

Medtronic

Esoflip™

Dilation balloon catheters

Dilate patients in a controlled manner¹
with Esoflip™ dilation balloon catheters
and advanced dilation technology.



Esoflip™ dilation balloon catheters with the Endoflip™ system provide a comprehensive view of the esophagus to accurately measure stricture size before and after each stage of balloon dilation.

This enables physicians to dilate patients in a controlled manner, raising the benchmark of patient care provided in dilation of esophageal strictures without the need for fluoroscopy.¹



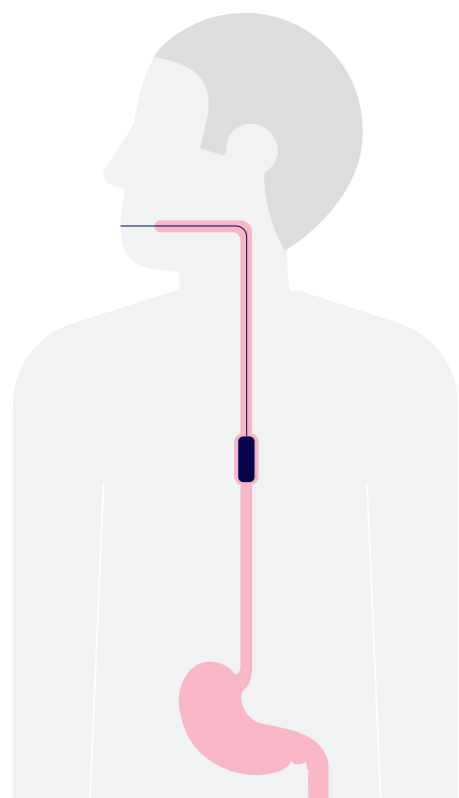
Benefits²⁻⁴

Esoflip™ dilation balloon catheters are designed to dilate esophageal strictures due to esophageal surgery, primary gastroesophageal reflux and radiation therapy (ES-310, ES-320). They can also be used to dilate the gastroesophageal junction (GEJ) of a patient with achalasia (ES-330).

Esoflip™ dilation balloon catheters are designed for use with the Endoflip™ system.

As the dilation balloon inflates under user control, the Endoflip™ system uses a technique called impedance planimetry to characterize the geometry of the measurement area (for more information refer to the Endoflip™ system Instructions for use).

Esoflip™ dilation balloon catheters act as functional lumen imaging probes (FLIP), showing dynamic changes in the geometry of the strictures (ES-310, ES-320) or GEJ (ES-330) in a real-time image.



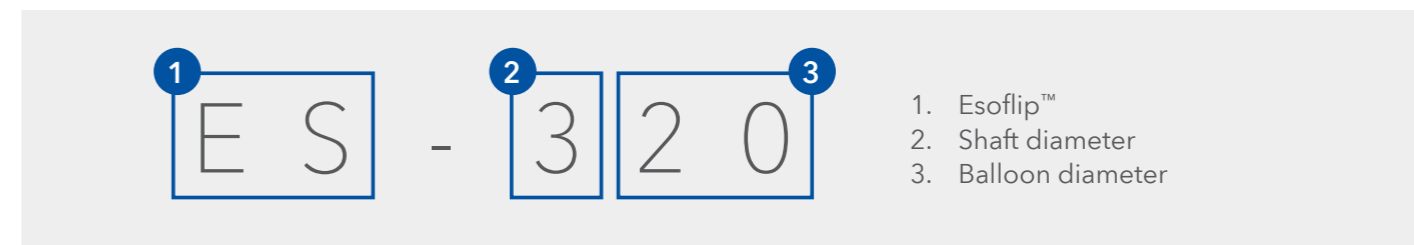
Esoflip™ dilation balloon catheters enable physicians to:

- Locate strictures easily²⁻⁴
- Measure strictures at intermediate levels of dilation²⁻⁴
- Perform hands-free, slow and controlled dilation²⁻⁴
- Stop and evaluate before dilating further²⁻⁴
- Determine if balloon is moving during procedure²⁻⁴
- Effectively measure recoil after dilation diameter²⁻⁴
- Avoid fluoroscopy, minimizing patient and staff radiation exposure²⁻⁴



Esoflip™ dilation catheters

Understanding the numbers and differences²⁻⁴



Catheter ES-310

The Esoflip™ ES-310 balloon catheter is indicated for use to dilate esophageal strictures due to esophageal surgery, primary gastro-esophageal reflux and radiation therapy.

Indication

- Features**
- 8 measurement points over a length of 40 mm along the balloon
 - 5 mm electrode spacing
 - Pressure monitor required (not supplied)
 - 6-10 mm dilation range
 - Guidewire tip

Catheter ES-320

The Esoflip™ ES-320 balloon catheter is indicated for use to dilate esophageal strictures due to esophageal surgery, primary gastro-esophageal reflux and radiation therapy.

- 16 measurement points over a length of 80 mm along the balloon
- 5 mm electrode spacing
- Pressure monitor required (not supplied)
- 8-20 mm dilation range
- Guidewire tip

Catheter ES-330

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.

- 14 measurement points over a length of 70 mm along the balloon
- 5 mm electrode spacing
- Pressure monitor required (not supplied)
- 8-30 mm dilation range
- Guidewire tip

How it works²⁻⁴

Esoflip™ dilation balloon catheters have a specific diameter dilation balloon which acts as a functional lumen imaging probe (flip) showing dynamic changes in the geometry of the stricture in a real-time image.

The catheter connects to the Endoflip™ system, which injects a conductive solution into the dilation balloon placed in the stricture area. The balloon contains an array of electrodes that measure voltage.

As the balloon inflates under user control, the Endoflip™ system uses these voltages to estimate the diameter at 16 points (ES-320), 14 points (ES-330), 8 points (ES-310), 5 mm apart, along the measurement area (Figure 1).

Refer to the Endoflip™ System Instructions for Use for a further description of the system.

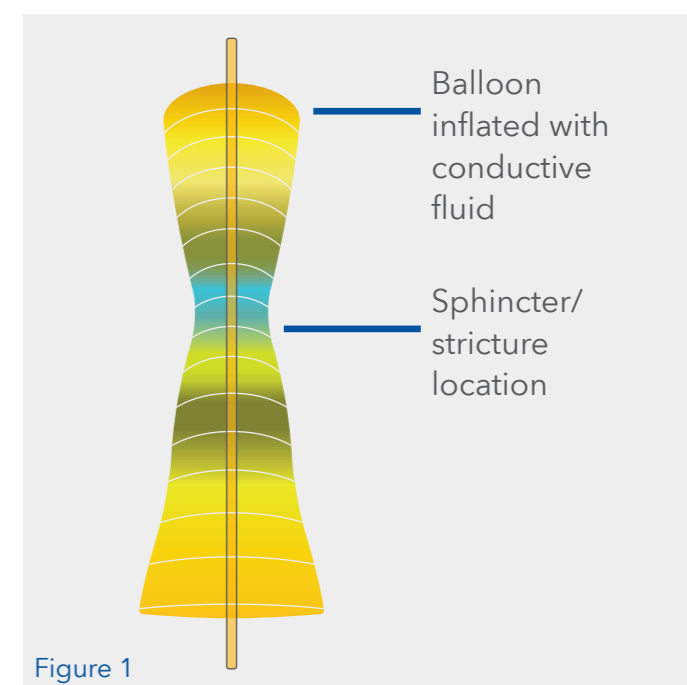


Figure 1

Catheters

Part number

Esoflip™ dilation balloon catheter (10 mm) 5/box **ES-310**

Esoflip™ dilation balloon catheter (20 mm) 5/box **ES-320**

Esoflip™ dilation balloon catheter (30 mm) 5/box **ES-330**



Note: The Esoflip™ catheter is to be used only with the Endoflip™ system.

References:

1. Alexandra J. Baumann, Dustin A. Carlson. Esoflip for Esophageal Dilation: Proposed Advantages. *Curr Opin Gastroenterol.* 2020 July ; 36(4): 329-335. doi:10.1097/MOG.0000000000000639.
2. Esoflip™ ES-310 Catheter Instructions for Use, PT00140542 Rev A 2021-02.
3. Esoflip™ ES-320 Catheter Instructions for Use, PT00140523 Rev A 2021-02.
4. Esoflip™ ES-330 Catheter Instructions for Use, PT00140543 Rev A 2021-02.

Indications For Use: The Esoflip™ ES-310 and the ES-320 balloon dilation 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: include allergic reaction, anaphylaxis, bleeding, cardio-respiratory complications, dental trauma, infection, pain, perforation, pulmonary aspiration, vasovagal response.

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