ELATION™
BALLOON DILATOR

Pulmonary Balloon Dilation Catheter

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MERIT MEDICAL
ENDOTEK®

ELATION™ BALLOON DILATOR

ENGLISH

Pulmonary Balloon Dilation Catheter
INSTRUCTIONS FOR USE

CONTENTS:
• Balloon Dilation Catheter

DESCRIPTION:
The Elation™ Pulmonary Balloon Dilation Catheter is a multistage balloon that provides three (3) distinct diameters at three corresponding pressures. These pressures are clearly indicated on the device packaging and are also found on an information tag attached to the balloon catheter body. The catheter is compatible with a 0.035" (0.89mm) X min. 150cm guidewire that is passed through a designated guidewire lumen and port found on the proximal end of the balloon catheter. Inflation of the balloon is performed by attaching an appropriate inflation system with pressure monitoring gauge (such as the BIG60 Inflation Device), to the balloon luer (Conical 6% Female Luer Lock) on the proximal portion of the balloon catheter. The Elation™ Pulmonary Balloon Dilation Catheter can also be passed through a minimum 2.8mm working channel bronchoscope. Two fluoroscopic markers are located at the proximal and distal shoulders of the balloon to aid in placement of the balloon in relation to anatomical landmarks. Black reference marks are located on the proximal and distal ends of the catheter. The marks are 1cm apart, with a double black mark located every 5 cm.

100 CM CATHETER

	Balloon Length	Balloon OD Ø		Inflation Pressure	
Ref #	cm	mm	F	ATM	kPa
P6L20	2	6-7-8	18-21-24	6-8.5-10	608-861-1013
P8L20	2	8-9-10	24-27-30	4-6-8	405-608-811
P10L20	2	10-11-12	30-33-36	4.5-6.5-8	456-659-811
P12L20	2	12-13.5-15	36-40.5-45	4-6.5-8	405-659-811
P6L30	3	6-7-8	18-21-24	6-8.5-10	608-861-1013
P8L30	3	8-9-10	24-27-30	4-6-8	405-608-811
P10L30	3	10-11-12	30-33-36	4.5-6.5-8	456-659-811
P12L30	3	12-13.5-15	36-40.5-45	4-6.5-8	405-659-811
P12L55	5.5	12-13.5-15	36-40.5-45	4-6.5-8	405-659-811
P15L55	5.5	15-16.5-18	45-49.5-54	4-5.5-7	405-557-709
P18L55	5.5	18-19-20	54-57-60	3.5-5-6	355-507-608

This product contains no detectable latex.

INDICATIONS FOR USE:
The Elation™ Pulmonary Balloon Dilation Catheter is intended to be used to endoscopically dilate strictures of the trachea and bronchi.

CONTRAINDICATIONS:
Balloon dilation is contraindicated in any patient whose general medical condition and degree of respiratory failure would not allow the patient to tolerate bronchoscopy (rigid or flexible) and/ or the manipulation required to accomplish balloon dilation.
Balloon dilation is contraindicated in the presence of any of the following:
• Significant active bleeding from the site of the proposed dilation.
• Known perforation at the site of proposed dilation.
• Known fistula between the tracheobronchial tree and the esophagus mediastinum or pleural space unless the dilation was being performed in preparation for the placement of a stent to treat the perforation or fistula.

WARNING:
• DO NOT ATTEMPT TO REPAIR.
• Never use gas or air to inflate the Elation™ Pulmonary Balloon Dilation Catheter.
• Check for proper position of the balloon catheter using endoscopic visualization. Balloon inflation in an improper location may lead to patient injury.

PRECAUTIONS:

WARNING: Clinicians performing fluoroscopic-guided procedures should be trained in safety measures and aware of the potential for serious radiation-induced injury caused by long periods of fluoroscopy especially in the pediatric population.
• Oximetry should be monitored throughout the procedure to ensure safe airway management during dilation procedures.
• Inspect the Elation™ Pulmonary Balloon Dilation Catheter and packaging for damage prior to use. Do not use product if opened or damaged. Confirm that the device is consistent with the package label. Contact Customer Service to report and replace damaged product.
• For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the 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 disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
• The Elation™ Pulmonary Balloon Dilation Catheter is designed to pass over a 0.035" (0.89mm) guidewire, through a minimum 2.8mm working channel of the bronchoscope.
• Any use for procedures other than those indicated in these instructions is not recommended.

INSTRUCTIONS FOR USE:
1. Choose the appropriate Elation™ Pulmonary Balloon: The recommended application is printed on the package label. When choosing diameter and length, the balloon should initially accommodate narrowed, strictured or stenosed airway segments. The maximum diameter should not exceed the diameter of the healthy lumen. Healthy lumen diameter can be assessed endoscopically with direct visualization or via reconstructed CT scan imagery. It is recommended to use a 2cm or 3cm length balloon in the bronchi and the 5.5cm length balloons should be used in the trachea.
2. Prepare a 60ml inflation system, with pressure monitoring gauge (such as the BIG60® Inflation Device), with sterile water or sterile saline.

NOTE: Refer to the manufacturer's directions accompanying the inflation system for instructions on preparation and use.

3. Remove the Elation™ Pulmonary Balloon Dilation Catheter from the packaging. Unclip the catheter from the tag clip located at the proximal end of the catheter. Attach the Elation™ Pulmonary Balloon Dilation Catheter luer to the appropriately prepped inflation system. A stopcock may be used between the connection of the catheter luer and inflation system to aid in removal of air from system.
4. To minimize balloon profile, apply vacuum to the catheter before removing the protective sheath. Remove the protective sheath and inspect the catheter for any signs of damage.

CAUTION: Balloon dilation catheters should be used by or under the supervision of physicians thoroughly trained in bronchoscopic balloon dilation. A thorough understanding of the technical principals, clinician application and risks associated with balloon dilation of the trachea and bronchi is necessary before using this device.

NOTE: Elation™ Pulmonary Balloon Dilation Catheter balloons have been tested to withstand 10 successive, 30 second inflations each, to maximum labeled inflation pressure.

CAUTION: Avoid inflating or pre-dilating the balloon catheter prior to insertion into the bronchoscope. If resistance is met during the

procedure, do not advance the catheter without first determining the cause of the resistance and taking remedial action.

Method of balloon dilation with long guidewire:

5. Pass the guidewire (such as 260cm MAXXWIRE®) through the working channel of the bronchoscope.
6. Utilizing direct vision, pass the guidewire past the area of dilation. Fluoroscopy is required when direct vision isn't possible.
7. Insert the Elation™ Pulmonary Balloon Dilation Catheter over the proximal end of the guidewire. Advance the balloon catheter over the guidewire and through the working channel of the bronchoscope using short and deliberate motions.
8. When the balloon catheter has reached the area of dilation (confirmed through direct vision or under fluoroscopic visibility), pass the balloon into the position of desired dilation.

Method of balloon dilation using short guidewire:

5. Preload guidewire (such as 180cm MAXXWIRE®) into the Elation™ Pulmonary Balloon Dilation Catheter by inserting through the .035" luer until the guidewire extends to tip of catheter.
6. Maintaining vacuum with prepped inflation system, insert catheter with guidewire into working channel of bronchoscope using short and deliberate motions.
7. When catheter tip reaches the end of bronchoscope, utilize direct visualization to extend guidewire out of balloon catheter and bronchoscope past the area of dilation. Fluoroscopy is required when direct vision isn't possible.
8. Advance the Elation™ Pulmonary Balloon Dilation Catheter over the guidewire using short and deliberate motions until the balloon is in the position of desired dilation.

Alternative methods: If desired, the Elation™ Pulmonary Balloon Dilation Catheter may be introduced alongside the flexible bronchoscope or through the flexible bronchoscope without a guidewire. If resistance is met do not advance the catheter.

PRECAUTION: Endoscopic and/or fluoroscopic visualization should be used when advancing catheter and to confirm proper placement of the catheter. Verify that the shaft segment of the catheter is within endoscopic view. This ensures that the balloon has exited the bronchoscope completely prior to inflation. Fluoroscopy may also be used to confirm balloon placement. Radiopaque markers are included at the proximal and distal shoulders of the balloon.

Balloon Inflation:

9. Once the balloon is positioned across the stricture, inflate the Elation™ Pulmonary Balloon Dilation Catheter using the prepped inflation system, to the first of the three diameter stages. The diameter of the balloon is dictated by a corresponding pressure, as indicated on the product label and information tag attached to the catheter body.
10. Use direct visualization of the balloon and the pressure monitoring gauge on the inflation system to determine complete balloon expansion.
11. To achieve larger diameters, continue applying pressure until the remaining diameters of the Elation™ Pulmonary Balloon Dilation Catheter have been reached. Do not over inflate past the maximum pressure indicated on the product labeling.

NOTE: Fluctuations in pressure may be observed during dilation. These fluctuations may require additional pressure adjustments from the inflation system (a slight drop in pressure at each diameter is normal).

WARNING: To prevent balloon burst, do not exceed the inflation pressure given for the largest diameter on the catheter and package label. If the balloon does rupture or a significant loss of pressure within the balloon occurs, deflate the balloon completely and carefully remove the balloon and bronchoscope together as a unit. Do not attempt to withdraw a ruptured balloon through the bronchoscope. Continue the procedure with a new catheter.

CATHETER REMOVAL:

12. Using the inflation system, create a negative pressure to completely deflate the Elation™ Pulmonary Balloon Dilation Catheter prior to removal. Confirm that the balloon has been completely deflated (approximately 5-20 seconds depending on balloon size and inflation medium) using fluoroscopic and/or endoscopic visualization.
13. Remove the Elation™ Pulmonary Balloon Dilation Catheter.

WARNING: THE BALLOON MUST BE THOROUGHLY DEFLATED AND ALL FLUID REMOVED PRIOR TO WITHDRAWAL.

PRECAUTION: Do not pull back on the catheter until the balloon is deflated completely. For improved withdrawal, straighten the distal end of the bronchoscope as much as possible. Any excess bend in the working channel will increase the force needed to withdraw the Elation™ Pulmonary Balloon Dilation Catheter through the bronchoscope. If excessive resistance is felt, remove the bronchoscope & deflated balloon catheter together as a complete unit to prevent damage to body tissue, the catheter or bronchoscope.

DEVICE DISPOSAL:

After use, the sheath, catheter, guidewire, locking device, inflation device & stopcock should be disposed of in a manner consistent with standard protocols for biohazard waste disposal.

RECOMMENDED ACCESSORIES:

• Inflation system with pressure monitoring gauge (such as BIG60® Inflation Device) – 60ml 0-12 ATM (max. 5% error), with conical 6% male luer lock
• Guidewire – 0.035" (0.89mm X min.150 cm)

STORAGE:

Store in a cool, dry place.

COMPLICATIONS:

Possible complications that may result from a tracheobronchial dilation are, but may not be limited to:

• Bleeding
• Perforation
• Rupture (partial or complete) resulting in pneumomediastinum
• Pneumothorax
• Mediastinitis secondary to tracheal dilation,
• Chest pain
• Bronchospasm
• Atelectasis
• Pain and tenderness
• Pneumonia
• Pulmonary Edema

WARRANTY:

The manufacturer warrants that reasonable care has been used in the design and manufacture of this device. This warranty is exclusive and manufacturer makes no other representations or warranties of any kind to customers, its end users, or to any third parties with respect to the device and hereby expressly disclaims any and all other warranties, express or implied, statutory or otherwise, including, but not limited to, infringement and the implied warranties of merchantability and fitness for a particular purpose, even if manufacturer is aware of such purpose. Handling and storage of this device, as well as other factors relating to the patient, diagnosis, treatment, implant procedures, and other matters beyond the control of the manufacturer, directly affect the device and the results obtained from its use. The manufacturer's obligation under this warranty is limited to the replacement of the device. Under no circumstances shall manufacturer be liable to customer or any other person or entity for any punitive, special, incidental or consequential damages directly or indirectly arising from the use of this device. The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty shall not apply, and manufacturer assumes no liability with respect to, devices that have been (i) modified, changed, altered, misused, mishandled, repaired, reused, reprocessed, refurbished or resterilized; (ii) subjected to improper maintenance, testing or storage, accident, tampering, or inadequate protection against shock, vibration, excessively high or low temperatures, overpressure, or physical, environmental or electrical stress; (iii) been used outside the approved "Indications for Use" as cleared by the relevant competent authority, used contrary to the use outlined in the device specifications, or in an application or environment for which such device was not designed or contemplated; or (iv) distributed or used contrary to applicable federal, state, local or regulatory standards.

	Single Use
	**CAUTION:** Consult accompanying documents
	Maximum Inflation Pressure
	Sterilized using ethylene oxide
	**RX Only: CAUTION:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
	Do not use if package is damaged
	Minimum working channel

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