

Reprocessed by



Sustainability Solutions

Instructions for Use Reprocessed Pressure Infuser Bag


Reprocessed Device for Single Use

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

- **STERILE**

Explanation of Icons


 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

 Product Code

 Do Not Reuse

 See Instructions For Use

Reprocessed Pressure Infuser Bag

This insert is intended for reprocessed Pressure Infuser Bags. The reprocessed Pressure Infuser Bags covered under this insert were originally marketed by Ethox, Statcorp, Medex and Vital Signs.

Indications

Pressure Infuser Bags are designed to be used to increase pressure on I.V. bags to assist the infusion of fluids.

Warnings

- Prior to infusion it is recommended that the IV administration set be properly primed and residual air removed from the fluid bag and tubing to minimize the risk of air embolism.
- Make sure that pressure gauge is clear of any obstructions and allowed to move freely.
- Check pressure of infuser bag periodically during infusion process.
- Do not inflate over the maximum pressure. See box below.

Maximum Pressures:

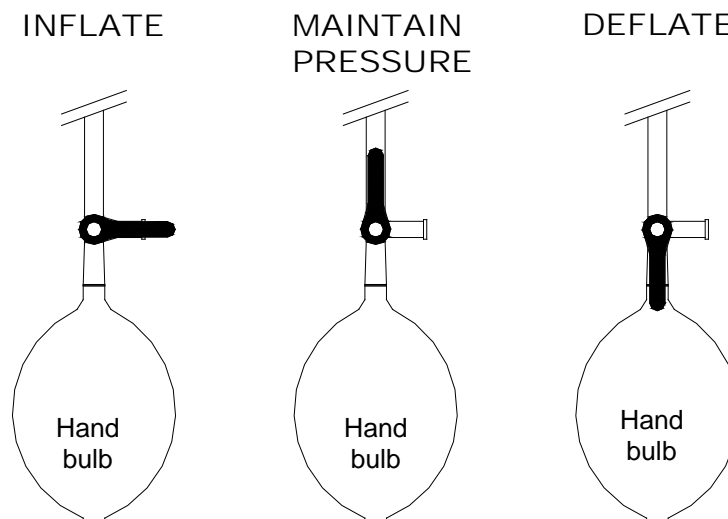
Ethox Infu-Surg® Pressure Infuser Bag – 300mmHg
Statcorp Unifusor® Pressure Infuser Bag – 400mmHg
Vital Signs Infusable® Pressure Infuser Bag – 300mmHg
Medex Clear-Cuff® Pressure Infusor Bag – 300mmHg

Precautions

- Rough handling or abuse may affect the gauge accuracy.

Directions for Use

1. Hang infuser bag on IV pole using infuser bag loop.
2. Carefully insert fluid bag between cuff and sleeve. Hang fluid bag on fluid bag hook.
3. Turn the stopcock handle to point toward the open stopcock vent. (see diagram below). If the infuser bag has a thumb-control, turn clockwise to close air valve.
4. Inflate infuser bag to desired pressure. Do not exceed the pressure limits as stated under “Warnings”.
5. To maintain pressure, turn stopcock up, toward the infuser bag. (see diagram below)
6. To deflate, turn stopcock down, toward the inflation bulb. (see diagram below) If the infuser bag has a thumb-control, turn counter-clockwise to open air vent.



Reprocessed Pressure Infuser Bag

Returning the Compression Device to Ascent Healthcare Solutions for Reprocessing

1. Place the used device in the collection container provided by Ascent Healthcare Solutions.
2. Excessively stained, soiled, or wet compression devices cannot be reprocessed and should be disposed with medical waste.
3. The collection container is ready for shipment once it is at least $\frac{3}{4}$ full.
Filler packing material within the container is not required.

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.

Reprocessed Pressure Infuser Bag

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.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.