Reprocessed by

stryker®

Sustainability Solutions

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**

Explanation of Icons

STERILE EO	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
REF	Product Code
2	Do Not Reuse
	See Instructions For Use

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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 radioplaque 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 Stryker Sustainability 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 Intellisystem 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 contract 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 Stryker Sustainability 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 Sporicidin® 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 FUNTION.
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

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.

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.