



Reprocessed by Stryker Sustainability Solutions

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English

REPROCESSED EXTERNAL FIXATION DEVICES

ATTENTION OPERATING SURGEON

The use of reprocessed external devices provides the surgeon with a means of bone fixation for the management of fracture and reconstructive surgery. These devices are intended only to assist healing and are not intended to replace normal bone structures. External fixation devices are intended to hold fractured bone surfaces in apposition to facilitate normal healing. While proven successful, the devices are manufactured from metal, plastic and composite materials. No such fracture fixation device, subject to fatigue, can be expected to withstand activity levels in the same way as would a normal healthy bone. The external fixation system, therefore, will not be as strong, reliable or durable as a normal human bone.

In using these devices, the surgeon should be aware of the following:

- A. Stryker Sustainability Solutions only reprocesses the external parts of the systems. The pins that are inserted through the skin to the bone are not reprocessed.**
- B. Reprocessed Stryker External Fixation Devices are not compatible with magnetic resonance imaging (MRI) techniques, unless specified otherwise in the product labeling. Only the following devices are compatible with magnetic resonance imaging (MRI) techniques; Hoffman II MRI, Hoffmann II Compact MRI, and Hoffman Xpress.**
- C. The correct selection and positioning of the device is extremely important. Success of the procedure requires the selection of the proper size, shape and model fracture fixation appliances.**
- D. The following factors are of extreme importance to the eventual success of the procedure.**
 - 1. The patient's weight.** An overweight or obese patient can produce higher loads on the device which can lead to failure of the device. The effect of these loads will be accentuated when a small sized device must be used because of bone size.
 - 2. Patient's activity.** If the patient's activity comprises significant impact loads (walking, running, lifting or turning) the resulting forces could lead to failure of the fixation, the system or both. The system will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations. (See PRECAUTIONS section for more information)

3. **A condition of senility, mental illness, alcoholism, and/or chemical dependence.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the device, leading to failure or other complications.
4. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection.

DESCRIPTION

External fixation devices are used to treat those situations listed in the **INDICATIONS** section. Materials used may include metal alloys, plastic and composites. These materials conform to ASTM and/or ISO standards.

INDICATIONS

Reprocessed External Fixation Devices are indicated for use in patients requiring external 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.

CONTRAINDICATIONS

Since external fixation devices are often used in emergency situation to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and/or the procedure being utilized.

Conditions presenting an increased risk of failure include:

1. Insufficient quantity or quality of bone which would inhibit appropriate fixation of the device.
2. Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site.
3. Previous history of infections.
4. Any neuromuscular deficit which could interfere with the patient's ability to limit weight bearing.
5. Malignancy in the fracture area.
6. Mental, physical or neurological conditions which may impair the patient's ability to cooperate with the postoperative regimen.

WARNINGS

Preparation. The surgeon should be thoroughly familiar with the surgical procedure, instruments and device characteristics as well as the mechanical and material aspects of the external fracture fixation appliances prior to performing surgery.

Device Selection. The correct selection of the fracture fixation appliance is extremely important. Failure to use the appropriate appliance for the fracture condition may accelerate clinical failure. Failure to use the proper component, to maintain adequate blood supply and provide appropriate fixation may result in loosening, bending, cracking or fracture of the appliance and/or bone.

Device Sizing. The correct-sized appliance for a given patient should be utilized. This can be determined by evaluating the patient's height, weight, functional demands and anatomy. The appliance should be used in the correct anatomic location, consistent with accepted standards of external fixation.

PRECAUTIONS

Information for patient. The patients should be instructed to report any unusual changes of the operated site to their physician. The patient should be closely monitored if a change at the fracture site has been detected. The surgeon should evaluate the possibility of subsequent clinical failure, and discuss with the patient the need for reduced activity levels, and/or possible revision surgery in order to aid fracture healing.

The surgeon should discuss all physical and psychological limitations inherent in the use of external fracture fixation appliances with the patient. Particular attention should be given to premature weight bearing, activity levels and the necessity for periodic medical follow-up.

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma.

Instruments. Specialized instruments are available and must be used to assure the accurate placement of these devices. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage, prior to surgery.

ADVERSE EFFECTS

In many instances, adverse results may be clinically related rather than device related.

1. These devices can break when subjected to the increased loading associated with delayed unions and/or nonunions. External fixation devices are load sharing devices which are intended to hold fractured bone surfaces in apposition to facilitate healing. If healing is delayed, or does not occur, the appliance may eventually break due to fatigue. Loads on the device produced by load bearing, and the patient's activity level, will dictate the longevity of the appliance.
2. Conditions attributable to nonunion, osteoporosis, osteomalacia, diabetes, inhibited revascularization and poor bone formation can cause: loosening, bending, cracking, fracture of the device or premature loss of fixation with the bone.
3. Delayed union or nonunion of the fracture site.
4. Improper alignment can cause a malunion and/or bending or fracture of the device.
5. Early or late infection, both deep or superficial.

6. Deep venous thrombosis.
7. Avascular necrosis.
8. Shortening of the affected bone/fracture site.
9. Subclinical nerve damage may possibly occur as a result of the surgical trauma.
10. Metal sensitivity reactions in patients treated with external fixation devices have rarely been reported, and their significance awaits further clinical evaluation.

Sterilization

Unless otherwise noted, reprocessed 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:







Method (US):	Moist-Heat Sterilization
Cycle:	Pre-Vacuum (Pre-Vac)
Temperature:	270° F (132° C)
Exposure Time:	4 minutes
Pressure:	2-15 PSIA
Dry-Time:	30 minutes (minimum, in chamber)
Cool-Time:	60 minutes (minimum, at room temperature)

Note: Any cycle should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

CAUTION

Federal Law in the USA restricts this device to sale by or on the order of a physician.

Explanation of symbols and abbreviation used on product labels

	date of reprocessing
	consult instructions for use
	catalog number
	batch number
	single use
	non-sterile

Rx ONLY Federal Law in the USA restricts this device to sale by or on the order of a physician.

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.

Stryker® External Fixation Devices Reprocessed

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.

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