



SALVATION® EXTERNAL FIXATION SYSTEM

151660-3

The following languages are included in this packet:

English (en)
Español (es)

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Nederlands (nl)
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Français (fr)
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Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
U.S.A.

EC REP

Wright Medical UK Ltd.
3rd Avenue
Letchworth
Hertfordshire, SG6 2JF
UK

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION
SALVATION® EXTERNAL FIXATION SYSTEM
(151660-3)

OUTLINE

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
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DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry

	Keep away from sunlight
	Date of manufacture
	Manufacturer
	Authorized EC Representative in the European Community
	Sterilized using ethylene oxide
	Sterilized using radiation
	Sterilized using gas plasma
	Sterilized using aseptic processing techniques
	For prescription use only
Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy

CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
Al	Aluminum

I. GENERAL PRODUCT INFORMATION

Through the advancement of surgical hardware, the surgeon has been provided a means of correcting deformity and reducing pain for many patients. While the implants used are largely successful in attaining these goals, it must be recognized that they are manufactured units, and that no implant can be expected to withstand the activity levels and loads as would normal, healthy bone after healing occurs.

Each patient must be evaluated by the surgeon to determine the risk/benefit relationship.

In using external fixation implants, the surgeon should be aware of the following:

- **The correct selection and sizing of the implant is extremely important.** Selection of the proper size, shape, and design of the implant increases the potential for success. The implants require careful seating and adequate bone support.
- **In selecting patients for surgery, the following factors can be critical to the eventual success of the procedure:**
 1. **Patient's occupation or activity.** If the patient is involved in an occupation or activity which includes substantial lifting or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The implant will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.

2. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
3. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

DESCRIPTION

The SALVATION® External Fixation System is an external support for the lower extremities at or below the ankle for post surgical conditions. The system is provided with all parts necessary to support the surgeon during final stabilization of complex foot and ankle surgery.

A. PATIENT SELECTION

Use of surgical hardware requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bone stock to receive implant
- Availability of post-operative therapy
- Cooperative patient

B. INDICATIONS

Wright's SALVATION® External Fixation System is intended for:

- Fusions of the foot including:

- Triple arthrodesis
- Isolated hindfoot arthrodesis
- Midfoot arthrodesis
- Joints involved include tibiotalar, subtalar, talonavicular, calcaneocuboid, pantalar, tibio-talo-calcaneus, naviculocuneiform, metatarsal cuneiform (first, second, third – e.g. Lapidus, TMT), metatarsal cuboid
- Treatment of fractures including:
 - Treatment of LisFranc fracture/dislocations in diabetic and Charcot neuropathy patient
 - Fractures and/or comminuted fractures (open or closed) of the calcaneus, talus, cuboid, navicular, cuneiforms, and/or metatarsals (including Jones fractures), ankle, and distal tibia
 - Additional fixation adjunct to internal fixation of the distal tibia, calcaneus, talus, navicular, cuboid, cuneiforms, and/or metatarsals in patients with significant comorbidities (i.e. diabetes) that may preclude use of isolated internal fixation
- Reconstruction of deformities including:
 - Neuropathic deformities
 - Charcot reconstruction with or without corrective osteotomies
 - Diabetic Charcot Reconstruction
 - Prevention and treatment of contracture of joints and tendons in equinus
- Treatment of infected unions, nonunions, or malunions
- Offloading and or immobilization of ulcers and/or wounds of the foot or ankle
- Stabilization associated with tendon or ligament surgeries. Tendon lengthening, repairs and transfers both deep and or superficial around the foot and ankle including posterior tibial, tibialis anterior, flexor digitorum longus, achilles, flexor hallucis longus, peroneus brevis, peroneus longus, extensor hallucis longus, extensor digitorum longus

- Tumor and neoplasm resection and reconstruction
- Stabilization associated with rotation flaps, free flaps, muscle flaps, advancement flaps, fasciocutaneous flap, split thickness skin grafting, biological graft alternatives
- Pseudoarthrosis or non-unions of long bones, limb lengthening by epiphyseal or metaphyseal distraction osteogenesis including bone transport
- Correction of bony or soft tissue deformities
- Correction of segmental or nonsegmental bony or soft tissue defects
- Use on long bones including the tibia and fibula
- Use with or without IM nail in the ankle in Charcot patients

C. CONTRAINDICATIONS

Absolute contraindications include:

- Mentally unfit patients
- Poorly vascularized patients

Conditions presenting increased risk of failure include:

- Active Infection
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Growing patients with open epiphyses
- Patients with high levels of activity
- Fevers and white blood cells
- Obesity

Contraindications may be relative or absolute and are left to the discretion of the surgeon.

D. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Bone resorption or over-production
- Allergic reaction(s) to implant material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Embolism
- Abnormal pain and sensations due to the device
- Infection
- Neurologic complication with possible palsy
- Pseudarthrosis

E. WARNINGS AND PRECAUTIONS

- The SALVATION® System is designed for single use only.
- Do not use damaged devices.
- Do not reuse this device. The device is designed to be applied and used during the normal healing process of the aforementioned surgical procedures.
- Advise the patient of any complications that may arise because of this procedure and any changes in lifestyle they should adhere to.

PREOPERATIVE

- Proper understanding of the devices and technique is essential
- Patient selection should be in accordance with the listed indications and contraindications for use of the device
- Evidence supports that factors such as elevated preoperative glucose levels and extended tourniquet times may lead to increased complications. If possible, make efforts to reduce these risks.

Recommendations Regarding Device Fragments

- Wright Medical Technology strongly advises against the use of another manufacturer's device with any Wright Medical Technology external fixators.
- Use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - a. The material composition of the fragment (if known);
 - b. The size of the fragment (if known);

- c. The location of the fragment;
- d. The potential mechanisms for injury, e.g., migration, infection;
- e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Concerning Magnetic Resonance Environments

There are inherent risks associated with the use of metallic implants in the MR environment; including component migration, heat induction, and signal interference or distortion near the component(s). Heat induction of metallic implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants.

The SALVATION® External Fixation System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the SALVATION® External Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Since these devices have not been tested, Wright cannot make a recommendation for the use of MRIs with these implants, neither for safety considerations nor imaging accuracy.

These components are passive metallic devices, and as with all passive devices, there is potential for reciprocal interference with certain imaging modalities; including image distortion for MR and X-ray scatter in CT.

FRAME ASSEMBLY

Preliminary frame assembly should be performed by the surgeon as recommended in the surgical technique.

IMPLANT REMOVAL

External fixators are intended to be left in place for stabilization until complete healing. After that, removal should be considered. However, early removal is recommended in the following situations:

- pain due to implants
- infection
- implant breakage

POSTOPERATIVE

Directions and warnings to patients regarding

- restricted physical activity
- adverse effects
- knowing that no metal device will ever be as strong as a healthy bone structure

CHECKING

- Implantation under image intensifier control
- Assessment of motor activity
- Check proper tightening of all locking elements

INTERFERENCE

Check compatibility of implants with all the materials of the fixator.

PACKAGING

Any component with damaged packaging should be discarded.

F. HANDLING AND STERILIZATION

IMPLANTS

The implants described in this package insert are either provided sterile or non-sterile as indicated on the individual product's label. Implants that are presented in instrument trays are provided non-sterile.

Implants in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. If the inner package integrity has been compromised, contact the manufacturer for further instructions. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

This product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

DO NOT sterilize the SALVATION® Open Rocker Plate (SEF02401), INSOLE (EF003700), or OUTSOLE (EF002500).

End-user sterilized implants should be processed according to the recommended parameters for instruments (below).

INSTRUMENTS

Surgical instruments (and end-user sterilized implants) should be cleaned and sterilized according to the following parameters:

For part numbers SEF99100 (SALVATION® Leg Support), SEF99200 (SALVATION® Side Leg Support), SEF99501 (SALVATION® Leg Positioner), and SEF99500 (SALVATION® Foot Positioner) disassemble threaded knobs from assembly for cleaning and sterilization.

Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly/flush with deionized/reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. **Rinse** thoroughly/flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Sterilization

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the parameters in the tables below.

Table 1: Minimum recommended steam sterilization conditions for:

SEF02400 SALVATION® ROCKER PLATE

SEFA0160 SALVATION® 160MM FRAME ASSEMBLY

SEFA0180 SALVATION® 180MM FRAME ASSEMBLY

SEFA0200 SALVATION® 200MM FRAME ASSEMBLY

SEFA1160 SALVATION® 160MM FRAME

SEFA1180 SALVATION® 180MM FRAME

SEFA1200 SALVATION® 200MM FRAME

Cycle Type	Parameter	Minimum Set Point
Prevacuum 270°F (132°C)	Exposure Temperature	270°F (132°C)
	Exposure Time	18 minutes
	Dry Time	75 minutes

Table 2: Minimum recommended steam sterilization conditions for SEF90000 SALVATION® WIRE TENSIONER

Cycle Type	Parameter	Minimum Set Point
Prevacuum 270°F (132°C)	Exposure Temperature	270°F (132°C)
	Exposure Time	18 minutes
	Dry Time	45 minutes

Disassembly Note: If the frame assemblies (Part numbers: SEFA0160, SEFA0180, SEFA0200, SEFA1160, SEFA1180, and SEFA1200) are completely disassembled, they may be sterilized using the parameters in Table 3 below.

Table 3: Minimum recommended steam sterilization conditions for all other WMT reusable instruments and non-sterile implants not listed above

Cycle Type	Parameter	Minimum Set Point
Prevacuum 270°F (132°C)	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

These 18 minute sterilization cycles with 45 or 75 minute dry time are not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators,

biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

The specified steam sterilization parameters result in a sterility assurance level (SAL) of 10^{-6} . These parameters were validated according to ISO 17665-1 "Sterilization of health care products". This cycle is not for use in prion inactivation.

G. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution, and use by or on the order of a physician.

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