enovis™

EF1

Mini Rail Frame

Instructions for Use

SINGLE USE ONLY

1. DEVICE DESCRIPTION

The Enovis External Fixation System (Mini Rail Frame) is available in various configurations. These fixators use pin designs of various diameters. Pins are available in 316L implantable stainless steel (ASTM F138). The fixators are made of aluminum and stainless steel.

2. CONDITIONS OF USE

The implants should be used by surgeons who received adequate training. The surgical technique can be obtained from the company at the address below. The Enovis External Fixation System (Mini Rail Frame) may not be reused under any circumstances.

3. INDICATIONS FOR USE

The Enovis External Fixation System (Mini Rail Frame) is indicated for use in external fixation of fractures and/or reconstruction of small bones, including metacarpal and metatarsal.

4. PERFORMANCE

The Enovis External Fixation System (Mini Rail Frame) is designed to maximize intraoperative flexibility for the stabilization and realignment of small bone fractures. However, misuse of the device or patient noncompliance may adversely affect performance. In no case this system will replace a healthy bone structure.

5. WARNINGS AND PRECAUTIONS

Preoperative

- Fracture management and deformity correction should be preoperatively planned to ensure proper frame and component selection.
- 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 the surgical technique.
- Inspect devices prior to use for damage during shipment or storage or any out-of-box defects that might increase the likelihood of device failure during a procedure.
- Proper pin placement requires anatomical consideration to avoid nerve and vessel damage.
- Another manufacturer’s device should never be used with any Enovis external fixator.

Postoperative

- Provide 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
- Clamp and tube integrity must be monitored regularly
- Bone screw site hygiene is required and all patients must be instructed o the use and maintenance of the fixator and bone screws. A 2% hydrogen peroxide and sterile water solution should be used until wounds are healed. Routine showering should follow with an antibacterial soap.
- Patients should report any adverse or unanticipated effects to the treating physician.

The Enovis External Fixation System (Mini Rail Frame) has not been evaluated for safety and compatibility in the MR environment. The Enovis External Fixation System (Mini Rail Frame) has not been tested for heating or migration in the MR environment.

6. CHECKING

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

7. CONTRAINDICATIONS

- Active infection
- High white blood cell count or infection
- Inadequate skin, bone, or neurovascular status
- Patients with high levels of activity
- Rapid joint disease, bone absorption, osteopenia and/or osteoporosis
- Suspected or documented metal allergy or intolerance
- Any patient having inadequate tissue coverage over the operative site
- Severe comminuted fractures such that segments may not be maintained in satisfactory proximate reduction
- Use in displaced, non-reduced fractures with bone loss
- Patients with metal or neurologic conditions who are unwilling or incapable of following postoperative care instructions

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

8. POSSIBLE ADVERSE EFFECTS

- Early or late loosening of the components
- Abnormal pain and sensations due to the device.
- Infection
- Foreign body reaction to the implant

- Pressure on the skin from component parts where there is inadequate tissue coverage over the implant, causing skin irritation
- Non-union (pseudarthrosis) or bone fractures
- Implants cutting through bone, especially soft osteoporotic or cancellous bone
- Bone forming around the implant, making removal difficult or impossible
- Hemorrhage of blood vessels
- Cessation of growth of the operated portion of the bone

9. INTERFERENCE

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

10. PACKAGING

Sterilizer type	**Pre-vacuum**
Temperature	132°C (270°F)
Full Cycle Time	4 Minutes
Minimum Dry Time	20-30 Minutes
Condition	Wrapped
Wrap	The wrap should be FDA cleared for the proposed cycle specifications

Sterilizer type	**Gravity Displacement**
Temperature	132°C (270°F)
Full Cycle Time	15 Minutes
Minimum Dry Time	15-30 Minutes
Condition	Wrapped
Wrap	The wrap should be FDA cleared for the proposed cycle specifications

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 sterilization process for medical devices".

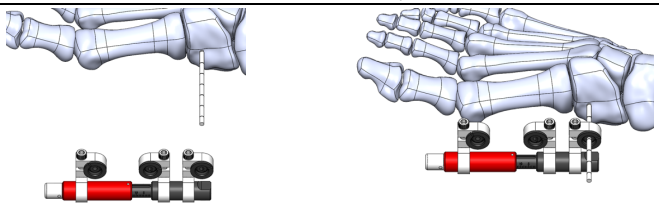
Any components with damaged packing should be discarded.

11. Frame Assembly

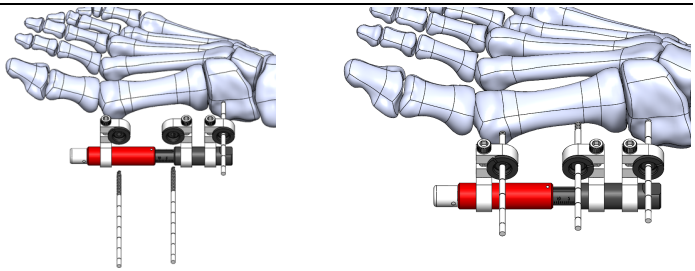
Preliminary frame assembly should be performed by the surgeon as recommended in the surgical technique.

Clamps assembled onto tube

Collets assembled into clamps



Slide collet over pin previously drilled into bone



Next pins inserted using collets as drill guides

See surgical technique for more details.

12. IMPLANT REMOVAL

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

13. ENVIRONMENTAL CONDITIONS

External fixators are intended to be used under normal environmental conditions.

All components must be stored in a clean, dry environment and be protected from extreme temperature.

14. FURTHER INFORMATION

For further information and a copy of a surgical technique, please contact:

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