



## INFORMED CONSENT FOR ESOPHAGOGASTRODUODENOSCOPY WITH BRAVO CAPSULE PLACEMENT

Direct visualization of the esophagus, stomach, and the beginning portion of the small intestine with lighted instruments is referred to as upper gastrointestinal endoscopy, esophagogastroduodenoscopy, or EGD. Your physician has advised you of your need to have this type of examination and placement of a BRAVO capsule during this procedure. The following information is presented to help you understand the reasons for and the possible risks of these procedures.

The BRAVO capsule is placed in your esophagus during the examination of your esophagus using an instrument especially designed for this purpose. You will be given detailed instructions on what you should do during the next 48 hours while the capsule information is being recorded. If you have any questions about your symptoms following your procedure, you should address these with your physician.

The BRAVO requires you to wear a recording device for a specified period of time. You will be instructed to return the recording device by a certain date (usually after 48 hours) so that your information can be reviewed by your physician. Failure to return this device will result in an incomplete diagnostic test and we will be obligated to charge you for the device the cost of which could exceed \$8,000.

### PRINCIPAL RISKS AND COMPLICATIONS

The frequency of complications with upper gastrointestinal endoscopy is exceedingly rare. Passage of the instrument may cause an injury to the esophageal wall, stomach, or small intestine with subsequent leakage of its contents into a body cavity. If this occurs, a major surgical procedure to close the hole and/or drain the region is usually required.

The potential complications associated with the BRAVO capsule include, but are not limited to, perforation, hemorrhage, aspiration, fever, infection, hypertension, respiratory arrest, and cardiac arrhythmia or arrest. Complications associated with the BRAVO capsule insertion include premature detachment of the capsule, failure of the capsule to slough off in a timely period, or discomfort associated with the capsule requiring endoscopic removal. Although extremely rare, the BRAVO recording device can fail to work correctly which may require a repeat exam.

**You are restricted from having an MRI (Magnetic Resonance Imaging) test for 60 days after the procedure.**

To provide comfort and relaxation during the procedure, medications which produce conscious sedation will be administered through an intravenous solution. Conscious sedation is a minimally decreased level of consciousness which allows the patient to retain the ability to breathe independently and to respond appropriately to touch and/or verbal commands.

**YOU MUST ASK YOUR PHYSICIAN IF YOU HAVE ANY QUESTIONS ABOUT YOUR TEST.**

### CONSENT

I understand the above information regarding gastrointestinal endoscopy with BRAVO capsule placement, and I have been fully informed of the risks and possible complications thereof; I hereby authorize and permit

and whomever he/she may designate as his/her assistants to perform upon me the following:

**Esophagogastroduodenoscopy with BRAVO capsule placement with Moderate Sedation (Conscious Sedation)**

I have received and read a copy of "What You Should Know about the BRAVO Capsule Placement".

I have read or have had read to me and understand the above information. I have crossed out and initialed any paragraphs above which do not pertain to me.

DATE: \_\_\_\_\_ TIME: \_\_\_\_\_

\_\_\_\_\_  
Signature by patient, parent, or legally authorized person

\_\_\_\_\_  
Signature of Interpreter (if applicable)

WITNESS: \_\_\_\_\_ PHYSICIAN: \_\_\_\_\_