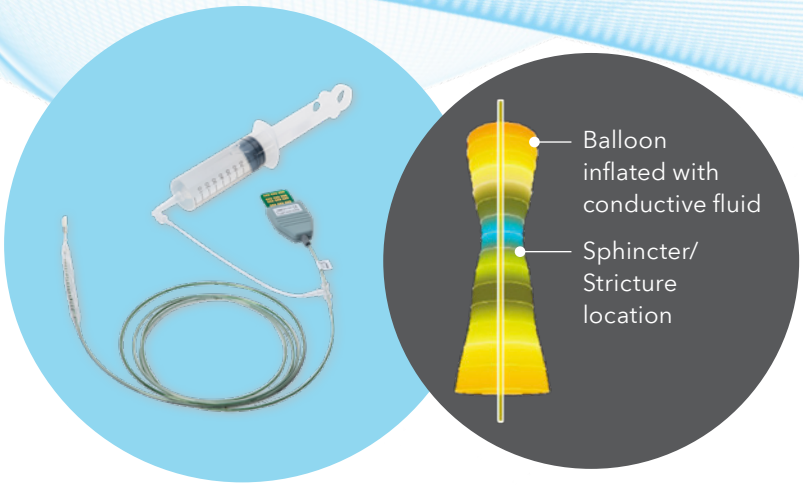
Medtronic

Esoflip™ balloon dilation catheter

Standard protocol quick reference guide



Esoflip™* ES-310

1. Placed trans-orally during sedated upper endoscopy
2. Connect a pressure monitor with a range of at least 0 to 5ATM (507kPa) to the Balloon Inflation Monitor Port. See statement from product labeling. Do not exceed the maximum inflation pressure of 1.5 ATM (152 kPa)

   8 sensors 0.5 cm spaced
3. Positioned with Stricture waist mid - balloon
4. Guide wire port in tip (0.035")

   Catheter markings referenced from center of balloon

   *Initial fill **5 ml** to measure Stricture diameter pre-dilation*
5. Inflate to desired dilation diameter

Precautions

- Balloon Rated Burst Pressure (RBP): **3 ATM (304 kPa)**
- Maximum inflate volume: **16 ml**
  Do not exceed the maximum inflation pressure of 1.5 ATM (152 kPa)

Esoflip™* ES-320

1. Placed trans-orally during sedated upper endoscopy
2. Connect a pressure monitor with a range of at least 0 to 5ATM (507kPa) to the Balloon Inflation Monitor Port. See statement from product labeling. Do not exceed the maximum inflation pressure of 2ATM (203kPa).

   16 sensors 0.5 cm spaced
3. Positioned with Stricture waist mid - balloon
4. Guide wire port in tip (0.035")

   Catheter markings referenced from center of balloon

   *Initial fill **20 ml** to measure Stricture diameter pre-dilation*
5. Inflate to desired dilation diameter

Precautions

- Balloon Rated Burst Pressure (RBP): **4 ATM (405 kPa)**
- Maximum inflate volume: **42 ml**
  Do not exceed the maximum inflation pressure of 2ATM (203kPa).

Esoflip™* ES-330

1. Placed trans-orally during sedated upper endoscopy
2. Connect a pressure monitor with a range of at least 0 to 5ATM (507kPa) to the Balloon Inflation Monitor Port. See statement from product labeling. Do not exceed the maximum inflation pressure of 1.5 ATM (152 kPa).

   14 sensors 0.5 cm spaced
3. Positioned with EGJ sphincter waist mid-balloon
4. Guide wire port in tip (0.035")

   Catheter markings referenced from center of balloon

   *Initial fill **30 ml** to measure EGJ sphincter diameter pre-dilation*
5. Inflate to desired dilation diameter

Precautions

- Balloon Rated Burst Pressure (RBP): **3 ATM (304 kPa)**
- Maximum inflate volume: **75 ml**
  Do not exceed the maximum inflation pressure of 1.5 ATM (152 kPa).

*If the catheter pre-use check procedure detects a problem, a message notifies you that the catheter may be faulty and should be replaced.

Indications for use
The Esoflip™ ES-310 and the ES-320 balloon catheter are indicated for use to dilate esophageal strictures due to esophageal surgery, primary gastro-esophageal reflux and radiation therapy. The Esoflip™ ES-330 balloon dilation catheter is indicated for use in a clinical setting for dilating the gastroesophageal junction of a patient with Achalasia. **Note:** The Esoflip™ catheter is to be used only with the Endoflip™ system.

Contraindications
The Esoflip™ catheter is contraindicated where endoscopy is contraindicated. Do not use the Esoflip™ catheter on patients with actively-bleeding varices in the esophagus or with active esophageal perforation. The Esoflip™ ES-310 catheter is not suitable for diameter measurements and dilation of strictures smaller than 6 mm or greater than 10 mm. The Esoflip™ ES-320 catheter is not suitable for diameter measurements smaller than 8 mm or greater than 20 mm.The Esoflip™ ES-330 catheter is not suitable for diameter measurements smaller than 8 mm or greater than 30 mm.

Potential complications
Potential complications include allergic reaction, anaphylaxis, bleeding, cardio-respiratory complications, dental trauma, infection, pain, perforation, pulmonary aspiration, vasovagal response.

References
1. Esoflip™ ES-310 Catheter Instructions for Use, PT00140542 Rev A 2021-02
2. Esoflip™ ES-320 Catheter Instructions for Use, PT00140523 Rev A 2021-02
3. Esoflip™ ES-330 Catheter Instructions for Use, PT00140543 Rev A 2021-02

Important: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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