Diversatek™
Healthcare

Viper® 3-Stage Wire Guided Balloon Dilator

Instructions for use.
Read carefully prior to use.

Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

Diversatek Healthcare

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INTENDED USE

The single use Viper 3-Stage Wire Guided Balloon Dilator is used to dilate strictures of the gastrointestinal tract.

Part Number	Description
1205-08	3-Stage Balloon 6-7-8mm
1205-10	3-Stage Balloon 8-9-10mm
1205-12	3-Stage Balloon 10-11-12mm
1205-15	3-Stage Balloon 12-13.5-15mm
1205-18	3-Stage Balloon 15-16.5-18mm
1205-20	3-Stage Balloon 18-19-20mm

INTENDED USER

Gastroenterologists experienced in esophageal balloon dilatation. Use of this device is restricted to a trained healthcare professional.

CONTRAINDICATIONS

Contraindications include those specific to upper GI endoscopy. Contraindications to dilation include but are not limited to: uncooperative patient; asymptomatic rings, webs, or strictures; inability to advance the balloon through the strictured area; coagulopathy; known or suspected perforation; severe inflammation or scarring near the dilation site; recent myocardial infarction; active ulcer; acute corrosive injury of less than one week duration; severe cervical arthritis.

POTENTIAL COMPLICATIONS

Potential complications associated with upper gastrointestinal endoscopy and esophageal dilation include, but are not limited to perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

WARNINGS AND PRECAUTIONS

1. Refer to package label for minimum channel size required for this device.
2. **Do not pre-inflate balloon.** A balloon material failure can occur if the balloon is inflated prior to advancement through the endoscope.
3. During dilation, do not inflate balloon beyond the maximum indicated Inflation Pressure as this could result in overextension, material failure, and/or bursting of the balloon. The recommended Maximum Inflation Pressure can be found on the package label and catheter label.
4. Do not advance the balloon dilator if resistance is encountered. Assess cause of resistance to determine if dilation should be reattempted.
5. Do not use air or any gaseous substance as balloon inflation medium as this may cause the balloon to burst. The balloon may be filled with sterile water, sterile saline or up to a 1:1 contrast medium mixture consisting of contrast and sterile saline.
6. The entire balloon should be extended beyond the tip of the endoscope, and be completely visualized and positioned, before inflation. Balloon inflation in an improper location may lead to patient injury or damage to the device.
7. **THE BALLOON MUST BE THOROUGHLY DEFLATED AND ALL FLUID REMOVED PRIOR TO WITHDRAWAL (approximately 10-30 seconds depending on balloon size and inflation medium).** Apply negative pressure to the catheter before withdrawal and maintain negative pressure throughout the withdrawal process. Negative pressure is required to maintain balloon deflation.
8. If excessive resistance is felt when advancing or withdrawing the balloon, remove the endoscope and balloon catheter together as a complete unit to prevent damage to body tissue, the catheter or the endoscope. Failure to follow these withdrawal procedures may result in damage to the scope and/or increased difficulty during withdrawal of the balloon.
9. Products marked “single-use” are for single-use only. Do not re-use, reprocess, or re-sterilize single-use products. The materials used in the manufacture of the device may not withstand repeated reprocessing. The device may not perform as intended by the manufacturer if it is reused. This may lead to failure of the device

to perform as intended and/or material degradation, which may result in patient injury, illness or death. Reuse, reprocessing, or resterilization may also increase the 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 the device may lead to injury, illness or death of the patient.

PREPARATORY INSTRUCTIONS

1. Select a Viper Balloon Dilator in a size determined to be medically appropriate for the stricture.
2. Applying a water soluble lubricant to the balloon before using may enable easier passage and withdrawal through the accessory channel.

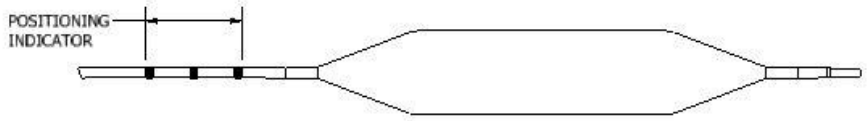
COMPATIBILITY WITH INFLATION DEVICES

This device is used in conjunction with an inflation device or manometer with inflation syringe. Do not use air or gaseous substances to inflate balloon, as this will result in reduced balloon effectiveness. **NOTE: Use at least 35ml (cc) and no more than 40ml (cc) of inflation medium.**

INSTRUCTIONS FOR USE

1. Attach the balloon to a 60 ml (cc) inflation device with gauge to monitor balloon pressure.
2. To facilitate passage through the endoscope, apply negative pressure to the catheter.
3. Remove the protective sheath from the balloon. **Note:** The guidewire can be removed from the balloon catheter prior to use and replaced with a standard .035" guidewire to aid in bridging difficult strictures or the device can be back loaded over a pre-positioned guidewire.
4. Applying a lubricating agent to the balloon may facilitate passage through the endoscope accessory channel.
5. Position the tip of the guidewire within the tip of the catheter and lock the guidewire position by moving the slide to the "off" (closed) position. The guidewire should not be beyond the distal end of the catheter.
6. Maintain balloon deflation with negative pressure and introduce into the accessory channel of the endoscope, advancing in short increments until the balloon is completely visualized endoscopically. The positioning indicator (see Figure 1) on the catheter indicates balloon clearance from the endoscope accessory channel.
7. Once 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. To use the guidewire as a catheter guide, move the slide to the "on" (open) position. Advance the guidewire into the desired position beyond the catheter tip.
   Note: Fluoroscopy is recommended if advancing guidewire without direct visualization. Approximate guidewire advancement can be determined using markers located at 5-cm increments on guidewire.
8. Prior to advancing device over positioned guidewire, flush guidewire lumen of catheter with sterile water. Advance the catheter over extended portion of guidewire until balloon segment is in desired position. Continue to monitor endoscopically until the balloon is in the desired position within the stricture.
   Note: When balloon and guidewire are in desired location, guidewire can be secured to maintain its position by moving slide to the "off" (closed) position.
9. Inflate the balloon to the pressure corresponding to the smallest balloon diameter and maintain until desired dilation is achieved. To achieve increasingly larger balloon diameters, increase pressure as indicated on catheter tag. **Do not exceed the maximum indicated inflation pressure.**
10. To deflate balloon, apply a vacuum, and remove all fluid from the balloon while observing the balloon endoscopically.
11. While maintaining vacuum, remove the deflated balloon from the accessory channel. **Caution:** A compromised balloon may prohibit removal from the endoscope accessory channel. Removal of the endoscope along with the compromised balloon may be required.

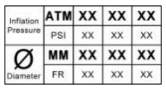
Figure 1 – Positioning Indicator



PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of the product in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

DESCRIPTION OF SYMBOLS USED ON LABELS

	Balloon Diameter with Corresponding Maximum Inflation Pressure
	Minimum Endoscope Size ≥ 2.8 mm
	Manufacturer
	Use-by date (YYYY-MM-DD)
	Lot Number / Batch Code
	Catalog number
	Sterilized using ethylene oxide
	Do not use if package is damaged
	Do not re-use
	Caution, consult accompanying documents
	Not made with natural rubber latex