

# ACADIANA GASTROENTEROLOGY ASSOCIATES, LLC.

*The Center for Digestive Care*

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## STRETTA PROCEDURE INFORMATION

### What is GERD?

Gastroesophageal reflux disease (GERD) is a common chronic digestive disorder. It causes stomach acid and sometimes stomach content to back up into the throat. This is called acid reflux, and over time it can damage the lining of the esophagus. Heartburn is also a common symptom of people with GERD.

Most people experience acid reflux and heartburn from time to time, especially after eating a spicy or heavy meal. GERD is diagnosed when these symptoms occur at least twice a week or are severe enough to interfere with your daily life.

Other common symptoms of GERD include:

- Sour taste in the mouth
- Chest pain
- Problems swallowing
- Dry cough
- Sore throat
- Hoarseness when speaking
- Feeling a lump in your throat

Acid reflux back up into the throat due to problems with the muscular sphincter in the esophagus where it joins the stomach. These muscles are tight most of the time, but relax when you swallow. This created an opening that allows food and liquids to enter the stomach. Then the muscles tighten and close again until the next time you swallow.

It's when these muscles weaken or relax abnormally that acid reflux can occur.

Common treatments for GERD include antacids and other medication, lifestyle changes, and surgery. Another option is the STRETTA procedure. It's a minimally invasive, non-surgical treatment that only takes about an hour to perform most often in an outpatient setting and allows most people to return to their everyday activities within a day.

Most people with GERD have damage to the sphincter muscle at the end of the esophageal muscular tube that connects the throat to the stomach. The STRETTA procedure helps strengthen these muscles. This results in better muscle control and the fewer acid reflux episodes.

The STRETTA procedure is an advanced state-of-the-art endoscopic technique for the correction of Gastro Esophageal Reflux Disease (GERD) performed by Acadiana Gastroenterology's GI Physicians.

The STETTA catheter is a specially designed, FDA approved device with a balloon and four small short needles. The catheter is connected to a control module, which delivers precisely monitored and controlled amounts of radio-frequency energy to the lower esophageal sphincter muscle or LES.

The entire procedure consists of two parts. Initially, an upper endoscopy of EGD is performed while the patient is sedated. This allows the physician to take the precise measurements of the distance from the mouth to the LES or sphincter muscle between the esophagus and stomach. After measuring the distance, the physician will then insert the STRETТА catheter, through the mouth, to the specifically measured distance. The balloon is then inflated, the needles pushed into the muscle of the sphincter, and radio-frequency energy is transmitted via the needles.

### **The cause of GERD**

GERD, or reflux disease, has been shown to be caused by too many relaxations of the LES. These relaxations are known as transient lower esophageal relaxations or TLESR's. Normally, these relaxations only occur 2-3 times per hour. In patients with GERD, the transient relaxations may occur dozens of times in an hour, allowing the stomach contents to vent up into the esophagus or throat. The associated symptoms may be chest burning or pain, sore throat, chronic cough; hoarseness, choking, difficulty swallowing, bloating, or fullness after meals.

There is mounting evidence that the abnormal number of TLESR's and therefore GERD, is due to excessive nerve impulses to the LES muscle, causing it to relax too often.

### **How the STRETТА procedure correct GERD**

When the STRETТА procedure is performed, radio-frequency energy is transmitted via the small needles in the STRETТА catheter. This creates pinpoint areas of the heat in the sphincter muscle, which in turn deactivates a percentage of the nerve tissue.

There are two predominant effects, which then occur. The first effect is largely temporary and can be thought of as the *barrier effect*. There is an immediate swelling or edema of the tissue, which is followed by the body depositing a substance called collagen into the sphincter muscle. The thickened area helps to immediately reduce the reflux of stomach contents into the esophagus. While this effect last for a period of time, eventually the swelling or edema will disappear within the first several days; however, much later most of the collagen is removed by the body, and some tissue thickening appears to remain. The reabsorption of the collagen usually takes 2-3 weeks.

The second or more permanent effect is known as the *neurolysis effect*. This refers to the actual deactivation of the nerves responsible for the cause of the disease. Medical research has clearly demonstrated that as the result of the nerve deactivation, the number of TLESR's is significantly reduced and symptoms usually completely disappear.

### **Medical evidence of effectiveness**

In the past 10 years, many studies have been conducted with the STRETТА procedure in human subjects. The data reveals that, following the STETTA procedure, TLESR's and the symptoms of GERD or heartburn are significantly reduced or eliminated. The procedure is successful for majority of patients. Currently, the longest results show that in patient 10-11 years after STRETТА, there is usually no significant return of symptoms, and the majority of patients remain either off of medication or on reduced doses. The procedure

has also been demonstrated to reverse the problem of bloating and fullness, caused by delayed stomach emptying, associated with reflux disease in one third of patients with GERD

### **What to expect after the STRETTA procedure?**

Immediately after the procedure, due to sedation, you may expect to feel very tired for the remainder of the day. Some patients have a sore throat or mild soreness in the chest area. You will be able to with some mild dietary restrictions and resume your normal medications immediately after the procedure. When eating you may experience a sensation of the food moving slowly down into your stomach.

You must continue your acid controlling medications, until instructed otherwise, by your physician for at least an additional 4-8 weeks.

Your reflux symptoms are *not* expected to improve immediately. The STRETTA procedure is a long-term correction for reflux or heartburn. The effects usually develop slowly over time. It is very important that you *do not expect immediate results*. It may sometimes take as long as 8-12 months before the final improvements take place.

### **Dos and Don'ts**

1. Do *not* eat any food with hard or sharp edges for 4-5 days, such as chips, pretzels, nuts or bones. Chew your food well, and do not eat rapidly.
2. Do resume normal activities as tolerated, including exercise, the day following the STRETTA procedure.
3. Do *not* forget to take your acid lowering medication, such as Prilosec, Prevacid, Protonix, Aciphex, Dexilant, Zantac, Prevacid or Nexium, for at least the first month after your procedure. If you are not taking these medications, you must immediately tell your doctor.
4. Do call your doctor immediately if you experience any of the following:
  - Severe chest or abdominal pain
  - Nausea or vomiting
  - Fever or chills
  - Vomiting of blood or coffee ground appearing material
  - Bloody or black tarry looking bowel movements
  - Difficulty swallowing
  - Difficulty breathing
5. Do carry your STRETTA information card with you at all times for the first month after your procedure. If you are hospitalized or visit the ER, do not allow any tubes or instruments to be introduced into your esophagus, unless the doctor who performed your STRETTA procedure is first notified.

### **Side Effects**

The main side effect experienced after a STRETTA procedure is chest discomfort or pain. The discomfort ranges from a mild sensation of pressure or aching to intense pain. Up to 15% of patients experience chest discomfort and only 1-2% have severe pain. Your physician will supply you with detailed instructions on what medications to take for the pain and a prescription for a strong pain medication. The pain will normally only last 1-5 days, but rarely up to 1-2 weeks. If you have any questions at all contact your physician.

Another problem, which occurs in only 2-3% of patients, is bloating, or increased belching or passes excess gas rectally. This may occur for 1-3 days or up to 2 weeks after the procedure. It usually requires no treatment

and will stop spontaneously. Some people report relief with either antacids or anti-gas medication like Phazyme.

### **How fast will I get better?**

This is both the most frequent and most important question. It is very important to not expect an immediate or instant improvement after the procedure. It takes at least 2 weeks for the tissue to heal, which is when a few patients may begin to experience some initial relief from their symptoms.

Everyone is different in their ability to heal and develop scar tissue. It is only when the tissue heals and the nerve tissue is deactivated, that the reflux begins to improve. This process may take as long as 8-12 months to occur, but for many it occurs by 3-5 months.

Do not set unrealistic expectations for when you will feel better. Otherwise you will be unnecessarily disappointed. The recovery and healing process is best described as “slow and steady wins the race.” Look for small weekly improvements to occur over time. Also, be aware that occasionally, despite an initial rapid improvement, you may experience a return of your symptoms of heartburn and reflux. This usually occurs when there is a reduction or disappearance of the *barrier effect* of the procedure prior to the full onset of the *neurolysis effect*.

This period, known as a **lag phase**, which typically is seen 3 to 8 weeks after the procedure, is only a temporary setback, which responds to the reintroduction of medication. If this lag phase or recurrence of symptoms occurs, it will usually pass in several weeks and continued improvement will resume. Only 25% of patients will experience the **lag phase**.

Once your heartburn and reflux symptoms begin to improve, your physician will start to decrease and eventually discontinue your medications.

### **Summary**

The STRETTA procedure is an effective and safe means of correction for the symptoms of heartburn and reflux. It is the only therapy available that was developed specifically to treat the underlying root cause of heartburn and reflux, known as transient lower esophageal sphincter relaxations. This is accomplished by administering radiofrequency energy, during a simple endoscopic procedure, which allows rapid recovery, without surgery. The results of the 10-year data after the procedure clearly demonstrate continued effectiveness, in those patients who initially responded to treatment.