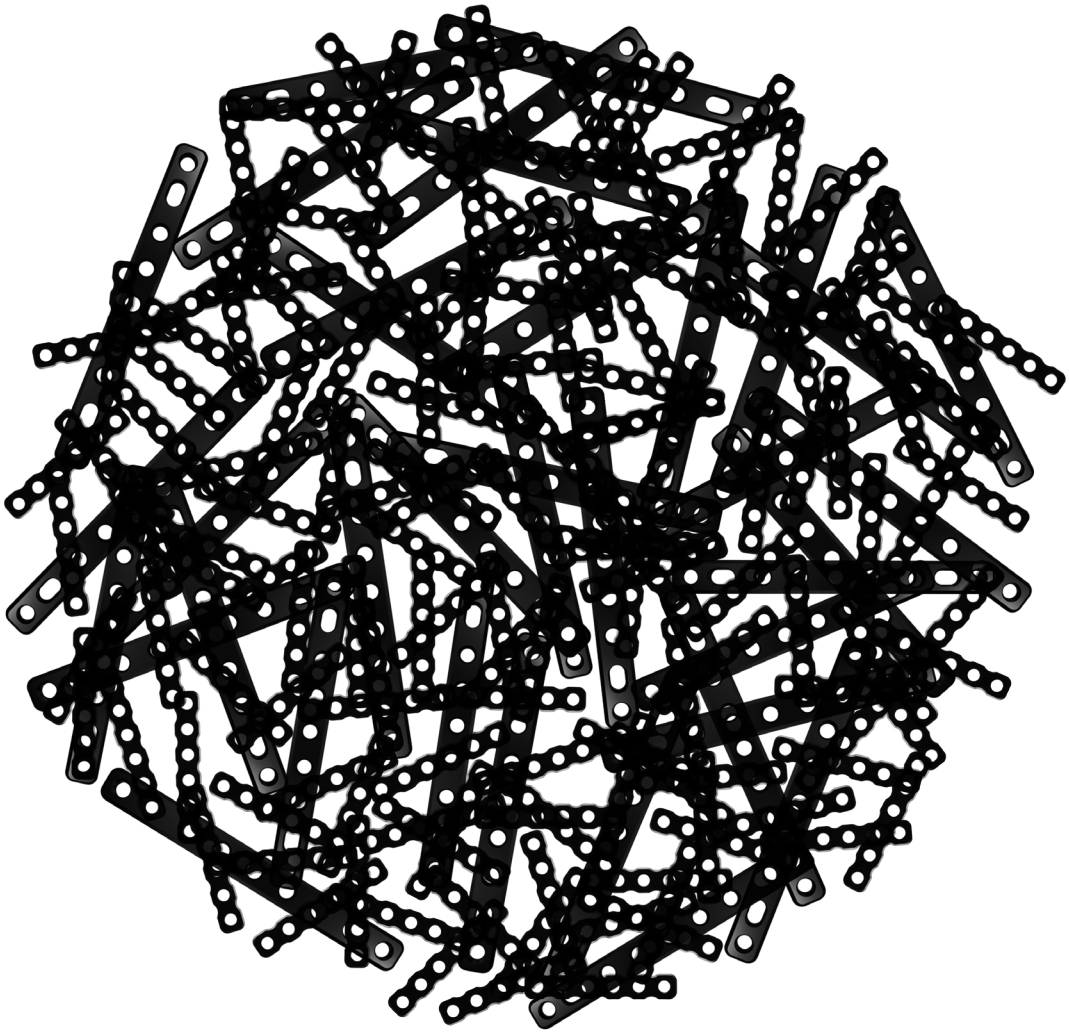
ITS.

Implants
trauma



SLS

Straight 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

1.

Preface

ITS. provides various Straight Locking Plates with different plate strengths and lengths covering a wide range of indications for shaft fractures.

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 oblong hole).

The free choice of screw angulation (+/- 15°, see page 17) provides an advantage in fracture treatment, especially in the case of complex fractures.

Screws Straight Locking Plate 1.5/2.0mm

37351-XX-N	Cortical Screw, locking, D=3.5mm, SH
61273-100	Spiral Drill, D=2.7mm, L=100mm, AO Connector
56252	Screwdriver, WS 2.5, self-holding sleeve

32351-XX	Cortical Screw, D=3.5mm
61273-100	Spiral Drill, D=2.7mm, L=100mm, AO Connector
56252	Screwdriver, WS 2.5, self-holding sleeve

37352-XX-N	Cancellous Screw, locking, D=3.5mm, SH
61203-100	Spiral Drill, D=2.0mm, L=100mm, AO Connector
56252	Screwdriver, WS 2.5, self-holding sleeve

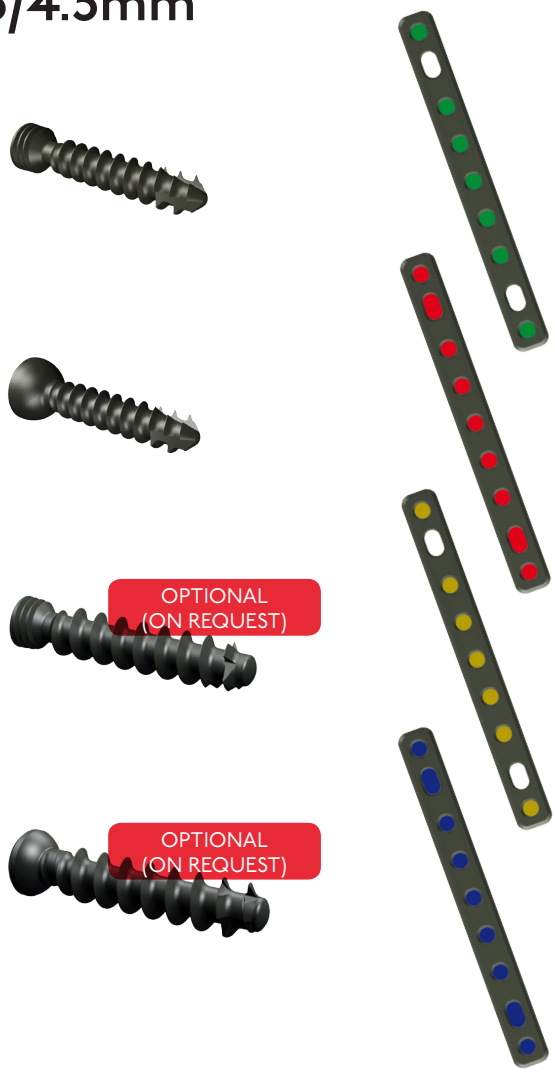
Screws Straight Locking Plate 3.5/4.5mm

37455-XX	Cortical Screw, locking, D=4.5mm
61323-145	Spiral Drill, D=3.2mm, L=145mm, AO Connector
56352-SH	Screwdriver, WS 3.5, conic, self-holding

32455-XX	Cortical Screw, D=4.5mm
61323-145	Spiral Drill, D=3.2mm, L=145mm, AO Connector
56352-SH	Screwdriver, WS 3.5, conic, self-holding

37592-XX	Cancellous Screw, locking, D=5.9mm
61353-110	Spiral Drill, D=3.5mm, L=110mm, AO Connector
56352-SH	Screwdriver, WS 3.5, conic, self-holding

30591-XX	Cancellous Screw, D=5.9mm
61353-110	Spiral Drill, D=3.5mm, L=110mm, AO Connector
56352-SH	Screwdriver, WS 3.5, conic, self-holding



Properties

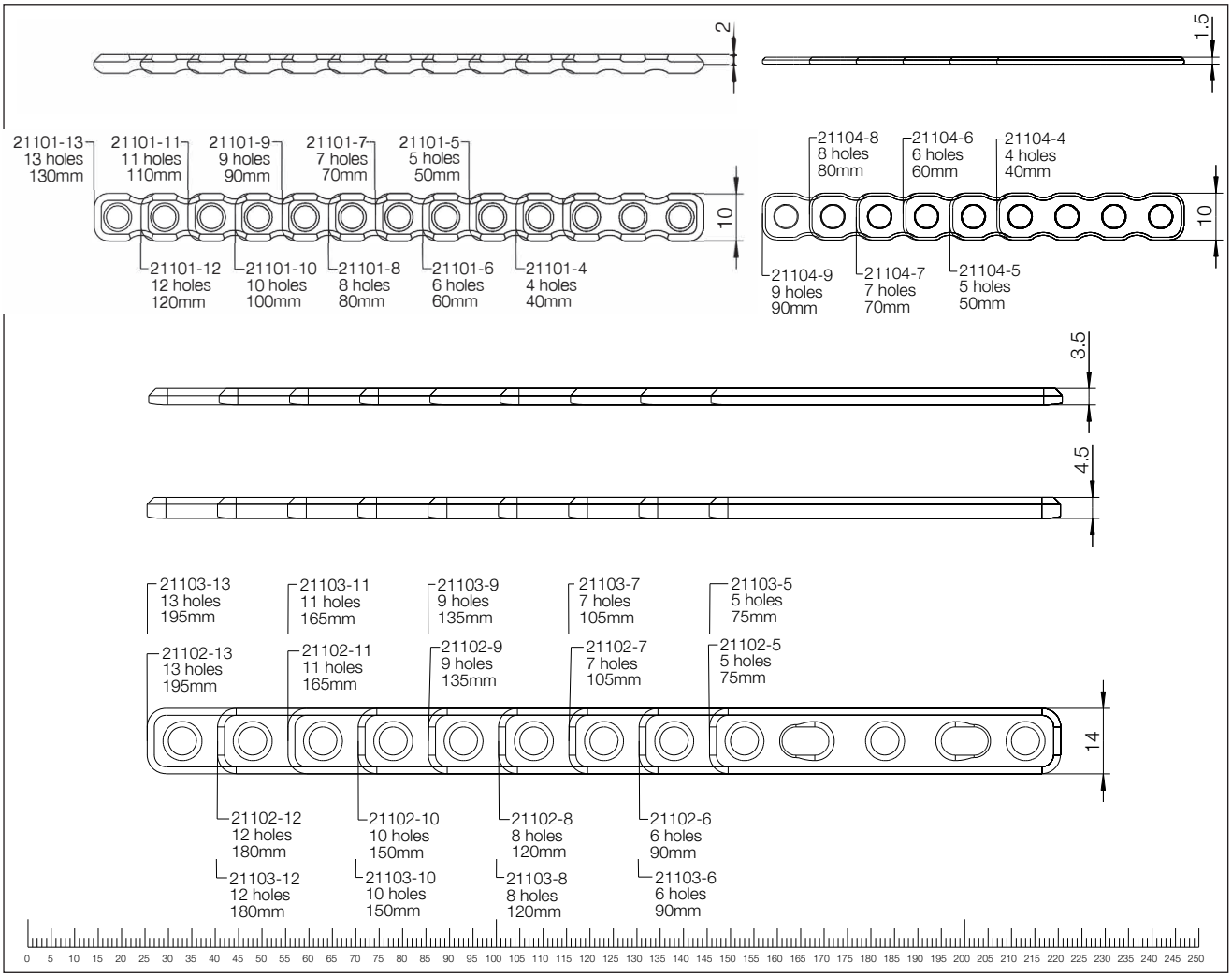
Properties of the material:

- 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
- Anatomical plate design
- Accurate fitting of the plate on the bone
- Plate lenghts, 1.5mm: 4, 5, 6, 7, 8, 9-hole
- Plate lenghts, 2.0mm: 4, 5, 6, 7, 8, 9, 11, 13-hole
- Plate lenghts, 3.5/4.5mm: 5, 6, 7, 8, 9, 10, 11, 12, 13-hole

- Straight Plate 3.5/4.5mm: Fracture gap compression up to 8mm



Time of operation

- Immediately after trauma or delayed
- After regression of swelling

Pre-operative patient preparation

- General anaesthesia, regional anaesthesia or combination can be used
- Tourniquet/partial deprivation of the blood supply

Exposure

- Intra-operative x-ray fluoroscopy observation is required during the entire procedure
- Incision to the limb subchondral bone fracture site
- Transection of musculature if possible along the course of muscle fibers

Surgical Technique

2.

Straight Locking Plate 1.5mm

Indications:

- The plate should primarily be used to reconstruct an anatomic situation
- Corrective osteotomies

Contraindications:

- The plate is not intended for shaft fractures of large bones such as humerus, femur and tibia
- Advanced osteoporosis
- In case of skin and soft tissue problems
- Existing infections
- Obesity
- Lack of patient compliance

Plate insertion

- Anatomical reduction of the fracture parts
- Temporary fixation of the plate using guide wires
- Subsequent control under fluoroscopy

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

Placement of the screws

Use the drill guide, D=2.7/2.0mm **(62202)** to bore with the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** into the plate holes close to fracture.
Use the screwdriver, WS 2.5, self-holding sleeve **(56252)** to insert D=3.5mm cortical screws **(32351-XX)** of appropriate lengths determined previously with the depth gauge, solid small fragment screws **(59022)**.

Attention: It is recommended that locking screws are not used close to the fracture.

Subsequently, place either D=3.5mm cortical or locking cortical screws **(32351-XX/37351-XX-N)** in plate holes far from fracture.

Finally, control plate position under fluoroscopy.

Straight Locking Plate 2.0mm

Indications:

- The plate should primarily be used to reconstruct an anatomic situation
- Corrective osteotomies

Contraindications:

- The plate is not intended for shaft fractures of large bones such as humerus, femur and tibia
- Advanced osteoporosis
- In case of skin and soft tissue problems
- Existing infections
- Obesity
- Lack of patient compliance

Plate insertion

- Anatomical reduction of the fracture parts
- Temporary fixation of the plate using guide wires
- Subsequent control under fluoroscopy

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

Placement of the screws

Use the drill guide, D=2.7/2.0mm **(62202)** to bore with the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** into the plate holes close to fracture.
Use the screwdriver, WS 2.5, self-holding sleeve **(56252)** to insert D=3.5mm cortical screws **(32351-XX)** of appropriate lengths determined previously with the depth gauge, solid small fragment screws **(59022)**.

Attention: It is recommended that locking screws are not used close to the fracture.

Subsequently, place either D=3.5mm cortical or locking cortical screws **(32351-XX/37351-XX-N)** in plate holes far from fracture.

Finally, control plate position under fluoroscopy.

Straight Locking Plate 3.5/4.5mm

Indications:

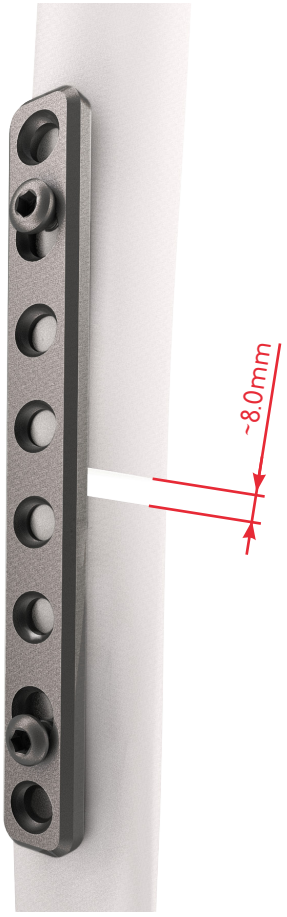
- All diaphyseal fractures, especially when compression for fracture treatment is needed
- Corrective osteotomies

Contraindications:

- Advanced osteoporosis
- In case of skin and soft tissue problems
- Existing infections
- Obesity
- Lack of patient compliance

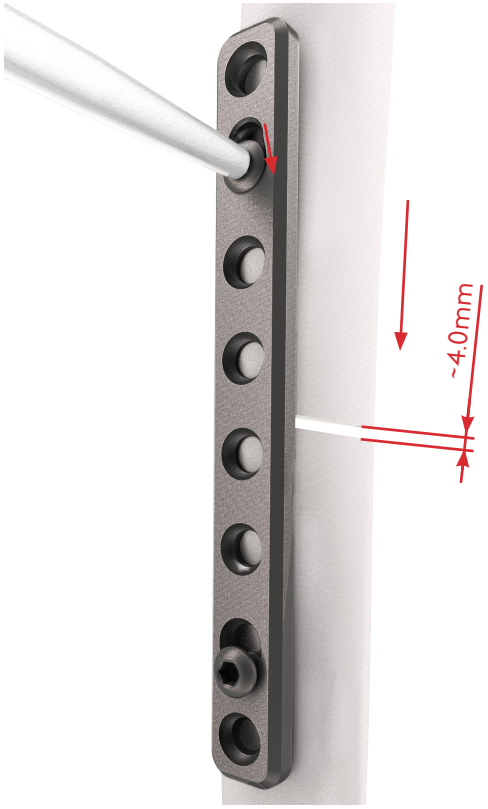
Plate insertion

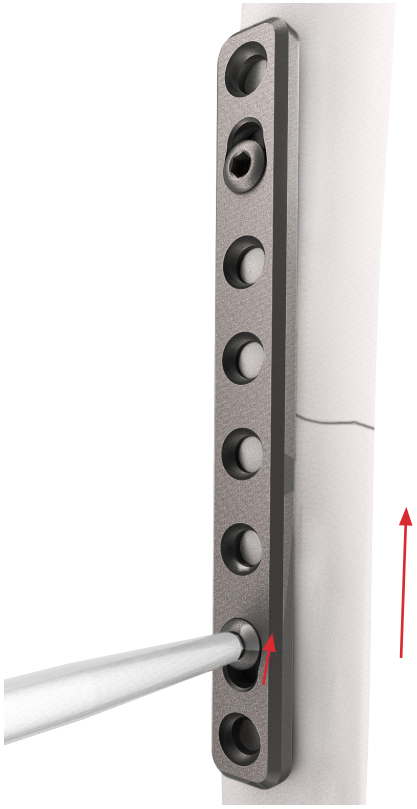
- Anatomical reduction of the fracture parts
- Temporary fixation of the plate using forceps
- Subsequent control under fluoroscopy



Placement of the screws

For compression up to 8mm the D=4.5mm cortical screws or D=5.9mm cancellous screws **(32455-XX/30591-XX)** are used at both sides of the fracture for compression.

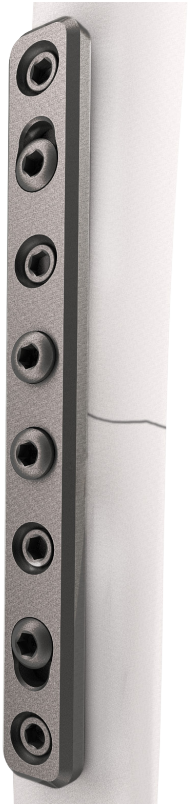




Subsequently, place screws in the remaining plate holes.

Attention: It is recommended that locking screws are not used close to the fracture.

Finally, control plate position under fluoroscopy.



Postoperative treatment

- Drainage is recommended for 12-24 hours to prevent postoperative hematoma is recommended
- Proper bandage dressing for 2 weeks (until the wound heals)
- Physical therapy for 5-7 weeks

- When a locking screw connection has been used, it is necessary to be aware that the diagnosis of a non-union may be very delayed.

Explantation

If desired by the patient, the implant can be removed.
Removal should be performed at the earliest 6 months - 1 1/2 years later or after radiographic verification of the healed bone.

The problem of cold welding was resolved by using a special surface treatment (for further information see page 17).

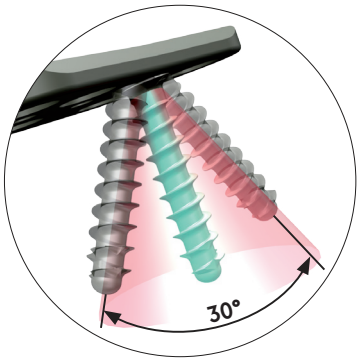
Information

3.

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:

- ± 15° and Locking
- No pre threading
- No cold welding
- No debris
- You can re-set the screw up to 3 times

Dotize®

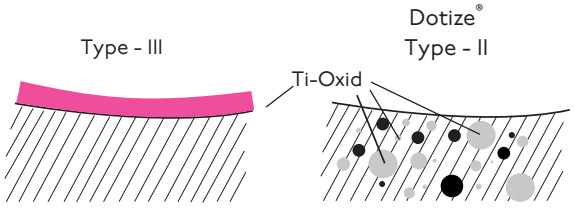
Chemical process - anodization in a strong alkaline solution*

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

* White Paper: Ti6Al4V with Anodization Type II: Biological Behavior and Biomechanical Effects; Axel Baumann, Nils Zander

Order list, Straight Locking Plate 1.5/2.0mm

Straight Plate, 1.5mm, 4-hole	21104-4
Straight Plate, 1.5mm, 5-hole	21104-5
Straight Plate, 1.5mm, 6-hole	21104-6
Straight Plate, 1.5mm, 7-hole	21104-7
Straight Plate, 1.5mm, 8-hole	21104-8
Straight Plate, 1.5mm, 9-hole	21104-9

Straight Plate, 2.0mm, 4-hole	21101-4
Straight Plate, 2.0mm, 5-hole	21101-5
Straight Plate, 2.0mm, 6-hole	21101-6
Straight Plate, 2.0mm, 7-hole	21101-7
Straight Plate, 2.0mm, 8-hole	21101-8
Straight Plate, 2.0mm, 9-hole	21101-9
Straight Plate, 2.0mm, 11-hole	21101-11
Straight Plate, 2.0mm, 13-hole	21101-13

Instruments and Screws, Straight Plate 1.5/2.0mm

Cortical Screw, D=3.5mm, L=10mm	32351-10
Cortical Screw, D=3.5mm, L=12mm	32351-12
Cortical Screw, D=3.5mm, L=14mm	32351-14
Cortical Screw, D=3.5mm, L=16mm	32351-16
Cortical Screw, D=3.5mm, L=18mm	32351-18
Cortical Screw, D=3.5mm, L=20mm	32351-20
Cortical Screw, D=3.5mm, L=22mm	32351-22
Cortical Screw, D=3.5mm, L=24mm	32351-24

Cortical Screw, Locking, D=3.5mm, L=12mm, SH	37351-12-N
Cortical Screw, Locking, D=3.5mm, L=14mm, SH	37351-14-N
Cortical Screw, Locking, D=3.5mm, L=16mm, SH	37351-16-N
Cortical Screw, Locking, D=3.5mm, L=18mm, SH	37351-18-N
Cortical Screw, Locking, D=3.5mm, L=20mm, SH	37351-20-N
Cortical Screw, Locking, D=3.5mm, L=22mm, SH	37351-22-N
Cortical Screw, Locking, D=3.5mm, L=24mm, SH	37351-24-N

Screwdriver, WS 2.5, self-holding sleeve	56252

Spiral Drill, D=2.7mm, L=100mm, AO Connector	61273-100

Depth Gauge, Solid Small Fragment Screws	59022

Drill Guide, D=2.7/2.0mm	62202

Sterilization Tray, Straight Plate 1.5mm	50250
Sterilization Tray, Straight Plate 2.0mm	50251

Optional (on request)

Temporary Plate Holder	58164-150

Trays

Order list, Straight Locking Plate 3.5/4.5mm

Straight Plate, 3.5mm, 5-hole	21102-5
Straight Plate, 3.5mm, 6-hole	21102-6
Straight Plate, 3.5mm, 7-hole	21102-7
Straight Plate, 3.5mm, 8-hole	21102-8
Straight Plate, 3.5mm, 9-hole	21102-9
Straight Plate, 3.5mm, 10-hole	21102-10
Straight Plate, 3.5mm, 11-hole	21102-11
Straight Plate, 3.5mm, 12-hole	21102-12
Straight Plate, 3.5mm, 13-hole	21102-13

Straight Plate, 4.5mm, 5-hole	21103-5
Straight Plate, 4.5mm, 6-hole	21103-6
Straight Plate, 4.5mm, 7-hole	21103-7
Straight Plate, 4.5mm, 8-hole	21103-8
Straight Plate, 4.5mm, 9-hole	21103-9
Straight Plate, 4.5mm, 10-hole	21103-10
Straight Plate, 4.5mm, 11-hole	21103-11
Straight Plate, 4.5mm, 12-hole	21103-12
Straight Plate, 4.5mm, 13-hole	21103-13

Cortical Screw, D=4.5mm, L=16mm	32455-16
Cortical Screw, D=4.5mm, L=20mm	32455-20
Cortical Screw, D=4.5mm, L=24mm	32455-24
Cortical Screw, D=4.5mm, L=28mm	32455-28
Cortical Screw, D=4.5mm, L=32mm	32455-32
Cortical Screw, D=4.5mm, L=36mm	32455-36
Cortical Screw, D=4.5mm, L=40mm	32455-40
Cortical Screw, D=4.5mm, L=44mm	32455-44
Cortical Screw, D=4.5mm, L=48mm	32455-48

Cortical Screw, Locking, D=4.5mm, L=16mm	37455-16
Cortical Screw, Locking, D=4.5mm, L=20mm	37455-20
Cortical Screw, Locking, D=4.5mm, L=24mm	37455-24
Cortical Screw, Locking, D=4.5mm, L=28mm	37455-28
Cortical Screw, Locking, D=4.5mm, L=32mm	37455-32
Cortical Screw, Locking, D=4.5mm, L=36mm	37455-36
Cortical Screw, Locking, D=4.5mm, L=40mm	37455-40
Cortical Screw, Locking, D=4.5mm, L=44mm	37455-44
Cortical Screw, Locking, D=4.5mm, L=48mm	37455-48

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

Screwdriver, WS 3.5, Conic, self-holding	56352-SH	
Spiral Drill, D=3.2mm, L=145mm, AO Connector Spiral Drill, D=3.5mm, L=110mm, AO Connector	61323-145 61353-110	
Depth Gauge, Solid Small Fragment Screws	59022	
Drill Guide, D=2.5/3.5mm	62252	
Sterilization Tray, Straight Plate 3.5/4.5mm	50223	

Trays

Notes

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