For people with GERD who need an alternative to medications or surgery.

The NEXT WAVE in GERD Treatment

stretta®
Stretta is a non-surgical outpatient procedure that takes 60 minutes or less. During the procedure, a Stretta device goes through the mouth to treat the muscle between the stomach and esophagus (LES), delivering radiofrequency (RF) energy to the muscle. This treatment regenerates the tissue, resulting in improved barrier function that may prevent reflux and reduce GERD symptoms.

HOW STRETTA WORKS

Stretta has been widely studied. Studies show a high rate of effectiveness and durability without the complication rates or costs of surgery, and without reliance on long-term daily medications.*

Ask your doctor if Stretta Therapy is right for you.

Go to stretta-therapy.com for more information.

*Clinical studies on file
INDICATIONS, CONTRAINDICATIONS AND WARNINGS

INDICATIONS FOR USE: The Stretta System is intended for general use in the electrosurgical coagulation of tissue and intended for use specifically in the treatment of gastroesophageal reflux disease (GERD).

CONTRAINDICATIONS: The use of electrosurgery is contraindicated when, in the judgment of the physician, electrosurgical procedures would be contrary to the best interest of the patient. The following is a list of patient groups in which the use of the Stretta System for the treatment of GERD is contraindicated:
- Subjects under the age of 18
- Pregnant women
- Patients without a diagnosis of GERD
- Hiatal hernia >2cm
- Achalasia or incomplete LES relaxation in response to swallow
- Poor surgical candidates
- ASA IV classification

WARNINGS: The following is a list of patient groups who have not been specifically studied using the Stretta System for the treatment of GERD. The performance characteristics of the device for the following groups of patients have not been established:
- Patients with an implant near the LES that could be conductive with RF energy
- Normal 24-hour pH study
- ALL GERD symptoms completely unresponsive to properly dose-escalated anti-secretory medication
- Barrett’s metaplasia
- Poor surgical candidate
- Presence of dysphagia, esophageal bleeding, or gas bloating
- Active esophagitis grades III or IV by Savary criteria
- Endocarditis risk (mitral valve prolapse, heart valve replacement, etc.)
- Untreated or unstable hypertension, diabetes mellitus, heart disease, collagen vascular disease, steroid use, immunosuppressed state, or cardiac pacemaker
- Abnormal blood coagulation or use of anticoagulant or platelet anti-aggregation therapy.

WARNINGS: These complications are rarely seen but could potentially occur with the use of electrosurgery for the treatment of GERD: transient bleeding, bloating, transient chest pain, transient difficulty belching, transient dysphagia, transient epigastric discomfort, transient esophageal mucosal laceration, transient fever, Injury to esophageal mucosa, perforation, pharyngitis, vomiting transient with potential for bleeding or Esophageal injury if any vomiting occurs, contact your treating physician immediately. Excessive vomiting may result in perforation and more serious injury resulting in death. The following complications have not been seen, but could possibly occur infrequently: Achalasia, transient delayed gastric emptying, dental injury, dyspnea, infection, larynx injury, worsened GERD (Note: Consult instructions for use for full contraindications, warnings and precautions).

After Stretta, what can patients expect?

Every patient is different in their response to Stretta.
- The effect of Stretta works over time, patients usually begin to see improvement after about 2-months
- Some patients improve more quickly than others
- Studies show that symptoms may continue to improve for 6 months or longer

Patients may experience pain immediately after Stretta Therapy.
- In most cases pain can be managed with over-the-counter analgesics (liquid acetaminophen), or prescription pain medication if needed.

Patients should:
- Continue their previous GERD medication regimen for 2 months after Stretta
- Follow a modified diet of full liquids for 24 hours and a soft diet for 2 weeks
- Crush all medications or use liquid medications for at least one month after treatment
- Stop using NSAIDS for two weeks after Stretta
- Avoid any instrumentation of the esophagus for at least one month