This document is intended to provide guidance for the clinical staff for patients scheduled for a PillCam™ Crohn's system exam.

**At Least Two Days Prior to the PillCam™ Crohn's System Exam**

- It is advised to have a telephone conversation with the patient to verify:
  - Patient has a copy of the *Patient Procedure Checklist for the PillCam™ Crohn's system*
  - Patient has the required laxatives and medications:
    - 4 L PEG SF ELS
    - SUPREP™ kit
    - 10 mg Reglan™ tablet
    - 10 mg bisacodyl suppository
  - Patient has the approved items for their clear liquid diet:
    - Apple and white grape juice
    - Tea or black coffee
    - Water
    - Popsicles or Jell-O™
    - Clear carbonated or sports drinks
    - Bubblegum or hard candy (hard candy should be dissolved slowly)
  - **NOTE:** NO RED OR PURPLE COLORS. NO BROTH OR SOUP.
  - Patient understands the diet and prep requirements for the day prior to the exam:
    - Should ingest 64 oz of clear liquid throughout the day to assist with hydration and successful bowel preparation
    - 2 L of PEG ingested within 2 hours from 7 p.m. – 9 p.m.
  - **Patient understands the instructions for the day of their exam:**
    - Maintain clear liquid diet
    - Wear comfortable, two-piece, opaque (dark-colored) clothing
    - Arrive at clinic by ________________
    - Bring the rest of the PEG solution, Reglan™ tablet, SUPREP™ kit, and 10 mg bisacodyl suppository with them to their exam
    - 2 L of PEG will be ingested within 2 hours from 7 a.m. – 9 a.m.*

*Note: The patient may drink the PEG in the morning before arriving at the hospital/clinic earlier than 7 a.m. If times are changed, the time intervals between steps should remain the same.

- Review medications with patient and discuss recommendations by the physician for any restrictions.
- Encourage the patient to call about any questions or uncertainty during the preparation process.

**Equipment Preparation**

- Materials (e.g., sensor arrays, capsules), should be prepared in accordance with the number of patients that are scheduled.
- Prepare PillCam™ recorder 3:
  - Verify that the PillCam™ recorder 3 is fully charged.
  - Initiate the recorder through the Patient Check-in process, making sure to select “Crohn's” as the capsule, select “Crohn's regimen,” and uncheck the “Delay first instruction.”
- Prepare the PillCam™ Crohn's and COLON 2 sensor array (insert sensors into white sleeves) or use the PillCam™ Crohn's and COLON 2 sensor belt.
Day of the PillCam™ Crohn's System Procedure

- Use Patient Procedure Checklist to document all procedure steps. Mark a ✓ by each step that is completed and document any deviation.
- Patient may resume most of their daily activities, but cannot lay down or sleep until the end of the procedure.
- After the PillCam™ Crohn's capsule is excreted, the patient should continue to wear the equipment until they receive the “End of Procedure” alert icon.
- The equipment can be removed after PillCam™ recorder 3 “End of Procedure” alert appears.
- If the physician approves that the patient can be sent home prior to the end of the procedure, ask the patient to follow instructions provided for removing the sensor array or sensor belt (disconnect it from the recorder, turn off recorder, and document End of Procedure time). Give the patient instructions on how and when to return the equipment to the clinic.

PillCam™ Recorder 3

The PillCam™ recorder 3 is ready for operation when its battery is charged, removed from the cradle, and the sensor array/sensor belt is connected.

When ON, the PillCam™ recorder 3 initiates the pairing procedure as soon as a signal is received from a capsule. When the capsule LED on the PillCam™ recorder 3 blinks in blue, it is receiving data from a paired capsule. If the capsule LED is blinking white, the pairing process needs to be completed by confirming the capsule ID and pressing the middle navigation button. The LED will then blink blue, confirming that the pairing is successful.
STAFF PROCEDURE CHECKLIST
PillCam™ Crohn’s System

Step by Step Guidelines for the Procedure

Note: The time of procedure can move to earlier or later in the day, but the intervals between tasks must remain the same. For example, If a patient comes in at 5:50 a.m., the following procedure time points will be adjusted to the earlier schedule, and the Patient Procedure Checklist should be corrected accordingly.

<table>
<thead>
<tr>
<th>Pre-ingestion Process</th>
<th>Patient should drink the 2 L of PEG solution — one 8–10 oz glass every 10–15 minutes, typically between 7 a.m. and 9 a.m., until the 2 L has been ingested. Then, instruct the patient to remain NPO until capsule ingestion.</th>
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<tr>
<td></td>
<td>Patients who ingested their PEG at home should arrive at the clinic by 9:30 a.m. to prepare for capsule ingestion by 10 a.m. The capsule should be ingested 1 hour after the last glass of PEG was consumed, typically at 10 a.m.</td>
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<td>Check the Patient Procedure Checklist and verify that the patient followed all required steps. If needed, mark a ✓ by each step and notify physician of any deviation from the preparation requirements.</td>
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<td>Place the PillCam™ Crohn’s and COLON 2 sensor array or PillCam™ Crohn's and COLON 2 sensor belt on the patient in accordance with the PillCam™ Crohn’s Procedure Manual.</td>
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<td>Adjust the PillCam™ recorder 3 pouch on the patient. Verify that the PillCam™ recorder 3 is checked-in for the correct patient. Then connect the PillCam™ Crohn’s and COLON 2 sensor array or PillCam™ Crohn's and COLON 2 sensor belt to the PillCam™ recorder 3.</td>
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<tr>
<th>PillCam™ Crohn’s Capsule Ingestion Process</th>
<th>Turn on PillCam™ recorder 3 (press the “Power” button until the logo appears).</th>
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<tbody>
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<td>Verify that you have the correct PillCam™ recorder 3 by looking at the screen for the patient name.</td>
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<td></td>
<td>Open a PillCam™ Crohn’s capsule box, note the Capsule ID (printed on the back side of the box) of the activated capsule, and document the ID on the Patient Procedure Checklist.</td>
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<td>Hold the PillCam™ Crohn’s capsule close to one of the sensors that are placed on the patient’s abdomen and verify that the indication lights on the PillCam™ recorder 3 are blinking white.</td>
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<td>Once the PillCam™ Crohn’s capsule and Capsule ID matching has occurred, the activated capsule ID will be displayed on the PillCam™ recorder 3 screen as two unpaired RED capsules. Use the center navigation button to select the capsule ID code and complete the pairing process.</td>
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<td>Verify that the PillCam™ recorder 3 indication light is blinking blue and the red unpaired capsules are now paired and GREEN.</td>
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<td>If you entered the capsule ID during Patient Check-in, the capsule pairing process will complete automatically once the recorder receives the signal from the capsule. The LED light will blink blue and the capsules on the recorder screen will appear green. The capsule is ready for ingestion once the green capsules and blue LED light appear.</td>
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<td>Ask the patient to ingest the PillCam™ Crohn’s capsule with a glass of water.</td>
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<td>Immediately after PillCam™ Crohn’s capsule ingestion, the patient is NPO. Remind the patient to refrain from any drinking until he/she is instructed otherwise. They may resume most of their daily activities, but cannot lay down or sleep until the end of the procedure.</td>
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</table>
STAFF PROCEDURE CHECKLIST
PillCam™ Crohn's System

Step by Step Guidelines for the Procedure (cont.)

Post-ingestion Procedure

☐ Alert 0: If this alert is received, the patient should take one Reglan™ 10 mg tablet by mouth with a sip of water. Reglan™ helps empty the stomach. The patient should not have anything else by mouth until the next alert is received.

☐ Alert 1: When this alert is received, the patient will need to take SUPREP™. This laxative will cause bowel movements and is used as a boost to propel the capsule through the colon. SUPREP™ must be mixed with water before ingesting. See Patient Procedure Checklist for instructions on mixing SUPREP™. Once finished, the patient will need to drink an additional 34 oz of water. The clear liquid diet will resume, and the patient may resume most of their daily activities, but cannot lay down or sleep until the end of the procedure. At this time, the patient will need to wait for the next alert, which may be “End of Procedure” or “Alert 2.”

☐ Alert 2: Three hours later if this alert is received, the patient will need to take a lower dose of SUPREP™. See Patient Procedure Checklist for instructions on mixing SUPREP™. Once finished, an additional 34 oz of water will need to be consumed. The clear liquid diet will continue, and the patient can resume most of their daily activities, but cannot lay down or sleep until the end of the procedure. They should then wait for the next alert, which may be “End of Procedure” or “Alert 3.”

☐ Alert 3: Two hours later if this alert is received, the patient will need to insert a 10 mg Bisacodyl™ suppository into their rectum and let it dissolve. Bisacodyl™ is a laxative that causes bowel movements. He/she will continue a clear liquid diet and may resume most of their daily activities, but cannot lay down or sleep until the end of the procedure. The patient will wait for their next alert, which may be “End of Procedure” or “Alert 4.”

☐ Alert 4: Two hours later if this alert is received, the patient will need to eat a standard light meal. Once the meal has been eaten, the patient should continue drinking plenty of fluids and wait for the “End of Procedure” alert.

☐ End of Procedure Alert: When the patient receives the alert, this signals the end of the procedure. This alert can occur anytime after the patient has received “Alert 1.” Once this alert is received, the patient should remove the equipment and return it to the office as instructed. The physician will review the image results and determine the best next steps for the patient’s care.

☐ The patient will continue to wear the equipment and follow the instructions until they receive the "End of Procedure" alert icon.

End of Procedure

☐ Ask the patient if they observed the capsule exit the body.

☐ Remove sensor array or sensor belt and PillCam™ recorder 3 from the patient (for patients staying at the office during the procedure).

☐ Provide instructions to the patient, if released prior to “End of Procedure” alert, on the removal and return of the equipment once they receive the “End of Procedure” alert.

☐ Ensure the PillCam™ recorder 3 is disconnected from the sensor array or sensor belt. Place the PillCam™ recorder 3 into the cradle and create the video.
Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

Indications: The PillCam™ Crohn’s capsule is intended for visualization of the small bowel and colonic mucosa.
- It may be used in the visualization and monitoring of lesions in the small bowel that may indicate Crohn’s disease not detected by upper and lower endoscopy, and for the visualization of inflammation of the colon in patients with colonoscopy-diagnosed Crohn’s disease.
- It may be used in the visualization and monitoring in the small bowel of lesions that may be a source of obscure bleeding (either overt or occult) or that may be potential causes of iron deficiency anemia (IDA) not detected by initial upper and lower endoscopy.
- The PillCam™ Crohn’s capsule may be used as a tool in the detection of abnormalities of the small bowel. It is intended for use in adults.

Contraindications: The PillCam™ Crohn’s capsule is contraindicated for use under the following conditions:
- In patients with known or suspected gastrointestinal obstruction, strictures, or fistulas based on the clinical picture or pre-procedure testing and profile
- In patients with cardiac pacemakers or other implanted electromedical devices
- In patients with dysphagia or other swallowing disorders
- In patients with allergies or known contraindication to the medications and preparation agents used in the procedure as described in the relevant instructions for use

Risk Information: The risks of the PillCam™ Crohn’s system 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™ Crohn’s 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™ Crohn’s 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. Please refer to the product user manual for detailed information.