## LANDMARK STRETTA META-ANALYSIS 2017

LANDMARK STUDY:

STRETTA SAFE AND EFFECTIVE FOR GERD

> 28 STUDIES

2468
GERD PATIENTS

25
MONTHS AVERAGE
FOLLOW-UP (6-120)

- 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 in esophageal acid exposure
- ▼ Low adverse event rate of <1%</p>

# 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

#### 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

Corley et al. 2003 - Gastroenterology - RCT

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

건강보험	분류번호	코드	분류
행위 급여	자-760	Q7600	위식도 역류질환의 내시경적 고주파 치료술 Radiofrequency Energy Delivery for the Treatment of Gastroesophageal Reflux Disease
치료재료 급여		M2064001	위식도 역류질환의 내시경적 고주파 치료술용 "STRETTA"

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최소침습적인 외래환자 치료법

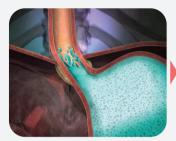


JPI Healthcare Solutions

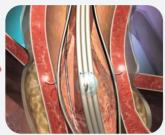
수술치료 후에도 STRETTA 시술가능 60분내외의 간단한 시술 1%미만의 합병증 STRETTA, GERD Solution \_\_

# 치료원리

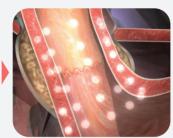
LES (하부식도괄약근) 와 Gastric cardia(위분문) 부위에 낮은 온도의 고주파를 60초 동안 근육층에 전달하여 치료를 진행하며 근육층의 리모델링을 통한 수축 이완 능력 개선하여 위산의 역류를 방지하는 원리이다.



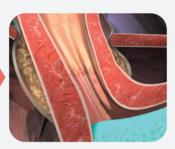
LES(하부식도괄약근)등의 기능 악화로 위식도 역류발생



Stretta 카테터 경구 삽입으로 고주파 에너지 전달



그림과 같은 부위 총 6레벨의 위치에 고주파 전달 치료 진행



하부식도괄약근(LES)의 리모델링을 통한 수축 이완 능력 개선 (위산의 역류 방지)

#### PATIENT SELECTION CRITERIA - THE SPECTRUM OF GERD TREATMENTS

**Medications (PPIs)** 

# stretta

#### **ANTI-REFLUX SURGERY:**

• Transoral Fundoplication

5% Have Anti-Reflux Surgery

- Surgically Implanted Devices
- Laparascopic Fundoplication

#### **70% Respond to Meds**

- 가벼운 GERD 증상의 환자
- 하부식도괄약근의 기능 수행에 문제가 없는 환자
- 치료에 대한 의지가 강한 환자
- 치료생활 개선에 순응하는 환자
- 약물치료에 순반응하는 환자
- 부작용이 없는 환자
- 약물 상호작용이 없는 환자

#### 25-30% Refractory GERD

- 일반적인 GERD 증상의 환자
- 2Cm 미만의 식도열공탈장 환자
- 약물치료에 부분적인 반응만 보이는 환자
- 치료생활 개선이 힘든 환자
- 장기간의 약물치료에 대하여 순반응 하지 않는 환자
- 부작용이 있는 환자
- 약물 상호작용이 있는 환자
- 비만치료 수술을 받은 환자중 GERD 증상이 있는 환자
- 비미란성 위식도 역류질환 환자
- 항역류 수술을 받았음에도 GERD 증상이 있는 환자

- 극심한 GERD 증상
- 장기간 약물치료에 대하여 순반응 하지 않는 환자
- 부작용이 있는 환자
- 약물 상호작용이 있는 환자
- Stretta 치료를 받은 환자중 GERD 증상이 있는 환자
- 미란성식도염 환자
- 2Cm 이상의 식도열공탈장 환자(ARS)

# Special Indication 경구 위저부 주름술

- 2Cm 미만의 식도열공탈장 환자
- 35 미만의 체질량 지수(BMI)의 환자

# **STRETTA Results & Efficacy**

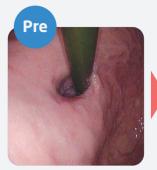
Esophageal acid exposure 식도 산 역류 노출 개선, LES 순간적 이완 상태 개선, fibrosis 없이 조직순응도 감소, LES 벽 두께 증가, LES 압력 증가



Esophageal view, LES pre-Stretta: poor tone with significant opening



Esophageal view, LES ith post-Stretta: immediate closure of LES



Cardia view, LES pre-Stretta: incompetence of sphincter



Cardia view, LES post-Stretta: immediate closure effect

# STRETTA - THE NUMBER

86%
PATIENTS OFF MEDS - 4YRS

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 ≥50% in 64% of Patients
- 41% off PPIs entirly
- Regression of pre-existing Barrett's was observed

# The sele of a

#### GUIDELINE

The role of endoscopy in the management of GERD

That is now of a series of disliments discussing the darked of Practice Committee of the American Social Generalization and the Committee of the American Social Committee of the American Social Generalization and the series of the Intelligent of the path by the Committee of the Committee of the Publish Additional references were obtained from the Dispute of the Mentiling antices and from a real data exist from a real designed propositive train, expert is given in reason from large series and expert recognitive deports. Guideleine for appropriate recognitive deports. The committee of the mentile of the committee of the committe

technology, new data, or other aspects practice. The recommendations user based attacks and sever guided on the strength of the 17th guideline is intended to be an otherand to provide information that may exist em practifing care to patients. This guideline is and should not be construed as establish standard of care or as econocinging. Clinical decisions in our particular case in plex analysis of the patients condition as course of action. Therefore, clinical or comp lead an endocapole to she a course of may lead an endocapole to she a course of may lead an endocapole to she a course of may lead an endocapole to she a course of may lead an endocapole to she a course of may lead an endocapole to she a course of may lead an endocapole to she a course of may lead an endocapole to she a course of may lead an endocapole to she a course of may lead an endocapole to she a course of may lead to the may lead to the course of may lead to may l

GEBD is a condition that develops when is an observation of the contract causes insulableouse symptoms and contents causes insulableouse symptoms (as). If an account systematic review, the GEBD in the United States was ociliarted 20%, when GEBD was defined as least we calculate the Cellon of GEBD and effect as least was calculated as the content of GEBD have increased sign time. It is also the most common indicate the United States. In addition so its impact

complexed disease (e.g. Opsylaga), units visited as a legal merch so-oplogue (BB), ""I fisk Less of land legal merch so-oplogue (BB), ""I fisk Less of land legal merch so-oplogue (BB), ""I fisk Less of land legal merch leg

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ASGE (미국소화기내시경학회)에서 2015년 6월 " 위식도역류질환(GERD) 치료의 새로운 가이드라인으로 STRETTA가 효과적인 치료법이다"라고 발표 하였다.



#### nical Spotlight Review – Endoluminal Treatments for Gastroesophageal flux Disease (GERD)

ical Spotlight Review published on: 02/2013 he Society of American Gastrointestinal and Endoscopic Surgeor

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More than 30 peer reviewed studies, including 4 ac meta-analysis and multiple prospective clinical trial Durable treatment outcomes to at least to 48 mon reduction or elimination of medications used to tre

The following clinical spotligitor physicians who manage

om scores. Stretca may be recommended as an appropriate interapeutic option for patients with 16-bb who mee it indications and patient selection criteria and choose endoluminal therapy over laparoscopic fundoplication. The include:

attents (age >=18) with symptoms of heartburn, regurgitation, or both for >= 6 months who have been partial.

ompacery responsive to anissectively prainineologic tirelapy: procedure has not been studied and should not be applied in treating patients with severe esophagitis, hiatus hernias cm, long segment Barrett esophagus, dysphagia, or those with a history of autoimmune disease, collagen vascular

Recommendation: Stretta is considered appropriate therapy for patients being treated for GERD who are 18 years age or older, who have had symptoms of heartburn, regurgitation, or both for 6 months or mor who have been partially or completely responsive to anti-secretory pharmacologic therapy, an

Quality of Evidence: (+++++). Should recommendation: Strong

SAGES (미국소화기내시경외과학회)에서 대규모 임상 데이터 검토로 STRETTA Therapy를 가장 강력한 추천 Clinical Spotlight Review guideline을 받았다.