

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed External Fixation Components
Manufactured by SterilMed, Inc.
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Caution: Federal law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

These devices are reprocessed external fixation components. Reprocessed external fixation components consist of various rods, tubes, clamps, and connectors that are assembled into a frame that fits on or around a limb or extremity. These devices are comprised of materials discussed below: Note: Devices labeled as *MR SAFE* are made from non-magnetic materials and are intended for use in the MR environment.

Original Equipment Manufacturers (OEMs) provide an Instruction for Use (IFU) document for each original device. The health institution that wishes the device to be reprocessed should retain this original document.

Reprocessed external fixation components are devices that have been cleaned and evaluated for continued integrity following a prior use. Devices are tracked throughout the reprocessing steps to monitor and ensure the number of times reprocessed maximum allowable reprocessings.

The devices are provided **NON-STERILE**.

This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.

INDICATIONS FOR USE

The reprocessed external fixation device is intended to be used in the construction of an external fixation frame. When used with sterile bone pins and Kirschner wires, this device is used to provide stabilization of open and/or unstable fractures where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts, or other means of internal fixation; fracture fixation of (open and closed) fractures and disease generally resulting in joint contractures or loss of range of motion and fractures requiring distraction; post-traumatic joint contracture which has resulted in loss of range of motion; pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; joint arthrodesis; correction of segmental bony or soft tissues; and management of comminuted intra-articular fractures of the distal radius.

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CONTRAINDICATIONS

These devices are contraindicated in patients in whom cooperation or mental competence is lacking thereby reducing patient compliance; or those with alcohol or substance abuse problems that may lead to poor patient compliance.

WARNINGS AND PRECAUTIONS

1. This device should be used in conjunction with recommended procedures and techniques by individuals with adequate training and familiarity the orthopedic surgical techniques employed. For further information about techniques, complication, and hazards consult available medical and OEM literature.
2. Patients should be informed of how the device is used, the rationale for its use, and potential complications that may arise.
3. Patient selection should be in accordance with the listed indications and contraindications.
4. The correct selection of device components is of the utmost importance. The type and size should be appropriate and selected base on injury, weight, compliance, etc.
5. Preliminary frame assembly is recommended in order to reduce operative time and ensure adequate supply of device components.
6. Examine all instruments for wear and damage prior to surgery. Intraoperative fracture or instrument breakage may occur. Replace pieces where necessary.
7. Wire and pin cutting may produce projectile causing injury to patient or medical personnel during surgery.
8. Anatomical considerations are of the utmost importance during wire and pin placement to avoid damage to nerves, muscles, tendons, and vessels. Gently push, **Do Not Drill**, wires through soft tissue to reduce the possibility of injury.
9. Slowly drill wire through the bone to avoid heat necrosis of surrounding tissues and bone.
10. Handle sharp tips of wires with care, hold the tip of the wire while clipping, and wear eye protection while clipping and cutting wires and pins.
11. Daily pin and wire site care management is essential in reducing infections.
12. Periodic postoperative follow-up and radiographs should be done during the distraction phase
13. Handle and store components with care and avoid cutting, bending, or scratching the components. Damage to components can reduce the strength and fatigue life of the piece.
14. Only components from the same system should be used together unless otherwise specified.
15. Proper fixation and secure assembly of components are essential. Parts should be securely fastened with the appropriate instruments. Tension wires according to product literature.
16. Smith & Nephew recommends 1.8 mm wires for the tibia and femur in normal adults and 1.5 mm wires for upper limbs and pediatric lower limb application.
17. To accommodate swelling ensure frame diameter is approximately 4 cm larger than the maximum diameter of the limb.

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18. The gap at the fracture site should be reassessed during healing and adjustments should be made as needed. Device frame integrity, including wire/pin bone security and wire tension, should be checked regularly.
19. The patient should be instructed to report all adverse and unexpected effects to the physician as soon as possible and be advised of the distraction and adjustment requirement.
20. Touch down weight bearing may be allowed postoperatively with weight bearing being increased as the callus thickens.

ADVERSE EVENTS

1. Wire and pin insertion can result in damage to nerves and vessels
2. Pin/wire site infection and chronic osteomyelitis
3. Edema
4. Loss of range of motion, joint contracture, joint subluxation, and joint dislocation
5. Compartment Syndrome
6. Septic Arthritis
7. Delayed unions and intractable pain
8. Initial condition may persist or recur requiring further treatment
9. Replacement of apparatus or components resulting in reoperation
10. Wire/pin insertion leading to tissue necrosis
11. External components leading to skin pressure
12. Foreign body reaction to device components
13. Muscle tendon impalement and excessive operative bleeding
14. Nonunion pseudoarthrosis development and persistence and failure of the bone regenerating satisfactorily
15. Premature consolidation of bone during lengthening
16. Loss of bone mass
17. Abnormal growth plate development
18. Bone fractures of regenerated bone after device removal
19. Discrepancy in limb length
20. Excessive motion at the fracture site to improper device set-up
21. Heat build-up and bone necrosis with bone sequestration due to rapid drilling of the bony cortex
22. Ankle stiffness due to multiple transfixion pins used in tibial fractions
23. Bone deformity
24. Thrombosis, late erosion or arteriovenous fistulas
25. Osteomyelitis and persistent drainage at wire site after wire removal
26. Inability to compress the bone surface due to poorly secured pins seated in the bone

GENERAL INSTRUCTIONS AND INFORMATION

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage.

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Use of this reprocessed device should be limited to those physicians trained in use of this device and associated equipment. Physicians should consult available OEM literature on surgical technique. For specific information on clinical studies, individualization of treatment, patient counseling, and procedural use of this reprocessed device, refer to the medical literature and rely on training and practical experience.

If additional reprocessing of the product is desired, wipe the device with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to SterilMed.

METHODS TO TEST REPROCESSED DEVICES

Devices are comprised of materials that are known to be biocompatible. Validated methods are used for cleaning and packaging. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

Instructions for Use can be found at www.sterilmed.com. Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.

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