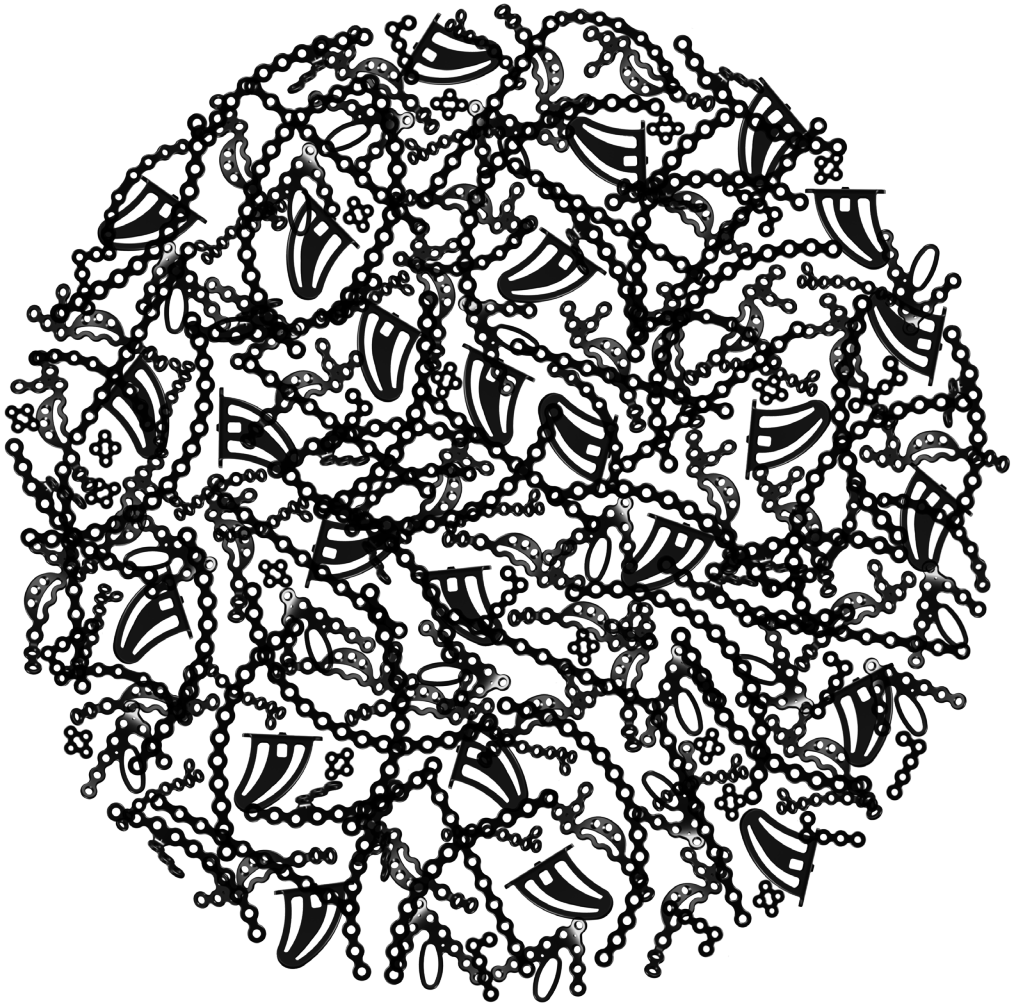
ITS.

Implants
trauma



PRS RX

Revolution X Pelvic Reconstruction 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.

Contents

1. Introduction

2. Surgical Technique

3. Information

Introduction

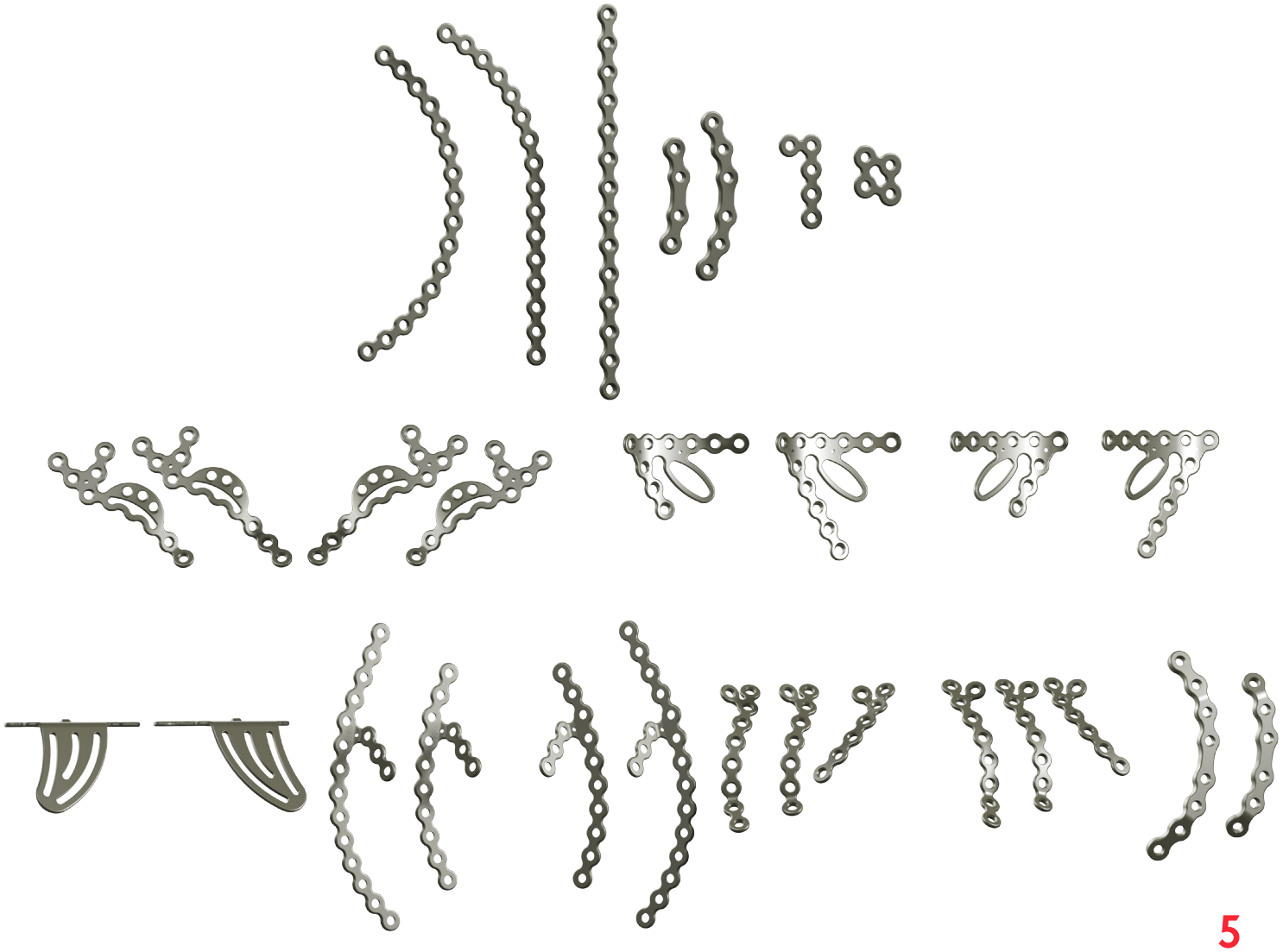
Preface

The **Revolution X** Pelvic Reconstruction System is a proven osteosynthesis system for different fractures of the pelvis.

The special plate types cover an extended range of indications for fracture treatment of the acetabulum and the quadrilateral surface.

The free choice of screw placement is the special feature of these implants.
The user is able to set any desired screw in any-hole either locking or non-locking screw.

The free choice of screw angulation (+/- 15°, see page 21) provides an advantage in fracture treatment, especially in the case of complex fractures.



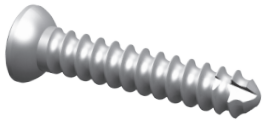
Screws

32351-XX Cortical Screw, D=3.5mm

61273-220 Spiral Drill, D=2.7mm, L=220mm, AO Connector

KM 48-348 Hexagon-Shank, WS 2.5, L=135mm

54253-300 Hexagon-Shank, WS 2.5, L=300mm

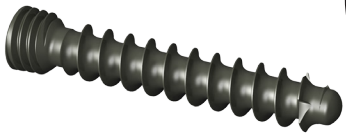


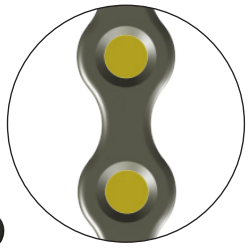
37422-XX-N Cancellous Screw, Locking, D=4.2mm

61253-220 Spiral Drill, D=2.5mm, L=220mm, AO Connector

KM 48-348 Hexagon-Shank, WS 2.5, L=135mm

54253-300 Hexagon-Shank, WS 2.5, L=300mm





37351-XX-N Cortical Screw, Locking, D=3.5mm

61273-220 Spiral Drill, D=2.7mm, L=220mm, AO Connector

KM 48-348 Hexagon-Shank, WS 2.5, L=135mm

54253-300 Hexagon-Shank, WS 2.5, L=300mm

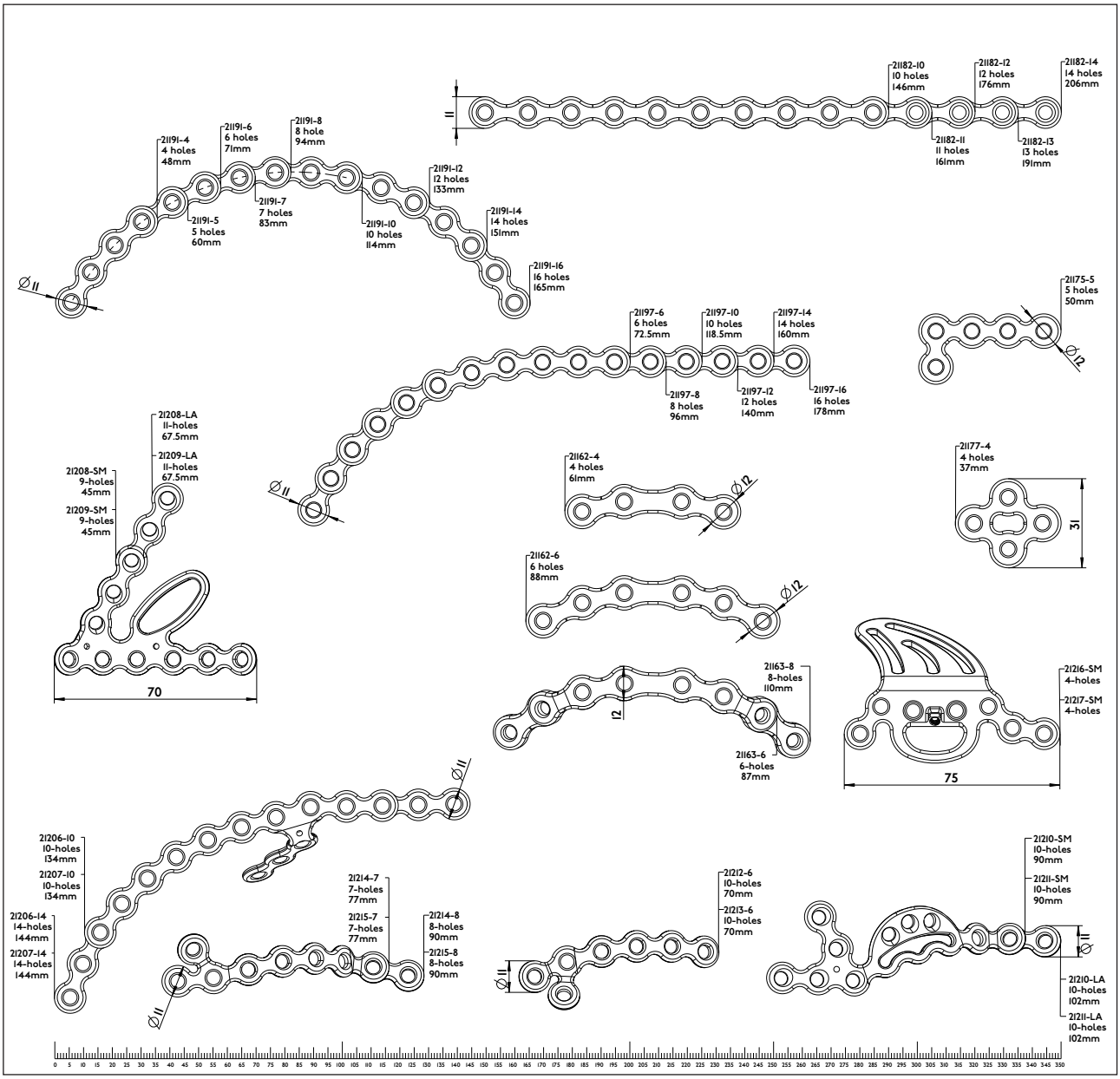
Properties

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

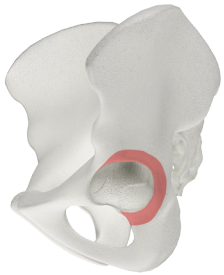
Properties of the implant:

- Multi-directional Locking
- Can be anatomically shaped with bending irons
- Plate strength: 2.5mm (Symphysis Plate 4.0mm)
- Special plate types for fracture treatment of the acetabulum and the quadrilateral surface



Indications

- **Fractures of the acetabulum:**

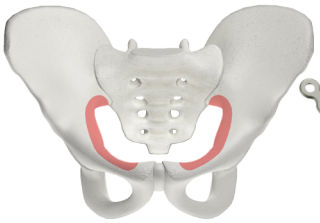


Posterior Pelvic Wall Plate Ext.

Posterior Pelvic Wall Plate & II

Curved Plate

- **Fractures of the pelvic ring:**

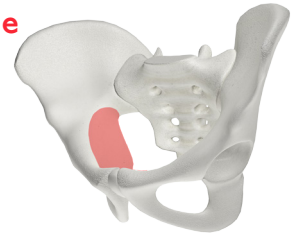


Rim Plate

J-Plate

Curved Plate

- **Fractures of the quadrilateral surface:**

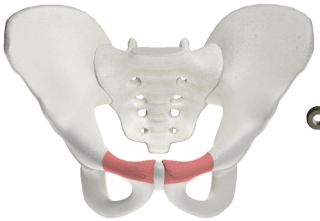


Quadrilateral Plate

Quadrilateral Column Plate

Rim Plate

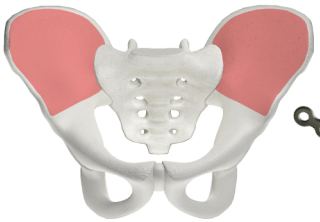
- **Fractures of the symphysis:**



Symphysis Plate

Symphysis Plate Curved

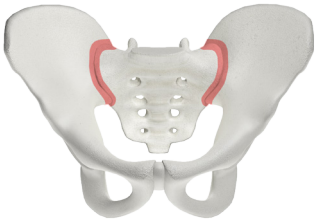
- **Fractures of the ilium:**



J-Plate

Curved Plate

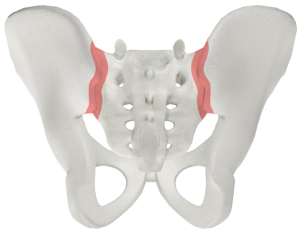
- **Fractures of the SIJ:**



SIJ Plate Closed

SIJ Plate 5-hole

- **Ilio-Iliac distance-osteosynthesis:**



Straight Plate

Contraindications & Time of operation

Contraindications:

- Existing infections in the fracture zone and operation area
- Common situations that do not allow osteosynthesis
- Obesity
- Lack of patient compliance

Time of operation:

- Immediately after trauma or delayed

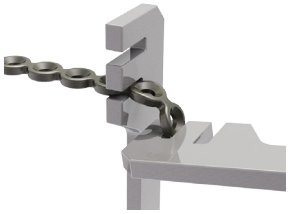
Surgical Technique

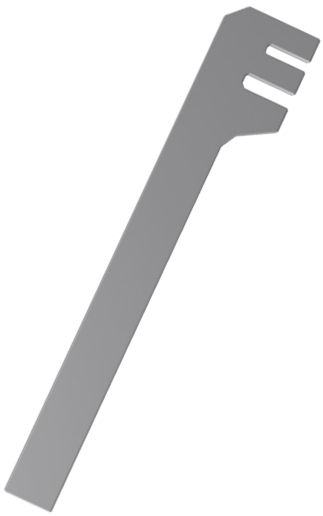
2.

Instruments

Bending Irons:

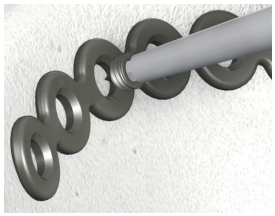
- To form the plate to the respective pelvic region

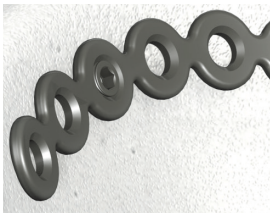




Spike (optional):

- For fixation of the plate to bone fragments where screw fixation is not possible because of the anatomic situation



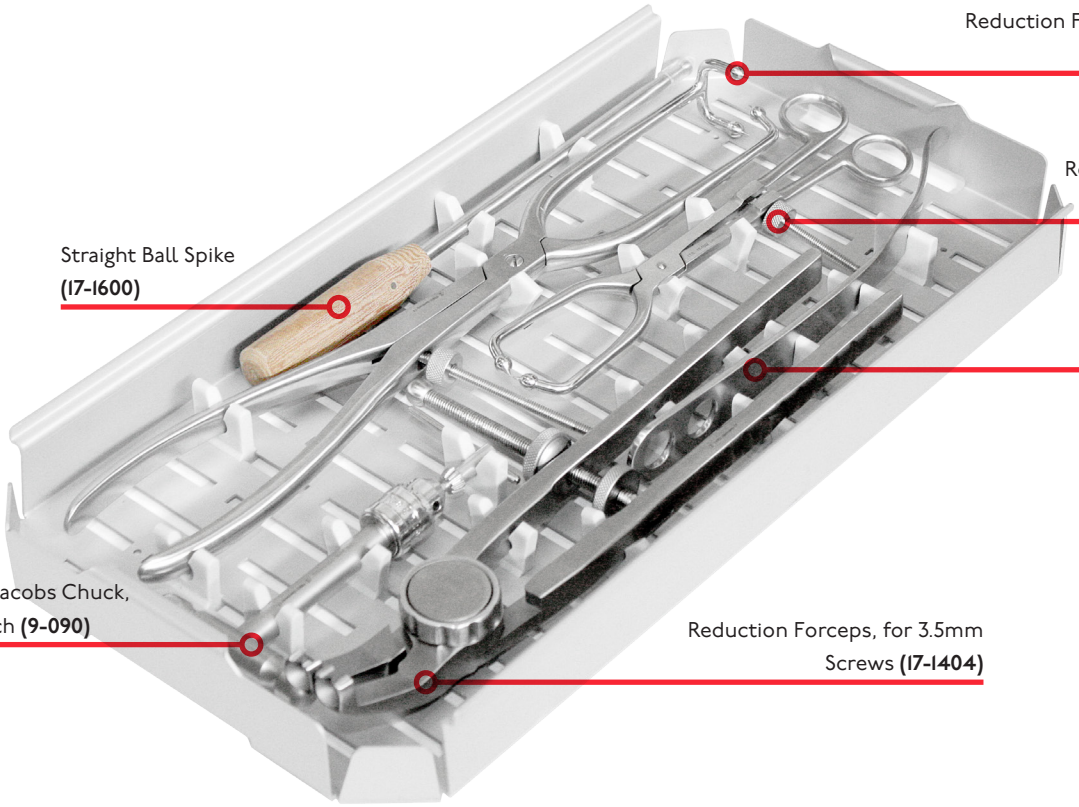


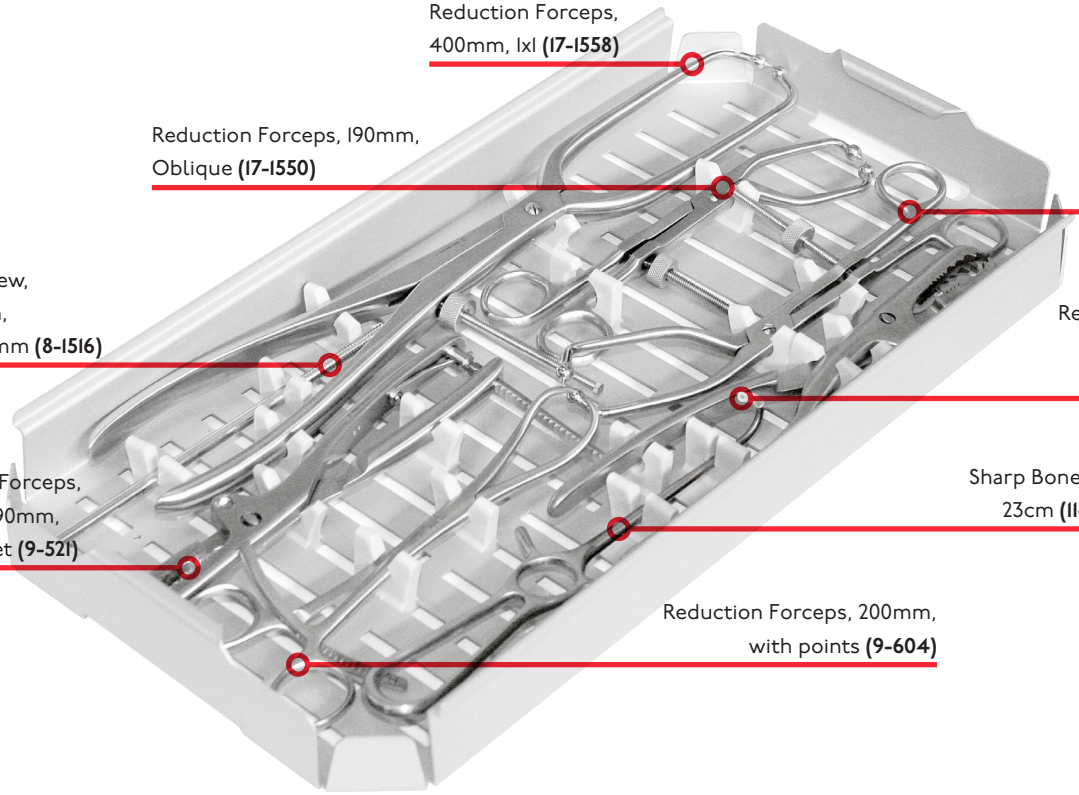
Pelvic Extension System (optional)

- Especially complex fractures can therefore be treated more simply
- The Pelvic Extension System expands the range of indications, due to the fact that any PRS plate can be combined with one or more plates

Pelvic Basic Set (optional)

The optional Pelvic Basic Set includes reduction forceps and various instruments to ensure proper reduction.





Fractures of the acetabulum

- Access by means of Kocher-Langenbeck approach, possibly using trochanter-flip osteotomy and surgical luxation
- Reduction and temporary fixation using a K-wire
- Appropriate final adjustment of the plate
- Application of the plate and temporary fixation using spikes and fluoroscopic or X-ray inspection
- Finally, insertion of cortical or cancellous screws (either locking or non-locking) into the holes of the plate
- Fluoroscopic or X-ray inspection
- Drainage of the area and layered closure of the wound (refixation of greater trochanter if required)

Posterior Pelvic Wall Plate
Extended

Posterior Pelvic Wall Plate
Posterior Pelvic Wall Plate II

Curved Plate

Fractures of the pelvic ring

- Ilio-inguinal approach or possibly modified Stoppa approach
- Reduction using Weber or Jungbluth forceps, Schanz screw and temporary K-wire fixation if required
- Fluoroscopic or X-ray inspection
- Adjustment and setting of reconstruction plate using bending irons
- Attachement of the plate and temporary fixation using spikes and fluoroscopic or X-ray inspection
- Finally, insertion of cortical or cancellous screws (either locking or non-locking)
- Conclude with fluoroscopic or X-ray inspection
- Drainage, closure of wound

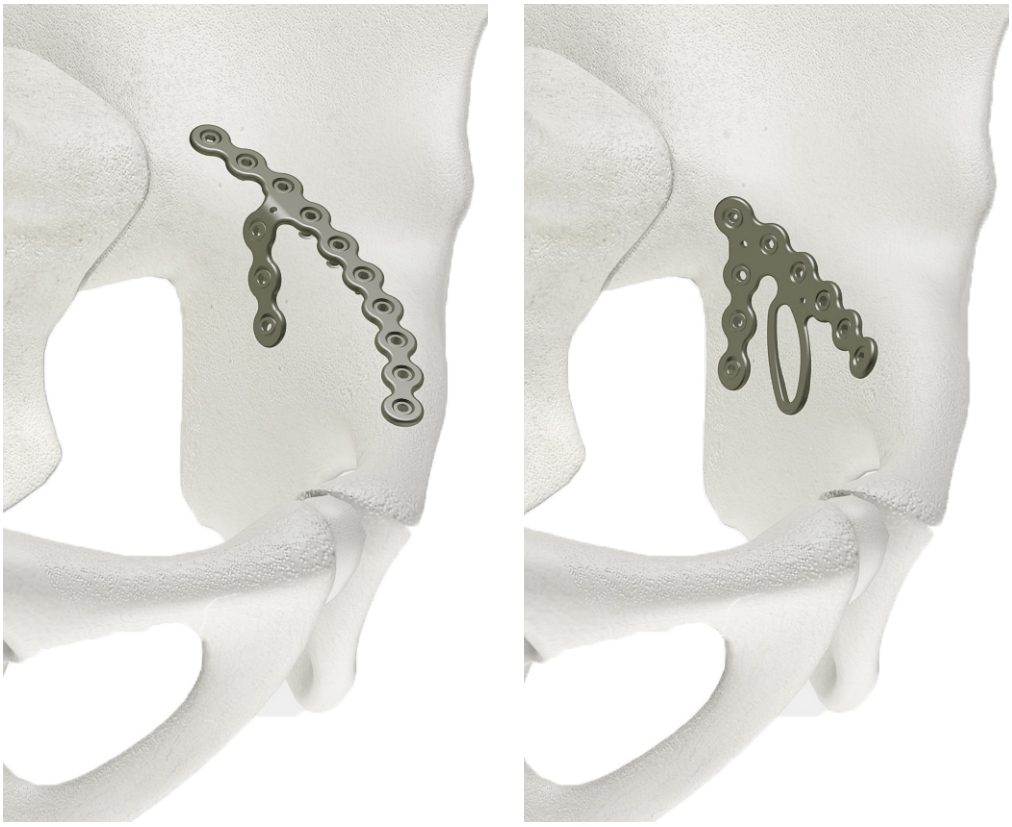
Rim Plate

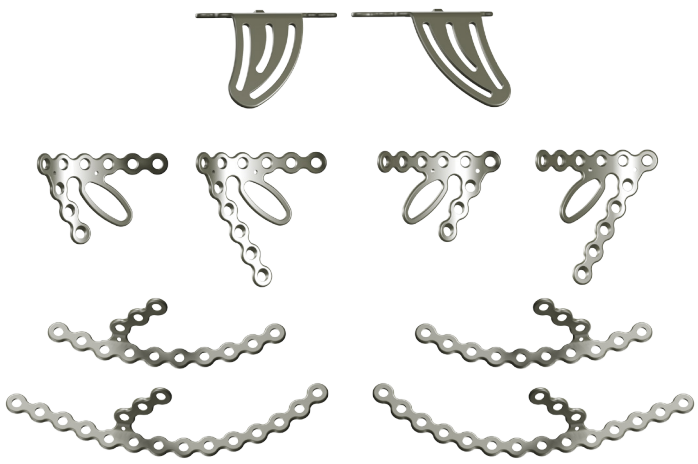
J-Plate

Curved Plate

Fractures of the quadrilateral surface

- Ilio-inguinal approach or possibly modified Stoppa approach
- Reduction using Weber or Jungbluth forceps, Schanz screw and temporary K-wire fixation if required
- Fluoroscopic or X-ray inspection
- Adjustment and setting of reconstruction plate using bending irons
- Attachement of the plate and temporary fixation using spikes and fluoroscopic or X-ray inspection
- Finally, insertion of cortical or cancellous screws (either locking or non-locking)
- Conclude with fluoroscopic or X-ray inspection
- Drainage, closure of wound





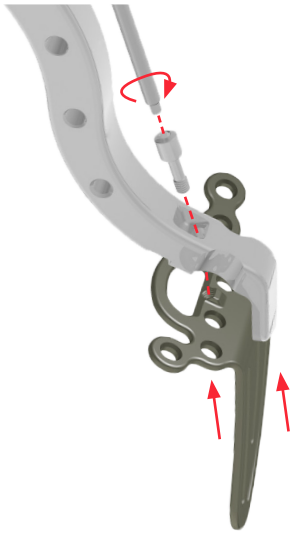
Quadrilateral Plate

Quadrilateral Column Plate

Rim Plate

Assembly of the clamp for the quadrilateral plate

1



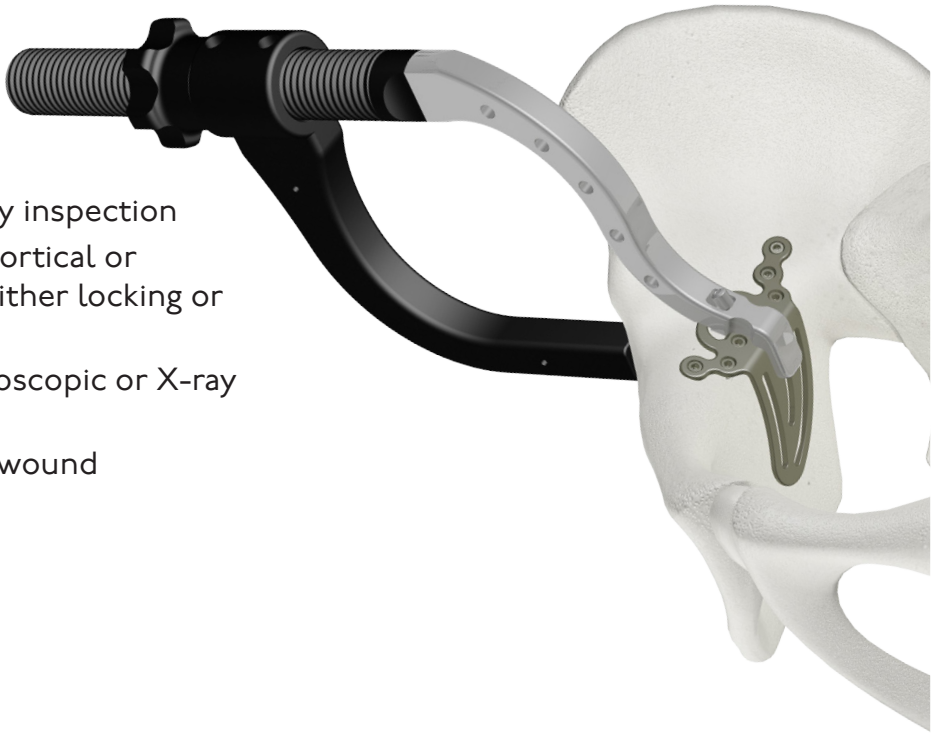
2

1. Assemble the clamp **(118009-7)** on the plate with the fixation screw **(118009-12)**.

2. Push the sliding part **(118009-8)**, either with mounted pushing tip **(118009-10)** or pushing plate **(118009-11)**, on the clamp **(118009-7)**. Subsequent, turn the nut **(118009-9)** on the clamp.

Application of the quadrilateral plate

- Ilio-inguinal approach or possibly modified Stoppa approach
- Insert the quadrilateral plate, assembled on the clamp through the choosen approach
- Anatomic reduction of the quadrilateral surface and the acetabulum
- Fluoroscopic or X-ray inspection
- Finally, insertion of cortical or cancellous screws (either locking or non-locking)
- Conclude with fluoroscopic or X-ray inspection
- Drainage, closure of wound



Fractures of the symphysis

- Lower medial laparotomy (emergency) or Pfannenstiel incision
- Extra-peritoneal opening of the pelvis minor in the linea alba
- Notch the muscle attachment of the muscle rectus abdominis from inside, if possible do not sever laterally
- Resection using pointed reduction or pelvic reduction forceps
- Positioning of 4 or 6-hole plate superiorly (adjust using bending irons if required)
- Temporary fixation using spikes and fluoroscopic or X-ray inspection
- Finally, insertion of cortical or cancellous screws (either locking or non-locking)
- Drainage of retropubic space, closure of the wound

Symphysis Plate

Symphysis Plate Curved

Fractures of the ilium

- Ilio-inguinal approach or possibly modified Stoppa approach
- Reduction using Weber or Jungbluth forceps, Schanz screw and temporary K-wire fixation if required
- Fluoroscopic or X-ray inspection
- Adjustment and setting of reconstruction plate using bending irons
- Attachement of the plate and temporary fixation using spikes and fluoroscopic or X-ray inspection
- Finally, insertion of cortical or cancellous screws (either locking or non-locking)
- Conclude with fluoroscopic or X-ray inspection
- Drainage, closure of wound

J-Plate

Curved Plate

Fractures of the SIJ

- Antero-lateral approach or first window in the context of an ilio-inguinal approach
- Adjustment of sacroiliac joint with Hohmann retractors
- Resection using pointed reduction or pelvic reduction forceps
- Adjustment of a SIJ plate closed or 5-hole
- Temporary fixation using spikes, fluoroscopy or X-ray inspection
- Finally, insertion of cortical or cancellous screws (either locking or non-locking)
- Drainage, closure of wound

SIJ Plate
5-hole

SIJ Plate
Closed

Ilio-iliac distance osteosynthesis

- Approach: bilateral superior 50 mm long incision from the anterior inferior to the posterior superior
- Bilateral exposure of the rear iliac crest and reduction using Schanz screw, longitudinal traction on leg, if necessary with the help of reduction forceps
- Determination of plate length
- Chisel off plate bearing (approx. 4 mm deep)
- Bend the plate from one side. Push the plate through behind the sacrum. Bend the plate on the other side in situ
- Adjust plate and insert both screws on iliac crest. Alternate tightening of screws
- Insert locking screws in both holes of the short side piece of the plate, at the same time making sure that the screwing angle is 10-15° to the plane of the already attached screw on iliac crest (to prevent collision of the screws)
- Drainage, closure of wound

Straight Plate

Postoperative treatment

- The postoperative treatment may vary depending on the patients age, bone quality or type of fracture.

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.

Removal should be performed at the earliest 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 21).

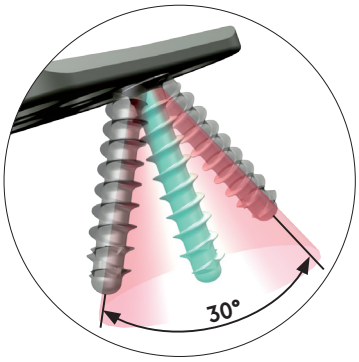
Information

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®

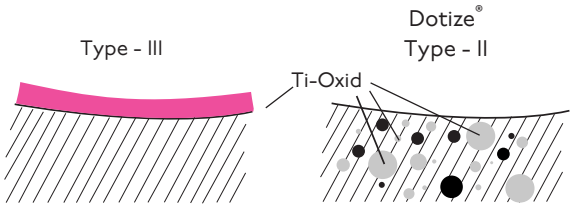
Chemical process - anodization in a strong alkaline solution*

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

Curved Plate, 4-hole	21191-4
Curved Plate, 5-hole	21191-5
Curved Plate, 6-hole	21191-6
Curved Plate, 7-hole	21191-7
Curved Plate, 8-hole	21191-8
Curved Plate, 10-hole	21191-10
Curved Plate, 12-hole	21191-12
Curved Plate, 14-hole	21191-14
Curved Plate, 16-hole	21191-16

Straight Plate, 10-hole	21182-10
Straight Plate, 11-hole	21182-11
Straight Plate, 12-hole	21182-12
Straight Plate, 13-hole	21182-13
Straight Plate, 14-hole	21182-14

SIJ Plate, Closed	21177-4

SIJ Plate, 5-hole	21175-5

J-Plate, 6-hole	21197-6
J-Plate, 8-hole	21197-8
J-Plate, 10-hole	21197-10
J-Plate, 12-hole	21197-12
J-Plate, 14-hole	21197-14
J-Plate, 16-hole	21197-16

Symphysis Plate, 4-hole	21162-4
Symphysis Plate, 6-hole	21162-6

Symphysis Plate Curved, 6-hole	21163-6
Symphysis Plate Curved, 8-hole	21163-8

Rim Plate, Right, 10-hole	21207-10
Rim Plate, Left, 10-hole	21206-10
Rim Plate, Right, 14-hole	21207-14
Rim Plate, Left, 14-hole	21206-14

Posterior Pelvic Wall Plate, Right, 6-hole	21213-6
Posterior Pelvic Wall Plate, Left, 6-hole	21212-6

Posterior Pelvic Wall Plate II, Right, 7-hole	21215-7
Posterior Pelvic Wall Plate II, Left, 7-hole	21214-7
Posterior Pelvic Wall Plate II, Right, 8-hole	21215-8
Posterior Pelvic Wall Plate II, Left, 8-hole	21214-8

Quadrilateral Column Plate, Right, Small	21209-SM
Quadrilateral Column Plate, Left, Small	21208-SM
Quadrilateral Column Plate, Right, Large	21209-LA
Quadrilateral Column Plate, Left, Large	21208-LA

Quadrilateral Plate, Right, Medium	21217-ME
Quadrilateral Plate, Left, Medium	21216-ME

Posterior Pelvic Wall Plate Extended, Right, Small	21211-SM
Posterior Pelvic Wall Plate Extended, Left, Small	21210-SM
Posterior Pelvic Wall Plate Extended, Right, Large	21211-LA
Posterior Pelvic Wall Plate Extended, Left, Large	21210-LA

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
Cortical Screw, D=3.5mm, L=42mm	32351-42
Cortical Screw, D=3.5mm, L=44mm	32351-44
Cortical Screw, D=3.5mm, L=46mm	32351-46
Cortical Screw, D=3.5mm, L=48mm	32351-48
Cortical Screw, D=3.5mm, L=50mm	32351-50
Cortical Screw, D=3.5mm, L=55mm	32351-55
Cortical Screw, D=3.5mm, L=60mm	32351-60
Cortical Screw, D=3.5mm, L=65mm	32351-65
Cortical Screw, D=3.5mm, L=70mm	32351-70
Cortical Screw, D=3.5mm, L=75mm	32351-75
Cortical Screw, D=3.5mm, L=80mm	32351-80
Cortical Screw, D=3.5mm, L=85mm	32351-85
Cortical Screw, D=3.5mm, L=90mm	32351-90
Cortical Screw, D=3.5mm, L=95mm	32351-95
Cortical Screw, D=3.5mm, L=100mm	32351-100
Cortical Screw, D=3.5mm, L=105mm	32351-105
Cortical Screw, D=3.5mm, L=110mm	32351-110
Cortical Screw, D=3.5mm, L=115mm	32351-115
Cortical Screw, D=3.5mm, L=120mm	32351-120

Cancellous Screw, Locking, D=4.2mm, L=16mm, SH	37422-16-N
Cancellous Screw, Locking, D=4.2mm, L=18mm, SH	37422-18-N
Cancellous Screw, Locking, D=4.2mm, L=20mm, SH	37422-20-N
Cancellous Screw, Locking, D=4.2mm, L=22mm, SH	37422-22-N
Cancellous Screw, Locking, D=4.2mm, L=24mm, SH	37422-24-N
Cancellous Screw, Locking, D=4.2mm, L=26mm, SH	37422-26-N
Cancellous Screw, Locking, D=4.2mm, L=28mm, SH	37422-28-N
Cancellous Screw, Locking, D=4.2mm, L=30mm, SH	37422-30-N
Cancellous Screw, Locking, D=4.2mm, L=32mm, SH	37422-32-N
Cancellous Screw, Locking, D=4.2mm, L=34mm, SH	37422-34-N
Cancellous Screw, Locking, D=4.2mm, L=36mm, SH	37422-36-N
Cancellous Screw, Locking, D=4.2mm, L=38mm, SH	37422-38-N
Cancellous Screw, Locking, D=4.2mm, L=40mm, SH	37422-40-N

Order list

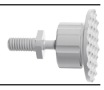
Cancellous Screw, Locking, D=4.2mm, L=42mm, SH	37422-42-N
Cancellous Screw, Locking, D=4.2mm, L=44mm, SH	37422-44-N
Cancellous Screw, Locking, D=4.2mm, L=46mm, SH	37422-46-N
Cancellous Screw, Locking, D=4.2mm, L=48mm, SH	37422-48-N
Cancellous Screw, Locking, D=4.2mm, L=50mm, SH	37422-50-N
Cancellous Screw, Locking, D=4.2mm, L=55mm, SH	37422-55-N
Cancellous Screw, Locking, D=4.2mm, L=60mm, SH	37422-60-N
Cancellous Screw, Locking, D=4.2mm, L=65mm, SH	37422-65-N
Cancellous Screw, Locking, D=4.2mm, L=70mm, SH	37422-70-N
Cancellous Screw, Locking, D=4.2mm, L=75mm, SH	37422-75-N
Cancellous Screw, Locking, D=4.2mm, L=80mm, SH	37422-80-N
Cancellous Screw, Locking, D=4.2mm, L=85mm, SH	37422-85-N
Cancellous Screw, Locking, D=4.2mm, L=90mm, SH	37422-90-N
Cancellous Screw, Locking, D=4.2mm, L=95mm, SH	37422-95-N
Cancellous Screw, Locking, D=4.2mm, L=100mm, SH	37422-100-N
Cancellous Screw, Locking, D=4.2mm, L=105mm, SH	37422-105-N
Cancellous Screw, Locking, D=4.2mm, L=110mm, SH	37422-110-N
Cancellous Screw, Locking, D=4.2mm, L=115mm, SH	37422-115-N
Cancellous Screw, Locking, D=4.2mm, L=120mm, SH	37422-120-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, Locking, D=3.5mm, L=42mm, SH	37351-42-N
Cortical Screw, Locking, D=3.5mm, L=44mm, SH	37351-44-N
Cortical Screw, Locking, D=3.5mm, L=46mm, SH	37351-46-N
Cortical Screw, Locking, D=3.5mm, L=48mm, SH	37351-48-N
Cortical Screw, Locking, D=3.5mm, L=50mm, SH	37351-50-N
Cortical Screw, Locking, D=3.5mm, L=55mm, SH	37351-55-N
Cortical Screw, Locking, D=3.5mm, L=60mm, SH	37351-60-N
Cortical Screw, Locking, D=3.5mm, L=65mm, SH	37351-65-N
Cortical Screw, Locking, D=3.5mm, L=70mm, SH	37351-70-N
Cortical Screw, Locking, D=3.5mm, L=75mm, SH	37351-75-N
Cortical Screw, Locking, D=3.5mm, L=80mm, SH	37351-80-N
Cortical Screw, Locking, D=3.5mm, L=85mm, SH	37351-85-N
Cortical Screw, Locking, D=3.5mm, L=90mm, SH	37351-90-N
Cortical Screw, Locking, D=3.5mm, L=95mm, SH	37351-95-N
Cortical Screw, Locking, D=3.5mm, L=100mm, SH	37351-100-N
Cortical Screw, Locking, D=3.5mm, L=105mm, SH	37351-105-N
Cortical Screw, Locking, D=3.5mm, L=110mm, SH	37351-110-N

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

Cortical Screw, Locking, D=3.5mm, L=115mm, SH	37351-115-N
Cortical Screw, Locking, D=3.5mm, L=120mm, SH	37351-120-N
Ratchet Handle, AO Connector	53014 
Hexagon-Shank, WS 2.5, L=135mm, AO Connector	KM 48-348
Hexagon-Shank, WS 2.5, L=300mm, AO Connector	54253-300
Measuring Sleeve, Measuring length 120mm	59326 
Measuring Rod, Measuring length 120mm	59327
Drill Guide, D=2.5/2.7mm	62219 
Spiral Drill, D=2.5mm, L=220mm, AO Connector	61253-220
Spiral Drill, D=2.7mm, L=220mm, AO Connector	61273-220
Wire Drill, D=2.5mm, L=400mm	35256-400
Wire Drill, D=2.7mm, L=400mm	35276-400
Bending Heaver 14cm, 3.5mm and 2.7mm	KJ.207.14 
Flatwrench, WS 10	70010 
Insertion Guide, Quadrilateral Plate	118009A 
Sterilization Tray, PRS RX System	50254

Spare Parts List Insertion Guide / Optional (on request)

Clamp, Quadrilateral Plate	118009-7 
Sliding Clamp, Quadrilateral Plate	118009-8 
Nut, Clamp, Quadrilateral Plate	118009-9 
Pushing Tip, Clamp, Quadrilateral Plate	118009-10 
Pushing Plate, Clamp, Quadrilateral Plate	118009-11 
Fixing Screw, Clamp, Quadrilateral Plate	118009-12 

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

Order list

Special sizes & instruments optional on request *

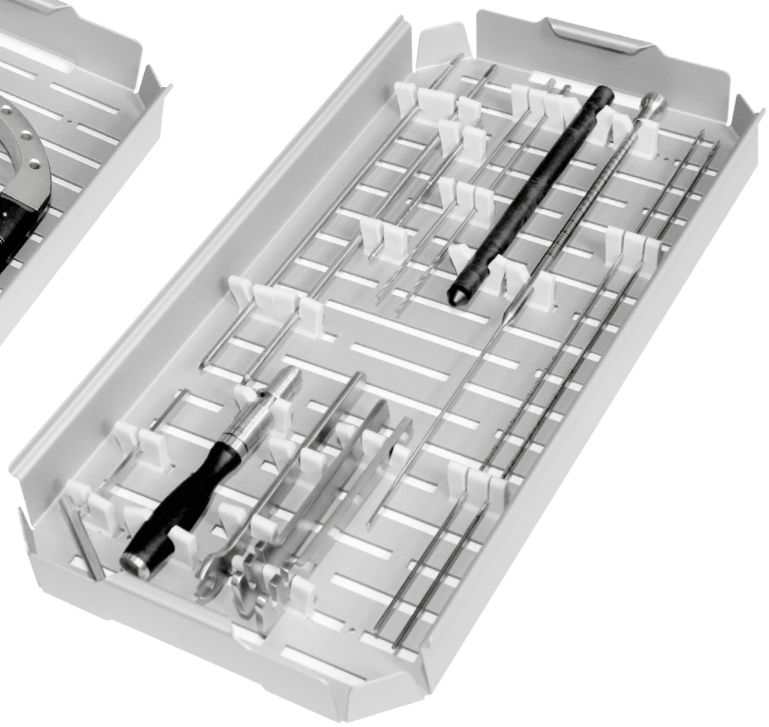
Fixation Screw, PRS RX System	70312
Bolt, PRS RX System	70313
Spike, Short, PRS RX System	70314

Pelvic Basic Set / Optional (on request) *

T-Handle Jacobs Chuck, with wrench	9-090
Sharp Bone Hook, 23cm	11-4604
Bone Lever, 24mm width tip	9-676
Reduction Forceps, Farabeuf, 190mm, with ratchet	9-521
Reduction Forceps, Farabeuf, 260mm	9-522
Reduction Forceps, 200mm, with points	9-604
Reduction Forceps, for 3.5mm Screws	17-1404
Reduction Forceps, 190mm, Oblique	17-1550
Reduction Forceps, 250mm	17-1552
Reduction Forceps, 230mm, Oblique	17-1554
Reduction Forceps, 400mm, 2x1	17-1556
Reduction Forceps, 400mm, 1x1	17-1558
Straight Ball Spike	17-1600
Schanz Screw, 6.0x200mm, Thread 60mm	8-1516
Sterilization Tray, Pelvic Basic Set	50247

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

Tray setting



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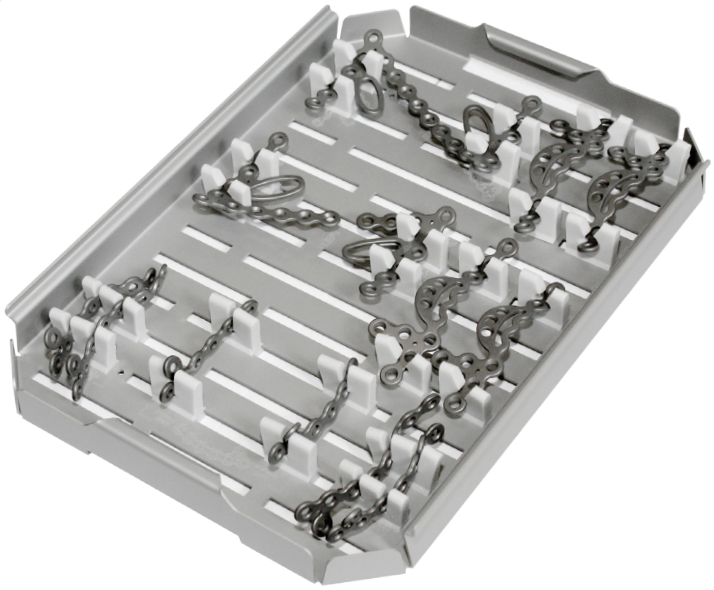

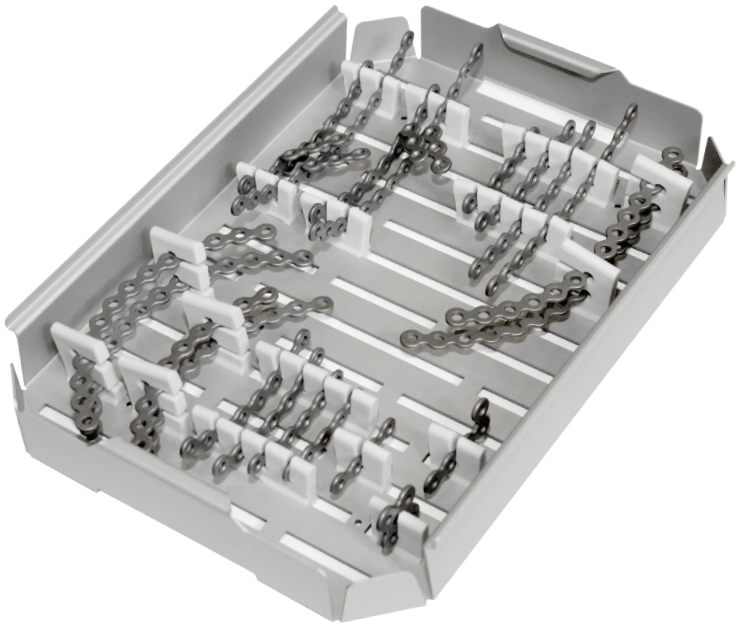


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Order No. PRS RX-OP-0218-USA
Edition: February/2018