

SALVATION[®]

Fusion Bolts and Beams

SURGICAL TECHNIQUE



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Wright 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 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 surgical technique and the Instructions For Use package inserts are available on wright.com under the link for Prescribing Information.

Please contact your local Wright representative for product availability.

Device Description

The SALVATION® Fusion Bolts and Beams 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 and lateral columns, with or without corrective osteotomies. Patients with poor quality, soft bone (e.g. Charcot), require implants specifically designed to deliver strength and maintain purchase in these difficult cases. The SALVATION® Fusion Bolts and Beams System is designed to specifically address these patients, while providing easy to use instrumentation that assists in attaining reproducible results.

The SALVATION® Fusion Bolts and Beams System should be used in conjunction with external fixation, additional beams, plates, or contact casting until bony fusion has occurred.

Intended Use

The SALVATION® Fusion Beams and Bolts System is indicated for fracture fixation, osteotomies, reconstruction procedures, non-unions, and fusions of bones in the foot and ankle including the Metatarsals, Cuneiforms, Cuboid, Navicular, Calcaneus and Talus. Specific examples include: Medial Column Fusion and Lateral Column Fusion resulting from neuropathic osteoarthropathy (Charcot).

Contraindications

General Surgical Contraindications:

- Active Infection
- Psychologically inadequate patient
- Growing patients with open epiphyses
- Insufficient quantity or quality of bone to permit stabilization of the arthrodesis
- Suspected or documented metal allergy or intolerance

There are no contraindications specific to the products.

The SALVATION® Fusion Bolts and Beams System should be used in conjunction with external fixation, additional beams, plates, or contact casting until bony fusion has occurred.

Fusion Beams

7.0mm Fusion Beam Partially Threaded



- Lengths: 50mm to 170mm by 5mm increments
- Thread Length, Proximal End: 11mm
- Thread Length, Distal End: 34mm

7.0mm Fusion Beam Fully Threaded



- Lengths: 50mm to 170mm by 5mm increments
- Thread Length, Proximal End: 11mm

Fusion Bolts

5.0mm Fusion Bolt



- Lengths: 60mm to 160mm by 5mm increments
- Thread Length, Proximal End: 10mm
- Thread Length, Distal End: 22mm

6.5mm Fusion Bolt



- Lengths: 80mm to 170mm by 5mm increments
- Thread Length, Proximal End: 10mm
- Thread Length, Distal End: 24mm

Preoperative Planning

Preoperative planning is left to the discretion of the surgeon.

A gastrocnemius slide or percutaneous tendo–Achilles lengthening should be considered in midfoot reconstruction to minimize stress across the midfoot.

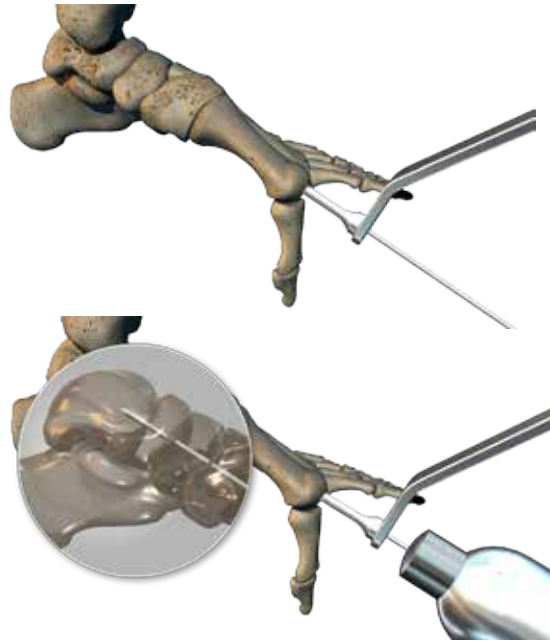
Perform osteotomies as needed to correct deformity and properly align the foot. Utilize 2.0mm (smooth or olive) wires or 2.4mm K-Wires to provisionally hold the foot in the proper neutral plantigrade position during the procedure, if needed. Keep in mind the intended placement of permanent fixation when placing these temporary wires.

Fusion Beam

Make a medial utility incision along the axis of the medial column to allow access and exposure of the medial column joints. In some cases, a bi-planar wedge resection may be needed to correct deformity. This is left to the discretion of the surgeon and individual case needs. It is recommended when intending to fuse a joint, that the joint be resected and prepared when possible. Debride the tarsometatarsal (TMT), naviculocuneiform (NC) and talonavicular (TN) joints down to bleeding subchondral bone. Identify and avoid the tibialis anterior tendon, during the procedure. In some cases, the anterior tendon will need to be transected and advanced once deformity correction is complete. Expose the first metatarsal phalangeal joint by making a dorsal incision.



Plantarflex the first MTP and insert the 2.4mm K-Wire (200072) through the articular surface of the first metatarsal into the medial column. Advance the wire into the 1st metatarsal intramedullary canal and follow the canal trajectory through the cuneiform, navicular, and into the talus. Keep in mind that minor changes in angulation of the wire can substantially effect the distal position of this wire due to the length of the throw. Utilizing fluoroscopy, advance the wire until the tip of the wire is in the desired implant position in the talus.



200072
2.4x229mm K-wire



SB090001
Tissue Protector/Guide



SB090002
Depth Gauge

It is not recommended that the wire penetrate the posterior cortex of the talus. In fact, it is recommended to keep the wire behind the ½ way point of the talar body to allow compression of the construct.

Place the depth gauge (SB090002) over the 2.4mm K-Wire and slide the tip down to the articular surface of the metatarsal to determine the appropriate length of the implant. Read the appropriate length from the graduations on the Depth Gauge.

IMPORTANT NOTE: *If countersinking the implant into the metatarsal canal, subtract the countersink length from the reading on the Depth Gauge.*



Remove the Depth Gauge and pre-drill over the K-Wire with the 5.0mm (SB080050) drill. Utilize fluoroscopy to ensure that the drill is not advanced further than the K-Wire.



Attach the Ratcheting T-Handle (SB090009) to the T25 Driver (SB090025) and insert the SALVATION® Fusion Beam over the 2.4mm K-Wire, making sure that the head of the Beam is seated below the articular surface of the metatarsal.



*SB080050
5.0mm Drill*



*SB090025
T25 Driver*



The Fusion Beam may initially be inserted under power using the T25 Driver, but should always be seated by hand. Always use the Ratcheting T-Handle and the T25 Driver when engaging the threads on the driving (distal) end of the Fusion Beam and for final implant seating.

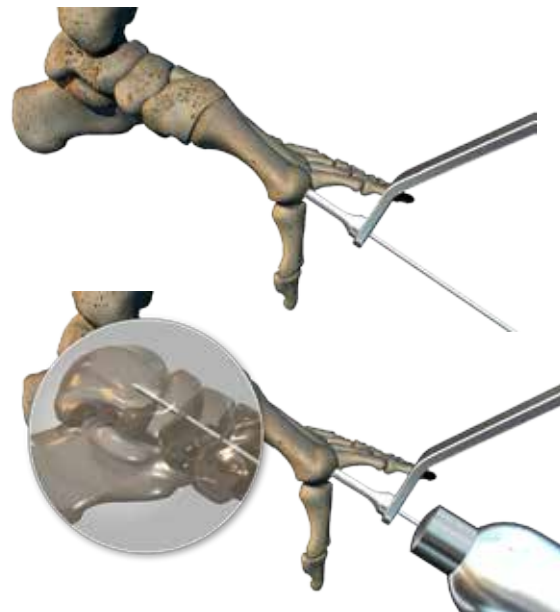


Fusion Bolt

Make a medial utility incision along the axis of the medial column to allow access and exposure of the medial column joints. In some cases, a bi-planar wedge resection may be needed to correct deformity. This is left to the discretion of the surgeon and individual case needs. It is recommended when intending to fuse a joint, that the joint be resected and prepared when possible. Debride the tarsometatarsal (TMT), naviculocuneiform (NC) and talonavicular (TN) joints down to bleeding subchondral bone. Identify and avoid the tibialis anterior tendon, during the procedure. In some cases, the anterior tendon will need to be transected and advanced once deformity correction is complete. Expose the first metatarsal phalangeal joint by making a dorsal incision.



Plantarflex the first MTP and insert the 2.4mm K-Wire through the articular surface of the first metatarsal into the medial column. Advance the wire into the first metatarsal intramedullary canal and follow the canal trajectory through the cuneiform, navicular, and into the talus. Keep in mind that minor changes in angulation of the wire can substantially affect the distal position of this wire due to the length of the throw. Utilizing fluoroscopy, advance the wire until the tip of the wire is in the desired implant position in the talus.



It is not recommended that the wire penetrate the posterior cortex of the talus. In fact, it is recommended to keep the wire behind the ½ way point of the talar body to allow compression of the construct.

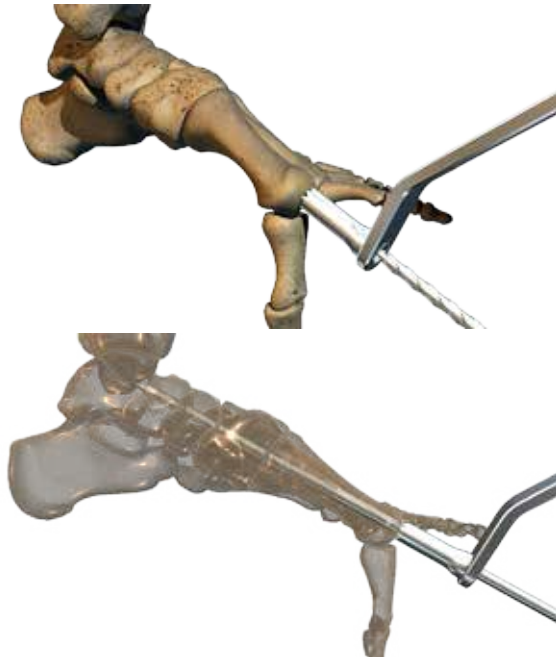
Place the depth gauge over the 2.4mm K-Wire and slide the tip down to the articular surface of the metatarsal to determine the appropriate length of the implant. Read the appropriate length from the graduations on the Depth Gauge.

IMPORTANT NOTE: When countersinking the implant into the metatarsal canal, subtract the countersink length from the reading on the Depth Gauge.



SB080060
6.0/5.0mm Taper Drill

Remove the Depth Gauge and pre-drill over the K-Wire with the 6.0/5.0mm taper drill (SB080060). Utilize fluoroscopy to ensure that the drill is not advanced further than the K-Wire. The Fusion Bolts are self-tapping, not self-drilling. You must drill the entire length of the corresponding implant.



Remove the K-Wire to insert the Fusion Bolt. Using the 6.5mm Bolt Compression T-Handle (SB090065) and the Star 25 Driver (SB090125), insert the SALVATION® Fusion Bolt. Advance the Fusion Bolt until the Compression T-Handle contacts the articular surface of the metatarsal.



SB090065
Bolt Compression T-Handle 6.5mm



Confirm implant position in the talus using fluoroscopy. It is critically important to attain good purchase in talar bone. Continue to advance the Compression T-Handle to compress the medial column until desired compression is achieved.



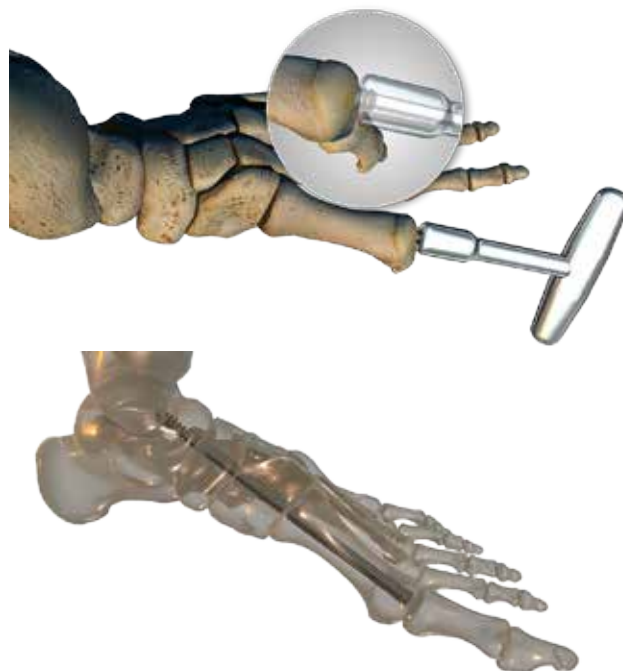
Confirm compression and implant position using fluoroscopy. The threads on the driving end of the implant should be positioned just outside of the distal metatarsal.



Attach the T25 Driver to the Ratcheting Handle and insert the T25 Driver through the Compression T-Handle.



Manually advance the Fusion Bolt until the distal threads have advanced into the first metatarsal. A laser mark is on the driver to help indicate when the implant will disengage from the T-Handle. Back off the Compression T-Handle to visualize final seating of the implant, and advance the implant using the T25 Driver as needed until the implant is seated below the metatarsal head.



In midfoot reconstruction cases, consider placing a Fusion Bolt in the third or fourth metatarsal in addition to a medial column implant.

The SALVATION® Fusion Beam and Bolts System offers 5.0mm Fusion Bolts for the lesser rays and lateral column when needed. The procedure for the 5.0mm Fusion Bolt is similar to the 6.5mm Fusion Bolt with a few exceptions.



56010228
2.0mm K-Wire



SB080045
4.5/3.2mm Tapered Drill



SB090005
5.0mm Compression T-Handle



The 5.0mm Fusion Bolt utilizes the 2.0mm K-Wire (56010228), the smaller diameter implant also requires the use of the 4.5/3.2mm Tapered Drill (SB080045). The 5.0mm implant is advanced with the smaller 5.0mm Compression T-Handle (SB090005), and requires the smaller T15 Driver (SB090015).

Explant Information

chapter 6

Utilize the T25 Driver on the Ratcheting Handle to back out the 7.0mm Fusion Beam and the 6.5mm Fusion Bolt. Utilize the T15 Driver to remove the 5.0mm Fusion Bolt.

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 surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Postoperative Care

Postoperative care is left to the discretion of the surgeon.

Part Number	Description
SB006580	SALVATION® BOLT 6.5 X 80MM
SB006585	SALVATION® BOLT 6.5 X 85MM
SB006590	SALVATION® BOLT 6.5 X 90MM
SB006595	SALVATION® BOLT 6.5 X 95MM
SB065100	SALVATION® BOLT 6.5 X 100MM
SB065105	SALVATION® BOLT 6.5 X 105MM
SB065110	SALVATION® BOLT 6.5 X 110MM
SB065115	SALVATION® BOLT 6.5 X 115MM
SB065120	SALVATION® BOLT 6.5 X 120MM
SB065125	SALVATION® BOLT 6.5 X 125MM
SB065130	SALVATION® BOLT 6.5 X 130MM
SB065135	SALVATION® BOLT 6.5 X 135MM
SB065140	SALVATION® BOLT 6.5 X 140MM
SB065145	SALVATION® BOLT 6.5 X 145MM
SB065150	SALVATION® BOLT 6.5 X 150MM
SB065155	SALVATION® BOLT 6.5 X 155MM
SB065160	SALVATION® BOLT 6.5 X 160MM
SB065165	SALVATION® BOLT 6.5 X 165MM
SB065170	SALVATION® BOLT 6.5 X 170MM
SB005060	SALVATION® BOLT 5.0 X 60MM
SB005065	SALVATION® BOLT 5.0 X 65MM
SB005070	SALVATION® BOLT 5.0 X 70MM
SB005075	SALVATION® BOLT 5.0 X 75MM
SB005080	SALVATION® BOLT 5.0 X 80MM
SB005085	SALVATION® BOLT 5.0 X 85MM
SB005090	SALVATION® BOLT 5.0 X 90MM
SB005095	SALVATION® BOLT 5.0 X 95MM
SB050100	SALVATION® BOLT 5.0 X 100MM

SB050105	SALVATION® BOLT 5.0 X 105MM
SB050110	SALVATION® BOLT 5.0 X 110MM
SB050115	SALVATION® BOLT 5.0 X 115MM
SB050120	SALVATION® BOLT 5.0 X 120MM
SB050125	SALVATION® BOLT 5.0 X 125MM
SB050130	SALVATION® BOLT 5.0 X 130MM
SB050135	SALVATION® BOLT 5.0 X 135MM
SB050140	SALVATION® BOLT 5.0 X 140MM
SB050145	SALVATION® BOLT 5.0 X 145MM
SB050150	SALVATION® BOLT 5.0 X 150MM
SB050155	SALVATION® BOLT 5.0 X 155MM
SB050160	SALVATION® BOLT 5.0 X 160MM
SB017050	SALVATION® BEAM FT 7.0 X 50MM
SB017055	SALVATION® BEAM FT 7.0 X 55MM
SB017060	SALVATION® BEAM FT 7.0 X 60MM
SB017065	SALVATION® BEAM FT 7.0 X 65MM
SB017070	SALVATION® BEAM FT 7.0 X 70MM
SB017075	SALVATION® BEAM FT 7.0 X 75MM
SB017080	SALVATION® BEAM FT 7.0 X 80MM
SB017085	SALVATION® BEAM FT 7.0 X 85MM
SB017090	SALVATION® BEAM FT 7.0 X 90MM
SB017095	SALVATION® BEAM FT 7.0 X 95MM
SB170100	SALVATION® BEAM FT 7.0 X 100MM
SB170105	SALVATION® BEAM FT 7.0 X 105MM
SB170110	SALVATION® BEAM FT 7.0 X 110MM
SB170115	SALVATION® BEAM FT 7.0 X 115MM
SB170120	SALVATION® BEAM FT 7.0 X 120MM
SB170125	SALVATION® BEAM FT 7.0 X 125MM
SB170130	SALVATION® BEAM FT 7.0 X 130MM
SB170135	SALVATION® BEAM FT 7.0 X 135MM

SB170140	SALVATION® BEAM FT 7.0 X 140MM
SB170145	SALVATION® BEAM FT 7.0 X 145MM
SB170150	SALVATION® BEAM FT 7.0 X 150MM
SB170155	SALVATION® BEAM FT 7.0 X 155MM
SB170160	SALVATION® BEAM FT 7.0 X 160MM
SB170165	SALVATION® BEAM FT 7.0 X 165MM
SB170170	SALVATION® BEAM FT 7.0 X 170MM
SB007050	SALVATION® BEAM 7.0 X 50MM
SB007055	SALVATION® BEAM 7.0 X 55MM
SB007060	SALVATION® BEAM 7.0 X 60MM
SB007065	SALVATION® BEAM 7.0 X 65MM
SB007070	SALVATION® BEAM 7.0 X 70MM
SB007075	SALVATION® BEAM 7.0 X 75MM
SB007080	SALVATION® BEAM 7.0 X 80MM
SB007085	SALVATION® BEAM 7.0 X 85MM
SB007090	SALVATION® BEAM 7.0 X 90MM
SB007095	SALVATION® BEAM 7.0 X 95MM
SB070100	SALVATION® BEAM 7.0 X 100MM
SB070105	SALVATION® BEAM 7.0 X 105MM
SB070110	SALVATION® BEAM 7.0 X 110MM
SB070115	SALVATION® BEAM 7.0 X 115MM
SB070120	SALVATION® BEAM 7.0 X 120MM
SB070125	SALVATION® BEAM 7.0 X 125MM
SB070130	SALVATION® BEAM 7.0 X 130MM
SB070135	SALVATION® BEAM 7.0 X 135MM
SB070140	SALVATION® BEAM 7.0 X 140MM
SB070145	SALVATION® BEAM 7.0 X 145MM
SB070150	SALVATION® BEAM 7.0 X 150MM
SB070155	SALVATION® BEAM 7.0 X 155MM
SB070160	SALVATION® BEAM 7.0 X 160MM
SB070165	SALVATION® BEAM 7.0 X 165MM
SB070170	SALVATION® BEAM 7.0 X 170MM

56010228	Kwire 2.0 x228
200072	Kwire 2.4 x228
SB090015	T15 Driver, Solid
SB090125	T25 Driver, Solid
SB080045	Drill, Step 4.5/ 3.2mm
SB090005	Bolt Compression T-Handle 5.0
SB080060	Drill, Step 6.0/ 5.0mm
SB090065	Bolt Compression T-Handle 6.5
SB090025	T25 Driver, Cannulated
SB080050	Drill 5.0mm
SB090009	Ratcheting T-Handle
SB090001	Tissue Protector / Guide
SB090002	Depth Gauge



1023 Cherry Road
Memphis, TN 38117
800 238 7117
901 867 9971
www.wright.com

62 Quai Charles de Gaulle
69006 Lyon
France
+33 (0)4 72 84 10 30
www.tornier.com

Unit 1, Campus Five
Letchworth Garden City
Hertfordshire SG6 2JF
United Kingdom
+011 44 (0)845 833 4435

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