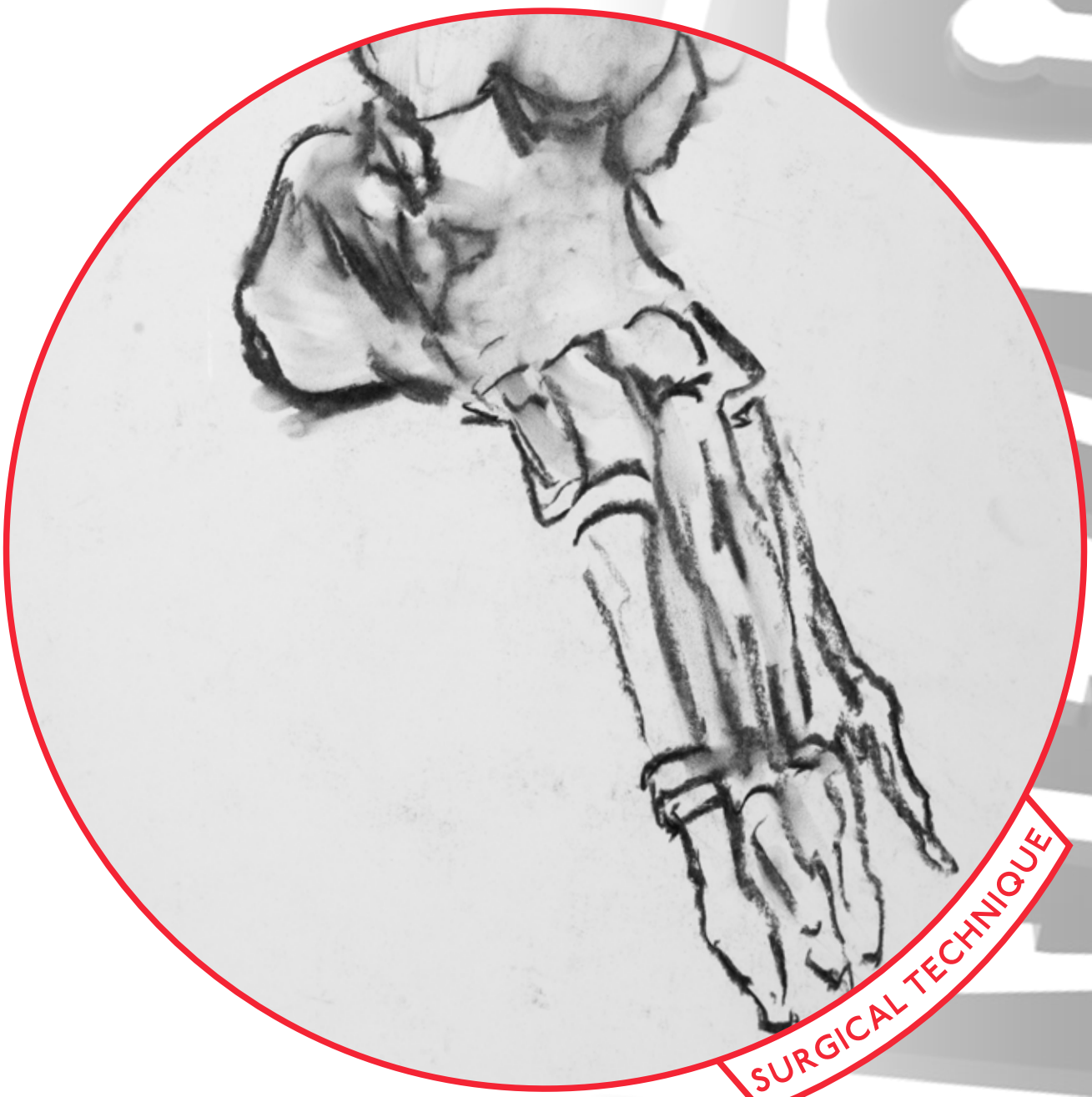
ITS.

Implants for Trauma Surgery



SURGICAL TECHNIQUE

Hallux Osteotomy Locking Plate

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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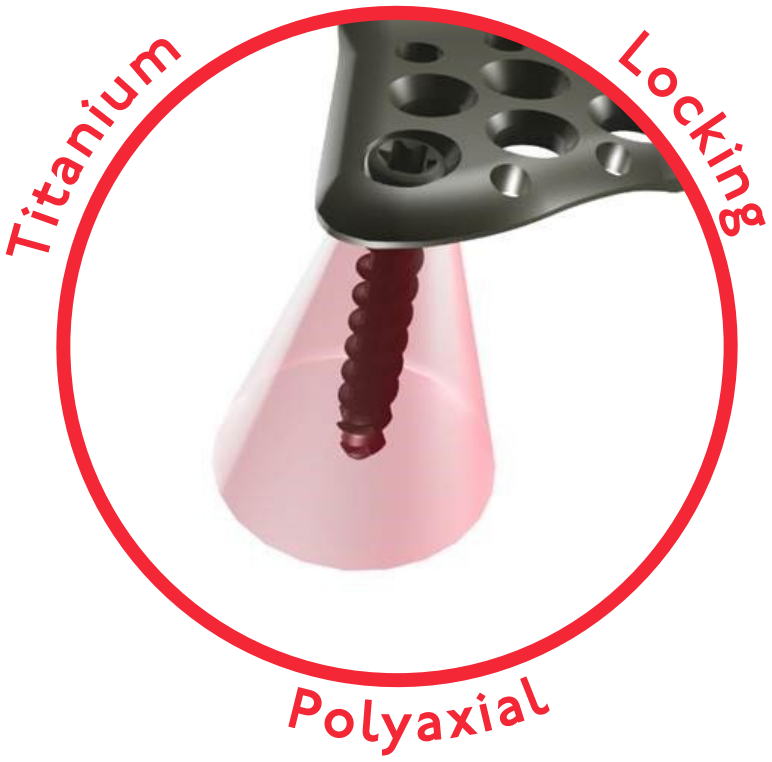
Introduction

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.



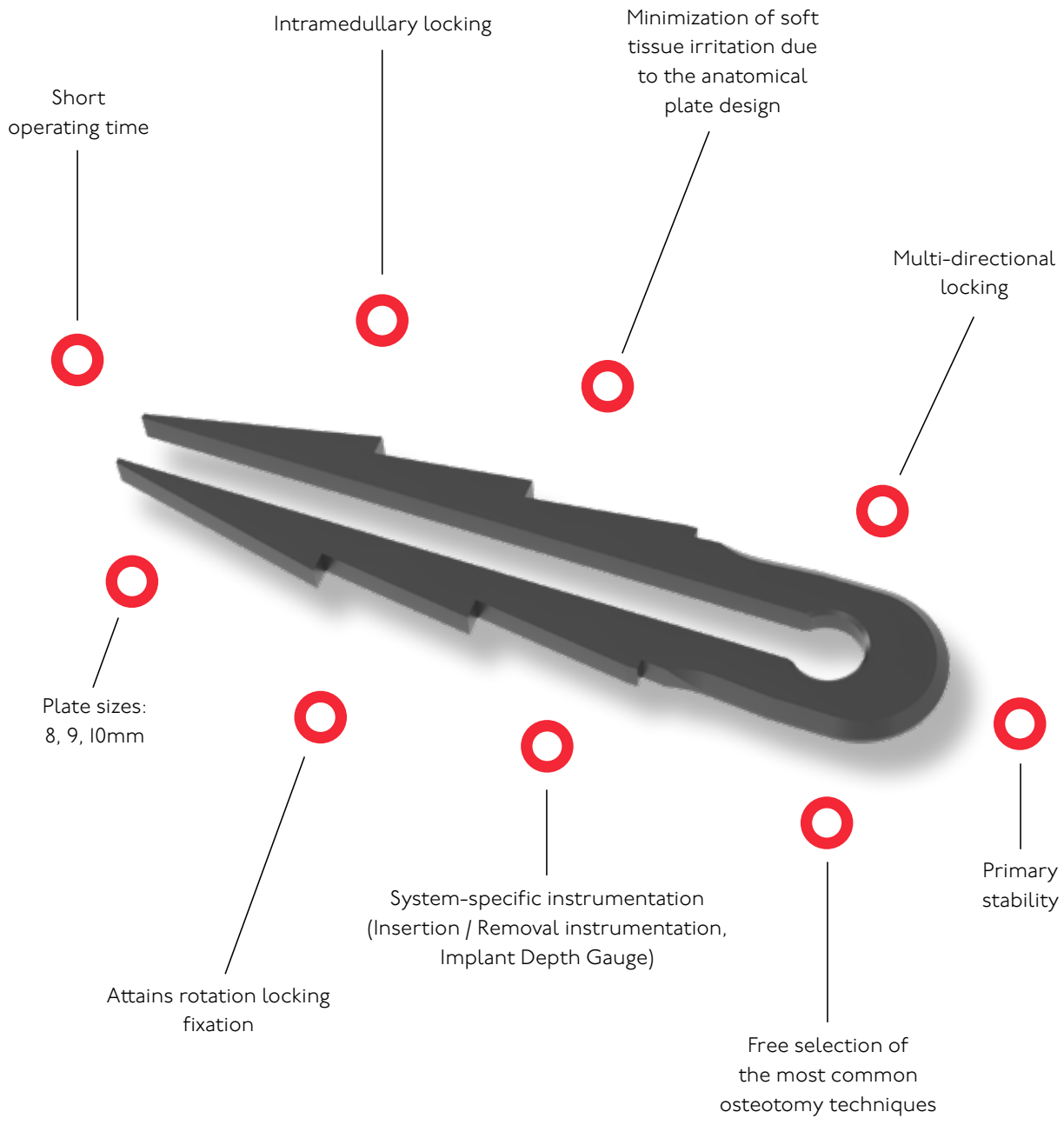
When a locking screw is inserted, it forms threads into the plate. There is no cutting and thus no debris created. Each locking screw can be locked at a free placement within a cone of angulation up to ± 15°, and can be re-positioned up to three times.

System Overview

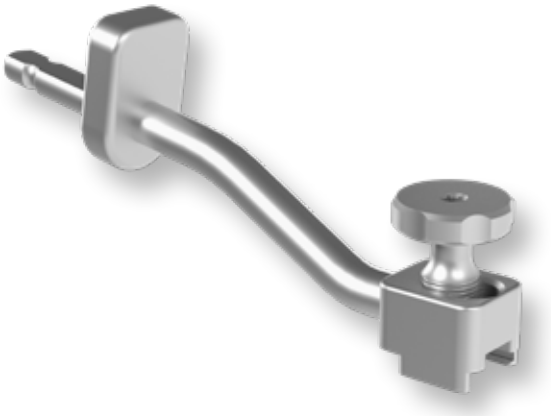
The Hallux Osteotomy Locking Plate from ITS. is an intramedullary self-locking plate designed for distal metatarsal osteotomies. As the screw is inserted, the two flanks are splayed out, providing the implant with a secure intramedullary hold.

This implant stands out for its versatility, allowing the selection of your preferred osteotomy technique. It features a straightforward and efficient surgical procedure, ensuring rotational alignment to be held, and support early weight-bearing.

Properties


Short operating time
Intramedullary locking
Minimization of soft tissue irritation due to the anatomical plate design
Multi-directional locking
Plate sizes: 8, 9, 10mm
Attains rotation locking fixation
System-specific instrumentation (Insertion / Removal instrumentation, Implant Depth Gauge)
Free selection of the most common osteotomy techniques
Primary stability

Instruments



Insertion / Removal Instrumentation

- AO Connector
- Plateau for simple insertion & removal
- Ability to insert the screw through the insertion instrumentation

Implant Depth Gauge

- 3-star implant depth and width gauge to measure the correct plate size

Screw

37303-XX **LOCKING**
Cancellous Stabilization Screw, D=3.0mm
Spiral Drill, D=1.8mm
Torque T9

Indications

- Intramedullary self-locking plate for distal metatarsal osteotomies
- For Hallux Valgus up to a corrective angle of 25°

Contraindications

- Existing bone or soft tissue infections at the surgical site
- Common situations that do not allow osteosynthesis
- With advanced osteoporosis
- Skin and soft-tissue problems which prevent a tension-free closure of the skin
- Obesity
- Lack of patient compliance

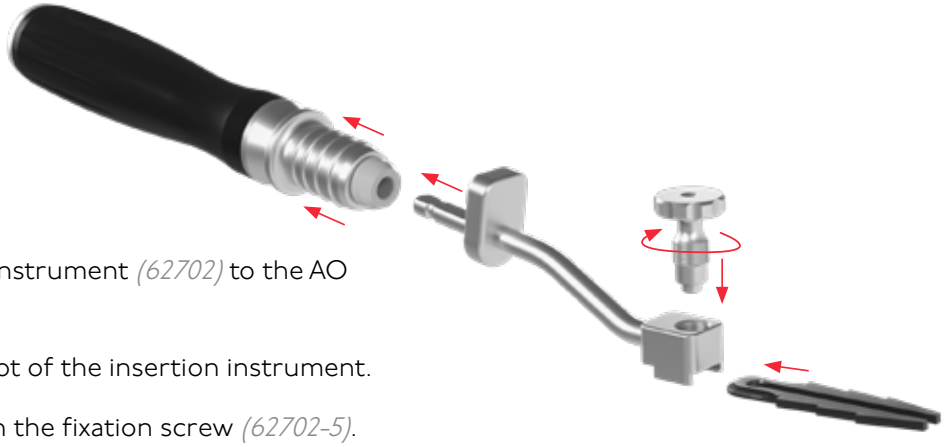
Intended purpose

The Hallux Valgus plate system – P29 is used for distal metatarsal osteotomies.

Surgical Technique

2.

Assembly Insertion Instrument



- First, attach the insertion instrument *(62702)* to the AO handle *(53013)*.
- Insert the plate into the slot of the insertion instrument.
- Then secure the plate with the fixation screw *(62702-5)*.

Pre-operative Patient Preparation

- Position the patient supine on a radiolucent table
- Leg freely mobile

Access

Medial Access:

- Access is on the medial side of the first metatarsal bone subcapitally (osteotomy height) to distal of the base of the joint of the first metatarsal bone.
- Horizontal capsular incision and removal of the thickened capsular lobe from the extosis (potential fusiform capsular resection).
- Dependent on the hospital, execution of a lateral capsulotomy and tenetomy.

Osteotomy

- The plate bed is prepared by resecting the medial pseudoexostosis with a fine oscillating saw up to a maximum of the diaphyseal level to create a flat surface for the plate head.
- Selection of the appropriate osteotomy technique according to preoperative planning (e.g., Chevron, Austin, or Hohmann osteotomy).
- Performance of the subcapital osteotomy with careful consideration of the soft tissue structures, using a low-heat and atraumatic sawing technique whenever possible to prevent thermal bone necrosis and soft tissue damage.

ATTENTION: In order to guarantee the greatest possible stability, the implant must rest flat on the small head of the first metatarsal bone.

Identification of the Plate size

- The size of the hallux osteotomy plate is determined using the implant gauge *(59028)*.

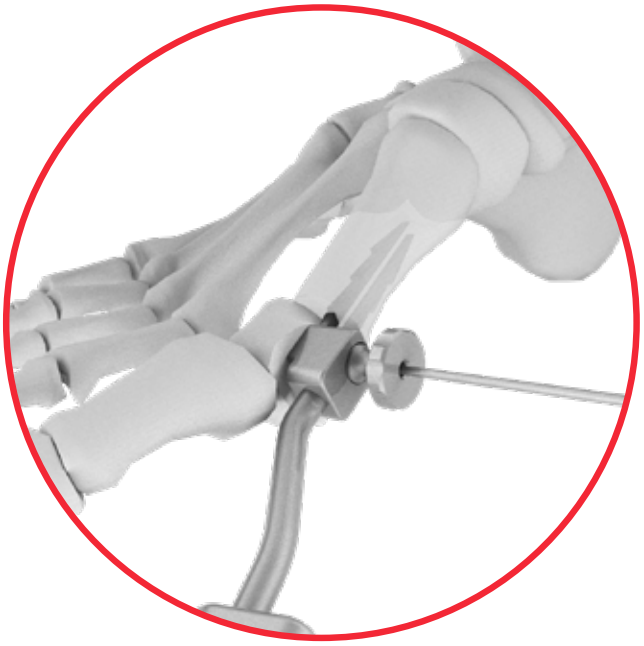
IMPORTANT: The measuring gauge has three differently sized ends, each corresponding to the available plate sizes (8, 9 & 10mm).

- In order to determine the appropriate size, the ends are inserted intramedullary into the first metatarsal sequentially, starting with the smallest size. The goal is to achieve the best possible fit so that the proper gauge end has no play within the bone canal.

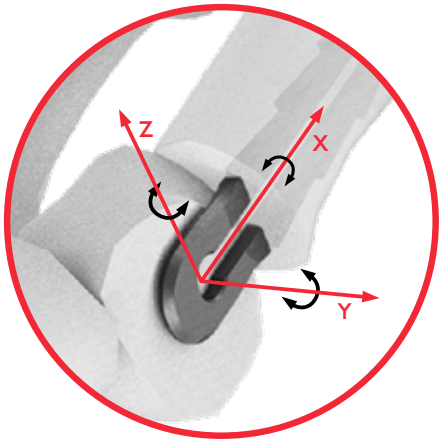
Plate Insertion / Temporary Fixation / Drilling

- In accordance with the measured size, the plate is inserted freely or with the aid of the insertion instrumentation *(62702 / 62702-5)* in an intramedullary position.

TIP: If necessary, insertion can be gently assisted by light hammer taps on the plateau.



- Additionally, the Hallux Osteotomy Plate can be temporarily fixed with a guide wire, D=1.2mm, L=100mm, TR, w. thrd. *(35124-100)*.
- Subsequent control of plate and screw position under fluoroscopy.



- The location of the small head of the shaft can be adjusted where necessary with the insertion axis and angle.

- Drilling is performed with the spiral drill, D=1.8mm, L=100mm, AO Connector *(611183-100)* through the eye of the plate head at a right angle where possible (+/- 15° Locking).

IMPORTANT: Heed the correct position and bone contact of the small head of the first metatarsal bone.

- When using the insertion instrumentation *(62702)*, drilling is performed through the fixation screw *(62702-5)*.

ATTENTION: To avoid disruption of soft tissue, nerves and/or blood vessels use an oscillating drill.

Identification of the Screw length

- When measuring with the depth gauge *(59027)* through the fixation screw at the insertion / removal instrumentation, read off the required screw length on the rear edge of the sliding handle.

- When measuring directly on the plate, read off the required screw length on the front edge of the sliding handle.

Screw Placement

- In accordance with the measured length, a cancellous stabilization screw, D=3.0mm, RH *(37303-XX)* is now inserted with the Torque-Shank, T9xl00 *(54095-l00)*.
- The screw can be inserted by the insertion instrumentation *(62702)* or freely after removal of the fixation screw.

ATTENTION: When inserting the screw ensure that the screw head is flush with the plate.

- Subsequent control of plate and screw position under fluoroscopy.

Wound Closure

- Suture the capsule with absorbable sutures
- Drainage is usually not necessary
- Suture the skin
- Apply the redression bandage

Postoperative Treatment

- Elevation and preventative edema measures on the day of the operation
- Mobilization with forefoot relief shoe
- Free weightbearing according to symptoms and stipulations of the operating surgeon

Explantation

Removal is possible, if desired by the patient. This is facilitated by the fact that cold welding never occurs.

Implant removal is performed after radiographic verification of the healed bone, vice versa of implantation.

- Skin incision following the old scar
- Remove the screw with the Torque-Shank, T9x100 *(54095-100)*
- Remove the plate simply by pulling (e.g. with a bone hook) or with the removal instrumentation
- Optional (removal):
  - With light hammer taps on the plateau
  - Take a Kocher, compress the plate to loosen the flanks, and then pull distally to expand

The ITS. Type II anodization surface treatment reduces the risk of cold welding of titanium implants (for more information, see page 23).

Case Study

Case I:

Pre-, intra- and postoperative x-rays of a Hallux Valgus Osteotomy

PRE-OP

INTRA-OP

POST-OP

Case 2:

Pre-, intra- and postoperative x-rays of a Hallux Valgus Osteotomy

PRE-OP

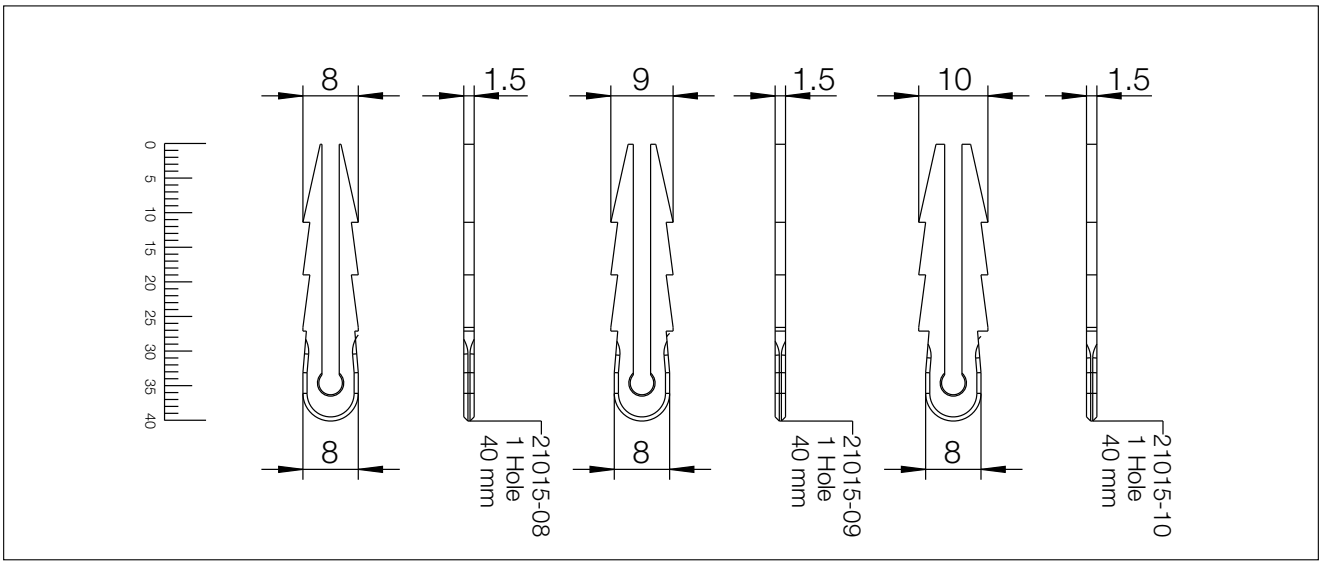
INTRA-OP

POST-OP

Information

3.

Technical Information



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

Not true to scale

Type II Anodization

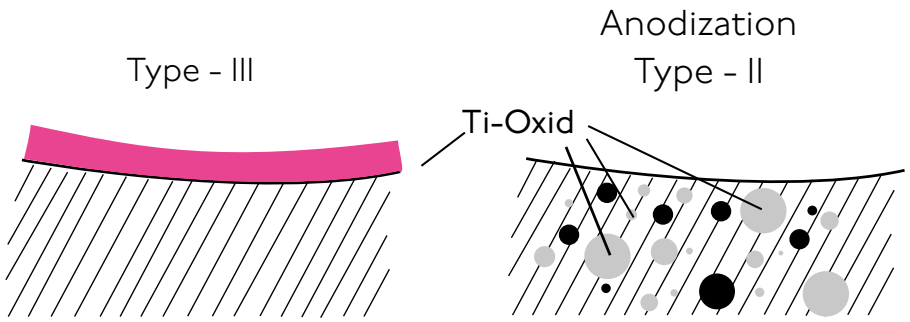
Chemical process - anodization in a strong alkaline solution*

Type III anodization

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

Type II anodization

- Layer thickness 1000-2000nm
  - \+ 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

Hallux Osteotomy Plate

21015-08 21015-09 21015-10

Description	Size	Article Number
Hallux Osteotomy Plate	8mm	21015-08
Hallux Osteotomy Plate	9mm	21015-09
Hallux Osteotomy Plate	10mm	21015-10

Screw

Cancellous 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

Instruments

Guide Wire

35124-100

Description	Article Number
Guide Wire, Steel, D=1.2mm, L=100mm, TR, w. Thrd.	35124-100

Spiral Drill

61183-100

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

Depth Gauge

59027

Description	Article Number
Depth Gauge, Hallux Osteotomy Plate	59027

AO Silicone Handle

53013

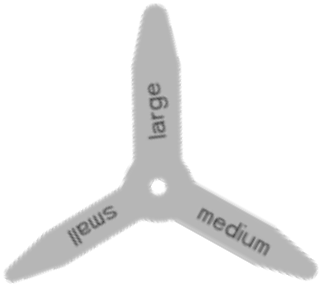
Description	Article Number
AO Silicone Handle	53013

Torque-Shank

54095-100 T9

Description	Article Number
Torque-Shank, T9x100, AO Connector	54095-100

Implant Depth Gauge



59028

Description	Article Number
Implant Depth Gauge, Hallux Osteotomy Plate	59028

Insertion / Removal Instrumentation & Fixation Screw

62702

62702-5

Description	Article Number
Insertion / Removal Instrumentation, Hallux Osteotomy Plate	62702
Fixation Screw, Hallux Osteotomy Plate	62702-5

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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