

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.
- Airway Balloon dilation catheters should be used by or under supervision of physicians thoroughly trained in airway balloon dilatation. A thorough understanding of the technical principles, clinical application, and risk associated with balloon dilatation of the airway tree is necessary before using this device.

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 *Inspira AIR™* Balloon Dilation System 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 *Inspira AIR™* Balloon Dilation System is composed of:

- An *Airway Balloon Catheter* with an integrated shaft system and a high pressure airway balloon near the distal tip. The shaft is a coaxial catheter. The outer lumen is used for inflation of the airway balloon with sterile water or saline. The inner lumen permits the use of the *Airway Stylet* to facilitate advancement of the balloon catheter to the target location, such as the trachea or upper bronchi. The luer at the proximal end is used for inflation and stylet access. The balloon is inflated by injecting sterile water or saline through the side port of the luer.
- An *Airway Stylet* that is intended to facilitate the use of *Airway Balloon Dilation Catheters*. The proximal end has a luer connector that allows the stylet to lock into the stylet port of the balloon catheter. The distal end consists of an atraumatic tip.

INDICATIONS FOR USE

- The *Inspira AIR™* Balloon Dilation System is an instrument intended to dilate strictures of the airway tree.

CONTRAINDICATIONS

- Balloon dilation is contraindicated in any patient whose degree of respiratory failure would not allow the patient to tolerate the manipulation required to accomplish balloon dilatation.
- Balloon dilation is contraindicated in the presence of:
 - significant active bleeding from the site of the proposed dilation
 - and/or presence of a known perforation at the site of proposed dilation
 - and/or presence of a known fistula between the tracheobronchial tree and esophagus, mediastinum or pleural space

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 try to move the balloon catheter while the balloon is inflated.
- Never advance or retract the devices against resistance as this could cause tissue trauma or device damage.
- Do not exceed the recommended maximum airway balloon inflation pressure indicated on the device labeling.
- Check for proper position of the balloon catheter using endoscopic visualization. Balloon inflation in an improper location may lead to patient injury.
- Balloon must be inflated with sterile water or sterile saline. Do not use air or a gas medium to inflate the balloon.
- Do not preinflate or pretest balloon.
- The balloon dilation system can be used side by side with a bronchoscope. Compatibility for use within the working channel of a bronchoscope has not been established.
- Carefully monitor patient oxygen levels during balloon dilation. Occlusion of the airway for an extended period of time may result in hypoxia.
- Use of a balloon catheter that is too large for the targeted anatomy may cause damage to the surrounding anatomy.
- Use of an undersized balloon catheter may result in failure to properly treat the target anatomy.

COMPATIBILITY

The *Inspira AIR™* Balloon Dilation System is compatible with the *Acclarent™* Inflation Device and the *Relieva®* Extension Tubing.

INSTRUCTIONS FOR USE

General

- Before opening any part of the balloon catheter's sterile package, visually inspect the package to ensure that the seals remain intact, the sterile integrity has not been compromised, and that no damage has occurred during shipping and handling.
- Visualization of the airway using endoscopy or bronchoscopy (flexible or rigid) is recommended in order to determine the location of the stricture and guide placement of the balloon across the stricture.
- Select the appropriate balloon size such that the diameter does not exceed the expected diameter of a healthy airway. Healthy airway diameter can be assessed endoscopically with direct visualization or via reconstructed CT scan imaging. When dilating a fixed congenital stenosis (e.g. complete tracheal rings), care should be taken to limit the diameter of the balloon to the anticipated diameter of the cartilage skeleton in that segment of stenotic airway.

Preparation of the Airway Balloon Catheter

Note: For steps requiring use of an Inflation Device, refer to the appropriate IFU.

1. Remove the Airway Balloon Catheter and Airway Stylet from the sterile package.
2. If using with the Airway Stylet, insert it into the stylet port of the balloon catheter (see Figure 1). The stylet may be locked into place by connecting the male luer on the Airway Stylet with the female luer on the Airway Balloon Catheter.

Note: Once locked into place, the stylet tip will extend 13mm past the distal end of the Airway Balloon Catheter.

3. Remove the protective sheath that covers the airway balloon. Wipe the surface of the airway balloon and catheter shaft with sterile saline or a water soaked gauze pad.
4. Prepare the *Acclarent™* Inflation Device.
5. Connect the balloon port (printed with the letter “B”, see Figure 1) to the connecting tube of the Inflation Device.
6. Prepare the balloon catheter by applying a vacuum with the Inflation Device.

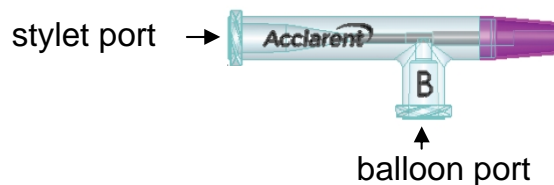


Figure 1. Stylet and balloon port location

Placement of the Airway Balloon Catheter

7. Locate the stricture using endoscopy or bronchoscopy.
8. If desired, the Airway Balloon Catheter may be shaped proximal to the balloon once the Airway Stylet is positioned inside.

Note: Do not shape the Airway Balloon Catheter without a stylet inside, as this may cause kinks in the balloon catheter.

9. Under endoscopic visualization, slowly and gently advance the Airway Balloon Catheter to the site of the stricture.
10. Center the airway balloon across the area to be dilated and confirm correct positioning.

Inflation of the Airway Balloon Catheter

11. Inflate the Airway Balloon Catheter to the desired pressure.

Note: Do not exceed the maximum pressure of the chosen balloon catheter.

12. As the airway balloon is inflating, monitor the diameter, shape, and position of the airway balloon under endoscopic visualization.

Note: Grasp the Airway Balloon Catheter firmly during inflation to prevent inadvertent movement.

13. Monitor pressure using the Inflation Device.
14. If at anytime during the inflation process it is noted that the airway balloon has ruptured (identified by a rapid decrease in pressure on the Inflation Device or visually noted under endoscopic visualization), deflate the balloon and carefully remove the balloon.
15. As dilatation takes place, the pressure reading may fluctuate. Adjust the balloon pressure as necessary to maintain the desired pressure.

Removal of the Airway Balloon Catheter

16. Once desired results are achieved, deflate the airway balloon completely. Maintain a view of the proximal end of the airway balloon as a vacuum is applied using the Inflation Device.
17. Confirm the deflation under endoscopic visualization. Once the airway balloon is fully deflated, remove the catheter from the patient.
18. Confirm that the stricture has been dilated under endoscopic visualization.

Note: Only advance or withdraw the Airway Balloon Catheter when the airway balloon is completely deflated. Advancing or retracting the airway balloon while it is partially or fully inflated may cause serious damage to surrounding anatomical structures.

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







19. If additional inflations are required, use fingers to re-wrap the Airway Balloon Catheter in a clockwise motion, patting the airway balloon from the distal to the proximal end. Repeat the steps for Airway Balloon Catheter placement and inflation.

Note: If the airway balloon does not re-wrap tightly, re-inflate the airway balloon to 2 atm. Place three fingers equally centered on the airway balloon to serve as a guide to form three wings. Release the lock lever on the Inflation Device and pull a vacuum to fully deflate the airway balloon. Gently re-wrap airway balloon as described in step 19.

Possible Complications

Possible complications that may result from airway balloon dilatation are bleeding, perforation, rupture (partial or complete) resulting in pneumomediastinum, pneumothorax, mediastinitis secondary to tracheal dilatation, chest pain, bronchospasm and atelectasis.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING

STERILE EO	Sterilized Using Ethylene Oxide		Keep Away from Sunlight
LOT	Batch Code		Do Not Re-Use
REF	Catalog Number	Rx ONLY	On Order of Physician Only
	Manufactured By		Date of Manufacture
	Use By		Consult Instructions For Use

	Contents of Package/Box		Upper Limit of Temperature
	Catheter Outer Diameter (OD)		Balloon Diameter
	Balloon Length		Maximum Pressure
	Catheter Length		Keep dry

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.

United States Patents Pending.

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