

Balloon Inflation Device

INDICATIONS FOR USE

The balloon inflation device is a high pressure syringe barrel with ergonomic piston handle, and a gauge used to monitor the inflation and deflation of balloon catheters. It is intended to use with balloon inflation catheters to create and monitor pressure in the balloon and to deflate the balloon. The extension tubing is intended to connect balloon catheters and the balloon inflation device when additional tube length is required.

CONTRAINDICATIONS

Potential adverse events that may occur during or after a procedure using balloon inflation device

Including but are not limited to:

- in an unprotected left main coronary artery Arrhythmia
- to treat coronary artery spasm in the absence of a significant stenosis
- Acute myocardial infarction
- Arrhythmias, including ventricular fibrillation
- Arteriovenous fistula
- Coronary artery spasm
- Coronary vessel dissection, perforation, rupture or injury
- Death
- Drug reactions, allergic reaction to contrast medium
- Embolism
- Hemorrhage or hematoma
- Hypo / hypertension
- Infection
- Restenosis of the dilated vessel
- Total occlusion of the coronary artery or bypass graft
- Unstable angina

STORAGE AND TRANSPORT

1. Store in a cool, dry, clean place.
2. Keep away from sunlight, rain, snow and water. Avoid bearing heavy weight during transport.

PRECAUTIONS AND WARNINGS

READ INSTRUCTIONS PRIOR TO USE.

DO NOT USE IF THE UNIT PACKAGING OR THE PRODUCT HAVE BEEN DAMAGED OR SOILED.

1. Do not exceed the recommended maximum inflation pressure of the balloon catheter being used.
2. Do not use air or a gas medium to inflate the balloon.
3. For single patient use only. Don't reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
4. This device can not be connected with active devices.

INSTRUCTIONS FOR USE

General

Unlock the piston handle by moving the lock lever to the left. Lock the piston handle by moving the lock lever to the centered position. In the unlocked position, the piston is free to move for aspiration or injection maneuvers. In the locked position, the piston can be moved in small increments by rotating the grip clockwise or counterclockwise.

Filling the balloon inflation device

1. Connect extension tubing, if desired.
2. Prepare saline or contrast mixture solution in a sterile bowl.
3. With the gauge held in a downward position, place the connecting tube into the solution.
4. Unlock the balloon inflation device and aspirate fluid into the syringe.
5. With the gauge held in an upward position, push the piston handle forward to purge air from the syringe and connecting tube(s).
6. Push the handle forward to adjust the syringe to the volume required for the balloon catheter as shown in Table 1.

Balloon Catheter	Syringe Volume
Balloon Catheters less than 10mm diameter	6-8cc
Balloon Catheters, 10mm diameter or greater	12cc

7. If contrast media is used, rinse the end of the connecting tube in saline to remove residual contrast.

Connecting to a balloon catheter

Connect the inflation Device connecting tube to the appropriate port on the balloon catheter.

Preparation of a balloon catheter

1. With the balloon inflation device unlocked and the gauge in a downward position, pull the piston handle fully backward and lock the inflation Device. This will maintain a vacuum in the balloon catheter.
2. Wait 10 seconds before proceeding with balloon inflation.

Inflation of a balloon catheter

1. Unlock the balloon inflation device and allow the piston handle to move forward to a neutral position. The gauge will read 0 ATM.
2. Lock the balloon inflation device.
3. Slowly and steadily turn the grip on the piston handle clockwise to increase the pressure in the balloon catheter. The lock function maintains the desired pressure.

NOTE: Turning the grip on the piston handle counterclockwise will decrease the pressure in the balloon catheter.

Deflation of a Balloon Catheter

1. Unlock the balloon inflation device to release the piston handle.
2. Pull the piston handle fully backward and lock the balloon inflation device.

Note: After use, the balloon inflation device may be a potential bio hazard. Handle and dispose of in accordance with accepted hospital procedures.

MAINTENANCE

1. To keep the clear of balloon inflation device.
2. The operation should according to the principle of aseptic strictly.
3. To observe whether there is abnormal situation or not.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING



Keep dry



Do not use if package is damaged



Consult operating instructions



Keep away from sunlight



Date of Manufacture



Sterilized using ethylene oxide



Lot number



Do not reuse



Do not resterilize



Attention, see instructions for use



Catalog number



Use by



CE Mark



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