

BRAVO[®]

pH Monitoring System

A patient-friendly test for heartburn.



Medtronic

Bravo[®] pH Monitoring System

Why Test for Heartburn?

Do you have a great deal of indigestion or a burning sensation in the center of your chest? Do you regularly get sour or bitter-tasting fluids in your throat or mouth? Do you need help sitting up when you're lying down, or avoid bending over to prevent acid from backing up into your throat?

If you can answer "yes" to any of these questions, you might have chronic heartburn or GERD (gastroesophageal reflux disease). Now, there is a minimally invasive test for heartburn—it's called the Bravo pH Monitoring System. Your doctor will analyze results from this test to determine what is causing your symptoms and the best treatment to prescribe for you.

What is Heartburn?

Heartburn usually begins as a burning feeling in the center of your chest. Often, there is a sensation of food or fluid coming back into your throat and mouth that typically tastes sour or bitter. The burning sensation can last for hours and is often worse after eating. Many people occasionally experience heartburn, but heartburn can be a symptom of a more serious condition, GERD.



Heartburn occurs when contents from the stomach flow back up into the esophagus.

Bravo[®] pH Monitoring System



Bravo is the world's first catheter-free pH monitoring system that allows patients to maintain their regular diet and activities without the embarrassment and discomfort associated with traditional pH catheter systems.

What is GERD?

Frequent or chronic heartburn (more than twice per week) may be associated with a more serious problem known as GERD. The heartburn may be so severe that it interferes with your daily routine.

Damage caused by GERD can lead to more serious medical problems such as difficulty in swallowing (dysphagia), narrowing of the esophagus (strictures), or Barrett's Esophagus.

How are Heartburn and GERD Diagnosed?

The traditional way to measure pH levels in the esophagus is to place a catheter, which is connected to a monitoring device on the patient's belt, down the nose and into the esophagus. Many patients complain of nasal discomfort and are embarrassed to go out with the catheter in their nose. Bravo is a more patient-friendly pH test for determining heartburn and GERD. This test allows your doctor to evaluate your heartburn symptoms to determine the frequency and duration of acid refluxing into your esophagus. Your doctor uses the pH data from the Bravo Receiver and clinical evidence to confirm your condition.

How the Bravo System Works

The test involves a miniature pH capsule, approximately the size of a gelcap that is attached to your esophagus.

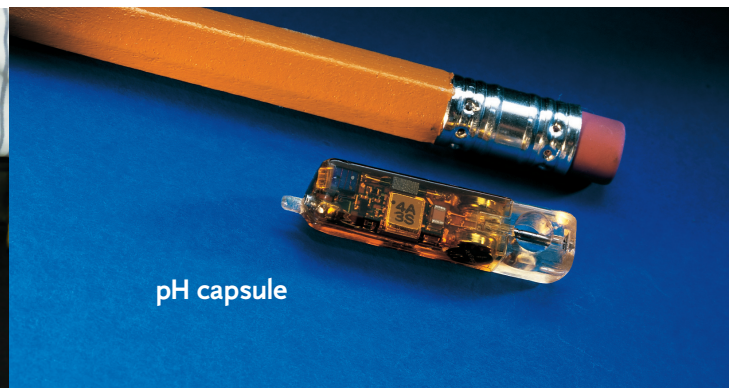
Throughout the test period, the Bravo pH capsule measures the pH in the esophagus and transmits this information to a pager-sized receiver worn on your belt or waistband just like a pager or mobile phone. You will be given a diary to write down the times when you have reflux symptoms (for example, coughing, heartburn, regurgitation), when eating or when lying down.

After the test is completed, you return the diary and the Bravo Receiver to your doctor. The test data is then uploaded to a computer, and analyzed by your doctor to diagnose your condition.

Receiver worn on waistband

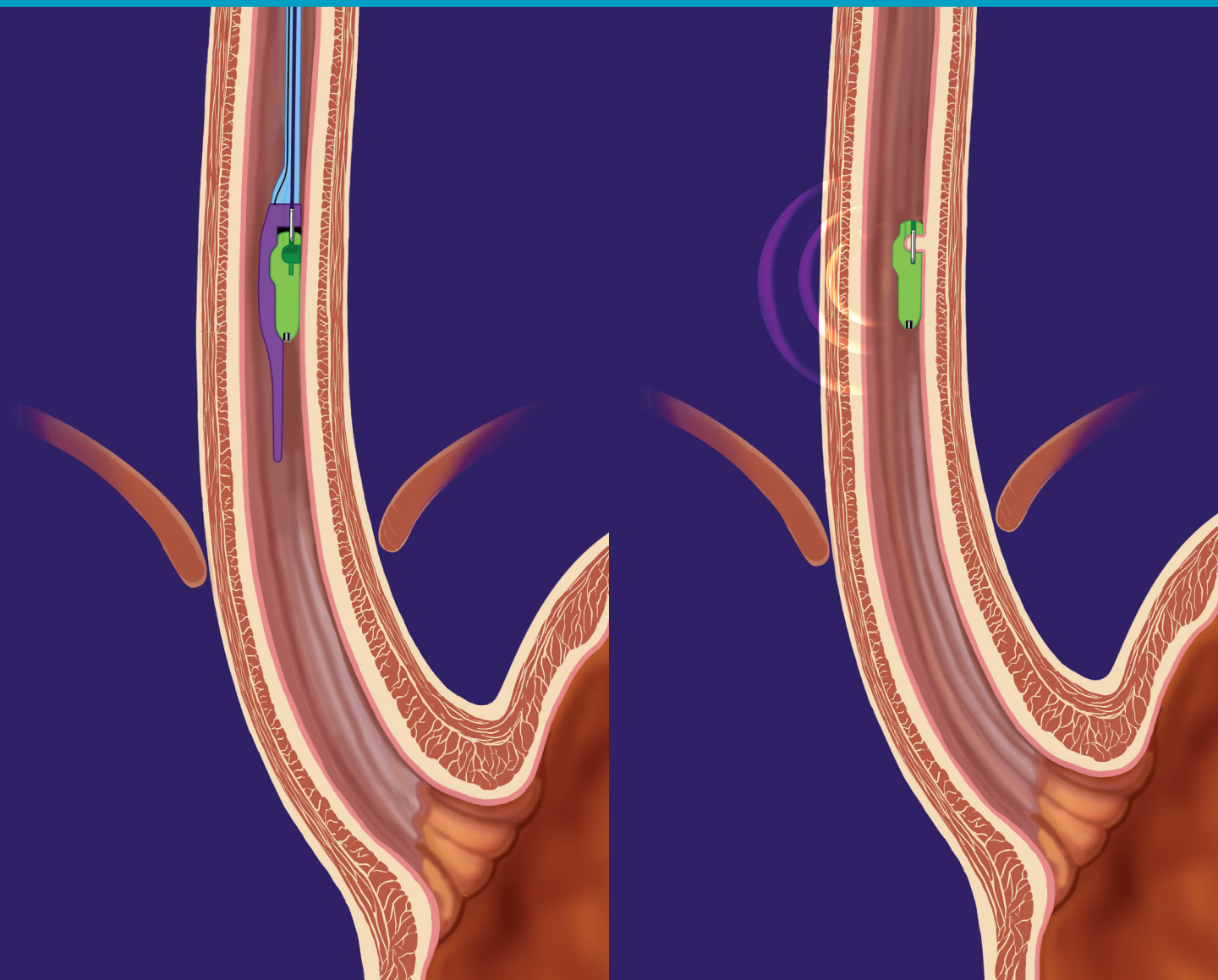


Receiver



pH capsule

How the Bravo[®] capsule is attached



Positioning the capsule
in the esophagus

Recording pH and transmitting
data to the Receiver

Frequently Asked Questions

What are the benefits of the Bravo pH Monitoring System?

The Bravo pH system provides convenience. Data is recorded when the capsule and receiver are within three feet of each other. You can bathe and get a restful night's sleep because you can place the receiver outside the shower or on your nightstand and the test will not be interrupted.

How long does the test take?

The capsule takes only moments to place in the esophagus. Then, the test period lasts either 24 or 48 hours, depending on what your doctor requests.

Will the test restrict my diet and activities?

The test is catheter-free and the capsule is small so you may eat normally and go about your daily routine.

What happens when the Bravo test is complete?

After the test is completed, you return the diary and the Bravo Receiver to your doctor. The test data is uploaded to a computer and analyzed by your doctor.

What happens to the capsule after the test?

Several days after the test, the capsule naturally falls off the wall of the esophagus and passes through your digestive tract.

Can I have an MRI (Magnetic Resonance Imaging) during the test?

Patients are restricted from undergoing an MRI study within 30 days of the Bravo procedure.

Will I feel the capsule during the test?

Some patients say they have a vague sensation that "something" is in their esophagus. Some patients say they feel the capsule when they eat or when food passes the capsule. Should you experience this, chewing food carefully and drinking liquids may minimize this sensation.

Is Bravo pH Monitoring for everyone?

Unfortunately, it is not for everyone. Patients with pacemakers or implantable defibrillators cannot use Bravo pH Monitoring. Patients with a history of bleeding diatheses, strictures, severe esophagitis, varices, and obstructions are not candidates for Bravo.

Please ask your doctor or nurse any other questions you have about Bravo pH Monitoring. Visit us at: www.bravophtesting.com.

REMOVE THIS CARD AND CARRY IT WITH YOU.

No MRI for 30 days, please!

I am restricted from having an MRI study within 30 days of the **Bravo pH Monitoring System** capsule placement procedure.

I cannot have an MRI until _____
DATE

Any questions, please call: _____

at: _____

Warnings/Precautions

Indications for use: The Bravo pH Monitoring System with Accessories is intended to be used for gastroesophageal pH measurement and monitoring of gastric reflux. The pH capsule can be delivered and placed endoscopically or with standard manometric procedures. The pH Software Analysis Program is intended to record, store, view and analyze gastroesophageal pH data. Potential complications associated with gastrointestinal endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, hypertension, respiratory arrest, cardiac arrhythmia, or arrest. Potential complications associated with nasal intubation include, but are not limited to: sore throat discomfort and nasopharyngeal damage resulting in bleeding and soft tissue damage. Potential complication associated with the Bravo pH capsule includes failure of the pH capsule to detach from esophagus within several days after placement, which may necessitate endoscopic removal. The safety and efficacy of the Bravo pH capsule with delivery system has not been established for pediatric use. Prior to the pH study, the patient should be NPO (not eating or drinking) a minimum of 6 hours.

Note: Reference product directions for use including indications, contraindications, warnings and precautions.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

World Headquarters

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
www.medtronic.com
Tel. 763-505-5000
Fax 763-505-1000
Toll-free 1-800-227-3191

UC200301933d EN NI5519d
© Medtronic, Inc. 2008
All Rights Reserved
Printed in USA



Medtronic

Alleviating Pain • Restoring Health • Extending Life

OTHER INSTRUCTIONS FROM MY DOCTOR OR NURSE:
