

# **ELATION 5**<sup>TM</sup>

FIVE-STAGE BALLOON DILATOR

## **Wire Guided Balloon Dilation Catheter**

### **INSTRUCTIONS FOR USE**



Wire Guided Balloon Dilation Catheter

**INSTRUCTIONS FOR USE**

**INDICATIONS FOR USE:**

The Elation5 Wire Guided Balloon Dilation Catheter is intended for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract.

**CONTENTS:**

- Wire Guided Balloon Dilation Catheter

**DESCRIPTION:**

The Elation 5<sup>™</sup> Wire Guided Balloon Dilation Catheter is a multistage balloon that provides five (5) distinct diameters for five 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. 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 Elation5 Wire Guided Balloon Dilation Catheter can also be passed through a minimum 2.8 mm working channel endoscope. Two fluoroscopic markers are located on the proximal and distal shoulders of the balloon to aid in placement of the balloon in relation to anatomical landmarks.

**CLINICAL BENEFITS:**

Increases patency of the alimentary track to allow for the passage of food, fluid, and bodily waste.

**180cm Catheter**

Ref #	Balloon OD Ø		Inflation Pressure	
	mm	F	ATM	kPa
EPX6	5-6-7-8-9	15-18-21-24-27	2-6-8.5-10-11.5	203-608-861-1013-1165
EPX8	7-8-9-10-11	21-24-27-30-33	2-4-6-8-9.5	203-405-608-811-963
EPX10	9-10-11-12-13	27-30-33-36-39	2-4.5-6.5-8-9.5	203-456-659-811-963
EPX12	11-12-13.5-15-16	33-36-40.5-45-48	2.5-4-6.5-8-9	253-405-659-811-912
EPX15	14-15-16.5-18-19	42-45-49.5-54-57	2.5-4.5-5.7-8	253-405-557-709-811
EPX18	17-18-19-20-21	51-54-57-60-63	2.5-3.5-5-6-7.5	253-355-507-608-760

**240cm Catheter**

Ref #	Balloon OD Ø		Inflation Pressure	
	mm	F	ATM	kPa
EPCX6	5-6-7-8-9	15-18-21-24-27	2-6-8.5-10-11.5	203-608-861-1013-1165
EPCX8	7-8-9-10-11	21-24-27-30-33	2-4-6-8-9.5	203-405-608-811-963
EPCX10	9-10-11-12-13	27-30-33-36-39	2-4.5-6.5-8-9.5	203-456-659-811-963
EPCX12	11-12-13.5-15-16	33-36-40.5-45-48	2.5-4-6.5-8-9	253-405-659-811-912
EPCX15	14-15-16.5-18-19	42-45-49.5-54-57	2.5-4-5.5-7-8	253-405-557-709-811
EPCX18	17-18-19-20-21	51-54-57-60-63	2.5-3.5-5-6-7.5	253-355-507-608-760

This product contains no detectable latex.

**CONTRAINDICATIONS:**

None known.

**WARNING:**

- DO NOT ATTEMPT TO REPAIR.
- Never use gas or air to inflate the Elation5 Wire Guided 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.
- 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 adolescent population.

**PRECAUTIONS:**

- Inspect the Elation5 Wire Guided 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 Elation5 Wire Guided Balloon Dilation Catheter is designed to pass through a minimum 2.8 mm working channel of the endoscope.
- Any use for procedures other than those indicated in these instructions is not recommended.

**INSTRUCTIONS FOR USE:**

1. Diameter of the balloon: Choose an appropriate Elation5 Wire Guided Balloon Dilation Catheter whose maximum diameter does not exceed the diameter of the healthy lumen. Healthy lumen diameter can be assessed endoscopically with direct visualization or via reconstructed CT scan imagery.
2. Remove the Elation5 Wire Guided Balloon Dilation Catheter from the packaging. Unclip the catheter from the connected clip located at the proximal end of the catheter. Attach the Elation5 Wire Guided Balloon Dilation Catheter luer to an appropriately prepped inflation system (with pressure monitoring gauge). A stopcock may be used between the connection of the catheter luer and inflation system to remove air.
3. 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 esophageal balloon dilation. A thorough understanding of the technical principles, clinician application, and risks associated with balloon dilation of the alimentary track is necessary before using this device.

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

**CAUTION:** Avoid inflating or pre-dilating the balloon catheter prior to insertion into the endoscope. If resistance is met during the procedure, do not advance the catheter without first determining the cause of the resistance and taking remedial action.

4. Maintain vacuum to the catheter during insertion through the endoscope. Advance the Elation5 Wire Guided Balloon Dilation Catheter into the endoscope channel using short, deliberate, 2-3 cm movements. Due to endoscope geometry, resistance may be experienced immediately upon entering the endoscope and again 2-3 cm before exiting the distal end of the working channel.
5. Once the balloon has exited the distal end of the endoscope and is within endoscopic view, the guidewire may be advanced beyond the distal end of the catheter.
6. To use the guidewire as a catheter guide:
  - a. Confirm position of switch on the locking device is in the "ON" position.
  - b. Advance the guidewire into the desired position beyond the catheter tip (fluoroscopy is recommended if advancing without direct visualization).
  - c. Length of guidewire advancement can be approximated using the white marking bands on the segment of the guidewire extending from the locking device (marking bands are placed 5 cm apart).

d. Advance the catheter over extended portion of the guidewire until the balloon segment is in the desired position.

e. To aid in proper placement of the balloon across the stricture, match the radiopaque markers, located at the distal and proximal shoulders of the balloon with the distal and proximal ends of the stricture.

**NOTE:** If desired, the guidewire may be removed from the catheter prior to endoscope insertion. A standard 0.035" (0.89mm) guidewire may be placed through the working channel of the endoscope and across the stricture. The catheter may then be advanced over the guidewire.

f. When balloon and guidewire are in the desired location, the guidewire can be secured with the Locking Device by moving the slide to the "OFF" position.

7. Position the balloon in the appropriate location to dilate the stricture.

**PRECAUTION:** Endoscopic or Fluoroscopic visualization should be used to confirm proper placement of the catheter. Verify that the black of the catheter is within endoscopic view. This ensures that the balloon has exited the endoscope completely prior to inflation. Fluoroscopy may also be used to confirm balloon placement. Radiopaque markers are located at the proximal and distal shoulders of the balloon.

8. Balloon must be filled with fluid. Depending on technique, the balloon can be filled with sterile water, sterile saline or a contrast mixture (up to 50% contrast medium).

9. Once the balloon is positioned across the stricture, inflate the Elation5 Wire Guided Balloon Dilation Catheter using a prepped 60 mL inflation system, with pressure monitoring gauge (such as the BIG60<sup>®</sup> Inflation Device), to the first of the five 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. Monitor pressure by utilizing the pressure gauge of the inflation system attached to the catheter luer.

11. To achieve larger diameters, continue applying pressure until the remaining diameters of the Elation5 Wire Guided Balloon Dilation Catheter have been reached. Do not over inflate past the maximum pressure indicated on the product labeling.

12. The Elation5 Wireguided Balloon Dilation Catheter is designed to pass over a 0.035" (0.89 mm) guidewire, through a minimum 2.8 mm working channel of the endoscope.

#### **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 endoscope together as a unit. Do not attempt to withdraw a ruptured balloon through the endoscope. Continue the procedure with a new catheter.

**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).

#### **CATHETER REMOVAL:**

1. Using the inflation system, create a negative pressure to completely deflate the Elation5 Wire Guided Balloon Dilation Catheter prior to removal. Confirm that the balloon has been completely deflated (approximately 10-30 seconds depending on balloon size and inflation medium) using fluoroscopic and/or endoscopic visualization.

2. Remove the Elation5 Wire Guided 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 endoscope as much as possible. Any excess bend in the working channel will increase the force needed to withdraw the Elation5 Wire Guided Balloon Dilation Catheter through the endoscope.

**CAUTION:** If excessive resistance is felt, remove the endoscope & deflated balloon catheter together as a complete unit to prevent damage to body tissue, the catheter or endoscope.

#### **DEVICE DISPOSAL:**

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

#### **NECESSARY ACCESSORIES:**

- Inflation system with pressure monitoring gauge – 60 mL, 0-12 ATM (max. 5% error), with conical 6% male luer lock.

#### **INCLUDED OPTIONAL ACCESSORIES:**

- Guidewire Locking Device
- 0.035" (0.89 mm) Guidewire

#### **STORAGE:**

Store in a cool, dry place.














#### **COMPLICATIONS:**

Possible complications that may result from an alimentary track dilation procedure include, but may not be limited to:

- Perforation
- Hemorrhage
- Hematoma
- Sepsis/Infection
- Allergic reaction to contrast medium
- Pain and tenderness

#### **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.

<b>EC REP</b>	Authorized Representative in European Community
	Use by date: YYYY-MM-DD
<b>REF</b>	Catalog number
<b>LOT</b>	Batch code
	Do Not Re-sterilize
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single Use
<b>STERILE EO</b>	Sterilized Using Ethylene Oxide
	Non-pyrogenic
<b>Rx ONLY</b>	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Consult Instructions for Use For electronic copy scan QR code, or go to <a href="http://www.merit.com/ifu">www.merit.com/ifu</a> and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
	Date of Manufacture: YYYY-MM-DD
	Manufacturer
	Keep Dry
	Keep away from sunlight
 MAX GUIDE WIRE	Maximum diameter guide wire
<b>MD</b>	Medical Device
	Single Sterile Barrier System
<b>WC</b>	Minimum working channel
	Maximum Inflation Pressure
<b>UDI</b>	Unique Device Identifier

 **MERITMEDICAL**  
**ENDOTEK**

**CE** 2797

[merit.com/endoscopy](http://merit.com/endoscopy)



Manufacturer: Merit Medical Endotek  
1600 West Merit Parkway, South Jordan, Utah 84095  
U.S.A. 1-801-253-1600  
U.S.A. Customer Service 1-800-356-3748

**EC REP**

Authorized Representative: Merit Medical Ireland Ltd,  
Parkmore Business Park West, Galway, Ireland