

ITS.

Implants for Trauma Surgery



Universal Forearm Locking Plates System

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

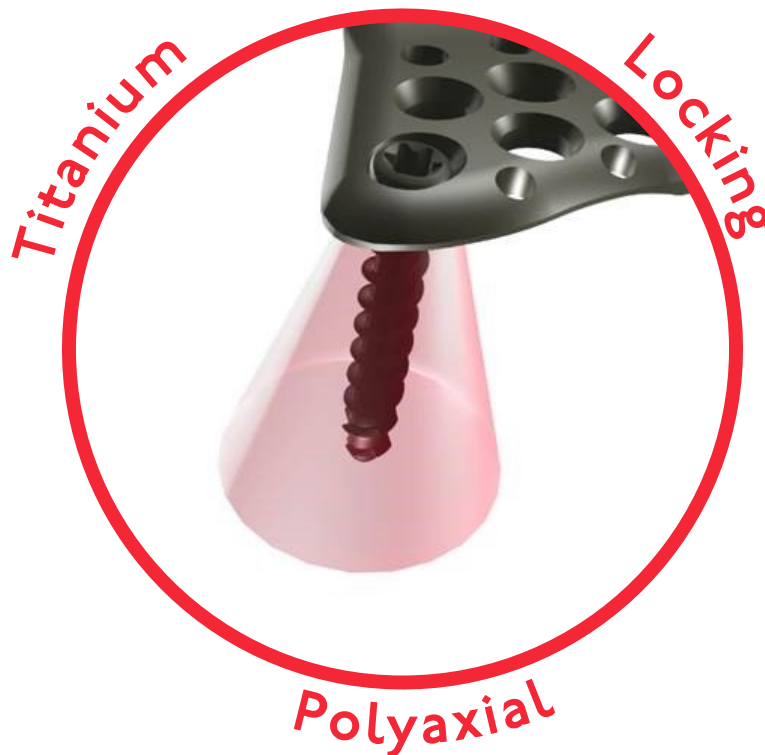


○ Plate Technology

At I.T.S., 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.

○NE Technology for all implants

All I.T.S. 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 $\pm 15^\circ$ and can be re-positioned up to three times.

○ System Overview

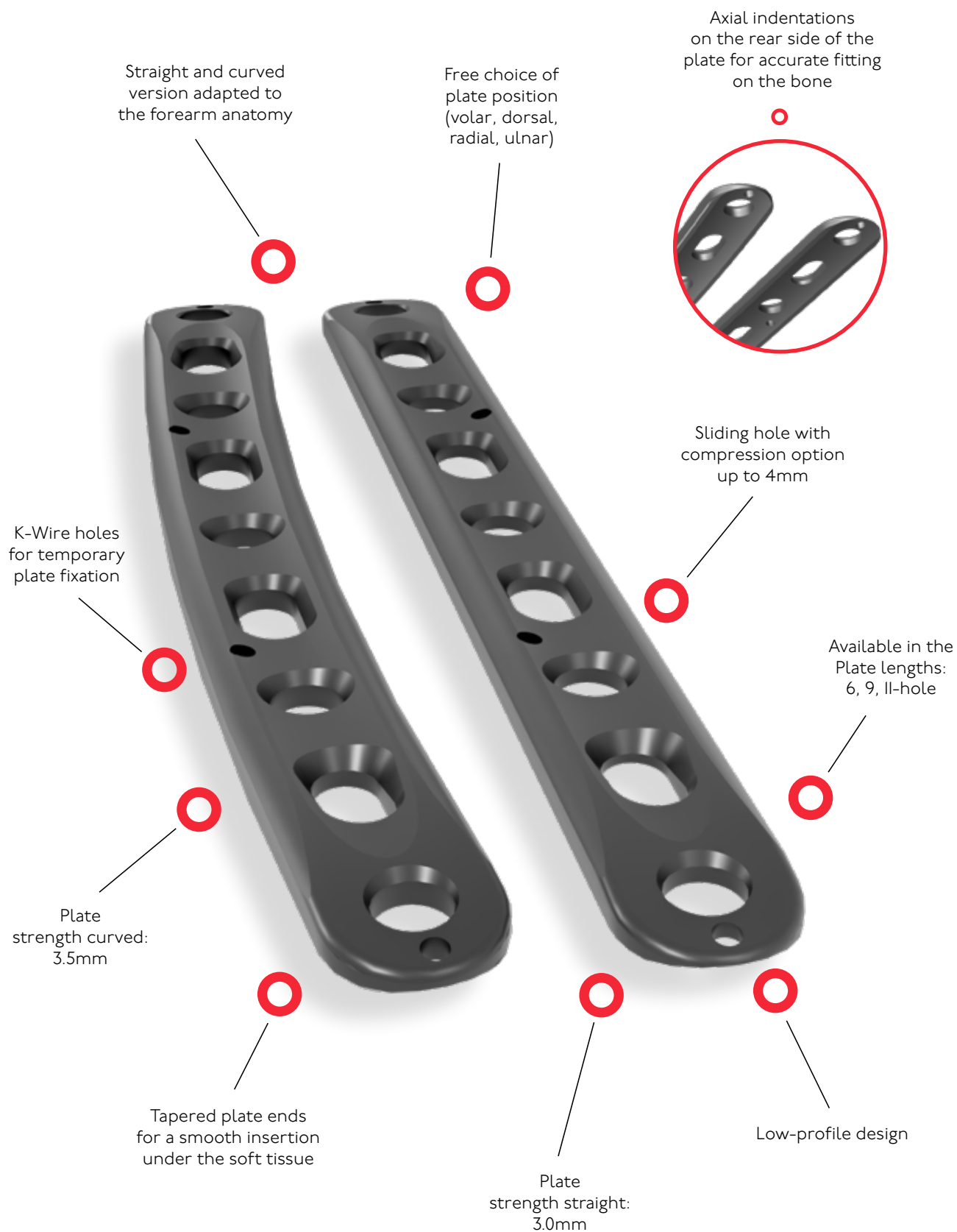
The ITS. Universal Forearm Locking Plates System is an osteosynthesis system for various forearm shaft fractures.

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, either locking or non-locking screw (except compression and oblong hole).

The free choice of screw angulation ($\pm 15^\circ$) provides an advantage in fracture treatment, especially in the case of complex fractures.



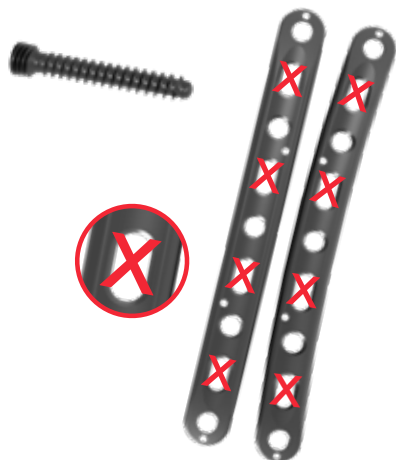
○ Properties



○ Screws

3735I-xx-N LOCKING

Cortical Screw, D=3.5mm
Spiral Drill, D=2.7mm
WS 2.5



3235I-xx

NON-LOCKING

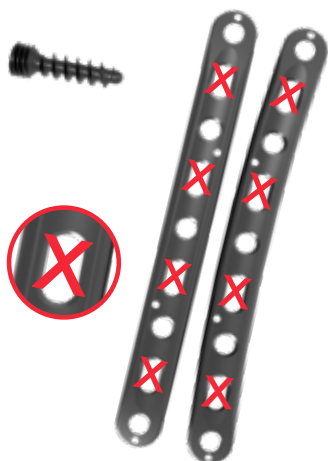
Cortical Screw, D=3.5mm
Spiral Drill, D=2.7mm
WS 2.5



OPTIONAL

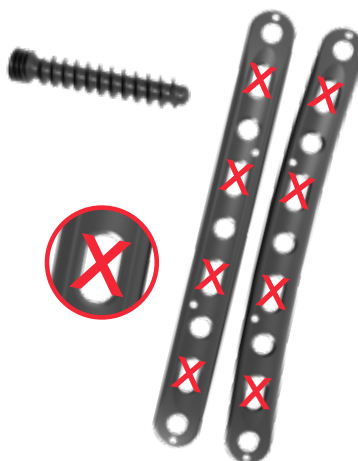
37352-xx-N LOCKING

Cancellous Screw, D=3.5mm
Spiral Drill, D=2.0mm
WS 2.5



37422-xx-N LOCKING

Cancellous Screw, D=4.2mm
Spiral Drill, D=2.5mm
WS 2.5



○ Indications

- For treatment of fractures, osteotomies and degenerative transformations.
Primary: radius, ulna; secondary: fibula
- Pediatric humeral and tibia fractures
- Comminuted fractures, supercondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, nonunions, and malunions. And as well, a fracture or osteotomy of the tibia, fibula, femoral, condyle, acetabulum, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; hip arthrodesis, and provisional hole fixation.

○ Contraindications

- The plates are not intended for shaft fractures of large bones such as humerus, femur and tibia (except pediatric humeral and tibia fractures)
- Common situations that do not allow osteosynthesis
- With advanced osteoporosis
- In cases of skin and soft tissue problems that prevent a tension-free skin closure
- Obesity
- Lack of patient compliance

○ Time of operation

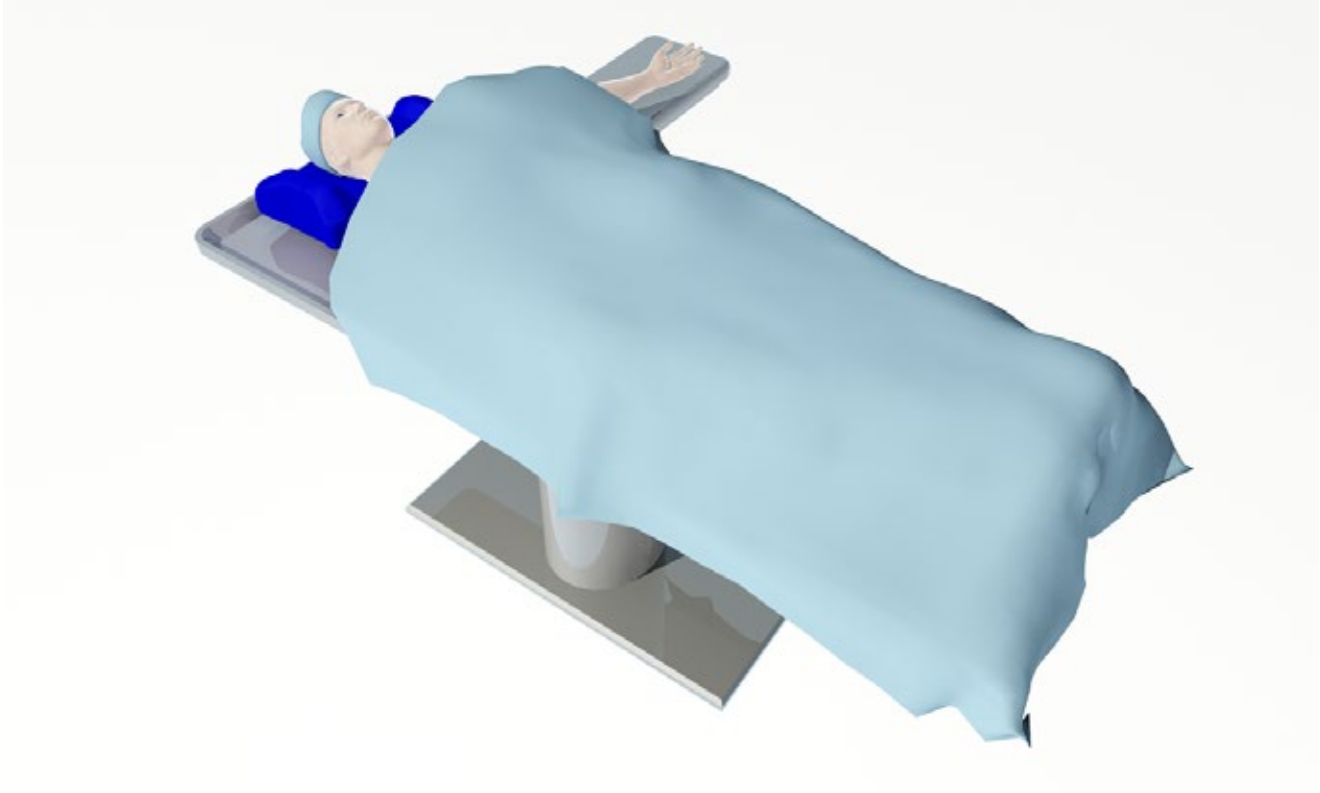
- Immediately after trauma or delayed
- After regression of swelling

Surgical Technique

2.

○ Pre-operative patient preparation

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



○ Reduction

- Temporary reduction of the fractured sections with the aid of forceps or guide wires.
- Subsequent control under fluoroscopy.



○ **OPTIONAL:** Temporary Plate Fixation

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



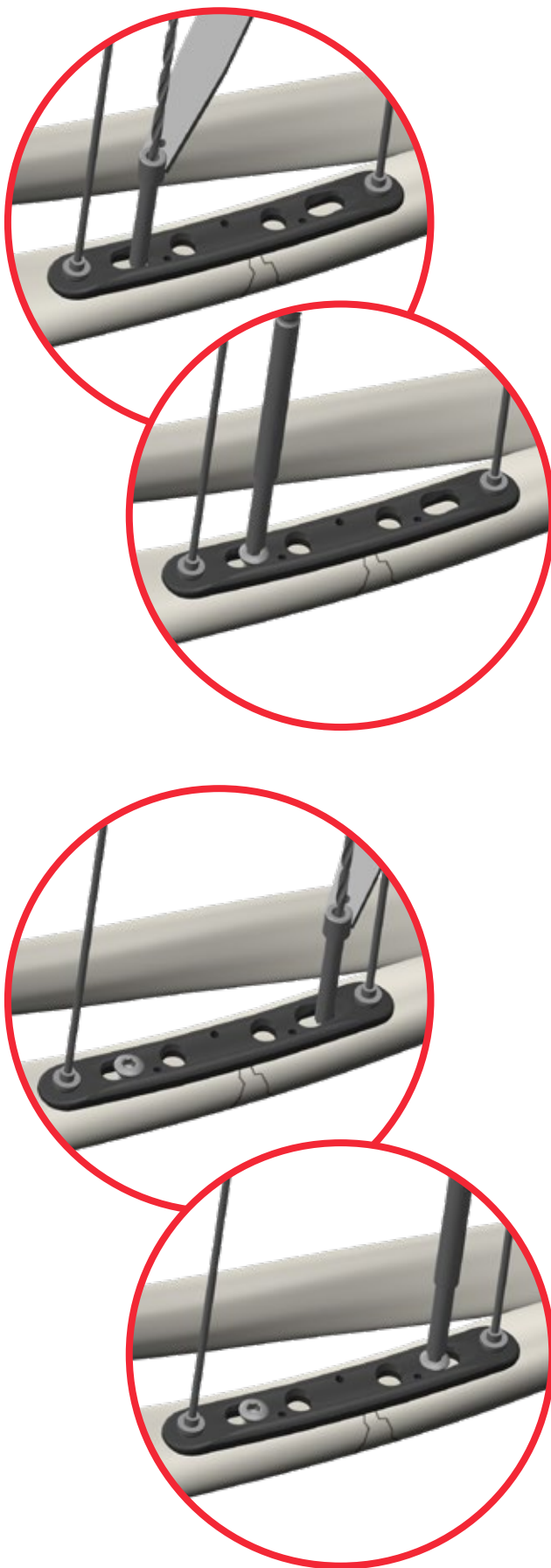
○ Screw Placement

- With the spiral drill, D=2.7mm, L=100mm, AO Connector (61273-100), drill through the drill guide, D=2.7/2.0mm (62202) into the distal compression hole.

- Determine appropriate length using the depth gauge, solid small fragment screws (59022). Insert the D=3.5mm cortical screw (3235I-XX) with the screwdriver, WS 2.5, self-holding sleeve (56252).

- Then, using the spiral drill, D=2.7mm, L=100mm, AO Connector (61273-100), drill through the drill guide, D=2.7/2.0mm (62202) into the proximal compression hole.

- Determine appropriate length using the depth gauge, solid small fragment screws (59022). Insert the D=3.5mm cortical screw (3235I-XX) with the screwdriver, WS 2.5, self-holding sleeve (56252).



- Using the spiral drill, D=2.7mm, L=100mm, AO Connector (61273-100) drill through the drill guide, D=2.7/2.0mm (62202) into the most distal plate hole.



- Determine appropriate length using the depth gauge, solid small fragment screws (59022). Insert the D=3.5mm cortical screw (3235I-XX) or the D=3.5mm locking cortical screw (3735I-XX-N) with the screwdriver, WS 2.5, self-holding sleeve (56252).



- The remaining plate holes are then filled, with either locking or non-locking screws.
- Subsequent control of plate and screw position under fluoroscopy.



○ Postoperative Treatment

- Physical therapy immediately following surgery (no immobilization required).
- In case of poor bone quality or insecure fixation, movement fixator for a maximum of 6 weeks.
- When a locking screw connection has been used, it is necessary to be aware that the diagnosis of a non-union may be very delayed.

○ Explantation

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

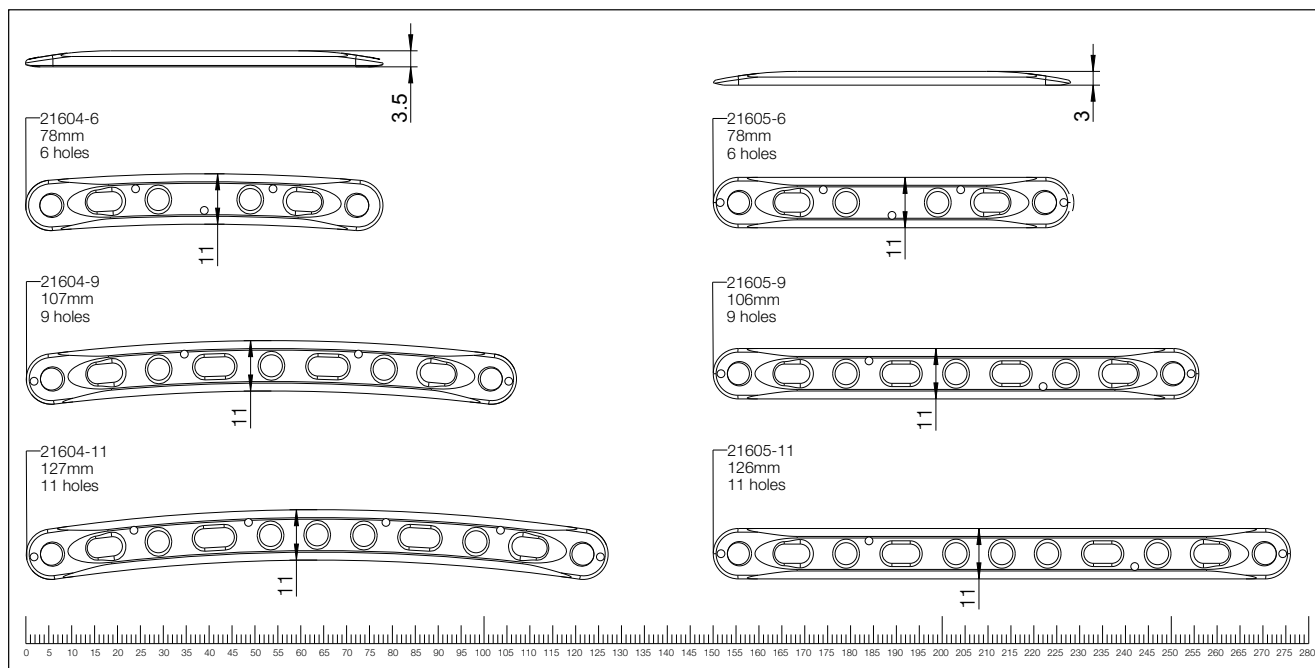
Removal should be performed at the earliest 6 months - 1 1/2 years later or after radiographic verification of the healed bone.

The ITS. Type II anodization surface treatment reduces the risk of cold welding of titanium implants (for more information, see page 21).

Information

3.

○ Technical Information



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

Not true to scale

○ Type II Anodization

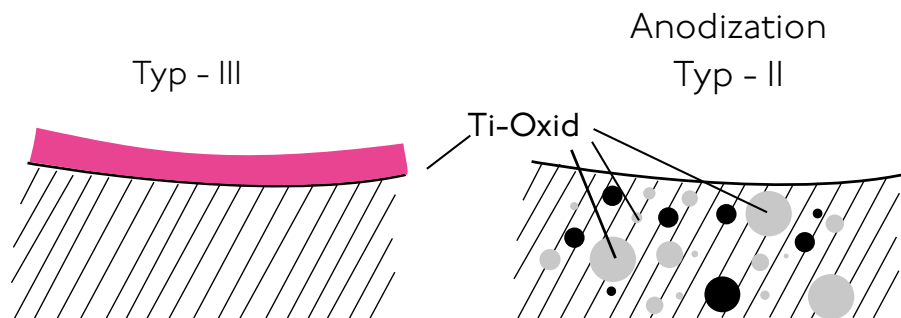
Chemical process - anodization in a strong alkaline solution*

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 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

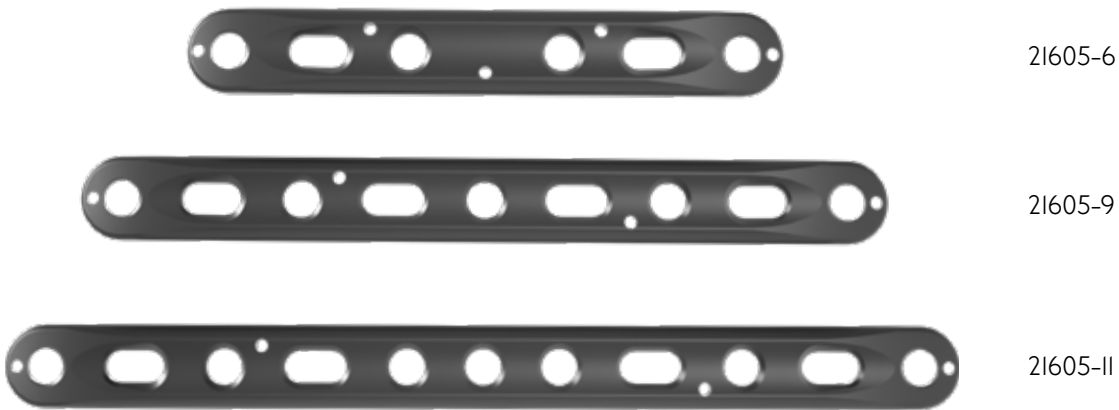
* White Paper: Ti6Al4V with Anodization Type II: Biological Behavior and Biomechanical Effects; Axel Baumann, Nils Zander

○ Ordering Information

Forearm Plate





Description		Holes	Article Number
Forearm Plate	Curved	6	21604-6
Forearm Plate	Curved	9	21604-9
Forearm Plate	Curved	11	21604-11




Description		Holes	Article Number
Forearm Plate	Straight	6	21605-6
Forearm Plate	Straight	9	21605-9
Forearm Plate	Straight	11	21605-11


Screws


Cortical Screw, D=3.5mm	Length	Article Number
	12	3235I-12
	14	3235I-14
	16	3235I-16
	18	3235I-18
	20	3235I-20
	22	3235I-22
	24	3235I-24
	26	3235I-26
	28	3235I-28
	30	3235I-30


Cortical Screw, D=3.5mm	Length	Article Number
	12	3735I-12-N
	14	3735I-14-N
	16	3735I-16-N
	18	3735I-18-N
	20	3735I-20-N
	22	3735I-22-N
	24	3735I-24-N
	26	3735I-26-N
	28	3735I-28-N
	30	3735I-30-N

(Optional)

Cortical Screw, D=3.5mm	Length	Article Number
	32	3235I-32
	34	3235I-34
	36	3235I-36
	38	3235I-38
	40	3235I-40
	42	3235I-42
	44	3235I-44
	46	3235I-46
	48	3235I-48
	50	3235I-50

Cortical Screw, D=3.5mm	Length	Article Number
	32	3735I-32-N
	34	3735I-34-N
	36	3735I-36-N
	38	3735I-38-N
	40	3735I-40-N
	42	3735I-42-N
	44	3735I-44-N
	46	3735I-46-N
	48	3735I-48-N
	50	3735I-50-N

Cancellous Screw, D=3.5mm	Length	Article Number
	12	37352-I2-N
	14	37352-I4-N
	16	37352-I6-N
	18	37352-I8-N
	20	37352-20-N
	22	37352-22-N
	24	37352-24-N
	26	37352-26-N
	28	37352-28-N
	30	37352-30-N
	32	37352-32-N
	34	37352-34-N
	36	37352-36-N
	38	37352-38-N
	40	37352-40-N
	42	37352-42-N
	44	37352-44-N
	46	37352-46-N
	48	37352-48-N
	50	37352-50-N

Cancellous Screw, D=4.2mm	Length	Article Number
	12	37422-I2-N
	14	37422-I4-N
	16	37422-I6-N
	18	37422-I8-N
	20	37422-20-N
	22	37422-22-N
	24	37422-24-N
	26	37422-26-N
	28	37422-28-N
	30	37422-30-N
	32	37422-32-N
	34	37422-34-N
	36	37422-36-N
	38	37422-38-N
	40	37422-40-N
	42	37422-42-N
	44	37422-44-N
	46	37422-46-N
	48	37422-48-N
	50	37422-50-N

Instruments

Guide Wire



35164-I50

Description	Article Number
Guide Wire, Steel, D=1.6mm, L=150mm, TR, w. Thread	35164-I50

(Optional) Plate Holder



58164-I50

Description	Article Number
Temporary Plate Holder, For 3.5/4.2mm Screws	58164-I50

Depth Gauge



59022

Description	Article Number
Depth Gauge, Solid Small Fragment Screws	59022

Spiral Drill



61273-I00

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

(Optional) Spiral Drill



61203-100



61253-180

Description	Article Number
Spiral Drill, D=2.0mm, L=100mm, AO Connector	61203-100
Spiral Drill, D=2.5mm, L=180mm, AO Connector	61253-180

Screwdriver



56252



Description	Article Number
Screwdriver, WS 2.5, with self-holding sleeve	56252

Drill Guide



62202

Description	Article Number
Drill Guide, D=2.0/2.7mm	62202

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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