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Suffering from **Reflux or Heartburn?**



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No more pills
No more pain
Get back to living

.....



A new
*Incisionless
Surgical*
procedure is
now available!

.....



EsophyX™ *Getting it right*

GastroEsophageal Reflux Disease (GERD) & Heartburn

If you suffer from heartburn you are not alone. One in four people in Western countries suffer from heartburn at least once per month, experience the burning and pain at least once per week, and more than suffer on a daily basis.

If you have heartburn twice a week or more you may have GastroEsophageal Reflux Disease, also known as GERD. Heartburn is the most common symptom associated with GERD but you may also experience:

- inflammation and/or ulceration of the esophagus
- hoarseness or sore throat
- excessive clearing of the throat
- frequent swallowing
- persistent cough
- asthma or asthma-like symptoms
- burning in the mouth or throat
- pain or discomfort in the chest
- intolerance to certain foods
- yellow fluid or stains on your pillow after sleep
- dental erosions or therapy-resistant gum disease or inflammation

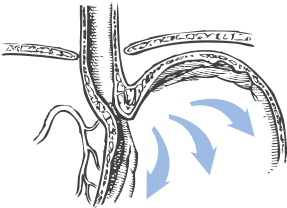
While medication alleviates the symptoms, it does not restore the natural anatomy and generally doesn't stop disease progression. Overtime you may need to increase your dosage and, like many GERD sufferers, it may mean taking medication for the rest of your life. If your symptoms are severe, surgery is an option but is rather invasive and carries significant risks.

If you do not want a life long regimen of medication or do not want to undergo an invasive surgical procedure, a transoral incisionless option is available that addresses both the cause and symptoms of GERD.

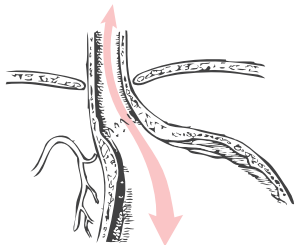
Moayyedi, P. *Lancet*, June 24, 2006; vol 367; pp 2086-2100. News release, The Lancet

What is GERD?

Normally, after swallowing, a valve between the esophagus and stomach opens to allow food to pass and then closes to prevent stomach contents from refluxing into the esophagus. The angle at which the esophagus enters the stomach creates a long flap of tissue that functions as a one-way gastroesophageal valve, or GE valve, and is now believed to be the primary component of the antireflux barrier. For many people who suffer from GERD the valve is compromised, or no longer intact, and is unable to prevent acid from refluxing into the esophagus. A hiatal hernia, where part of the stomach moves up above the diaphragm, may also be present and may contribute to the loss of functionality of the valve.



Normal Anatomy: GE Valve intact



GERD: Funnel-shaped GE Valve

Other factors that may contribute to GERD symptoms include:

- excessive weight
- smoking
- eating fast
- eating large meals
- eating late at night
- pregnancy

In addition, consuming certain foods and drinks may contribute to an increase in GERD symptoms:

- citrus fruits juices
- chocolate
- caffeinated carbonated drinks
- tomato-based foods sauces
- spicy foods
- fatty fried foods
- garlic onions
- food items teas containing mint
- alcoholic beverages

What are the consequences of GERD?

In people who suffer from GERD, a weakened or absent GE valve allows acidic stomach contents to reflux back into the esophagus. The inner lining of the esophagus is not designed to handle persistent, long term exposure to stomach acid and, over time, can damage it. This can result in chronic inflammation or esophagitis, which can lead to Barrett's Esophagus.

In some cases, GERD sufferers may experience complications associated with extra-esophageal reflux, where stomach acid spills into the larynx, lungs, mouth or nose. Symptoms include sore throat, cough, laryngitis, dental erosions, discomfort in the ears and nose, and asthma-like symptoms caused by the aspiration of stomach contents into the lungs. These symptoms are typically not resolved through drug treatment alone and requires anatomical repair to prevent reoccurrence and disease progression.

In severe cases, Barrett's Esophagus can be a potentially life threatening complication of GERD. Once manifested, Barrett's Esophagus can cause malignant degeneration increasing the risk of progression to esophageal adenocarcinoma to times.

2. Practice guidelines on the diagnosis, surveillance, and therapy of Barrett's Esophagus. Sampliner R., Am J Gastroenterol 1998; 93: 1028-1032

Do you have GERD?

Do you have heartburn more than once per week?

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Do certain foods or drinks, exercise, or stress give you heartburn?

-

Do you need to sleep with your head elevated (ie. with several pillows) to prevent nighttime reflux?

-

Is there fluid on your pillow after sleep?

-

Do you frequently have a sour or bitter taste in your mouth especially after sleep?

-

Do you salivate more than you used to?

-

Is it difficult or painful to swallow when you have heartburn?

-

Do you experience asthma-like symptoms especially at night?

-

Do you frequently have sore throat or hoarseness?

-

Do you take non-prescription or prescription medication for heartburn?

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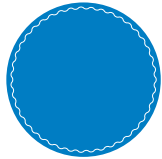
Do you often have pain or discomfort in your chest but are not having a heart attack?

-

Do you sometimes feel food or drink coming up from your stomach into your esophagus?

-

If you answered *yes* to any of these questions, please continue. Then talk to your doctor about your options.



Tests your doctor may perform

Upper GI Endoscopy

A flexible tube with a light on the end, or endoscope, is passed into the esophagus and on to the stomach. This allows your doctor to view the lining of your esophagus & stomach and assess the condition of your valve & antireflux barrier. The doctor may also take one or more biopsies if required.

Barium Swallow Radiograph

After drinking a barium liquid contrast that coats the esophagus & stomach, x-rays are taken so your doctor can see the path that food takes as it passes through the esophagus & stomach. This allows your physician to see reflux as it happens as well as determine if there is narrowing of the esophagus (stricture), ulcers, hiatal hernia, or other indicators of upper gastrointestinal disease.

Esophageal Manometry

A tube is passed into the esophagus to measure how well the esophagus can move food into the stomach and to assess the length and degree of failure of your valve & antireflux barrier.

pH Monitoring

Your doctor may perform this test by implanting a small capsule in the tissue of your esophagus. The capsule transmits data to a small receiver you wear on your waist. Another method involves passing a thin catheter with a monitoring device through your nose into the throat and on to the end of your esophagus. Both methods monitor your pH levels for 24 hours while you continue with your normal daily activities, including eating and drinking.



What can you do about it?

In addition to dietary controls, you and your doctor have options including medications, surgical options, and an incisionless endoluminal solution.

MEDICATIONS:

Non-prescription antacids

Intended to neutralize stomach acid, antacids are usually taken as needed to relieve heartburn symptoms. They are short acting, and are usually used for infrequent or occasional heartburn.

PPIs (proton pump inhibitors)

PPIs are designed to reduce the production of acid in the stomach. While effective for some people, PPIs must be taken daily for patients with frequent symptoms, and usually require an increase in dosage over time.

H₂ blockers

H₂ blockers are designed to treat acid production by blocking histamine, which encourages acid secretion in the stomach. They take longer than antacids to be effective and provide relief for some patients.



Surgical Options

Few people have turned to surgery as a solution to GERD despite the fact that surgical fundoplication procedures, such as Nissen, have long been known to be an effective long term solution. Both open and laparoscopic fundoplication procedures carry significant risk because surgical fundoplication involves:

LAPAROSCOPIC FUNDOPLICATION

*Cutting
of the
Skin*

Cutting of skin and tissue and insertion of - trocars through the abdomen to gain access to the operative site.

*Changes
the natural
anatomy*

Cutting of the blood vessels supplying the top of the stomach and wrapping the stomach around the esophagus.

Revision

Because the procedure is invasive, scar tissue forms on the operative site, making redo or revision difficult.

Infection

Risk of wound infection.

During fundoplication surgery, hiatal hernia, if present, is reduced and the upper portion of the stomach, or fundus, is severed from its attachments. The fundus is then wrapped around the esophagus, reinstating the valve. Complications may include difficulty swallowing, gastric pain, gas bloating, abdominal cramping and the inability to vent air from the stomach (belch).

No pills, no pain. Get your life back.

The EsophyX TIF™ Procedure

Medical therapies and basic changes in diet can help reduce symptoms, but the only way to fix the underlying problem that causes GERD is through proven surgical principles. EsophyX™ offers a giant leap in the evolution of treatment of GERD and focuses on restoring the natural anatomy of the antireflux barrier.

The key difference from conventional open and laparoscopic surgical procedures is that EsophyX™ is a transoral incisionless procedure. It is introduced into the body through the mouth, not through an incision.

Benefits of EsophyX™:

- **No external skin incisions—No scarring**
- **No internal cutting or dissecting of the natural anatomy**
- **Fewer adverse events and complications**
- **Does not limit future treatment options**

EsophyX™ lowers the hurdle for having surgery because it is safer and less invasive. The TIF™ (Transoral Incisionless Fundoplication) procedure expands the group of patients that can benefit from an anatomical repair, reducing or eliminating the need for life-long PPI medication.

Live life on your terms!



Eat or drink the foods you want when you want.



Sleep the way you desire.



Rapid recovery – back to work and life.

Do you limit foods you can eat, alcohol, caffeine, chocolate, citrus, or carbonated beverages due to reflux?

Do you suffer from nighttime symptoms?

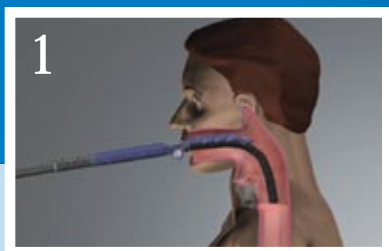
Does reflux require you to manage how late at night you eat, how large your meals are, how soon you can exercise after eating, or when you take medication?

Well, in recent studies of EsophyX™, patients reported improvement in quality of life, significantly improved satisfaction, and reduction/elimination of heartburn symptoms. All patients discontinued medication after the EsophyX™ procedure and were still completely off daily medication and symptom free one year after the procedure.

Clearly, EsophyX™ is the the best alternative for treating GERD. It provides an anatomical restoration and addresses the underlying cause of reflux, getting you back to living your life.

How EsophyX TIF™ works

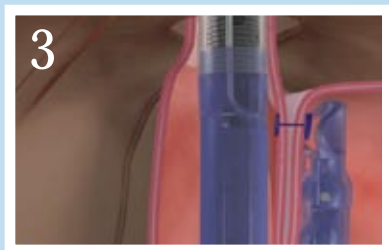
The device and endoscope are inserted through the mouth.



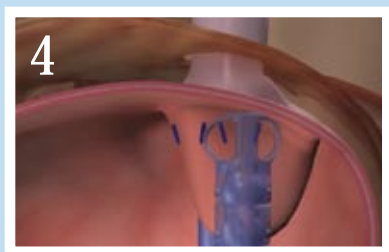
Hiatal hernia is reduced.



The device pulls and fastens a tissue fold.



Step 3 is repeated multiple times until the valve is reconstructed.



Talk to your doctor about your symptoms and your options today.

On the day of your visit, remember to bring with you the GERD test on page 9 so that your physician can better understand your condition.

A directory of trained EsophyX TIF™ physicians is located at www.endogastricsolutions.com/directory.

EsophyX™ is FDA cleared, CE marked, and available in the USA and European Union.

www.endogastricsolutions.com



Manufactured by

EndoGastric Solutions™

Ave NE | Redmond, WA, USA

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