ITS.

Implants for Trauma Surgery

SURGICAL TECHNQUE

Hand 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 preShapeed 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 deShapeation 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

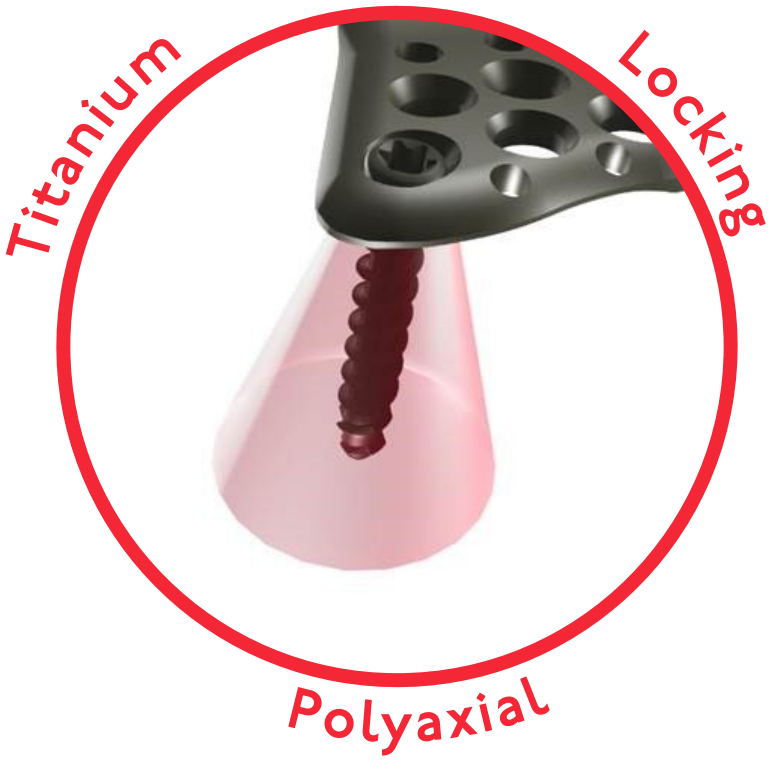
Introduction

Plate Technology

At 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.

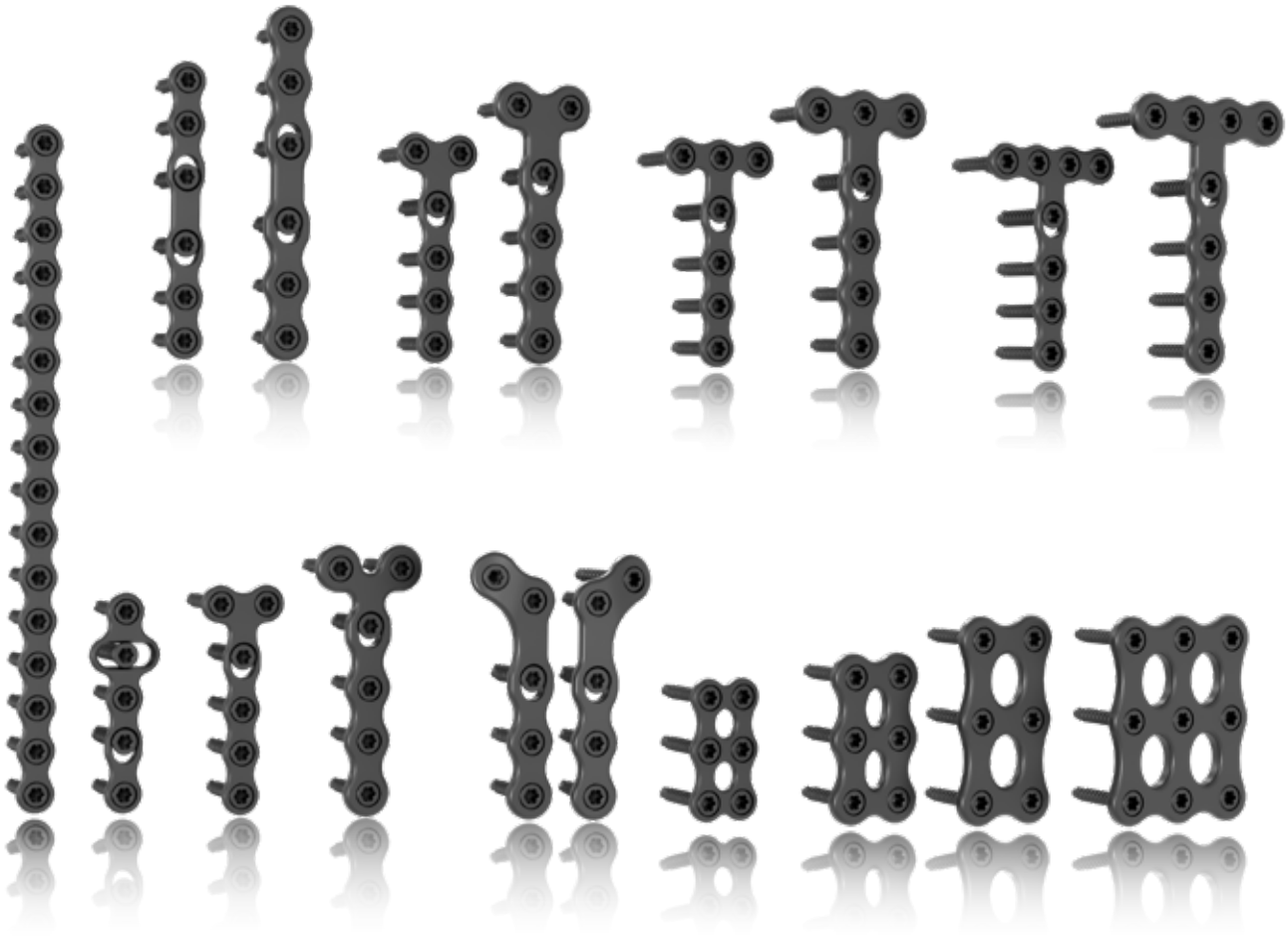


When a locking screw is inserted, it Shapes threads into the plate. There is no cutting and thus no debris created. Each locking screw can be locked at a free placement within a cone of angulation up to ± 15°, and can be re-positioned up to three times.

System Overview

The ITS. Hand Locking Plates System is a trusted osteosynthesis solution, offering a variety of plate types to address a range of hand fractures.

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



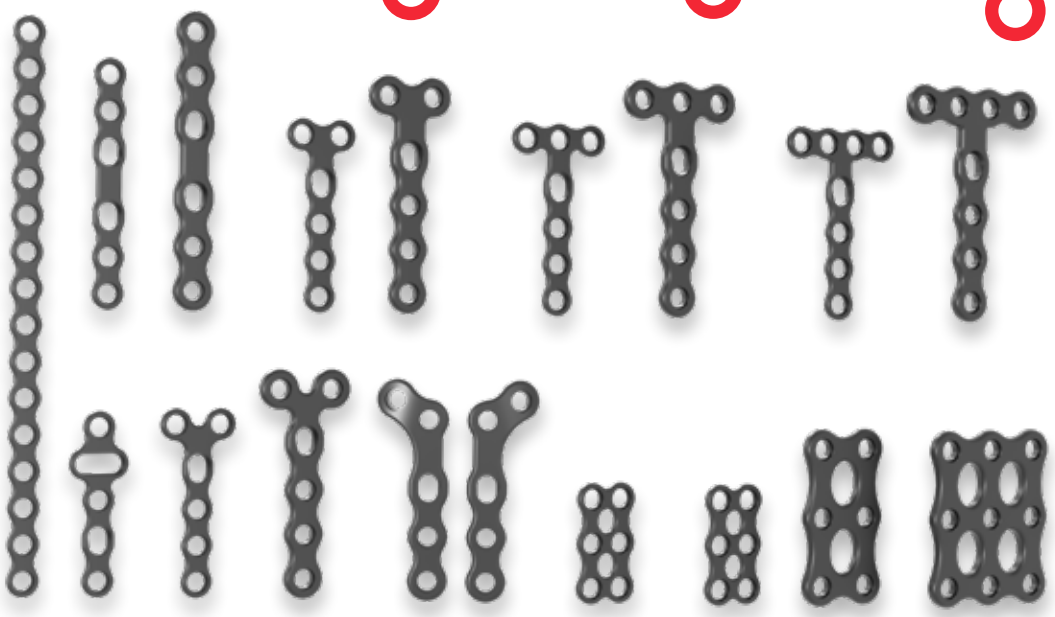
Properties

Sliding hole with compression option (to create tension)

Anatomical Plate Design

L, Y, and T plates for periarticular and intraarticular fractures

Multi-directional Locking



T-Shape Extended: Oblong hole for additional correction of the rotational axis

Various plate types and lengths

Minimization of soft tissue irritation due to anatomical plate design

Low Plate Profile (1.0 & 1.5mm)

Screws

37151-xx **LOCKING**
Stabilization Screw, D=1.5mm
Spiral Drill, D=1.1mm
Torque, T5

37251-xx **LOCKING**
Stabilization Screw, D=2.3mm
Spiral Drill, D=1.8mm
Torque, T5

32151-xx **NON-LOCKING**
Cortical Screw, D=1.8mm
Spiral Drill, D=1.5mm
Torque, T5

Indications

The ITS. HLS - Hand Locking Plates System is indicated for use in fracture fixation of:

- the phalanges
- the metacarpal bones
- the carpal bones
- for arthrodesis
- for corrective osteotomies and
- for subcapital radial head fractures

Contraindications

- Existing infections in the fracture zone and operation area
- 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

Time of Operation

- Immediately after trauma or delayed
- After regression of swelling

Intended purpose

The hand plate system - P32 is used to treat arthrodeses in the hand area as well as subcapital radial head fractures. In addition, it can also be used in the Shape of corrective osteotomies. Other indications include fractures of the phalanges, carpal and metacarpal bones.

Surgical Technique

2.

Pre-operative Patient Preparation

- Elevated upper body approx. 30° - 40° inclination, shoulder freely movable (optional shoulder-table).
- The arm should be freely movable to have the possibility of fracture reduction
- General anaesthesia, regional anaesthesia or a combination can be used
- Possible use of medication for blood arrest

The following surgical steps are illustrated using the HLS Plate 2 T-Shape 1.0mm on the OS metacarpale V. and also apply to other plates.

For details on screw, drill, and screwdriver allocation, *see the screw overview p. II.*

Access

Dorsal access to the middle finger joint: Straight skin incision centrally over the joint, careful dissection through the subcutaneous tissue. The extensor tendon is held aside paratendinously and the joint is then exposed.

IMPORTANT: The incision depends on the affected area of the hand!

Reduction

- Temporary fixation of the fracture parts using forceps
- Subsequent control under fluoroscopy

OPTIONAL: Temporary Plate Fixation

Optionally, the plate can be stabilized using the Temporary Plate Holder *(58100-100)*.

Screw Placement

- Use the spiral drill to drill through the drill guide, D=1.2/1.9mm *(62211)* (drill diameter depends on the choice of screw - see page 11).

- The screw length is determined using the depth gauge *(9-110)*.

- Depending on the measured length, either locking stabilization screws or non-locking stable cortical screws *(37151-XX or 37251-XX / 32151-XX)* are used. The screws are inserted using the torque shank T5x80, AO Connector *(54101-80)*, in combination with the AO handle *(53013)*.

- Subsequent control of the plate and screw position under fluoroscopy.

Postoperative Treatment

- Elevation and preventative edema measures on the day of the operation
- Free weightbearing according to symptoms and stipulations of the operating surgeons

Explantation

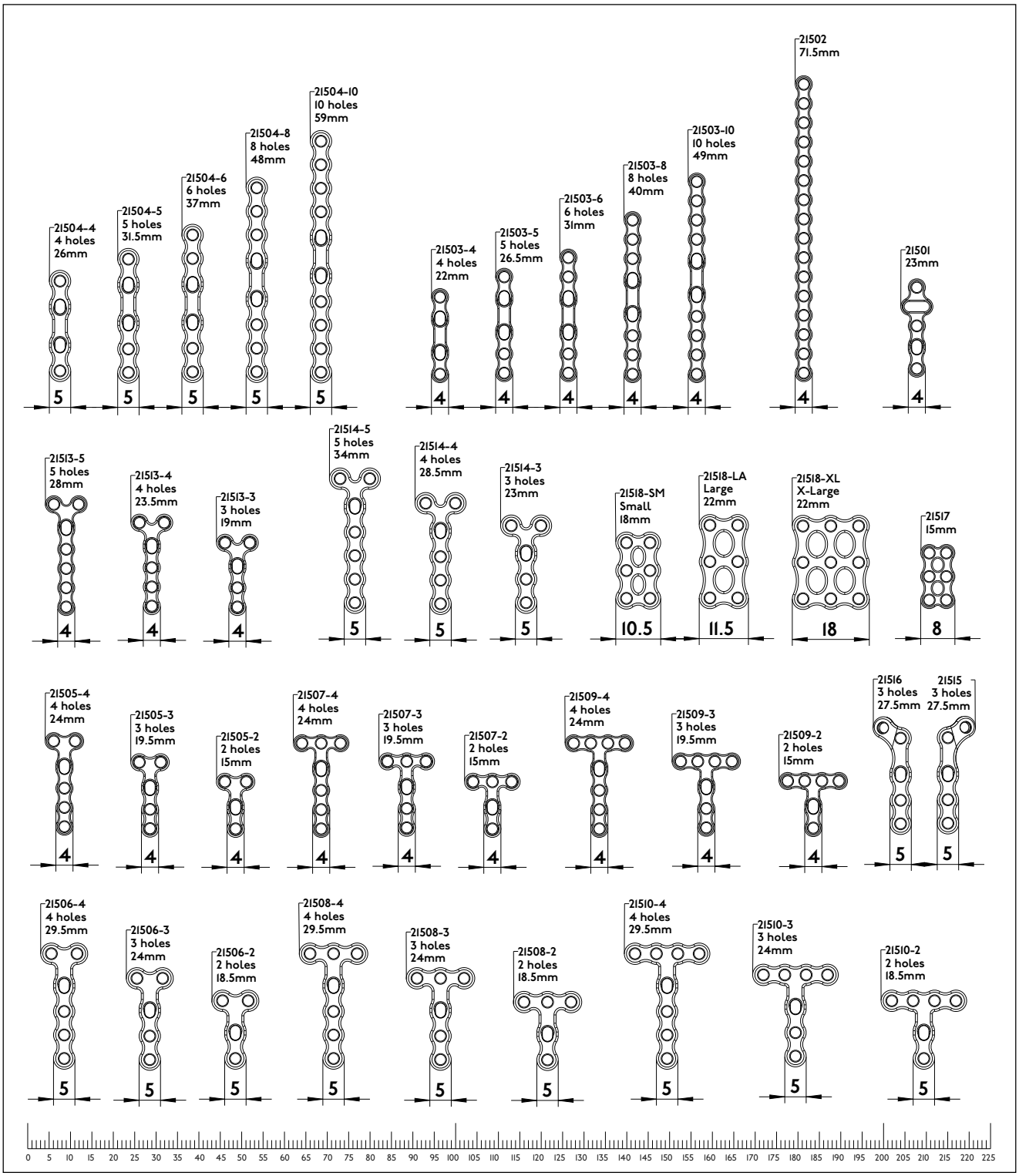
Removal is possible, if desired by the patient. This is facilitated by the fact that, due to different materials of plate and screws, cold welding never occurs.

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

Information

3.

Technical Information



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

Not true to scale

Type II Anodization

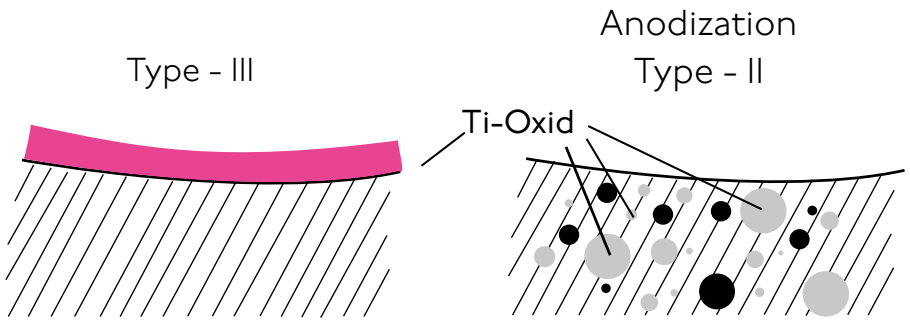
Chemical process - anodization in a strong alkaline solution*

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

HLS Plates - Straight

21502

Description	Article Number
HLS Plate, Straight, Individual	21502

HLS Plates - Straight

1.0mm

21503-4

21503-5

21503-6

21503-8

21503-10

1.5mm

21504-4

21504-5

21504-6

21504-8

21504-10

Description	Holes	Article Number
HLS Plates, Straight 1.0mm	4	21503-4
HLS Plates, Straight 1.0mm	5	21503-5
HLS Plates, Straight 1.0mm	6	21503-6
HLS Plates, Straight 1.0mm	8	21503-8
HLS Plates, Straight 1.0mm	10	21503-10
HLS Plates, Straight 1.5mm	4	21504-4
HLS Plates, Straight 1.5mm	5	21504-5
HLS Plates, Straight 1.5mm	6	21504-6
HLS Plates, Straight 1.5mm	8	21504-8
HLS Plates, Straight 1.5mm	10	21504-10

(Optional)

1.0mm

21503-16

1.5mm

21504-16

Description	Holes	Article Number
HLS Plates, Straight 1.0mm	16	21503-16
HLS Plates, Straight 1.5mm	16	21504-16

HLS Plates - T-Shape

1.0mm

21505-2

21505-3

21505-4

1.5mm

21506-2

21506-3

21506-4

Description	Holes	Article Number
HLS Plates, 2 T-Shape 1.0mm	2	21505-2
HLS Plates, 2 T-Shape 1.0mm	3	21505-3
HLS Plates, 2 T-Shape 1.0mm	4	21505-4
HLS Plates, 2 T-Shape 1.5mm	2	21506-2
HLS Plates, 2 T-Shape 1.5mm	3	21506-3
HLS Plates, 2 T-Shape 1.5mm	4	21506-4

(Optional)

1.0mm

21505-7

1.5mm

21506-8

Description	Holes	Article Number
HLS Plates, 2 T-Shape 1.0mm	7	21505-7
HLS Plates, 2 T-Shape 1.5mm	8	21506-8

1.0mm

21507-2

21507-3

21507-4

1.5mm

21508-2

21508-3

21508-4

Description	Holes	Article Number
HLS Plates, 3 T-Shape 1.0mm	2	21507-2
HLS Plates, 3 T-Shape 1.0mm	3	21507-3
HLS Plates, 3 T-Shape 1.0mm	4	21507-4
HLS Plates, 3 T-Shape 1.5mm	2	21508-2
HLS Plates, 3 T-Shape 1.5mm	3	21508-3
HLS Plates, 3 T-Shape 1.5mm	4	21508-4

(Optional)

1.0mm

21507-7

1.5mm

21508-8

Description	Holes	Article Number
HLS Plates, 3 T-Shape 1.0mm	7	21507-7
HLS Plates, 3 T-Shape 1.5mm	8	21508-8

HLS Plates - T-Shape

1.0mm

21509-2

21509-3

21509-4

1.5mm

215010-2

215010-3

215010-4

Description	Holes	Article Number
HLS Plates, 4 T-Shape 1.0mm	2	21509-2
HLS Plates, 4 T-Shape 1.0mm	3	21509-3
HLS Plates, 4 T-Shape 1.0mm	4	21509-4
HLS Plates, 4 T-Shape 1.5mm	2	21510-2
HLS Plates, 4 T-Shape 1.5mm	3	21510-3
HLS Plates, 4 T-Shape 1.5mm	4	21510-4

HLS Plates - T-Shape Extended

21501

Description	Article Number
HLS Plates, T-Shape Extended	21501

HLS Plates - Y-Shape

1.0mm

21513-3

21513-4

21513-5

1.5mm

21514-3

21514-4

21514-5

Description	Holes	Article Number
HLS Plates, Y-Shape 1.0mm	3	21513-3
HLS Plates, Y-Shape 1.0mm	4	21513-4
HLS Plates, Y-Shape 1.0mm	5	21513-5
HLS Plates, Y-Shape 1.5mm	3	21514-3
HLS Plates, Y-Shape 1.5mm	4	21514-4
HLS Plates, Y-Shape 1.5mm	5	21514-5

(Optional)

1.0mm

21513-7

1.5mm

21514-7

Description	Holes	Article Number
HLS Plates, Y-Shape 1.0mm	7	21513-7
HLS Plates, Y-Shape 1.5mm	7	21514-7

HLS Plates - L-Shape

21516

21515

Description		Article Number
HLS Plates, L-Shape	Left	21516
HLS Plates, L-Shape	Right	21515

(Optional)

21516-7

21515-7

Description		Holes	Article Number
HLS Plates, L-Shape	Left	7	21516-7
HLS Plates, L-Shape	Right	7	21515-7

HLS Plates - Square

21517

Description	Article Number
HLS Plates, Square 1.0mm	21517

21518-SM

21518-LA

21518-XL

Description		Article Number
HLS Plates, Square 1.5mm	Small	21518-SM
HLS Plates, Square 1.5mm	Large	21518-LA
HLS Plates, Square 1.5mm	X-Large	21518-XL

Screws

Stabilization Screw, D=1.5mm	Length	Article Number
Locking	5	37151-5
	6	37151-6
	7	37151-7
	8	37151-8
	9	37151-9
	10	37151-10
	11	37151-11
	12	37151-12
	13	37151-13
	14	37151-14
	15	37151-15
	16	37151-16
	18	37151-18
	20	37151-20
	22	37151-22
	24	37151-24
	26	37151-26

Stabilization Screw, D=2.3mm	Length	Article Number
Locking	5	37251-5
	6	37251-6
	7	37251-7
	8	37251-8
	9	37251-9
	10	37251-10
	11	37251-11
	12	37251-12
	13	37251-13
	14	37251-14
	15	37251-15
	16	37251-16
	18	37251-18
	20	37251-20
	22	37251-22
	24	37251-24
	26	37251-26

Cortical Screw, D=1.8mm	Length	Article Number
Non-Locking	5	32151-5
	6	32151-6
	7	32151-7
	8	32151-8
	9	32151-9
	10	32151-10
	11	32151-11
	12	32151-12
	13	32151-13
	14	32151-14
	15	32151-15
	16	32151-16
	18	32151-18
	20	32151-20

Instruments

(Optional) Plate Holder

58100-100

Description	Article Number
Plate Holder for Hand System	58100-100

Spiral Drill

61113-60

9-012

61183-100

Description	Article Number
Spiral Drill, D=1.1mm, L=60mm, AO Connector	61113-60
Spiral Drill, D=2.5mm, L=85mm, AO Connector	9-012
Spiral Drill, D=1.8mm, L=100mm, AO Connector	61183-100

Drill Guide

62211

Description	Article Number
Drill Guide, D=1.2/1.9mm	62211

Depth Gauge

9-110

Description	Article Number
Depth Gauge	9-110

AO-Silicone Handle

53013

Description	Article Number
AO-Silicone Handle	53013

Torque-Shank

54101-80 T5

54101-80-2

Description	Article Number
Torque-Shank, T5x80, AO Connector	54101-80
Self Holding Sleeve, Torque, T5 Shank	54101-80-2

Tweezer

HB 2001

Description	Article Number
Tweezer, Straight	HB 2001

Plate Holding Forceps

06-586

Description	Article Number
Plate Holding Forceps, 15.5cm	06-586

Bending Forceps

9-406

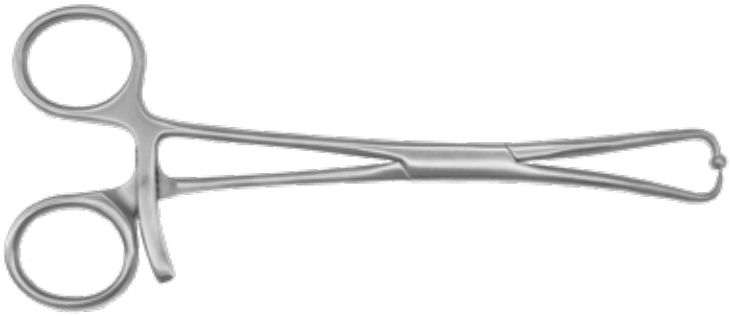
Description	Article Number
Bending Forceps	9-406

Pointed Forceps

9-596

Description	Article Number
Pointed Forceps	9-596

Forceps

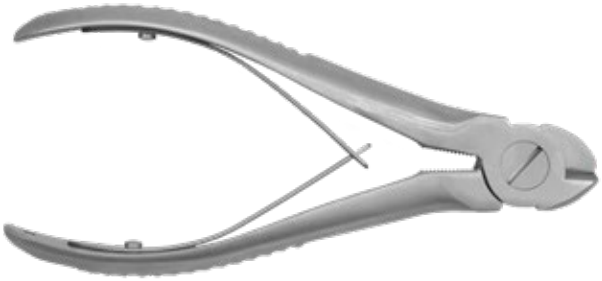


9-646

62820

Description	Article Number
Forceps, Plate Holder	9-646
Forceps, Drill Guide	62820

Plate Cutter



KH.267.16-L

Description	Article Number
Plate Cutter, Long	KH.267.16-L

Notes

Notes

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 inShapeation 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 inShapeation, please visit www.its-implant.com or contact us at office@its-implant.com. Unless otherwise noted, all inShapeation herein is the intellectual property of I.T.S. GmbH.

HEADQUARTER
I.T.S. GmbH
Autal 28, 8301 Lassnitzhöhe, Austria
Tel.: +43 (0) 316/ 211 21 0
office@its-implant.com
www.its-implant.com

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