

INSTRUCTIONS FOR USE, Cont'd

Deflating & Removing the Balloon:

1. Deflate balloon completely by applying negative pressure. If you have used more than 20cc fluid, you may have to repeat the deflation step with the device until all fluid has been removed.
2. While maintaining negative pressure, slowly remove the balloon from the patient.
3. On completion of the procedure, dispose of the contaminated balloon dilator according to your health care facility's contaminated disposable device protocol.

For further information: Please contact Hobbs Medical

WARNING

Potential adverse effects associated with GI endoscopy include but are not limited to: perforation, hemorrhage, aspiration, fever, infection, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

WARNING

This device has been validated and is warranted for single-use only. Any re-use, reprocessing or re-sterilization could destabilize the design structure of the device, which could result in device failure, which in turn could result in patient and/or user injury, illness or death. Also, any re-use, reprocessing or re-sterilization could create the risk of cross-contamination of the device, which could result in patient infection or cross-infection.



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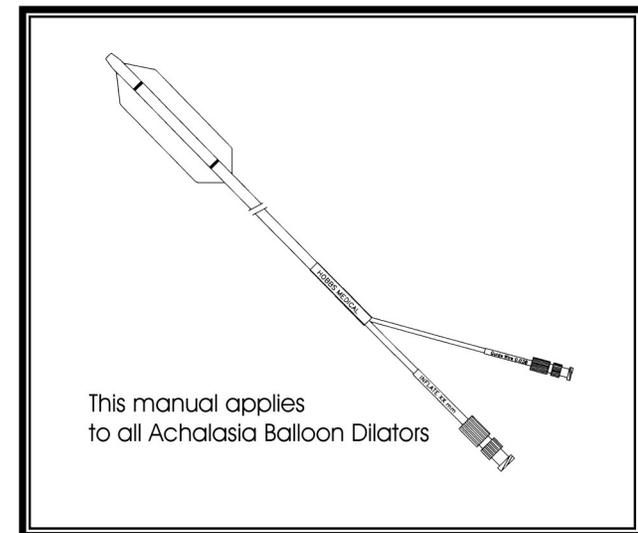


HOBBS MEDICAL, INC.

Precision Instruments for Endoscopy

Achalasia Balloon Dilator Single Use

INSTRUCTIONS FOR USE



HOBBS MEDICAL, INC.

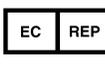
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READ CAREFULLY BEFORE USING

SYMBOLS

The meanings of the symbols shown on the package and/or this instrument are as follows:

| | | | |
|---|------------------------------|---|---|
|  | Consult Instructions |  | Package Damaged |
|  | Use By |  | Manufacturer |
|  | Date of Manufacture |  | CE Mark |
|  | Single Use |  | Batch Code |
|  | Catalog Number |  | Do Not Re-Sterilize |
|  | Sterile using Ethylene Oxide |  | Federal Law (USA) restricts this device to sale by or on the order of a physician |
|  | EU Authorized Representative |  | Quantity |

SIGNAL WORDS

The following signal words are used throughout this manual:

WARNING

Indicates a potentially hazardous situation, which if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation, which if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

SAFETY

Indications for Use: To be utilized by a trained physician for dilatation of the lower esophageal sphincter (LES) when a stricture is present.

CAUTION

Excessive pressure or force applied may cause damage to either the accessory and/or endoscope.

WARNING

A thorough understanding of the technical principles, clinical applications and risks associated with GI endoscopy is necessary before using this device.

CONSTRUCTION

Design: Single use Achalasia Balloon Dilators are designed with two lumens, a Guide Wire lumen that accepts a .038in Guide Wire and an inflate lumen. The balloons are offered in a variety of inflated diameters. This device has been sterilized using Ethylene Oxide.

CONTRAINDICATIONS

Include but not limited to:

- Known or suspected perforation
- Severe inflammation or scarring near the dilatation site

INSTRUCTIONS FOR USE

Testing the Balloon:

1. Remove the balloon from the package. **Save the product lot number for future reference.**
2. Inspect for any functional abnormality. If any irregularities are noted, call Hobbs Medical for a return authorization number.
3. To test the balloon prior to use, attach fluid filled inflation/deflation system to the proximal end of the balloon. Inflate the balloon with fluid to ensure the integrity of the balloon.
4. Aspirate the fluid completely from the balloon prior to using.

WARNING

A balloon partially filled with air will not provide as consistent a radical force as one entirely filled with fluid. Therefore, it is necessary to bleed all air from the balloon by applying negative pressure.

Procedure:

1. Advance the endoscope into the patient until the Lower Esophageal Sphincter has been identified.
2. Advance a .038in Guide Wire through the endoscope's biopsy channel. Use short 2cm strokes until the wire is visualized at the distal tip of the endoscope.
3. Position the distal tip of the Guide Wire in the LES with fluoroscopy assistance.
4. Remove the endoscope taking care to maintain the Guide Wire's position.
5. Insert the proximal end of the Guide Wire into the distal tip of the balloon.
6. Generously lubricate the balloon before passing the balloon orally over the Guide Wire.
7. With fluoroscopy assistance, position the balloon within the LES. There are two radiopaque markers within the balloon to assist in precise positioning.

Inflating the Balloon:

WARNING

Follow the inflation device instructions. Care must be used when injecting fluid. A 20cc syringe can generate 100psi with a hand squeeze.

1. Slowly inflate the balloon with fluid until sufficient pressure is attained to relax the LES.
- ### CAUTION
- DO NOT EXCEED THE MAXIMUM RATED PRESSURE. IT IS NOT ALWAYS NECESSARY TO MEET MAXIMUM PRESSURE TO ACHIEVE A SUCCESSFUL DILATATION.**
2. Once sufficient pressure has been attained, maintain pressure.
 3. The physician's preference will dictate the length of dilatation required.