
EKM Inflation Device

Product Description

EKM Inflation Device is a one-piece, plastic, 20cc disposable inflation device with a lock lever design that controls the piston, a manometer, and a connecting tube with a male rotating adapter. The manometer measures pressures ranging from vacuum to 30atm; the gauge is marked in 1atm increments.

The gauge also has an inner scale of comparable PSI measurements. The accuracy of the manometer has been determined to be within 1atm over the range.

Indications

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

Contraindication

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.**

Precaution

- ◆ 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.

INSTRUCTIONS FOR USE

Preparation

1. Make all aspiration and injection maneuvers with the lock lever pushed left, i.e., unlocked.
2. 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.
3. Prepare a solution of contrast medium and normal saline in a small sterile bowl. Check balloon catheter and contrast medium instructions for specific contrast mixture recommendations.
4. Orient the tubing downward into the contrast medium.
5. Push the release lever left and aspirate enough solution to fill the syringe. (Attach stopcock, if applicable.)
6. 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.
7. Inspect the syringe and tubing to ensure that the device has been completely purged.
8. Adjust the syringe volume to 3 to 4cc. If more contrast is needed, submerge the syringe tip into the basin of solution and aspirate.

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. Create a fluid-fluid connection between the balloon and the connecting tube (male rotating adapter) of the inflation device by placing a drop of contrast solution from the syringe into each hub.
3. Hand-tighten the hubs securely.

Balloon Inflation and Deflation

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.
3. To deflate the balloon, push the lock lever left, releasing the piston, and pull back. Slide the lock lever back to lock, if desired.

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

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

Sterile unless package opened or damaged • Single use only • Do not reuse • Do not re-sterilize

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