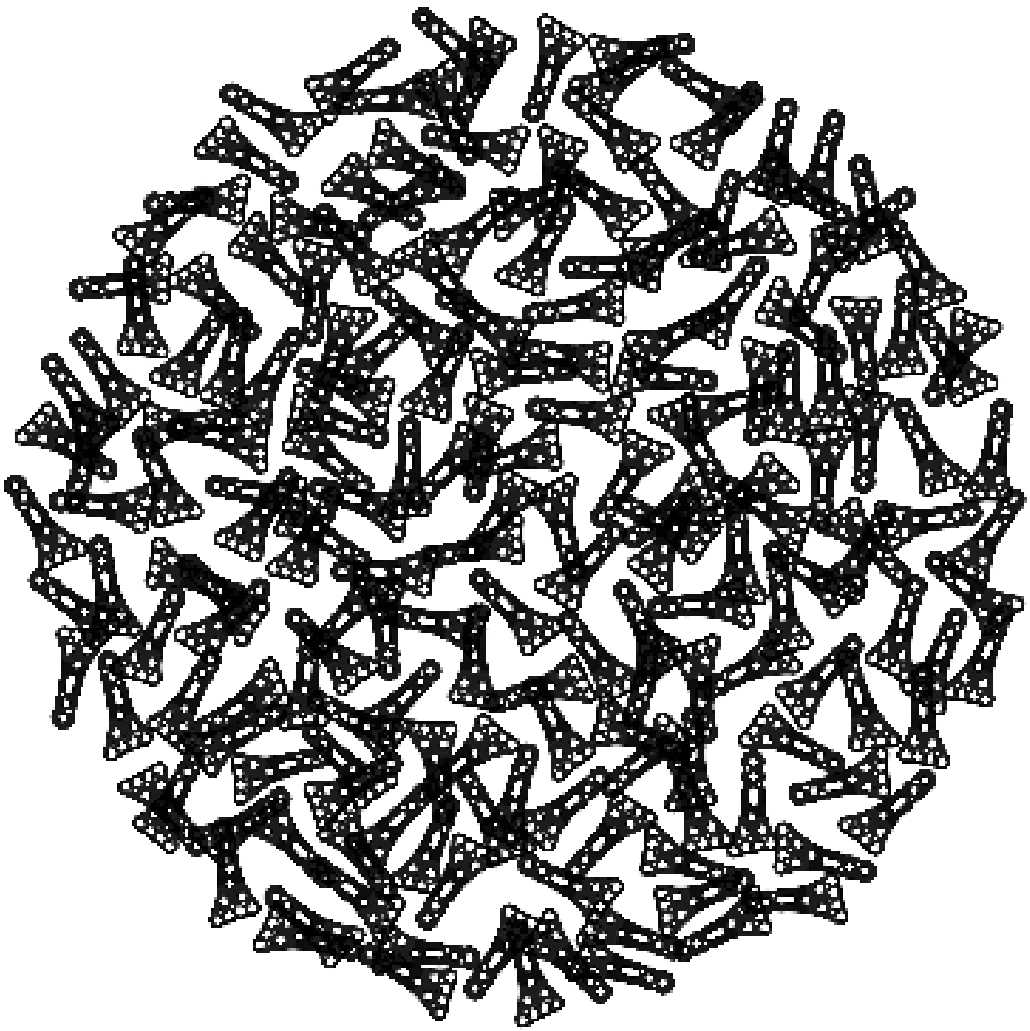
ITS.

Implants
trauma



PRL

PROlock Radius 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.

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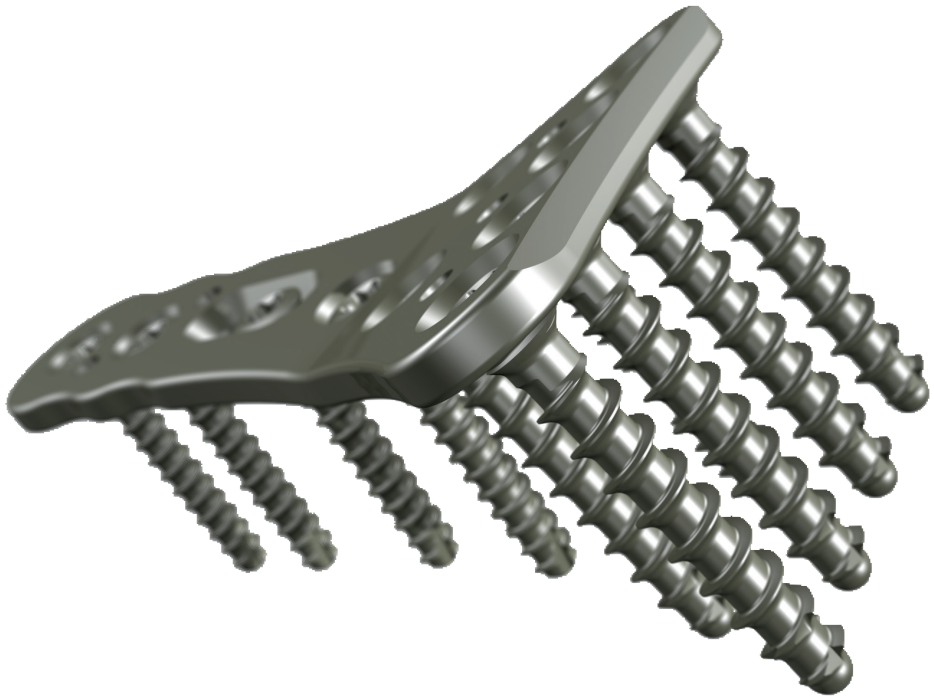
Introduction

Preface

Minimization of flexor tendon irritation due to anatomical plate design and rounded edges of the PROlock Radius Locking Plate.

The special feature of this implant is the free choice of screw placement. The user is able to set any desired screw in any hole (except oblong hole).

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



Screws

32271-XX	Cortical Screw, D=2.7mm
61203-100	Spiral Drill, D=2.0mm, L=100mm, AO Connector
56095-70	Screwdriver, Torque, T9x70,
56095-70-2	Self-holding sleeve, Screwdriver, Torque 9

37302-XX	Cancellous Screw, Locking, D=3.0mm
61203-100	Spiral Drill, D=2.0mm, L=100mm, AO Connector
56095-70	Screwdriver, Torque, T9x70,
56095-70-2	Self-holding sleeve, Screwdriver, Torque 9

35164-150	Guide Wire, Steel, D=1.6mm, L=150mm, TR, w. Thrd.

WARNING: Only the screw types listed above are compatible for this plate system.
All other screw types are not intended for this use.

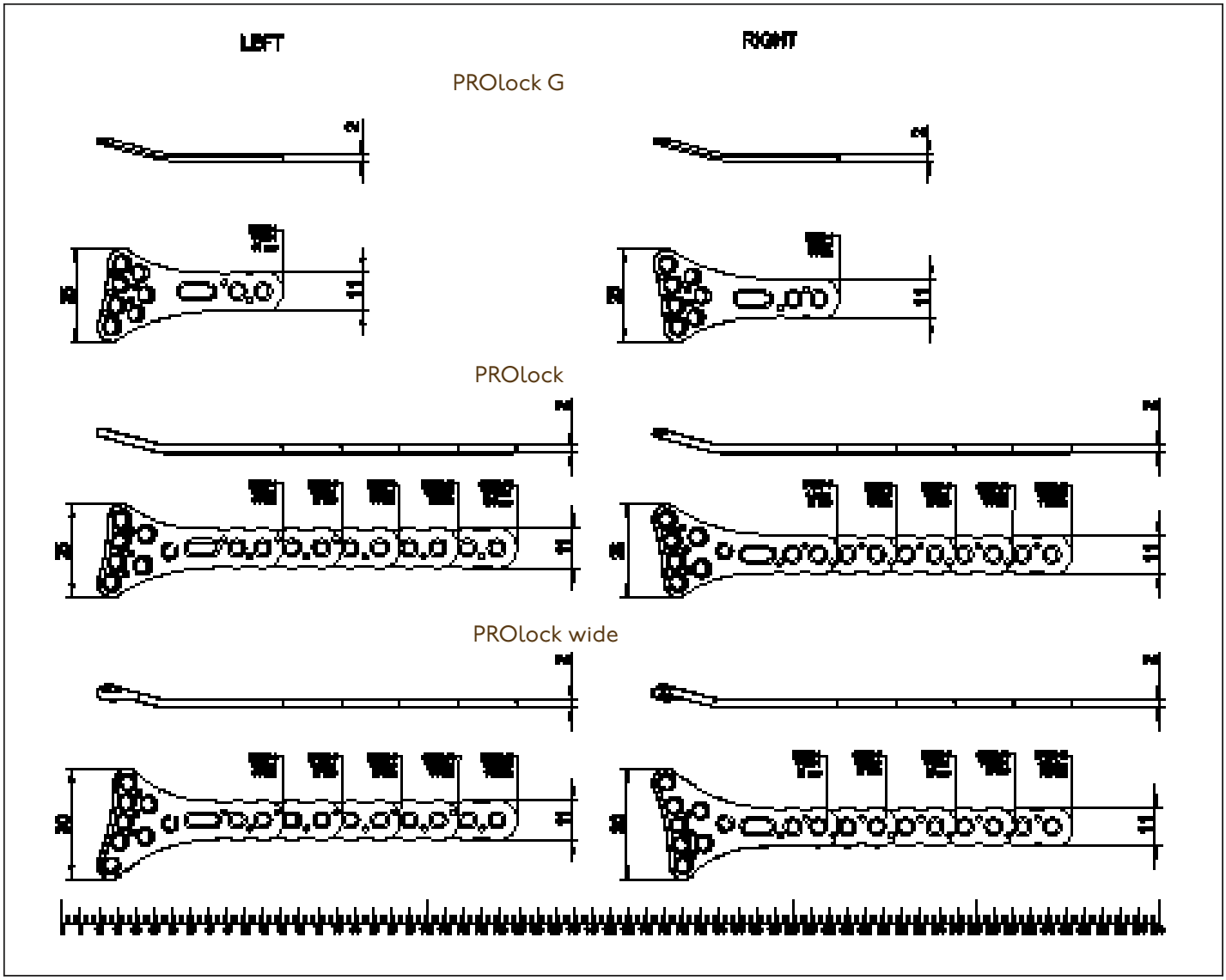
Properties

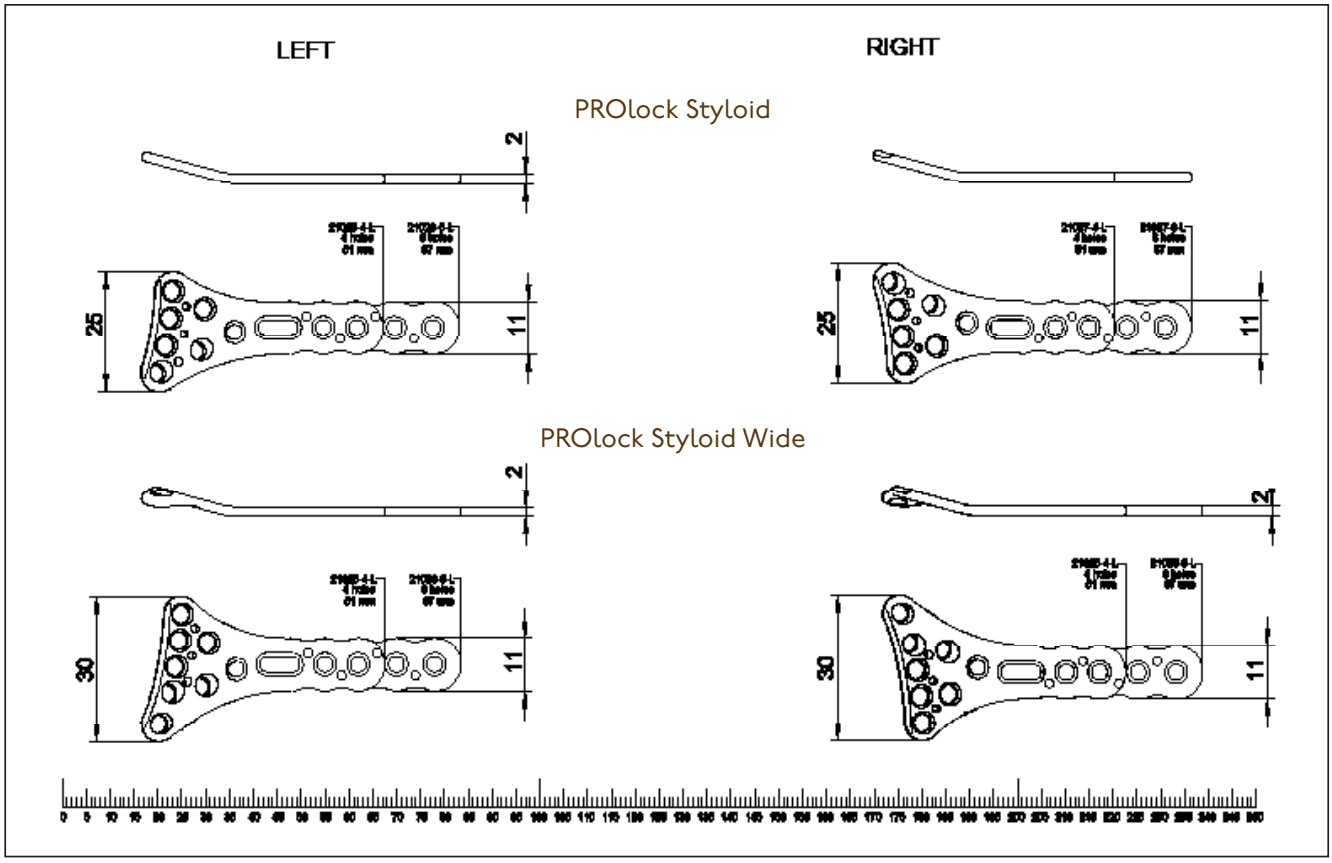
Properties of the material:

- 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
- Design for left and right
- External contour adapted to the distal radius
- Design: wide (5 distal holes), narrow (4 distal holes), long (6 shaft holes), short (4 shaft holes)
- Optional long plates (8, 10, 12-hole)





Indications, Contraindications & Time of operation

Indications:

- Complex intra- & extra-articular fractures of the distal radius with comminuted zone
- Corrective osteotomy of the distal radius

Contraindications:

- Disintegration of the radius-joint surfaces to the extent that there is no support for screws
- Existing infections in the fracture zone and operation area
- Common situations that do not allow osteosynthesis
- Obesity
- Lack of patient compliance

Time of operation:

- Acute, on the day of the accident
- After regression of the swelling

Surgical Technique

2.

Preoperative

- An X-ray of the healthy wrist (opposite side) is obligatory to serve as a comparsion
- The patient is placed in the supine position with pneumatic partial deprivation of blood supply
- The hand is positioned on a radiolucent surgical hand table

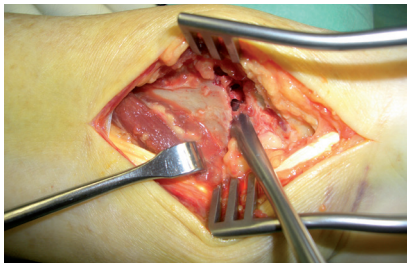
Access

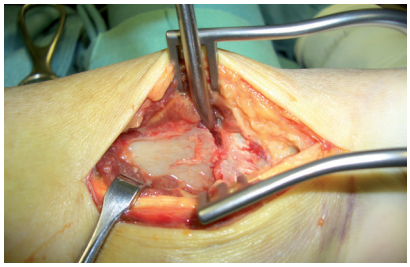
Approach over the tendon of the flexor carpi radialis muscle:

- The skin incision is performed volarly on the distal forearm above the tendon of the flexor carpi radialis and reaching to the crease of the wrist (FCR-approach).
- Splitting of the deep fascia of the forearm, releasing the pronator quadratus muscle from the distal radius beginning at the radial edge.

Reduction

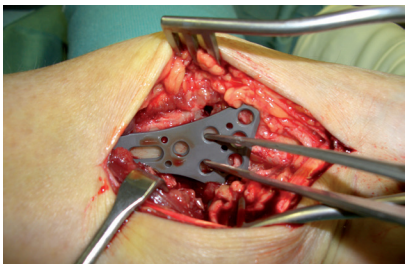
- Suspending the thumb with a counterpoise, the fracture is loosened and the length restored.
- The individual fragments are positioned using the raspatory, and, if necessary, the comminuted zones are filled with bone substitute to achieve a provisional reduction in position and length.



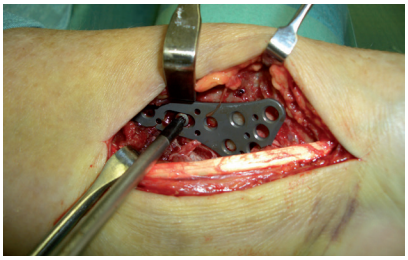


Implantation

- Possible temporary fixation of individual fragments using K-Wires. Check reduction using the fluoroscope.
- After anatomical reduction is achieved, the implant is chosen and, if required, its shape can be additionaly adapted.



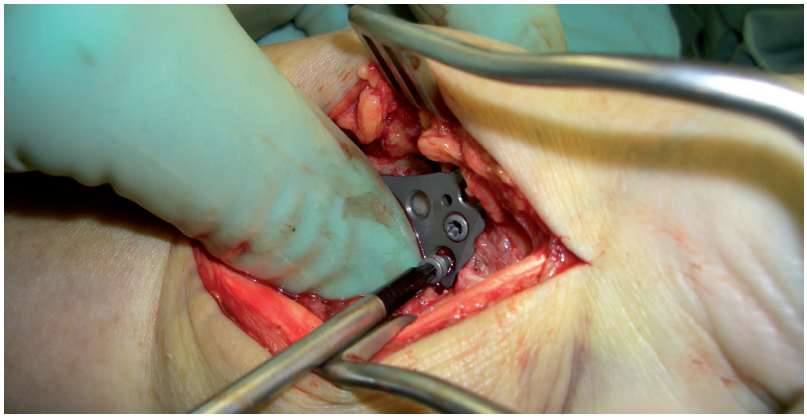
- First, occupy the sliding hole with a Cortical Screw **(32271-XX).** It is also possible to fasten the plate on the bone using the PROlock Fixation Wires. Then check the reduction and position of the plate using the fluoroscope.
- It should be paid attention that the distal locking screws **(37302-XX)** should be attached as closely to the wrist surface as possible in order to take advantage of the hard subchondral bone.

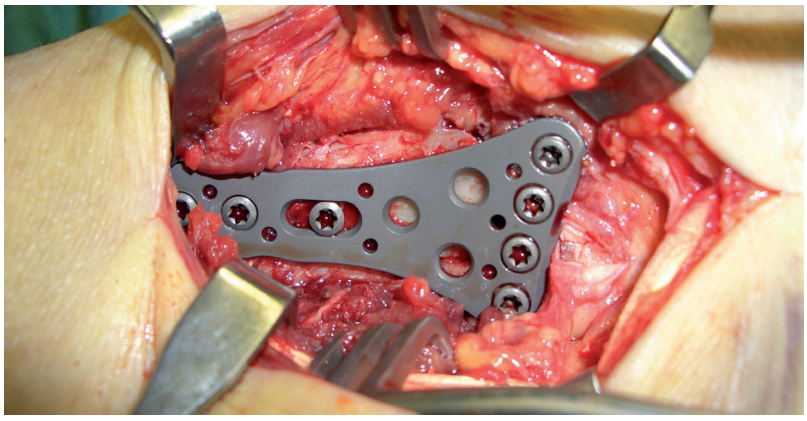


- Another 2 cortical screws are then attached to the shaft.
- Then the distal end of the radius is reduced on the plate and 4 or 5 locking screws attached to the relevant fragments.
- Final check using the fluoroscope.

Fixation of the distal fracture fragments

- The locking D=3.0mm cancellous screws should only be used in the two distal hole series, and the cortical screws should only be used in the shaft holes.





Postoperative treatment

- Dorsal splint (1-2 weeks)
- Physical therapy

Explantation

If desired by the patient, the implant can be removed.
Removal should be performed, at the earliest, 6 months 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 15).

Summary

The locking Radius Plate of I.T.S. has proved itself in extension fractures of the distal radius with dorsal comminution zone.
Using this technology, an anatomic reduction was achieved and maintained until healing occurred.
Due to the low immobilization time of 2 weeks, rapid rehabilitation and early movement of the wrist could be achieved.
Development of the PROlock Radius Plate is based on the excellent results of the I.T.S. plate. A series of improvements have increased the range of indications and have simplified the handling.

Case study

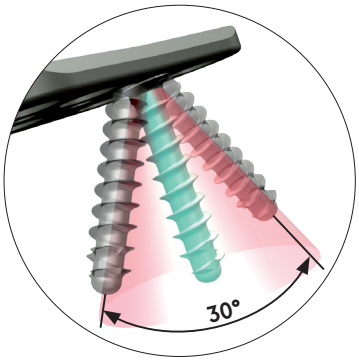
Information

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®

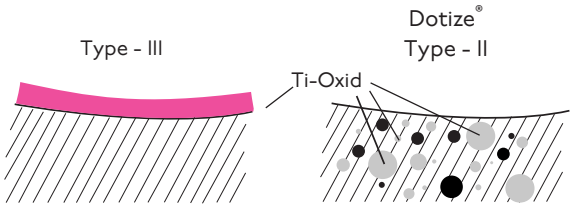
Chemical process - anodization in a strong alkaline solution*

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

Radius Plate PROlock, Small, 4-hole, Left	21028-4
Radius Plate PROlock, Small, 4-hole, Right	21027-4
Radius Plate PROlock, Small, 6-hole, Left	21028-6
Radius Plate PROlock, Small, 6-hole, Right	21027-6

Radius Plate PROlock, Wide, 4-hole, Left	21026-4
Radius Plate PROlock, Wide, 4-hole, Right	21025-4
Radius Plate PROlock, Wide, 6-hole, Left	21026-6
Radius Plate PROlock, Wide, 6-hole, Right	21025-6

Special lengths (on request)

Radius Plate PROlock, Wide, 4-Hole, Right, STY	21025-4-L
Radius Plate PROlock, Wide, 4-Hole, Left, STY	21026-4-L
Radius Plate PROlock, Wide, 6-Hole, Right, STY	21025-6-L
Radius Plate PROlock, Wide, 6-Hole, Left, STY	21026-5-L

Radius Plate PROlock, Small, 4-Hole, Right, STY	21027-4-L
Radius Plate PROlock, Small, 4-Hole, Left, STY	21028-4-L
Radius Plate PROlock, Small, 6-Hole, Right, STY	21027-6-L
Radius Plate PROlock, Small, 6-Hole, Left, STY	21028-6-L

Radius Plate PROlock, G, 4-Hole, Right	21029-4
Radius Plate PROlock, G, 4-Hole, Left	21030-4

Radius Plate PROlock, Small, 8-hole, Left	21028-8
Radius Plate PROlock, Small, 8-hole, Right	21027-8
Radius Plate PROlock, Small, 10-hole, Left	21028-10
Radius Plate PROlock, Small, 10-hole, Right	21027-10
Radius Plate PROlock, Small, 12-hole, Left	21028-12
Radius Plate PROlock, Small, 12-hole, Right	21027-12

Radius Plate PROlock, Wide, 8-hole, Left	21026-8
Radius Plate PROlock, Wide, 8-hole, Right	21025-8
Radius Plate PROlock, Wide, 10-hole, Left	21026-10
Radius Plate PROlock, Wide, 10-hole, Right	21025-10
Radius Plate PROlock, Wide, 12-hole, Left	21026-12
Radius Plate PROlock, Wide, 12-hole, Right	21025-12

Cortical Screw, D=2.7mm, L=10mm	32271-10
Cortical Screw, D=2.7mm, L=12mm	32271-12
Cortical Screw, D=2.7mm, L=14mm	32271-14
Cortical Screw, D=2.7mm, L=16mm	32271-16
Cortical Screw, D=2.7mm, L=18mm	32271-18
Cortical Screw, D=2.7mm, L=20mm	32271-20
Cortical Screw, D=2.7mm, L=22mm	32271-22
Cortical Screw, D=2.7mm, L=24mm	32271-24

Cancellous Screw, Locking, D=3.0mm, L=10mm	37302-10
Cancellous Screw, Locking, D=3.0mm, L=12mm	37302-12

Cancellous Screw, Locking, D=3.0mm, L=14mm	37302-14
Cancellous Screw, Locking, D=3.0mm, L=16mm	37302-16
Cancellous Screw, Locking, D=3.0mm, L=18mm	37302-18
Cancellous Screw, Locking, D=3.0mm, L=20mm	37302-20
Cancellous Screw, Locking, D=3.0mm, L=22mm	37302-22
Cancellous Screw, Locking, D=3.0mm, L=24mm	37302-24
Cancellous Screw, Locking, D=3.0mm, L=26mm	37302-26
Cancellous Screw, Locking, D=3.0mm, L=28mm	37302-28
Cancellous Screw, Locking, D=3.0mm, L=30mm	37302-30
Screwdriver Torque, T9x70	56095-70
Self-holding sleeve Screwdriver, Torque 9	56095-70-2
Depth Gauge, PROlock	59023
Drill Guide, D=2.0/2.7mm	62202
Spiral Drill, D=2.0mm, L=100mm, AO Connector	61203-100
Guide Wire, Steel, D=1.6mm, L=150mm, TR, w. Thrd.	35164-150
Temporary Plate Holder	58165-150
Sterilization Tray, Radius Plate PROlock	50180

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

Tray

Notes

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