

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Balloon Inflation Device
Manufactured by SterilMed, Inc.
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www.SterilMed.com

Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

The reprocessed Balloon Inflation Device is intended for use with balloon dilatation catheters to create and monitor pressure in the balloon and to deflate the balloon.

Original Equipment Manufacturers (OEMs) provide an Instructions for Use (IFU) document for each original device. The health institution that wishes the device to be reprocessed should retain this original document.

DEVICE DESCRIPTION

The SterilMed Reprocessed Inflation Device employs a threaded plunger and locking mechanism activated by a finger latch. When the finger latch is depressed the threaded plunger is unlocked and may be advanced or withdrawn as required. When the finger latch is released the device is in the locked position. This allows for the generation and monitoring of pressure in atmospheres (atm) and pounds per square inch (psi). The device incorporates a pressure gauge with a 0-26 atm/bar (0-2,634 kPa), a 20 ml (cc) syringe, and a connecting tube. The gauge is inspected per ANSI/ASME Standard B40.1-1985, with respect to relevant requirements. The gauge accuracy is 3-2-3 indicating an accuracy of $\pm 3\%$ in the upper and lower quarter of the scale and is $\pm 2\%$ in the middle half of the scale. The balloon inflation device, when connected to the PTCA catheter, is a closed system and does not allow delivery of contrast media or drugs to the circulatory system. The SterilMed Reprocessed Balloon Inflation Device is not inclusive of any type of connector set and or a PTCA catheter.

This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.

CONTRAINDICATIONS

There are no known contraindications for the device at this time.

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WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of balloon inflation devices.
2. Inspect the packaging and the balloon inflation device prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. Store inflation device in a dry, dark cool place.

GENERAL INSTRUCTIONS AND INFORMATION

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage or sterility compromise.

Open product using appropriate sterile technique.

Use of this reprocessed device should be limited to those physicians trained in use of this device and associated equipment.

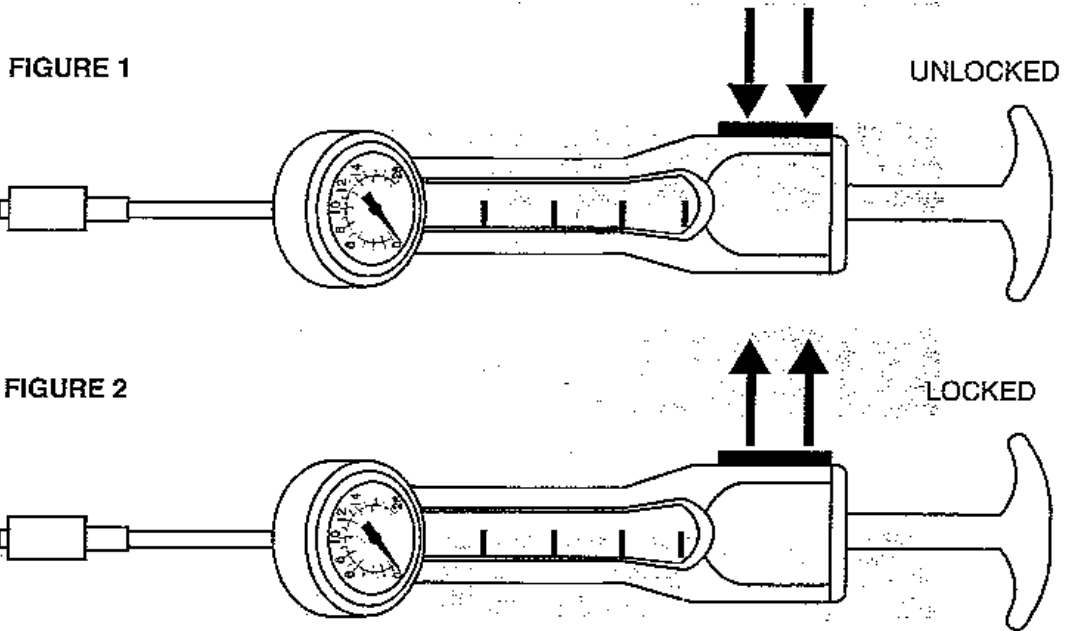
If additional reprocessing of the product is desired, rinse and flush the device as soon as possible after use. Also, wipe the device with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to SterilMed Inc.

DIRECTIONS FOR USE

1. Hold the device in one hand and depress the finger latch to unlock or disengage the threaded plunger. **(Figure 1)**
2. Pull back on the threaded plunger to fill the syringe with contrast and saline (see catheter manufacturers recommendations)
3. Aspirate 5 to 8 ml (cc) into syringe then hold upright and eliminate any air that may have collected in the syringe and tubing.
4. Place a meniscus of fluid on the balloon luer port of the prepared catheter and attach the connecting tube to the luer port.
5. A negative pressure may be applied to the catheter to maintain deflated balloon profile by pulling the plunger back to the desired volume and locking it in place by releasing the finger latch. **(Figure 2)**
6. Pressure is increased by rotating the plunger handle in a clockwise direction with the finger latch in the locked position (out). Pressure can be decreased instantaneously by depressing the finger latch to the unlocked position (in) while slightly rotating the plunger handle.

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METHODS TO TEST REPROCESSED DEVICES

Validated methods are used for cleaning, packaging, routine sterilization, and functionality testing. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product back for reuse.

**Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product 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.*

Instructions for Use can be found at www.SterilMed.com. Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.

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