

## Medtronic announces 510(k) clearance for PillCam™ Small Bowel 3 @HOME endoscopy procedure

*Latest approval for PillCam™ further enables patients to receive gastrointestinal care in the comfort of their own home*

DUBLIN, Nov. 15, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for its PillCam™ Small Bowel 3 system for remote endoscopy procedures. The PillCam™ SB3 @HOME program combines Medtronic's PillCam technology with Amazon logistics, a combination intended to ensure both timely and accurate results for patients from the comfort of their homes.

PillCam SB3 @HOME provides a telehealth option for direct visualization and monitoring of the small bowel, to help better detect lesions not detected by upper and lower endoscopy that may: 1) indicate Crohn's disease, 2) locate obscure bleeding, or 3) identify sources of iron deficiency anemia (IDA).

"As the future of medicine continues to move toward remote settings, we have great opportunity to deliver diagnostic testing and other minimally invasive procedures from patients' homes," said Giovanni Di Napoli, president of the Gastrointestinal business, which is part of the Medical Surgical Portfolio at Medtronic. "The pandemic necessitated more remote innovation, and our capabilities have exceeded expectations to provide better quality care to patients without the risk of COVID infection and without adding to the burden on the medical staff. PillCam SB3 @HOME offers a convenient option for a contactless procedure and helps ensure that patients can access care in a timely manner."

The system is designed to deliver images of the mucosa and offers innovative features, such as adaptive frame rate technology, to support image acquisition that is uniquely suited to each patient's motility, as well as the tools needed to record those images and allow the clinician to interpret study results. The software's advanced technology helps providers read and interpret study results, efficiently.

"Early diagnosis and treatment are key to achieving the best outcome for GI patients, and fortunately with telehealth options, patients can receive their GI diagnosis conveniently from home," said Dr. Michael Bass of GI Specialist of Delaware. "The COVID-19 pandemic has underscored the importance of early detection and not delaying care following the onset of symptoms. This system allows for patients to remain in the comfort and safety of their own home while giving providers access to the high-quality images needed to make a diagnosis."

PillCam Small Bowel 3 is only cleared for remote use in the U.S. It is not approved for this use in other geographies.

### **About PillCam™ SB3 @Home**

Once a GI physician identifies a patient and places an order for a PillCam SB3 @HOME procedure kit, the procedure date is confirmed and the PillCam SB3 @HOME kit is delivered directly to the patient. Through a telehealth appointment, a healthcare provider guides the patient through the remote procedure, and the patient returns the data recorder and sensor belt to Medtronic once the procedure is complete. Over the course of the eight-hour procedure, the PillCam SB3 capsule transmits approximately 50,000 images. These images are securely transferred to the cloud where they are accessed by a GI physician who reviews the images to make a diagnosis.

Prior to the 510(k) clearance, PillCam SB3 @HOME was given temporary FDA-approval during the National Public

Health Emergency. Medtronic's PillCam™ capsule endoscopy has been used for more than 20 years as a minimally invasive, patient-friendly option for the detection of gastrointestinal diseases. PillCam SB is now in its 3rd generation and has impacted more than 4 million patients worldwide.

### **About Medtronic**

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, 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 90,000+ passionate people across 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 (NYSE:MDT), visit [www.Medtronic.com](http://www.Medtronic.com) and follow [@Medtronic](https://twitter.com/Medtronic) on Twitter and [LinkedIn](https://www.linkedin.com/company/medtronic).

**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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