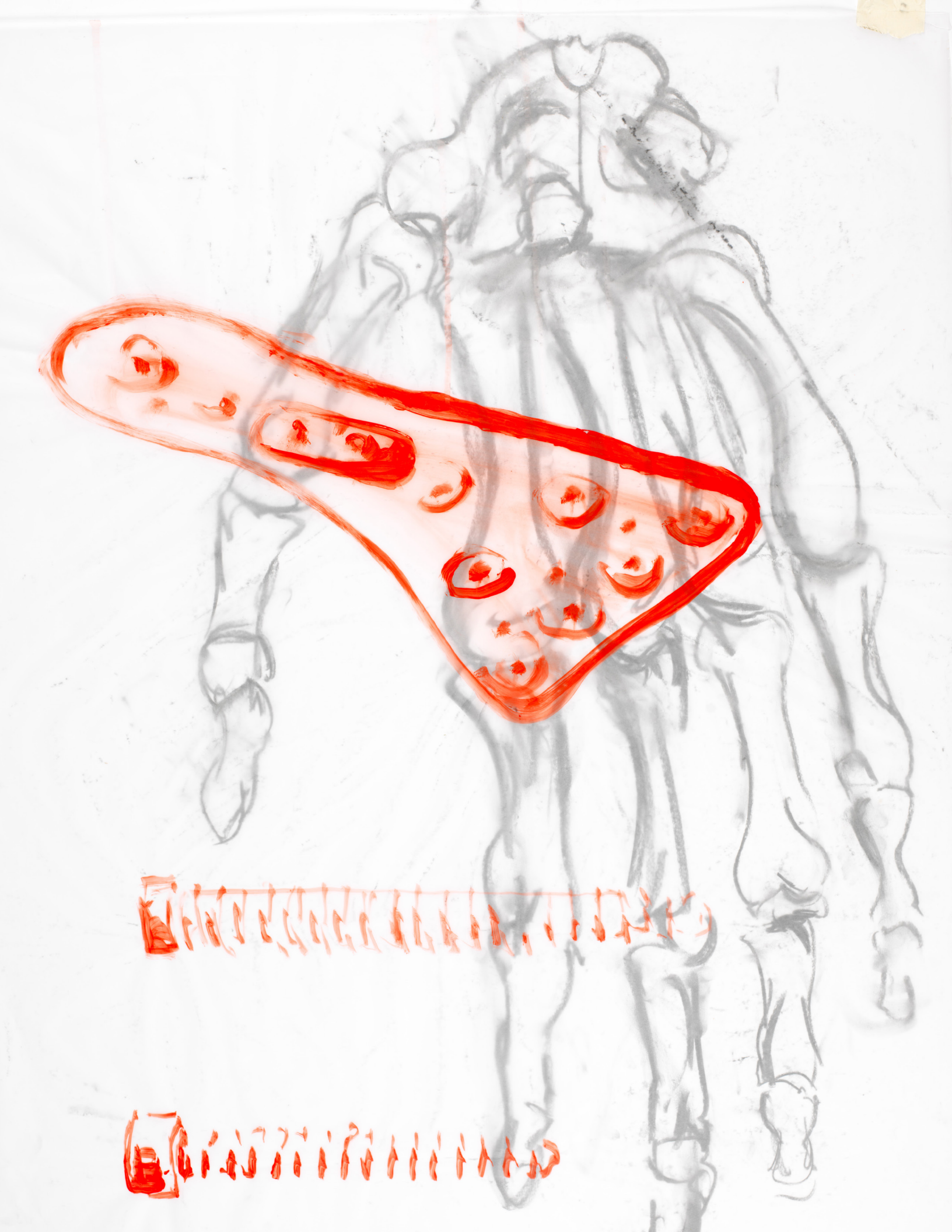
At I.T.S., we stand for long-term, trusting relationships with our customers, suppliers, and development partners. Through our devotion to innovation and development, we continuously seek to improve and optimize products and techniques in the field of traumatology.

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.



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.

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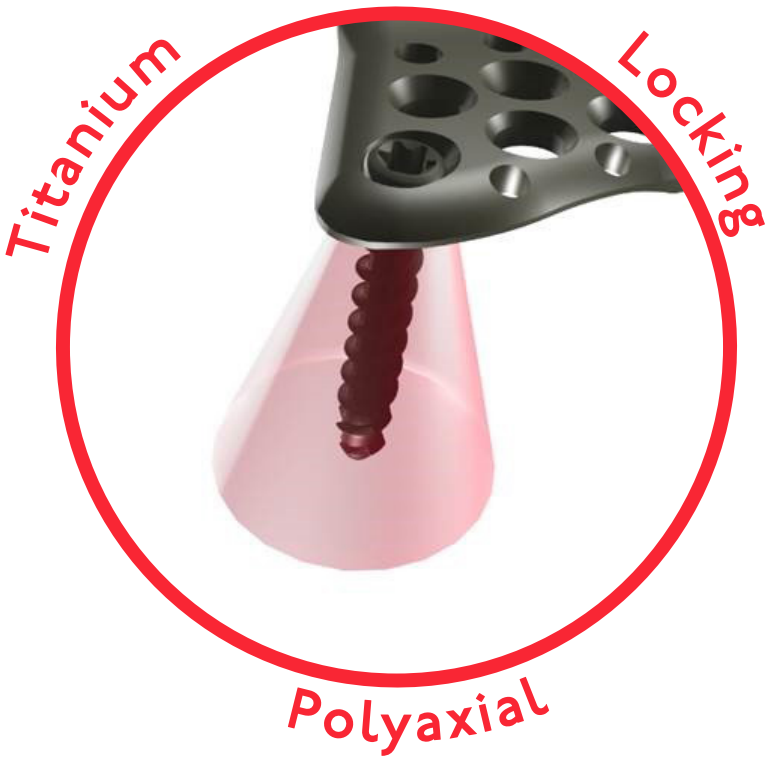
Introduction

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 is 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

The PROlock Radius Locking Plate II is the next generation distal radius plating system developed based on these excellent results of the previous ITS. Radius Plates.

The plates are designed as a left and right version and available in differnt lenghts and widths.

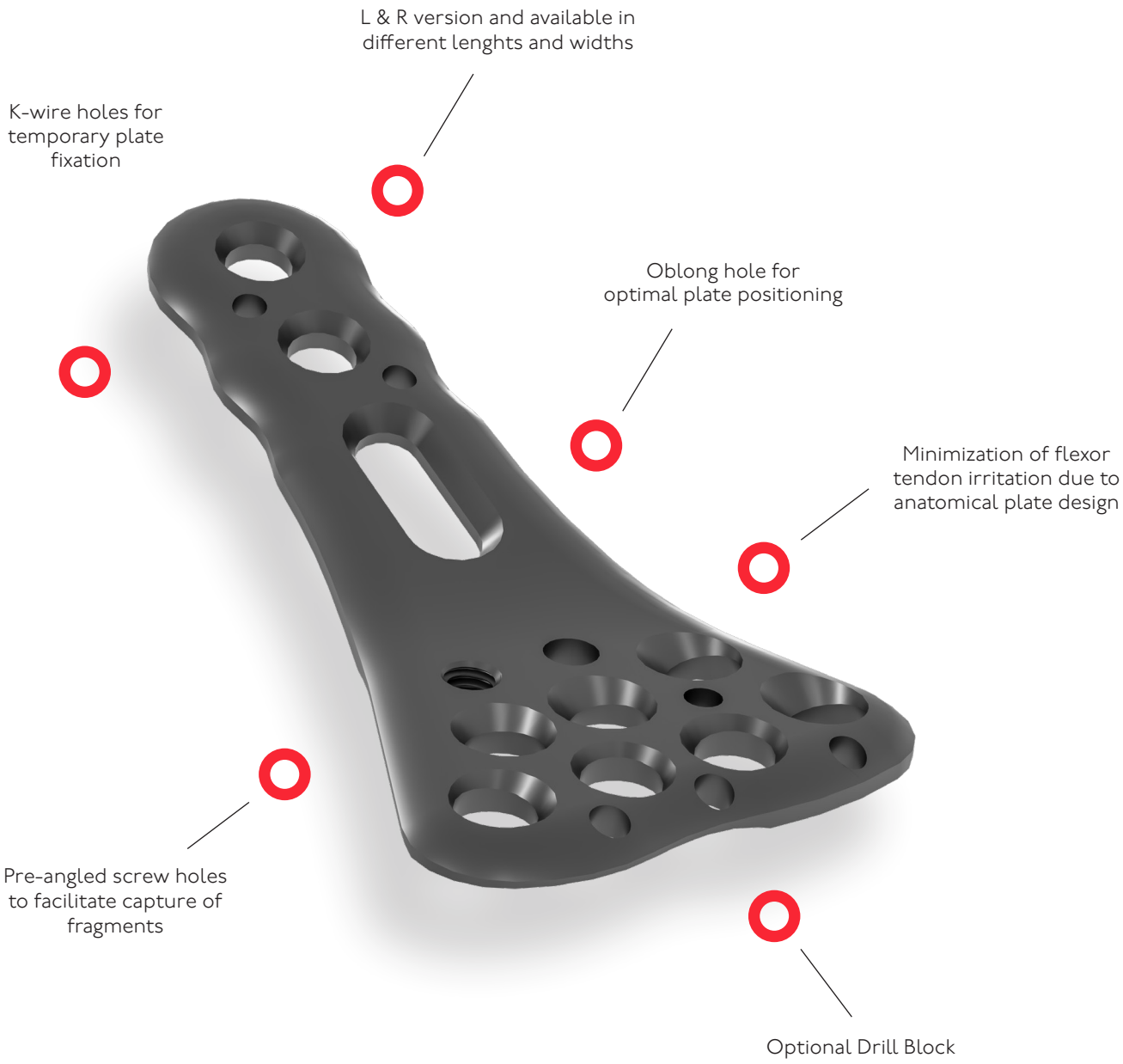
The tapered watershed line design allows for a distal placement of the plate, while minimizing the risk of tendor irritation.

Adhering to the technology principles of all ITS. plates, PRL system offers the option of polyaxial locking capabilities in all screw holes (except oblong). The screw holes are pre-angled, facilitating screw insertion, and increasing reach, e.g. into the styloid.

The optional, radiolucent drill block further facilitates precise and rapid screw placement of the distal plate holes with predefined angles.

Properties

PROlock Radius Locking Plate II



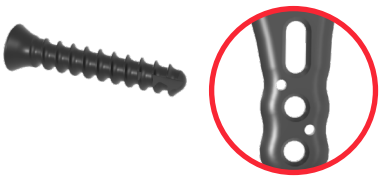
OPTIONAL: Drill Block for PRL II

- Precise and rapid screw placement with predefined angles
- Easy mounting and dismounting
- Radiolucent
- Allows for screw insertion through drill block
- Color coding for left and right version

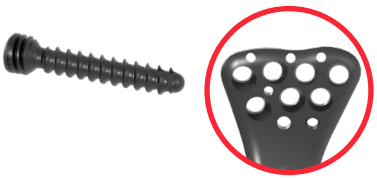
LEFT **RIGHT**

Screws

3227I-xx **NON-LOCKING**
Cortical Screw, D=2.7mm
Spiral Drill, D=2.0mm
Torque, T9

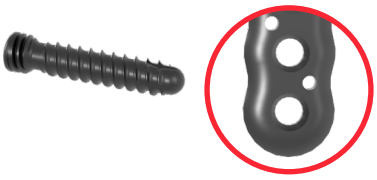


3724I-xx **LOCKING**
Stabilization Screw, D=2.4mm
Spiral Drill, D=I.8mm
Torque, T9



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



Predefined Angles of the distal holes

PROlock Radius Locking Plate II

LEFT

RIGHT

24.5mm Plate								
	1	2	3	4	5	6	7	8
Proximal	0°	5°	5°	5°	0°	0°	0°	0°
Distal	15°	0°	0°	0°	5°	5°	10°	3°
Ulnar	0°	0°	0°	0°	0°	0°	0°	5°
Radial	8°	8°	3°	3°	0°	7°	13°	0°

Indications

- Complex intra- & extra-articular fractures of the distal radius with comminuted zone
- Corrective osteotomy of the distal radius

Contraindications

- Very advanced osteoporosis with soft bones
- Disintegration of the radius-joint surfaces to the extent that there is no support for screws
- Obesity
- Lack of patient compliance

Time of Operation

- Acute, on the day of the accident
- After regression of the swelling
- In the case of additional questions concerning the wrist surface, a CT scan can be performed.

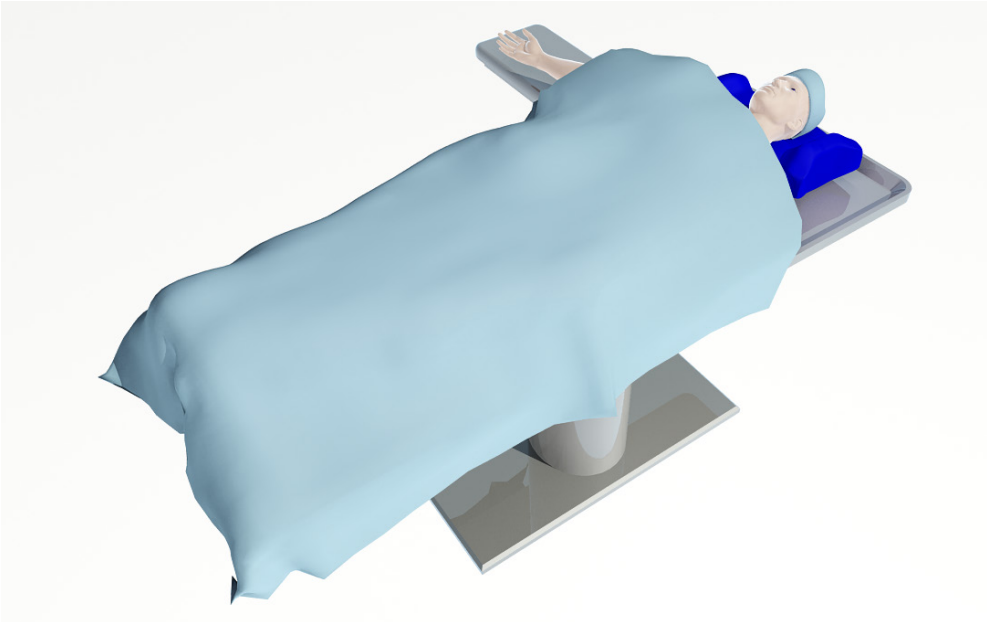

QSTOCKER

Surgical Technique

2.

Pre-operative patient preparation

- The patient is placed in the supine position with pneumatic partial deprivation of blood supply
- The hand is positioned on a radiolucent surgical hand table



Access

- The skin incision is performed volarly on the distal forearm above the tendon of the flexor carpi radialis and reaching to the crease of the wrist (FCR-approach).
- Split the deep fascia of the forearm.
- Release the pronator quadratus muscle from the distal radius beginning at the radial edge.

Reduction

- Suspending the thumb with a counterpoise, the fracture is loosened and the length restored.
- The individual fragments are reduced with the appropriate instrumentation, and, if necessary, the comminuted zones are filled with bone substitute to achieve a provisional reduction in position and length.

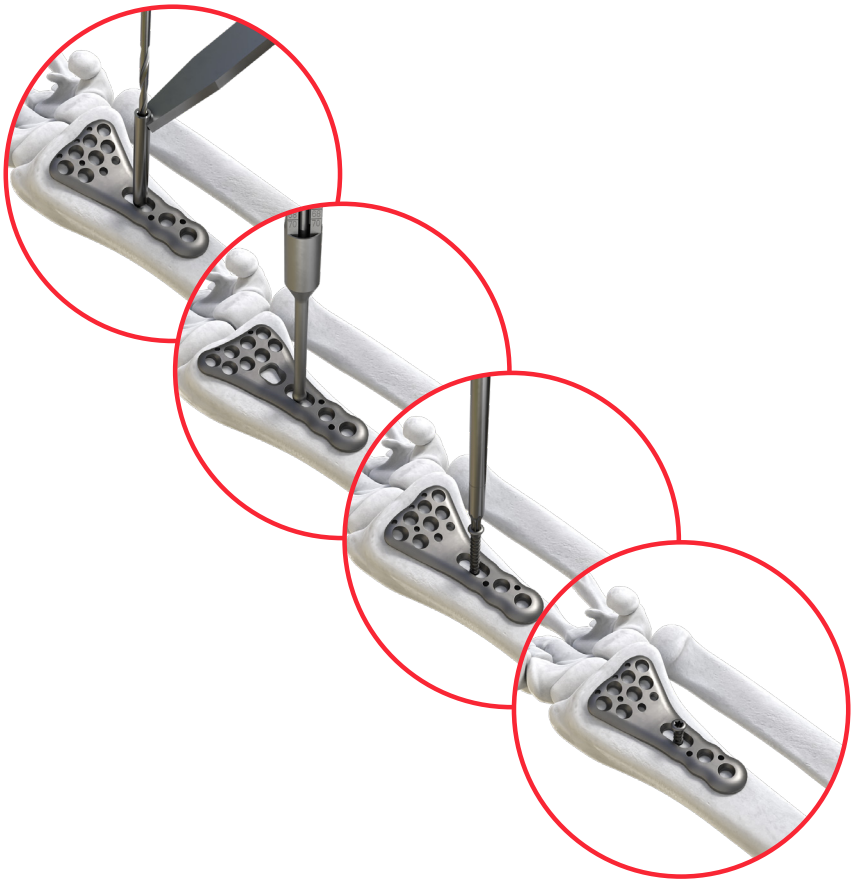
TIP: Temporary fixation of individual fragments is possible using a guide wire.

Plate Insertion

- Check reduction under fluoroscopy.
- After anatomical reduction is achieved, the implant is chosen and, if required, its contour can slightly be modified.

- For optimal alignment of the plate, use the spiral drill D=2.0mm, L=100mm, AO Connector *(61203-100)* with drill guide to drill both cortices through the oblong hole in the shaft of the plate.
- Determine appropriate length using the depth gauge, PROlock *(59023)*.
- Insert the D=2.7mm cortical non-locking screw *(32271l-xx)* with the screwdriver, T9x70 *(56095-70)*.

TIP: Not fully tightening the screw at this point will allow for positional adjustments of the plate if necessary.



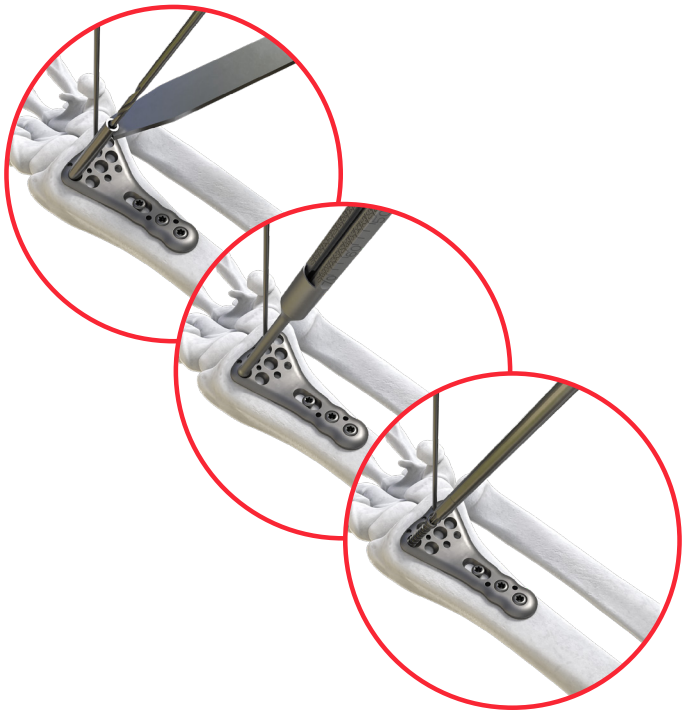
- Check the reduction and position of the plate under fluoroscopy.

TIPP: For temporary fixation of the fragments, both plates feature distal guide wire holes.

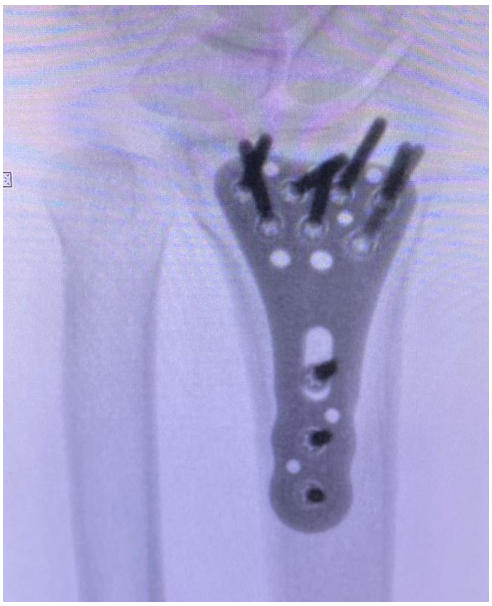
- Next fill the shaft holes with either D=3.0mm cortical stabilization screws *(37304-XX)* or with D=2.7mm cortical screws *(32271-XX)*.

- After re-checking the reduction, 4 or more D=3.0mm cancellous screws *(37303-XX)* or D=2.4mm stabilization screws *(37241-XX)* should be used for the relevant fragments.

ATTENTION: The distal locking screws should be placed as closely to the wrist surface as possible in order to take advantage of the hard subchondral bone.

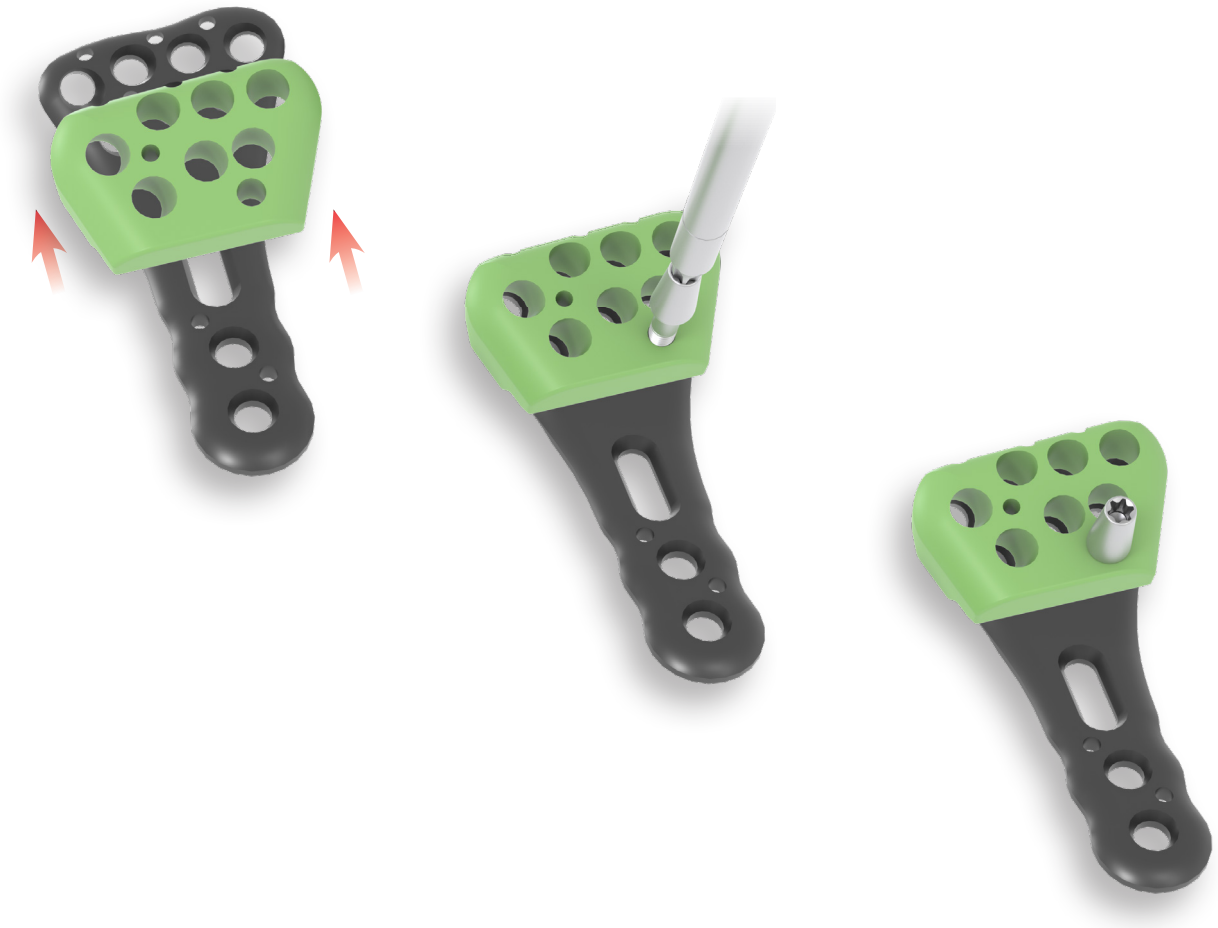


IMPORTANT: Two rows of screws are recommended to provide optimal support to the articular surface especially if only the stabilization screw D=2.4mm is used.



OPTIONAL: Assembly of the Drill block PRL II

- The drill block is placed on the plate before implantation. Push the drill block distally until it audibly engages in the holes provided.
- Then fix the drill block (62500, 62501, 62502, 62503) with the fixation screw *(62507)* using the screwdriver (56095-70).
- Once the drilling block is correctly fixed, you can start drilling.



Postoperative Treatment

- Dorsal splint (1-2 weeks)
- Physical therapy

Explantation

If desired by the patient, the implant can be removed.
Implant removal 6 months after surgery.

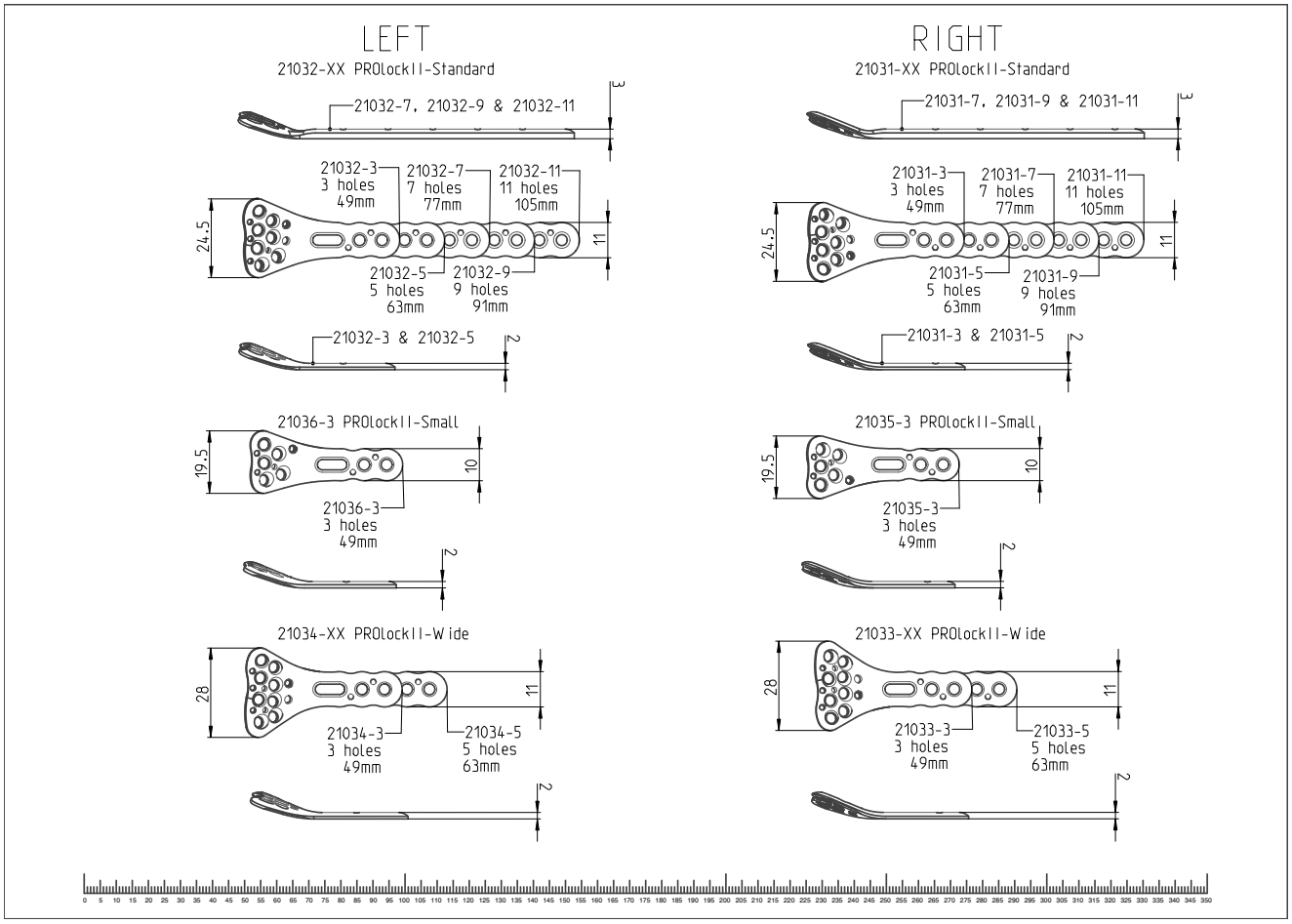
The ITS. Type II anodization surface treatment reduces the risk of cold welding of titanium implants (for more information, see page 28).

Information

3.

Technical Information

PROlock Radius Plate II



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

Not true to scale

Type II Anodization

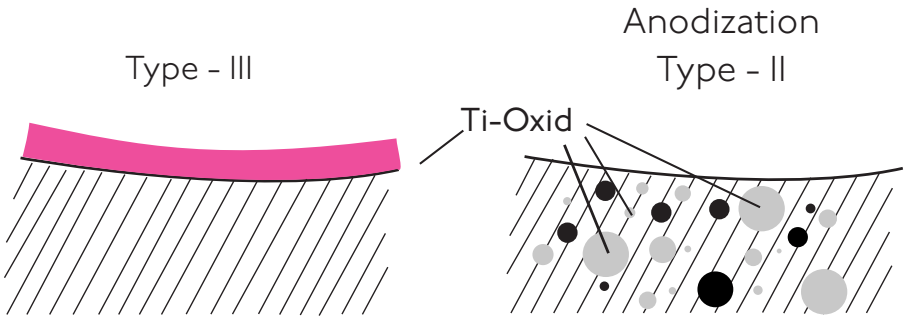
Chemical process - anodization in a strong alkaline solution*

Type III anodization

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

Type II anodization

- Layer thickness 1000-2000nm
  - \+ 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

Ordering Information

PROlock Radius Plate II

21032-3 21031-3

21032-5 21031-5

Description		Holes	Article Number
Radius Plate PROlock II	Left	3	21032-3
Radius Plate PROlock II	Right	3	21031-3
Radius Plate PROlock II	Left	5	21032-5
Radius Plate PROlock II	Right	5	21031-5

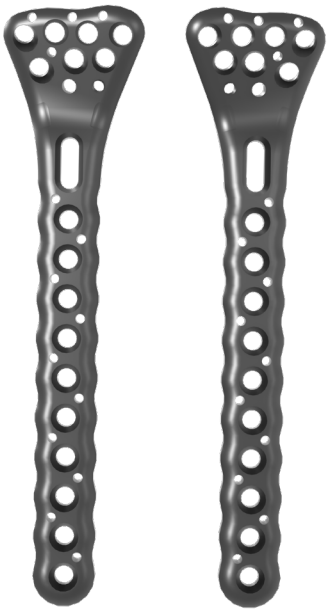
(Optional)

21032-7 21031-7

21032-9 21032-9

Description		Holes	Article Number
Radius Plate PROlock II	Left	7	21032-7
Radius Plate PROlock II	Right	7	21031-7
Radius Plate PROlock II	Left	9	21032-9
Radius Plate PROlock II	Right	9	21031-9

(Optional)



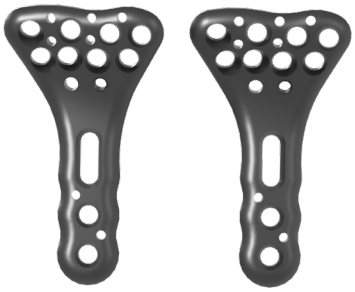
21032-II 21031-II

Description		Holes	Article Number
Radius Plate PROlock II	Left	II	21032-II
Radius Plate PROlock II	Right	II	21031-II

21036-3 21035-3

Description		Holes	Article Number
Radius Plate PROlock II, Narrow	Left	3	21036-3
adius Plate PROlock II, Narrow	Right	3	21035-3

(Optional)



21034-3 21033-3

21034-5 21033-5

Description		Holes	Article Number
Radius Plate PROlock II, Wide	Left	3	21034-3
Radius Plate PROlock II, Wide	Right	3	21033-3
Radius Plate PROlock II, Wide	Left	5	21034-5
Radius Plate PROlock II, Wide	Right	5	21033-5

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

Cancellous Stabilization Screw, D=3.0mm	Length	Article Number
Locking	14	37303-14
	16	37303-16
	18	37303-18
	20	37303-20
	22	37303-22
	24	37303-24
	26	37303-26
	28	37303-28
	30	37303-30

(Optional)

Stabilization Screw, D=2.4mm	Length	Article Number
Locking	14	37241-14
	16	37241-16
	18	37241-18
	20	37241-20
	22	37241-22
	24	37241-24
	26	37241-26
	28	37241-28
	30	37241-30

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

Instruments

Guide Wire

35162-150

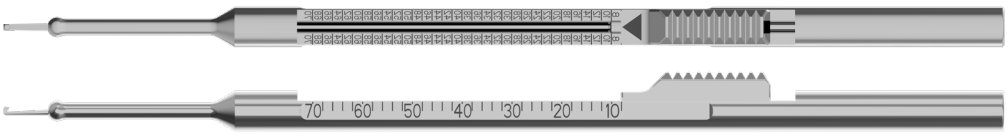
Description	Article Number
Guide Wire, Stahl, D=1.6mm, L=150mm, TR, RD	35162-150

(Optional) Plate Holder

58165-150

Description	Article Number
Plate Holder, for PROlock Screws	58165-150

Depth Gauge



59026

Description	Article Number
Depth Gauge, PROlock II	59026

Drill

61203-100

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

(Optional)

61183-100

61243-100

Description	Article Number
Spiral Drill, D=1.8mm, L=100mm, AO-Connector	61183-100
Spiral Drill, D=2.4mm, L=100mm, AO-Connector	61243-100

Drill Guide

62215

62221

Description	Article Number
Drill Guide, D=2.0/2.4mm	62215
Drill Guide, D=2.0/2.4mm	62221

Screwdriver

56095-70

T9

Description	Article Number
Screwdriver , Torque, T9x70	56095-70

AO-Silicone Handle

53016

Description	Article Number
AO Silicone Handle	53016

Torque-Shank

54095-I00 T9

Description	Article Number
Torque-Shank, T9xI00, AO-Connector	54095-I00

Drill Block - PROlock Radius Platte II

62500

62501

62502

62503

62507

Description	Article Number
Dril Block PROlock II, Left	62520
Drill Block PROlock II, Right	62520-I
Drill Block PROlock II, Left, Wide	62520-2
Drill Block PROlock II, Right, Wide	62520-3
Fixation Screw, Drill Block, PROlock II	62507

Notes

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. Unless otherwise noted, all information herein is the intellectual property of I.T.S. GmbH.

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