AMDT Mini-Rail Fixator
Instructions for Use

Description

The AMDT Mini-Rail Fixator is a unilateral fixator that provides a stable solution for fractures, for lengthening of bones and for correcting deformities.

Indications

The AMDT Mini-Rail Fixator is indicated for stabilizing various fractures including open and comminuted fractures, infected non-unions, fractures with length discrepancies, fusions and corrective osteotomies of the metacarpal, metatarsal, ulnar, and calcaneal bones.

Contraindications

1. Physiologically or psychologically inadequate patient.
2. Possibility for conservative treatment.
3. Failure to obtain patient's consent.

Conditions presenting an 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

Patient Selection

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

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

Warning

External fixators are intended for single use only.

Regarding Magnetic Resonance Environments

The AMDT Mini-Rail Fixator 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 AMDT Mini-Rail Fixator in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions

Pre-operative Precautions

1. Proper understanding of the devices and technique is essential.
2. Patient selection should be in accordance with the listed indications and contraindications for use of the device.
3. Misuse of the device or patient noncompliance may adversely affect performance. In no case will this device replace a healthy bone structure.
4. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
5. Preliminary frame assembly should be performed by the surgeon as recommended in the surgical technique.

6. External fixators are intended to be left in place for stabilization until complete healing is achieved. After healing is complete, removal should be considered. However, early removal should be considered in the following situations:
    - Pain due to implants
    - Infection
    - Implant breakage

FOLLOW-UP

1. Examine implantation under image intensifier.
2. Assessment of motor activity
3. Check proper tightening of all locking components.

POST-OPERATIVE PRECAUTIONS

Warnings and directions to patients regarding:

- Restricted physical activity.
- Adverse effects.
- Knowing that no metal device will ever be as strong as a healthy bone.

ADVERSE EFFECTS

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

- Infection or painful, swollen or inflamed implant site.
- Fracture of the device.
- Loosening or dislocation of the implant requiring revision surgery.
- Abnormal pain and sensations due to the device
- Allergic reaction to implant material.
- Infection
- Neurologic complication with possible palsy
- Pseudarthrosis.

PACKAGING

Unless specifically labeled "STERILE," the items of the AMDT Mini-Rail Fixator System fixators are provided non-sterile. All non-sterile components should be cleaned, decontaminated and sterilized by steam autoclaving before use.

Any component with damaged packaging should be discarded.

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 (STERILE)

Implants, such as Fixation Screws, are single-use only and provided sterile as indicated on the individual product's label. For these products provided sterile, the sterilization method is noted on the label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6}.

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

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.

FIXATOR COMPONENTS AND INSTRUMENTS (NON-STERILE)

For non-sterile external fixation components and instruments, remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization.

Cleaning Instruments

1. Rinse with cold tap water to remove gross contamination.
2. Scrub thoroughly with a soft brush.
3. Rinse with cold tap water.
4. Dry with a clean, soft, absorbent, disposable cloth.
5. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Sterilization of Instrumentation

Surgical instruments and non-sterile fixator components should be sterilized according to the following parameters:

Method:	Steam Sterilization
Type:	Prevacuum (wrapped*)
Minimum Pre-conditioning Pulses:	4
Minimal time:	4 minutes
Minimal temperature:	132 °C (270 °F)
Minimum Dry Time:	30 minutes

* FDA-cleared wrap.

The specified steam sterilization parameters result in a sterility assurance level (SAL) of 10^{-6}. These parameters were validated according to ISO 17665-1:2006 “Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.” This cycle is not for use in prion inactivation.

STORAGE CONDITIONS

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

NEVER steam sterilize or re-sterilize an implant should it inadvertently become contaminated. The implant should be discarded according to hospital procedures.

MANUFACTURER

AMDT Holdings, Inc.
328 Poplar View Lane East, Suite 2
Collierville, TN 38017
Phone: (901) 853-4366
Fax: (206) 222-9173

www.AMDTHoldings.com

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Symbol	Definition	Symbol	Definition
LOT	Batch code		Do not re-use
REF	Catalog number		Caution, consult product documents
	Consult operating instructions		Use by
	Date of manu-facture		Manu-facturer
STERILE R	Sterilized using radiation	NON STERILE	Non-sterile
Rx ONLY	For prescription use only		

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