

GREENBELT ENDOSCOPY CENTER

INFORMED CONSENT FOR CAPSULE ENDOSCOPY

PATIENT NAME: _____ DATE OF BIRTH: _____ SEX: _____

Explanation of procedure

Visualization of the digestive tract by ingestion of a non-invasive diagnostic imaging device is referred to as capsule Endoscopy. It is an endoscopic exam of the GI tract. It is not the preferred examination for the stomach or colon. Your physician has advised you of your need to have this type of examination. The following information is presented to help you understand the reasons for, and the possible risk of these procedures. This procedure involves ingesting a small (the size of a large vitamin pill) camera capsule, which will pass naturally through your digestive system while taking pictures of the GI tract. The images are transmitted to the sensor, which is placed on your body. The sensor is attached to a walkman-like data recorder that saves all the images. It is located in the recorder belt, which is worn around your waist. The recorder will be removed at the end of the procedure for data processing. The camera Capsule is disposable and will be excreted naturally in your bowel movement.

Principle risks and complications of Capsule Endoscopy

Capsule Endoscopy is generally a low risk, non-invasive procedure. However, all of the below complications are possible. Your physician will discuss their frequency with you, if you desire, with particular reference to your own indications for capsule Endoscopy.

YOU MUST ASK YOUR PHYSICIAN IF YOU HAVE ANY UNANSWERED QUESTIONS ABOUT YOUR PROCEDURE.

Bowel obstruction: Passage of the camera capsule may cause obstruction in the gastrointestinal tract if there is a narrowing of the gastrointestinal tract or abdominal / pelvic adhesion. If it occurs, hospital admission and surgery may be required.

Bleeding: Bleeding, if it occurs, is usually a complication of long time usage of NSAIDs or blood thinner such as Advil, Indocin, Aspirin or Coumadin. The bleeding usually will stop instantly but if in some special or unknown condition, it may require transfusions, endoscopic cautery or possible surgery.

Abdominal Pain: Pain is uncommon following capsule Endoscopy. However, patient may feel abdominal pain during the passage of the capsule in some unusual GI anatomy.

Incomplete images collection / lost of images: Occasionally, some images may be lost due to radio interference (e.g. from amateur radio transmitter, MRI, etc.) or due to some variation in intestinal motility. In the condition of severe intestinal motility disorder, the battery life of the capsule may be expired before the completion of the test. The capsule may only image part of the small intestine / esophagus. This may result in the need to repeat the capsule procedure.

Other Risks: Include but are not limited to: allergic reactions to the camera Capsule and complications from other disease you may already have. Instrument failure and death are extremely rare, but remain remote possibilities.

YOU MUST INFORM YOUR PHYSICIAN OF ALL YOUR ALLERGIC TENDENCIES AND MEDICAL PROBLEMS.

Alternatives to Gastrointestinal Endoscopy

Although Capsule Endoscopy is an extremely safe and effective means of examining the small intestinal tract, no test is 100% accurate in diagnosis. In a small percentage of cases, a failure of diagnosis or a miss-diagnosis may result. Other diagnostic procedures, such as x-ray, conventional Endoscopy and surgery are available. Another option is to choose no diagnostic studies. Your physician will be happy to discuss these options with you.

Diagnostic Procedures

CAPSULE ENDOSCOPY FOR SMALL BOWEL: A diagnostic endoscopic exam of the small intestine

CAPSULE ENDOSCOPY (ESO ENDOSCOPY) FOR ESOPHAGUS: A diagnostic endoscopic exam of the esophagus.

MRI Examination: I am aware that I should avoid MRI machines during the procedure and until I pass the capsule in my stool following the exam.

GREENBELT ENDOSCOPY CENTER

FOR SMALL BOWEL CAPSULE ENDOSCOPY ONLY:

DATA RECORDER AND EQUIPMENT: I agree that I will not disconnect the equipment or remove the belt at any time during the examination period. I shall treat the equipment with utmost care and protection.

PHYSICAL ACTIVITY: I agree to avoid any strenuous physical activity especially if it involves sweating and I also agree not to bend over or stoop during the procedure.

RETURN THE EQUIPMENT: I agree to return the entire Capsule Endoscopy equipment to the Greenbelt Endoscopy Center the day after the procedure before 10:00am. In the event there is a delay in returning the equipment or the equipment is lost, Greenbelt Endoscopy Center reserves the right to withhold the equipment retaining fee and collect from the patient for the lost of equipment as per current market value. (For small bowel capsule only)

I certify that I understand the information regarding these procedures and that I have been fully informed of the risks and possible complication thereof. I understand that images and data obtained from my Capsule Endoscopy may be used, under complete confidentiality, for education purpose in future medical studies.

I hereby authorize and permit the following physician and/or his assistant (s) to perform upon me the procedure listed below. I am aware that the practice of medicine and surgery is not an exact science, and I acknowledge that no guarantees have been made to me concerning the results of the procedure.

Procedure (s)

MD and his assistant (s) to perform the procedure

Patient signature

Print name here

Signature of Witness

Signature of physician

Date