Medtronic News

Medtronic Receives Expanded Indication From FDA for Pillcam(TM) Colon 2 Capsule

Potentially Reaching More Patients at Risk for Colon Cancer

DUBLIN - March 31, 2016 - Medtronic plc (NYSE: MDT) today announced that the U.S. Food and Drug Administration (FDA) cleared PillCam(TM) COLON 2 capsule for an expanded indication for use. The PillCam(TM) COLON 2 capsule is the only non-invasive diagnostic test that directly visualizes the colon for the evaluation of polyps in patients who are at major risks for colonoscopy or moderate sedation. The PillCam(TM) capsule- a vitamin-sized capsule endoscope that is taken orally - does not require sedation, anesthesia or radiation, which makes it a more convenient procedure than other invasive colon exams.

This expanded indication is for the detection of colon polyps in patients with evidence of gastrointestinal bleeding of lower gastrointestinal (GI) origin. This applies only to patients with major risks for colonoscopy or moderate sedation, but who could tolerate colonoscopy and moderate sedation in the event a clinically significant colon abnormality was identified on capsule endoscopy.

Colon cancer is the third most commonly diagnosed cancer and second leading cause of cancer death in both men and women combined in the U.S. An estimated 136,000 people will be diagnosed with colorectal cancer each year, but when it is caught at a localized stage, the overall 5-year survival rate is 90%.[i]

According to *Gastrointestinal Endoscopy*, 14 million colonoscopiesare performed in the U.S. each year - of these, more than 3 million are performed for lower GI bleeding, and 600 thousand of those patients are at elevated risk for complications. [ii][iii]

"The ability to offer PillCam COLON capsule to an expanded patient group represents a significant breakthrough in GI healthcare," said Douglas Rex, M.D., Distinguished Professor of Medicine and Chancellor's Professor, Indiana University School of Medicine and Director of Endoscopy, IU Health University Hospital. "The new indication allows gastroenterologists to provide their at-risk patients with a non-invasive and radiation free alternative to traditional colonoscopy."

"We are committed to the early detection and treatment of chronic GI diseases and cancers. We are pleased with the FDA's decision to clear this expanded indication for PillCam(TM) COLON capsule which will provide access to more patients who can benefit from this technology," said Vafa Jamali, president, Early Technologies business in the Medtronic Minimally Invasive Therapies Group.

PillCam(TM) COLON 2 capsule was previously cleared by the FDA for visualization of the colon and the detection of colon polyps in patients following an incomplete colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible. The PillCam(TM) capsule technology may also limit the risk of complications that could occur from a standard colonoscopy, such as colon perforation, bleeding or cardio-pulmonary complications.

Multimedia

A multimedia version of this release is available, including a downloadable photo.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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[i] ACS Colorectal Cancer Facts & Figures 2014-2016; http://www.cancer.org/acs/groups/content/documents/document/acspc-042280.pdf

[ii] Leiberman D, et al. Colonoscopy utilization and outcomes 2000 to 2011. Gastrointestinal Endoscopy, 2014.

[iii] Johnson D, Lieberman D, Pochapin M, et al. Occurrence of Delayed Non-GI Events Post-Colonoscopy and Patients with Identifiable Increased Risk [abstract]. Am J Gastroenterol 2014;109:S647.

Contacts:

John Jordan
Public Relations
+1-508-452-4891

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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