







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

• 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.





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

• 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

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- 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=I.2mm, L=I00mm, 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=I.8mm, L=I00mm, 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.





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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, T9xI00 (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, T9xI00 (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 I7)

• Case study

Case I:

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



Information

• 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:

- ± I5° and Locking
- No pre threading
- No cold welding
- No debris
- You can re-set the screw up to 3 times



Chemical process - anodization in a strong alkaline solution*

Type III anodization

Dotize Type II anodization

Dotize®

Type - II

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

Layer thickness 2000-10 000nm

- + Film becomes an interstitial part of the titanium
- No visible cosmetic effect

Ti-Oxid

Anodization Type II leads to following benefits*

Type - III

- 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



• Order list

Hallux Osteotomy Plate, 8mm	21015-08	
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	ITS.
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.



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C € 0297

Order No. HOL-OP-0218-E Edition: February/2018

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