**Intended Use**

The SmartPill GI Monitoring System measures whole gut and regional gut (stomach, small bowel, and colon) transit times. Measurements of gastrointestinal tract transit times are used for evaluating motility disorders.

Gastric transit time (gastric emptying time, GET) is indicated for the evaluation of patients with suspected gastroparesis. Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia.

Colonic transit time (CTT) is indicated for the evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation. Combined small and large bowel transit time (SLBTT) is used as a surrogate measure of colonic transit time in patients with chronic constipation when colonic transit time cannot be determined.

The system measures pH, pressure and temperature throughout the GI tract. Pressure contraction data from the antrum and duodenum can be used to calculate motility indices.

Not for use in pediatric populations.

Note: This brochure is not intended to replace physician consultation.

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**How does SmartPill work?**

First, you will be required to eat a small meal called the SmartBar. You 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.

**Why is the SmartPill Procedure 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.

**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.

**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.

**How long will it take to pass the capsule?**

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

**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.

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**Intended Use**

The SmartPill Corporation is a developer and manufacturer of ingestible, capsule-based medical devices, peripheral software and electronic components that aid in the diagnosis, definition and therapeutic intervention of gastrointestinal disorders and diseases.

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An exciting advancement in gastrointestinal testing

Do you experience gastrointestinal (GI) symptoms such as nausea, bloating, heartburn, constipation or an early feeling of fullness when eating? These are often symptoms of a motility disorder, such as gastroparesis and chronic constipation. If you suffer from these or other unexplained GI symptoms, your physician may determine the SmartPill Wireless Motility Capsule Procedure is right for you.

As the SmartPill capsule travels through your GI tract, it collects pressure, pH and temperature data. A data receiver worn on a belt or lanyard records the information collected by the capsule. After you return the data receiver to your physician, the data are downloaded to a computer providing your physician with GI transit information to evaluate your stomach, small bowel and colon.

How It Works

Day 1
The patient ingests the capsule in the physician’s office.

Day 1
While wearing the wireless data receiver, the patient leaves the physician’s office and resumes a normal schedule.

Day 1 - 5
The wireless data receiver is removed during bathing and sleeping.

Day 3 - 5
The patient returns the data receiver to the physician and the test data are downloaded in just minutes.

Consultation
The physician reviews the test results with the patient.

Physician Testimonials

“By using SmartPill we can identify which section of the GI tract is dysfunctional and can alter treatment to the specific abnormal site. In one patient’s case, SmartPill confirmed her GI motility was normal throughout her entire GI tract. We were able to take her off an unnecessary potentially adverse drug that she had been taking for years.”

- Steven Fern, D.O.
Specialists in Gastroenterology, St. Louis, MO

“SmartPill is a crucial test in evaluating patients with symptoms such as bloating, nausea, early satiety (fullness) and abdominal pain. The information gained through SmartPill has been instrumental in guiding therapy and has added to the care of my patients. 100% of my patients would choose to undergo the SmartPill procedure rather than be exposed to the x-rays associated with traditional gastric emptying testing.”

- Leonard Fischer, M.D.
Gastrointestinal Medicine Assoc., Fairfax, VA

Glossary

Motility Disorders: Conditions that affect the movement of the GI tract and the contents within it.

Transit Time: The amount of time it takes to move contents through a specific portion of the GI tract.

Gastroparesis: A disorder in which the contents of the stomach empty too slowly. Also called delayed gastric emptying.

Chronic Constipation: A disorder characterized by a recurrent complex of symptoms including slow, difficult or painful bowel movements.