

Reprocessed by



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

REF Ascent 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:

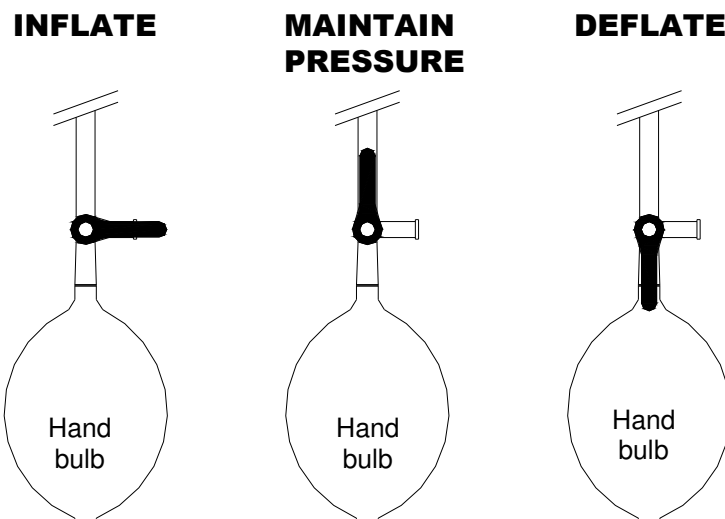
Ethox Infu-Surg® Pressure Infuser Bag – 300mmHg
Statcorp Unifusor® Pressure Infuser Bag – 400mmHg
Vital Signs Infusable® Pressure Infuser Bag – 300mmHg
Medex Clear-Cuff® Pressure Infusor Bag – 300mmHg

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

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

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. 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.