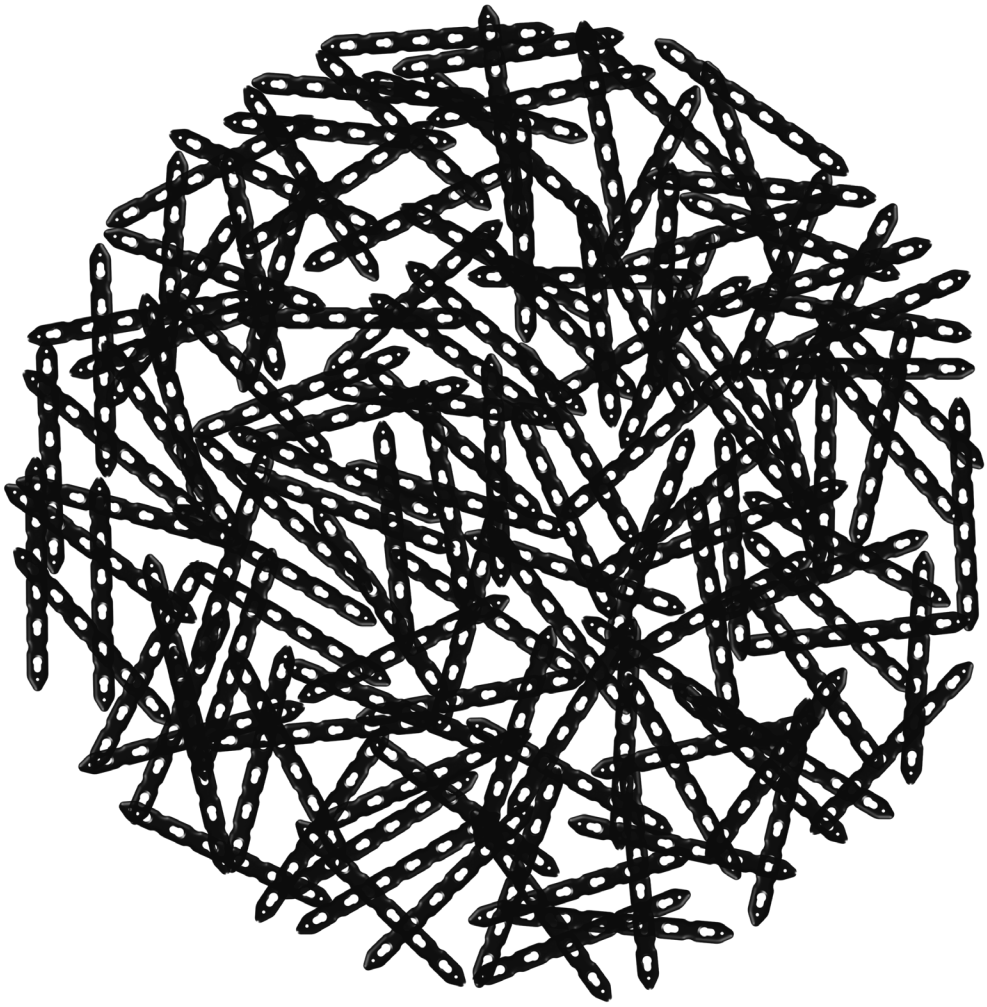
ITS.

Implants
trauma



SCL

Straight Compression Locking Plate

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.

Contents

1. Introduction

2. Surgical Technique

3. Information

Introduction

1.

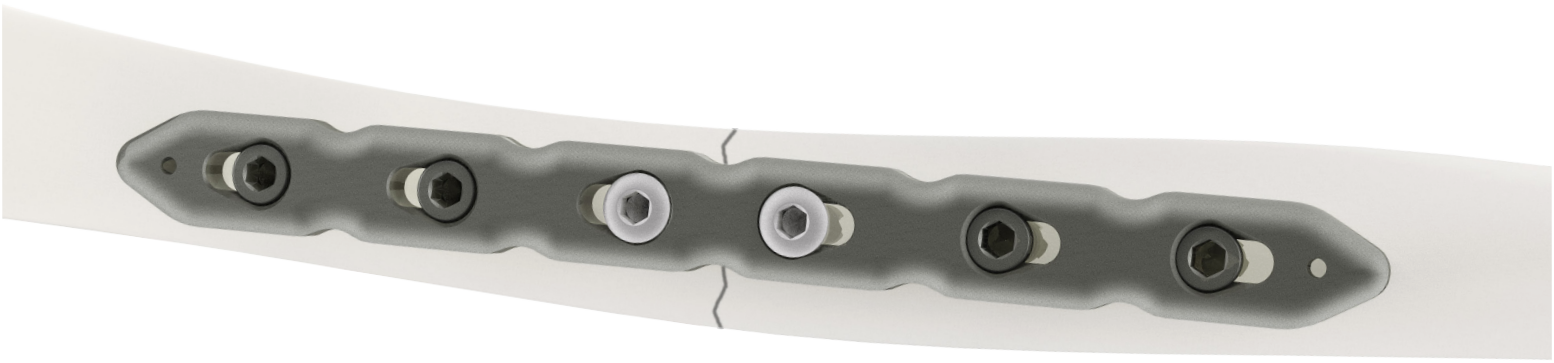
Preface

The special feature of this implant is its compression hole.

Due to an innovative technology it is possible to compress a fracture gap up to 7mm.

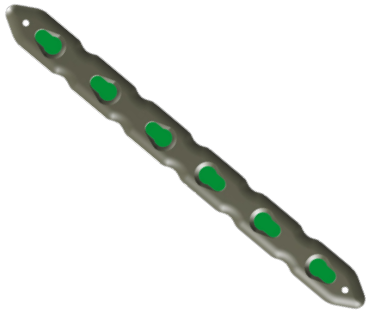
A special design of the compression hole enables the use of a locking screw, which locks automatically after the full distance of compression.

Indentations on the rear side of the plate for protection of the periosteum.



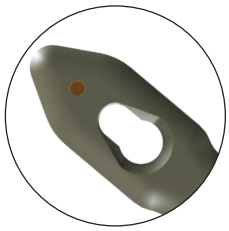
Screws

37351-XX-N-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

35164-150	Guide wire, steel, D=1.6mm, L=150mm, TR, w. thread



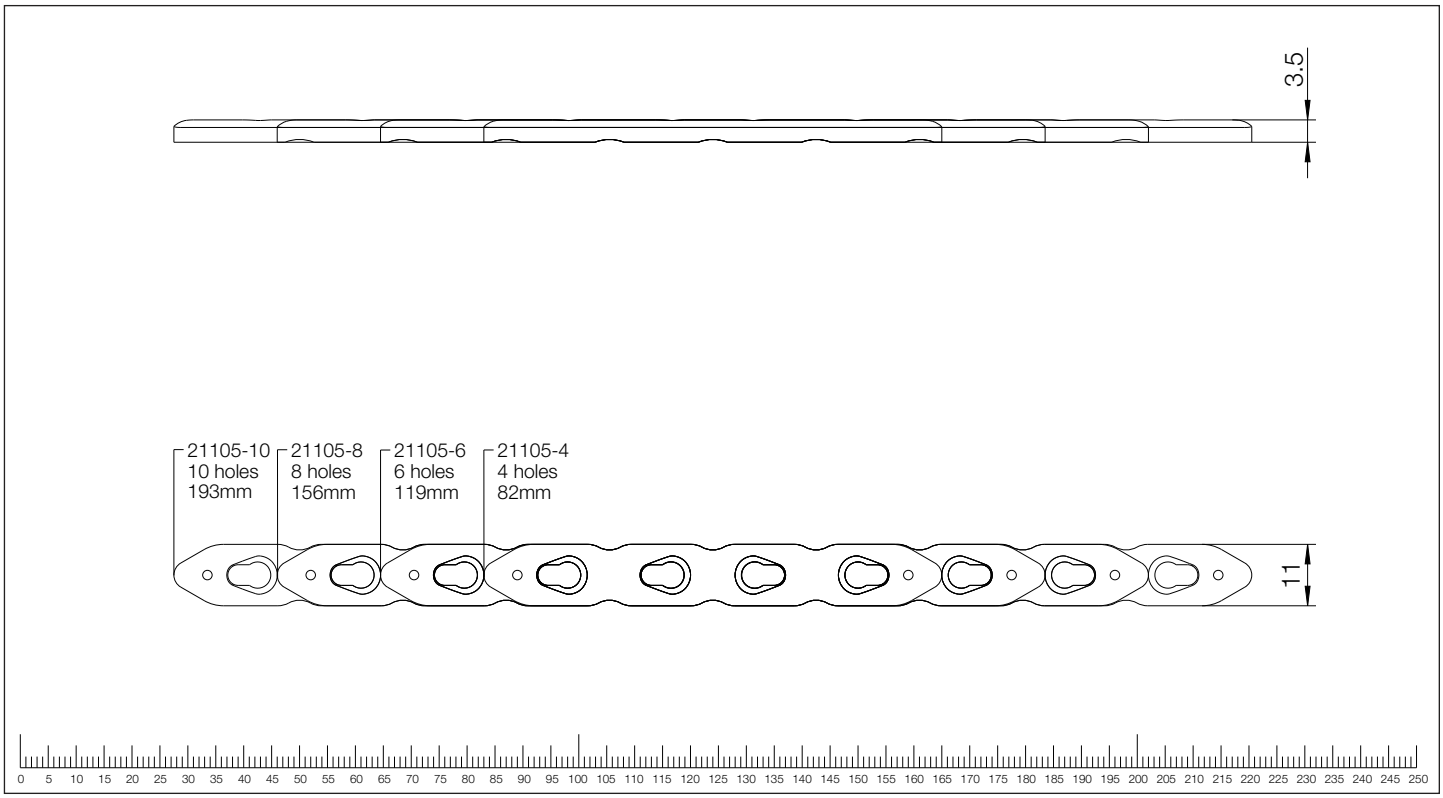
Properties

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
- Indentations on the rear side of the plate for protection of the periosteum
- Anatomical plate design
- K-Wire holes for preliminary plate fixation
- Fracture gap compression up to 7mm
- Plate lengths: 4, 6, 8, 10-hole
  Optional: 5, 7-hole



Indications, Contraindications & Time of operation

Indications:

- The plate should primarily be used to reconstruct an anatomic situation
- Corrective osteotomies
- Comminuted fractures, supercondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, nonunions, and malunions. And as well, a fracture or osteotomy of the tibia, fibula, femoral, condyle, acetabulum, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; hip arthrodesis, and provisional hole fixation.

Contraindications:

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

Time of operation:

- Within the first hours after trauma
- After swelling decreases

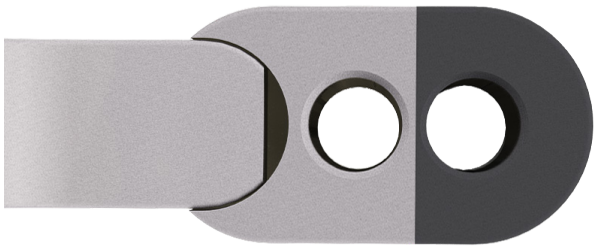
Surgical Technique

2.

Drill Guide

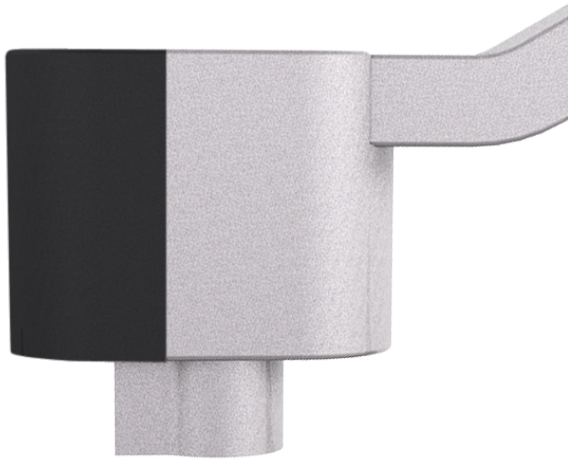
Properties:

- Two drill holes for free choice of using compression or static fixation
- Special design of drill guide enables centric placement in the plate hole



Hole close to handle for drilling a fixation screw

Dark grey marked hole for drilling a compression screw



Asymmetric centering assistance for easy placement in the plate hole

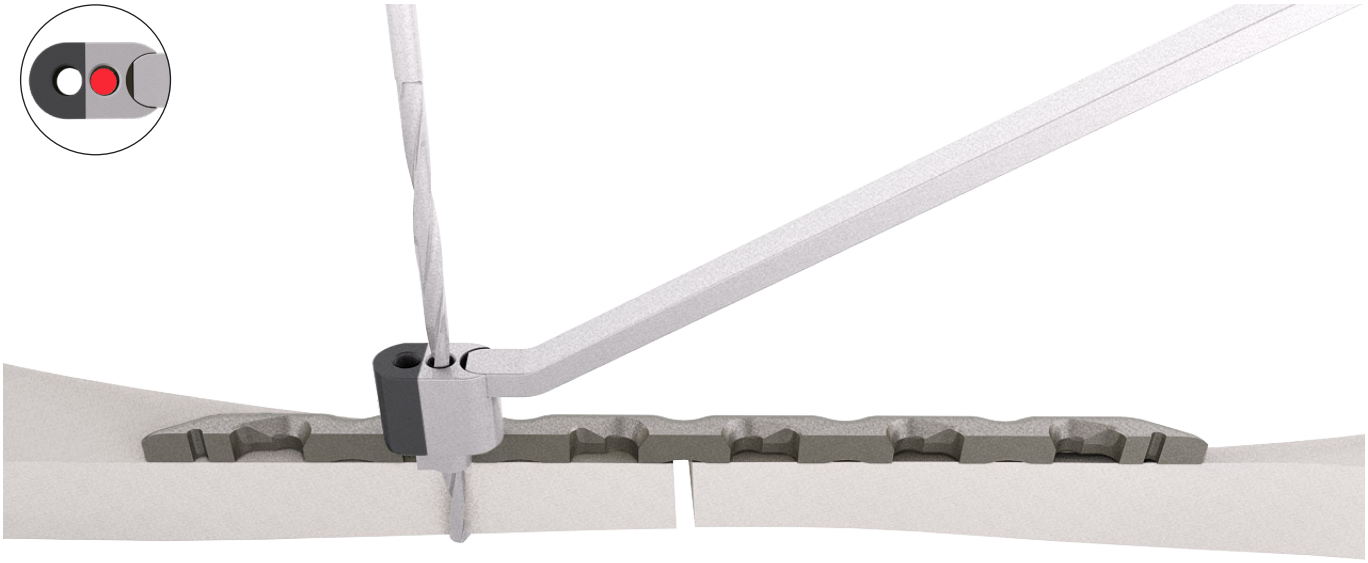
Implantation

- Prepare the patient with a general or regional anesthetic to the affected limb and use a pneumatic (tourniquet) for partial deprivation of the blood supply.
- During the procedure, observe (using intra-operative x-ray fluoroscopy) the fractured bone segment area(s).
- Make the proper incision to the limb subchondral bone fracture site.
- Proceed with transection of musculature if possible along the course of muscle fibers.
- Reduce and align fracture segments using bone holding forceps.

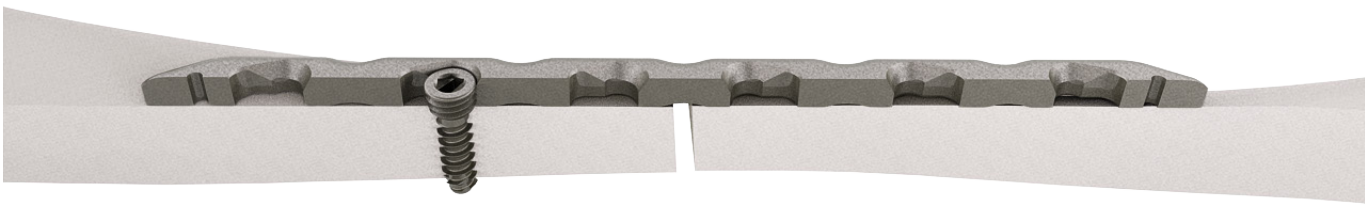
Compression 0 - 3.5mm

For the compression up to 3.5mm, a D=3.5mm cortical screw **(32351-XX)** and the D=3.5mm locking cortical screw **(37351-XX-N)** are placed on one side of the fracture for fixation of the plate on the bone. Always place a cortical (non-locking) screw in the hole closest to the fracture.

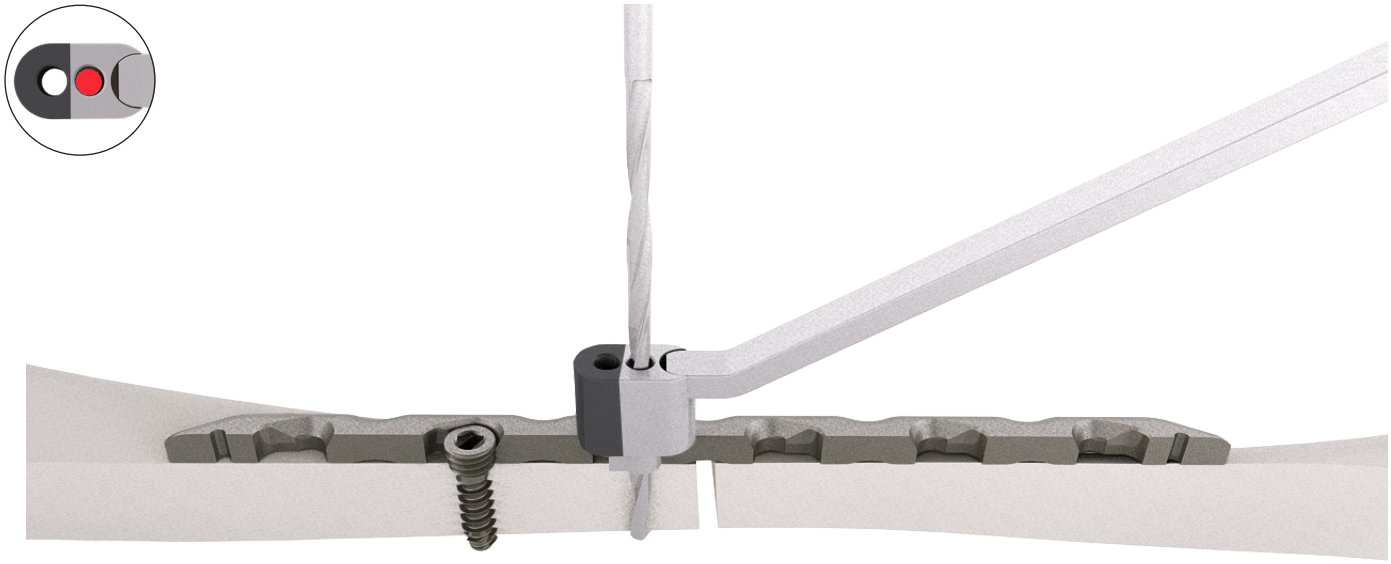
Attach the drill guide, D=2.7mm **(62216)** in any plate hole. Use the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** to drill through the hole close to handle of the drill guide.



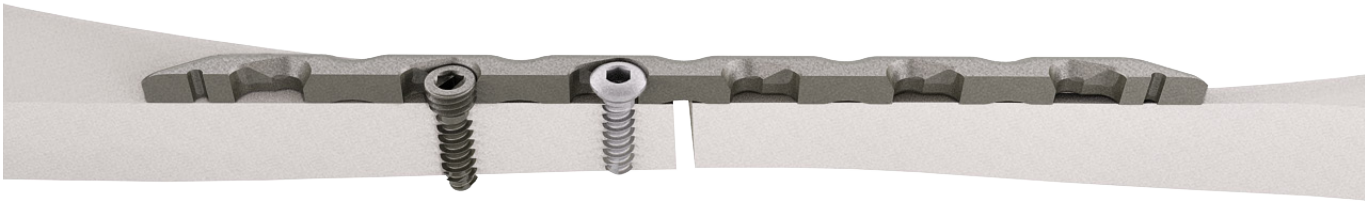
In accordance with the measured length, a D=3.5mm locking cortical screw **(37351-XX-N)** is placed.



Use the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** to drill through the hole close to handle of the drill guide, D=2.7mm **(62216)** in the plate hole near the fracture.

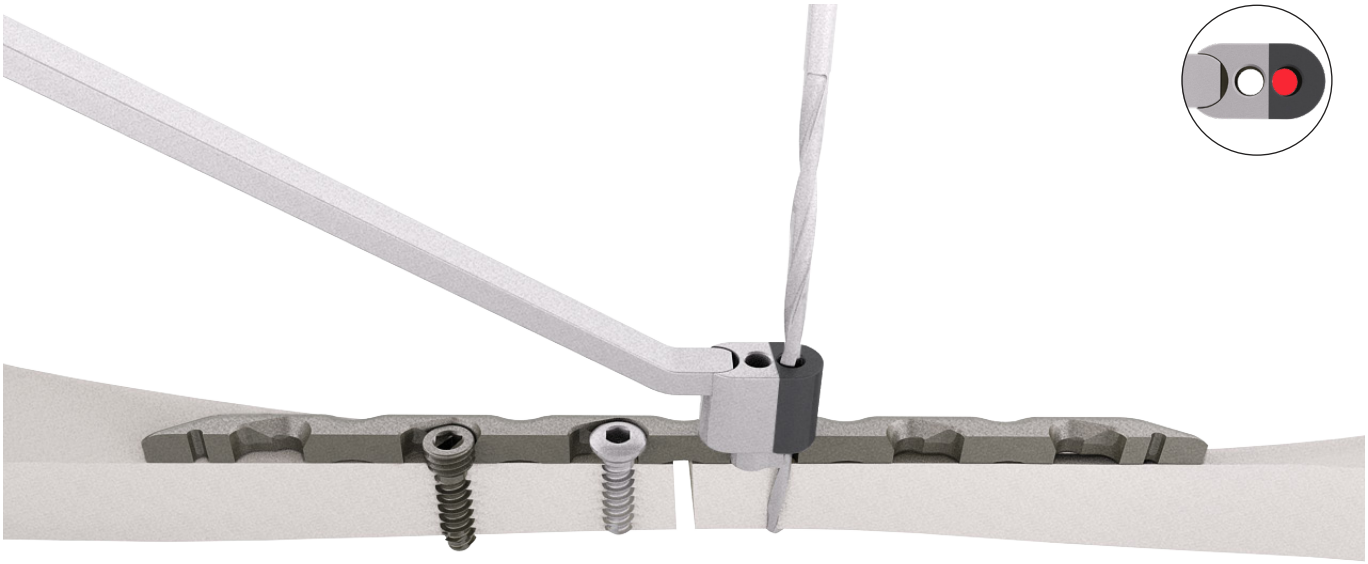


In accordance with the measured length, a D=3.5mm cortical screw **(32351-XX)** is placed.

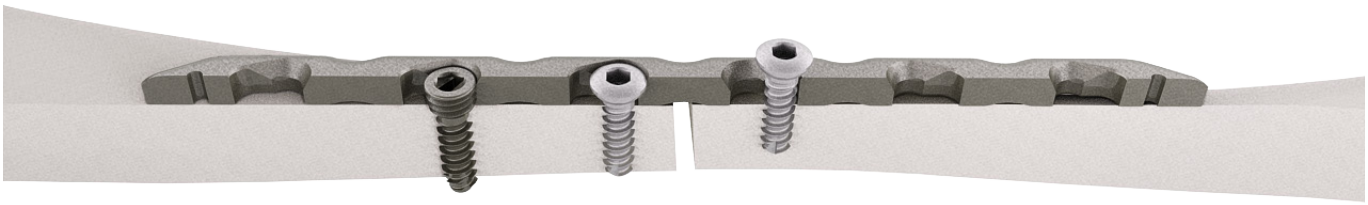


On the other side of the fracture, the D=3.5mm cortical screw **(32351-XX)** and the D=3.5mm locking cortical screw **(37351-XX-N)** are placed for compression.

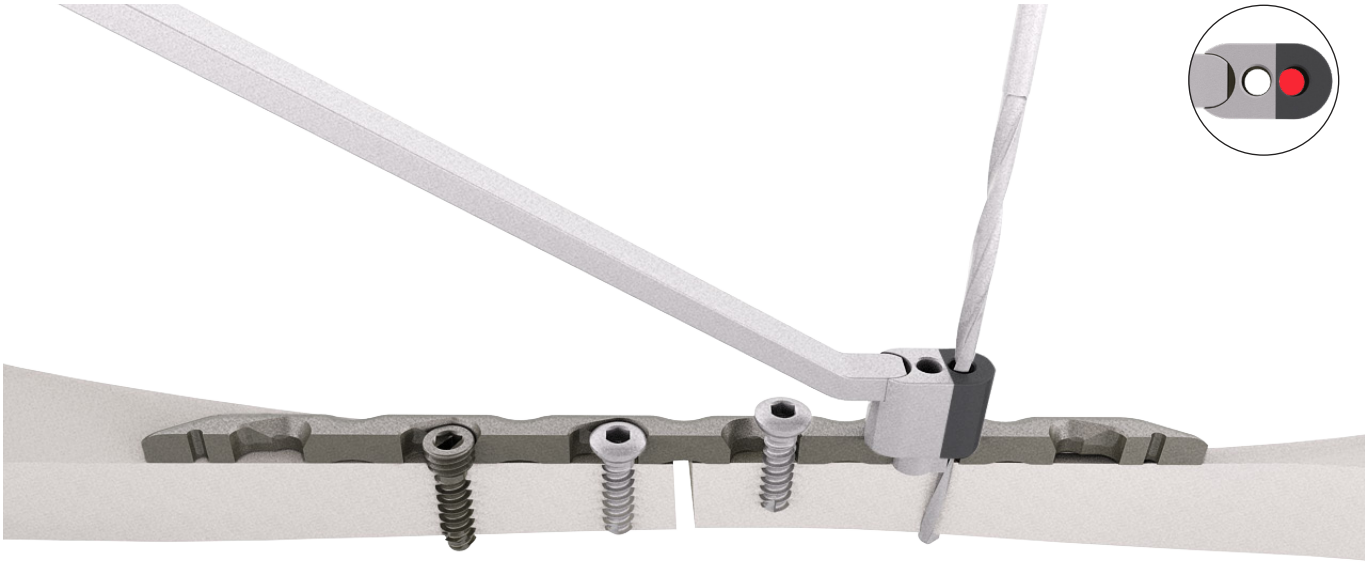
Attach the drill guide **(62216)** in the opposite plate hole. Use the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** to drill through the dark gray marked hole of the drill guide, D=2.7mm **(62216)**.



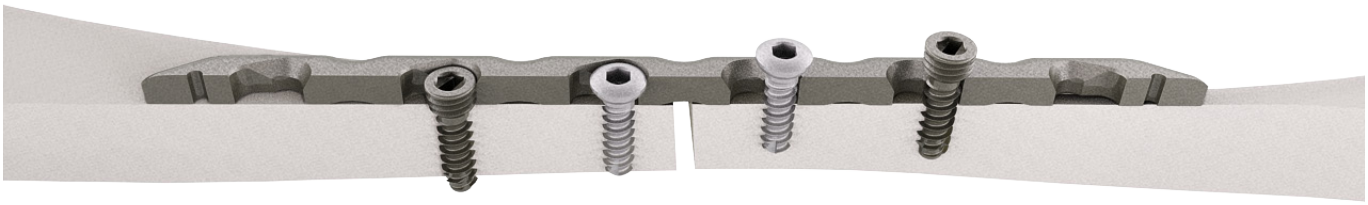
In accordance with the measured length, a D=3.5mm cortical screw **(32351-XX)** is placed half way down as it is used as a guide screw during the compression.



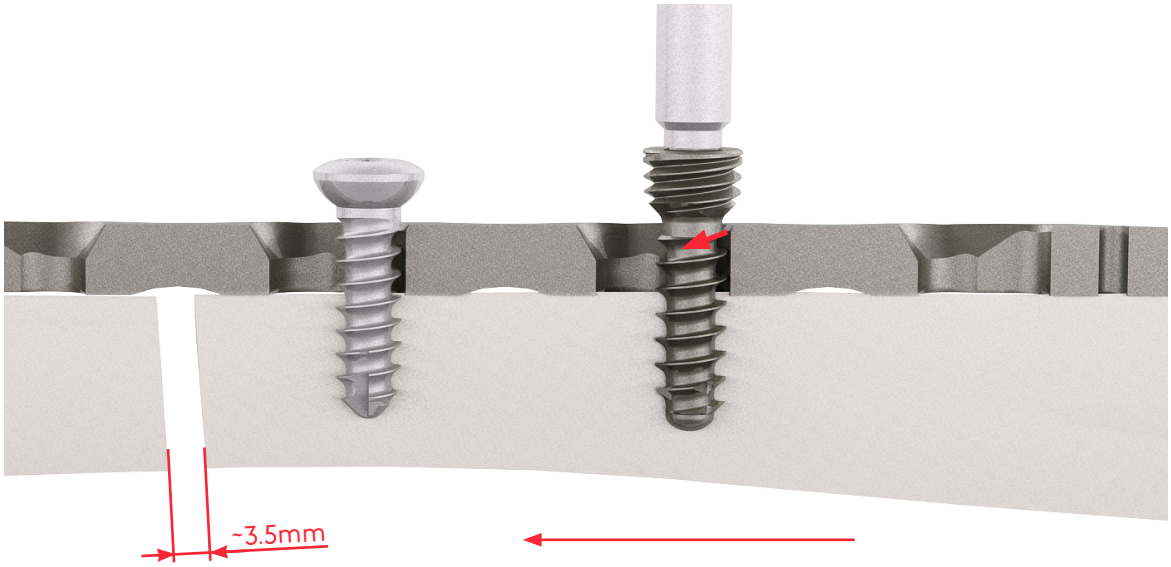
Attach the drill guide **(62216)** in the adjacent plate hole. Use the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** to drill through the dark gray marked hole of the drill guide, D=2.7mm **(62216)**.

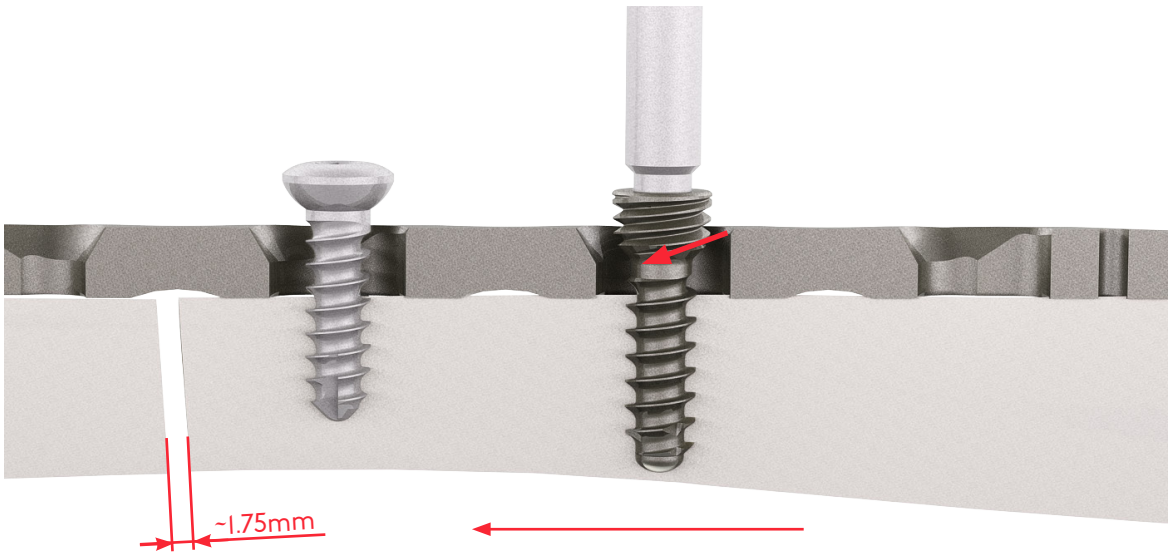


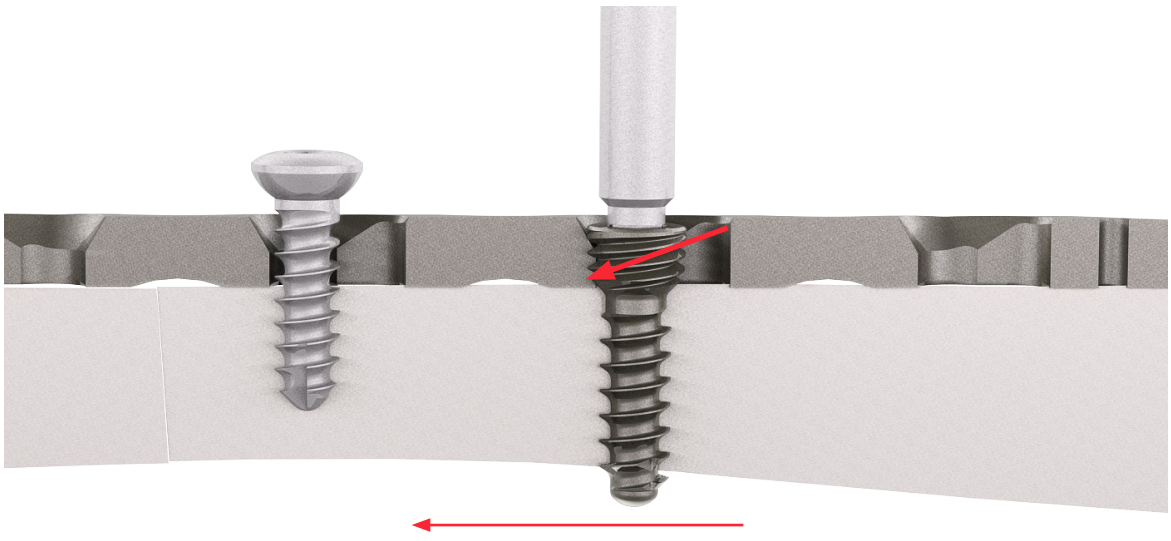
In accordance with the measured length, a D=3.5mm locking cortical screw **(3735I-XX-N)** is placed half way down.



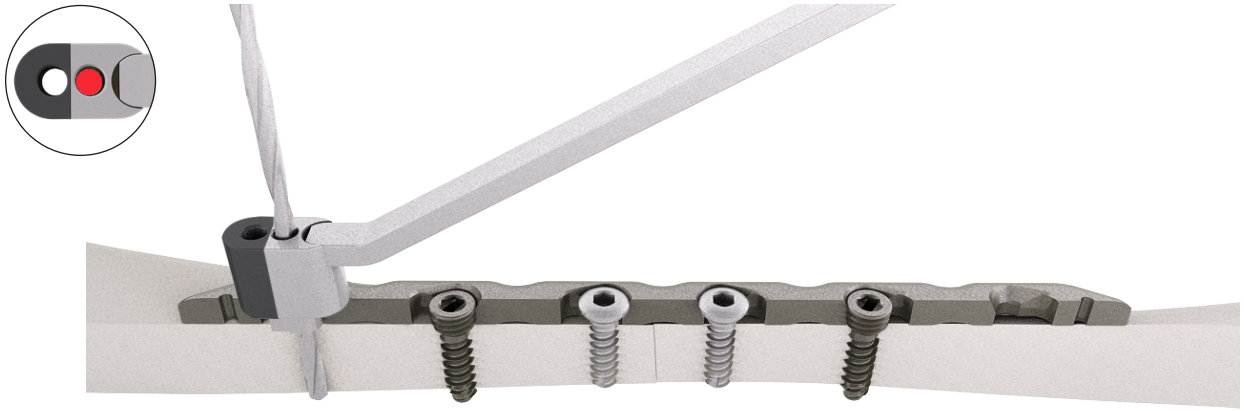
During screwing in the D=3.5mm locking cortical screw **(3735I-XX-N)**, compression is exerted to the fracture gap (see pictures below).





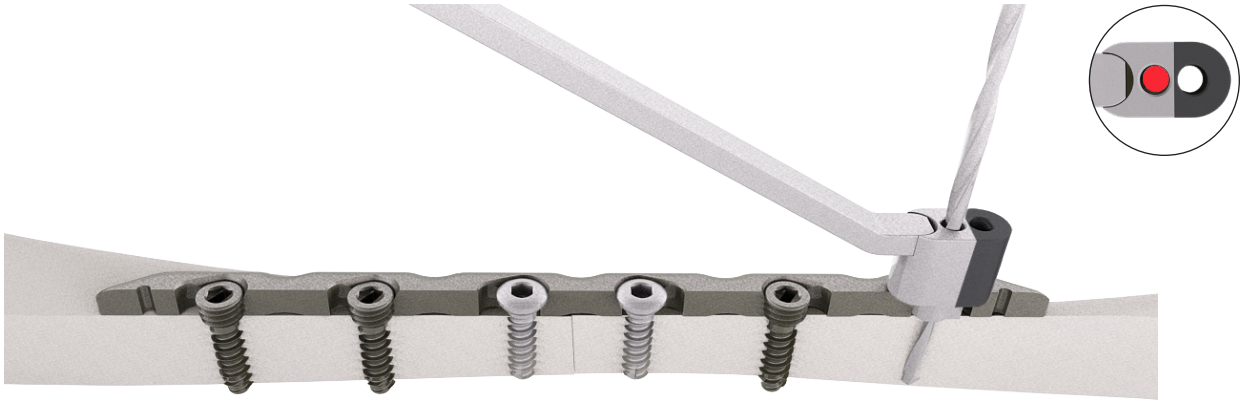


Afterwards, attach the drill guide, D=2.7mm **(62216)** to the furthest left plate hole. Use the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** to drill through the hole closest to handle of the drill guide.



In accordance with the measured length, a D=3.5mm locking cortical screw **(37351-XX-N)** is placed.

Attach the drill guide, D=2.7mm **(62216)** to the furthest right plate hole. Use the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** to drill through the hole close to handle of the drill guide.

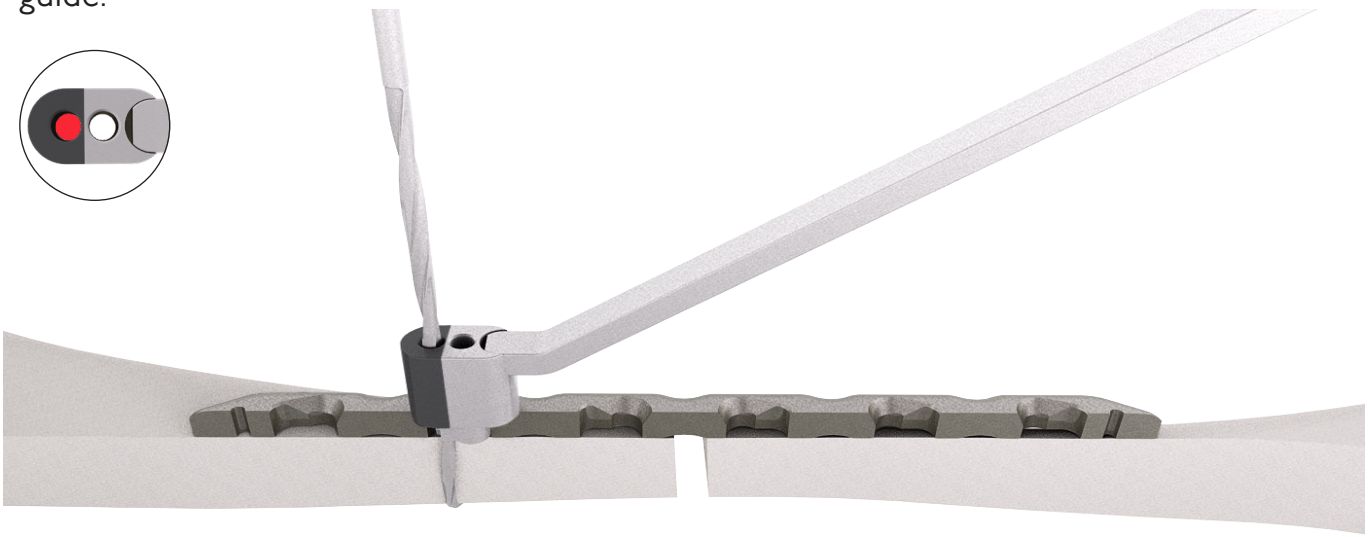


In accordance with the measured length a D=3.5mm locking cortical screw **(37351-XX-N)** is placed.
Finally, check the compression and the plate position with the fluoroscopy.

Compression 0 - 7mm

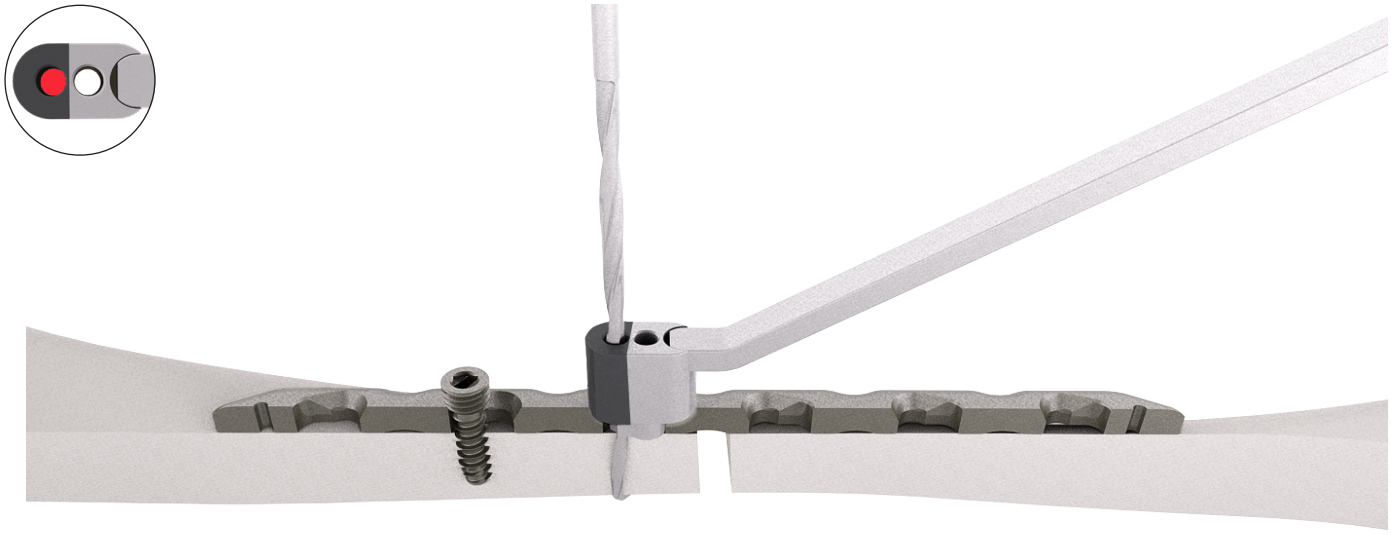
For the compression up to 7mm, the D=3.5mm locking cortical screws **(37351-XX-N)** are used at both sides of the fracture for compression. The D=3.5mm cortical screws **(32351-XX)** and the D=3.5mm locking cortical screws **(37351-XX-N)** in both plate holes farthest to the fracture are for fixation.

Attach the drill guide, D=2.7mm **(62216)** in any plate hole. Use the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** to drill through the dark gray marked hole of the drill guide.

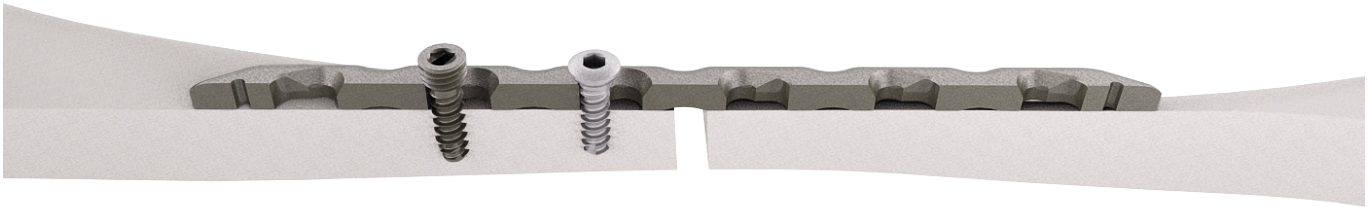


In accordance with the measured length, a D=3.5mm locking cortical screw **(37351-XX-N)** is placed half way down (screw head may not have contact to the plate).

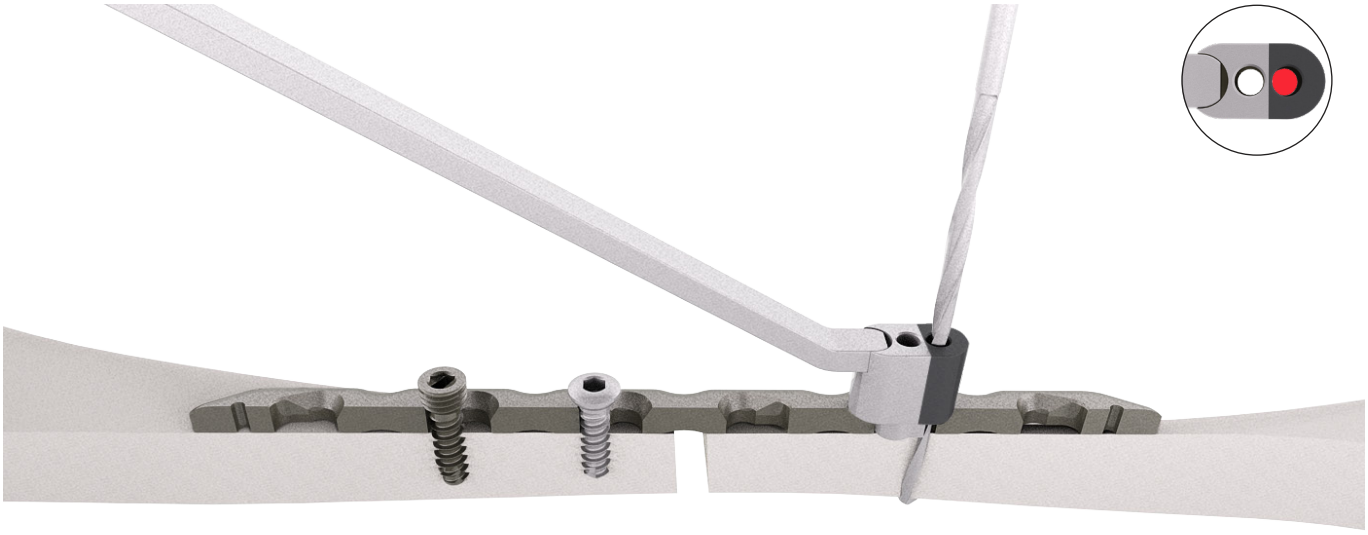
Use the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** to drill through the dark gray marked hole of the drill guide, D=2.7mm **(62216)** in the plate hole near the fracture.



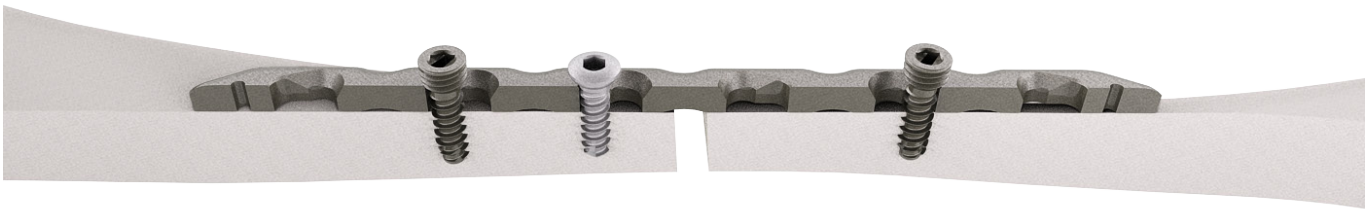
In accordance to the measured length, a D=3.5mm cortical screw **(32351-XX)** is placed half way down.



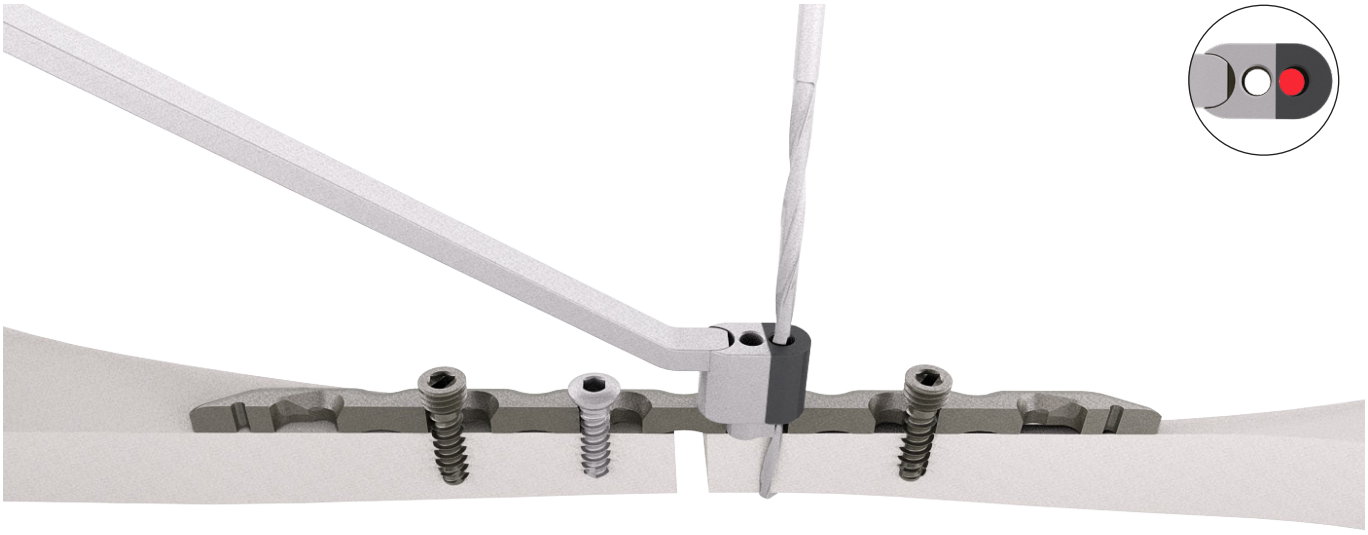
Attach the drill guide, D=2.7mm **(62216)** in the opposite plate hole. Use the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** to drill through the dark gray marked hole of the drill guide.



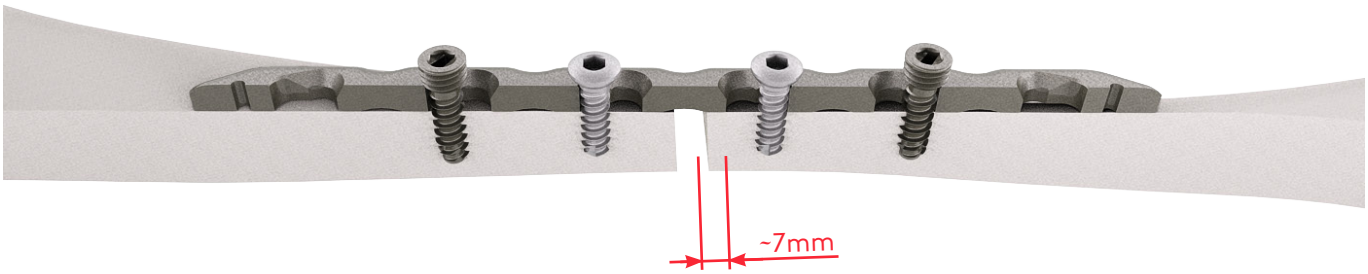
In accordance with the measured length, a D=3.5mm locking cortical screw **(37351-XX-N)** is placed half way down (screw head may not have contact with the plate).



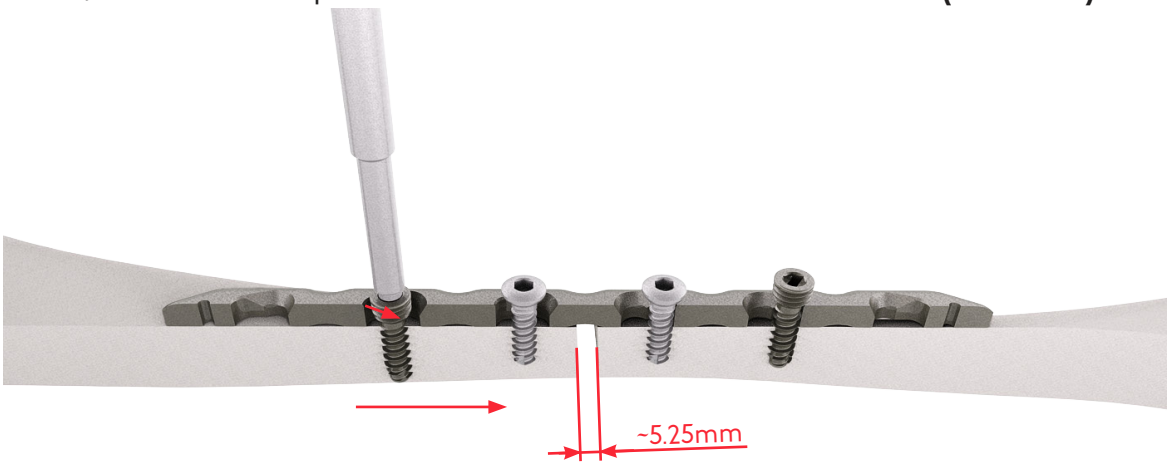
Use the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** to drill through the dark gray marked hole of the drill guide, D=2.7mm **(62216)** in the plate hole near the fracture.

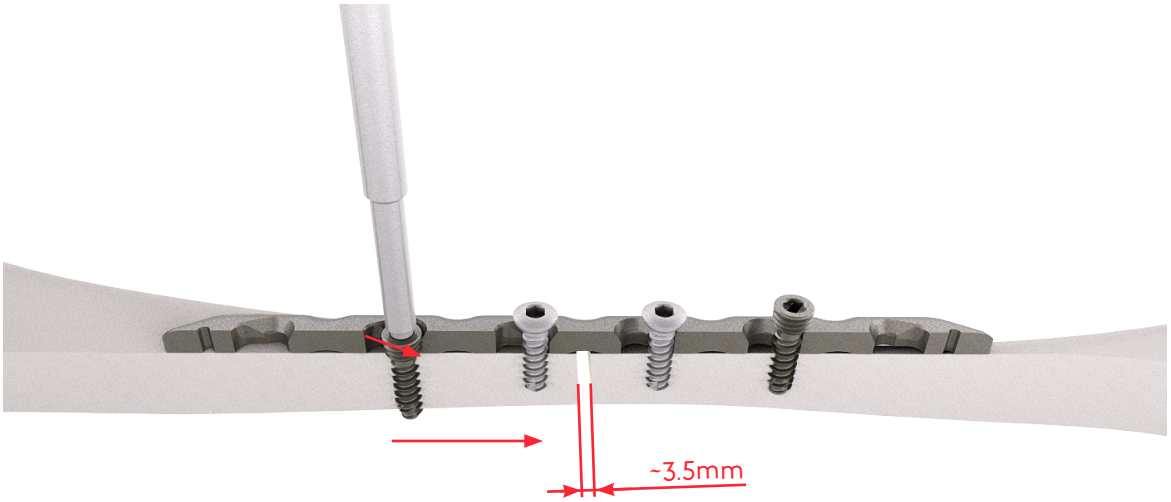


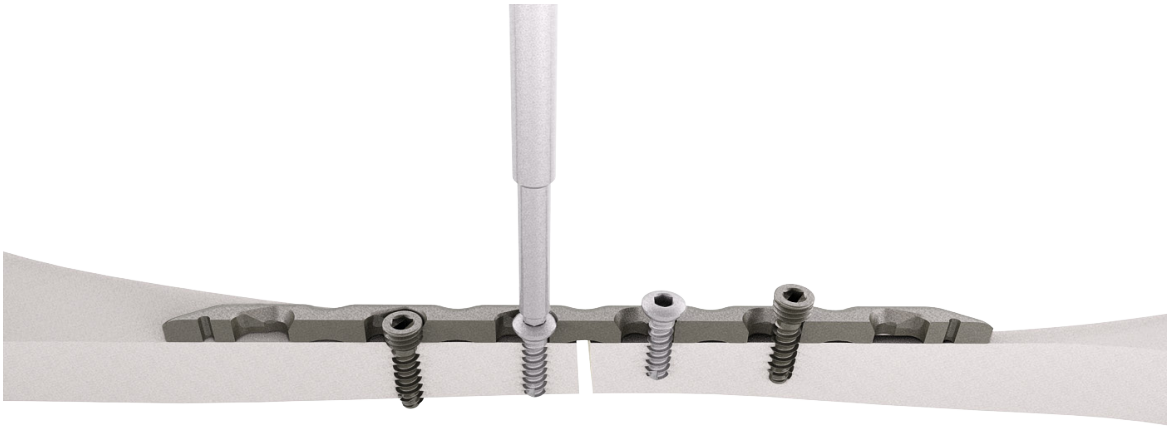
In accordance with the measured length, a D=3.5mm cortical screw **(32351-XX)** is placed half way down.



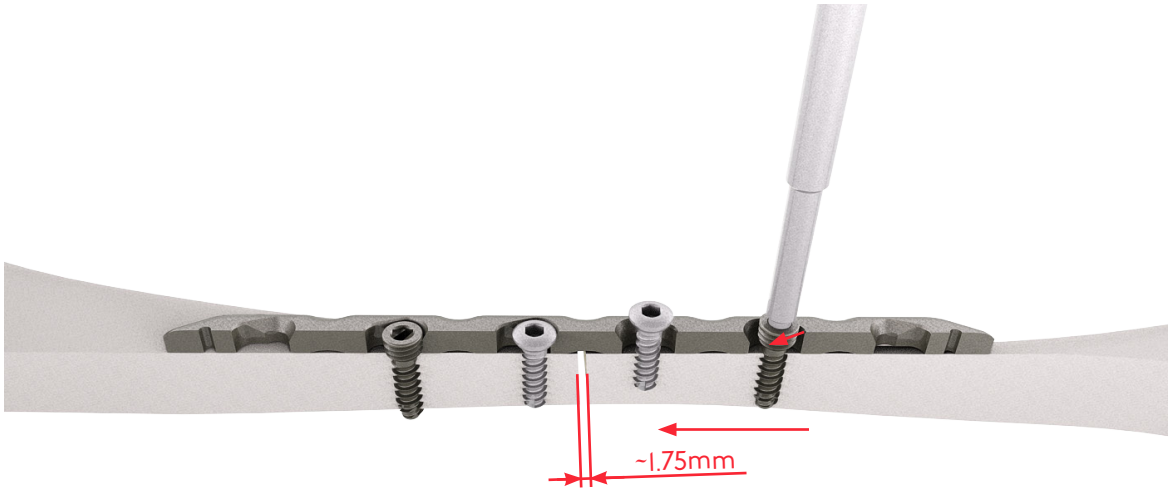
At a fracture gap up to 7mm, the compression occurs at both sides of the fracture. First screw in the D=3.5mm locking cortical screw **(37351-XX-N)**.
Afterwards, fixate the compression with the D=3.5mm cortical screw **(32351-XX)**.

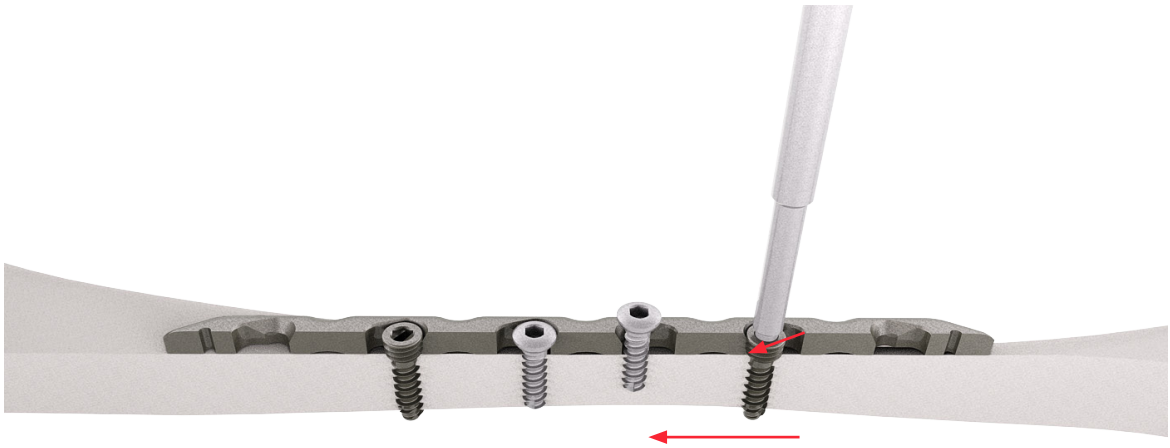


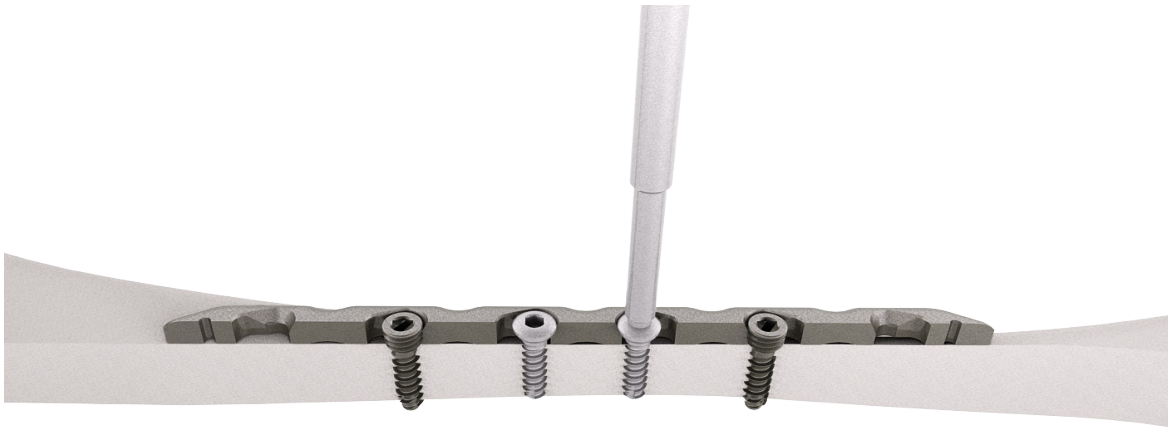




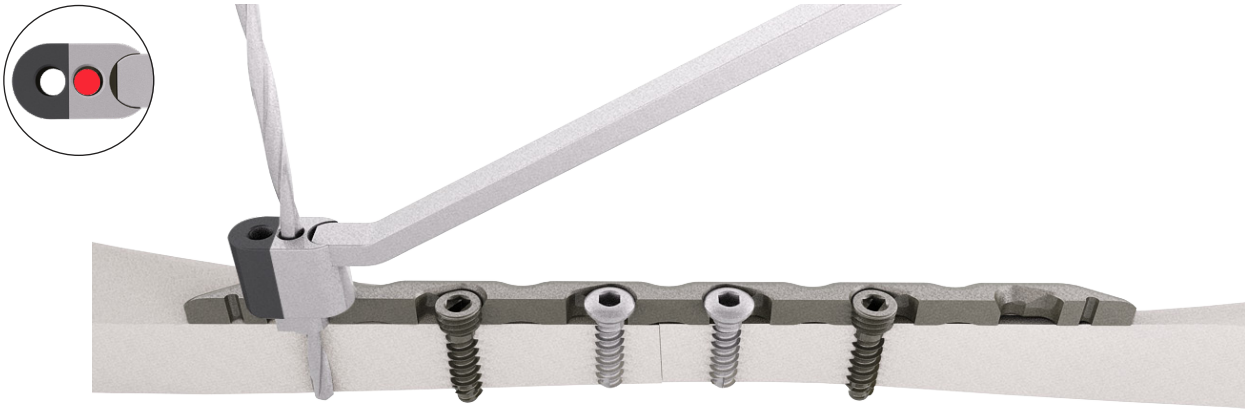
Afterwards, screw in the D=3.5mm locking cortical screw **(37351-XX-N)**. Then turn in the D=3.5mm cortical screw **(32351-XX)** to fixate the completed compression.





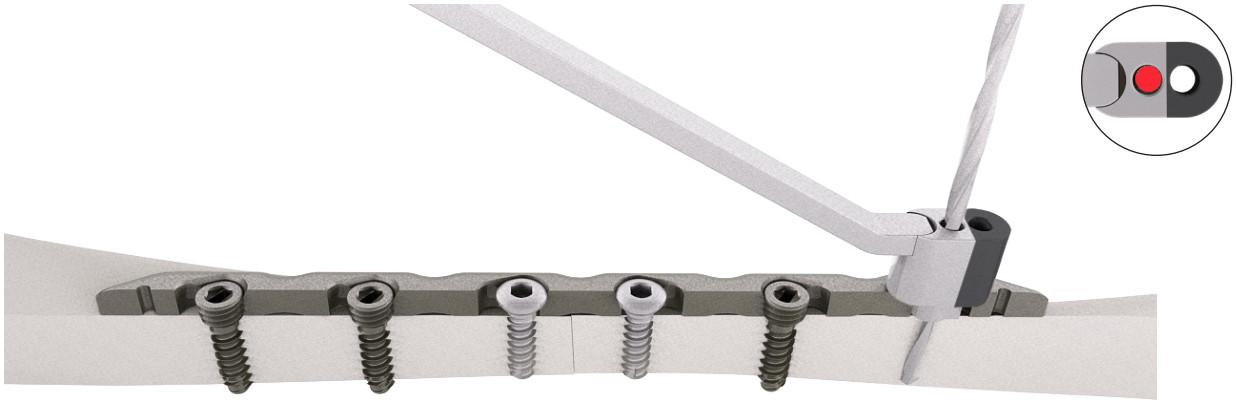


Afterwards, attach the drill guide, D=2.7mm **(62216)** to the furthest left plate hole. Use the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** to drill through the hole close to handle of the drill guide.

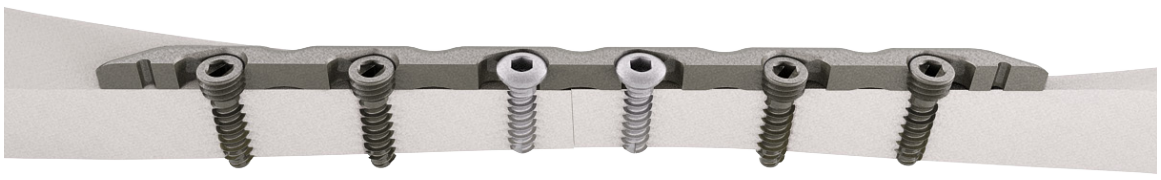


In accordance with the measured length, a D=3.5mm locking cortical screw **(37351-XX-N)** is placed.

Attach the drill guide, D=2.7mm **(62216)** to the furthest right plate hole. Use the spiral drill, D=2.7mm, L=100mm, AO Connector **(61273-100)** to drill through the hole close to handle of the drill guide.



In accordance with the measured length, a D=3.5mm locking cortical screw **(37351-XX-N)** is placed.
Finally, check the compression and the plate position with the fluoroscopy.



Redon drainage before skin closure for 12-24 hours can be useful to prevent postoperative haematoma in some cases and is recommended.

Postoperative treatment

- Proper bandage dressing for 2 weeks (until the wound heals)
- Physical therapy for 5-7 weeks
- Full weight-bearing: - approx. week 8 after fracture has healed

Explantation

Removal is possible, if desired by the patient.
Implant removal is performed 6 months - 1 1/2 years post-operative and if the fracture has healed.

The problem of cold welding was resolved by using a special surface treatment
(for further information see page 27).

Summary

The special feature of this implant is the compression hole.
Due to an innovative technology it is possible to compress a fracture gap up to 7mm.
A special design of the compression hole enables the use of a locking screw, which locks automatically after the full distance of compression.

Indentations on the rear side of the plate for protection of the periosteum.

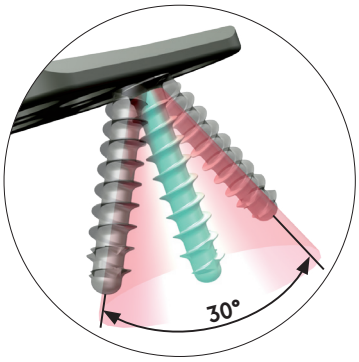
Information

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®

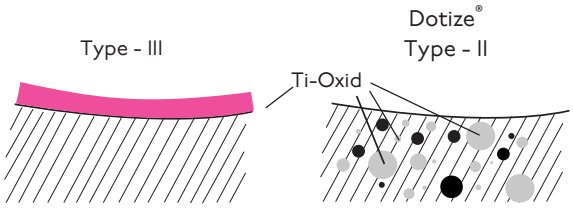
Chemical process - anodization in a strong alkaline solution*

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 Compression Plate, 4-hole	21105-4
Straight Compression Plate, 6-hole	21105-6
Straight Compression Plate, 8-hole	21105-8
Straight Compression Plate, 10-hole	21105-10

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
Cortical Screw, Locking, D=3.5mm, L=26mm, SH	37351-26-N
Cortical Screw, Locking, D=3.5mm, L=28mm, SH	37351-28-N
Cortical Screw, Locking, D=3.5mm, L=30mm, SH	37351-30-N
Cortical Screw, Locking, D=3.5mm, L=32mm, SH	37351-32-N
Cortical Screw, Locking, D=3.5mm, L=34mm, SH	37351-34-N
Cortical Screw, Locking, D=3.5mm, L=36mm, SH	37351-36-N
Cortical Screw, Locking, D=3.5mm, L=38mm, SH	37351-38-N
Cortical Screw, Locking, D=3.5mm, L=40mm, SH	37351-40-N

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, D=3.5mm, L=26mm	32351-26
Cortical Screw, D=3.5mm, L=28mm	32351-28
Cortical Screw, D=3.5mm, L=30mm	32351-30
Cortical Screw, D=3.5mm, L=32mm	32351-32
Cortical Screw, D=3.5mm, L=34mm	32351-34
Cortical Screw, D=3.5mm, L=36mm	32351-36
Cortical Screw, D=3.5mm, L=38mm	32351-38
Cortical Screw, D=3.5mm, L=40mm	32351-40

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=2.7mm	62216

Guide wire, steel, D=1.6mm, L=150mm, TR, w. thread	35164-150

Sterilization Tray, Straight Compression Plate	50231

Optional (on request)*

Straight Compression Plate, 5-hole	21105-5
Straight Compression Plate, 7-hole	21105-7

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

* Delivery times, prices & minimum quantities may vary from standard

Notes

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