

Reprocessed by



Instructions for Use Reprocessed Balloon Inflation 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.

- **STERILE**
- **NON-PYROGENIC**

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

Balloon Inflation Device Description

A Balloon Inflation Device consists of a clear 20 ml syringe with a threaded plunger, locking mechanism, luer-lock fitting, and pressure gauge. The device may be used in conjunction with other accessories such as a hemostatic valve or stopcock, a guide wire introducer, or torque device.

Indications for Use

Reprocessed Balloon Inflation Devices are used to inflate and deflate an angioplasty balloon or other interventional devices, and to measure the pressure within the balloon.

Warnings

- Prior to use, read and follow these instructions as well as those of any necessary devices used during the procedure.
- Use of this device should be restricted to qualified physicians trained in the techniques of interventional procedures.
- Do not use device in the presence of flammable anesthetics.
- Maximum inflation pressure of the balloon catheter should be noted prior to the procedure and should not be exceeded *in vivo* during the procedure.
- Only radiopaque inflation media recommended by the interventional device manufacturer should be used with this device.
- Improper connection of the inflation device with accessory equipment may introduce air bubbles into the fluid path and subsequently the vascular system. Prior to injecting fluid, verify that the fluid path is free of air bubbles.

Precautions

- Store device in a dry, cool place.
- Inspect the packaging before opening. The contents of the package are sterile if the packaging has not been compromised. Do not use the instrument if the sterility has been compromised. If the package is damaged or if it was opened and the instrument not used, return the instrument and package to Ascent Healthcare Solutions.
- Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted.
- Do not attempt to resterilize.
- Use the device prior to its 'Expiration Date' on the package label.
- Merit Itellisystem 25: use only with the Itellisystem monitor. While preparing the syringe, do not allow fluids to contaminate the cable connectors.
- Merit Monarch 25: Press the green button to activate the monitor. If "ER" is displayed and a number appears in the display unit, the device is defective and should be discarded. The blue button switches the monitor between ATM/BAR and PSI units. To conserve power, the display unit de-activates after 10 minutes of use without a change in pressure, but does continue to monitor pressure. Press the green button to re-activate the display. At pressures above or below the designed range of the inflation device, the monitor will display "↑" or "↓".

Directions for Use

The package label is detachable and may be affixed to the medical record of the patient.

Syringe Preparation

1. Prepare a 10 to 20 ml syringe solution of contrast media and sterile saline as directed in the Instructions for Use of the angioplasty balloon.
2. Remove the device from the package and place it in a sterile work area using aseptic technique.
3. Disengage the locking mechanism and advance the syringe plunger to 0 ml.
4. Connect the two syringes and repeat the following steps until the inflation device fluid path is free of air bubbles: i) Pull back slowly on the plunger handle until the appropriate amount of contrast medium is aspirated into the inflation device. ii) Evacuate any air within by slowly injecting back into the contrast syringe. Tap on the syringe as necessary to dislodge air bubbles.
5. Engage the plunger locking mechanism and disconnect the syringes.

Attaching Inflation Device to Balloon Catheter

1. Refer to catheter manufacturer's instructions for use in order to prepare and test the balloon catheter.
2. If a stopcock has been used in preparing the syringe with contrast, disconnect it from the inflation device. Use of a stopcock for connecting the inflation device to the catheter may compromise device performance.
3. Connect the luer connectors securely to create a fluid-fluid connection between the balloon and extension tubing.
4. Squeeze handle trigger and pull back on plunger handle to apply a vacuum to the balloon.

Balloon Inflation/Deflation

1. To quickly apply negative pressure to deflate the balloon, disengage the plunger lock, squeeze the handle trigger, and withdraw plunger. Re-engage the lock to maintain deflation during catheter insertion.
2. To quickly apply positive pressure to inflate the balloon, disengage plunger lock, squeeze the handle trigger, and advance plunger slowly. Re-engage the lock to maintain inflation.
3. If loss of balloon pressure occurs, check connections for a leak in the fluid path.
4. Small changes in balloon pressure can be made with the syringe in its locked position by rotating the handle clockwise to increase pressure (inflation) or counterclockwise to decrease pressure (deflation).
5. Fully deflate the balloon and engage the plunger lock prior to withdrawing the catheter from the patient.

Recommended Decontamination

1. **Segregation of Devices** – At the completion of each procedure, single-use devices to be reprocessed by Ascent Healthcare Solutions should be physically segregated from other devices. All devices to be reprocessed should be transported from the catheterization laboratory to an adequate decontamination area.
2. **Decontamination and Drying** - The exterior surface of each device to be reprocessed should be wiped down with damp cloth or gauze. The LCD pressure display should NOT be immersed or soaked in any fluid (cleaning solution or water) at any time. Immediately flush the interior surface of the device to avoid contrast media residues. This may be done by pulling cleaning or rinsing fluid into the syringe and expelling all fluid by actuating the plunger. An enzymatic solution such as Sporidicin® Enzymatic Cleaner and Geddis SurgiSoak® is generally recommended. Personnel should refer to the solution manufacturer's instructions for the correct dilution and temperature. **HIGH RESIDUES OF CONTRAST MEDIUM CAN PERMANENTLY STAIN THE INFLATION DEVICE AND IMPAIR ITS FUNCTION.**
3. After rinsing the interior surface of the Inflation Device, all fluid should be expelled by repeatedly pulling air into the syringe housing and advancing the plunger to force all fluid out of the syringe housing. After decontamination, the exterior surface of the inflation device should be wiped dry with fresh cloth or gauze.
4. **Collection and Staging** – The purpose of staging an Inflation Device for collection is to assist in maintaining the functionality of the LCD Pressure Display for those devices that have electronic pressure monitors. After decontamination, Inflation Devices to be reprocessed should be placed individually into the Inflation Device collection systems provided.

The user facility is responsible for providing personal protective equipment (PPE) for all service personnel. Such equipment must comply with OSHA regulations, and can include protective gloves, liquid-resistant clothing, face shields, and surgical face masks. PPE should be worn whenever an individual is performing collection and initial decontamination procedures. Additionally, personnel who might be exposed to infectious agents should receive training on how to recognize potentially unsafe conditions, when and how to use safety equipment, and how to decontaminate surfaces when this is practical. As an additional safety measure, the user facility should offer hepatitis B vaccinations to their service staff.

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.