

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

CAUTIONS:

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

PACKAGING

STERILE: Sterilized with ethylene oxide gas. Do not use if the package is open or damaged.

STORAGE: Store in a cool, dry place.

SINGLE USE: The Inflation Device is intended for single patient use only. **DO NOT** resterilize and/or reuse, as it may result in compromised device performance and risk of improper sterilization and cross contamination.

DESCRIPTION

- The Inflation Device is a high pressure syringe barrel, ergonomic piston handle, and a gauge used to monitor the inflation and deflation of balloon catheters
- When connected to sinus balloon catheters, the Inflation Device may be referred to as the Relieva® Sinus Balloon Inflation Device.

INDICATIONS FOR USE

- The Inflation Device is an instrument intended to inflate, deflate and monitor pressure in balloon catheters used in sinus procedures and dilation of the airway tree.
- The Extension Tubing is intended to connect Acclarent Balloon Catheters and the Acclarent Balloon Inflation device when additional tube length is required.

CONTRAINDICATIONS

- Refer to the appropriate balloon catheter Instructions For Use (IFU) for contraindications specific to the chosen clinical application.

WARNINGS AND PRECAUTIONS

- Intended for single patient use only. **DO NOT REUSE.**
- Do not use a device where the integrity of the sterile packaging has been compromised or if the device appears damaged.
- Do not exceed the recommended maximum inflation pressure of the balloon catheter being used.
- Do not use air or a gas medium to inflate the balloon.

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 Inflation Device

1. Connect Relieva® 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 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

Table 1. Syringe Volumes

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

Connecting to a Balloon Catheter

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

Preparation of a Balloon Catheter

1. With the 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 Inflation Device and allow the piston handle to move forward to a neutral position. The gauge will read 0 atm.
2. Lock the 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 desire 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 Inflation Device to release the piston handle.
2. Pull the piston handle fully backward and lock the Inflation Device.

Note: After use, the Inflation Device may be a potential biohazard. Handle and dispose of in accordance with accepted hospital procedures.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING

	Sterilized Using Ethylene Oxide		Keep Away from Sunlight
	Lot Number		Do Not Reuse
	Product Code	Rx ONLY	On Order of Physician Only
	Manufactured By		Date of Manufacture
	Use By		Consult Instructions For Use
	Contents of Package/Box		Tubing Length
	Keep dry		Upper Limit of Temperature
	CE mark		Maximum Pressure

Product Information Disclosure

Acclarent, Inc. has exercised reasonable care in the manufacture of this device. Acclarent, Inc. excludes all warranties, whether expressed or implied, by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device, as well as factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Acclarent, Inc.'s control, directly affect this device and the results obtained from its use. Acclarent, Inc. shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Acclarent, Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

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