

ITS.

Implants for Trauma Surgery



SURGICAL TECHNIQUE

Tubular Locking Plates System

THE ART of TRAUMA SURGERY

The Art of Trauma Surgery is a collaborative project between ITS. 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 ITS., 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 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

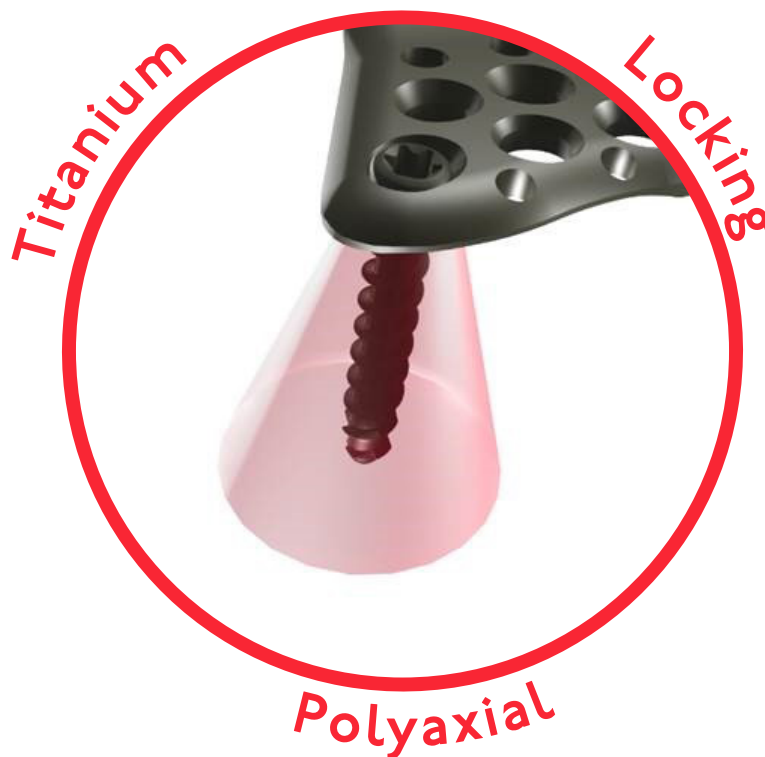


○ Plate Technology

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.

○NE 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 $\pm 15^\circ$ and can be re-positioned up to three times.

○ System Overview

The Tubular Locking Plates System is an osteosynthesis system for various diaphyseal and metaphyseal 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.

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



○ Properties

Distal Tubular Plate

Axial indentations on the rear side of the plate for accurate fitting on the bone

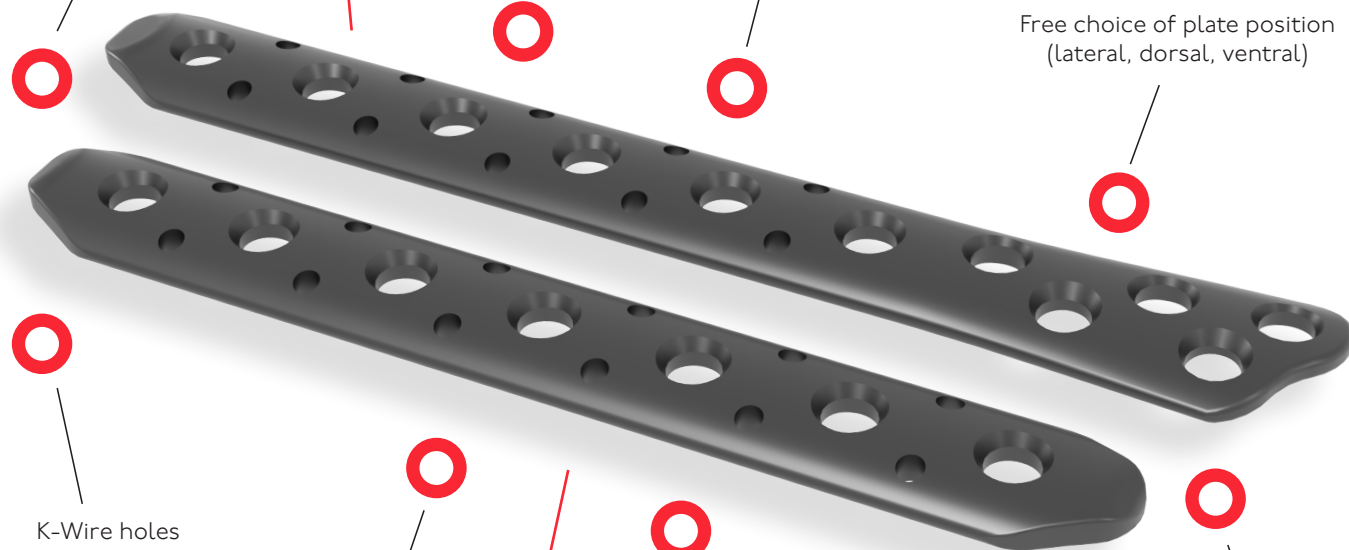
2 plate versions: diaphyseal and distal (multiple points of fixation in the distal area)

Plate strength, distal: 2.0mm (shaft), 1.5mm (distal)

Plate lengths, distal: 3, 4, 5, 6, 7, 8-hole



Free choice of plate position (lateral, dorsal, ventral)



K-Wire holes for temporary plate fixation

Plate strength, universal: 2.0mm

Plate lengths, universal: 5, 6, 7, 8, 10-hole

Anatomically shaped

Tapered plate ends for a smooth insertion under the soft tissue

Universal Tubular Plate

○ Screws

3227I-xx

NON-LOCKING

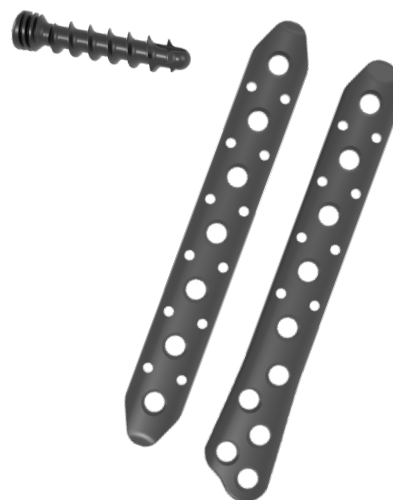
Cortical Screw, D=2.7mm
Spiral Drill, D=2.0mm
Torque, T9



37303-xx

LOCKING

Cancellous Stabilization Screw,
D=3.0mm
Spiral Drill, D=2.0mm
Torque, T9



OPTIONAL

37304-xx

LOCKING

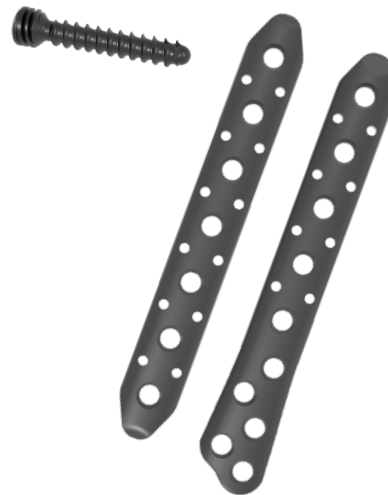
Cortical Stabilization Screw,
D=3.0mm
Spiral Drill, D=2.4mm
Torque, T9



3724I-xx

LOCKING

Stabilization Screw, D=2.4mm
Spiral Drill, D=1.8mm
Torque, T9



○ Indications

- For treatment of fractures, osteotomies and degenerative transformations.
Primary: Fibula
Secondary: Radius, ulna
- Pediatric humeral and tibia fractures
- Dislocated ankle-fractures group B+C according to Weber [with or without comminuted zones]

○ 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

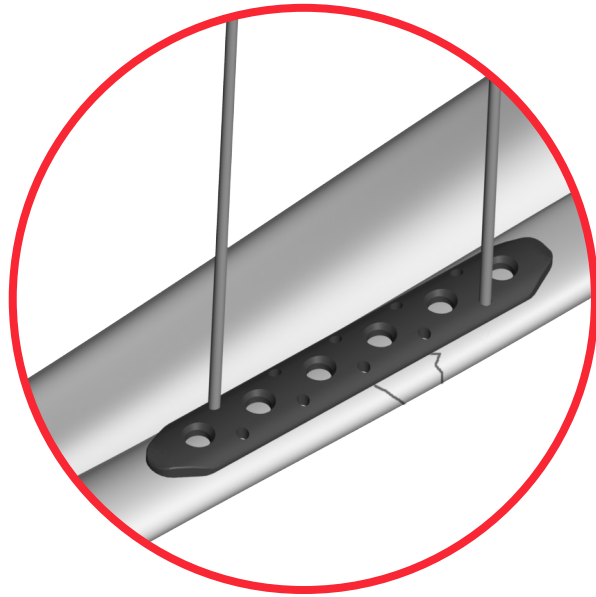
2.

○ Pre-operative patient preparation

- General anaesthesia, regional anaesthesia or combination can be used
- Tourniquet/partial deprivation of the blood supply

○ Reduction

- Temporary fixation of the plate using guide wires.
- Anatomical reduction of the fracture segments to the plate.
- Subsequent control under fluoroscopy.



○ **OPTIONAL:** Temporary Plate Fixation

- Optionally, the plate can be stabilized using the Temporary Plate Holder (58165-150).



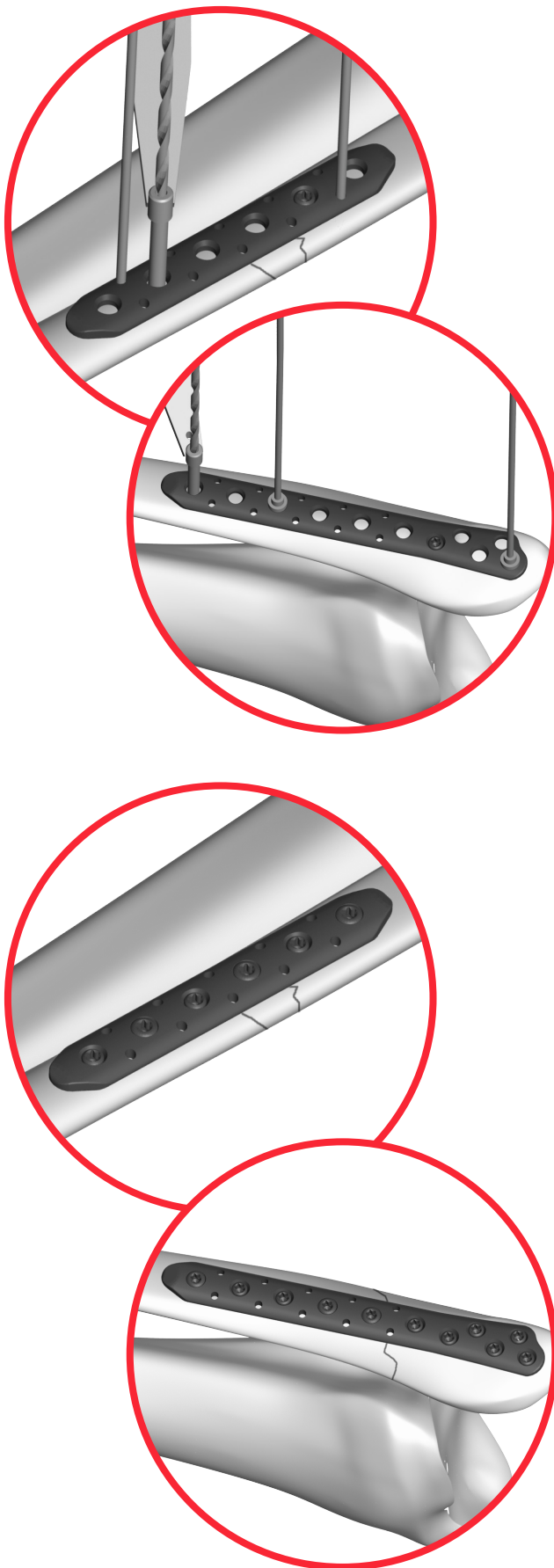
○ Screw Placement

- Use the spiral drill, D=2.0mm, L=100mm, AO Connector (61203-100) into the drill guide, D=2.0/2.4mm (62215) to bore with the plate holes close to fracture.

- Determine appropriate length using the depth gauge, PROlock II (59026). Insert the D=2.7mm cortical screws (32271-XX) with the screwdriver, torque, T9x70, (56095-70).

- Subsequently, place either locking or non-locking screws in the plate holes far from the fracture (suitable drills and screws see page II).

- 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.

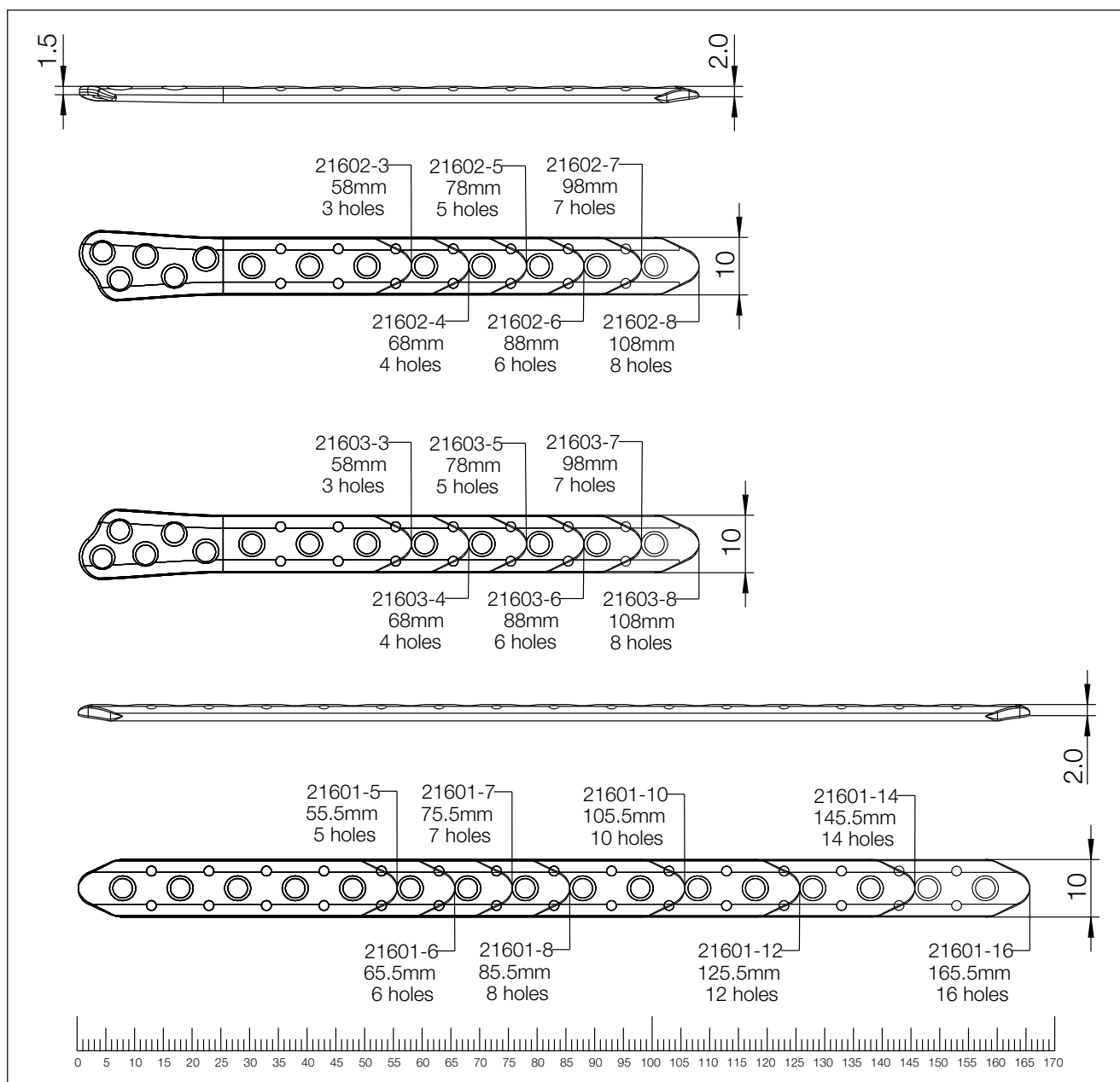
The problem of cold welding was resolved by using a special surface treatment (for further information see page 19).

Information

3.



Technical Information



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

Not true to scale

○ Type II Anodization

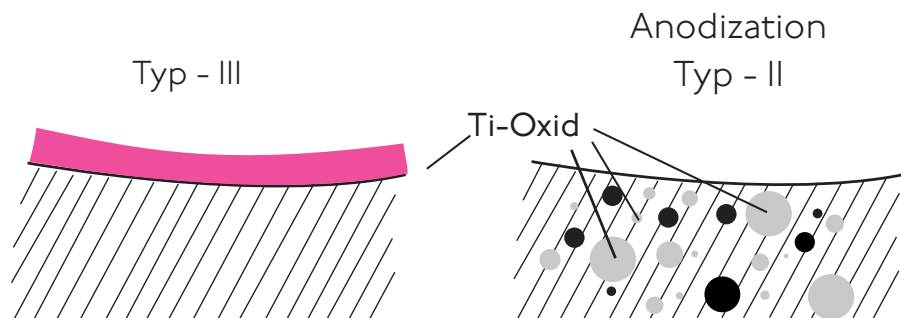
Chemical process - anodization in a strong alkaline solution*

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



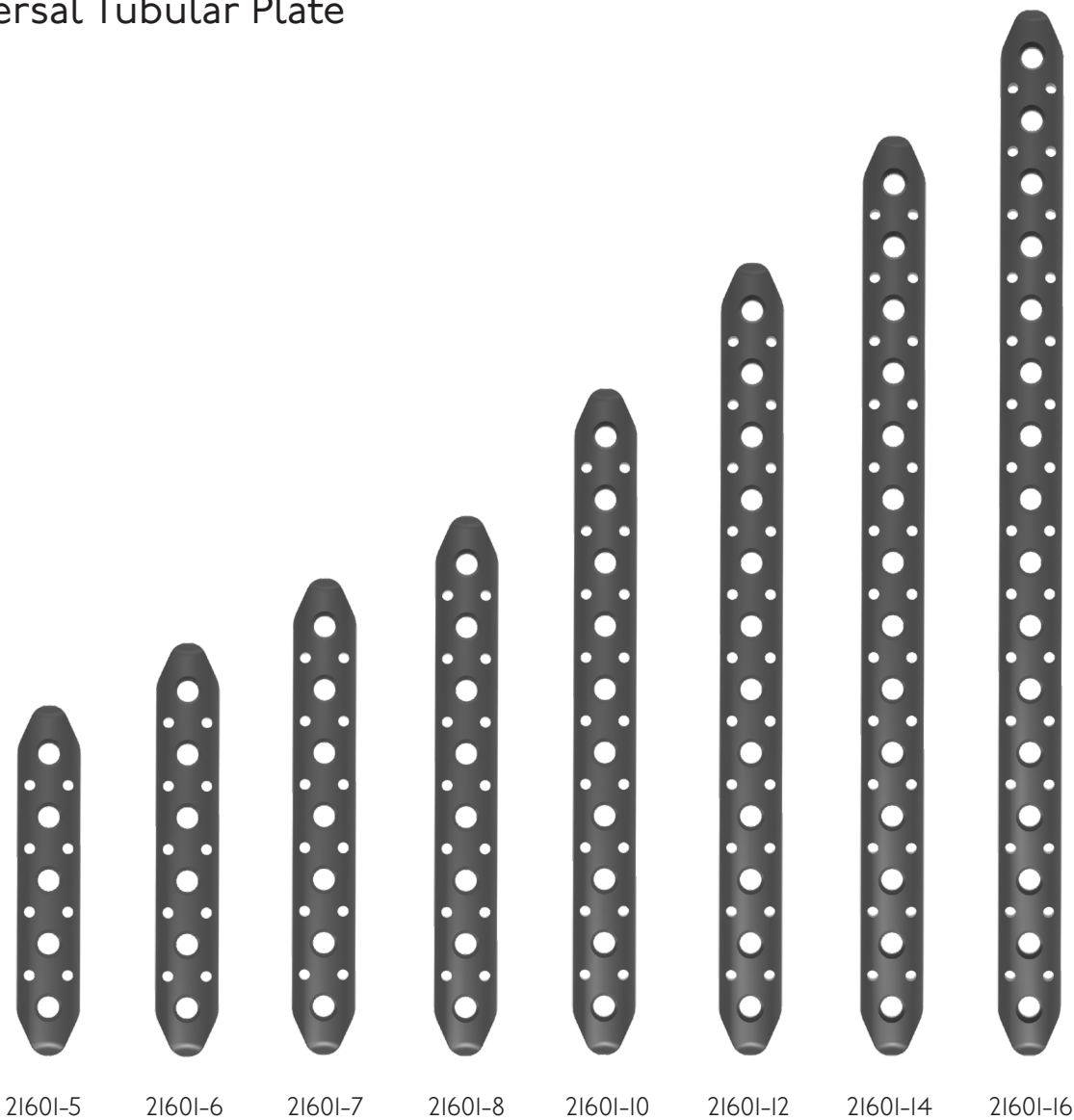
Anodization Type II leads to following benefits*

- 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

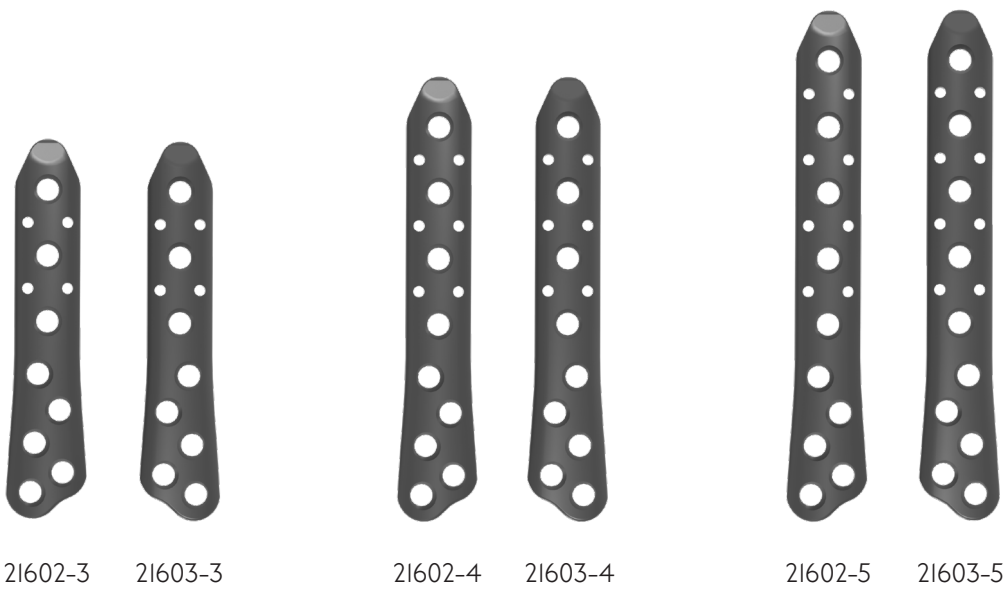
Universal Tubular Plate



Description	Holes	Article Number
Universal Tubular Plate	5	2I60I-5
Universal Tubular Plate	6	2I60I-6
Universal Tubular Plate	7	2I60I-7
Universal Tubular Plate	8	2I60I-8
Universal Tubular Plate	10	2I60I-10
Universal Tubular Plate	12	2I60I-12
Universal Tubular Plate	14	2I60I-14
Universal Tubular Plate	16	2I60I-16

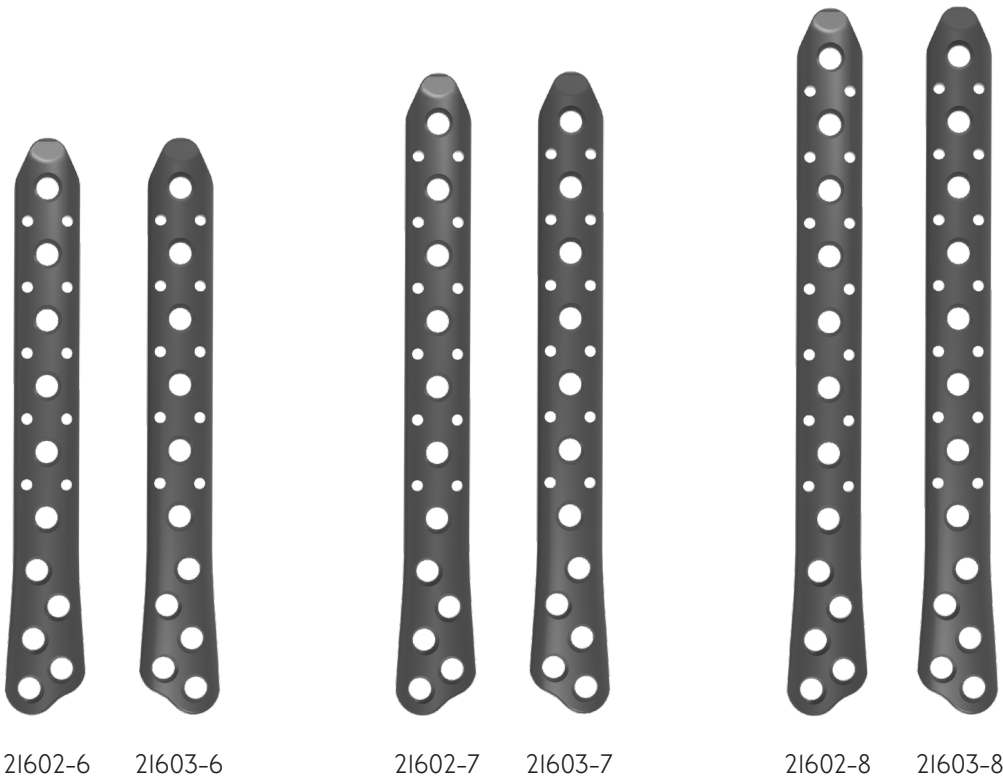
Ordering Information

Distal Tubular Plate



Description		Holes	Article Number
Distal Tubular Plate	Left	3	21602-3
Distal Tubular Plate	Right	3	21603-3
Distal Tubular Plate	Left	4	21602-4
Distal Tubular Plate	Right	4	21603-4
Distal Tubular Plate	Left	5	21602-5
Distal Tubular Plate	Right	5	21603-5


Distal Tubular Plate




Description		Holes	Article Number
Distal Tubular Plate	Left	6	21602-6
Distal Tubular Plate	Right	6	21603-6
Distal Tubular Plate	Left	7	21602-7
Distal Tubular Plate	Right	7	21603-7
Distal Tubular Plate	Left	8	21602-8
Distal Tubular Plate	Right	8	21603-8


Screws

Cancellous Stabilization Screw, D=3.5mm	Length	Article Number
	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 Screw, D=2.7mm	Length	Article Number
	10	32271-10
	12	32271-12
	14	32271-14
	16	32271-16
	18	32271-18
	20	32271-20
	22	32271-22
	24	32271-24

(Optional)

Cortical Stabilization Screw, D=3.0mm	Length	Article Number
	8	37304-8
	9	37304-9
	10	37304-10
	11	37304-11
	12	37304-12
	14	37304-14
	16	37304-16
	18	37304-18
	20	37304-20
	22	37304-22
	24	37304-24

Stabilization Screw, D=2.4mm	Length	Article Number
	8	37241-8
	10	37241-10
	12	37241-12
	14	37241-14
	16	37241-16
	18	37241-18
	20	37241-20
	22	37241-22
	24	37241-24

Instruments

Guide Wire



35I64-I50

Description	Article Number
Guide Wire, Steel, D=1.6mm, L=150mm, TR, w. Thread	35I64-I50

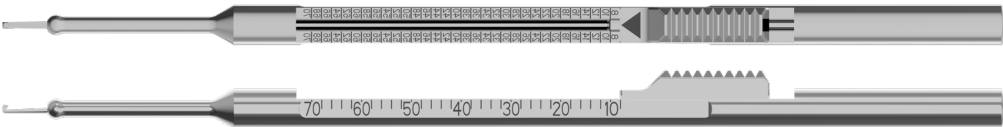
(Optional) Plate Holder



58I65-I50

Description	Article Numer
Temporary Plate Holder, for PROlock Screws	58I65-I50

Depth Gauge



59026

Description	Article Number
Depth Gauge, PROlock II	59026

Drill



6I203-I00

Description	Article Number
Spiral Drill, D=2.0mm, L=100mm, AO-Connector	6I203-I00

(Optional)



6I183-I00



6I243-I00

Description	Article Number
Spiral Drill, D=1.8mm, L=100mm, AO-Connector	6I183-I00
Spiral Drill, D=2.4mm, L=100mm, AO-Connector	6I243-I00

Drill Guide



622I5

Description	Article Number
Drill Guide, D=2.0/2.4mm	622I5

Screwdriver



56095-70



Description	Article Number
Screwdriver, Torque, T9x70	56095-70

AO-Silicone Handle



53016

Description	Article Number
AO Silicone Handle	53016

Torque-Shank



54095-I00



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

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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