Presto™ Inflation Device

Inflating to Ultra-High Atmospheres

BD

Single Solution Inflator

- The Only Duo Designed and Rated Up To 40 ATM
  - **Presto™ Inflation Device & Conquest™ 40 PTA Dilatation Catheter**
- Inflate to Both **Low and Ultra-High Pressures**

Fast and Adaptable

- **Ergonomic Design** Allows for Comfortable Handling
- Large Barrel Allows for **Rapid and Easy Deflation**
- Designed to Inflate Large or Small Balloons with a **Single Fill of Device**

Directions for Use

Attaching the inflation device to the angioplasty balloon dilatation catheter

1. Prepare and test the angioplasty balloon dilatation catheter according to the manufacturer's instructions for use.
2. If a separate syringe was used to prepare the angioplasty balloon dilatation catheter, remove it. Create a fluid-fluid connection between the catheter hub connector and the connecting tube of the inflation device by opening the stopcock and placing a drop of contrast medium and saline solution from the syringe into the catheter hub.
3. Hand-tighten the hubs securely. Do not over tighten the connection as this may damage the catheter hub or connecting tube.

Balloon inflation and deflation

1. With the lever in the up position, turn the handle clockwise to inflate the balloon to the desired pressure.
2. Alternatively, press the lever and push the handle forward to quickly fill the angioplasty balloon dilatation catheter.
3. To deflate the balloon, rotate the handle counter-clockwise to 0 atm prior to pressing the lever. Once 0 atm has been reached, press the lever and pull back on the handle to evacuate the balloon entirely.

Using additional angioplasty balloon dilatation catheters

1. Hold the device upright to purge the air from the syringe, connecting tube and stopcock. Tap the syringe lightly, if necessary, to remove all the air bubbles. Turn the handle clockwise to expel any air bubbles. Inspect the syringe, tubing and stopcock to ensure that the device has been completely purged of air bubbles.
2. If necessary, adjust the syringe volume to the desired amount by turning the handle clockwise to expel contrast medium and saline solution. If more solution is needed, submerge the connecting tube into the bowl of contrast medium and saline solution and draw up additional solution as described in steps 3 through 5 in the Preparation Section above. Close the stopcock.
3. Attach the next angioplasty balloon dilatation catheter using the steps listed above.

Presto™ Inflation Device Ordering Information

	Product Code	Description	Qty
☐	ID4030	Presto Inflation Device	5/Box

Representative's Name

Contact Phone No.

Physician's Signature

Indications for Use:
The Presto™ Inflation Device is indicated for use with angioplasty balloon dilatation catheters to create and monitor the pressure in the angioplasty balloon dilatation catheter and to deflate the angioplasty balloon dilatation catheter.

Contraindications:
None known.

Warnings:
1) Contents supplied STERILE using ethylene oxide (EO). Non-Pyrogenic. Do not use if sterile barrier is opened or damaged. Single patient use only. Do not reuse, reprocess or re-sterilize. **2)** This device has been designed for single 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 contamination of the device with pyrogens or microorganisms which may lead to infectious complications. **3)** Do not resterilize. After resterilization, the sterility of the device 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 components that are influenced by thermal and/or mechanical changes. **4)** After use, this device may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal laws and regulations. **5)** To reduce the potential risk of air embolism, never use air or other gaseous medium to inflate angioplasty balloon dilatation catheters. Ensure all air has been purged from the entire fluid path prior to patient use. **6)** Do not exceed 40 atm when inflating the device. Damage to the device or user injury may result. **7)** Refer to the angioplasty balloon dilatation catheter instructions for use for additional warnings.

Precautions:
1) Carefully inspect the device prior to use to verify that it has not been damaged during shipment. Do not use if device damage is evident. **2)** Discontinue use of the device if damage, malfunction or contamination is suspected during use. **3)** For experienced physician use only. **4)** Refer to the angioplasty balloon dilatation catheter instructions for use for additional precautions.

Conquest™ 40 PTA Dilatation Catheter
Warning: Do not exceed the RBP recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. To prevent over pressurization, use of a pressure monitoring device or indicated syringe is recommended

Please consult product labels and instructions for use for all indications, contraindications, hazards and warnings and precautions.

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