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### **Informed Consent for Gastrointestinal (GI) Procedure**

I authorize Dr. \_\_\_\_\_ (the "Doctor") to perform the following procedure: **Esophagogastroduodenoscopy (EGD) with placement of Bravo® pH capsule and possible biopsy, Polypectomy, injection therapy, cautery and/or dilation of narrowed areas.**

The following information is presented to help you understand the reasons for and the possible risks of these procedures:

#### **Procedural Sedation**

**Moderate Sedation** involves the injection of an anesthetic agent to reduce or eliminate pain. It is often combined with a pain medication and or sedative to relax and calm the patient. Moderate sedation is a medically controlled state of depressed consciousness that:

1. Allows protective reflexes to be maintained.
2. Retains the patient's ability to maintain a patent airway independently and continuously.
3. Permits appropriate response by a patient to physical stimulation or verbal commands (i.e. "open your eyes")
4. Moderate sedation is not anesthesia.

**Propofol** is a very short acting **anesthetic agent** that is administered by your physician. Propofol causes you to fall into a deep sleep which is maintained throughout the procedure. After your procedure, you will awaken within a few minutes.

Desired effects include:

1. Cooperation
2. Relaxation
3. Minimal vital sign and oxygen saturation variation

Undesired effects include:

1. Unarousable sleep
2. Hypotension
3. Agitation, combativeness
4. Respiratory depression/apnea
5. Cardiac arrhythmia or arrest

#### **Explanation of Procedure:**

Direct visualization of the digestive tract with lighted instruments is referred to as gastrointestinal endoscopy. The Bravo pH monitoring capsule is positioned and attached to your esophagus after your endoscopy. This monitoring system records and analyzes your gastro esophageal acid to diagnose reflux disorders. Your physician has advised you to have this type of examination. The following information is presented to help you understand the reasons for and the possible risks of these procedures.

At the time of your examination, the lining of the digestive tract will be inspected thoroughly and possibly photographed. If an abnormality is seen or suspected, a small portion of tissue (biopsy) may be removed or the lining may be brushed. These samples are sent for laboratory study to determine if abnormal cells are present. Small growths (polyps), if seen, may be removed (polypectomy). The Bravo pH delivery system is inserted in your esophagus and the pH capsule is attached to the wall with high powered suction and a surgical pin.

#### **Principal Risks and Complications of Gastrointestinal Endoscopy:**

Gastrointestinal endoscopy is generally a low risk procedure. However, all of the complications listed below are possible. Your physician will discuss their frequency with you, if you desire, with particular reference to your own indications for gastrointestinal endoscopy. **YOU MUST ASK YOUR PHYSICIAN IF YOU HAVE ANY UNANSWERED QUESTIONS ABOUT YOUR TEST.**

- 1. PERFORATION:** Passage of the instrument may result in an injury to the gastrointestinal tract wall with possible leakage of gastrointestinal contents into the body cavity. If this occurs, surgery to close the leak and/or drain the region is usually required.
- 2. BLEEDING:** Bleeding, if it occurs, is usually a complication of biopsy, polypectomy or dilation. Management of this complication may consist only of careful observation, or may require blood transfusions or possibly a surgical operation. You must inform your doctor of any bleeding disorders or tendencies you may have.

**3. MEDICATION PHLEBITIS:** Medications used for sedation may irritate the vein in which they are injected. This causes a red, painful swelling of the vein and surrounding tissue. The area could become infected. Discomfort in the area may persist for several weeks to several months.

**4. OTHER RISKS:** Include drug reactions, aspiration, possible breakage of teeth or gum trauma and complications from other diseases you may already have. Cardiopulmonary arrest and death are extremely rare, but remain remote possibilities. You must inform your physician of all your allergic tendencies, present medications, health or dental problems. Although gastrointestinal endoscopy is an extremely safe and effective means of examining the gastrointestinal tract, it is not 100 percent accurate in diagnosis. In a small percentage of cases, a failure of diagnosis or a misdiagnosis may result. Other potential complications when using the Bravo System include, but not limited to: perforation, premature detachment, or misplacement of pH capsule, failure of capsule to attach, discomfort associated with the capsule, capsule aspiration, capsule retention, and bleeding. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur.

**5. CONTRAINDICATIONS:** Patients with pacemakers, implanted defibrillators, strictures, and other bleeding disorders. The Capsule contains a small magnet, and patients should not undergo an MRI study within 30 days of the Bravo pH test.

#### **Alternatives to Gastrointestinal Endoscopy**

Other diagnostic or therapeutic procedures such as medical treatment, x-ray and surgery are available. Another option is to choose no diagnostic studies and/or treatment. Your physician will be happy to discuss these issues with you.

#### **Brief Description of Endoscopic Procedure**

##### **EGD (Esophagogastroduodenoscopy)**

Your throat may be sprayed with a local anesthetic or you may be asked to gargle with a local anesthetic. After administering IV sedation, your physician passes a fiber optic instrument through the mouth and back of the throat to allow examination of the esophagus, stomach and duodenum. Biopsies, polypectomies, dilation, or coagulation by heat of an active bleeding site may be performed if indicated, though all are accompanied by a slightly greater risk of bleeding or perforation.

**ESOPHAGEAL DILATION:** After passage of the Endoscope, dilating tubes and or balloons are used to stretch any narrow areas of the esophagus.

**PYLORIC DILATION:** Dilation of the pyloric sphincter (opening from the stomach to the small intestine). After passage of the endoscope dilating balloons are placed through the pyloric sphincter to enlarge the opening.

Consent to the taking of any photographs. I certify that I understand the information regarding conscious sedation procedures. I have been fully informed of the risks and possible complication of my procedure. I hereby authorize and permit The Doctor and whomever he may designate as his assistant to perform upon me the above noted procedure(s).

**EMERGENCY CARE:** If an emergency should arise, calling for additional procedures, operations, or medications. I authorize my physician and his/her designees to do whatever they deem advisable in my best interest. I authorize transfer to a hospital for in-patient care (including anesthesia and blood transfusions), if warranted by my condition.

**ACKNOWLEDGEMENTS:** I acknowledge that I am not to drive a motor vehicle or drink alcohol or make any critical decisions before tomorrow. No guarantees or warranties have been made concerning the procedure. I can expect to receive individualized discharge instructions after the procedure. I have had an opportunity to discuss the issues noted above with my physician and to have my questions answered.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Patient or Guardian Signature

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Translator