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PATIENT COUNSELING FORM Stretta Procedure

ENDOSCOPICALLY GUIDED DELIVERY OF RADIO-FREQUENCY ENERGY TO THE GASTRO-ESOPHAGEAL JUNCTION FOR THE TREATMENT OF GASTRO-ESOPHAGEAL REFLUX DISEASE

What is GERD?

Normally, swallowed food and liquids pass through a valve or sphincter located at the connection between the esophagus and stomach. This valve is called the lower esophageal sphincter, or LES. The LES prevents the backward flow or reflux of stomach contents into the throat. The stomach produces powerful acids and digestive juices to digest food, so proper function of the LES is essential. In Gastro-Esophageal Reflux Disease or GERD, the acid and digestive juices flow backward into the esophagus.

The most common symptom of GERD is heartburn. Other symptoms may include difficulty in swallowing, sore throat, hoarse voice, and cough or asthma.

Untreated GERD may result in serious complications such as injury to the esophagus, pre-cancerous changes in the esophagus, cancer of the esophagus, narrowing of the esophagus, bleeding from the esophagus, and lung infections.

The Stretta procedure utilizes radiofrequency energy (RF) which is used in many medical specialties for coagulating or heating tissues. Cardiologists use RF to stop dangerous heart rhythms. Urologists use RF for treating prostate enlargement (difficulty in passing urine in males). Ear, nose, and throat surgeons use RF, to eliminate snoring and sleep apnea (stoppage of breathing during sleep). General surgeons use RF to cut and coagulate tissue. RF has been used in surgery since 1921. The Stretta procedure was cleared by the FDA for the treatment of GERD in April 2000, and uses RF to tighten the valve between the stomach and the esophagus in order to reduce GERD symptoms.

Human tissue responds to the warming effect of RF by shrinking. A portion of the shrinking takes place immediately at the time of treatment, while the remainder takes place as the body heals over the next 6-12

months. GERD symptoms may take several months to improve and therefore you may require your present acid reducing medication for several months after treatment.

The Stretta procedure is performed as an outpatient in the endoscopy unit. There may be mild to moderate discomfort in the mid-chest during this procedure, but you will be given intravenous sedation to ease this discomfort. There are no cuts made in your skin and no scars on your skin after this procedure.

A specially designed, flexible tube is passed through your mouth, into your esophagus, and is positioned at your LES valve near your stomach. This tube places 4 small needles into the muscle of your LES to deliver the RF energy to the muscle, thereby warming the tissue to 85° C (185° F). Multiple areas in the region of the LES and upper stomach are treated. The procedure will take approximately 40-60 minutes. You will then be observed for a period of time after the procedure and then permitted to return home. Because you will receive sedation for the procedure, you will require a friend or family member to provide transportation. You are advised to modify your diet to include liquids only for the first 24 hours, followed by a soft diet for the next 7 days.

Potential patient benefits: The potential personal health benefit to you for undergoing the Stretta procedure is the possibility of resolution or improvement of your GERD symptoms and reduction or elimination of acid reducing medication use.

Potential patient risks: There are uncommon risks associated with the endoscopy procedure that precedes and follows the Stretta procedure, including mild discomfort, tooth injury, medication reaction, esophageal perforation, (creating a hole or tear in the esophagus) and bleeding. Specific risks related to the Stretta procedure include chest or abdominal discomfort lasting for
several days after the treatment. The Stretta procedure has the following possible, yet infrequent, risks: difficulty belching, esophageal ulceration (injury to the lining of the esophagus), bleeding, perforation or infection, the need for surgery to correct any infection or perforation, difficulty in relaxing the LES in response to a swallow, difficulty swallowing, stricture (scar)formation (over-tightening), vomiting which could lead to bleeding or esophageal injury, and failure to resolve your symptoms of GERD.

Other possible risks which are not known at this time may become known at a later time. You are encouraged to discuss each of these issues with your physician before the procedure.