Rx-Fix Mini Rail External Fixator

152237-0

The following languages are included in this packet:

English (en)

For additional information please contact the manufacturer or local distributor.

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℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

Rx-Fix Mini Rail External Fixator

(152237-0)

OUTLINE

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
	Non-sterile

Rx ONLY	For prescription use only
	Do not use if packaging is ripped or damaged.
Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
Al	Aluminum

I. PRODUCT INFORMATION

A. DESCRIPTION OF DEVICE

External Fixators manufactured by Wright Medical are available in various configurations. These fixators can use several pin designs of various diameters and lengths.

B. CONDITIONS OF USE

The implants should be used by surgeons who have received adequate information.

C. INDICATIONS

The Rx-Fix external fixator is indicated for stabilizing various fractures including open and/or comminuted fractures, infected non-unions, fractures with length discrepancies, fusions and corrective osteotomies. The selection of the appropriate type of fixator is left to the discretion of the surgeon, according to the type of fracture and patient's anatomy.

D. CONTRAINDICATIONS

The Rx-Fix external fixator is contraindicated for the following:

- Mentally unfit patients
- Poorly vascularized patients
- 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.

E. PERFORMANCE

Due to its mechanical properties, the device will ensure stabilization of fracture until complete healing. However, misuse of the devices or patient noncompliance may adversely affect performance. In no case will this system replace a healthy bone structure.

F. ADVERSE EFFECTS

- Abnormal pain and sensations due to the device;
- Infection;
- Neurologic complication with possible palsy;
- Pseudarthrosis;
- Death

G. WARNINGS AND PRECAUTIONS

For safe and effective use of this device, the surgeon should be familiar with the recommended surgical procedure for this device. In every case, accepted surgical practice should be followed in postoperative care. The patient should be made aware of the limitations of the implant and that physical activity has been implicated in the premature failure of similar devices. Patient sensitivity to implant materials should be considered and assessed prior to surgery. Do not modify implants.

Preoperative

- Proper understanding of the device and technique is essential;
- Patient selection should be in accordance with the listed indications and contraindications for use of the device;
- Non-sterile implants should be sterilized before use.

Intraoperative

- External fixators should be used according to the recommendations provided in training and surgical technique;
- Wright Medical strongly advises against the use of another manufacturer's device with any Rx-Fix external fixator;
- Checking implantation under image intensifier control;
- Checking assessment of motor activity;
- Check proper tightening on all locking parts of the device.

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.

H. FRAME ASSEMBLY

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

I. IMPLANT MATERIALS

The Rx-Fix is manufactured from titanium alloy (Ti-6Al-4V ELI, ASTM F136)

J. HANDLING AND STERILIZATION

IMPLANTS

The implants in this system are either provided sterile or non-sterile; the individual product's labeling will determine whether or not it is packaged sterile. 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. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

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.

Implants provided non-sterile should be processed according to the recommended parameters for instruments (below).

INSTRUMENTS

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

Cleaning

1. **Disassemble** 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 a similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
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

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.

These recommendations are consistent with AAMI ST79 and A1, Table 5, Row 1 guidelines and have been developed and tested using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

For additional information see Wright's "Cleaning and Handling of Wright Medical Instruments".

K. IMPLANT REMOVAL

External fixators are intended to be left in place for stabilization of a fracture/osteotomy 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

Recommendations Regarding Device Fragments

1. Use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
2. 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.
3. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
4. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
5. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
6. 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.

These implants have not been evaluated for safety and compatibility in the MR environment. These implants have not been tested for heating or migration in the MR environment. 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.

L. ENVIRONMENTAL CONDITIONS

The Rx-Fix is intended to be used under normal environmental conditions.

M. CAUTION

Federal Law (United States) restricts this device to sale, distribution, and/or use by or on the order of a physician