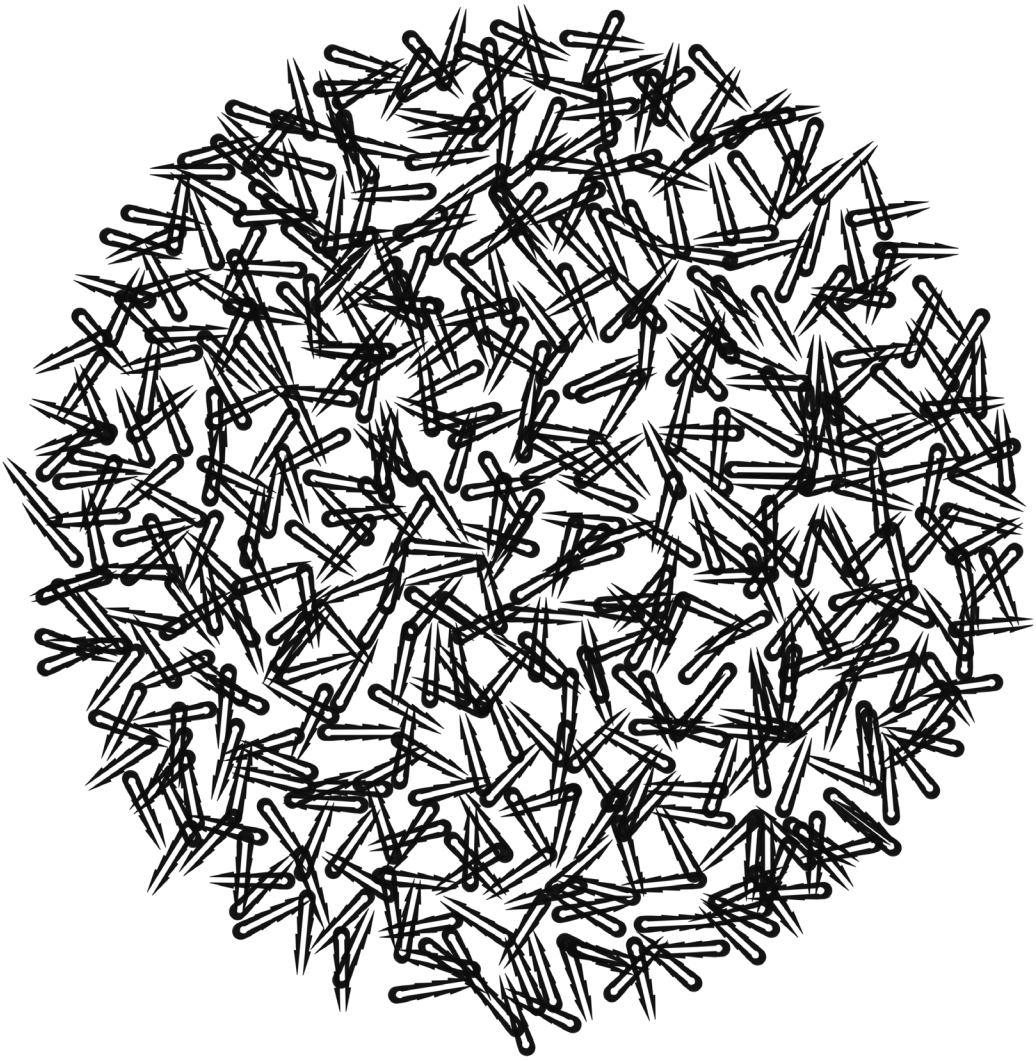
ITS.

Implants
trauma



HOL

Hallux Osteotomy Locking Plate

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

WARNING: If there is no sufficient bone healing, wrong or incomplete postoperative care, plate might break.

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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2. Surgical Technique

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Introduction

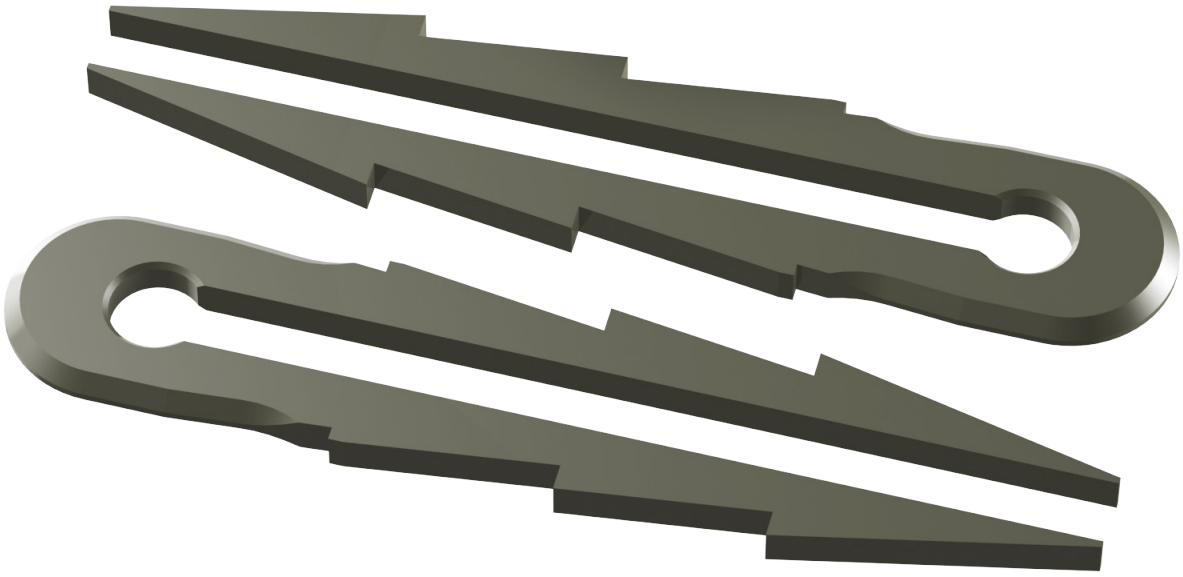
1.

Preface

The Hallux Osteotomy Locking Plate from ITS. is an intramedullary self-locking plate for distal metatarsal osteotomies.

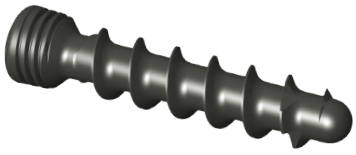
When the screw is inserted the 2 flanks are splayed out, and the implant acquires a firm intramedullary hold.

The special feature of this implant is the ability to choose your preferred osteotomy technique, the simple and brief surgical procedure, the stable implant position and weightbearing.



Screw

37303-XX	Cancellous Stabilization Screw, D=3.0mm, RH
61183-100	Spiral Drill, D=1.8mm, L=100mm, AO Connector
54095-100	Torque-Shank, T9x100



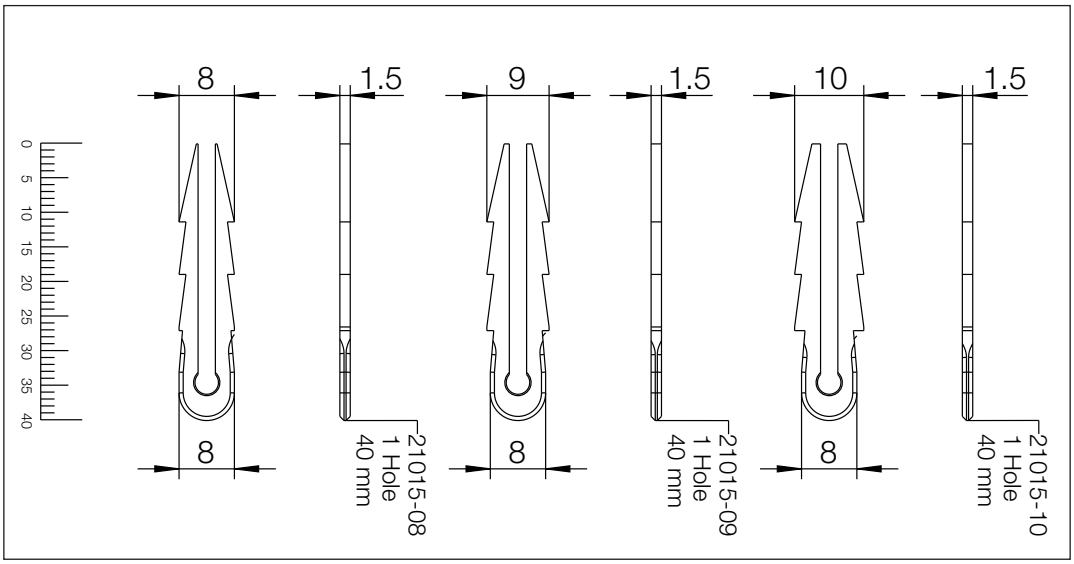
Properties

Properties of the material:

- Plate material: Titanium
- Material of screws: TiAl6V4 ELI
- Easier removal of the implant after the fracture has healed
- Improved fatigue strength of the implant
- Reduced risk of cold welding
- Reduced risk of inflammation and allergy

Properties of the implant:

- Multi-directional locking
- Intramedullary locking
- Minimization of soft tissue irritation due to the anatomical plate design
- Free selection of the most common osteotomy techniques
- Primary stability
- Simple surgical procedure
- Brief operation time
- 3 different plate sizes: 8, 9, 10mm



Intruments

AO Handle:

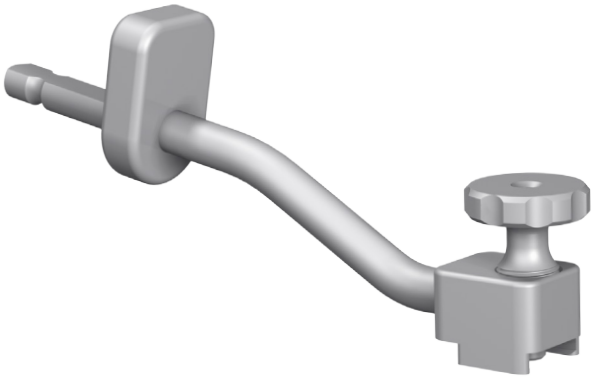
- AO Connector
- Cannulated

Depth Gauge:

- One-hand design
- Ability to measure through the insertion / removal instrumentation

Insertion / removal instrumentation:

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



Implant Depth Gauge:

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

Indications, Contraindications

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

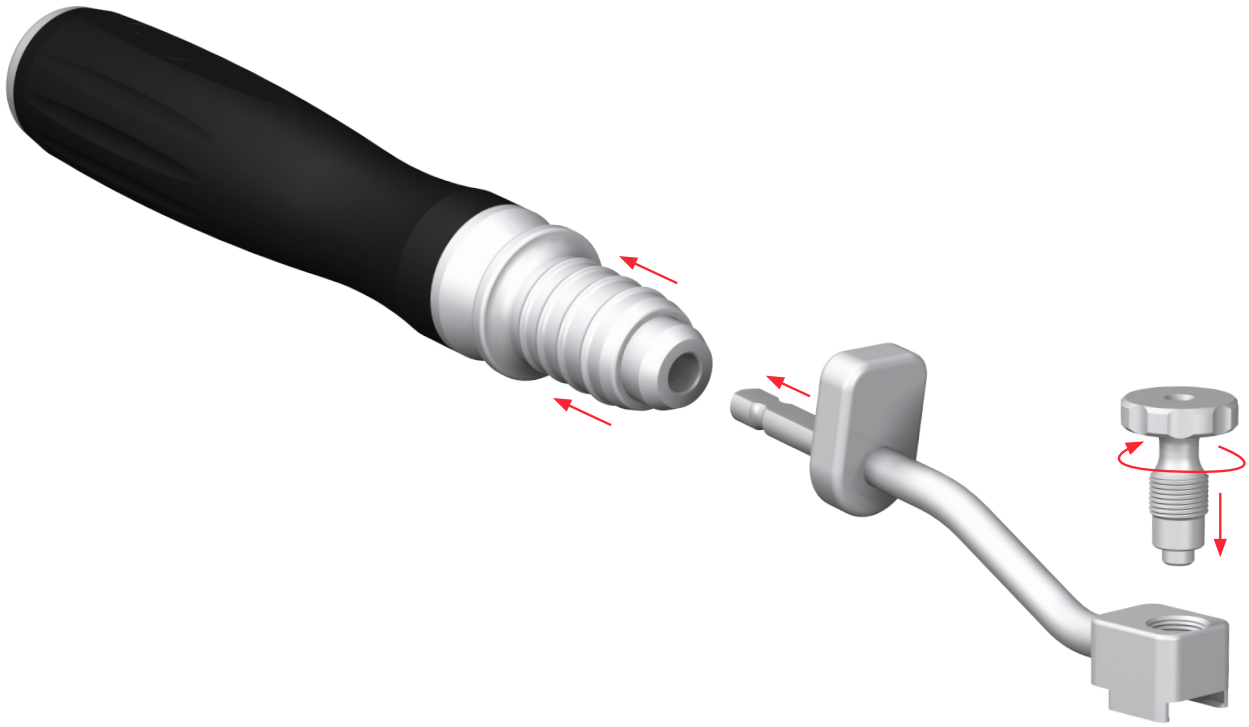
Surgical Technique

2.

Pre-operative patient preparation

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

Assembly of the insertion / removal instrumentation



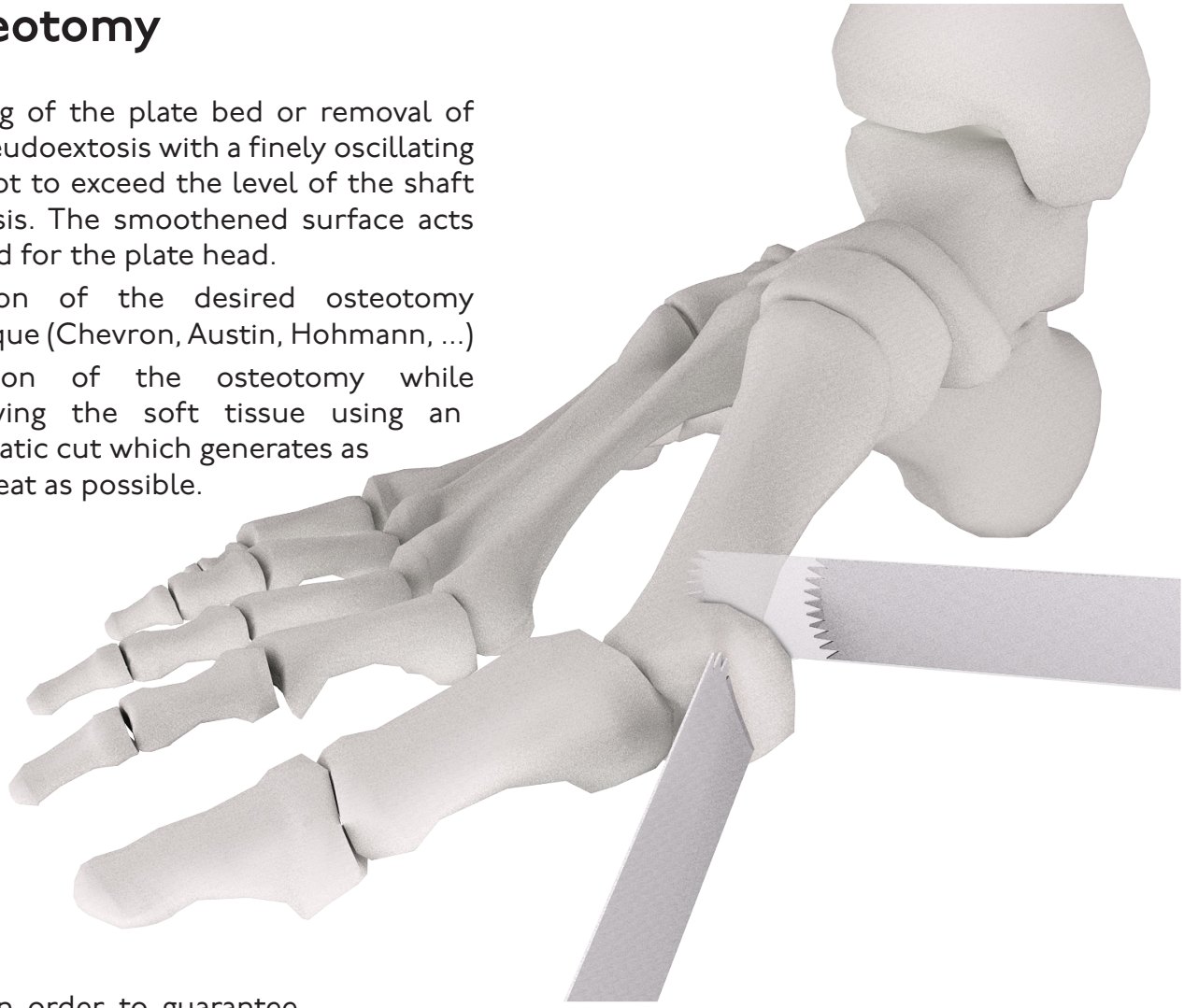
Access

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.
- Dependent on the hospital, execution of a lateral capsulotomy and tenetomy.
- Horizontal capsular incision and removal of the thickened capsular lobe from the extosis (potential fusiform capsular resection).

Osteotomy

- Leveling of the plate bed or removal of the pseudoextosis with a finely oscillating saw. Not to exceed the level of the shaft diaphysis. The smoothened surface acts as a bed for the plate head.
- Selection of the desired osteotomy technique (Chevron, Austin, Hohmann, ...)
- Execution of the osteotomy while preserving the soft tissue using an atraumatic cut which generates as little heat as possible.



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

Determination of plate size

- The size of the plate is determined with the assistance of the implant depth gauge **(59028)**.
- The implant depth gauge has 3 ends of different sizes which correspond to the 3 sizes of the Hallux Osteotomy Plate
- Beginning with smallest, the 3 ends are inserted intramedullary

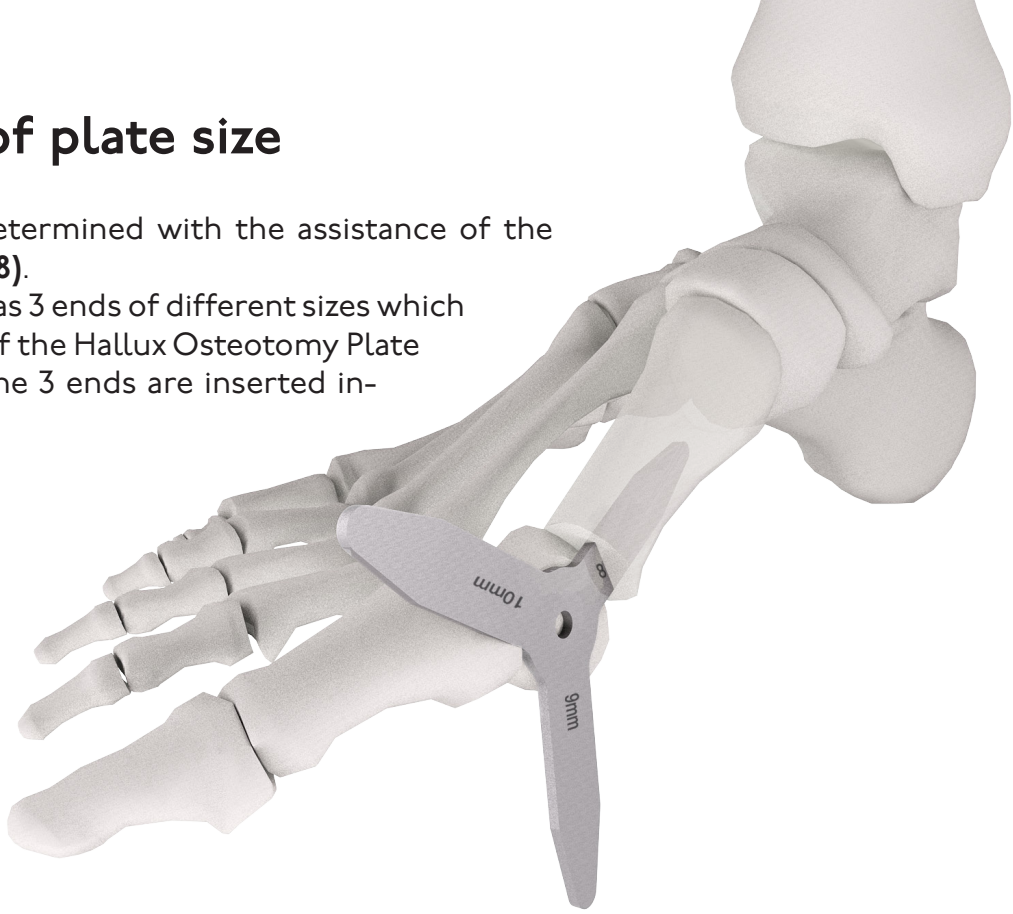
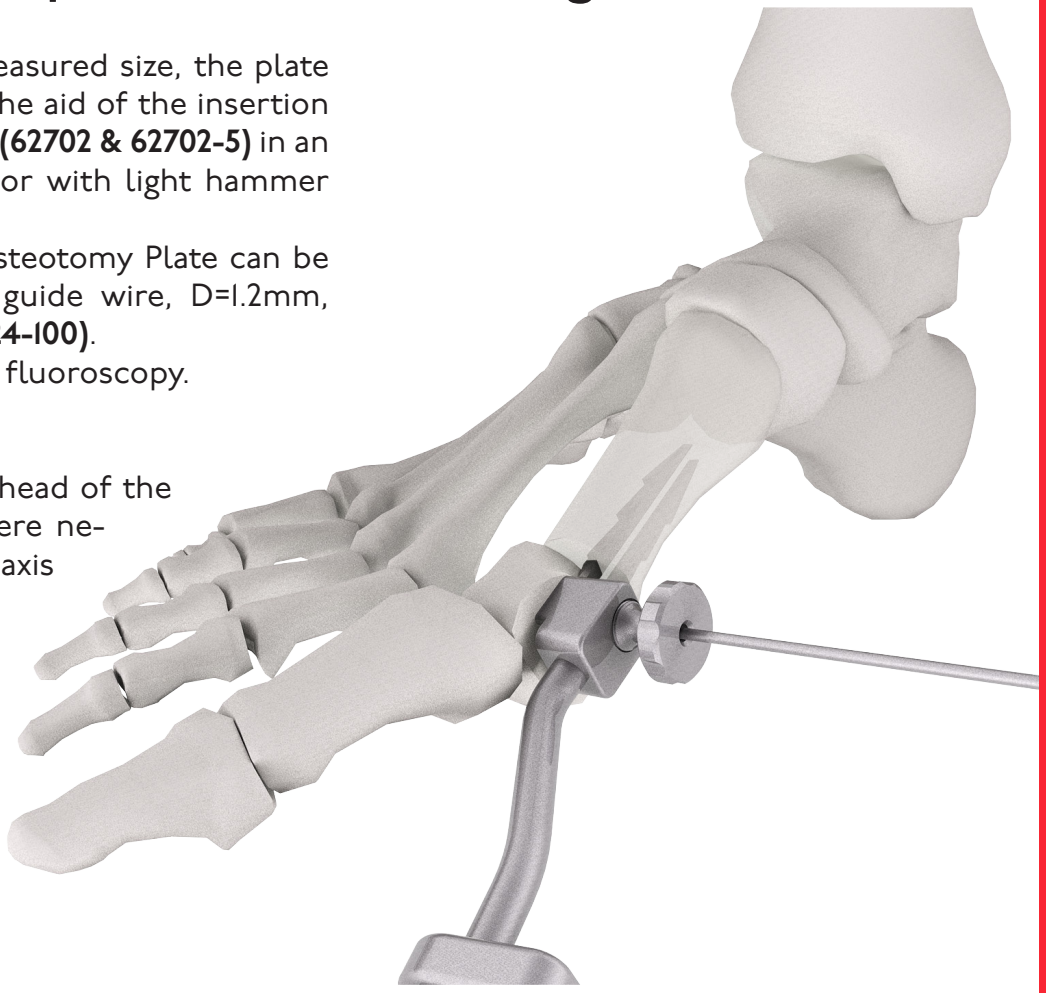
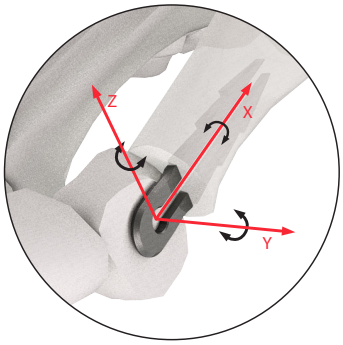


Plate insertion / optional fixation with guide wire

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

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

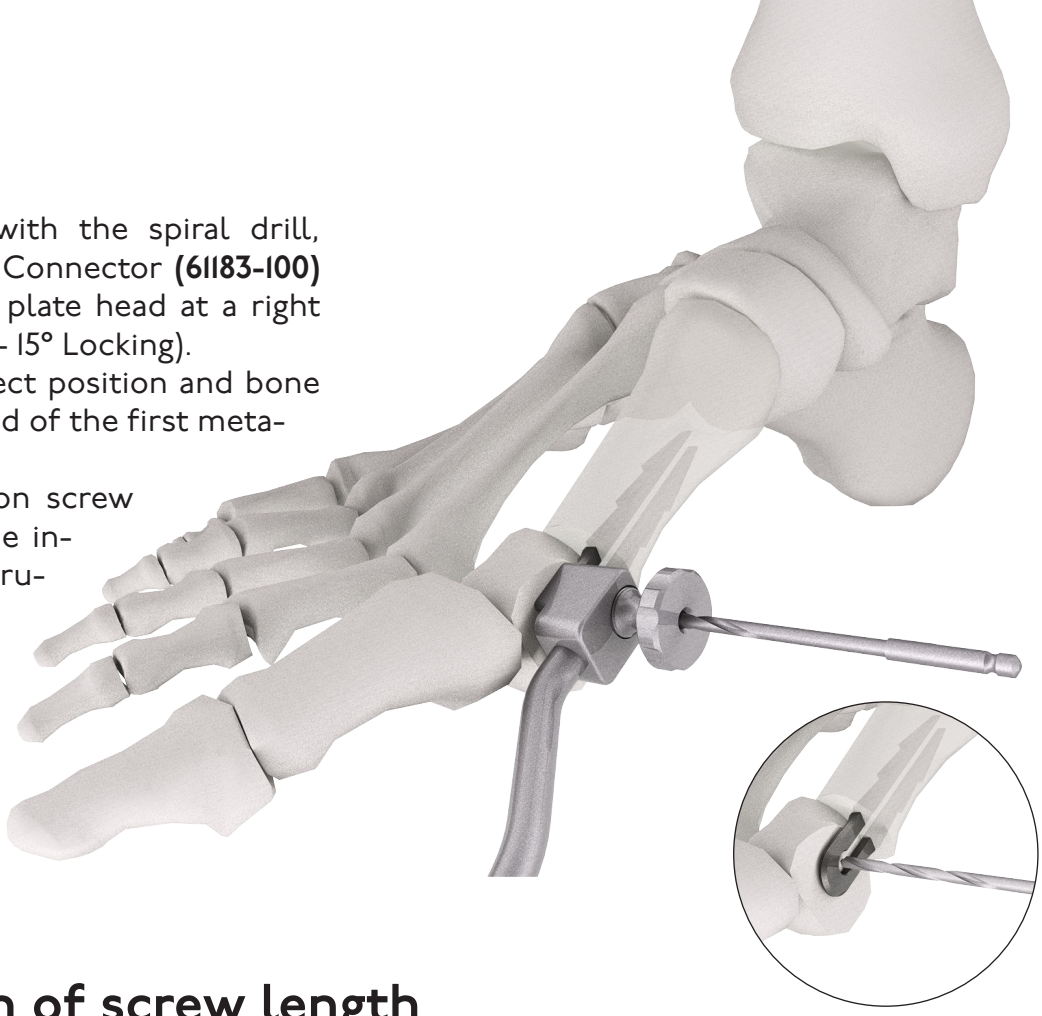




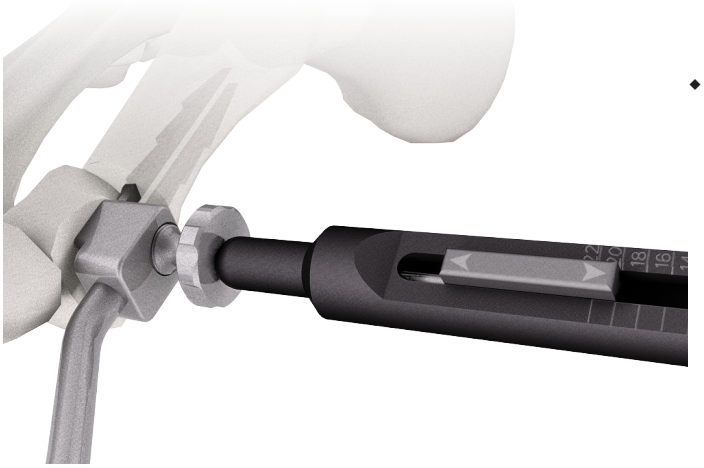
Drilling

Drilling is performed with the spiral drill, D=1.8mm, L=100mm, AO Connector **(61183-100)** through the eye of the plate head at a right angle where possible (+/- 15° Locking).
Caution: Heed the correct position and bone contact of the small head of the first metatarsal bone.
Drill through the fixation screw **(62702-5)** when using the insertion / removal instrumentation **(62702)**.

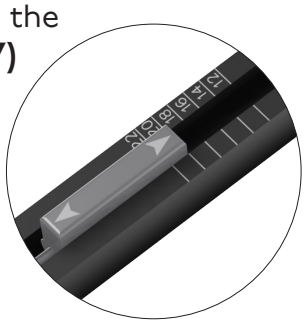
Caution: To avoid disruption of soft tissue, nerves and/or blood vessels use an oscillating drill.



Identification of screw length



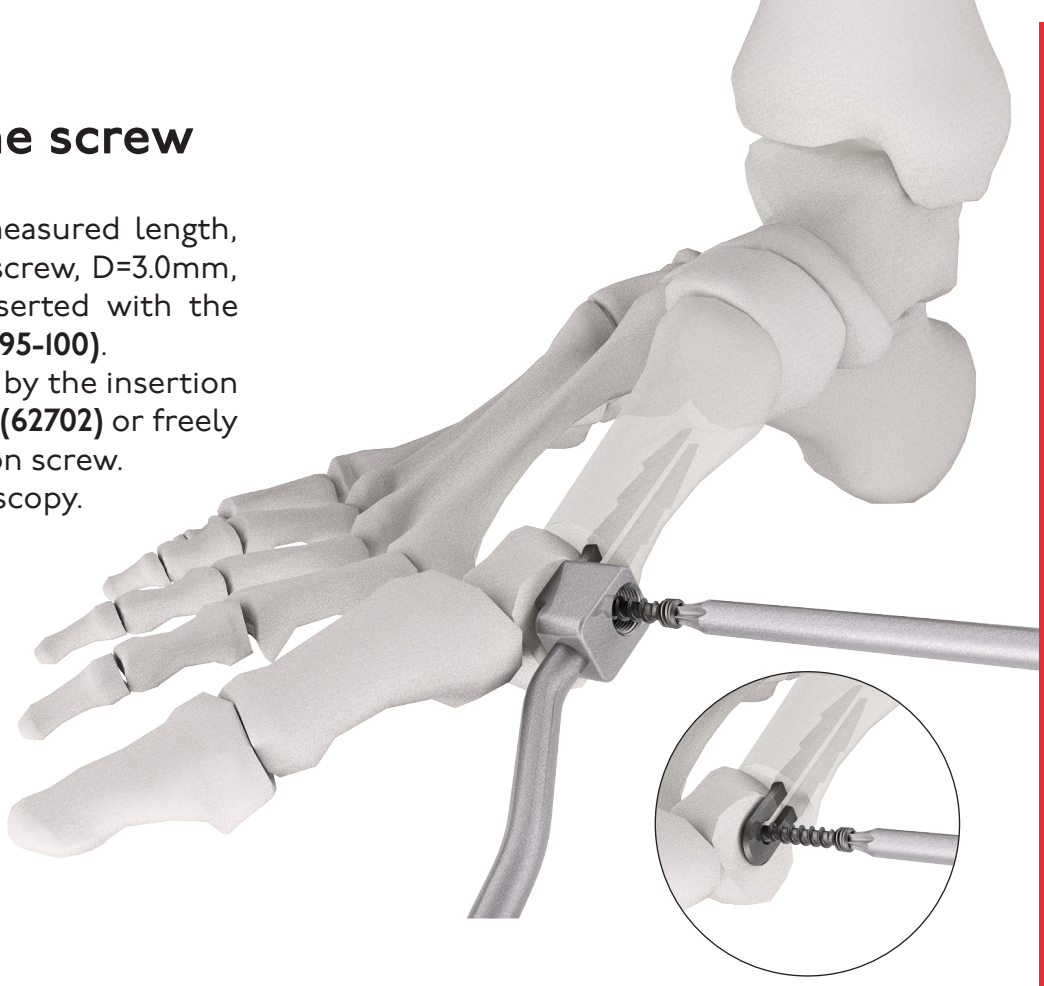
- When measuring with the depth gauge **(59027)** through the fixation screw at the insertion / removal instrumentation, read off the required screw length on the **rear** edge of the sliding handle.



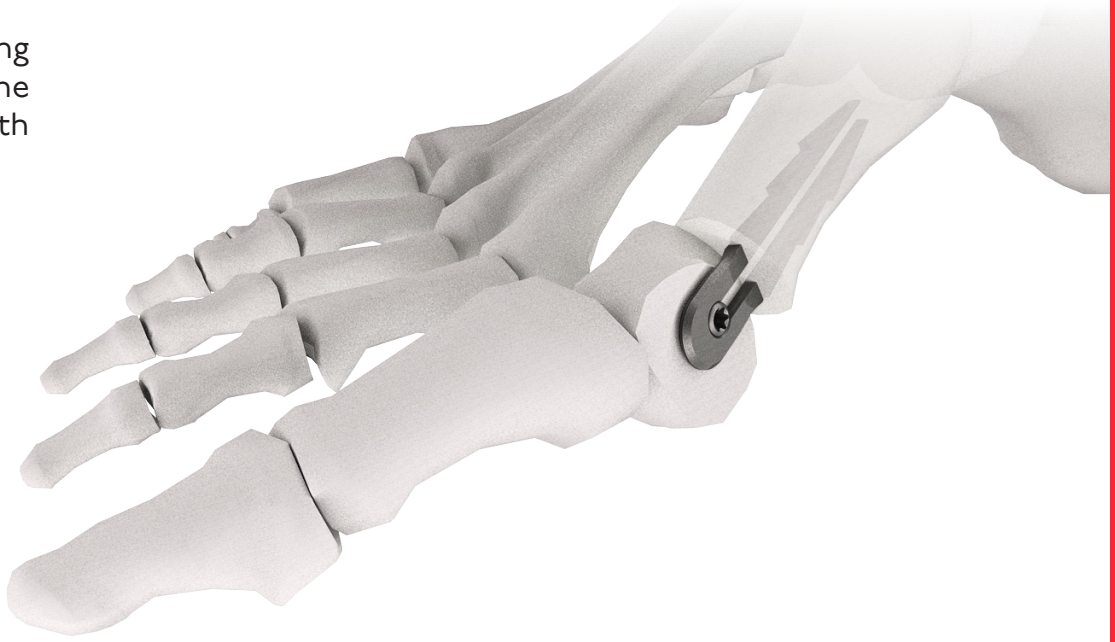
- When measuring directly on the plate, read off the required screw length on the **front** edge of the sliding handle.

Placement of the screw

- In accordance with the measured length, a cancellous stabilization screw, D=3.0mm, RH **(37303-XX)** is now inserted with the Torque-Shank, T9x100 **(54095-100)**.
- The screw can be inserted by the insertion / removal instrumentation **(62702)** or freely after removal of the fixation screw.
- Final control under fluoroscopy.



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



Wound closure

- Suture the capsule with absorbable sutures
- Drainage is usually not necessary
- Suture the skin
- Apply the appropriate dressing

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 hook) or with the insertion / removal instrumentation - optional light hammer blows on the plateau
- The problem of cold welding was resolved by using a special surface treatment (for further information see page 17)

Case study

Case 1:

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

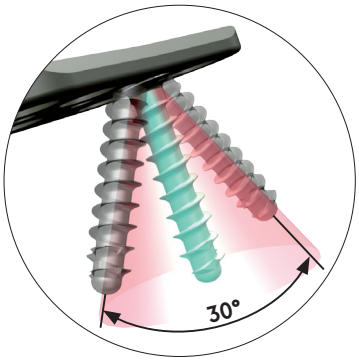
Information

3.

Locking

Locking works because:

- Screw material (TiAlV) is slightly harder than plate material (Titanium Grade 2)
- Screw head **forms** thread into the plate (no cutting)



Benefits:

- ± 15° and Locking
- No pre threading
- No cold welding
- No debris
- You can re-set the screw up to 3 times

Dotize®

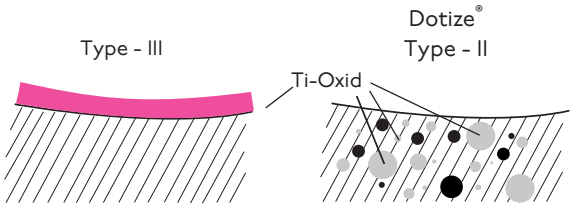
Chemical process - anodization in a strong alkaline solution*

Type III anodization

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

Dotize Type II anodization

- Layer thickness 2000-10 000nm
  - \+ Film becomes an interstitial part of the titanium
  - \- No visible cosmetic effect



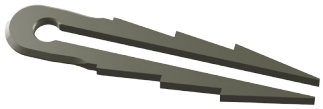
Anodization Type II leads to following benefits*

- 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

Order list

Hallux Osteotomy Plate, 8mm	21015-0
Hallux Osteotomy Plate, 9mm	21015-09
Hallux Osteotomy Plate, 10mm	21015-10



Cancellous Stabilization Screw, D=3.0mm, L=10mm, RH	37303-10
Cancellous Stabilization Screw, D=3.0mm, L=12mm, RH	37303-12
Cancellous Stabilization Screw, D=3.0mm, L=14mm, RH	37303-14
Cancellous Stabilization Screw, D=3.0mm, L=16mm, RH	37303-16
Cancellous Stabilization Screw, D=3.0mm, L=18mm, RH	37303-18
Cancellous Stabilization Screw, D=3.0mm, L=20mm, RH	37303-20
Cancellous Stabilization Screw, D=3.0mm, L=22mm, RH	37303-22
Cancellous Stabilization Screw, D=3.0mm, L=24mm, RH	37303-24

AO Handle	53013

Torque-Shank, T9x100	54095-100

Depth Gauge, Hallux Osteotomy Plate	59027

Implant Depth Gauge, Hallux Osteotomy Plate	59028

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

Insertion / Removal Instrumentation, Hallux Osteotomy Plate	62702

Fixation Screw, Hallux Osteotomy Plate	62702-5

Guide Wire, D=1.2mm, L=100mm	35124-100

Sterilization Tray, Hallux Osteotomy Plate	50233

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

Notes

I.T.S. USA
1778 Park Avenue N, Suite 200
Maitland, FL 32751

Tel.: 877 - 971 - 8054
Fax: 877 - 971 - 8056
info@its-implantusa.com
www.its-implantusa.com

CE 0297

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