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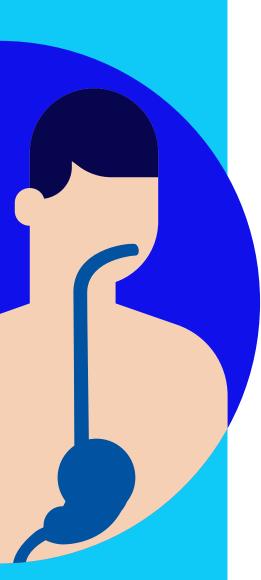
Objective means of diagnosing GERD & assessing motility disorders¹²

Motility disorders often mimic symptoms of GERD, making diagnosis of esophageal symptomatic patients a challenge³





Endoflip[™] 300 System



Shared symptoms of GERD and motility disorder patients

- Dysphagia
- Regurgitation
- Chest pain
- Heartburn
- Food impaction

Tests aren't conclusive.



Up to 50% of endoscopies for predominant esophageal symptoms are negative.⁴

Treatment isn't always effective.



One in three patients referred with ongoing symptoms while using PPI's do not have GERD.⁵



And PPI use has been associated with osteoporosis and other risks.⁶

You need an objective means of diagnosing GERD and assessing motility disorders

That's why we offer **two simple tests** that can provide the objective data you need to direct therapy decisions.



Dysphagia

Endoflip™ 300 System

displays real-time topography of the esophagus and gastroesophageal junction during sedated endoscopic and surgical procedures.^{7,8}

Automated procedure protocols with standard patient reports will help you:⁷

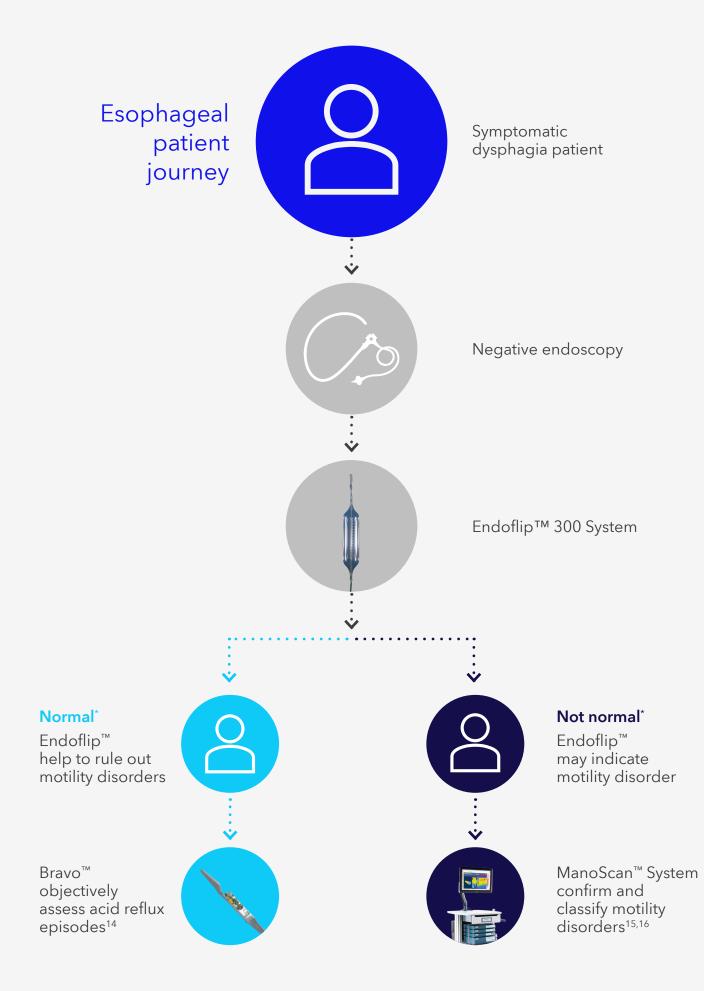
- Measure pressure and dimensions of the esophagus and gastroesophageal junction
- Gain valuable insight into esophageal function – without fluoroscopy⁹
- Identify or rule out major motility disorders^{10,11}

GERD

Bravo[™] pH Monitoring System

Esophageal (pH) testing is the gold standard for diagnosing GERD.¹² This capsule-based patientfriendly reflux test measures acid levels in the esophagus.^{12,13}

Test for GERD at the time of a negative endoscopy without disrupting your workflow.¹⁴ With on-demand placement of the Bravo[™] calibration-free reflux testing system, you can simply pair, place, and go.



*As indicated by clinician based on Distensibility Index (DI) and topographic patterns.

Endoflip[™] 300 System:

Indications for Use:

The following are the indications for use for the Endoflip 300 platform and Endoflip catheters:

The Endoflip 300 system is indicated for use in a clinical setting to measure pressure and dimensions in the esophagus, pylorus, and anal sphincters in adults and to measure pressure and dimensions in the esophagus, in patients from five years of age. It is intended to be used as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders.

The following are the indications for use for the Endoflip 300 platform and Esoflip catheters:

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.

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.

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.

Contraindications:

The Endoflip 300 system is contraindicated where endoscopy is contraindicated.

The Endoflip 300 system is contraindicated for use in patients with actively bleeding varices in the esophagus or, when using Esoflip catheters with active esophageal perforation.

Note:

Catheters have additional contraindications. Refer to the IDU for each catheter type for additional information.

Bravo™ pH Monitoring System:

Indications for Use:

The Bravo Monitoring System is intended to be used for gastroesophageal pH measurement and monitoring of gastric reflux in adults and children from 4 years of age.

The Bravo capsule can be attached following either endoscopy or manometry. The Reflux/Accuview software application is intended to record, store, view, and analyzegastroesophageal pH data.

Contraindications:

Patients with bleeding diathesis, strictures, severe esophagitis, varices, obstructions, pacemakers or implantable cardiac defibrillators are contraindicated.

For a full indications of use, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

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