

# Instructions For Use

## Rx-Fix - Mini Rail External Fixator

### Package Insert / Important Medical Information

# OrthoPro

THE FOOT AND ANKLE COMPANY

#### DESCRIPTION OF DEVICE

External Fixators manufactured by OrthoPro are available in various configurations. These fixators can use several pin designs of various diameters and lengths. The fixator is made of several materials: aluminum, stainless steel, titanium, and composite materials.

#### CONDITIONS OF USE

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

#### 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.

#### PERFORMANCE

Due to its mechanical properties, the device will ensure stabilization of fractures 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.

#### ADVERSE EFFECTS

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

#### 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 practices 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 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
- OrthoPro 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 of all locking.

##### **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.

#### FRAME ASSEMBLY

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

#### CONTRAINDICATIONS

- Active infection
  - Fevers and white blood cells
  - Obesity
  - Mental illness
  - Failure to obtain patient's consent
- Contraindications may be relative or absolute and are left to the discretion of the surgeon

#### STERILIZATION

The system is provided non-sterile and should be steam sterilized at the surgical facility before use.

The system must be cleaned prior to sterilization. Clean and inspect all instruments within the system to ensure they are suitable for use. Cracked or bent instruments should be replaced.

The system must be steam sterilized using the following process parameters:

Sterilizer Type:	Prevacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C ( 270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	20 Minutes
Sample Configuration:	Wrapped tray with a towel placed between tray and wrap

Sterilizer Type:	Gravity
Minimum Temperature:	132°C ( 270°F)
Full Cycle Time:	18 Minutes
Minimum Dry Time:	20 Minutes
Sample Configuration:	Wrapped tray with a towel placed between tray and wrap

The use of flash sterilization is not recommended.

Remove all packaging materials prior to sterilization. Only implants and instruments should be used in surgery. Immediately clean and re-sterilize all items removed from the surgical field before handling. Surgical implants shall not be re-used. Any implant once used shall be discarded. Even though it may appear undamaged, it may have small defects or internal stress patterns which may lead to failure.

#### 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

#### ENVIRONMENTAL CONDITIONS

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

#### CAUTION:

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

#### FURTHER INFORMATION

For further information, please contact:  
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Please contact company for product inquiries and surgical techniques, or to report any adverse experience.