

***Refer to the device directions for use for complete instructions on device use.***

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

***Reuse Warning***

For single 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, 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.

***Intended Use/Indications For Use***

The Rigiflex II Achalasia Balloon Dilator is indicated for dilatation of the cardia (LES) in patients with achalasia.

***Contraindications***

- Acute or incompletely healed esophageal perforation.
- Bleeding disorders.
- Large thoracic aortic aneurysm.
- Pharyngeal or cervical deformity.
- Recent esophageal perforation or surgery.
- Recent laparotomy.
- Recent myocardial infarction.
- Severe pulmonary disease.

***Adverse Events***

Complications may include:

- Aspiration
- Bleeding
- Esophageal Intramural Hematoma
- Esophageal Tear
- Infection
- Inflammation
- Pain (e.g., throat, stomach, chest, etc)
- Perforation
- Pneumonia
- Reflux
- Respiratory Distress

***How Supplied***

The Rigiflex II Achalasia Balloon Dilator is supplied in a Tyvek pouch and is supplied sterile using an ethylene oxide (EO) process and is intended for single use only.

Do not use if package is damaged or unintentionally opened before use.

Do not use if labeling is incomplete or illegible.