



Instructions for Use
aeris® balloon dilation catheter

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

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

This device is for operating room use only.

DEVICE DESCRIPTION:

- The aeris® Balloon Dilation Catheter is comprised of a single lumen catheter with a high pressure balloon near the distal tip. A stylet is provided to facilitate advancement of the balloon dilation catheter to the desired location. The stylet must be removed before inflation of the high pressure balloon. A luer at the proximal end is used for placement of the stylet and injecting sterile water into the balloon. Two radiopaque markers, located on the catheter inside the balloon can be used to confirm balloon placement under fluoroscopy.

Product Number	Balloon Size (diameter x length)	Maximum Inflation Pressure	Inflation Device/ Syringe Volume
KG0530	5x30 mm	17 ATM	10 cc
KG0630	6x30 mm	17 ATM	10 cc
KG0730	7x30 mm	17 ATM	10 cc
KG0830	8x30 mm	17 ATM	10 cc
KG0930	9x30 mm	17 ATM	10 cc
KG1030	10x30 mm	17 ATM	20 cc
KG1240	12x40 mm	10 ATM	20 cc
KG1440	14x40 mm	10 ATM	20 cc
KG1640	16x40 mm	10 ATM	20 cc
KG1840	18x40 mm	10 ATM	20 cc

INDICATIONS FOR USE:

- The aeris® Balloon Dilation Catheter is intended to dilate strictures of the airway.

CONTRAINDICATIONS:

- Balloon dilation of the airway 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

WARNING:

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call Bryan Medical.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the integrity of this device and or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of this device may lead to injury, illness or death of the patient.

PRECAUTIONS:

- Use the catheter prior to the “Use By” date specified on the package
- Store in a cool dry location.
- This device should be used only by or under the supervision of a physician thoroughly trained in airway balloon dilation. A thorough understanding of the technical principles, clinical application and risks associated with balloon dilation of the airway is necessary before using this device.
- If resistance is met during the procedure do not advance the catheter without first determining the cause of resistance and taking necessary action.
- After use, dispose of product and packaging in accordance with hospital, administrative and or local government policy.
- Intended for single patient use only, DO NOT REUSE.
- Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.
- Appropriate anesthetic techniques to minimize respiratory effort should be used before this device is used. Negative pressure pulmonary edema may result in patient as a result of ongoing vigorous respiration while the balloon is dilated and the airway occluded.
- Careful monitoring of patients oxygen levels is necessary during balloon dilation. Hypoxia may occur as a result of extended periods of occluding the airway.
- During dilation caution should be used to avoid any interference and possible obstruction of other devices such as tracheostomy tubes and endotracheal tubes.
- Compatibility of this device has not been determined for use within the working channel of a bronchoscope.
- The balloon must be inflated with sterile water.

- Do not pretest or preinflate the balloon.
- The catheter lumen is occluded at the distal end and cannot be used to ventilate.
- Use of a balloon that is too large for the target anatomy and may cause damage to the surrounding anatomy.
- Use of an undersized balloon may result in failure to properly treat the target anatomy.
- Do not try to force movement of the balloon catheter if balloon is inflated.
- If the balloon catheter migrates during inflation of the balloon do not attempt to advance or retract the balloon without deflating the balloon first.
- Do not advance, retract, or hold the balloon catheter or balloon catheter with stylet against resistance. Tissue damage or tissue trauma may occur as a result.
- Do not advance, retract, or hold the balloon catheter or the balloon catheter with stylet against resistance as damage to the device may occur.
- If at any point during the procedure the balloon does not deflate rupture the balloon with a sharp instrument to allow removal.
- Position balloon catheter properly by using direct visualization. Improperly inflating the balloon in the incorrect location may harm the patient.
- The aeris® balloon dilation catheter is compatible with the Bryan Medical Inc. Inflation Device.

INSTRUCTIONS FOR USE: PREPARATION

- Before using inspect the pouch for any breach of the packaging to ensure sterile product and that no damage has occurred to product during shipping.
- 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.
- Selection of the proper balloon size is critical such that the diameter of the balloon fully inflated does not exceed the expected diameter of a healthy airway. Endoscopic direct visualization or imaging can assist in determining a healthy airway diameter. The cartilage skeleton i.e. tracheal rings should be taken into account in limiting the balloon size.
- A sharp instrument which can reach the site of dilation should be made available in the event that difficulties arise during deflation of the balloon.
 1. Open the sterile package and remove the airway balloon catheter with the stylet in place.
 2. If using the stylet confirm that it is locked in place onto the luer at proximal end of the balloon dilation catheter. If not, unlock the stylet, remove and place aside.
 3. Prepare the Bryan Medical Inflation Device.
 4. Remove the green protective sheath that covers the balloon.

- Wipe the outer surface of the balloon and catheter with sterile water soaked gauze pad.

PLACEMENT

- Locate the stricture using, flexible or rigid, bronchoscopy or endoscopy. Fluoroscopy may be used to confirm balloon placement. Two radiopaque markers are located on the catheter inside the balloon.
- The aeris® Balloon may be shaped if desired. The Airway Stylet must be in place and locked for shaping. Kinking may occur without Stylet locked in place.
- Under endoscopic visualization slowly and gently advance the Airway Balloon to the site of the stricture.
- Center the balloon portion of the device across the area to be dilated. The proximal end of the balloon should be positioned proximal to the stricture.

NOTE: The balloon on the aeris® balloon dilation catheter will upon initial inflation present two hubs proximally and distally on the balloon. This is to help secure the balloon in place during inflation. The body of the balloon will increase to create a uniform diameter balloon at recommended inflation pressure. This should be considered an adjunct to the procedures and actions normally taken to prevent slippage in either direction of the intended area to be dilated. Firm control of the balloon catheter should be maintained during the entire procedure.

- Remove the Airway Stylet, if it has not been removed already, and attach the balloon dilation catheter luer to the connecting tube of the Inflation Device with gauge to monitor balloon pressure.
- Inflate the balloon with sterile water to desired pressure. Monitor the balloon pressure using the gauge on the inflation device. Visualize endoscopy during inflation of the balloon assessing the diameter, shape and the position of the balloon. Ensure the proximal end of the balloon remains proximal to the stricture throughout inflation.

WARNING: Do not exceed the Maximum Inflation Pressure stated on the label or in product table in the Device Description section of this Instructions for Use.

WARNING: If the balloon moves distally or proximally, out of position, at any time during the procedure do not hold the balloon against any resistance. Deflate the balloon and reposition to desired position. Once the balloon has been repositioned re-inflate.

WARNING: Holding the balloon against resistance may damage the balloon dilation catheter or anatomy. If the balloon does not deflate rupture the balloon with a sharp instrument to allow removal.

NOTE: If the balloon ruptures at any time during the procedure, identified by a rapid decrease in pressure on the inflation gauge or visually. Carefully, deflate the balloon and remove the balloon dilation catheter.

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- As dilation takes place the pressure readings may fluctuate. Adjust the balloon pressure as necessary to meet the desired target.

WITHDRAWING THE BALLOON DILATION CATHETER:

- To deflate maintain an endoscopic view of the proximal end of the balloon as vacuum is applied using the inflation/deflation device. Completely deflate the balloon, using vacuum, before pulling back on the balloon dilation catheter. Visually confirm endoscopically the balloon is deflated before removing the balloon dilation catheter.
- If additional inflations are required, slightly inflate the balloon using fingers gently re-wrap the airway balloon in a clockwise motion, compressing the balloon starting at the distal end of the balloon working back as you apply vacuum. Use the inflation device to apply vacuum.

NOTE: After the balloons first inflation the hubs on the distal and proximal ends of the balloon may not appear upon inflation.

NOTE: Only advance or withdraw the balloon dilation catheter when the balloon is completely deflated and without the green protective sheath covering the balloon. Advancing the balloon partially or fully inflated may cause serious damage to anatomy or the device.

NOTE: Do not rotate the balloon dilation catheter after placing it into the patient.

- Dispose of the catheter in accordance with accepted hospital guidelines.

POSSIBLE COMPLICATIONS:

Possible complication 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, bronchospasm, atelectasis, pulmonary edema, airway obstruction due to edema and hypoxia.

WARRANTY:

Bryan Medical Inc. warrants that reasonable care has been used in the design and manufacture of the device. This warranty is in lieu of and excludes all other warranties and not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to any implied warranties of merchantability or fitness for a particular purpose. Handling and storage of the device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Bryan Medical's control directly affect the device and the results obtained from its use. Bryan Medical Inc.'s obligation under this warranty is limited to the replacement of this device and Bryan Medical Inc. shall not be liable for any incidental or consequential damage or expense directly or indirectly arising from the use of this device. Bryan Medical Inc. neither assumes, nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this device.

Patents:

This device and its use are covered by the following US patent: 7,771,446B2.

SYMBOLS CONTAINED IN DEVICE LABELING

	Product Code		Keep Dry
	Lot Number		Do Not Re-Use
	Use By		Consult Instructions for Use
	Sterilized Using Ethylene Oxide		Keep Away from Sunlight
	Prescription Only		Manufactured By

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