A COLON EXAM IN A CAPSULE

The PillCam™ COLON System
The small way to evaluate your entire colon
In the clinical trial presented to the FDA, the PillCam™ COLON system correctly identified 68.8% of patients with at least one polyp of 6 mm or larger in size, and 64.9% of the patients with at least one polyp of 10 mm or larger in size that was identified by colonoscopy. Therefore, the PillCam™ COLON system missed 31.2% of the patients with polyps that were 6 mm or larger, and 35.1% of patients with polyps that were 10 mm or larger. The PillCam™ COLON system falsely identified a polyp of 6 mm or larger in 18.7% of patients, and a polyp of 10 mm or larger in 7.1% of patients who had no polyps identified by colonoscopy. False identification of a polyp may lead to unnecessary follow-up procedures.

The PillCam™ COLON system provides thorough, accurate visualization of the colon and detects a large number of polyps.

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**Number of Patients with Polyps Identified**

<table>
<thead>
<tr>
<th>Polyp Size</th>
<th>Colonoscopy</th>
<th>PillCam™ COLON system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diminutive Polyps</td>
<td>115</td>
<td>143</td>
</tr>
<tr>
<td>Small Polyps</td>
<td>77</td>
<td>81</td>
</tr>
<tr>
<td>Large Polyps ≥ 10 mm</td>
<td>219</td>
<td>194</td>
</tr>
</tbody>
</table>
If your doctor decides a colonoscopy is not the best option for you, you can still receive an accurate colon exam with good sensitivity for detecting polyps. The PillCam™ COLON system provides accurate results and supports your doctor in making a confident diagnosis—so you can have the peace-of-mind of knowing you’re getting the right care.

This system may be best for you if:

- You have had an incomplete colonoscopy with adequate preparation
- You have evidence of lower gastrointestinal bleeding and are at major risk for colonoscopy or sedation
HOW IT WORKS

The PillCam™ COLON capsule, which is about the size of a multi-vitamin, captures images as it travels naturally through your gastrointestinal tract. The images are then transmitted to a recorder that you wear in a pouch and strap around your shoulder.

This non-invasive procedure does not require you to be admitted to a hospital, and you can continue most daily activities while the capsule is in your body. You can also continue taking your regular medications.

ADVANCED TECHNOLOGY

The PillCam™ COLON capsule features the most innovative technology to provide accurate images of the colon. It uses dynamic camera technology that allows your doctor to identify the most relevant information. The capsule is disposable and passes naturally with a bowel movement. The clear images the capsule collects help your doctor determine the best plan for your health.
PREPARATIONS FOR THE TEST

Before the PillCam™ COLON capsule procedure, your colon needs to be completely emptied. To clean your colon, your doctor will ask you to take laxatives before the procedure. It is important that you follow all of the instructions and ingest all prep solution to ensure your doctor can see the colon properly.

In addition, you will drink about one cup of laxative after the capsule is swallowed and the recorder will alert you if this step needs to be repeated to ensure a complete procedure.

Reminder

Your doctor cannot see the colon properly if there is any remaining waste. Make sure you follow all instructions and drink all of the prep solution.
Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

Indications for Use: The PillCam™ COLON 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. In addition, it is intended for detection of colon polyps in patients with evidence of gastrointestinal bleeding of lower GI origin. This applies only to patients with major risks for colonoscopy or moderate sedation, but who could tolerate colonoscopy and moderate sedation in the event a clinically significant colon abnormality was identified on capsule endoscopy.

Risk Information: The risks of the PillCam™ COLON capsule include capsule retention, aspiration, and skin irritation. The risks associated with colon preparation are 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. 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 the capsule is excreted, patients should not be near any source of powerful electromagnetic fields, such as one created near an MRI device. Please consult your physician for further information.