



## **Informed Consent** for PillCam Capsule Endoscopy/Agile Patency Capsule

*NOTE: You will be asked to sign a procedure consent form at the time of your appointment. We have included the consent form for your review. Should you have any questions, please contact our office prior to your appointment. You do not need to bring this form with you.*

**I, for myself or on behalf of the patient, consent to the gastrointestinal endoscopic procedure of:**

PillCam Capsule Endoscopy OR  Agile Patency Capsule

**by the physicians of Dayton Gastroenterology, Inc. as well as assistants as may be designated by those physicians.**

**I. EXPLANATION OF PROCEDURE:** PillCam Capsule Endoscopy is an endoscopic examination of the small intestine. It is not intended to examine the esophagus, stomach, or colon. It does not replace upper endoscopy or colonoscopy. This is a visual examination only and no biopsies may be taken with this technology. Additional procedures may be necessary to treat abnormalities that are identified.

Agile Patency Capsule is the same size as the PillCam capsule and is used to determine if the PillCam capsule can be expected to pass freely through the digestive tract. The Agile Patency Capsule does not transmit images of the digestive tract.

**II. RISKS AND COMPLICATIONS:** Examination of the small intestine with PillCam capsule endoscopy is generally safe. Complications are uncommon. Risks and complications include but are not limited to the following:

- In approximately 1 out of 100 procedures, the capsule can become lodged above a stricture or narrowed area. Patients who have Crohn's disease or have had abdominal surgery in the past are at increased risk for this complication. If an obstruction or stricture prevents passage of the capsule, surgery may be required for removal, with the associated risks of bleeding, infection, prolonged hospitalization and even death. An abdominal x-ray may be ordered in the weeks after the procedure if the physician is not able to determine that the capsule passed into the large intestine during the course of the study.
- There have been reports of the capsule becoming lodged at the back of the throat. Should this occur, it may need to be removed by a physician.
- There is a risk of aspiration (swallowing the capsule accidentally into the lung). Should that occur, pneumonia and other complications could result.
- Patients who have difficulty swallowing may be at increased risk for complications. It is important that you notify the nursing staff or physician prior to the capsule endoscopy procedure if you have difficulty swallowing.
- The capsule is not approved for use in patients with pacemakers or implanted cardiac defibrillators. The capsule has been used in some centers in these patients without complications related to the pacemaker or implanted defibrillator.
- Due to variations in the patient's intestinal motility, the capsule may only image part of the small intestine. It is also possible that due to technical factors, including but not limited to food debris in the intestine and device malfunction, some images may be inadequate and this may result in the need to repeat the capsule procedure.
- Due to the metallic components of the capsule, MRI studies should not be performed until the capsule has passed out of the body. If you require an MRI study, notify the ordering physician that you have recently had capsule endoscopy and that the capsule must be passed out of the body before the MRI is performed.
- Capsule endoscopy is not a perfect study. Abnormalities, including cancer, might not be seen in some cases.
- For patients receiving the Agile Patency Capsule: This capsule is the same size as the PillCam capsule, but can partially dissolve to pass through a narrowed area. This test is used to determine if there is a risk of the PillCam capsule becoming lodged in the digestive tract. All of the possible complications described for the PillCam capsule are possible also with the Patency Capsule. As with the PillCam capsule, acute obstructive symptoms such as abdominal pain and vomiting may occur. Emergency surgery to correct the problem may be necessary, though this is less likely with the patency capsule since it is able to partially dissolve.

**III. ALTERNATIVE PROCEDURES:** Small bowel enteroscopy using a standard endoscope is an alternative to examination of the small bowel, but cannot view the entire small bowel, as is the case with capsule endoscopy. Small bowel x-rays can view the entire small bowel, but are much less accurate. Should you have questions regarding alternative ways to examine the small intestine, please be sure to ask the nurse or physician at Dayton Gastroenterology before proceeding with the capsule exam.

**IV.** I am aware the practice of medicine is not an exact science and I acknowledge guarantees have not been made to me concerning the results of the procedures to be performed. I certify that I have read the above consent form, understand the information regarding the capsule endoscopy procedure, its risks, possible complications and alternatives to my satisfaction and do hereby consent to the performance of the examination specified above.