Attaching the inflation device to the balloon dilation catheter:

1. Prepare and test the balloon dilation catheter according to the manufacturer's directions for use.
2. If a separate syringe was used to prepare the balloon catheter, remove it. When a stopcock is installed on the end of the inflation device connecting tube, it should be opened and purged with contrast media from the inflation device to eliminate air.
3. Create a fluid-fluid connection between the balloon and the stopcock or connecting tube (male rotating adapter) of the inflation device by injecting a drop of contrast solution from the syringe into each hub.
4. Hand-tighten the hubs securely.

Operating inflation device:

1. Release the lock lever and allow the piston to move forward into neutral position (0 atm).
2. To inflate the balloon, engage the lock lever, turn the palm grip on the piston clockwise slowly until the desired inflation pressure is reached. The lock lever maintains the increasing pressure.

Deflation Instructions:

1. To gradually deflate the balloon, turn the palm grip on the piston counter-clockwise slowly until the desired inflation pressure is reached.
2. To rapidly deflate the balloon, push the lock lever left, releasing the piston, and pull back. Slide the lock lever to lock, if desired.

Manufacturer:
Atrion Medical Products, Inc.
1426 Curt Francis Road
Arab, Alabama 35016

US Patent No. 5,713,242,
6,796,959, and 6,938,319

Note: After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practices and applicable laws and regulations.

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

WARRANTY: B. BRAUN INTERVENTIONAL SYSTEMS INC. WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

Ordering Information:

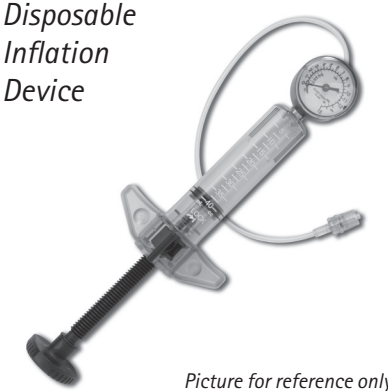
Reference Number	Description	Case Quantity
622513	**40cc** Inflation Device with high pressure tubing, rotating male adapter and 3 way stopcock	10

Manufactured for:
B. Braun Interventional Systems Inc.
824 Twelfth Avenue
Bethlehem, PA 18018
www.bisusa.org

Voluminous 40cc Inflation Device

INSTRUCTIONS FOR USE

Disposable Inflation Device



Picture for reference only

74541 REV A 03/2014

Rx only

Store at room temperature

Keep dry

Do not reuse

Do not resterilize

REF Catalog number

LOT Batch code

DEHP free

Do not use if package is damaged

Non-pyrogenic

LATEX Components and packaging do not contain natural rubber latex

Keep away from sunlight

Consult instructions for use

Use by

STERILE EO Sterilized using ethylene oxide

Manufactured for:
B. Braun Interventional Systems Inc.
824 Twelfth Avenue
Bethlehem, PA 18018
www.bisusa.org

Customer Service, ordering
TEL: (877) VENA-CAV (836-2228)
FAX: (610) 849-1334
Technical Support
TEL: (800) 443-VENA (8362)

Made in U.S.A.

Instructions for Use:

Contents of unopened, undamaged package are:
STERILE • NONPYROGENIC
Disposable - This device is intended for one use only. Do not reuse or resterilize. Sterilized with Ethylene Oxide.

This device has been designed for single patient use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices (particularly those with long and small lumina, joints, and/or crevices between components) are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the combination of the device with pyrogens or microorganisms, which may lead to infectious complications.

Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination, which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on the components that are influenced by thermal and/or mechanical changes.

Indications:

The inflation device is recommended for use while performing balloon dilation procedures to inflate the balloon, monitor the pressure within the balloon and deflate the balloon.

Description:

The Voluminous Inflation Device is a one-piece plastic, disposable inflation device with a lock lever design that controls the piston, a manometer, and connecting tube with a male rotating adapter. A 3-way stopcock is included to aid in preparation of the device. The manometer measures pressures ranging from vacuum to gauge capacity; the gauge is marked in 1 atm increments. The gauge also has an inner scale of comparable PSI measurements. The accuracy of the manometer has been determined to be within 1 atm over range.

Contraindications:

None

Warnings:

- Use only liquid inflation media. Do not inflate with air.
- Always follow the manufacturer's directions accompanying the balloon dilation catheter for instructions for use, maximum balloon inflation pressure, precautions, and warnings for that device.
- Re-use of single-use devices creates a potential risk to patient or user; it may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

Precautions:

- Before use, inspect the device to verify that no damage has occurred during shipping and handling.
- Before use, ensure the connector tubing is completely free of air.
- Use the sterile contrast media that the balloon dilation catheter manufacturer recommends.
- The balloon dilation catheter manufacturer's recommended maximum balloon inflation pressure should not be exceeded.
- DO NOT exceed a pressure of 220 psi (15 atm) when using this device.

WARNING: Refer to the manufacturer's directions accompanying the balloon dilation catheter for specific information on use, maximum inflation pressure, precautions and warnings for that device. Inflation pressures should be closely monitored when inflating balloon. The inflation syringe is a high volume, low compliance system capable of generating high pressures with relative ease.

Instructions for Use:

Preparation:
Make all aspiration and injection maneuvers with the lock lever pushed left, i.e., unlocked. Unlock the piston by pushing the lock lever left. In this position, you can freely pull the piston back for aspiration, or push it forward for injection. To lock the piston in position, slide the lever right to the straight up position.

1. Prepare a solution of contrast medium and normal saline in a small sterile bowl. Check catheter and contrast medium instructions for specific contrast mixture recommendations.
2. Orient the tubing downward into the contrast medium mixture.
3. Push the release lever left and aspirate enough solution to fill the syringe.
   (Attach stopcock, if applicable.)
4. Hold the device upright to purge the air from the syringe and connecting tube. Tap the syringe lightly, if necessary, to remove all the air bubbles and fill the connecting tube completely.
5. Inspect the syringe and tubing (and stopcock, if applicable) to ensure that the device has been completely purged of air bubbles.
6. Adjust the syringe volume to the desired amount. If more contrast is needed, submerge the syringe tubing Luer Adapter into the basin of solution and aspirate. (Close stopcock, if applicable.)