

PillCam[®] SB Video Capsule Fact Sheet

PillCam[®] SB is the first non-invasive method for visualizing small bowel mucosa. This patient-friendly procedure, which enables physicians to make a final diagnosis, requires no bowel preparation or sedation and is clinically validated by close to 1,000 peer-reviewed studies.

Overview

- Ingestible capsule is about the size of a large vitamin pill and is equipped with a miniature video camera to visualize the small intestine; it measures 11 mm x 26 mm and weighs less than four grams
- Patient-friendly alternative to conventional endoscopic and radiological procedures to help the physician diagnose and evaluate disorders of the small intestine, including suspected Crohn's disease, unexplained bleeding, small bowel tumors, celiac disease, NSAID-related ulcers, and other conditions
- First non-invasive device able to visualize the entire small bowel mucosa, previously visible only by surgery
- Procedure has proven higher diagnostic efficacy than traditional methods for small bowel imaging
- For Crohn's disease patients whose physicians suspect a narrowing of the small intestine, the Agile™ patency capsule can ensure safe passage.

How It Works

- Now in its second generation, PillCam SB 2 transmits two color images per second to a recording device worn by the patient during the procedure. This results in more than 50,000 images of the small bowel per patient.
- Data are transferred from the DataRecorder to the PillCam[®] Platform, which uses RAPID[®] software to compile the video data and to enable the physician to review and report the results of the PillCam study.

Procedure

- Patient fasts for a minimum of 10 hours prior to the procedure
- Capsule endoscopy of the small bowel is initiated by the patient's ingesting the PillCam SB video capsule with a glass of water
- Images and data are transmitted wirelessly as the PillCam SB passes through the digestive system
- Image and data information is then captured and stored in a DataRecorder worn by the patient
- A typical procedure lasts between eight to ten hours
- Natural digestive contractions propel the disposable PillCam SB through the gastrointestinal (GI) tract until it is passed naturally and painlessly from the body



Expanding the scope of GI

Benefits over Traditional Methods

- Offers a simple, safe and non-invasive alternative
- Does not require sedation
- Does not require patient to swallow barium or other contrast media often required for radiological imaging
- Greater patient satisfaction
 - Ease of ingestion
 - Minimal discomfort during procedure
 - Convenience
- Immediate recovery
- Allows patient to continue with normal daily activity

Acceptance

- Over 5,000 participating centers and over 1,000,000 patients worldwide have benefited from this procedure
- American Society for Gastrointestinal Endoscopy (ASGE) Technology Review on PillCam Capsule Endoscopy – last updated April 2006
- Worldwide over 509.7 million people have reimbursable access to the PillCam SB.
- American Medical Association (AMA) assigned CPT® 91110 for reimbursement of PillCam SB capsule endoscopy, effective January 1, 2004
- U.S. Food and Drug Administration Clearance of PillCam SB – August, 2001; received CE Mark – May 2001
- The Company's second-generation capsule, PillCam SB2, received U.S. Food and Drug Administration Clearance in May 2007