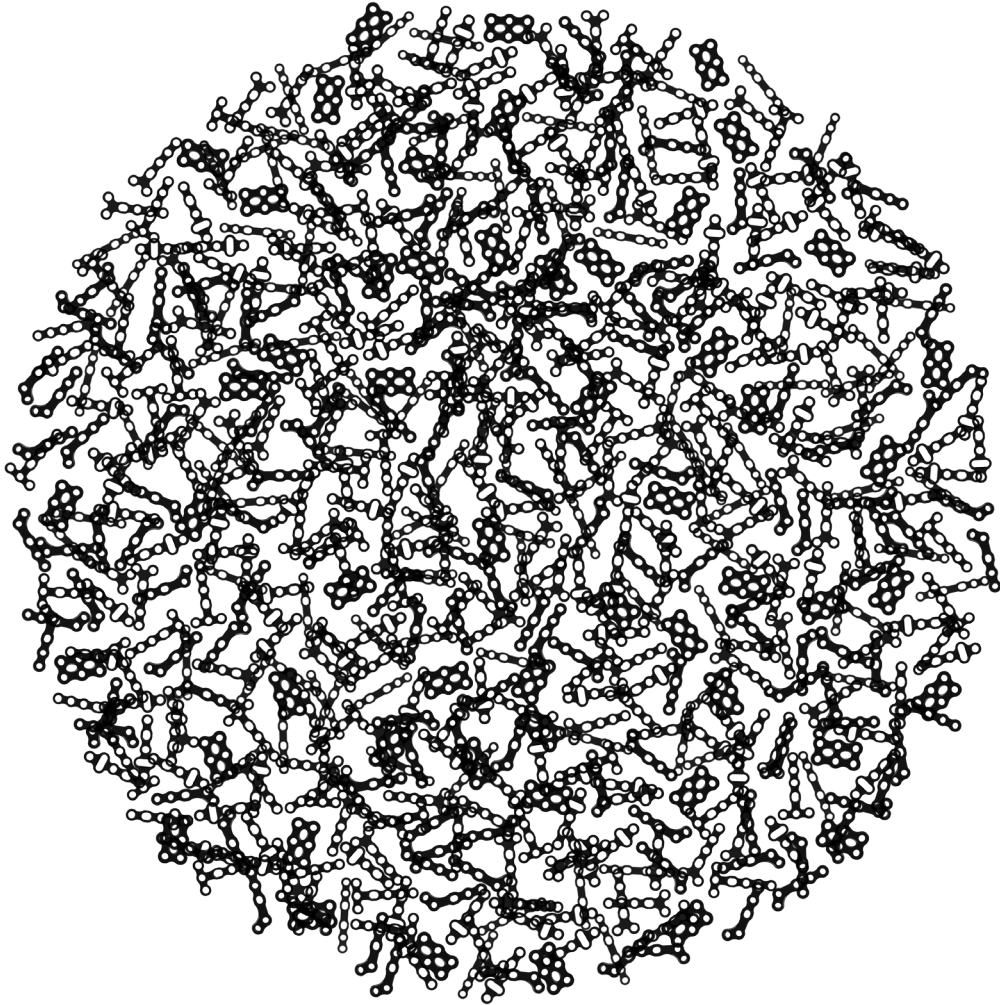


ITS.

Implants
trauma



HLS

Hand Locking Plates System

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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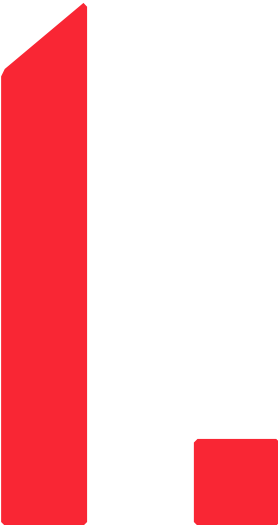
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Introduction



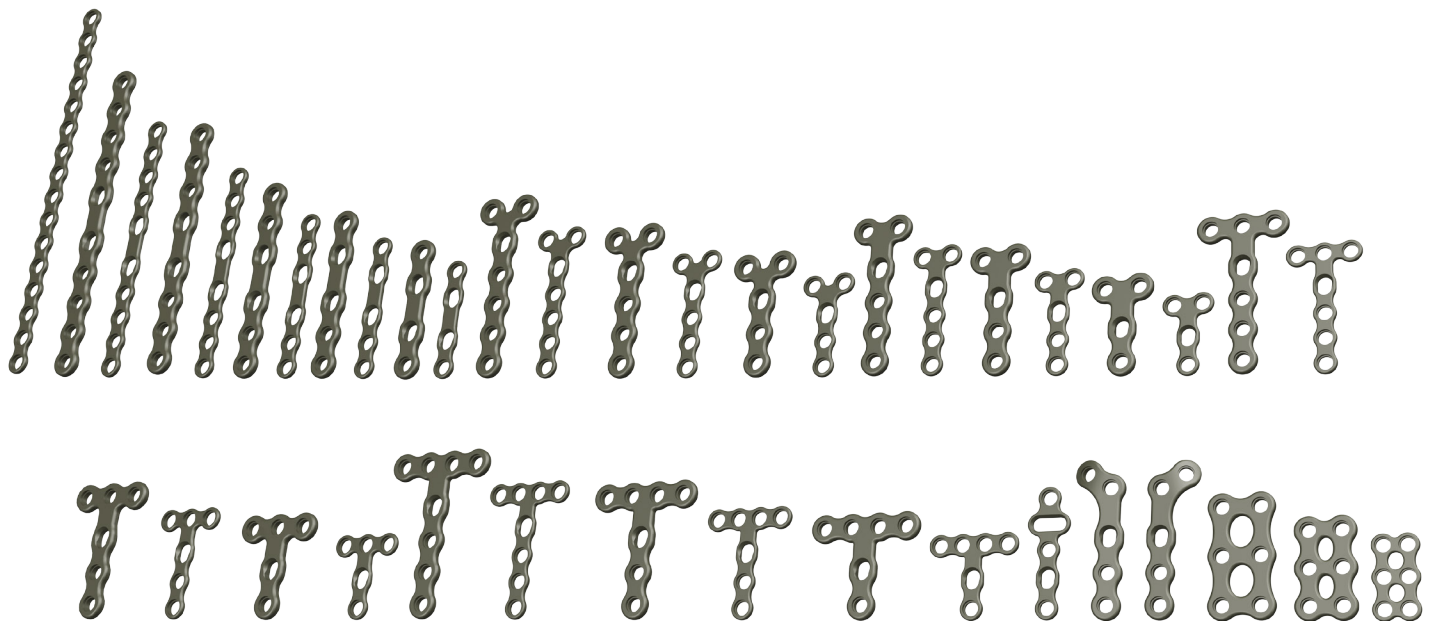
○ Preface

The HLS - Hand Locking Plates System from I.T.S. 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.

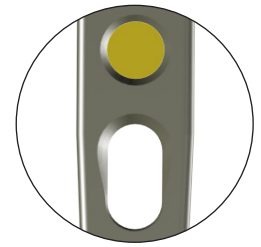
The user is able to set any desired screw in any hole either locking or non-locking screw (except in the compression hole).

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.

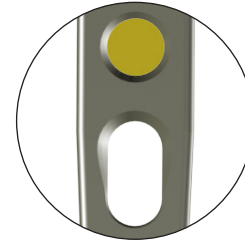


○ Screws

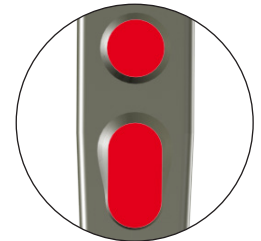
- 37151-XX Stabilization Screw, D=1.5mm
61113-60 Spiral Drill, D=1.1mm, L=60mm, AO Connector
54101-80 Torque-Shank, T5x80, AO Connector



- 37251-XX Stabilization Screw, D=2.3mm
61183-100 Spiral Drill, D=1.8mm, L=100mm, AO Connector
54101-80 Torque-Shank, T5x80, AO Connector



- 32151-XX Cortical Screw, D=1.8mm
9-012 Spiral Drill, D=1.5mm, L=85mm, AO Connector
54101-80 Torque-Shank, T5x80, AO Connector



○ Properties

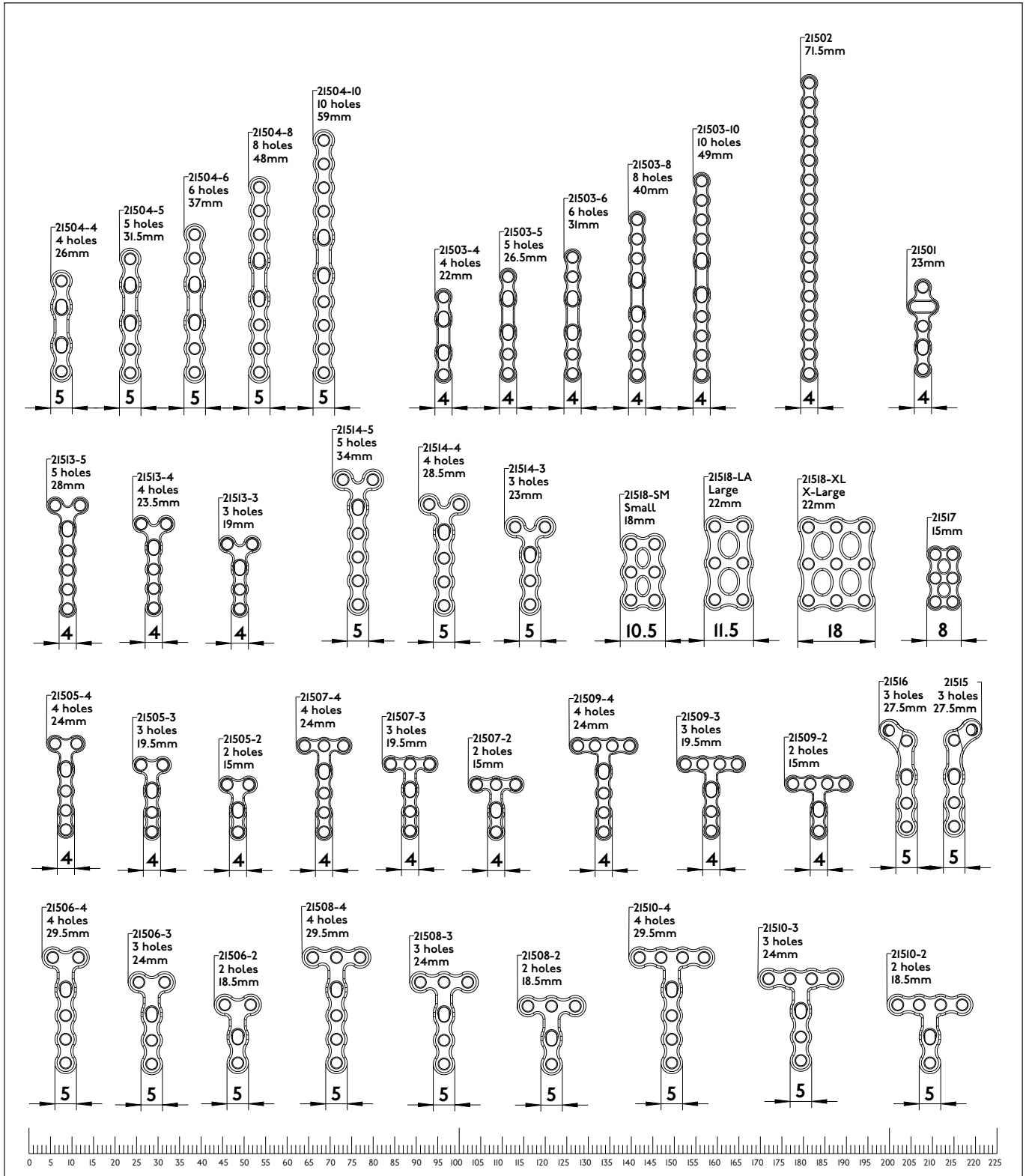
Properties of the material:

- ◆ 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 intended use of the ITS. HLS - Hand Locking Plates System is to draw two or more aligned bone fragments together to facilitate healing in an adult patient.

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

The ITS. HLS - Hand Locking Plates System is not for spinal use.

Surgical Technique

2.

○ HLS Plate 2 T-Shape 1.0mm

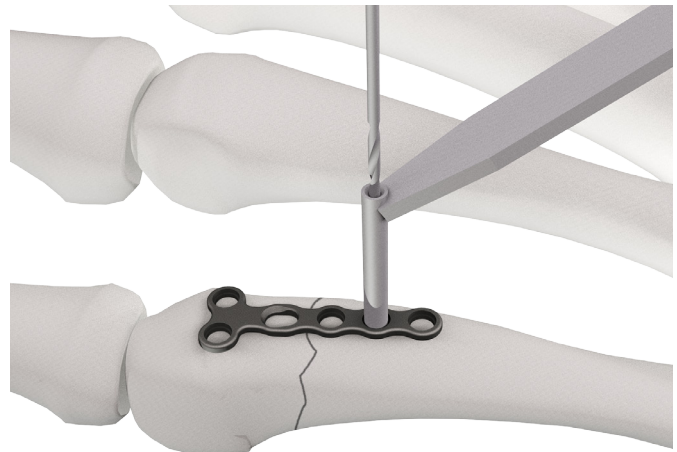
Example of use of a HLS Plate 2 T-Shape 1.0mm on metacarpal bone V.

○ Reduction

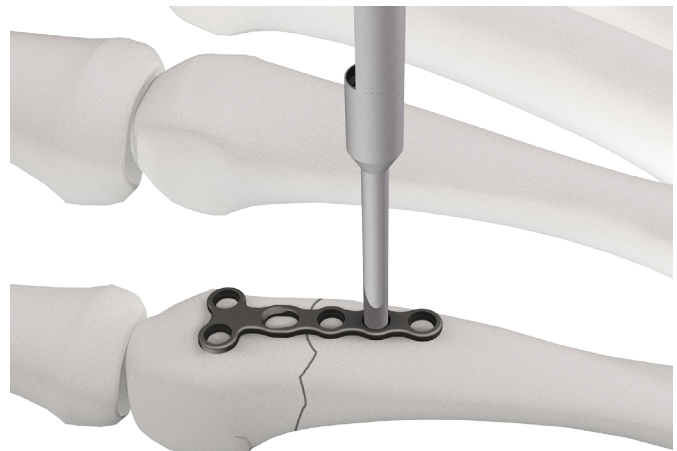
- ◆ Temporary fixation of the fracture parts using forceps
- ◆ Subsequent control under fluoroscopy

○ 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 13).

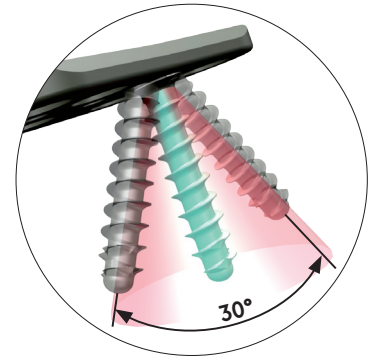
Information

3.

○ 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:

- ◆ $\pm 15^\circ$ and Locking
- ◆ No pre threading
- ◆ No cold welding
- ◆ No debris
- ◆ You can re-set the screw up to 3 times

○ Dotize®

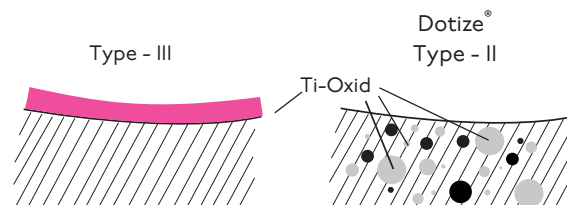
Chemical process - anodization in a strong alkaline solution*

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


○ 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	

○ Order list

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	
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





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