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Medtronic receives CE Mark for its next generation Endoflip™ 300 system

Endoflip™ is an advanced diagnostic tool that can help expedite accurate diagnosis of esophageal motility disorders, conditions often missed during endoscopies.^{1,2}

Medtronic plc, a global leader in healthcare technology, today announced it has received CE (Conformité Européenne) Mark for its next generation Endoflip™ 300 system to measure pressure and dimensions in the esophagus and pylorus in adults.¹ The Endoflip™ 300 System will help thousands of patients across Europe with esophageal motility disorders achieve a diagnosis.² Research suggests these disorders are missed in up to 50% of endoscopies and patients can wait years to receive a diagnosis.¹ Endoflip™ can be performed under sedation in around 5 minutes and can be utilized from the very first endoscopy.²

Timely diagnosis of these conditions is key to improving patient outcomes.^[3] As pinpointing the underlying cause of patient symptoms can be very difficult, Endoflip™ represents a valuable tool as a convenient, well tolerated method for assessment.^{2,6-9} The device uses a balloon catheter to display diameter estimates of the measurement area in real-time. It can measure and display diameter estimates at up to 16 points within the balloon while also displaying balloon pressure.³ This may allow for a more precise diagnosis and treatment planning from the very first endoscopy, preventing unnecessary distress for patients.^{2,8}

“Medtronic is committed to transforming esophageal care for patients by providing physicians with cutting-edge solutions to their clinical challenges,” comments Darin Wilson, Endoscopy Business Unit Leader, Western Europe, which is part of the Medical Surgical Portfolio at Medtronic. “We are excited to have received CE Mark for Endoflip™ 300, which will help gastroenterologists & GI surgeons across Europe diagnose esophageal motility disorders much earlier, plan and implement precise and effective treatment and, ultimately, improve patient outcomes. We are fueled by our resolve to change each individual’s life for the better and strive to achieve this through continued technological innovation.”

Dr. Rehan Haidry, Clinical Lead of Endoscopy and Consultant Gastroenterologist at the Cleveland Clinic, London adds: “Endoflip™ is a game changer for us. Esophageal motility disorders, like achalasia and gastroparesis, are notorious for being hard to spot and patients are often given the wrong diagnosis. I've seen patients with symptoms for over a decade, undergoing numerous inconclusive endoscopies. Endoflip™ provides us with a significant advantage: by guiding diagnosis and treatment early on, Endoflip™ can drastically improve patient outcomes.”

Professor Silvana Perretta, Upper gastro-intestinal surgeon, from the Nouvel Hôpital Civil (NHC) University Hospital, Strasbourg concludes: "Incorporating Endoflip™ technology for perioperative use provides an additional functional tool that enhances diagnostic accuracy and helps prevent misdiagnosis and therefore mistreatment. In surgery there is no room for approximation. This innovation is pivotal in delivering more precise care, particularly in the era of precision surgery and treatment. A smart imaging probe for smart diagnosis can save health care dollars and improve patient's lives".

Esophageal motility disorders affect the normal functioning of the esophagus. They can disrupt the normal swallowing process (peristalsis) causing symptoms such as difficulty swallowing (dysphagia), chest pain, regurgitation, and heartburn.¹⁰ The best-defined esophageal motility disorder, achalasia, is rare with a prevalence of up to 15.7 per 100,000, while gastroparesis has a prevalence of 13.8 per 100,000 in Europe.^{11,12} But these conditions are misdiagnosed in up to 50% of endoscopies meaning, in Europe alone, there could be thousands more people living with these conditions that haven't been diagnosed.^{1,11-13} This is because symptoms can overlap with more common conditions such as gastro-esophageal reflux disease (GERD).

Misdiagnosis can lead to unnecessary tests which can cause distress and cost money. Depending on the healthcare system and whether procedures are performed publicly or privately costs can vary, however, upper GI endoscopies typically cost €2,000 - €4,000 in Western Europe, and sometimes as much as €7,000.¹⁴ Meanwhile, patients deteriorate and they suffer reduced quality of life due to ongoing symptoms.¹⁰

Key benefits of Endoflip™:

- Comfortable - can be performed under sedation⁴
- Fast - Can take around 5 minutes⁴
- Can be performed at the time of endoscopy²
- Can facilitate clinical diagnosis to direct management³
- Real time topography is displayed clearly on a screen alongside well established ranges^{2,8}
- Physicians trained in Endoflip™ may be able to make a diagnosis during the endoscopy⁴
- Indicated for adult patients (18+)

The Endoflip™ 300 System will be commercially available in the coming months and has already been cleared for sale or distribution in the United States. Visit <https://www.medtronic.com/covidien/en-gb/products/motility-testing/endoflip-impedance-planimetry-system.html> for more information.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission – to alleviate pain, restore health, and extend life – unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and

better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow on [LinkedIn](#).

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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<https://news.medtronic.com/Medtronic-receives-CE-Mark-for-its-next-generation-Endoflip-TM-300-system>