



CONSENT FOR CAPSULE ENDOSCOPY

It is very important that you understand and consent to the treatment your doctor or licensed healthcare provider may order or perform. You should be involved in all decisions concerning your healthcare. Sign this form only after you understand the procedure, the anticipated benefits, the risks, the alternatives, the risks associated with the alternatives and all of your questions have been answered.

About Capsule Endoscopy: Capsule endoscopy uses a video capsule that enable examination of the small intestine. A vitamin pill-sized video capsule is swallowed. The capsule has its own camera and light source. After swallowing the capsule, you are free to move about. While the video capsule travels through the body, it sends images to a data recorder worn on a waist belt. After sufficient time for the capsule to move through the system, the images captured are reviewed. Capsule endoscopy helps to determine the cause for recurrent or persistent symptoms, such as abdominal pain, diarrhea, bleeding, or anemia. In certain chronic gastrointestinal diseases, this test can also help to evaluate the extent to which the small intestine is involved or may be used to monitor the effects of therapy. The capsule endoscopy may be used to obtain motility data such as gastric or small bowel passage time. The capsule is disposable and passes naturally with a bowel movement.

The doctor or licensed healthcare provider has explained the benefits of the diagnostic test to me. However, I understand there is no certainty that I will achieve these benefits and no guarantee has been made to me regarding the outcome of the test.

Risks: The doctor or licensed healthcare provider has explained to me that there are risks and possible undesirable consequences associated with this procedure that may occur during the procedure or afterwards, ***including, but not limited to:***

<ul style="list-style-type: none">• Difficulty passing the capsule• Capsule may become lodged in the digestive tract• Bowel obstruction• Trouble swallowing• Chest or abdominal pain	<ul style="list-style-type: none">• Capsule failure• The capsule may miss polyps, growths or bowel disease• The capsule may not provide a complete study of the small bowel
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In the unlikely event that one or more of the above complications may occur, my healthcare providers will take appropriate and reasonable steps to help manage the clinical situation and be available to me and my family to address our concerns and questions.

Alternatives to the Procedure: The reasonable alternatives to the procedure, as well as the risks to the alternatives, have been explained to me. These alternatives ***include but are not limited to:*** esophagogastroduodenoscopy (EGD), small bowel follow-through, colonoscopy, or enteroscopy (examination by a doctor using an endoscope).

Risks to Alternatives: I understand the risks associated with the alternatives ***include, but are not limited to:*** bleeding, perforation, infection.

I consent to having images (photos/video recording) captured as part of this diagnostic test for use in my clinical care. I consent to the admittance of students or authorized equipment representatives to be present

at the time the diagnostic test is initiated for purposed of advancing medical education or obtaining important product information.

<u>Certification of Patient:</u>	<u>Certification of Physician:</u>
<p>By signing below, I certify that I have had an opportunity to ask the doctor all my questions concerning anticipated benefits, material risks, alternatives to this procedure, and risks of those alternatives, and all of my questions have been answered to my satisfaction.</p> <p>_____</p> <p>Patient Signature or Authorized Individual Date Time</p> <p>_____</p> <p>Printed Name of Authorized Individual</p> <p><u>Role of Authorized Individual:</u></p> <p><input type="checkbox"/> Parent <input type="checkbox"/> POA/Legal Guardian <input type="checkbox"/> Other: _____</p>	<p>I hereby certify that I have discussed with the individual granting consent, anticipated benefits, material risks, alternatives to this procedure and the risks associated with those alternatives.</p> <p>_____</p> <p>Signature of Physician</p> <p>_____</p> <p>Date Time</p>

The Patient/Authorized Representative has read this form or had it read to him/her.

The Patient/Authorized Representative states that he/she understands this information.

The Patient/Authorized Representative has no further questions.

Date Time Signature of Witness Printed Name of Witness

USE OF INTERPRETER OR SPECIAL ASSISTANCE: An interpreter or special assistance (indicated below) was used to assist the patient/authorized representative in understanding and completing this consent form.

<p><input type="checkbox"/> Language (specify): _____</p> <p><input type="checkbox"/> Sign Language</p> <p><input type="checkbox"/> Patient is sight impaired and the form was read to the Patient/Authorized Representative</p> <p><input type="checkbox"/> Other (specify): _____</p>	<p>_____</p> <p>Printed Name of Individual Providing Assistance</p> <p>_____</p> <p>Title or Relationship to Patient</p> <p>_____</p> <p>Signature Date</p>
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