

SAFE | EFFECTIVE | DURABLE | VERSATILE

# stretta®

Stretta therapy is a safe and effective, non-surgical 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.

## NEW! LANDMARK STRETТА META-ANALYSIS 2017 - 28 STUDIES

Large study included **2468 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 (PPIs)
- ▼ 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, et al. *Surgical Endoscopy*, online February 2017

## 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, non-surgical, 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.

## STRETТА - THE NUMBERS

# 86%

PATIENTS OFF MEDS - 4 YRS

# 4-10

YEARS DURABLE SYMPTOM RELIEF

# <1%

COMPLICATION RATE

# 40+

STUDIES

# 25,000+

PROCEDURES

# 10-Yr Data

## LASTING RESULTS!

- 72% normalized GERD HRQL
- PPI use reduced by  $\geq 50\%$  in 64% of patients
- 41% off PPIs entirely
- Regression of pre-existing Barrett's was observed

**SAGES CLINICAL SPOTLIGHT REVIEW GUIDELINE GIVES STRETТА STRONGEST RECOMMENDATION.**

Quality of Evidence: (++++)

Grade Recommendation: Strong

# stretta®



www.stretta-therapy.com

Clinical studies on file.

173-5024T

# 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).”**

Improvement of Gastroesophageal Reflux Symptoms After Radiofrequency Energy: A Randomized, Sham-Controlled Trial. Corley D, Katz P, Wo J, Stefan A, Patti M, Rothstein R, Edmundowicz S, Kline M, Mason R, and Wolfe MM. *Gastroenterology* 2003;125:668-676

**“ 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...”**

A prospective randomized trial of sham, single-dose Stretta, and double-dose Stretta for the treatment of gastroesophageal reflux disease. Abdel Aziz AM, El-Khayat HR, Sadek A, Mattar SG, McNulty G, Kongkam P, Guda MF, Lehman GA. *Curr Opin Gastroenterol.* 2009 Jul;25(4):352-7.

## 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.”**

A Double-Blind Sham-Controlled Study of the Effect of Radiofrequency Energy on Symptoms and Distensibility of the Gastro-Esophageal Junction in GERD. Arts J, Bisschops R, Blondeau K, Farré R, Vos R, Holvoet L, Caenepeel P, Lerut A, Tack J, *Am J Gast*, advance online publication, 22 November 2011; doi: 10.1038/ajg.2011.395

## INCREASED WALL THICKNESS

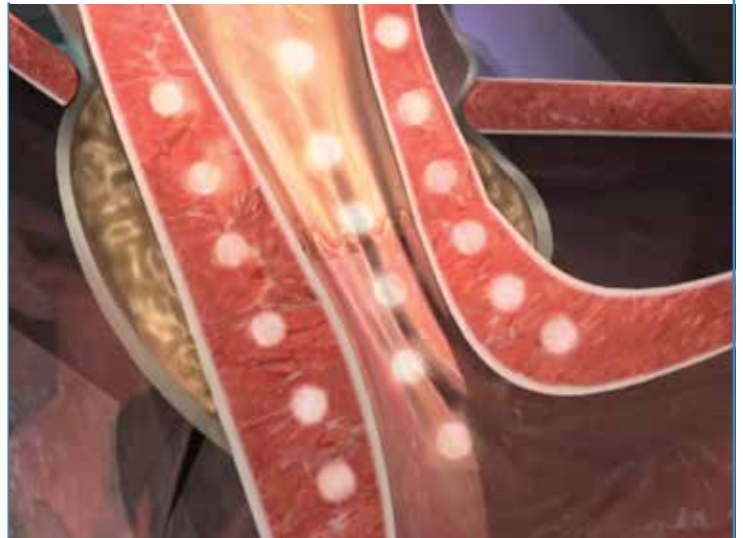
**“ EUS demonstrates that LES muscle is significantly thickened after RF delivery...thickening may result in reduced compliance of the GE junction and contribute to its mechanism of action.”**

Endoscopic ultrasound (EUS) in-vivo assessment of radiofrequency (RF) energy delivery to the gastroesophageal (GE) junction in a porcine model. Chang KJ, Utley DS. *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).”**

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. Tam WCE, Schoeman MN, Zhang Q, Dent J, Ridga R, Utley D, Holloway RH. *Gut* 2003;52:479-285.



## 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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