ITS.

Implants for Trauma Surgery

SURGICAL TECHNIQUE

CAlaneus
Locking Plates System

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.

Table of Contents

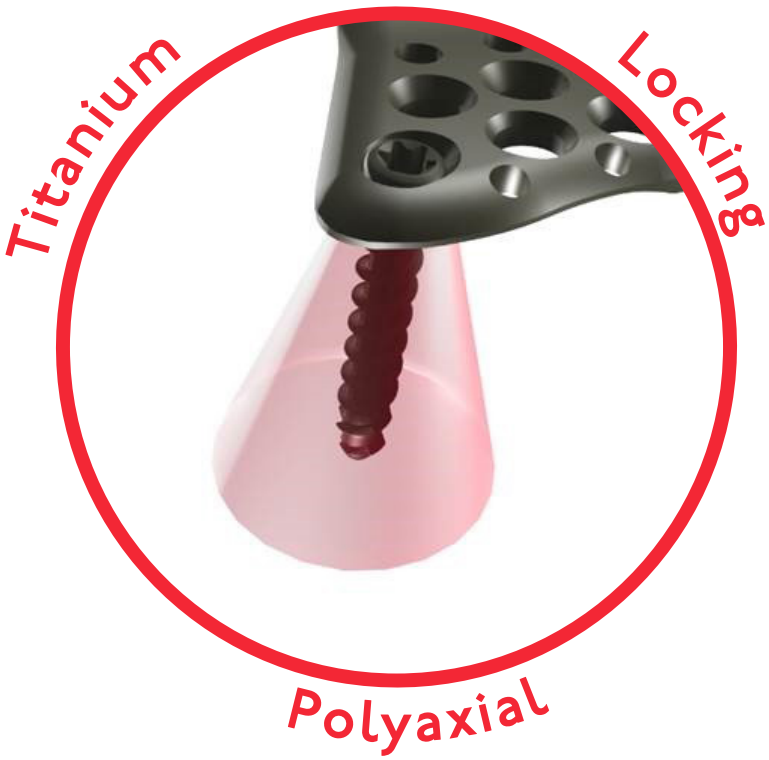
Introduction

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.

ONE 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 ± 15° and can be re-positioned up to three times.

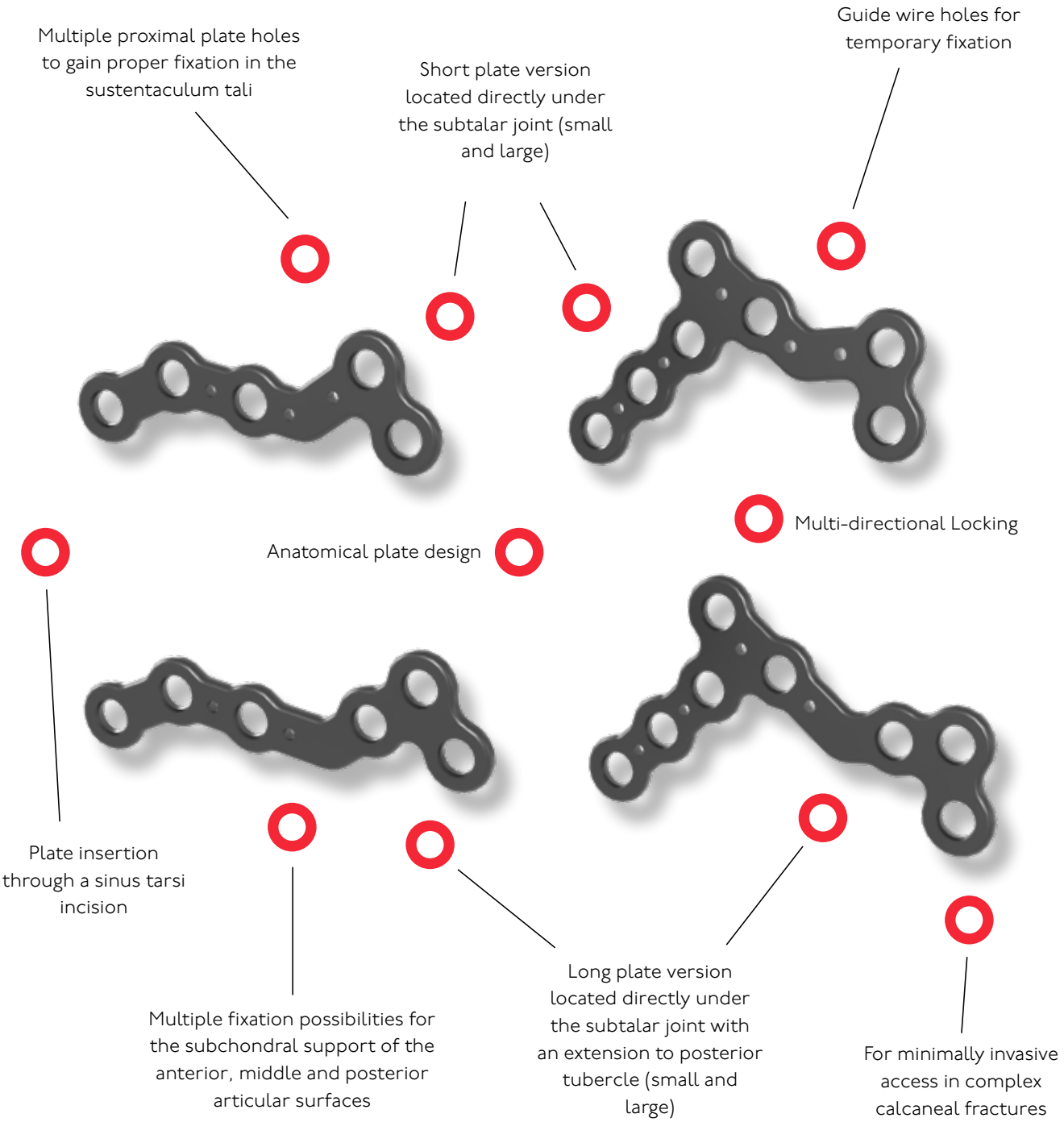
System Overview

The ITS. Anterolateral Calcaneus Locking Plate and the ITS. Calcaneus Locking Plate are proven osteosynthesis systems for treating a wide range of calcaneus fractures.

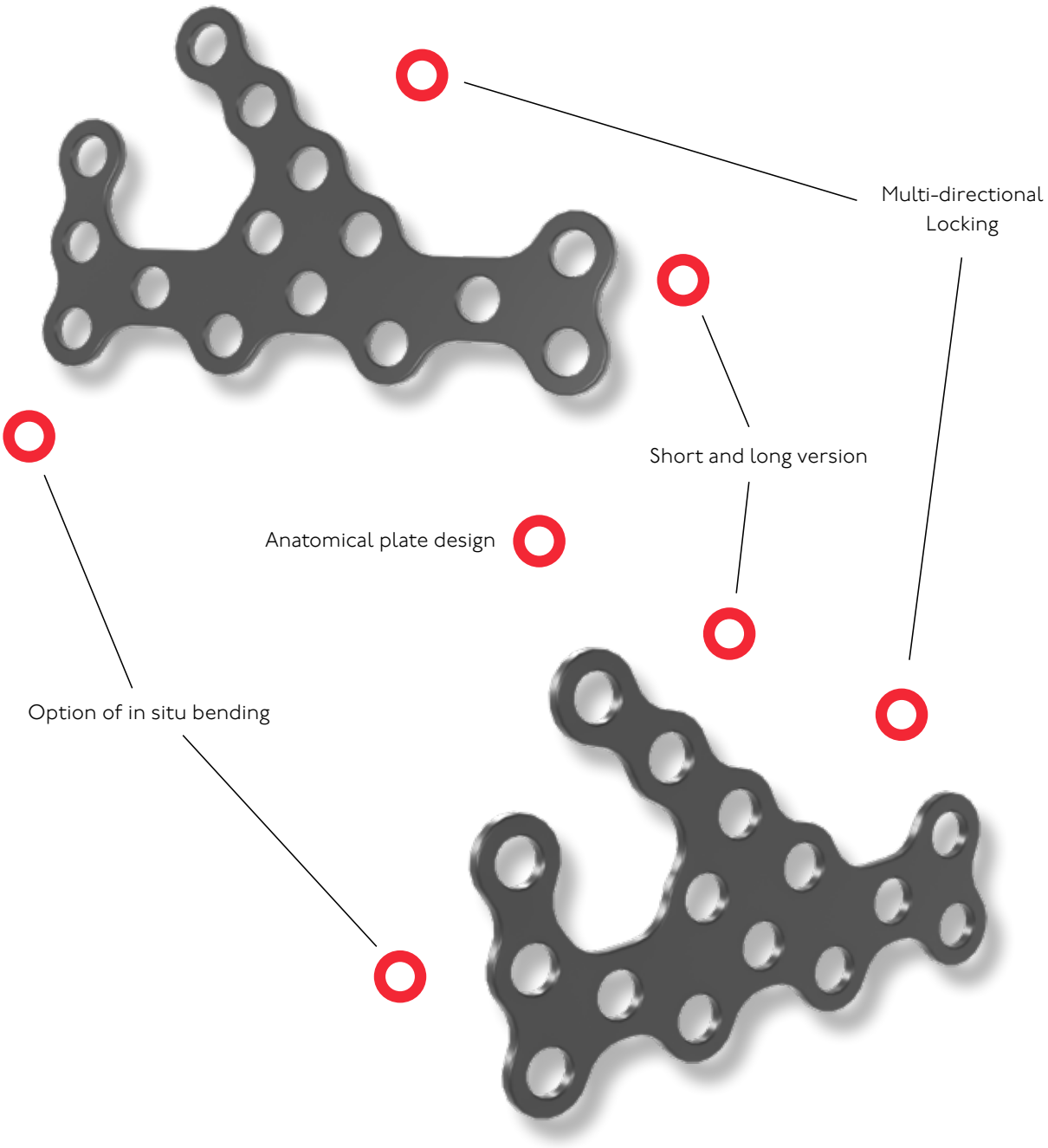
A special feature of both systems is the freely selectable hole configuration, which makes it possible to choose between locking and non-locking screws for each hole (except compression and oblong holes). With an angle selection of +/- 15°, they offer particular versatility, especially for complex fractures.

Properties

Anterolateral Clacaneus Plates

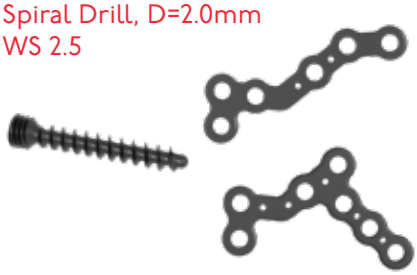


Calcaneus Plates



Screws

37352-xx-N **LOCKING**
Cancellous Screw, D=3.5mm
Spiral Drill, D=2.0mm
WS 2.5



32351-xx **NON-LOCKING**
Cortical Screw, D=3.5mm
Spiral Drill, D=2.7mm
WS 2.5

OPTIONAL

31404-xx Cancellous Screw, Cannulated, D=4.0mm
Spiral Drill, D=2.6mm
WS 2.5

37352-xx-N **LOCKING**
Cancellous Screw, D=3.5mm
Spiral Drill, D=2.0mm
WS 2.5

32351-xx **NON-LOCKING**
Cortical Screw, D=3.5mm
Spiral Drill, D=2.7mm
WS 2.5

OPTIONAL

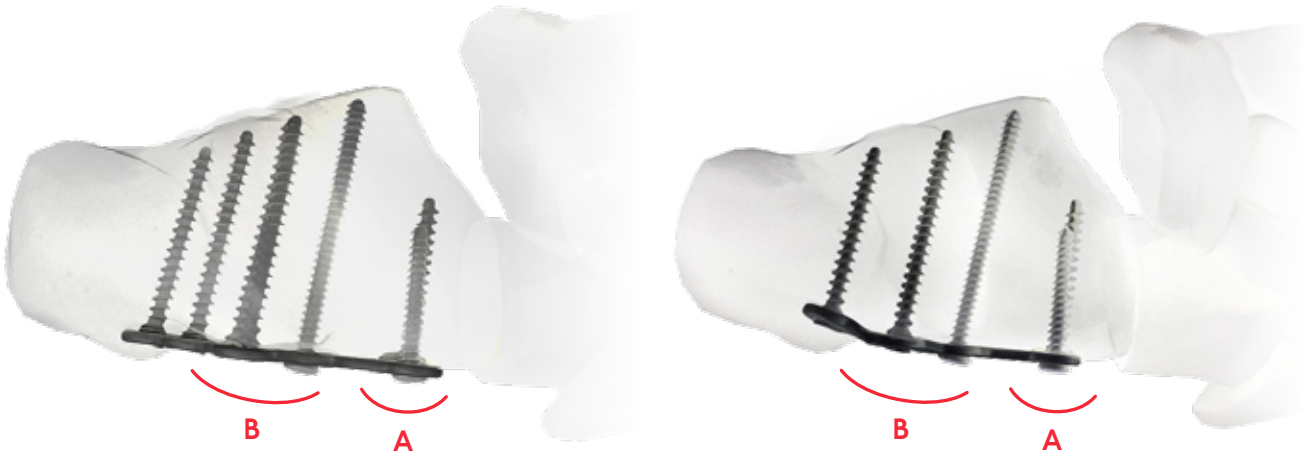
37422-xx-N **LOCKING**
Cancellous Screw, D=4.2mm
Spiral Drill, D=2.5mm
WS 2.5

Fixation Points

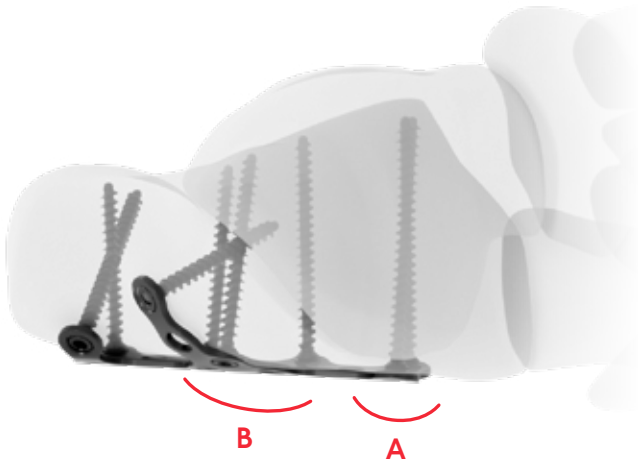
The plate design enables the use of multiple fixation points, optionally locking, especially to buttress the articular surface with subchondral screws.

At the process anterior the screws are inserted parallel to the calcaneocuboid joint **(A)**. Screws to buttress the posterior and middle facet **(B)** have to be inserted pre-angled anterior to achieve a proper fixation in the hard cortical bone of the sustentaculum tali.

Anterolateral Calcaneus Plate



Calcaneus Plate



Indications

Anterolateral Calcaneus Plate

- Complex calcaneal fractures
- Intra-articular fractures
- Comminuted fractures
- Fractures of the sustentaculum tali

Calcaneus Plate

- Complex fractures of the calcaneus
- All intra-articular fractures with relevant joint distortion and a comminution zone in which a semi-operative procedure (screws, drill wires) does not raise expectations of exact repositioning

Contraindications

- Existing infections in the fracture zone and operation area
- Common situations that do not allow osteosynthesis
- Obesity
- Lack of patient compliance

Time of Operation

- After regression of swelling

Surgical Technique

2.

Anterolateral Calcaneus Locking Plate

Pre-operative Patient Preparation

- Supine position or lateral position
- General anaesthesia, regional anaesthesia or a combination can be used
- Possible use of medication for blood arrest

Diagnosis

Standard X-ray of the calcaneus (AP, lateral view and Broden's view), axial and coronet CT with reconstructions.

Access

Lateral Access:

- Access by Ollier (Sinus tarsi access)
- Representation of the sinus tarsi, the posterior facet and where applicable the calcaneo-cuboid joint
- A 10 mm long stab incision is recommended to fill the plate holes on the tuber calcanei

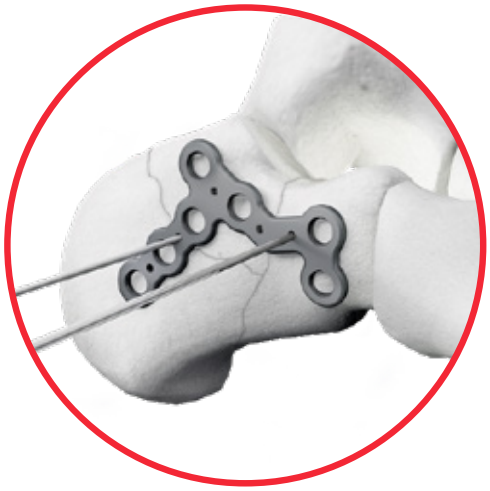
NOTE: Pay attention to the end of the sural nerve and the tendons of the peroneus longus and brevis during the incision.

Reduction

- Open reduction under view by mean of Schanz screw, Steinmann nails, guide wires or Fröhlich distractor
- Padding of comminuted zones with bone substitut

Temporary Plate Fixation

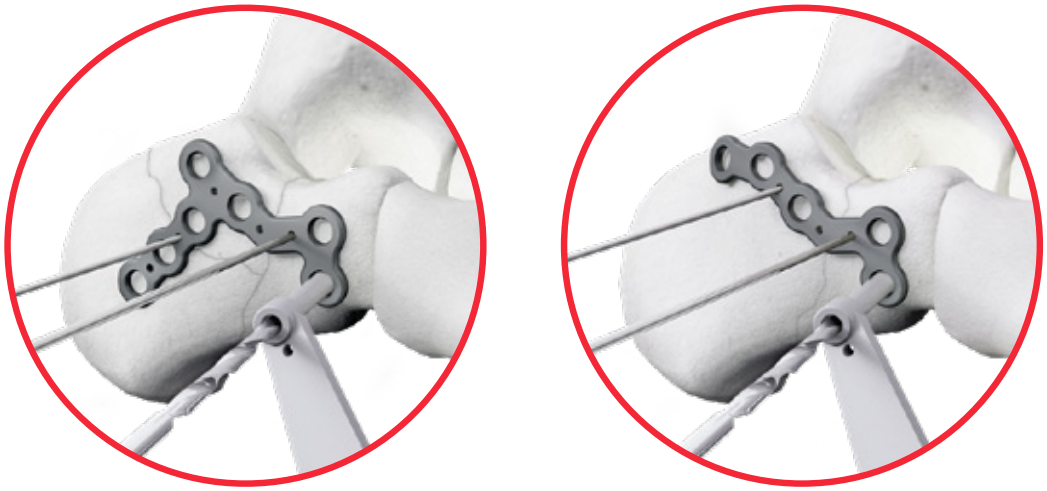
- Place the plate approximately 5-10mm below the posterior facet and aligned at the Böhler-Angle.
- Temporary fix the plate with guide wires on the calcaneus
- Subsequent control under fluoroscopy



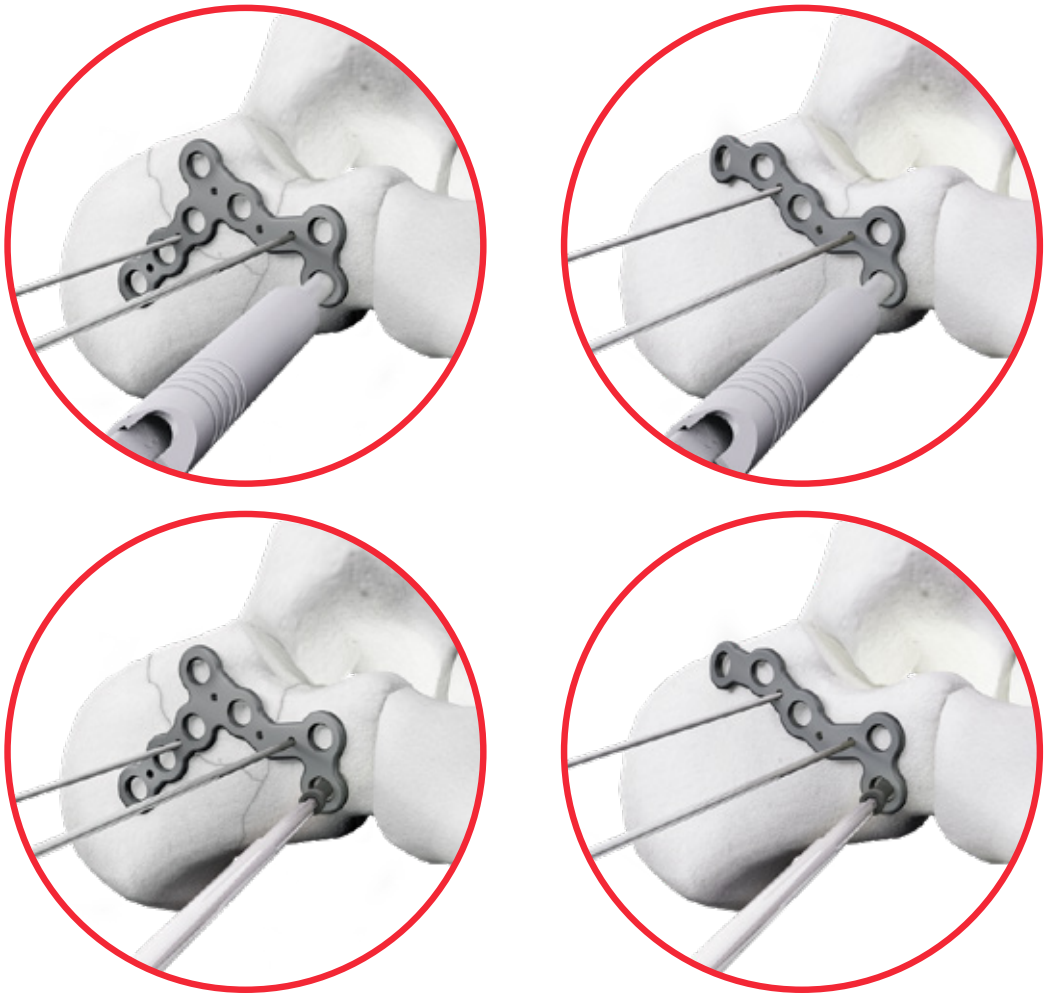
TIP: Optionally, the plate can be stabilized using the ITS. Temporary Plate Holder *(58164-150)*.

Screw Placement

- Use the drill guide D=2.7/2.0mm *(62202)* with the spiral drill, D=2.0mm, L=100mm, AO connector *(61203-100)* to drill the holes for the anterior plate holes.



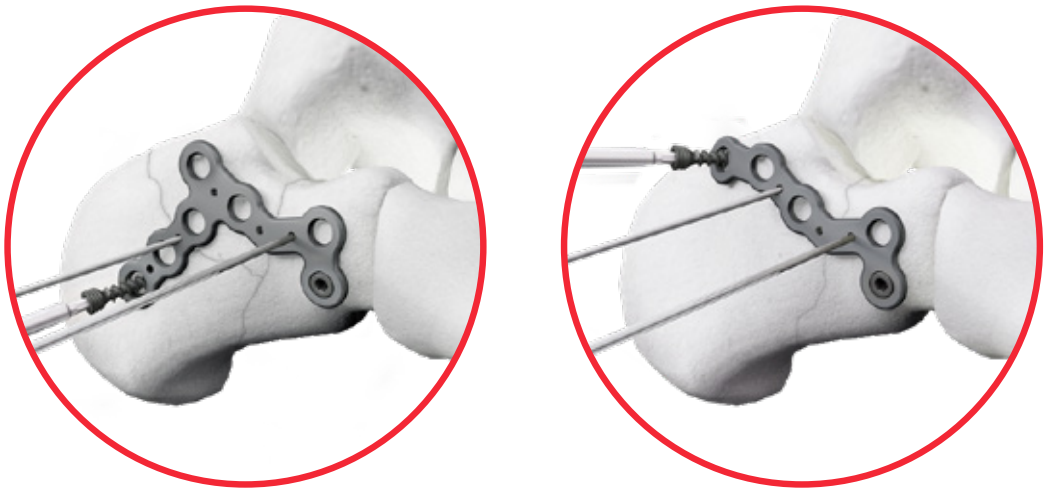
- Use the screwdriver, WS 2.5, self-holding sleeve *(56252)* to insert D=3.5mm cancellous screw *(37352-XX-N)* of appropriate lengths determined previously with the depth gauge, solid small fragment screws *(59022)*.



- Subsequently, drill a hole into one of the tubercle plate holes close to the posterior facet towards the sustentaculum tali using the drill guide, D=2.7/2.0mm *(62202)* with the spiral drill D=2.0mm, L=100mm, AO Connector *(61203-100)*.

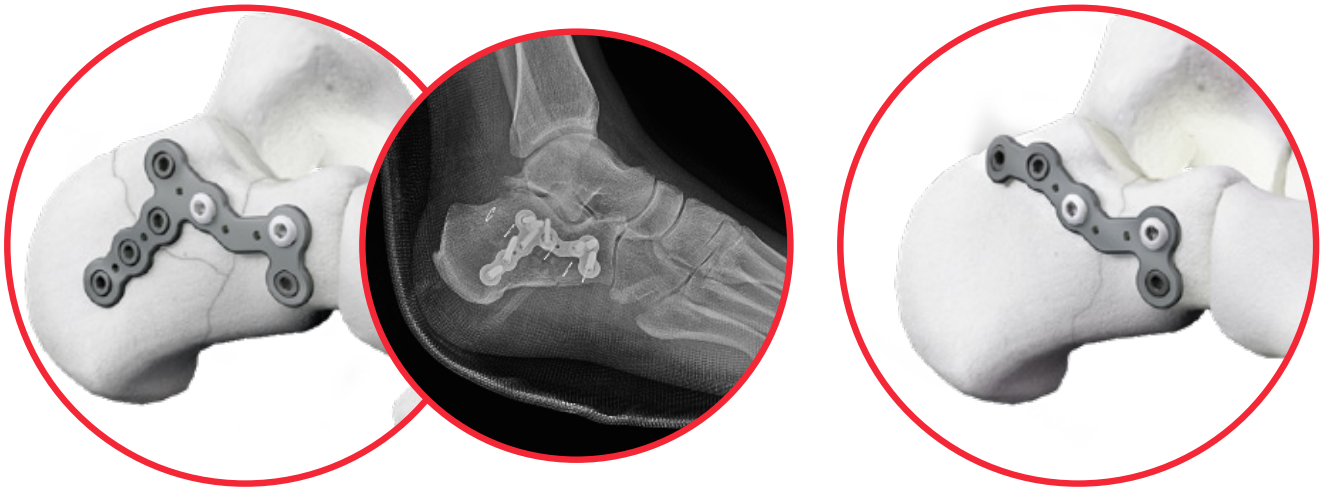
NOTE: Caution when inserting screws towards sustentaculum tali.

- Use the screwdriver, WS 2.5, self-holding sleeve *(56252)* to insert D=3.5mm cancellous screw *(37352-XX-N)* of appropriate lengths determined previously with the depth gauge, solid small fragment screws *(59022)*.



- The remaining plate holes are then filled, with either locking or non-locking screws.
- For placing screws at tuber calcanei a 10mm stab incision is recommended.

- Subsequent control of plate and screw position under fluoroscopy.



Calcaneus Locking Plate

Pre-operative Patient Preparation

- Supine position or lateral position
- General anaesthesia, regional anaesthesia or a combination can be used
- Possible use of medication for blood arrest

Diagnosis

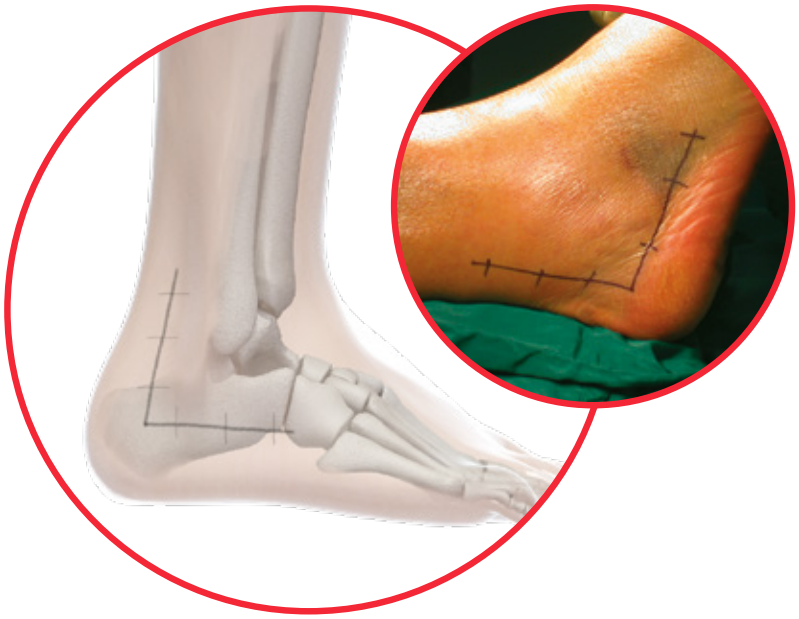
Standard X-ray of the calcaneus, axial and coronet CT with reconstructions.

Access

Expand lateral approach:

- Subperiostal single layered lifting of a lateral skin-soft tissue flap
- Hold away the flap by using bent guide wires

NOTE: Particular care should be taken to spare the terminal branch of the sural nerve and the tendons of the peroneus longus and brevis in order to avoid neurological deficits and tendon irritation.



Reduction

- Open reduction under view by mean of Schanz screw, Steinmann nails, guide wires
- Padding of comminuted zones with bone replacement

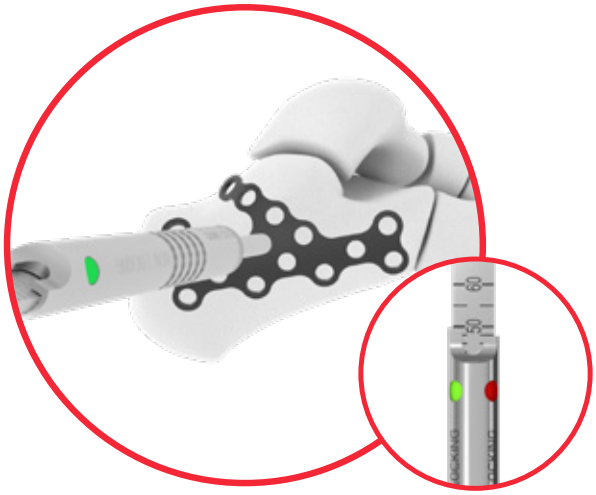
Temporary Plate Fixation

- The plate is temporarily fixed in place with the Temporary Plate Holder *(58164-150)*.

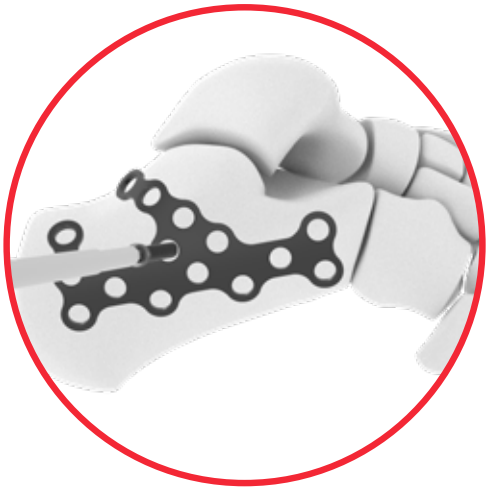
Screw Placement

- Use the spiral drill, D=2.0mm, L=100mm, AO connection *(61203-100)* to drill through the drill guide, D=2.7/2.0mm *(62202)* into one of the central holes of the plate.

- The screw length is determined using the screw gauge, small fragment screws *(59022)*.



- According to the measured length, either a locking cancellous bone screw *(37352-N-XX)* or a non-locking cortical bone screw *(32351-XX)* is inserted using the screwdriver WS 2.5 with 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

- Plastex cast of the lower leg for 2 weeks until healing
- Physical therapy
- Mobilization by crutches
- Relief of the strain for 8-12 weeks

Explantation

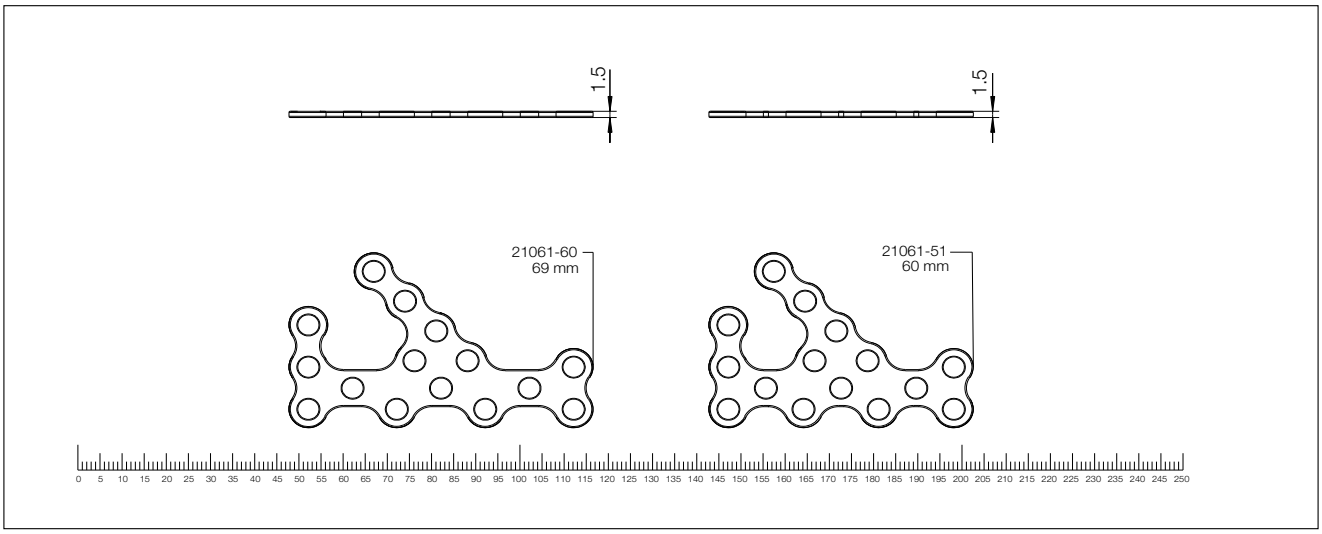
If desired by the patient, the implant can be removed.
Removal should be performed at the earliest 6 months later or after radiographic verification of the healed bone.

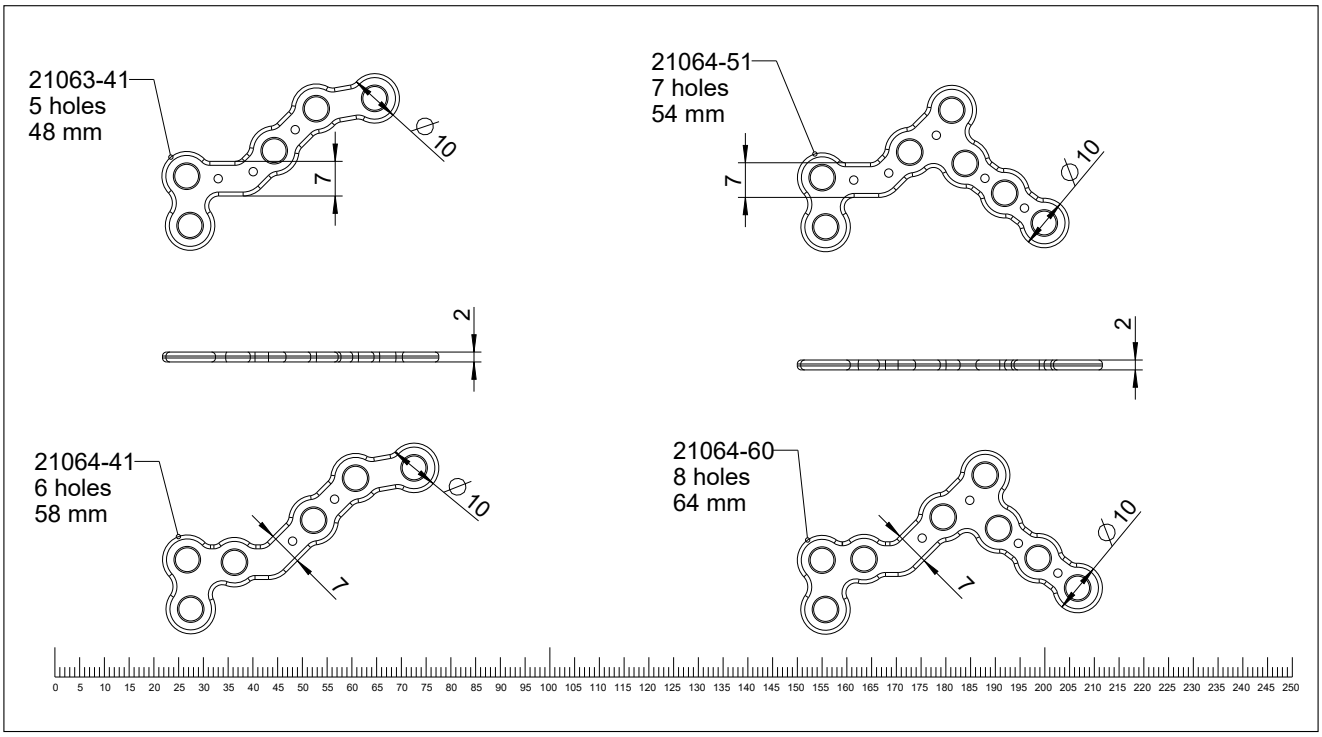
The ITS. Type II anodization surface treatment reduces the risk of cold welding of titanium implants *(for more information, see p. 27)*.

Information

3.

Technical Information





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

Not true to scale

Type II Anodization

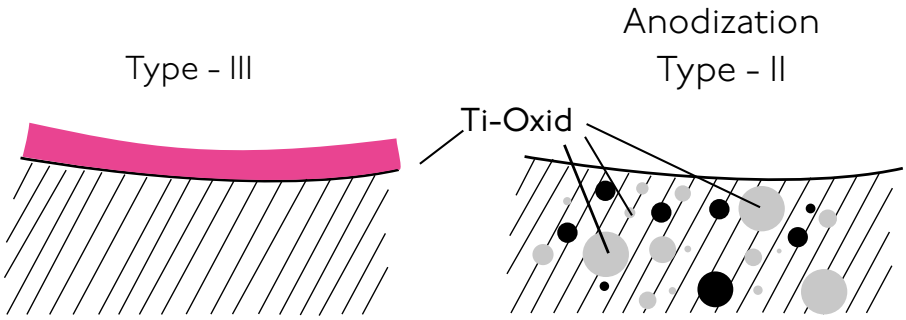
Chemical process - anodization in a strong alkaline solution*

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 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

Anterolateral Calcaneus Plate

21063-41

21064-41

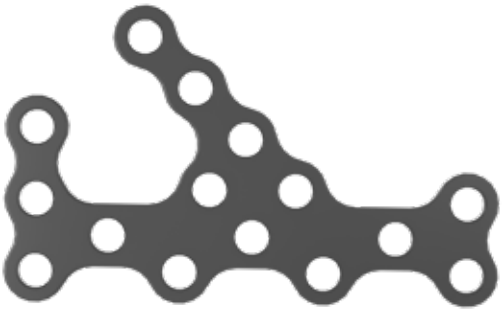
21064-51

21064-60

Description	Size	Article Number
Anterolateral Calcaneus Plate	Small	21063-41
Anterolateral Calcaneus Plate	Large	21064-41
Anterolateral Calcaneus Plate, Tuber	Small	21064-51
Anterolateral Calcaneus Plate, Tuber	Large	21064-60

Calcaneus Plate

21061-51



21061-60

Description	Size	Article Number
Clacaneus Plate	Short	21061-51
Clacaneus Plate	Long	21061-60

Screws

Cortical Screw, D=3.5mm	Length	Article Number
Non-Locking	26	32351-26
	28	32351-28
	30	32351-30
	32	32351-32
	34	32351-34
	36	32351-36
	38	32351-38
	40	32351-40
	42	32351-42
	44	32351-44
	48	32351-48
	50	32351-50

Cancellous Screw D=3.5mm	Length	Article Number
Locking	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

(Optional)

Cancellous Screw D=4.2mm	Length	Article Number
Locking	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

(Optional) Plate Holder

58164-150

Description	Article Number
Temporary Plate Holder, For 3.5/4.2mm Screws	58164-150

Guide Wire

35162-150

Description	Article Number
Guide Wire, Steel, D=1.6mm, L=150mm, TR, RD	35162-150

Spiral Drill

61203-100

61273-100

Description	Article Number
Spiral Drill, D=2.0mm, L=100mm, AO-Connector	61203-100
Spiral Drill, D=2.7mm, L=100mm, AO-Connector	61273-100

Drill Guide

62202

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

Depth Gauge

59022

Description	Article Number
Depth Gauge, Solid Small Fragment Screws	59022

Screwdriver

56252 WS 2.5

Description	Article Number
Screwdriver, WS 2.5, Self Holding Sleeve	56252

AO-Silicone Handle

53016

Description	Article Number
AO Silicone Handle	53016

Hexagon Shank

KM 48-348 WS 2.5

Description	Article Number
Hexagon Shank, WS 2.5,L=135mm, AO Connector	KM 48-348

(Optional)

Spiral Drill

61253-110

Description	Article Number
Spiral Drill, D=2.5mm, L=110mm, AO Connector	61253-110

Guide Wire

35164-150

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

(Optional)

Cancellous Screw, Cannulated 4.0

Cancellous Screw, Cannulated, D=4.0mm	Length	Article Number
	34	31404-34
	36	31404-36
	38	31404-38
	40	31404-40
	42	31404-42
	44	31404-44
	46	31404-46
	48	31404-48
	50	31404-50

Instruments Cancellous Screw, Cannulated 4.0

Guide Wire

35164-228

Description	Article Number
Guide Wire, Steel, D=1.6mm, L=228mm, TR, w. Thread.	35164-228

Spiral Drill

61262-220

Description	Article Number
Spiral Drill, Cannulated, D=2.6mm, L=220mm, AO Connector	61262-220

Depth Gauge

59162

Description	Article Number
Depth Gauge 1.6mm Can. 4.0mm Screw, Var. Thread	59162

Screwdriver

56253-120 WS 2.5

Description	Article Number
Screwdriver, Handle 25mm, WS 2.5, L=120mm, Can. 1.7mm	56253-120

Hexagon Shank

54100-100 WS 2.5

Description	Article Number
Hexagon Shank, WS 2.5, L=100mm Cannulated, AO Connector	54100-100

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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