**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 bloat
- 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).

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**After Stretta, what can patients expect in terms of improvements in their GERD symptoms?**

Every patient is different in their response to Stretta Therapy. Some patients see improvement more quickly than others, and studies show the symptoms may continually improve for six months or longer. Patients are advised to continue their previous anti-secretory regimen for two-months after Stretta, and follow a modified diet of full liquids for 24 hours and soft diet for two weeks.

**Do patients experience pain after Stretta Therapy?**

Patients may experience pain immediately after Stretta Therapy, which in most cases can be managed with OTC analgesia (liquid acetaminophen), or, in severe cases, narcotic pain medication. Patient should crush all medications or use liquid medications for at least one month after treatment. Patient should refrain from using NSAIDS for two weeks after the Stretta procedure, and avoid any instrumentation of the esophagus for at least one month.

**Stretta is a versatile option that addresses the special needs of chronic GERD patients:**
- Symptoms not responding to PPIs
- GERD post-bariatric procedures
- Respiratory GERD symptoms (LPR)
- GERD post-fundoplication

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*Clinical studies on file

**stretta®**
TREATS THE DISEASE, NOT JUST THE SYMPTOMS
GERD is a chronic condition where stomach contents “reflux” up from the stomach into the esophagus through the lower esophageal sphincter (LES). Normally, the LES acts as a one-way valve, enabling food to pass down into the stomach but not up into the esophagus. When the LES fails to function properly, patients may experience symptoms of GERD.

GERD can cause a wide range of symptoms:
- Persistent heartburn
- Difficulty swallowing
- Regurgitation
- Asthma/Chronic cough
- Chest pain
- Laryngitis

If left untreated, chronic GERD causes irritation of the esophagus that can result in inflammation (esophagitis), ulceration and pain. If these conditions persist, there may be a risk of esophageal cancer.

Treatments for GERD outlined in the chart below, depend on the severity of symptoms and include:
- Lifestyle and diet modifications
- Medications (PPIs)
- Minimally invasive therapy (Stretta)
- Anti-reflux surgery

In clinical trials evaluating Stretta, up to 93% of patients were satisfied with the outcome of their procedure. Stretta has exhibited symptom relief that remains durable in the majority of patients from four to 10-years*.

Stretta therapy is an outpatient procedure performed in 60 minutes or less. Patients generally return to normal activities the following day. The Stretta system delivers radiofrequency (RF) energy to the LES, which regenerates the muscle tissue, resulting in improved function and fewer of the random relaxations that cause GERD symptoms.

**HOW STRETTA WORKS**

**REFLUX - A WEAK MUSCLE ALLOWS STOMACH CONTENTS TO REFLUX INTO THE ESOPHAGUS**

**STRETTA THERAPY - TREATS THE MUSCLE WITH RADIOFREQUENCY ENERGY**

**POST STRETTA - THE REGENERATED, Thicker, MUSCLE PREVENTS REFLUX**

Because Stretta doesn’t alter the anatomy or introduce a foreign implant, it can be utilized in a variety of patient groups and doesn’t preclude other treatment options.

Stretta is by far the most widely studied of any new treatment option for GERD, with studies showing a high rate of effectiveness and durability without the complication rates or costs.

**stretta® is:**
A minimally invasive procedure that significantly reduces GERD symptoms, allowing a majority of patients to eliminate or significantly decrease use of PPIs. Stretta is an excellent option for patients that have failed or are intolerant of drug therapy, offering an alternative to invasive surgery or foreign implants.

**stretta®**

**REFLUX SURGERY:**
- Transoral Fundoplication
- Surgically Implanted Devices
- Laparoscopic Fundoplication

20-30% of adults experience GERD weekly...but up to 30% of those patients don’t respond to medications.

Ask your doctor if Stretta Therapy is right for you. Go to stretta-therapy.com for more information.