Medtronic





PillCam[™] capsule endoscopy platform



PillCam[™] SB 3 capsule



PillCam™ Crohn's capsule



PillCam™ COLON 2 capsule



PillCam[™] Patency capsule







Patient comfort. Patient safety. Patient-friendly.

PillCam[™]- A lasting commitment to GI visualization

The PillCam[™] capsule endoscopy platform enables comprehensive GI tract imaging – and supports you in providing the very best care.

Given Imaging, owned by Medtronic, was the pioneer in capsule endoscopy, developing new clinically backed products for an increasing number of applications.

Four Capsules - One System

The PillCam $^{\text{\tiny M}}$ capsule endoscopy platform offers the ability to visualize the small bowel as well as the colon in excellent image quality, while the PillCam $^{\text{\tiny M}}$ patency capsule verifies the GI patency prior to PillCam $^{\text{\tiny M}}$ capsule administration.



GI Bleeding



Iron Deficiency Anemia



Crohn's Disease



Polyps

PillCam[™] software v9 - Better experience, more powerful tools

The PillCam[™] capsule endoscopy platform offers a combination of the latest capsule technology and software algorithms to provide physicians and medical staff with a good balance of diagnostic accuracy and reading efficiency.

It offers several smart tools and features to help you provide the optimal GI care for your patients. Compatible with all PillCam $^{\mathsf{T}}$ capsule models.



Top 100 Mode

Efficient reading

- Smart tools, features and algorithms to assist you in diagnosing your GI patients.¹
- Top 100*: one hundred images that most likely include an ulcer, bleeding, or a polyp.
- QuickView*: Clinically validated algorithm provides rapid study preview in a few minutes (review of full video is still required).



Improved atlas

Diagnostic confidence

- Improved image atlas: New crisp and clear images to aid in more confident diagnosis.
- Integrated virtual chromoendoscopy to enhance visualization of suspicious patterns (FICE).
- New and improved GI map: Provides a more immediate representation of the progress of the capsule through the small bowel and colon. This feature is available with both the PillCam[™] sensor array and belt.**



Study comparison

Therapy support

- Real time viewing provided by the PillCam[™] recorder³
- Software-based polyp and ulcer size estimation tool (with PillCam[™] COLON 2 capsule and PillCam[™] Crohn's capsule respectively)***
- Ability to compare images, videos and treatment over time (available in combination with PillCam™ Crohn's capsule).
- Dedicated tools for assessment of Crohn's disease activity
- GI Map show the capsule location along.

- * The feature is not intended to detect pathology in lieu of a physician and should not be used as a substitute for reviewing the entire studio
- ** Localization of the capsule is only an estimate. Use of reader defined landmarks may improve this tool. Discretion should be used when relying on the capsule progress indicator and localization tools to make diagnostic and treatment decision
- *** Ulcer Size Estimation is a tool for research purposes only and the values displayed should not be used in making diagnostic or treatment decisions. Polyp Size Estimation measurement is only an estimate. Use discretion when making diagnostic or treatment decisions



Leader in small bowel diagnostics

PillCam[™] SB 3 capsule



GI Bleeding



Iron Deficiency Anemia



Crohn's Disease



Ampulla of Vater



Ulcer



Edematous Villi



Active Bleeding

Complete and detailed visualization of the small bowel through:

- Adaptive Frame Rate (AFR): 2-6 images per second based on the capsule movement
- Wide angle view

High accuracy:

- Excellent image quality
- Exclusive software features





Crohn's Disease

PillCam[™] Crohn's capsule

Pan-intestinal imaging for a pan-intestinal disease

Efficient and Patient-friendly Monitoring:

The PillCam[™] Crohn's platform allows physicians to directly and in a minimally-invasive way visualize the small bowel and the colon in a single procedure.

- 172° field of view (per camera)
- No sedation
- No radiation

Comprehensive Visualization:

Advanced optics and innovative imaging features may also have a role in assessing mucosal healing after medical therapy.

Adaptive Frame Rate (AFR) technology increases the rate of image capture from 4 to 35 frames per second based on the speed of the capsule.



PillCam™ COLON 2 capsule

Direct visualization of the colon with a minimally-invasive procedure



Polyps



Sessile Serrated Polyp with Mucous Cap * Confirmed by histology



Large Mass



Pedunculated Polyp



Sessile Polyp

Bi-directional communication between the PillCam[™] COLON 2 capsule and the PillCam[™] recorder 3 enables:

- Compliance with physician instructions on bowel prep through active reminders for the patient throughout the procedure
- Automatic detection of the small bowel to ensure gastric emptying
- Image acquisition that is uniquely suited to each patient

Optimal visualization of colon mucosa:

- 2 camera heads
- Adaptive Frame Rate (AFR): changes acquisition rate from 4 fps to 35 fps when the capsule is moving quickly
- Extra wide angle of view allows for maximum tissue coverage (172° per camera)
- System optimizes video length while also saving battery energy



PillCam[™] patency capsule

Safety has the highest priority

- The PillCam[™] patency capsule is intended to verify adequate patency of the GI tract prior to PillCam[™] capsule administration
- Dissolvable and biocompatible
- Agile patency system eliminates risk of capsule retention in patients with known intestinal strictures who undergo capsule endoscopy
- Timer plugs facilitate controlled disintegration of capsule body
- Compatible with PillCam™ SB 3 capsule, PillCam™ COLON 2 capsule and PillCam™ Crohn's capsule



PillCam[™] capsule endoscopy equipment

The PillCam $^{\text{\tiny M}}$ capsule endoscopy platform includes the video capsule, the data recorder, the sensor belt (or sensor array) and the PillCam $^{\text{\tiny M}}$ software.



PillCam[™] data recorder 3

- Active control of capsule frame rate
- Real time viewing with color LED monitor
- Audio and visual alerts to remind the patient of the next procedure steps
- Integrated rechargeable battery



- Very comfortable
- Easier and more convenient procedure for the medical staff
- No need for shaving, skin preparation or adhesive pads reduces preparation and post procedure time

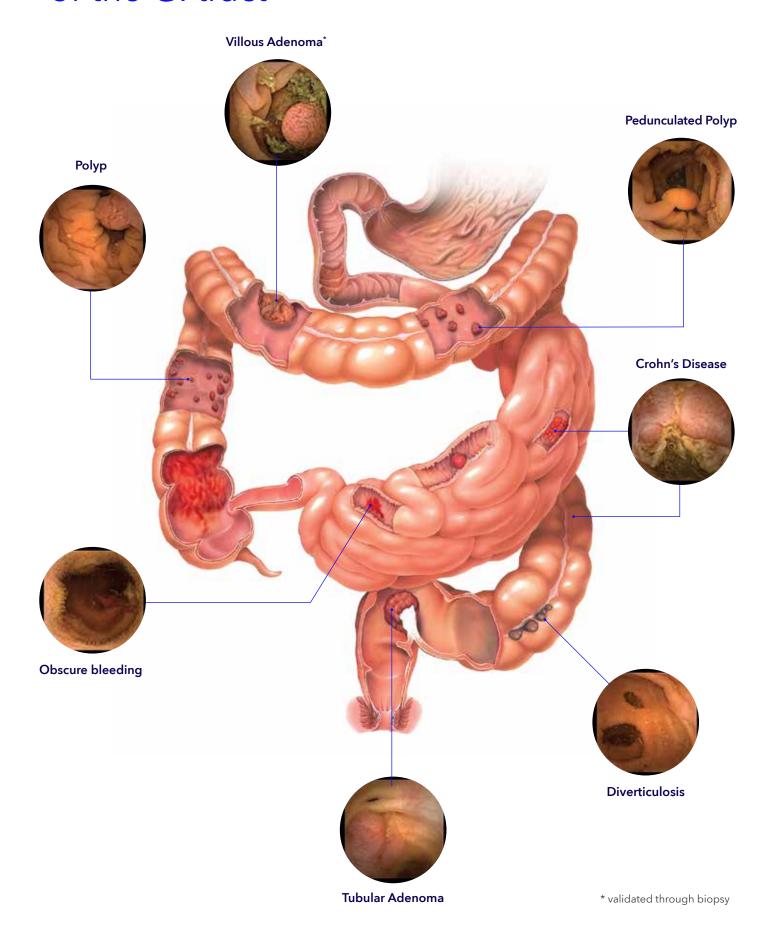


More flexibility

PillCam[™] software provides the solution when you need flexible access to software and data from different places in the hospital or from home through free of charge PillCam[™] Reader Software.

CFN	Description
FGS-0400	PillCam™ SB3 capsule, 10-pack
FGS-0608	PillCam [™] Crohn's capsule, 10-pack
FGS-0519	PillCam™ COLON 2 capsule, 10-pack
FGS-0659	PillCam [™] patency capsule, 1-pack, EU
FGS-0660	PillCam [™] patency capsule, 5-pack, EU
FGS-0590	PillCam [™] sensor belt, Small Bowel
FGS-0591	PillCam [™] sensor array
FGS-0510	PillCam [™] sensor belt 2 disp kit, 5-pk
FGS-0453	PillCam [™] sensor sleeves, 10-pack
FGS-0605	PillCam [™] C2 / Crohn's sensor belt
FGS-0666	Single-use covers for PillCam™ C2/Crohn's sensor belt, 5-pack

The PillCam[™] capsule endoscopy platform can be used to visualize many pathologies of the GI tract



Clinical evidence

 More than 2000 publications on the PillCam[™] capsule endoscopy platform

More than 3 million procedures performed using PillCam[™]

• Periodic literature reviews and newsletters available

Training

- Online e-learning modules
- Curriculum developed by capsule experts
- Capsule training, performed exclusively on the PillCam[™] capsule endoscopy platform
- Quality guidelines for capsule endoscopy
- Initial on-site training

Technical service

- Replacement service
- Consultations with qualified service technicians
- Customer-friendly handling of all technical inquiries
- On-site support provided by dedicated Medtronic personnel



References

- 1. REP-05-11-044 Rapid 9 SB3 AAM report. DOC-10000070597, April 4, 2016 (data on file).
- Rondonotti E., Spada C., Adler S., et al., Small-bowel capsule endoscopy and device-assisted enteroscopy for diagnosis and treatment of small-bowel disorders: European Society of Gastrointestinal Endoscopy (ESGE) Technical Review, Endoscopy 2018; 50(04): 423-446.

Potential adverse events associated with the use of this PillCamTM Capsule endoscopy system may include delayed or no excretion of the capsule, aspiration, obstruction, perforation, and mucosal injury or bleeding. In some instances, intervention is required to remove the capsule.

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