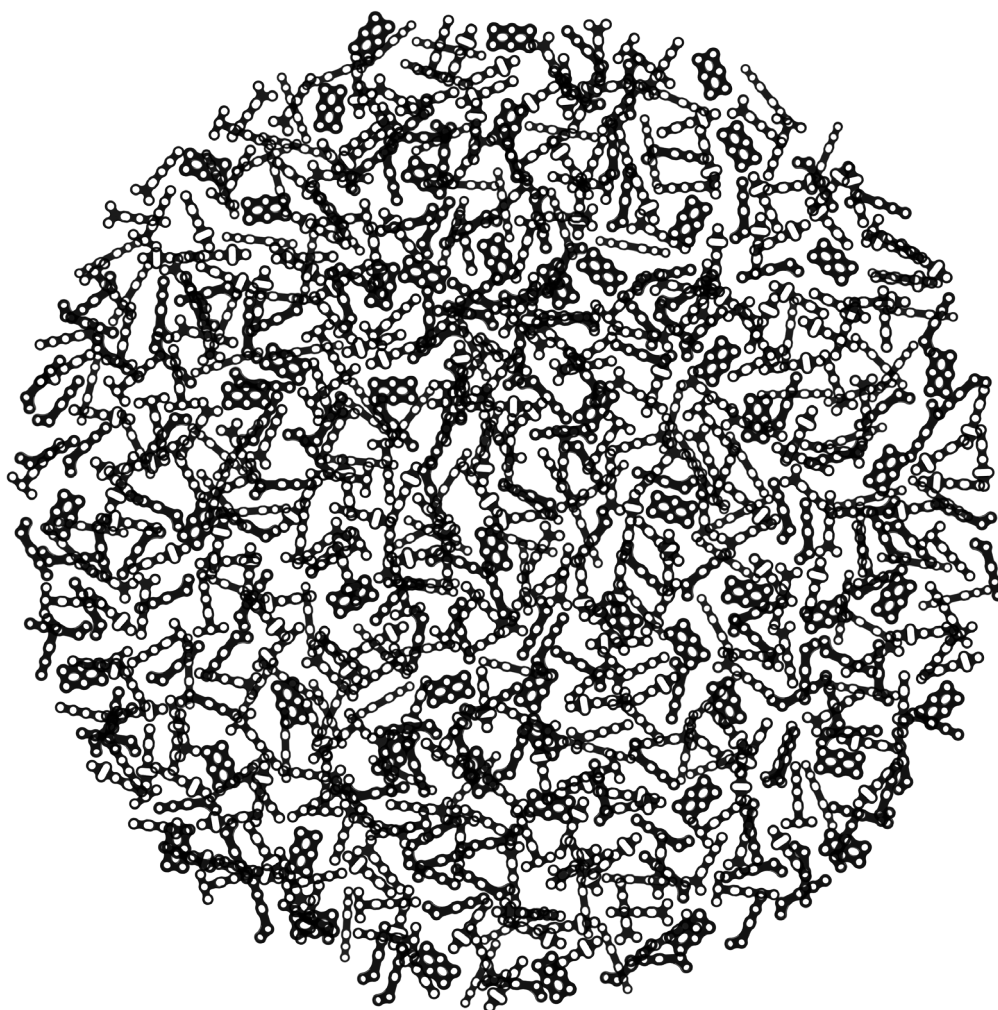


# ITS.

Implants  
trauma



# HLS

Hand Locking Plates System

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



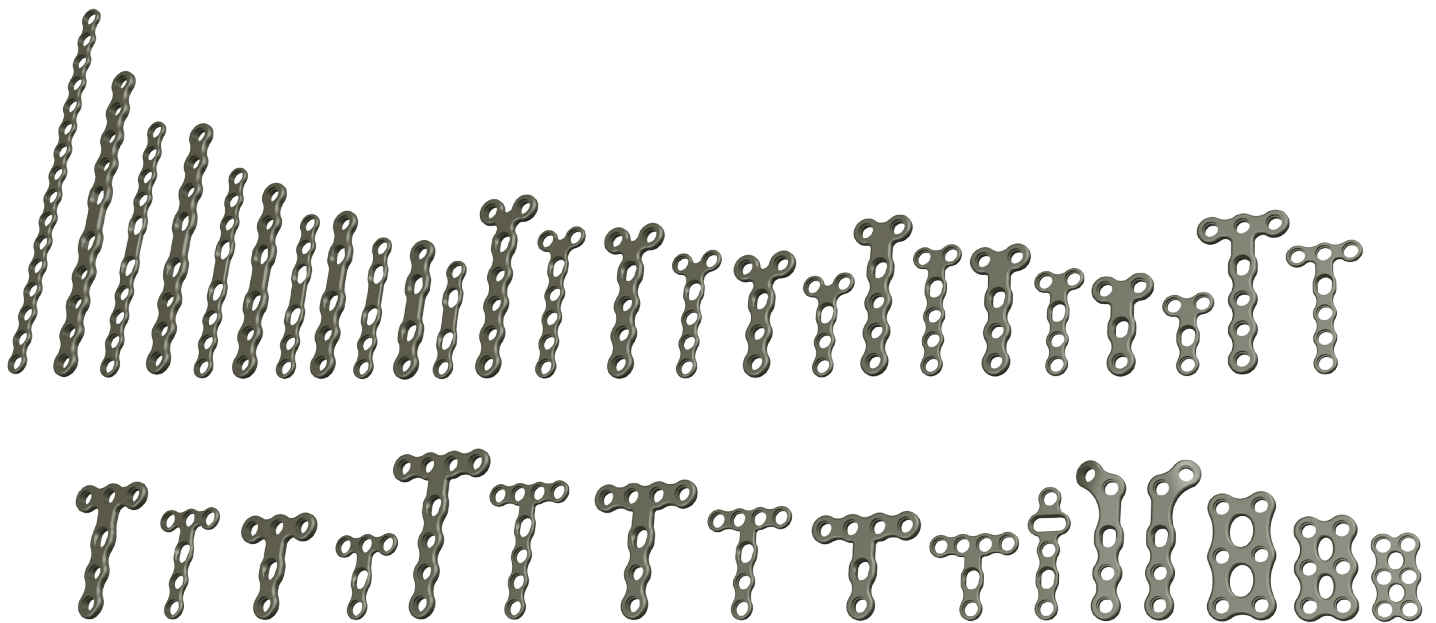
## ○ Preface

The HLS - Hand Locking Plates System from ITS. is a proven osteosynthesis system with various plate types for different fractures of the hand.

The special feature of these implants is the free choice of screw placement.

The user is able to set any desired screw in any hole either locking or non-locking screw (except in the compression hole).

The free choice of screw angulation ( $\pm 15^\circ$ , see page 13) provides an advantage in fracture treatment, especially in the case of complex fractures.



## ○ Screws

3715I-XX Stabilization Screw, D=1.5mm

61113-60 Spiral Drill, D=1.1mm, L=60mm, AO Connector

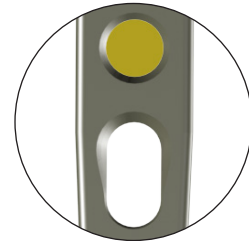
5410I-80 Torque-Shank, T5x80, AO Connector



3725I-XX Stabilization Screw, D=2.3mm

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

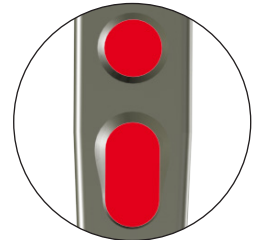
5410I-80 Torque-Shank, T5x80, AO Connector



3215I-XX Cortical Screw, D=1.8mm

9-012 Spiral Drill, D=1.5mm, L=85mm, AO Connector

5410I-80 Torque-Shank, T5x80, AO Connector



## ○ Properties

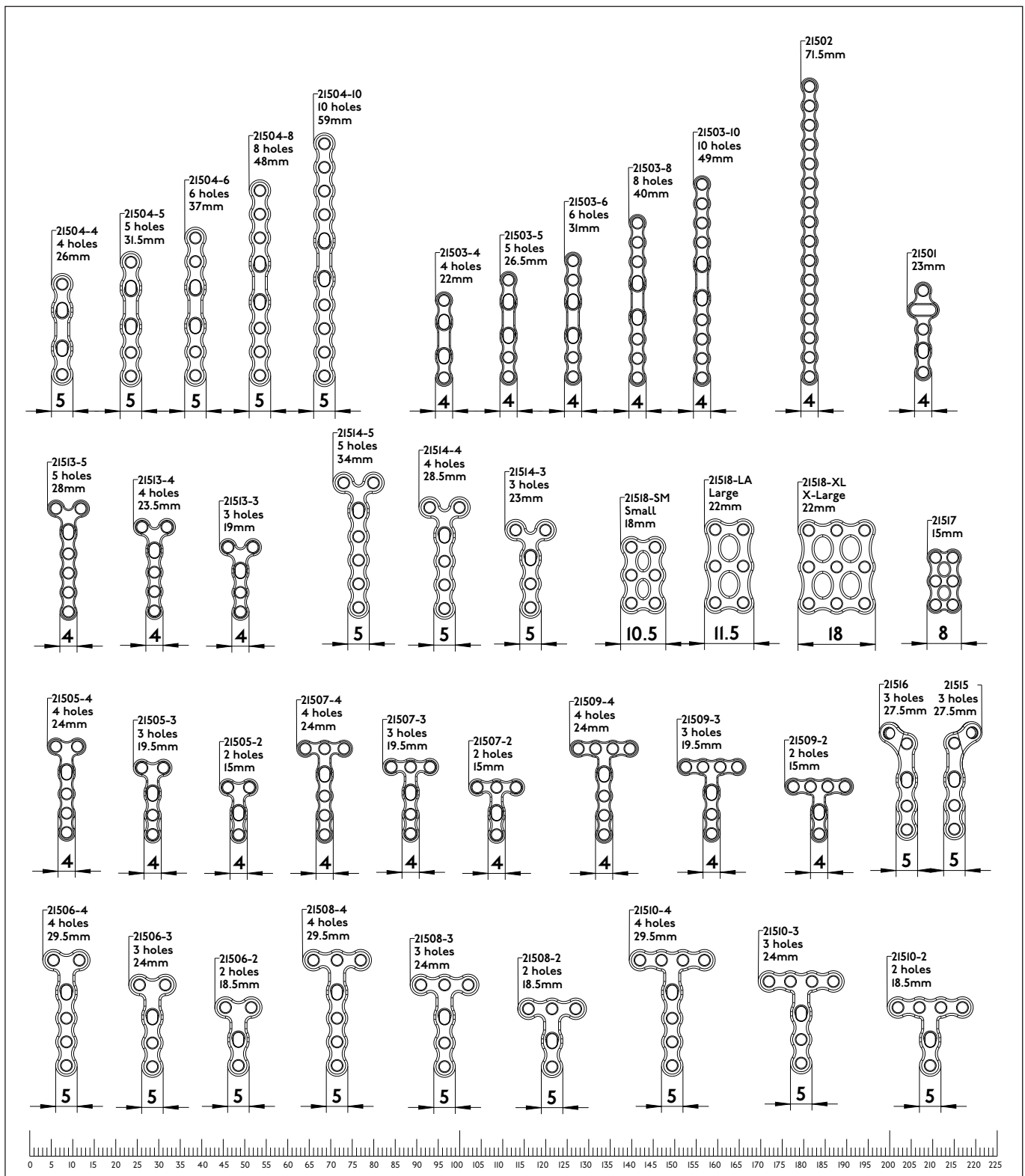
### Properties of the material:

- ◆ 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
- ◆ Minimization of soft tissue irritation due to anatomical plate design
- ◆ Various plate types and lengths
- ◆ Plate strengths: 1.0mm & 1.5mm
- ◆ Sliding hole with compression option (to create tension)
- ◆ T-Shape Extended: Oblong hole for additional correction of the rotational axis

## ○ Plate types



## ◦ Indications, Contraindications & Time of operation

### 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



# Surgical Technique

2.

## ◦ HLS Plate 2 T-Shape 1.0mm

Example of use of a HLS Plate 2 T-Shape 1.0mm on metacarpal bone V.

### ◦ Reduction

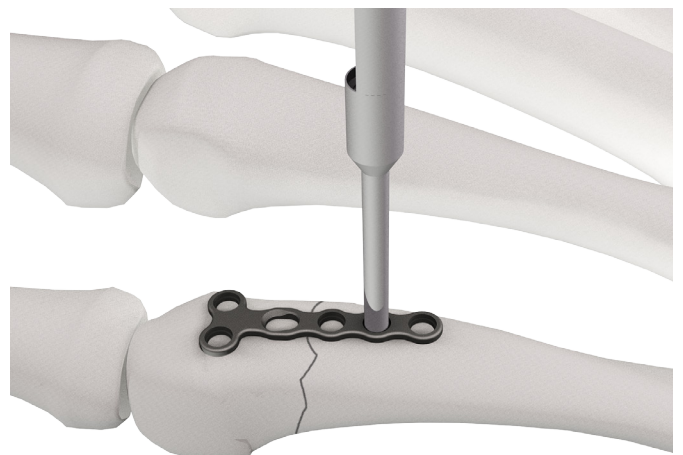
- Temporary fixation of the fracture parts using forceps
- Subsequent control under fluoroscopy

### ◦ Placement of the screws

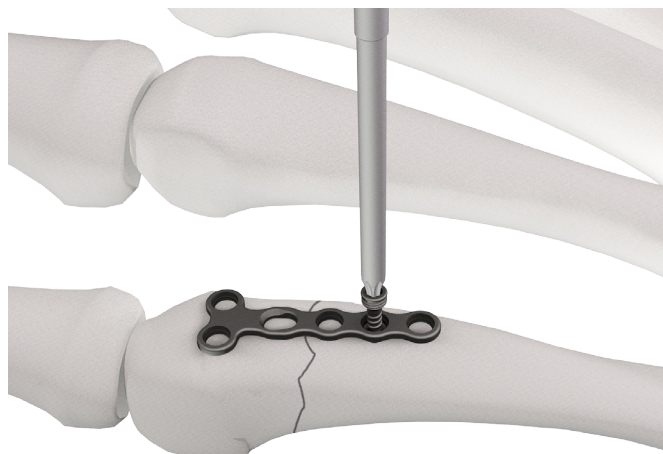
Use the spiral drill to drill through the drill guide, D=1.2/1.9mm **(62211)** (bore diameter depends on the choice of screw - see page 6).



Determine appropriate length using the depth gauge **(9-110)**.



Then insert one of the four screwtypes with the Torque-Shank screwdriver, T5x80, AO Connector **(54101-80)**.



Afterwards the remaining plate holes are filled, with either locking or non-locking screws (except oblong hole, see page 6). Subsequent control of plate 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 problem of cold welding was resolved by using a special surface treatment (for further information see page I3).

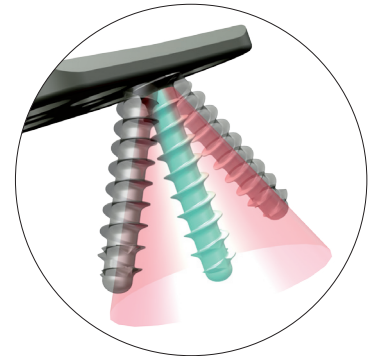
## Information



## ○ Locking

### Functionality of Locking:

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



### Benefits:

- ◆ 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\*

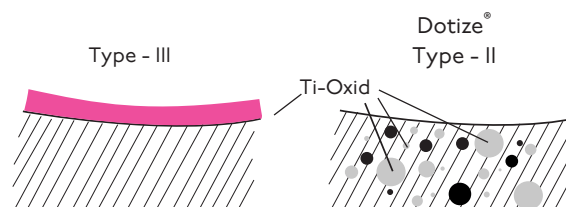
#### Type III anodization

- ◆ 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

## Order list

HLS Plate, Straight Individual	21502	
HLS Plate, Straight 1.0mm, 4-hole	21503-4	
HLS Plate, Straight 1.0mm, 5-hole	21503-5	
HLS Plate, Straight 1.0mm, 6-hole	21503-6	
HLS Plate, Straight 1.0mm, 8-hole	21503-8	
HLS Plate, Straight 1.0mm, 10-hole	21503-10	
HLS Plate, Straight 1.5mm, 4-hole	21504-4	
HLS Plate, Straight 1.5mm, 5-hole	21504-5	
HLS Plate, Straight 1.5mm, 6-hole	21504-6	
HLS Plate, Straight 1.5mm, 8-hole	21504-8	
HLS Plate, Straight 1.5mm, 10-hole	21504-10	
HLS Plate, 2 T-Shape 1.0mm, 2-hole	21505-2	
HLS Plate, 2 T-Shape 1.0mm, 3-hole	21505-3	
HLS Plate, 2 T-Shape 1.0mm, 4-hole	21505-4	
HLS Plate, 2 T-Shape 1.5mm, 2-hole	21506-2	
HLS Plate, 2 T-Shape 1.5mm, 3-hole	21506-3	
HLS Plate, 2 T-Shape 1.5mm, 4-hole	21506-4	
HLS Plate, 3 T-Shape 1.0mm, 2-hole	21507-2	
HLS Plate, 3 T-Shape 1.0mm, 3-hole	21507-3	
HLS Plate, 3 T-Shape 1.0mm, 4-hole	21507-4	
HLS Plate, 3 T-Shape 1.5mm, 2-hole	21508-2	
HLS Plate, 3 T-Shape 1.5mm, 3-hole	21508-3	
HLS Plate, 3 T-Shape 1.5mm, 4-hole	21508-4	
HLS Plate, 4 T-Shape 1.0mm, 2-hole	21509-2	
HLS Plate, 4 T-Shape 1.0mm, 3-hole	21509-3	
HLS Plate, 4 T-Shape 1.0mm, 4-hole	21509-4	
HLS Plate, 4 T-Shape 1.5mm, 2-hole	21510-2	
HLS Plate, 4 T-Shape 1.5mm, 3-hole	21510-3	
HLS Plate, 4 T-Shape 1.5mm, 4-hole	21510-4	
HLS Plate, T-Shape Extended	21501	
HLS Plate, Y-Shape 1.0mm, 3-hole	21513-3	
HLS Plate, Y-Shape 1.0mm, 4-hole	21513-4	
HLS Plate, Y-Shape 1.0mm, 5-hole	21513-5	
HLS Plate, Y-Shape 1.5mm, 3-hole	21514-3	
HLS Plate, Y-Shape 1.5mm, 4-hole	21514-4	
HLS Plate, Y-Shape 1.5mm, 5-hole	21514-5	
HLS Plate, L-Shape, Left	21516	
HLS Plate, L-Shape, Right	21515	

HLS Plate, Square 1.0mm

21517



HLS Plate, Square 1.5mm, Small

21518-SM

HLS Plate, Square 1.5mm, Large

21518-LA

HLS Plate, Square 1.5mm, X-Large

21518-XL



Locking Stabilization Screw, D=1.5mm, L=5mm

37151-5

Locking Stabilization Screw, D=1.5mm, L=6mm

37151-6

Locking Stabilization Screw, D=1.5mm, L=7mm

37151-7

Locking Stabilization Screw, D=1.5mm, L=8mm

37151-8

Locking Stabilization Screw, D=1.5mm, L=9mm

37151-9

Locking Stabilization Screw, D=1.5mm, L=10mm

37151-10

Locking Stabilization Screw, D=1.5mm, L=11mm

37151-11

Locking Stabilization Screw, D=1.5mm, L=12mm

37151-12

Locking Stabilization Screw, D=1.5mm, L=13mm

37151-13

Locking Stabilization Screw, D=1.5mm, L=14mm

37151-14

Locking Stabilization Screw, D=1.5mm, L=15mm

37151-15

Locking Stabilization Screw, D=1.5mm, L=16mm

37151-16

Locking Stabilization Screw, D=1.5mm, L=18mm

37151-18

Locking Stabilization Screw, D=1.5mm, L=20mm

37151-20

Locking Stabilization Screw, D=1.5mm, L=22mm

37151-22

Locking Stabilization Screw, D=1.5mm, L=24mm

37151-24

Locking Stabilization Screw, D=1.5mm, L=26mm

37151-26



Locking Stabilization Screw, D=2.3mm, L=5mm

37251-5

Locking Stabilization Screw, D=2.3mm, L=6mm

37251-6

Locking Stabilization Screw, D=2.3mm, L=7mm

37251-7

Locking Stabilization Screw, D=2.3mm, L=8mm

37251-8

Locking Stabilization Screw, D=2.3mm, L=9mm

37251-9

Locking Stabilization Screw, D=2.3mm, L=10mm

37251-10

Locking Stabilization Screw, D=2.3mm, L=11mm

37251-11

Locking Stabilization Screw, D=2.3mm, L=12mm

37251-12

Locking Stabilization Screw, D=2.3mm, L=13mm

37251-13

Locking Stabilization Screw, D=2.3mm, L=14mm

37251-14

Locking Stabilization Screw, D=2.3mm, L=15mm

37251-15

Locking Stabilization Screw, D=2.3mm, L=16mm

37251-16

Locking Stabilization Screw, D=2.3mm, L=18mm

37251-18

Locking Stabilization Screw, D=2.3mm, L=20mm

37251-20

Locking Stabilization Screw, D=2.3mm, L=22mm

37251-22

Locking Stabilization Screw, D=2.3mm, L=24mm

37251-24

Locking Stabilization Screw, D=2.3mm, L=26mm

37251-26



Cortical Screw, D=1.8mm, L=5mm

32151-5

Cortical Screw, D=1.8mm, L=6mm

32151-6

Cortical Screw, D=1.8mm, L=7mm

32151-7

Cortical Screw, D=1.8mm, L=8mm

32151-8

Cortical Screw, D=1.8mm, L=9mm

32151-9

Cortical Screw, D=1.8mm, L=10mm

32151-10

Cortical Screw, D=1.8mm, L=11mm

32151-11

Cortical Screw, D=1.8mm, L=12mm

32151-12

Cortical Screw, D=1.8mm, L=13mm

32151-13

Cortical Screw, D=1.8mm, L=14mm

32151-14

Cortical Screw, D=1.8mm, L=15mm

32151-15

Cortical Screw, D=1.8mm, L=16mm

32151-16

Cortical Screw, D=1.8mm, L=18mm






32151-18

Cortical Screw, D=1.8mm, L=20mm

32151-20



## Order list

Cortical Screw, D=1.8mm, L=22mm	32151-22	
Cortical Screw, D=1.8mm, L=24mm	32151-24	
Cortical Screw, D=1.8mm, L=26mm	32151-26	
Drill Guide, D=1.2/1.9mm	62211	
Spiral Drill, D=1.1mm, L=60mm, AO Connector	61113-60	
Spiral Drill, D=1.5mm, L=185mm, AO Connector	9-012	
Spiral Drill, D=1.8mm, L=100mm, AO Connector	61183-100	
Depth Gauge	9-110	
AO Handle	53013	
Torque-Shank, T5x80, AO Connector	54101-80	
Self Holding Sleeve, Torque, T5 Shank	54101-80-2	
Plate Holder	58100-100	
Tweezer, Straight	HB 2001	
Plate Holding Forceps, 15,5cm	06-586	
Bending Forceps	9-406	
Pointed Forceps	9-596	
Forceps, Plate Holder	9-646	
Forceps, Drill Guide	62820	
Sterilization Tray, HLS	50246	

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



Tray setting



# Reconditioning Manual

The information below should help you in reconditioning medical devices.

## IMPORTANT INDICATIONS FOR DOCTORS & OPERATING THEATRE PERSONNEL

This instruction leaflet refers to all supplied non-sterile implants and all reusable instruments from I.T.S. GmbH. Detailed information for the identification of the product (such as system classification, cat. no.) can be found in the product identification code and/ or on the packaging label. Make sure that you are familiar with the possible application, combinability and correct handling of the product. Please note that product systems can undergo modifications which can affect the combinability of the implant with other implants or instruments. Detailed user information can be found in the respective surgical instructions.

## Intended Use of the Implant

The implant temporarily stabilises bone segments until bony consolidation has taken place. After this, the implant has no more use and can be removed.

## Indications and Contra-Indications of the Implant

Indications and contra-indications are determined by current medical practice.

## Side Effects of the Implant

Up to now, no allergic reactions have been identified with titanium implants. Allergic reactions to steel implants cannot be ruled out.

## Warnings and Preventive Measures

- Pay attention to the instructions on the packaging.
- Implants are only to be used once.
- Always treat implants carefully to avoid surface damage or geometric alterations.
- Any alterations to the design of implants from I.T.S. GmbH are prohibited.
- Regular postoperative follow-up examinations (e.g. X-ray check-ups) are to be carried out.
- For metallurgical, mechanical and design reasons, never combine implants from different producers. The materials used are stated in the product catalogue or on the label.
- The length, angle and right or left version of a particular type of implant can differ.
- The precise positioning and fastening of a properly made connection between the implant and instrument must be repeatedly checked during the course of an operation.
- In the case of magnetic resonance imaging (MRI), it is generally recommended to check back with the manufacturer of the MR scanner. The use of MRI with steel implants is prohibited by I.T.S. GmbH, and in such cases the user must contact the manufacturer of the MRI scanner.
- Staff who come into contact with contaminated or potentially contaminated medical products should follow the generally recognised preventive measures. Due care is to be taken when handling medical products with sharp points or edges.
- Appropriate protective measures must be taken to ensure safe handling when dealing with contaminated or potentially contaminated medical products (e.g. gloves, etc.).
- In countries with stricter safety requirements regarding recycling medical products, these safety requirements apply and are to be adhered to.
- Any supplied non-sterile medical products must be thoroughly prepared according to these instructions before use.
- No metal brushes or abrasive cleaning materials are to be used for manual cleaning purposes. The use of these materials can lead to damage of surfaces and coatings. Instead, soft brushes made of nylon should be used.
- Steam (damp heat) is the recommended sterilization method of medical products from I.T.S. GmbH.
- All the following described steps for cleaning and sterilization are made easier when contaminants (e.g. blood) are not allowed to dry beforehand.

## Restrictions

- Unless otherwise stated, repeated preparation of re-usable instruments of I.T.S. GmbH has minimal effects on them when following the procedures mentioned below.
- The end of the product service life is usually determined by wear and damage caused by use.
- Instruments containing aluminium or anodised aluminium can be damaged by alkaline (pH value > 7) cleaning agents and solutions.

## INSTRUCTIONS FOR RECYCLING REUSABLE INSTRUMENTS

### Preparation at the location of use

- Remove surface dirt using a disposable cloth or paper towel. Rinse out the hollow parts with A. dest. Saline solution (NaCl) may only be used if reconditioning is carried out immediately afterwards – risk of corrosion!

### Storage and Transport

- No special requirements.
- It is recommended that medical products are reconditioned as soon as possible after their previous use.

## Cleaning/Disinfection/Drying

### Cleaning preparation

Each instrument that can be dismantled should be taken apart for cleaning.

### Automatic cleaning/disinfection

Only a washer-disinfector (WD) that conforms to standards (in accordance with EN ISO 15883) and that is regularly maintained and inspected should be used for automatic cleaning and disinfection in accordance with the manufacturer's information.

Recommended equipment: Appropriate loading trolleys to accommodate all instruments (e.g. instrument trolleys with MIC bar, MIC trolleys); commercially available cleaning agent authorised for use with medical products (pH value 9-11) e.g. Neodisher® Mediclean forte by Dr. Weigert.

I.T.S. GmbH recommends the following validated steps for automatic cleaning and thermal disinfection. The basic device should be a Miele PG 8536 machine. Validation is carried out in accordance with EN ISO 15883 and guideline no. 3 of the Austrian Association for Sterile Services (ÖGSV).

Phase	Water quality	Temperature [°C]	Time [min]*	Dosage	
				m/L	DT [°C]
Pre-rinsing I	SW	cold	2	-	-
Pre-rinsing 2	SW	cold	5	-	-
Cleaning**	PW	55	10*	6	45
Rinsing	SW	50	3	-	-
Thermal disinfection	PW	90	5	-	-
Drying	-	110	15	-	-

SW: Softened water; PW: Purified water; DT: Dosage temperature

Cleaning agent: Neodisher® Mediclean forte

\* When temperature is reached

\*\* When using highly alkaline cleaners (e.g. a neutralization step is required for Neodisher® FA)

- Step 1 Jointed instruments are to be opened so that water can flow out of cannulae and blind holes. Place cannulated instruments onto or connect them to appropriate rinsing nozzles (use a rinsing adapter where necessary).
- Step 2 Start the relevant cycle.
- Step 3 Adhere to the guidelines of the WD manufacturer. After removing the instruments from the disinfector, check the cannulae, blind holes, etc, for visible dirt. If required, repeat cycle or clean by hand.

### Manual cleaning/disinfection

A manual cleaning and disinfection procedure, even when using an ultrasound bath, should generally be avoided and should only be used if an automatic process is not available, due to very low levels of efficacy. In addition, the manual procedure can be used to support automatic reconditioning, particularly in the case of heavily soiled instruments.

Recommended equipment: Commercially available cleaning agent authorised for medical products (pH value 9-11) or combined cleaning agent and disinfectant (e.g. Sekusept® Aktiv 2% by ECOLAB); nylon brushes with soft bristles; running water.

Accessories	Gentle automatic treatment of the instruments using lint-free soft cloths, paper towels or soft plastic brushes.
Soaking the instruments	Fully submerge and soak the instruments in a suitable cleaning agent and disinfectant solution. Manufacturer's information, e.g. concerning concentration, temperature and exposure time should be followed when using all agents.
Cleaning agent/disinfectant	Use of a cleaning agent/disinfectant from the VAH list. I.T.S. GmbH recommends Sekusept® Aktiv 2% by ECOLAB. When using powdered products, it must first be checked that the powder has dissolved completely in the water before the instruments are added. In addition, adhere to the manufacturer's information regarding material tolerance. If applicable: the cleaning agent must be suitable for ultrasound cleaning. (Non-foaming).  Do not use highly alkaline or acidic additives. Recommended pH range 4.5 - 10.5. Prepare freshly every day.
Ultrasound treatment	Treatment in an ultrasound bath is carried out for 5 minutes in the above-mentioned cleaning agent/disinfectant. The instrument set is then left in the solution for 15 minutes.
Rinsing/drying the instruments	Remove the instruments from the solution and rinse thoroughly with running tap water until there are no visible traces of blood or other contaminants in the rinsing water. Particular attention should be paid to lumen, openings and other areas that are not easily accessible. Rubber and flexible plastics require longer rinsing times and any dirt that remains on the instruments may have to be removed manually (no metal brushes, no abrasive cleaners). Thorough final rinsing using purified water. Dry the instruments immediately (e.g. using a lint-free disposable cloth or pressurised air gun).

### Manual disinfection

If a cleaning agent without a disinfectant effect is used, separate disinfection must be carried out after manual cleaning. (Order: Decontamination for staff protection, cleaning, disinfection).

Equipment: Commercially available disinfectant authorised for use with medical products from the VAH list. Manufacturer's information, e.g. concerning concentration, temperature and exposure time should be followed. The steps described in the table above also apply.

### Drying

See table above.

### Checking, Maintenance and Inspection

- Each instrument or implant is to be inspected carefully to make sure that all visible dirt has been removed. If any ingrained dirt is found, the cleaning/disinfection cycled should be repeated.
- Any instruments with an attached movable mechanism should be treated with a commercially available lubricant authorized for sterilisable surgical instruments.
- The mobility of movable parts should be checked to ensure that the planned sequence of motion can be completely carried out.
- In the case of instruments which can be reassembled into larger units, check whether the single parts can be put together easily.

### Packaging

The delivery packaging is purely for transport purposes and is not suitable for sterilisation.

The hospital is responsible for in-house procedures regarding assembly, inspection and packaging of instruments. Packaging is carried out in accordance with the general standard packaging guidelines of relevant standards and guidelines of specialist organisations using sterile barrier systems that conform with standards.

### Sterilization

- All instruments and implants should be laid out in such a way that the steam can reach all the surfaces of the medical devices.
- Each instrument that can be dismantled should be taken apart for sterilisation.
- Carry out sterilisation of the products using the fractionated pre-vacuum procedure, in accordance with EN 285 (or EN 13060) and EN ISO 17665. I.T.S. GmbH recommends the following validated methods for sterilising instruments:

Sterilisation with steam: Fractionated vacuum procedure (at least 3 pre-vacuum phases)	
Temperature	Duration of sterilization
134°C (273°F)	5 minutes 18 minutes*

\* Parameters for sterilisation with steam recommended by the World Health Organisation (WHO) for recycling instruments if contamination with Creutzfeldt-Jakob Disease (CJD) pathogens is suspected.

### Disposal

The valid guidelines of the hospital operator apply for disposal.

### Responsibility of the Hospital for Instruments lent by I.T.S. GmbH

- Surgical instruments generally have a long service life. But their life expectancy can be quickly reduced due to misuse or insufficient protection. Instruments which no longer work correctly, whether due to wear, misuse or improper care, have to be disposed of.
- Medical products which are returned to I.T.S. GmbH must undergo cleaning, disinfection, inspection and a final sterilization. Products returned to I.T.S. GmbH must be accompanied by a confirmation of the decontamination they were subjected to.
















### Important information

- The above-mentioned instructions have been validated by the manufacturer of medical devices for reconditioning a medical device, the re-use of which is deemed to be suitable. It is the responsibility of the reconditioner to ensure that reconditioning actually carried out using the equipment, materials and staff available in the preparation facility achieves the desired results. For this, validation and routine inspections of the process are necessary. Likewise, any deviation from the instructions provided by the reconditioner should be evaluated for its efficiency and possible negative consequences.
- Should you have questions or problems, please contact us at the address above.

### Patient Information

Implantation has consequences for the discomfort, mobility and general life circumstances of the patient. For this reason, the patient should be given instructions about appropriate behaviour to adopt after implantation, and it should be explained to him or her the necessity and the importance of reporting negative changes in the area of the implant as well as any falls and accidents which may appear not to have damaged the implant or the site of the operation.

### Symbols

	Prescription
	Single use
	Expiry date (year/month)
	Charge number
	Sterilization by steam
	Sterilization by radiation
	Sterilization by ethylene oxide
	Order number
	Material used
	Package content (no. of items)
	Size
	Pay attention to instructions
	Latex Free
	Non Sterile
	Do not use if package is damaged

 0297  
RL 93/42/EWG  
ÖNORM EN ISO 13485  
ISO 17664



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