

SAFE | EFFECTIVE | DURABLE | VERSATILE

stretta®



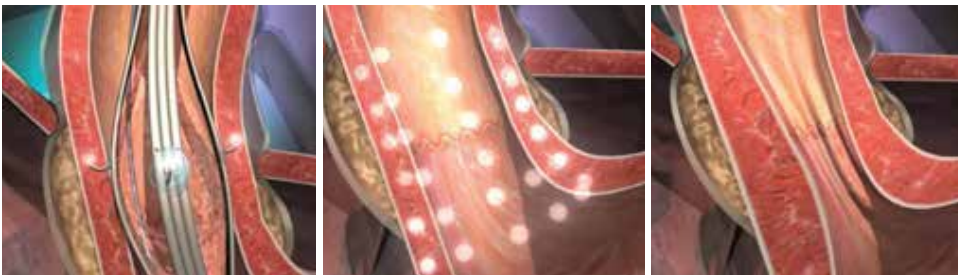
Stretta therapy is a safe and effective, minimally invasive procedure that significantly reduces symptoms of GERD and esophageal acid exposure, and improves quality of life for chronic GERD sufferers.

STRETТА FILLS AN UNMET NEED IN A VARIETY OF GERD PATIENTS

- Patients who don't respond completely to, or are intolerant of PPIs
- Patients with chronic GERD who don't wish to have surgery or an implant
- Post-gastric sleeve/bypass patients with GERD
- Post-Nissen patients with recurring reflux
- Non-erosive reflux (NERD) patients
- Laryngopharyngeal reflux (LPR) patients

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

HOW STRETТА WORKS



CONTROLLED, LOW POWER, NON-ABLATIVE RF ENERGY DELIVERED TO TISSUE

MULTI-LEVEL TREATMENT IMPROVES MUSCLE OF THE LES AND GASTRIC CARDIA

LES MUSCLE AND BARRIER FUNCTION SIGNIFICANTLY IMPROVED

Stretta therapy is an endoscopically-guided, minimally invasive, outpatient procedure performed in approximately 60 minutes. The Stretta Catheter, powered by the MDRF1 Generator, is an innovative design for precise and safe delivery of radiofrequency energy to the lower esophageal sphincter (LES), and gastric cardia.

LANDMARK STRETТА META-ANALYSIS 2017 - 28 STUDIES, ~2,500 PATIENTS

Large study included 2,468 Patients, up to 10-yr follow-up (avg 25 months).

Results showed that Stretta significantly and consistently improved GERD symptoms and physiological parameters noted below:

- Significant improvement in GERD HRQL scores
- Significant reduction in heartburn symptom scores
- Majority of patients off proton pump inhibitors (PPI's)
- Significant healing of erosive esophagitis
- Significant reduction in esophageal acid exposure
- Low adverse event rate of <1%

Systematic Review and Meta-Analysis of Controlled and Prospective Cohort Efficacy Studies of Endoscopic Radiofrequency for Treatment of Gastroesophageal Reflux Disease.

Fass R, et al. *Surg Endosc.* 2017 Dec;31(12):4865-4882.

STRETТА - THE NUMBERS

86%

PATIENTS OFF MEDS - 4 YRS

DURABLE RESULTS WITH FOLLOW UP STUDIES UP TO **15 YEARS**

<1%

COMPLICATION RATE

50+

STUDIES

35,000+

PROCEDURES

15 Year Data

LASTING RESULTS!

- 72% normalized GERD HRQL
- Regression of pre-existing Barrett's observed

SAGES CLINICAL SPOTLIGHT REVIEW GUIDELINE GIVES STRETТА STRONGEST RECOMMENDATION

Quality of Evidence: (+++) Grade Recommendation: Strong

ASGE GUIDELINES ON ENDOSCOPIC MANAGEMENT OF GERD

Adverse events were infrequent and typically minor. The technique appears to durably relieve GERD symptoms for up to 10 years in the majority of patients.

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STRETTA FOR GERD | RF MECHANISMS OF ACTION

DECREASED ACID EXPOSURE

“Analyses of symptom improvement vs. acid exposure suggested that symptom improvement was associated with decreased esophageal acid exposure...”

A comparison of patients before vs. after treatment indicated that acid exposure decreased significantly (median decrease, -2.4%; $P=0.01$) between baseline and 12 months for all treated patients (both initial active treatment and crossed over patients).”

Corley DA, et al. Improvement of gastroesophageal reflux symptoms after radiofrequency energy: a randomized, sham-controlled trial. *Gastroenterology*. 2003 Sep;125(3):668-76.

“At 12 months, the mean HRQL scores of those off medications, the LES basal pressure, the 24-h pH scores, and the proton pump inhibitor daily dose consumption were significantly improved...”

Aziz AM, et al. A prospective randomized trial of sham, single-dose Stretta, and double-dose Stretta for the treatment of gastroesophageal reflux disease. *Surg Endosc*. 2010 Apr;24(4):818-25.

DECREASED TISSUE COMPLIANCE-NO FIBROSIS

“Stretta improved GERD symptoms and decreased GEJ compliance. Decreased GEJ compliance, which reflects altered LES neuromuscular function, may contribute to symptomatic benefit by decreasing refluxate volume.”

Arts J, et al. A double-blind sham-controlled study of the effect of radiofrequency energy on symptoms and distensibility of the gastro-oesophageal junction in GERD. *Am J Gastroenterol*. 2012 Feb;107(2):222-30.

INCREASED WALL THICKNESS

“EUS demonstrates that LES muscle is significantly thickened after RF delivery...thickening may result in reduced compliance of the GE junction and contribute to its mechanism of action.”

Chang KJ, Utley DS. Endoscopic ultrasound (EUS) in-vivo assessment of radiofrequency (RF) energy delivery to the gastroesophageal (GE) junction in a porcine model [abstract]. *Gastrointest Endosc* 2001;53:AB4191.

DECREASED TLESRS- INCREASED LES PRESSURE

“RFe reduced the rate of postprandial transient LOS relaxations from 6.8 (5.7-8.1) (median (interquartile range) per hour to 5.2 (4.2-5.8) per hour ($p<0.01$), and increased mean basal LOS pressure from 5.2 (SEM 0.3) mm Hg to 8.0 (SEM 0.4) mm Hg ($p<0.01$).”

Tam WC, et al. Delivery of radiofrequency energy to the lower oesophageal sphincter and gastric cardia inhibits transient lower oesophageal sphincter relaxations and gastro-oesophageal reflux in patients with reflux disease. *Gut*. 2003 Apr;52(4):479-85.



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REDUCTION IN ESOPHAGEAL ACID EXPOSURE

- Fass et al. 2017 - *Surg Endosc*
- Perry et al. 2012 - *Surg Lap, Endo & Perc Tech*
- Aziz et al. 2010 - *Curr Opin Gastroenterol* - RCT
- Arts et al. 2007 - *Digestive Disease Science*
- Mattar et al. 2006 - *Surg Endosc*
- Lufti et al. 2005 - *Surg Endosc*
- Cipoletta et al. 2005 - *Surg Endosc*
- Torquati et al. 2004 - *Surg Endosc*
- Triadafilopoulos et al. 2004 - *Surg Endosc*
- Houston et al. 2003 - *Surg Endosc*
- Richards et al. 2003 - *Annals of Surgery*
- Triadafilopoulos et al. 2002 - *Gastrointest Endosc*
- Corley et al. 2003 - *Gastroenterology* - RCT

REDUCTION IN TRANSIENT LES RELAXATIONS

- Arts et al. 2012 - *Am Journal of Gastroenterol* - RCT
- Tam et al. 2003 - *Gut*
- Kim et al. 2003 - *Gastrointestinal Endosc*

DECREASED TISSUE COMPLIANCE WITHOUT FIBROSIS

- Arts et al. 2012 - *Am Journal of Gastroenterol* - RCT

INCREASE IN LES WALL THICKNESS

- DiBaise et al. 2002 - *Am Journal of Gastroenterol*
- Chang et al. 2001 - *Gastrointestinal Endosc*
- Kim et al. 2003 - *Gastrointestinal Endosc*

INCREASED LES PRESSURE

- Aziz et al. 2010 - *Curr Opin Gastroenterol* - RCT
- Meier et al. 2007 - *Scandinavian Journal of Gastro*
- Tam et al. 2003 - *Gut*
- Utley et al. 2000 - *Gastrointest Endosc*



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