



INFORMED CONSENT- CAPSULE ENDOSCOPY

PATIENT CONSENT TO MEDICAL TREATMENT OR SURGICAL PROCEDURE AND ACKNOWLEDGMENT OF RECEIPT OF MEDICAL INFORMATION

READ CAREFULLY BEFORE SIGNING

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.

I, for myself or on behalf of the patient, consent to the gastrointestinal endoscopic procedure of: Capsule Endoscopy by the providers of Miss Lou GI as well as assistants as may be designated by those providers.

EXPLANATION OF PROCEDURE

Capsule Endoscopy is a video examination of the small intestine. You will swallow a pill the size of a vitamin which will transmit images to a recording device as it travels through your intestinal tract spontaneously and will be passed later in a bowel movement. 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.

RISK AND COMPLICATIONS

Examination of the small intestine with capsule endoscopy is generally safe. Complications are uncommon. Risk 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 risk of bleeding, infection, prolonged hospitalization and even death. An abdominal x-ray may be ordered in the weeks after the procedure if the provider is not able to determine that 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 provider.
- There is an extremely rare 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 provider 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 or do other testing.
- 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 MRI study, notify the ordering provider that you have recently had a 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.



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ALTERNATIVE PROCEDURES

Push enteroscopy cannot view the entire small bowel. Balloon enteroscopy, which can sometimes view the entire small bowel using a specialized, small bowel scope, is an alternative to examination of the small bowel, but cannot always view the entire small bowel, as in 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 provider at Miss Lou GI before proceeding with the capsule examination.

ACKNOWLEDGMENTS

- A. No Guarantees: All information given to me and, in particular, all estimates made as the likelihood of occurrence of risk of the or alternate procedures or as to the prospects of success, are made in the best professional judgment of my provider. The possibility and nature of complications cannot always be accurately anticipated and, therefore, there is and can be no guarantee, either expressed or implied, as to the success or the results of the medical treatment or surgical procedure.
- B. Additional Information: Nothing has been said to me, no information has been given to me, and I have not relied upon any information that is inconsistent with the information set forth in this document.
- C. Particular Concerns: I have had an opportunity to disclose to and discuss with the provider providing information, those risks or other potential consequences of the medical treatment or surgical procedure that are of particular concern to me.
- D. Questions: I have had an opportunity to ask, and I have asked, any questions I may have about the information in this document and any other questions I have about the proposed treatment or procedure, and all such questions were answered in a satisfactory manner.
- E. Authorized Provider: The provider authorized to administer or perform the medical treatment, surgical procedures or other therapy described in item 2 is:

PROVIDER CERTIFICATION

I hereby certify that I have provided and explained the information set forth herein, including any attachment, and answered all questions of the patient, or the patient's representative, concerning the medical treatment or surgical procedure, to the best of my knowledge and ability.

Printed Name of Provider: _____

Provider Signature: _____

Date: _____



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Consent

I hereby authorize and direct the designated authorized provider /group, together with associates and assistants of his choice, to administer or perform the medical treatment or surgical procedure described in item 2 of this Consent Form, including any additional procedures or services as they may deem necessary or reasonable, including the administration of any general or regional anesthetic agent, x-ray or other radiological services, laboratory services, and the disposal of any tissue removed during a diagnostic or surgical procedure, and I hereby consent thereto.

I have read and understand all information set forth in this document and all appropriate blanks were filled in prior to my signing. This authorization for and consent to medical treatment or surgical procedure is and shall remain valid until revoked.

I acknowledge that I have had the opportunity to ask any questions, about the contemplated medical procedure or surgical procedure described in item 2 of this consent form, including risks and alternatives, and acknowledge that my questions have been answered to my satisfaction.

Printed Name of Patient or Authorized Representative: _____

Relationship to Patient: _____

Patient or Authorized Representative's Signature: _____ Date: _____

Witness Signature: _____ Date: _____