PillCam® COLON 2
PillCam® COLON 2: Indications for Use

The PillCam COLON 2 capsule endoscopy system is intended to provide visualization of the colon. It may be used for detection of colon polyps in patients after an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible.
PillCam® COLON 2: Contraindications

- Patients with known or suspected GI obstruction, strictures or fistulas based on the clinical picture or pre-procedure testing and profile
- Patients with cardiac pacemakers or other implanted electro-medical devices
- Patients with swallowing disorders
- In patients with allergies or known contraindications to the medications and preparation agents used in the procedure as described in the relevant instructions for use
PillCam® COLON 2: Features

- 2 Cameras
- Adaptive Frame Rate
- Advanced Optics/3 Lenses
- Advanced Automatic Light Control
- Extra-wide Angle of View - 172°
- 11.6 mm x 31.5 mm
- Depth of Field 0-30 mm
PillCam® COLON 2 Feature: Adaptive Frame Rate (AFR)

- Image capture rate changes from 4 or 35 frames/sec with capsule movement
- 4 frames/sec when capsule is virtually stationary
- 35 frames/sec when capsule is in motion
- Maximizes mucosa coverage
- Optimizes video length
- Conserves battery energy
PillCam® COLON 2:
Capsule Frame Rate Comparison

PillCam COLON
4 frames/sec

PillCam COLON
35 frames/sec

Click Video

Click Video
Bowel Preparation: Success Rate

- The excretion percentage with the regimen used in the US registration trial was 89% and a 10 hour excretion time.
- The median excretion time was 3 hours and 59 minutes.
<table>
<thead>
<tr>
<th>Colonoscopy</th>
<th>PillCam® COLON 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Colonoscopy Image" /></td>
<td><img src="image2" alt="PillCam Image" /></td>
</tr>
<tr>
<td>Ulcerative Colitis</td>
<td></td>
</tr>
<tr>
<td><img src="image3" alt="Colonoscopy Image" /></td>
<td><img src="image4" alt="PillCam Image" /></td>
</tr>
<tr>
<td>Diverticulosis</td>
<td></td>
</tr>
</tbody>
</table>

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Colonoscopy

PillCam® COLON 2

~8 mm flat polyp at right colon

Flat polyp at left colon
Colonoscopy

> 10 mm polyp at sigmoid

PillCam® COLON 2

> 10 mm polyp at right colon

> 10 mm polyp at sigmoid
Colonoscopy

PillCam® COLON 2

> 10 mm tumor at right flexure

> 10 mm tumor at sigmoid-rectum
Colonoscopy:
Disruption of the contour of mucosal fold

PillCam® COLON 2 Images:
Sessile Serrated Lesion; 6 mm, Cecum

PillCam COLON 2: Rim of debris and different tissue vs. neighboring tissue
PillCam® Colon 2 Accuracy: Published Trials

The Eliakim Multi-Center Trial - 98 Patients

<table>
<thead>
<tr>
<th>Accuracy</th>
<th>≥ 6 mm</th>
<th>≥ 10 mm</th>
</tr>
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<tbody>
<tr>
<td>Sensitivity % (95% CI)</td>
<td>89% (70%-97%)</td>
<td>88% (56%-98%)</td>
</tr>
<tr>
<td>Specificity % (95% CI)</td>
<td>76% (72%-78%)</td>
<td>89% (86%-90%)</td>
</tr>
</tbody>
</table>

- Polyps ≥ 6 mm a true positive result = PillCam COLON (CCE) finds 1 polyp ≥ 4 mm, OC at least 1 polyp ≥ 6mm
- Polyps ≥ 10 mm a true positive result = PillCam COLON (CCE) finds 1 polyp ≥ 7mm, OC at least 1 polyp ≥ 10 mm
- Assumes CCE size plus 50 % to account for size measuring errors

### PillCam® Colon 2 Accuracy: Published Trials

#### The Spada Multi-Center Trial - 109 Patients in Analysis

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<tr>
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<th>≥ 6 mm</th>
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<tr>
<td><strong>Accuracy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensitivity %</td>
<td>84% (74%-95%)</td>
<td>88% (76%-99%)</td>
</tr>
<tr>
<td>(95% CI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specificity %</td>
<td>64% * (52%-76%)</td>
<td>95% (90%-100%)</td>
</tr>
<tr>
<td>(95% CI)</td>
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</table>

- For polyp to match had to be within 50% of the size of the largest estimate of the two measures and found in same or adjacent segment

- True positive is at least one of polyps of each size class found in same or adjacent segment

*After un-blinding there was a substantial rate of false positive polyps because of size mismatch (20/25) cases. When these misclassified polyps are considered “true”, specificity for any polyp would be as high as 92%.

CCE vs CT In Patients With Incomplete Colonoscopy

- Feasibility study to determine if CCE could complement incomplete optical colonoscopy
- 98 patients included in the efficacy analysis

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<tr>
<th>Polyps ≥ 6mm</th>
<th>CCE</th>
<th>CTC</th>
</tr>
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<tbody>
<tr>
<td>Sensitivity (%)</td>
<td>100 (CI 86-100)</td>
<td>35 (CI 19-41)</td>
</tr>
<tr>
<td>Specificity (%)</td>
<td>91  (CI 67-91)</td>
<td>92  (CI 71-100)</td>
</tr>
<tr>
<td>PPV (%)</td>
<td>95  (CI 82-95)</td>
<td>86  (CI 46-99)</td>
</tr>
<tr>
<td>NPV (%)</td>
<td>100 (CI 74-100)</td>
<td>52  (CI 40-56)</td>
</tr>
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<table>
<thead>
<tr>
<th>Polyps ≥ 10mm</th>
<th>CCE</th>
<th>CTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (%)</td>
<td>100 (CI 60-100)</td>
<td>67  (CI 30-67)</td>
</tr>
<tr>
<td>Specificity (%)</td>
<td>96  (CI 86-96)</td>
<td>100 (CI 91-100)</td>
</tr>
<tr>
<td>PPV (%)</td>
<td>86  (CI 51-86)</td>
<td>100 (CI 44-100)</td>
</tr>
<tr>
<td>NPV (%)</td>
<td>100 (CI 89-100)</td>
<td>92  (CI 84-92)</td>
</tr>
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<td></td>
<td>CCE was adequate in 83% of patients.</td>
<td>CTC procedure was adequate in 88% of patients.</td>
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Utility of CCE After an Incomplete Colonoscopy

- Multi-center study enrolled 96 patients
- Most common cause of incomplete colonoscopy was repeated loop that could not be overcome with standard colonoscopy
- Combined approach of CCE plus colonoscopy permitted complete visualization of colonic mucosa in 93% of the patients
- CCE revealed new lesions in 58 patients (60%)
- In 43 of these patients (45%), the new findings modified the therapeutic approach
  - Repeat colonoscopy for polyp resection
  - Surgery in case of colon neoplasia

Objective: to measure accuracy of CCE in detecting polyps 6mm or larger

Design CCE->read->OC->OC repeated if false positive
- Lesion matching by location and size
- Stricter criteria
- 884 pts/689 included in analysis/22% excluded 2/2 prep or too rapid transit
- Excretion rate of 91%

ADR = 39% in OC/Mean withdrawal time 10.6 min.

Sensitivity by histologic class:
- Adenomas (6mm/1cm): 88%/92%
- SSA (6mm/1cm): 29%/33%
Most Commonly Asked ?s
Question #1.

- What is the preparation and how is it tolerated?
Prep Used in the US Registration Study For PillCam® COLON 2

Before ingestion of PillCam COLON:
- 4 (12mg) Senna tablets - 2 days prior to the procedure
- 2 liters PEG the evening prior to the procedure
- 2 liters PEG the morning of the procedure

After ingestion of PillCam COLON:
- Reglan: If necessary during procedure for gastric emptying*
- 2 boosts of SUPREP® - to enhance capsule propulsion and maintain adequate cleansing
  - 6 oz. SUPREP** solution
  - 3 oz. SUPREP** solution*
- Suppository, if needed*
- Light meal, if needed*

*Indicates potential procedure requirements
** SUPREP © Braintree Laboratories Inc., Braintree, MA.
Question #2.

- When can patients leave the office after capsule ingestion?
Our experience.....

- No significant issues with preparation to date.
  - 1 patient did require additional preparation prior to capsule ingestion of PEG.
  - Sensitivity to Suprep issue
  - Suppository complaints
  - Patients able to follow instructions and tolerate preparation outside of office after 1st SUPREP boost.
Question # 3.

Who is the capsule indicated for?
The PillCam COLON 2 capsule endoscopy system is intended to provide visualization of the colon. It may be used for detection of colon polyps in patients after an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible.
Question # 4.

- Does poor preparation count as incomplete colonoscopy?

*Unfortunately not.*
Question # 5.

- How big is the capsule?
- 2 Cameras
- Adaptive Frame Rate
- Advanced Optics/3 Lenses
- Advanced Automatic Light Control
- Extra-wide Angle of View - 172°
- 11.6 mm x 31.5 mm
- Depth of Field 0-30 mm

Slightly larger than a standard multivitamin or standard potassium chloride tablet
Question #6.

- Do I need to retrieve the capsule?
Question # 7.

- What issues are encountered with billing?

- 0355T procedure code invalid

- Can’t bill patient as a result of a category 3 code not being part of our agreement.

- 26 modifier - professional component only.

- Office visit required to document incomplete colonoscopy
Question # 8.

- How long does it take to read a capsule study?

- 45 minutes
Question # 9.

- If I read small bowel capsule can I easily learn colon capsule endoscopy?

- Different procedure
- Double head
- Careful attention to viewing and analysis
Question #10.

- What are your options once a finding is identified?
  - Observation
  - Repeat colonoscopy
  - Repeat colonoscopy with different endoscopist
  - Repeat colonoscopy with single balloon technology
  - Repeat colonoscopy with DBE
  - Repeat colonoscopy with Smart Navi-Aid Balloon
  - Surgical intervention.
Question #11.

What has the response been in the community?
- WELL RECEIVED
- NON-Threatening
- Viewed as a “time saver.”
- Poised to replace CT colonography
- Significantly increased interest in learning capsule endoscopy

Other Questions?