QL® INFLATION DEVICE

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in serious complications.

Description:
The QL® Inflation Device is a one-piece, plastic, disposable inflation device with a lock lever design that controls the piston, a manometer, and a connecting tube with a male rotating adapter. An optional 3-way stopcock may also be enclosed for use during 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 the range.

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.

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.

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:
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 balloon catheter and contrast medium instructions for specific contrast mixture recommendations.
2. Orient the tubing downward into the contrast medium.
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 tip into the basin of solution and aspirate. (Close stopcock, if applicable.)

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. Create a fluid-fluid connection between the balloon and the stopcock or 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.

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.
3. To gradually deflate the balloon, turn the palm grip on the piston counterclockwise slowly until the desired deflation pressure is reached.
4. To rapidly 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.

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.
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 components that are influenced by thermal and/or mechanical changes.

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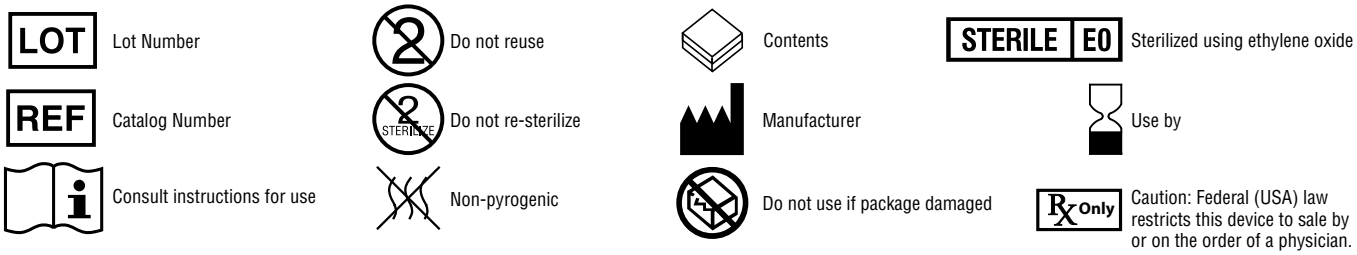
Explanation of Symbols



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