

Salvation™ 3Di Plating System

Operative technique



Salvation™ 3Di

Plating System

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Stryker recognizes that proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience, and patient condition. Prior to use of the system, the surgeon should refer to the product Instructions For Use package insert (151662) for additional warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this operative technique and the Instructions For Use package inserts are available on wmt.com under the link for prescribing information.

Please contact your local Stryker representative for product availability.

Introduction

The Salvation 3Di Plating System is designed to address the unique demands of advanced midfoot reconstruction. This system focuses on treating cases such as neuropathic deformity requiring arthrodesis of the medial column, with or without corrective osteotomies. Patients with poor quality, soft bone (e.g. Charcot), require a larger, more stable construct than traditional plates, as well as improved screw design for enhanced fixation. The Salvation 3Di Plating System is designed to specifically address these patients, while allowing for ease of soft tissue closure over the construct.

Each Salvation 3Di Implant has been designed with a focus on strength, versatility, and low-profile anatomic contours. The employment of the Salvation 3Di Polyaxial Locking Technology allows the surgeon the option of 4mm or 5.5mm locking and non-locking screws capable of locking at up to 15° off axis with the plate. These screws feature an osteopenic thread profile designed for better fixation in poor quality bone. All Salvation 3Di Implants are made from titanium alloy, and offer the benefits of type II anodization for better fatigue characteristics.

In cases with needs for greater fixation, the Salvation 3Di Plating System may be used in conjunction with ancillary fixation such as external fixation, bolts and beams, or contact casting until bony fusion has occurred.

System features

- Enhanced, contoured plate profile designed for additional stability
- Two different medial column plate styles to provide more options when matching patient anatomy
- All plate holes accept 4mm and 5.5mm locking and non-locking screws
- Osteopenic thread profile is designed to enhance screw purchase in poor quality bone
- Proximal taper on screw core diameter for increased strength
- Salvation 3Di Polyaxial Locking Capability
- Compression features in all plates

Intended use

Indications

The Salvation 3Di Plating System is indicated for the treatment of fracture stabilization/fixation, revision procedures, osteotomies, and reconstruction/arthrodesis of small bones, as well as patients with osteopenic bone. Specific examples include: medial column fusion (talus, navicular, cuboid, first metatarsal) for neuropathic osteoarthropathy (Charcot).

Contraindications

Patients should be warned of these contraindications:

- Infection
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity

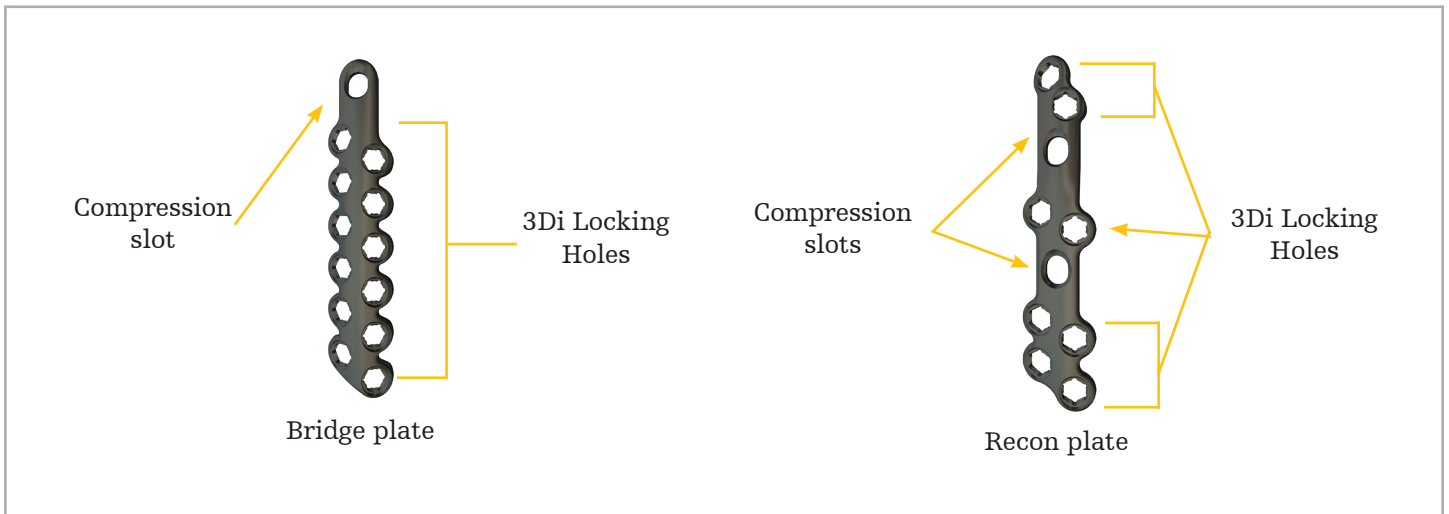
There are no device specific contraindications.

Prior to use of the system, the surgeon should refer to the product instructions for use package insert for warnings, precautions, indications, contraindications and adverse effects. Instructions for use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this operative technique and the instructions for use package inserts are available on ifu.stryker.com under the link for prescribing information.

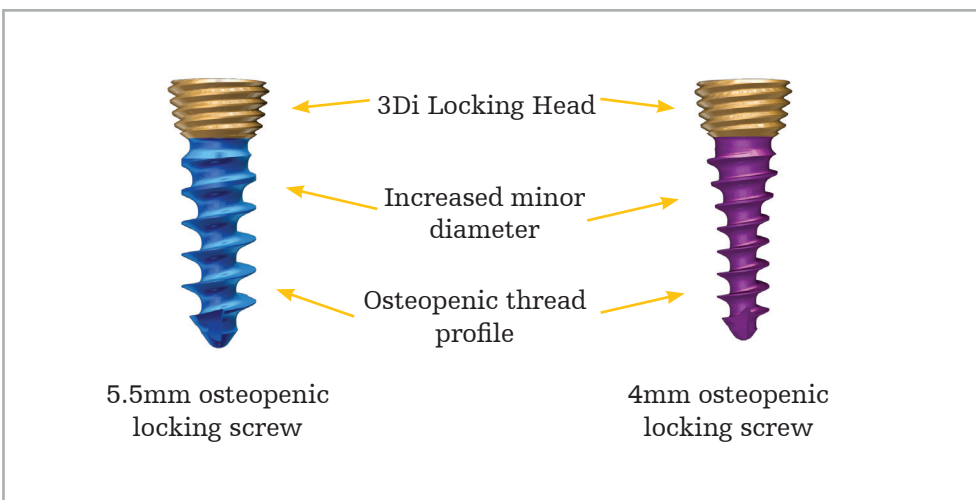
Device description

The Salvation 3Di Plating System features two distinct plate options. The specific plate geometry is designed to enhance construct strength while still facilitating soft tissue closure. All plates are made from titanium alloy with type II anodization and feature polyaxial locking screw holes and slots for compression.

The bridge plate is contoured to fit the specific anatomy of the medial column and provides the maximum number of screw hole options available in the system. The bridge plate comes in right or left options and is available in three different lengths to best match patient anatomy.



The recon plate offers a low profile option, while maintaining strength and anatomic fit. The recon plate comes in right or left options and is available in three different lengths to best match patient anatomy.



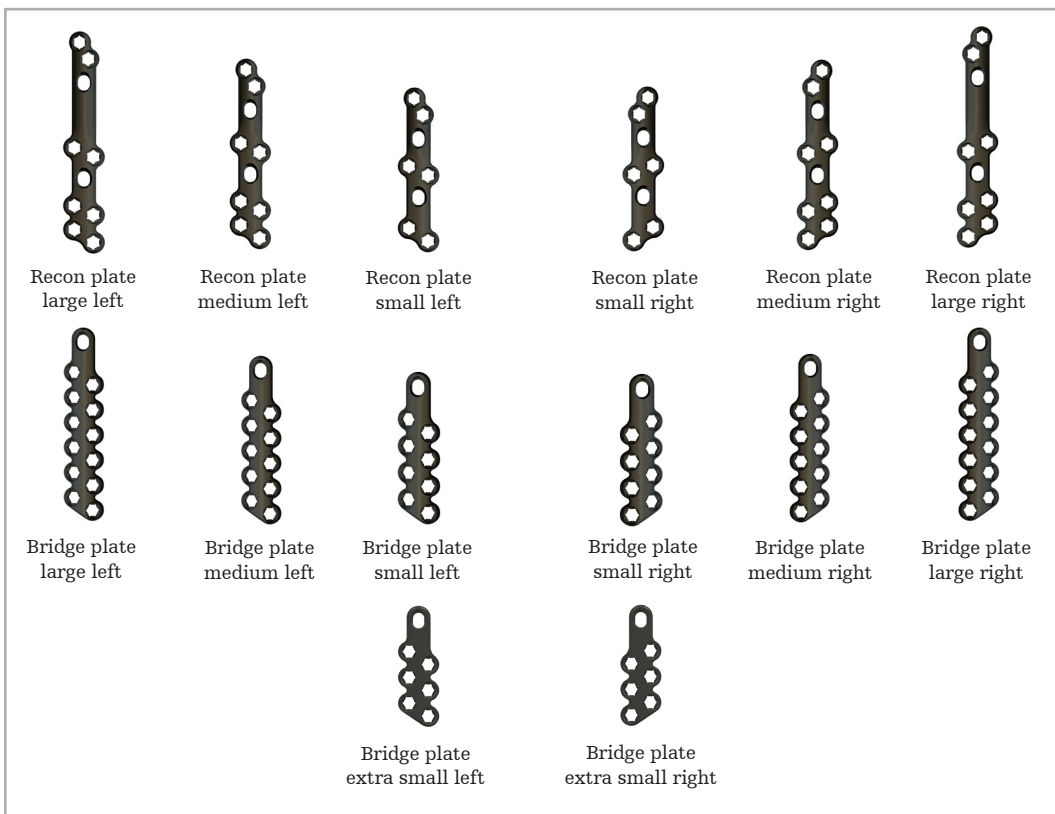
Preoperative planning

Implant Selection

Plates

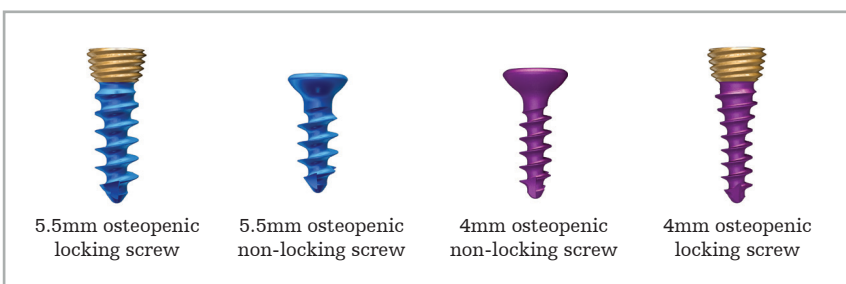
The Salvation 3Di Plating System comprises a variety of plating styles and sizes. Like any lower extremity procedure, preoperative planning is vital to the overall surgical outcome. Careful consideration must be given to implant selection. Choose an implant that addresses the specific needs dictated by the indication, patient anatomy, and overall surgical goals.

Note: The large recon plate and the large bridge plate are **not** included in the standard implant set. They are available to order separately.



Screws

The Salvation 3Di Locking Hole has been designed to accept 4mm and 5.5mm locking and non-locking (low-profile) screws. These screws feature an osteopenic thread profile for enhanced fixation in poor quality bone. Choose the most appropriate screw diameter and type based on anatomy and bone quality.



Operative technique

General system procedures

Screw fixation

When using a locking screw on-axis with the plate, thread the 2.5mm locking drill guide (SP090125) into the 3Di Locking Hole and use the 2.5mm x 60mm drill (SP082560) through the guide to the appropriate depth. | **Figures 1 and 2**

All 3Di Locking Holes and Locking Screws have polyaxial locking capabilities. To engage a locking screw off-axis to the plate threads, place the polyaxial drill guide into the desired locking hole. Ensure the guide mates properly with the Salvation 3Di Locking Feature, and remains firmly engaged with the plate at 90° to the hole trajectory. Drill to the appropriate depth, ensuring that the drill trajectory stays within the 30° guide cone (up to 15° from center axis). | **Figure 3**

Install the appropriate screw under power using the star 20 driver (59250090; 59250095) until the head of the screw comes in contact with the plate. Final tightening should be completed by hand using the driver and quick connect handle (44180025).

Note: As a bailout for a misdirected screw, the 3Di Locking Screws can be disengaged from a locking hole, redirected, and locked again up to three times.



Figure 1



Figure 2

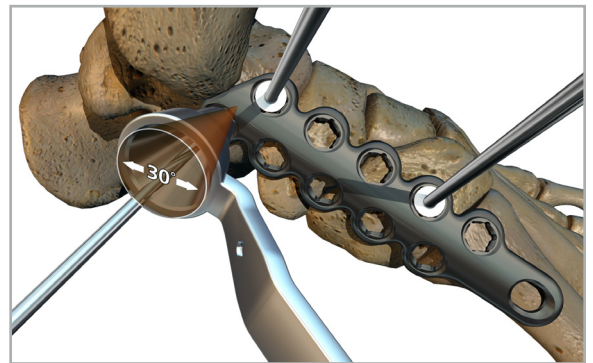


Figure 3



SP090125
2.5mm locking drill guide



SP090225
Drill guide poly axial/non-locking drill guide



SP082560
2.5mm x 60mm drill



59250090
Star 20 driver



59250095
Star 20 straight driver

Determining screw length

Screw length can be determined with the drill and either the locking or non-locking drill guides (SP090125; SP090126). Use the drill to penetrate through the near cortex and continue until the far cortex is reached. Stop drilling just as the far cortex of the bone is penetrated and note where the screw length reference on the drill meets the drill guide. As an alternative, a traditional screw depth gauge (SP090060) has also been provided in the system. | **Figure 4**

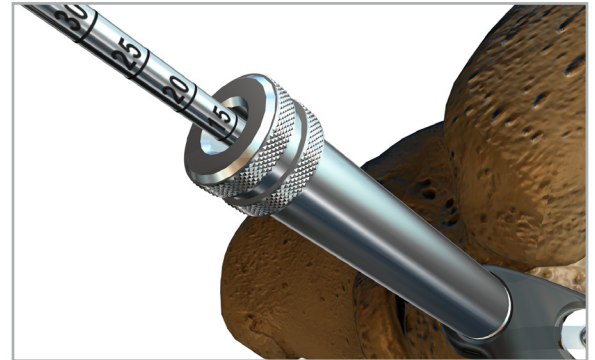


Figure 4

Caution: Do not use the polyaxial drill guide to measure screw length. This will result in short screw measurements and should be avoided.

Compression slots

Compression across the fusion site can be achieved using the oblong compression slots in the plates. Fixate the proximal side of the plate using the appropriate locking or non-locking screws. Using the 2.5mm x 60mm drill, drill a hole at the furthest point in the compression slot away from the fusion site, and drive the appropriate non-locking screw until fully seated in the plate. | **Figure 5**



SP090060
Depth gauge

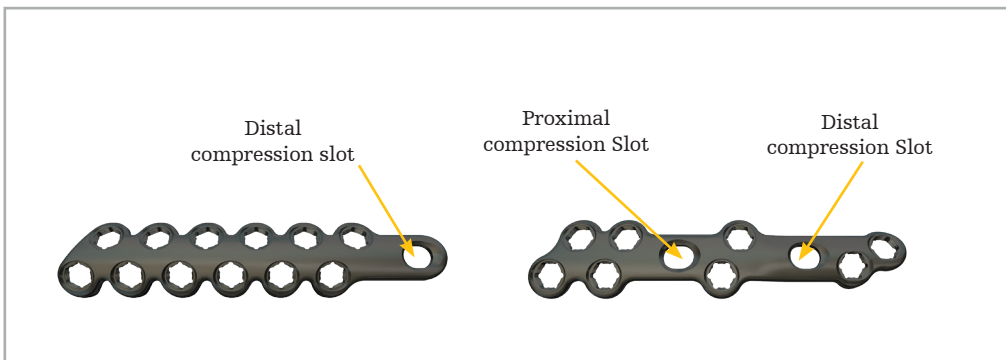


Figure 5

Compression across the fusion site is created as the screw travels to the center of the compression slot. Additional fixation is recommended after compression is achieved.

Plate contouring

The Salvation 3Di Plates have been designed to match the anatomic contours of the medial column. In most cases, intraoperative plate contouring will not be necessary. In cases where some contouring may be required, use the plate benders (SP090022) provided in the system to slightly modify plate contours as needed.

Caution: Care should be taken to avoid over-bending or bending in a back-and forth motion to prevent stress risers.

Order of operation

- Medial approach
- Application of wedge cut guide (SP090033) (for severe deformity)
- Removal of bone, joint space preparation, and provisional stabilization
- Application of medial column plate

Approach

A medial approach is used utilizing the interval between the tibialis anterior and tibialis posterior tendons. | **Figure 6**

The abductor hallucis muscle belly is reflected inferiorly. The tibialis anterior insertion is preserved if possible. There are cases where the tibialis anterior tendon is removed from its insertion and tagged for later re-attachment. Sharp dissection to bone is recommended. Subperiosteal dissection is used to create a dorsal and plantar space for soft tissue protectors that will be used during the wedge cut.

Osteotomy utilizing the wedge cut guide

In severe reconstructive cases, it may be necessary to perform corrective osteotomies to restore the arch and achieve a plantigrade foot. The Salvation 3Di Midfoot Plating System offers a wedge cut guide to facilitate making these cuts. The wedge cut guide features a series of holes for pinning the guide in place using 2.4mm K-wires (200072).

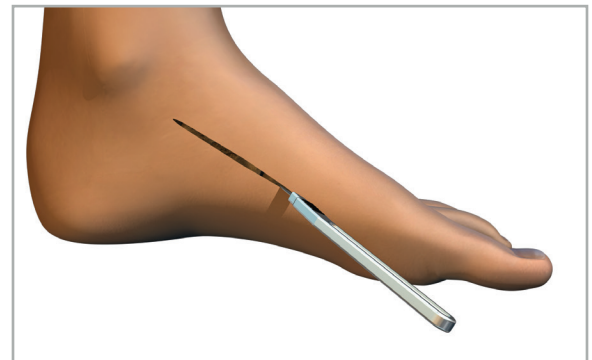
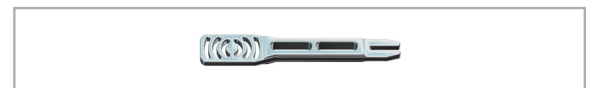
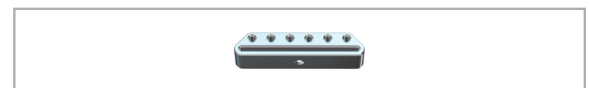


Figure 6



SP090022
Plate benders



SP090033
Wedge cut guide



200072
2.4mm K-wires

The osteotomy is a plantar medial based bi-planar wedge that is designed to correct abduction and arch collapse. The osteotomy is planned preoperatively with the apex targeted to the center in the frontal and lateral plane deformity. The wedge cut guide is placed following the preoperative plan with the first 2.4mm wire placed, from dorsomedial with fluoroscopic assistance targeting the apex. The wedge cut guide is applied and rotated into position to create the desired wedge base and the second 2.4mm wire is placed to secure the cutting guide. After fluoroscopic confirmation of position a sagittal saw is used to divide the bone following the contours of the wedge cut guide. The same procedure is followed for placing the wedge guide for the distal cut. | **Figure 7**

Technical tip: Placing the wedge cut guides perpendicular to the long axis of the hind foot and the forefoot creates a straight medial border and correction of the abduction deformity. There is a hole through the guide to facilitate using a K-wire as an alignment tool to facilitate cut alignment.



Figure 7

Removal of bone, joint space preparation, and provisional stabilization. Using osteotomes the wedge is removed. Any articular surface on which cartilage remains must be denuded of cartilage to facilitate bone healing. The foot is positioned in the corrected posture and provisional wire fixation is used to hold the reduction. | **Figure 7**

Plating

Place the selected plate medially on the bone, and provisionally fixate using the temporary fixation pins (59250050). Plate placement should be beneath the anterior tibial tendon. In more severe cases where osteotomies and/or deformity is being addressed, consider releasing the anterior tibial tendon from its insertion and reattaching once the deformity is corrected and internal fixation complete. | **Figure 8**



Figure 8



59250050
Temporary fixation pins

Compression across the joint(s) can be accomplished using the compression slots included on the recon and bridge plates. Use the appropriate 4mm or 5.5mm locking or non-locking screws in the most proximal holes, and then compress utilizing the compression slot(s).

Bridge plate compression

To achieve compression across the joints using the bridge plate, first secure the proximal aspect of the plate followed by the use of a non-locking screw in the compression slot located distally. | **Figure 9**

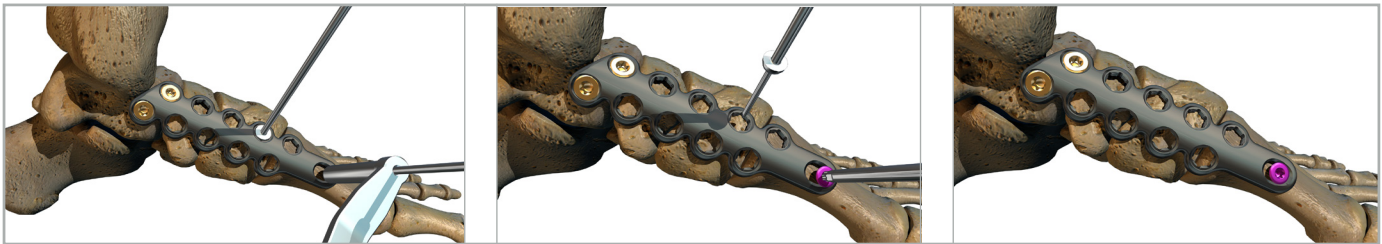


Figure 9

Finish by filling the remaining holes as necessary with the appropriate 3Di Locking or Non-Locking Screws. | **Figure 10**

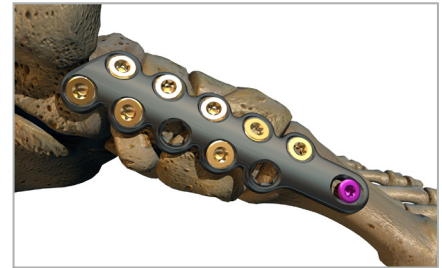


Figure 10

Recon plate compression

To achieve compression using the recon plate, first secure the proximal aspect of the plate followed by the use a non-locking screw in the compression slot located near the middle of the plate, and/or the compression slot located distally. | **Figure 11**

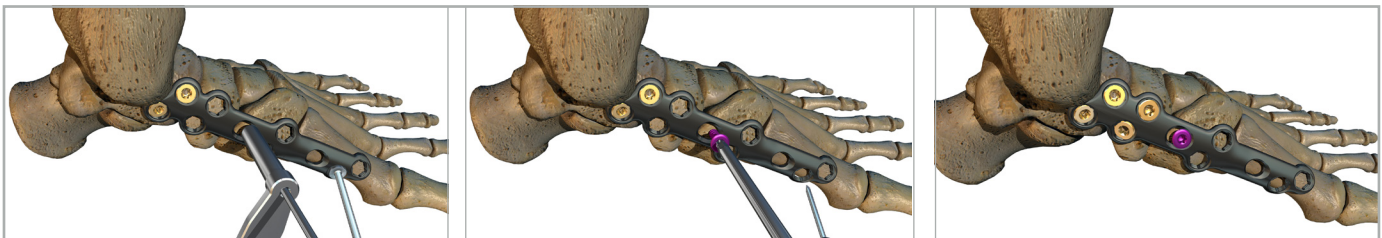


Figure 11

If you are utilizing both compression slots in the recon plate, compress with the more proximal slot first, and then compress with the distal slot.

| **Figure 12**



Figure 12

Finish by filling the remaining holes as necessary with the appropriate 3Di Locking or Non-Locking Screws. | **Figure 13**

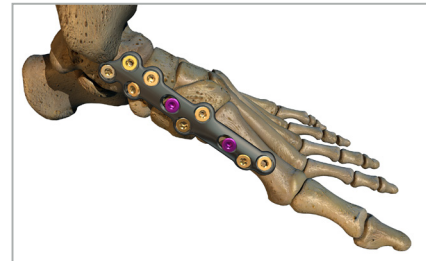


Figure 13

Explant information

Removal of the fusion plate may be performed by first extracting the plate screws using the star 20 straight driver (59250095) and then removing the plate from the bone.

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this operative technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Postoperative care

Postoperative care is the responsibility of the medical professional.

Ordering information

Part number	Description
SP235560	Osteopenic screw 5.5mm x 60mm
SP235555	Osteopenic screw 5.5mm x 55mm
SP235550	Osteopenic screw 5.5mm x 50mm
SP235545	Osteopenic screw 5.5mm x 45mm
SP235540	Osteopenic screw 5.5mm x 40mm
SP235538	Osteopenic screw 5.5mm x 38mm
SP235536	Osteopenic screw 5.5mm x 36mm
SP235534	Osteopenic screw 5.5mm x 34mm
SP235532	Osteopenic screw 5.5mm x 32mm
SP235530	Osteopenic screw 5.5mm x 30mm
SP235528	Osteopenic screw 5.5mm x 28m
SP235526	Osteopenic screw 5.5mm x 26m
SP235524	Osteopenic screw 5.5mm x 24m
SP235522	Osteopenic screw 5.5mm x 22mm
SP235520	Osteopenic screw 5.5mm x 20mm
SP235518	Osteopenic screw 5.5mm x 18mm
SP235516	Osteopenic screw 5.5mm x 16mm
SP234060	Osteopenic screw 4mm x 60mm
SP234055	Osteopenic screw 4mm x 55mm
SP234050	Osteopenic screw 4mm x 50mm
SP234045	Osteopenic screw 4mm x 45mm
SP234040	Osteopenic screw 4mm x 40mm
SP234038	Osteopenic screw 4mm x 38mm
SP234036	Osteopenic screw 4mm x 36mm
SP234034	Osteopenic screw 4mm x 34mm
SP234032	Osteopenic screw 4mm x 32mm
SP234030	Osteopenic screw 4mm x 30mm
SP234028	Osteopenic screw 4mm x 28mm
SP234026	Osteopenic screw 4mm x 26mm

Part number	Description (continued)
SP234024	Osteopenic screw 4mm x 24mm
SP234022	Osteopenic screw 4mm x 22mm
SP234020	Osteopenic screw 4mm x 20mm
SP234018	Osteopenic screw 4mm x 18mm
SP234016	Osteopenic screw 4mm x 16mm
SP225560	OP locking screw 5.5mm x 60mm
SP225555	OP locking screw 5.5mm x 55mm
SP225550	OP locking screw 5.5mm x 50mm
SP225545	OP locking screw 5.5mm x 45mm
SP225540	OP locking screw 5.5mm x 40mm
SP225538	OP locking screw 5.5mm x 38mm
SP225536	OP locking screw 5.5mm x 36mm
SP225534	OP locking screw 5.5mm x 34mm
SP225532	OP locking screw 5.5mm x 32mm
SP225530	OP locking screw 5.5mm x 30mm
SP225528	OP locking screw 5.5mm x 28mm
SP225526	OP locking screw 5.5mm x 26mm
SP225524	OP locking screw 5.5mm x 24mm
SP225522	OP locking screw 5.5mm x 22mm
SP225520	OP locking screw 5.5mm x 20mm
SP225518	OP locking screw 5.5mm x 18mm
SP225516	OP locking screw 5.5mm x 16mm
SP224060	OP locking screw 4mm x 60mm
SP224055	OP locking screw 4mm x 55mm
SP224050	OP locking screw 4mm x 50mm
SP224045	OP locking screw 4mm x 45mm
SP224040	OP locking screw 4mm x 40mm
SP224038	OP locking screw 4mm x 38mm
SP224036	OP locking screw 4mm x 36mm
SP224034	OP locking screw 4mm x 34mm
SP224032	OP locking screw 4mm x 32mm
SP224030	OP locking screw 4mm x 30mm
SP224028	OP locking screw 4mm x 28mm
SP224026	OP locking screw 4mm x 26mm
SP224024	OP locking screw 4mm x 24mm

Part number	Description (continued)
SP224022	OP locking screw 4mm x 22mm
SP224020	OP locking screw 4mm x 20mm
SP224018	OP locking screw 4mm x 18mm
SP224016	OP locking screw 4mm x 16mm
SP090225	Drill guide PA/NL 2.5mm
SP090125	Drill guide threaded 2.5mm
SP090060	Depth gauge
SP090033	Wedge cut guide
SP090022	Plate bender
SP090010	Case assem mid fusion plate
SP082560	Drill bit 2.5mm x 60mm (single use)
SP02004R	Bridge mid fusion plate LG RT
sP02004L	Bridge mid fusion plate LG LT
sP02003R	Bridge mid fusion plate MD RT
sP02003L	Bridge mid fusion plate MD LT
sP02002R	Bridge mid fusion plate SM RT
sP02002L	Bridge mid fusion plate SM LT
sP02001L	Bridge mid fusion plate XS LT
sP02001R	Bridge mid fusion plate XS RT
sP01004R	Recon mid fusion plate LG RT
sP01004L	Recon mid fusion plate LG LT
sP01003R	Recon mid fusion plate MD RT
sP01003L	Recon mid fusion plate MD LT
sP01002R	Recon mid fusion plate SM RT
sP01002L	Recon mid fusion plate SM LT
5882000X	X-track distractor
98792701	Darco cannulated depth gauge
98240532	Darco 5mm hex driver
98230532	Darco countersink
98101027	Darco drill sleeve
94045179	Benders
77706514	4.4mm drill bit (single use)
70709250	K-wire, 2.5mm x 270mm (single use)
59250138	Threaded drill guide 3.8mm
59250130	Threaded drill guide 3.0mm

Part number	Description (continued)
59250100	Depth gauge
59250095	Star 20 straight driver (single use)
59250090	SR driver (single use)
59250038	3.8mm drill bit (single use)
59250061	Trocar
59250060	Lateral targeting guide
59250050	2mm temp fixation pin (single use)
59250030	3mm drill bit (single use)
59250025	Non-locking drill guide 3mm/3.8mm
59250020	Polyaxial drill guide 3mm/3.8mm
59250010	Plate bender
59240000	Washer 4.5mm/5.5mm screws
59225560	Non-locking screw 5.5mm x 60mm
59225555	Non-locking screw 5.5mm x 55mm
59225550	Non-locking screw 5.5mm x 50mm
59225545	Non-locking screw 5.5mm x 45mm
59225540	Non-locking screw 5.5mm x 40mm
59225538	Non-locking screw 5.5mm x 38mm
59225536	Non-locking screw 5.5mm x 36mm
59225534	Non-locking screw 5.5mm x 34mm
59225532	Non-locking screw 5.5mm x 32mm
59225530	Non-locking screw 5.5mm x 30mm
59225528	Non-locking screw 5.5mm x 28mm
59225526	Non-locking screw 5.5mm x 26mm
59225524	Non-locking screw 5.5mm x 24mm
59225522	Non-locking screw 5.5mm x 22mm
59225520	Non-locking screw 5.5mm x 20mm
59224560	Non-locking screw 4.5mm x 60mm
59224555	Non-locking screw 4.5mm x 55mm
59224550	Non-locking screw 4.5mm x 50mm
59224545	Non-locking screw 4.5mm x 45mm
59224540	Non-locking screw 4.5mm x 40mm
59224538	Non-locking screw 4.5mm x 38mm
59224536	Non-locking screw 4.5mm x 36mm
59224534	Non-locking screw 4.5mm x 34mm

Part number	Description (continued)
59224532	Non-locking screw 4.5mm x 32mm
59224530	Non-locking screw 4.5mm x 30mm
59224528	Non-locking screw 4.5mm x 28mm
59224526	Non-locking screw 4.5mm x 26mm
59224524	Non-locking screw 4.5mm x 24mm
59224522	Non-locking screw 4.5mm x 22mm
59224520	Non-locking screw 4.5mm x 20mm
59215560	Locking screw 5.5mm x 60mm
59215555	Locking screw 5.5mm x 55mm
59215550	Locking screw 5.5mm x 50mm
59215545	Locking screw 5.5mm x 45mm
59215540	Locking screw 5.5mm x 40mm
59215538	Locking screw 5.5mm x 38mm
59215536	Locking screw 5.5mm x 36mm
59215534	Locking screw 5.5mm x 34mm
59215532	Locking screw 5.5mm x 32mm
59215530	Locking screw 5.5mm x 30mm
59215528	Locking screw 5.5mm x 28mm
59215526	Locking screw 5.5mm x 26mm
59215524	Locking screw 5.5mm x 24mm
59215522	Locking screw 5.5mm x 22mm
59215520	Locking screw 5.5mm x 20mm
59214560	Locking screw 4.5mm x 60mm
59214555	Locking screw 4.5mm x 55mm
59214550	Locking screw 4.5mm x 50mm
59214545	Locking screw 4.5mm x 45mm
59214540	Locking screw 4.5mm x 40mm
59214538	Locking screw 4.5mm x 38mm
59214536	Locking screw 4.5mm x 36mm
59214534	Locking screw 4.5mm x 34mm
59214532	Locking screw 4.5mm x 32mm
59214530	Locking screw 4.5mm x 30mm
59214528	Locking screw 4.5mm x 28mm
59214526	Locking screw 4.5mm x 26mm
59214524	Locking screw 4.5mm x 24mm

Part number	Description (continued)
59214522	Locking screw 4.5mm x 22mm
59214520	Locking screw 4.5mm x 20mm
58862515	K-wire, 2.5mm x 150mm (single use)
58850025	2.5mm drill (single use)
53620000	04 curved elevator
44180046	Hudson QC
44180046	Hudson quick connect adaptor
44180025	Handle
44180025	Hudson quick connect handle
200072	2.4mm x 229mm K-wire (single use)

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