

PillCam[®] COLON 2 Video Capsule Fact Sheet

Breakthrough technology in PillCam[®] COLON 2 enables a smarter approach to colon capsule endoscopy and a patient-friendly option for visualization of the colon. PillCam COLON 2 is complementary to traditional colonoscopy and an appropriate exam for those patients who have received incomplete colonoscopy, are contraindicated for colonoscopy or are unwilling to undergo traditional colonoscopy.

Breakthrough Technology

- System utilizes bi-directional communication between PillCam COLON 2 capsule and DataRecorder 3.
- Adaptive Frame Rate (AFR) adjusts the image capture rate from 4 frames per second (fps) to 35 fps based on capsule movement.
- New RAPID[®] v7 software provides unique tools to increase reading efficiency and aid in image interpretation.
- Data are transferred from the DataRecorder to a computer with RAPID software to compile the video data, enabling the physician to review and report the results of the PillCam study.

About PillCam COLON 2

- PillCam COLON 2 received a CE Mark in September 2009 and is commercially available throughout Europe, Latin America, Canada, Australia and parts of Asia.
- The PillCam COLON 2 capsule and platform offer intelligent functionality, superior imaging, and convenient workflow that provide a minimally invasive alternative for patients who are unwilling or unable to undergo traditional colonoscopy.
- PillCam COLON 2 is an ingestible capsule about the size of a large vitamin pill and is equipped with two miniature color video cameras (one on each end), a battery and an LED light source; it measures 11.6 mm X 31.5 mm.

Procedure

- Prior to capsule ingestion, preparation for the PillCam COLON procedure is similar to that of a traditional colonoscopy.
- A patient is typically on a liquid diet the day before and takes laxatives the night before the procedure.
- The procedure is initiated by ingestion of the PillCam COLON video capsule with a glass of water.
- Additional cleansing agents are required after capsule ingestion.
- Images and data are transmitted wirelessly as the PillCam COLON passes through the digestive system.
- The image and data information are captured and stored in a DataRecorder worn by the patient.
- Natural digestive contractions help propel the disposable PillCam COLON through the gastrointestinal (GI) tract until it is passed naturally and painlessly from the body, usually within 10 hours.



Benefits of PillCam COLON 2

- Patient-friendly option for visualization of the colon
- Does not require sedation, intubation, insufflation, or radiation
- Uses commercially available laxatives and prokinetic tablets for bowel preparation. PillCam COLON 2 has an evolving role in evaluating¹:
- Patients who are unable to undergo sedation
- Patients for whom colonoscopy was incomplete
- Patients unwilling to undergo traditional colonoscopy

Risk Information

All medical procedures carry some risks. The risks of PillCam[®] capsule endoscopy include capsule retention, aspiration, or skin irritation. Endoscopic placement may present additional risks. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. After ingesting the PillCam COLON capsule and until it is excreted, the patient should not be near any source of powerful electromagnetic fields such as one created near an MRI device. The risks associated with colon preparation are as follows: allergies or other known contraindications to any preparation agents or medications used for the PillCam COLON regimen, according to laxative medication labeling and per physician discretion. Please consult your physician or refer to www.givenimaging.com for detailed information.

References:

¹ Eliakim R, Yassin K, Niv Y, et al. Prospective Multicenter Performance Evaluation of the Second-Generation Colon Capsule Compared with Colonoscopy. *Endoscopy* 2009; 41:1026-1031.

All products are not cleared for marketing or available for commercial distribution in all markets.
Please verify if specific products have the necessary regulatory clearance in your country.