

enovis[™]

External Fixation System

Instructions for Use

Single Use Only

1. DEVICE DESCRIPTION

The Enovis External Fixation System is available in various configurations. These fixators use several pin designs of various diameters and lengths. Pins are available in Ti6Al4V, implantable titanium (ASTM F136), or 316L implantable stainless steel (ASTM F138). The fixators are made from aluminum and stainless steel.

2. CONDITIONS OF USE

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

3. INDICATIONS FOR USE

The Enovis External Fixation System and its components are indicated for open and closed fracture fixation, pseudarthrosis or nonunion of long bones, limb deformities, and correction of segmental or non-segmental bony or soft tissue defects. The Enovis External Fixation System is for use on all long bones including: the tibia, fibula, femur, humerus, radius, and ulna.

The selection of the appropriate type of fixators is left to the discretion of the surgeon according to the type of fracture and patient's anatomy.

4. 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.

5. ADVERSE EFFECTS

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

6. WARNINGS & PRECAUTIONS

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.
- Components are single use only and are delivered NON STERILE.

Intraoperative:

- External fixators should be used according to the recommendations provided in the surgical technique.

- ENOVIS strongly advises against the use of another manufacturer's device with any ENOVIS external fixator.

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.

The Enovis 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 Enovis External Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

7. CHECKING

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

8. 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.

9. INTERFERENCE

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

10. PACKAGING

Fixators are provided non-sterile; all components should be cleaned, decontaminated, and sterilized by steam autoclaving before use.

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

Sterilizer type: Pre-vacuum

Temperature: 132°C (270°F)

Full Cycle Time: 4 minutes

Minimum Dry Time: 30 minutes

Condition: Wrapped

Sets of instruments may be loaded into dedicated instrument trays or general-purpose sterilization trays for sterilization. Use standard medical grade, FDA approved steam sterilization wrap following the AAMI double wrap method (AAMI ST79).

The specified steam sterilization parameters result in a sterility assurance level (SAL) of 10^{-6} . These parameters were validated according to the biological indicator (BI) overkill method.

Any component with damaged packaging should be discarded.

11. FRAME ASSEMBLY

The Enovis Circular Frame, Speed Frame, Mini Frame, and Pin to Bar Frame systems can be preassembled and sterilized using the above sterilization parameters without disassembly.

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.

14. FURTHER INFORMATION

For further information, please contact:

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Printed in USA.
MK-10405 Rev 00. CRO-2023-0165.