Welcome to the Acclarent EVOLVE Professional Education Program

INSPIRA AIR® Balloon Dilation System
Acclarent® Devices are intended for use by or under the direction of a physician who is trained in the use of Acclarent® Technology. The INSPIRA AIR® Balloon Dilation System use has described risks, including serious complications such as airway obstruction, airway rupture (partial or complete) resulting in pneumomediastinum, pneumothorax and mediastinitis, chest pain, bronchospasm, atelectasis, pulmonary edema and bleeding. Prior to use, it is important to read the Instructions for Use and to understand the contraindications, warnings, and precautions associated with these devices.
Cautions

• Federal (US) law restricts the sale, distribution or use of these devices to, by or on the order of a physician. Third party trademarks used herein are trademarks of their respective owners. This site is intended for visitors from the United States and published by Acclarent, Inc., which is solely responsible for its contents.

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

The INSPIRA AIR® Balloon Dilation System is an instrument intended to dilate strictures of the airway tree (trachea and main stem bronchi).

**NOTE:**
The INSPIRA AIR® Balloon Dilation System has not been tested for use in premature infants (under 37 weeks gestation at the time of treatment).
Features

Designed Specifically for the Airway
• Custom balloon catheter and stylet for airway anatomy

Simplified Airway Access
• Soft, flexible tip guides device through delicate anatomy
• Low-profile system crosses narrow stenoses

Precise Placement Under Direct Visualization
• Integrated stylet provides support and maneuverability
• Malleable shaft can be custom-shaped for access

Controlled Dilation
• High pressure balloon maintains consistent diameter through multiple dilations
• Pressure regulation
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 dilation.

• 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

Size Selection

• 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.
• The INSPIRA AIR® Balloon Dilation System has not been tested for use in premature infants (under 37 weeks gestation at the time of treatment).

Balloon Preparation

• 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 preinflate or pretest balloon.
• Balloon must be inflated with sterile water or sterile saline. Do not use air or a gas medium to inflate the balloon.
Warnings and Precautions

Visualization

• 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.

• Check for proper position of the balloon catheter using endoscopic visualization. Balloon inflation in an improper location may lead to patient injury.

• The INSPIRA AIR® balloon catheter should only be placed in anatomical locations where a portion of the balloon may be continually visualized, to ensure access in the unlikely event of deflation difficulty.
Patient Monitoring

• Prior to dilation, use appropriate anesthetic techniques to minimize respiratory effort. Ongoing vigorous respiration during balloon dilation of the airway may result in patient injury, including possible negative pressure pulmonary edema.

• Carefully monitor patient oxygen levels during balloon dilation. Occlusion of the airway for an extended period of time may result in hypoxia.

• Do not use the stylet lumen to oxygenate or ventilate patient. Improper ventilation may result in patient injury.

• If patient is intubated during dilation, caution should be used to avoid interference with and potential obstruction of the ventilation tube (e.g. endotracheal tube, tracheostomy tube).
Warnings and Precautions

Balloon Inflation/Deflation

• Do not try to move the balloon catheter while the balloon is inflated.

• **IF THE BALLOON MOVES DISTAL TO THE STRICTURE DURING OR AFTER INFLATION, DO NOT ATTEMPT TO PULL IT BACK THROUGH THE STRICTURE UNTIL IT IS DEFLATED.**

• Never advance, retract, or hold the balloon catheter or balloon catheter with stylet against resistance as this could cause tissue trauma or device damage. Device damage may result in inability to deflate and/or difficulty removing the balloon.

• Do not exceed the recommended maximum airway balloon inflation pressure indicated on the device labeling.

• If at any point in the procedure the balloon does not deflate, rupture the balloon with a sharp instrument to allow removal.
Components

Airway Balloon Catheter
High pressure airway balloon

Airway Stylet
Intended to facilitate the use of Airway Balloon Catheter

Stylet locks into balloon catheter via luer lock
Balloon size clearly displayed
Balloon Inflation Port
Instructions for Use

General

• 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.

Note: Before any use of the device, the user should ensure that a sharp instrument which can reach the site of dilation is readily available in the operating room in the event that difficulties with balloon deflation are encountered.
Preparation of Airway Balloon Catheter

For steps requiring use of the Acclarent Inflation Device, refer to the appropriate IFU. When using the Acclarent Inflation Device, refer to the table below for syringe volumes and pressures.

<table>
<thead>
<tr>
<th>Balloon Size (diam x length)</th>
<th>Saline Required</th>
<th>Maximum Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 x 24 mm</td>
<td>6 – 8 cc</td>
<td>16 atm</td>
</tr>
<tr>
<td>7 x 24 mm</td>
<td>6 – 8 cc</td>
<td>16 atm</td>
</tr>
<tr>
<td>8.5 X 24 mm</td>
<td>12 cc</td>
<td>12 atm</td>
</tr>
<tr>
<td>10 x 40 mm</td>
<td>12 cc</td>
<td>12 atm</td>
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<tr>
<td>12 x 40 mm</td>
<td>12 cc</td>
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</tr>
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<td>12 cc</td>
<td>10 atm</td>
</tr>
<tr>
<td>16 x 40 mm</td>
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</table>
Preparation of Airway Balloon Catheter

1. Remove the Airway Balloon Catheter and Airway Stylet from the sterile package.

2. If using with the Airway Stylet, insert stylet into the stylet port of the balloon catheter. 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 13 mm past the distal end of the Airway Balloon Catheter.
Preparation of 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® Balloon Inflation Device.

5. Connect the balloon port (printed with the letter “B”, see below) to the connecting tube of the Inflation Device.

6. Prepare the balloon catheter by applying a vacuum with the Inflation Device.
Placement of the Airway Balloon Catheter

7. Locate the stricture using endoscopy or bronchoscopy (flexible or rigid).

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, ensuring the proximal end of the balloon is positioned proximal to the stricture. *Correct positioning helps to prevent the balloon from moving distally (“watermelon seeding”) during inflation.
11. Grasp the shaft of the Airway Balloon Catheter prior to inflation and maintain control of the catheter during the entire procedure.

12. Inflate the balloon to the desired pressure, monitoring pressure on the Inflation Device. During inflation, visualize endoscopically the diameter, shape, and position of the balloon. Ensure the proximal end of the balloon remains visible proximal to the stricture throughout inflation.

13. If at any time 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.

14. As dilation takes place, the pressure reading may fluctuate. Adjust the balloon pressure as necessary to maintain the desired pressure throughout inflation.
Inflation of the Airway Balloon Catheter

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

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**Warnings**

**Warning:** If the balloon moves distally or proximally during inflation or at any time during the procedure, do not hold the balloon against resistance. **Deflate the balloon, re-center it across the area to be dilated, and re-inflate.**

**Warning:** If the balloon is held against resistance, the shaft may be damaged resulting in difficulty deflating the balloon. **If the balloon does not deflate, rupture the balloon with a sharp instrument to allow removal.**
15. 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.

16. Confirm the deflation under endoscopic visualization. Once the airway balloon is fully deflated, remove the catheter from the patient.

17. 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 or the device.

**Note:** After use, the Airway Balloon Catheter may be a potential biohazard. Handle and dispose of in accordance with accepted hospital procedures.
18. 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 18.
Possible Complication

Possible complications that may result from airway balloon dilation are bleeding, perforation, injury to vocal cords, rupture (partial or complete) resulting in pneumomediastinum, pneumothorax, mediastinitis secondary to tracheal dilation, chest pain, laryngospasm or bronchospasm, atelectasis, pulmonary edema, airway obstruction due to edema, and hypoxia.
Q and A