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**SMART PILL WIRELESS MOTILITY CAPSULE
CONSENT FORM**

Smart Pill Wireless Motility Capsule Procedure is a test which utilizes an ingestible capsule device that allows your physician to monitor pH and pressure through your entire GI tract. Using these measurements, the physician can calculate regional transit times to evaluate your gastrointestinal motility.

I understand that there are risks associated with this examination, including BOWEL OBSTRUCTION (blockage). If such occurs I may experience abdominal pain or vomiting and I will contact my physician immediately. An obstruction may require immediate (emergency) surgery or removal by other means.

I understand that due to variations in a patient's intestinal motility, the capsule may only evaluate part of the GI tract. It is also possible that due to interference, some data may be lost. I understand and accept that the technology and the reading and interpretation of the data are not 100% accurate and pathology may not be identified or recognized by the technology or by the physician. Other potential risks, which I recognize and accept, include failure to diagnose, equipment failure, and inability to complete the procedure. I further acknowledge that every conceivable risk, complication and consequence, alternative, and benefit has not and cannot be explained, and that complications can occur even if all is performed correctly and appropriately by those involved in my care. No guarantees regarding the procedure or its outcome have been made.

I am aware that I should avoid MRI machines during the procedure and until the capsule passes following the exam.

I understand that images and data obtained from my SmartPill examination may be used for educational purposes and that my name will be removed.

My doctor or physician assistant has explained the procedure and its risks to me, along with alternatives methods for diagnosis and treatment, and I have been allowed to ask questions concerning the Smart Pill wireless motility capsule.

I understand that I am financially responsible for the Data Recorder.

I authorize the performance of the Smart Pill wireless motility capsule procedure and agree to proceed.

Name (print)

Signature

Date

Frequently Asked Questions:

1. How does SmartPill work?

First, you will be required to eat a small meal called the SmartBar. (The SmartBar is similar to a granola bar. It consists of rolled oats, puffed wheat, apple juice concentrate, wheat germ, dried apples and cranberries, and other ingredients.) You will then swallow the capsule and are free to leave the physician's office. As the capsule naturally travels through your GI tract, it collects pressure, pH and temperature data. A data receiver, worn for several days on a belt clip or lanyard around the neck, captures and stores the test data collected by the capsule.

2. Why is the SmartPill performed?

The test allows your physician to monitor pH and pressure through your entire GI tract. Using these measurements, the physician can calculate regional transit times to evaluate you for a motility disorder. Motility disorders are conditions that affect the movement of the GI tract and the contents within it. Transit time is the amount of time it takes to move contents through a specific portion of the GI tract.

3. How long will I be in the doctor's office?

An office visit of approximately 30 minutes is required. The test does not require a hospital visit and does not expose you to radiation. After capsule ingestion, you are able to go about your normal daily activities.

4. Is there any test preparation?

You will be required to fast 8 hours before the test. Your doctor may impose other restrictions as well such as taking you off certain medications prior to the procedure.

5. How long will it take to pass the capsule?

The single use, disposable capsule is usually passed within a few days.

6. What happens after I've passed the capsule?

The data receiver is returned to your doctor's office. Your doctor will download the test information to a computer and analyze the results.

Cautions:

The SmartPill capsule is single use only.

The SmartPill is not for use in children under the age of 18.

The patient must not have a Magnetic Resonance Imaging (MRI) until capsule passage is confirmed by physician review of the MotiliGI graph or KUB. An MRI test may result in damage to the GI tract.

The patient should seek medical attention if pain, nausea or vomiting occurs beyond his/her typical pattern. These symptoms could indicate capsule retention and GI tract obstruction.