WARNINGS

- This device is not made with natural rubber latex. There are no analytical methods currently* available that can identify all proteins and components in natural rubber latex that may lead to allergic reactions in medical products. Any claim of "latex-free" is not scientifically supportable.
  **as of FDA Guidance dated December 2, 2014*
- Prior to balloon introduction, advance the wire guide through a pre-positioned endoscope, maintaining endoscopic visualization as the wire guide exits the endoscope. Failure to do so may result in mucosal puncture and/or lacerations.
- Always advance the balloon dilator over a pre-positioned wire guide, as failure to do so may result in mucosal puncture.
- This product is not intended for use in the airway, above the upper esophageal sphincter, or adjacent to a second balloon, as this could result in oxygen desaturation, asphyxiation, airway occlusion, aspiration, perforation, pulmonary hemorrhage, cricoid fracture, minor bleeding, tissue trauma, infection, edema and tissue irritation.
- During dilation, do not inflate the balloon beyond the maximum indicated inflation pressure , as this could result in overextension or rupture of the balloon. Balloon rupture could result in unintended pressure against tissue, tissue irritation, bleeding, perforation, aspiration, oxygen desaturation, asphyxiation, and/or infection.
- Do not advance the balloon dilator if resistance is encountered. Assess the cause of resistance to determine if dilation should be attempted.
- Repeat inflation and deflation may result in device failure, including balloon rupture, inability to deflate, and loss of pressure. These device failures could result in patient harm such as unintended pressure against tissue, tissue irritation, bleeding, perforation, aspiration, oxygen desaturation, asphyxiation, and/or infection.
- Do not use air or gaseous substances to inflate balloon, as this could lead to balloon rupture, resulting in unintended pressure against tissue, tissue irritation, perforation, aspiration, bleeding, oxygen desaturation, asphyxiation and/or infection.
- This device is designed for single use only. Attempts to reprocess, re-sterilize, and/or reuse may lead to device failure and/or transmission of disease.
- If package is opened or damaged when received, do not use.
- Visually inspect with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working conditions, do not use.

PRECAUTIONS

This balloon can be inflated to one distinct diameter, as indicated on package and catheter tag.

This balloon is used in conjunction with an inflation device and may be filled with an appropriate inflation medium such as sterile water, saline, or up to a 1:1 mixture consisting of contrast and saline.

Do not pre-inflate the balloon.

POTENTIAL ADVERSE EVENTS

Potential complications associated with esophageal and upper esophageal sphincter dilation procedures include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest, bleeding.

INSTRUCTIONS FOR USE

Before any use of this device, the user should ensure that any appropriate endoscopic accessory used to facilitate balloon deflation is readily available and can reach the site of dilation in the event that difficulty with balloon deflation is encountered.

1. Visually inspect device with particular attention to kinks, bends, and breaks. If an abnormality is detected which would prohibit proper working condition, do not use.
2. Move the wire guide lock to the "on" position and remove the wire guide.
3. Introduce the wire guide into the accessory channel of a compatible, pre-positioned endoscope, advancing in short increments until the wire guide is completely visualized endoscopically. NOTE: The pre-positioned endoscope may be introduced either via the nasal or oral cavity.
4. Monitoring endoscopically, advance the wire guide across the stricture.
5. While maintaining wire guide position within the esophagus, remove the endoscope.
6. Reposition the endoscope within the esophagus adjacent to the wire.
7. Attach the balloon catheter to a pre-filled 60ml (cc) inflation device with a gauge to monitor the balloon pressure.
8. Apply negative pressure to the device to facilitate removal of the protective sleeve.
9. Remove the protective sleeve from the balloon.
10. Apply a water-soluble lubricant to the balloon to facilitate passage through the oral or nasal cavity, as appropriate.
11. Prior to advancing the device over the wire guide, flush the wire guide lumen (green).
12. Maintain negative pressure and introduce the device over the wire guide, advancing in short increments until the balloon is completely visualized endoscopically.
13. Monitoring endoscopically, advance the device until the balloon is in the desired position within the stricture.

NOTE: Ensure that the wire guide is in the correct position in the esophagus prior to final placement of the balloon in order to maintain the correct balloon position. When the balloon and the wire guide are in the desired location, the wire guide can be secured to maintain its position by moving the wire guide lock to the "off" position.

14. Inflate the balloon to the pressure corresponding to the catheter tag on the catheter near inflation hub to achieve proper ATM pressure.
15. To deflate the balloon, apply negative pressure and remove all fluid from the balloon while observing the balloon endoscopically.

NOTE: If the balloon is difficult to deflate, it may be punctured via endoscopic visualization using an endoscopically compatible needle or a spiked forceps to allow removal.

16. Remove the deflated balloon, the wire, and the endoscope from the esophagus.

NOTE: To ease withdrawal, keep the catheter as straight as possible during removal. Upon completion of the procedure, dispose of the device.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packaging. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool location. Avoid extended exposure to light. Upon removal form the package, check the product to ensure no damage has occurred.

Symbol Key

℞ ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician.		Do not use if package is damaged
	Consult instructions for use		Keep dry
	Caution, see instructions for use		Keep away from sunlight
	Do not resterilize		Do not reuse
STERILE EO	Sterilized using ethylene oxide	REF	Catalogue number
LOT	Batch code		Manufacturer
	Use-by date		

HOPE MEDICAL

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Infinity®
Esophageal Dilation System

Infinity Balloon Dilation Catheter

Product Information and Instructions for Use
℞ Only

DESCRIPTION

The Infinity Balloon Dilation Catheter is a single stage dilation balloon catheter that comes with a stainless steel guidewire. This device is supplied sterile and is intended for single use.

INDICATIONS FOR USE

This device is used to dilate strictures in the esophagus and the upper esophageal sphincter.

NOTES

Do not use this device for any purpose other than the stated intended use.

Store in a dry location, away from temperature extremes.

This device is to be used trans-nasally or trans-orally.

CONTRAINDICATIONS

Contraindications to dilation include, but are not limited to:

- Uncooperative patient
- Asymptomatic rings, webs or strictures
- Known or suspected perforation
- INR (international normalized ratio) > 1.3 at time of dilation
- Anticoagulated patients
- Pathologic coagulopathies
- Recent nasal, orbital or facial trauma or nasal surgery
- Inability to pass the balloon or scope through the nares
- History of epistaxis
- Obstructing nasal or nasopharyngeal polyps or tumor
- Failure to advance through the strictured area

Read and follow all warnings and instructions.
Failure to read and follow warnings may result in patient injury or death.