

Reprocessed by

stryker®







Sustainability Solutions

Instructions for Use Reprocessed Non Sterile External Fixation Devices

Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Explanation of Symbols

	Date of Reprocessing
	Do Not Reuse
	Consult Instructions For Use
	Non-sterile
	Catalog Number
	Batch Number

External Fixation Devices Description

External fixation devices are specially designed frames, clamps, rods, rod-to-rod couplings, pins, posts, fasteners, wire fixations, fixation bolts, washers, nuts, hinges, sockets, connecting bars and screws used for the management of bone fractures and reconstructive, as well as corrective, orthopedic surgery. Materials used include metal alloys, plastic and composites. These materials are chosen to address a wide range of fractures and applications as well as to allow for the appropriate amount of rigidity and stability. An external fixation system is a modular system. The system is designed to provide options in frame construction, simplicity in frame components, and ease of transition from one frame size to another.

NOTE: Stryker Sustainability Solutions only reprocesses the external parts of the systems. The pins that are inserted through the skin to the bone are single use implants that are not reprocessed.

Indications for Use

Synthes, Smith and Nephew, EBI/Biomet, Orthofix, DePuy, SBI: Reprocessed external fixation devices are indicated for use in patients requiring external skeletal fixation and treatment of fractures, osteotomy, arthrodesis, correction of deformities, fracture revision, bone reconstruction procedures, limb lengthening, correction of bony or soft tissue deformities and segmental bony or soft tissue defects.

Zimmer TransFx™ external fixation devices are indicated for fractures of the long bones and pelvis, joint fusion, limb lengthening, osteotomies, and periarticular fractures.

Contraindications for Use

Reprocessed external fixation devices are contraindicated for the following:

- When there is an active infection.
- For disabled or non-compliant individuals who cannot perform the necessary postoperative care.
- Fractures that will heal satisfactorily with conservative treatment.

Reprocessed external fixation devices are relatively contraindicated for use in patients with the following:

- Known sensitivity and/or allergies to the materials in the external fixation device model to be used.
- History of frequent infections.
- Neuromuscular deficiencies.
- Significant deficiency in bone quantity and quality.
- Inadequate or impaired blood flow in the body site(s) to be treated.
- Malignant bone growth in fracture area.
- Obesity that could lead to the failure of the device.

Warnings

- These external fixation devices are only intended for use by individuals with adequate training and familiarity with techniques associated with the orthopedic surgical procedure employed. For further information about techniques, complications and hazards, consult the medical literature.
- The use of these devices requires a thorough understanding of the techniques and principles of orthopedic surgery procedures.
- Projectiles from wire or pin cutting could cause injury to patient or medical personnel during surgery.
- Preoperative frame assembly and adequate supply of components is recommended.
- Intraoperative fracture or breakage of instruments can occur (e.g. due to excessive force, extensive use). Inspect all external fixation devices and components prior to surgery. Replace when necessary.
- As a part of the preoperative preparation and surgery planning phase it is advisable to anticipate varus, valgus, procurvatum and recurvatum distraction by selection of an appropriate prophylactic ring tilt and strategically positioning of wires with stoppers, fulcrums, half pins, and hinges.
- Avoid damage to nerves, muscles, tendons, and vessels by careful placement of wires and pins.
- Avoid heat necrosis of surrounding tissue and bone by drilling wires slowly through the bone.
- Hold wire tips when clipping and wear eye protection. Handle the sharp tips of wires with caution.
- Maintain meticulous daily pin and wire site care management to prevent infection.
- Use periodic postoperative follow-ups and radiographs to monitor the distraction phase.

Precautions

- Ensure compatibility of all devices used in a single procedure.
- Select the appropriate model and material of external fixation device(s) for the patient's treatment needs as well as the clinical outcome desired.
- Do not apply excessive force to external fixation devices.
- Reprocessed external fixation devices are not compatible with magnetic resonance imaging (MRI) techniques, unless specified otherwise in the Product Labeling or respective Product Literature.
- Use utmost care in handling and storing of devices to prevent cutting, bending or scratching of the device.
- Securely fasten all wires and miscellaneous parts. Refer to product literature for the tensioning of wires.
- Use a wire diameter with sufficient strength for maintaining the appropriate axial stiffness of the device.
- Allow for patient limb swelling when choosing sizes of rings, half rings and frames.
- Routinely check the security of wires and pins, the tension of wires, and the overall integrity of frame components.
- Preoperative Care
 - Preparation should include provision of a sufficient surplus supply of sterile components.
 - Ensure proper tightening of screws.

Postoperative Care

- Advise the patient of the importance of complying with:
 - The surgeon's warnings and recommendations regarding the use and daily care of the external fixation devices, including topical cleaning using 2% hydrogen peroxide solution in sterile water and routine showering with antibacterial soap.
 - Daily cleansing of pin-skin interface,
 - The limitations in weight bearing as compared to that of a normal, healthy bone,
 - The limitations of activity levels and
 - The medical follow-up required.
- Advise the patient to report unanticipated reactions or problems without delay.
- Visualize and reevaluate the bone healing progress and arrange for adjustments accordingly.
- When applicable, touch down weight bearing may be allowed after surgery and gradually increased as the callus thickens and matures.
- Weekly to biweekly follow-up and radiographs are recommended during the distraction phase.

Adverse Reactions

- Injury of nerves or vessel.
- Edema.
- Premature bone consolidation.
- Osteomyelitis.
- Damage to soft tissue (e. g. tendons or ligaments).
- Abnormal growth plate development (in patients who are skeletally immature).
- Necrosis due to bone screw or wire insertion.
- Pin loosening.
- Excessive operative bleeding.
- Intractable pain.
- Vascular disorders (thrombophlebitis, pulmonary embolus, wound hematomas, avascular necrosis).
- Compartment syndrome.
- Fracture of regenerated bone.
- Bone deformity.
- Chronic drainage of bone screw or wire sites after device removal.
- Inadequate fracture reduction because of failure to pin the bone segments correctly.
- Failure of bone to regenerate satisfactorily.
- Ankle stiffness (if multiple transfixion pins are used in tibial fractures).
- Deep or superficial infection.
- Thrombosis, late erosion or arteriovenous fistulas.
- Loss of bone mass.
- Septic Arthritis.
- Another operation to replace or change the device.
- Foreign body reaction or metal sensitivity.
- Neurological complications, including possibly palsy.
- Pressure problems caused by external components.
- Limb length discrepancy.
- Intrinsic risks associated with anesthesia.
- Tissue necrosis.
- Pin breakage or movement at the fracture site caused by use of too few pins or pins that are too small.
- Nonunion or pseudoarthrosis.
- Bone damage.
- Equinus deformity.
- Joint contracture, subluxation, dislocation or loss of range of motion.
- Excessive motion at the fracture site caused by failure to tighten the component parts of the device.
- Bone separation induced by rapid drilling of the bony cortex.

Directions for Use

1. Inspect the device for overall condition and physical integrity. Do not use the device if any damage is noted. Return the device to Stryker Sustainability Solutions if it is not in acceptable condition for surgery.
2. **Sterilization**

Unless otherwise noted, Stryker Sustainability Solutions external fixation components are provided NON-STERILE. All NON-STERILE components must be properly sterilized by means of a validated sterilization procedure before use.

The following process parameters are recommended for sterilization:

Reprocessed Zimmer, EBI/Biomet, and SBI devices:

Method	Cycle	Temperature	Exposure Time
Steam	Pre-Vacuum	132°C (270°F)	18 minutes

Reprocessed Orthofix devices:

Method	Cycle	Temperature	Exposure Time
Steam	Pre-Vacuum	132° - 135°C (270° - 275°F)	Minimum of 10 minutes

Reprocessed DePuy, Synthes, and Smith & Nephew devices:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	132°C (270°F)	4 minutes	<i>DePuy and Synthes:</i> Minimum of 20 minutes <i>Smith & Nephew:</i> Minimum of 30 minutes

Sterilizer manufacturer recommendations should always be followed. Sterility cannot be assured if the sterilization tray is overloaded. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded. Any cycle should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

Note: Steam sterilization is not recommended for any plastic component

Caution is recommended during sterilization and storage so as to prevent contact with metal or other hard objects that could damage the finish or prevent proper assembly.

3. Before beginning the procedure, verify compatibility of all devices and accessories to be employed in the planned surgical procedure.
NOTE: Additional equipment or tooling may be required to construct or de-construct the system.
4. Use the pins that are compatible with the external fixation system being used. Stryker Sustainability Solutions does not provide pins.
5. Place the components to be used in a sterile work area using aseptic technique.
6. Consider preliminary frame assembly to shorten the procedure.
7. Verify if the product supply is sufficient to complete the intended procedure.
8. Follow a suitable orthopedic surgery protocol.
9. Securely fasten all components.
10. Device is intended for single use during a single patient orthopedic procedure and can be returned to Stryker Sustainability Solutions for reprocessing.

Storage and Handling

- Store in a dry environment. The devices should never be stored in a wet or moist condition.

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Zimmer TransFx™ is a trademark of Zimmer Holdings, Inc.

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