



X-ray Grids



Radiography System



Detector



Software



Computed Radiography



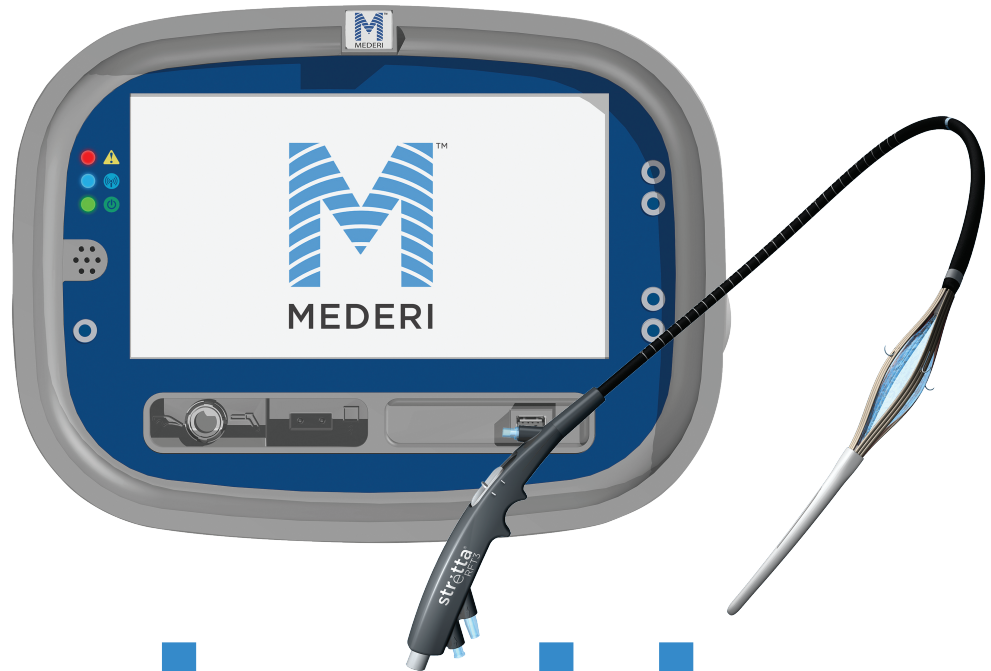
X-ray Accessories



Diagnostics



RF Treatment



stretta®

4년 이상 개선 효과
10년 이상 지속

생활습관 개선과
약물치료의
한계극복

최소침습적인
외래환자 치료법

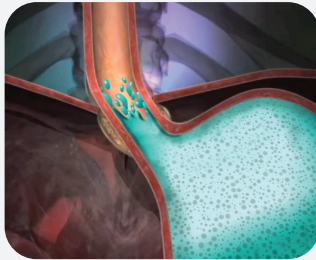
수술보다 빠른
일상생활 복귀

수술치료 후에도
STRETta 시술가능

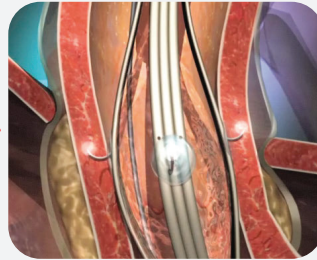
60분내외의
간단한 시술
1%미만의
합병증

치료원리

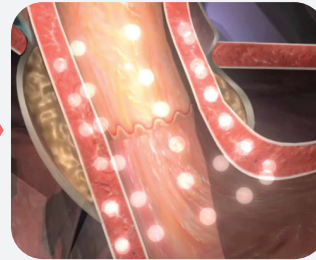
LES (하부식도괄약근) 와 Gastric cardia(위분문) 부위에 낮은 온도의 고주파를 60초 동안 근육층에 전달하여 치료를 진행하며 근육층의 리모델링을 통한 수축 이완 능력 개선하여 위산의 역류를 방지하는 원리이다.



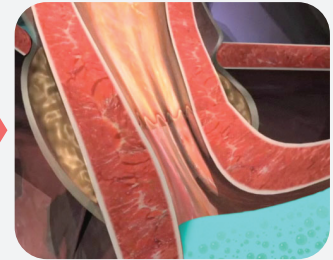
LES(하부식도괄약근)등의 기능 약화로 위식도 역류발생



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
- Surgically Implanted Devices
- Laparoscopic 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

5% Have Anti-Reflux Surgery

- 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

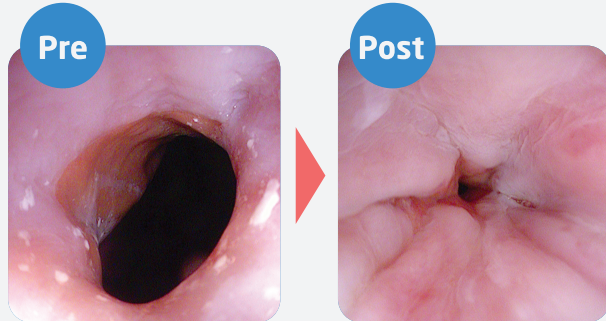
경구 위저부 주름술

- 2Cm 미만의 식도열공탈장 환자

- 35 미만의 체질량 지수(BMI)의 환자

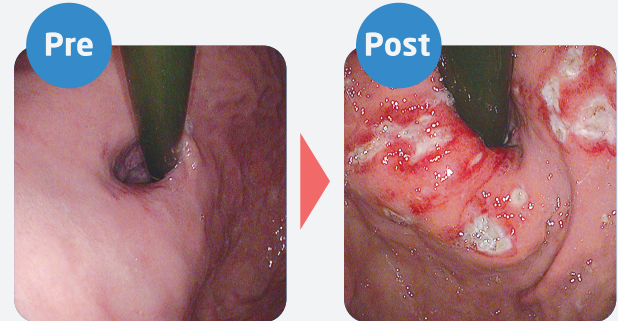
STRETTA Results & Efficacy

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 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 $\geq 50\%$ in 64% of Patients
- 41% off PPIs entirely
- Regression of pre-existing Barrett's was observed

GUIDELINE

The role of endoscopy in the management of GERD

This is one of a series of statements discussing the use of GI endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy prepared this text. In preparing this guideline, a search of the medical literature from January 2008 to August 2014 was performed by using PubMed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When limited or no data exist from randomized prospective trials, emphasis is given to results from large series and reports from recognized experts. Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time the guidelines are drafted. Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice. The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence (Table 1).

This guideline is intended to be an educational device to provide information that may assist endoscopists in providing care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve a complex analysis of the patient's condition and available resources of action. Therefore, clinical considerations may lead an endoscopist to take a course of action that varies from these guidelines. This guideline replaces our previous document on the role of endoscopy in GERD.

GERD is a condition that develops when reflux of stomach contents causes troublesome symptoms (eg, heartburn and regurgitation) or adverse events (eg, esophageal stricture).^{1,2} In a recent systematic review, the prevalence of GERD in the United States was estimated to be 10% to 20%, when GERD was defined as at least weekly heartburn and/or acid regurgitation.³ Despite visits for the evaluation of GERD have increased significantly over time. It is also the most common indication for EGD in the United States. In addition to its impact on quality of life,⁴ the numerous adverse events of chronic GERD, such as esophageal stricture formation, Barrett's metaplasia, and esophageal adenocarcinoma, necessitate adequate diagnosis and treatment of this common entity.

INDICATIONS FOR ENDOSCOPIC EVALUATION

A diagnosis of GERD can be made based on symptoms⁵ and confirmed by a favorable response to antireflux medical therapy.^{1,10,11} It is important to note that epigastric pain can be the major symptom of GERD.¹² If the patient's history is consistent with typical or atypical GERD, an initial trial of empiric medical therapy is appropriate before consideration of endoscopy in most patients.¹³ Endoscopy at presentation should be considered in patients who have symptoms suggestive of complicated disease (eg, dysphagia, unintentional weight loss, hematemesis) or those with multiple risk factors for Barrett's esophagus (BE).^{14,15} Risk factors for BE include older than 50 years of age, male sex, white race, a family history of BE or esophageal adenocarcinoma, prolonged reflux symptoms, smoking, and obesity.¹⁶ In addition, failure to respond to appropriate antireflux medical therapy should prompt evaluation with EGD and consideration of other diagnostic modalities, including ambulatory pH monitoring, esophageal manometry, and/or multichannel impedance testing.

The indications for EGD in patients with GERD are listed in Table 2. EGD may be necessary to detect esophageal stricture, peptic stricture, esophageal cancer, gastric outlet obstruction, and other potentially significant upper GI tract findings. Additionally, EGD is often performed as part of the preoperative evaluation of patients being considered for antireflux surgery or for the placement of wireless esophageal pH monitoring devices¹⁷ and is an inherent part of various endoscopic antireflux procedures. Endoscopy is often performed in the evaluation of patients with suspected extraesophageal manifestations of GERD who present with symptoms such as chronic coughing, hoarseness, asthma, laryngitis, chronic sinusitis, or dental erosion.¹⁸ Given that the majority of these patients will not have endoscopic evidence of erosive esophagitis, especially when taking empiric medical therapy for GERD, the routine use of EGD to evaluate extraesophageal symptoms of GERD is not recommended.^{19,20} Evidence is also lacking to support the routine use of EGD in patients with uncomplicated GERD who are responsive

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www.gastrojournal.org

Volume 81, No. 6 • 2015 GASTROINTESTINAL ENDOSCOPY 1395

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

Clinical Spotlight Review – Endoluminal Treatments for Gastroesophageal Reflux Disease (GERD)

Clinical Spotlight Review published on: 02/2013
by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

Conclusion

More than 30 peer reviewed studies, including 4 adequately powered randomized, controlled studies, a comprehensive meta-analysis and multiple prospective clinical trials have documented the safety and efficacy of the Stretta procedure. Durable treatment outcomes to at least 48 months also have been demonstrated in multiple studies, with significant reduction or elimination of medications used to treat the symptoms of GERD, as well as improvement in GERD QOL and symptom scores. Stretta may be an appropriate therapeutic option for patients with GERD who meet current indications and patient selection criteria and choose endoluminal therapy over laparoscopic fundoplication. Those criteria include:

Adult patients (age ≥ 18) with symptoms of heartburn, regurgitation, or both for ≥ 6 months who have been partially or completely responsive to antireflux pharmacologic therapy.

The procedure has not been studied and should not be applied in treating patients with severe esophagitis, hiatal hernias > 2 cm, long segment Barrett esophagus, dysphagia, or those with a history of autoimmune disease, collagen vascular disease, and/or coagulation disorders. Further studies are needed to evaluate the role of Stretta in children if it is to be considered a therapeutic option.

Recommendation:
Stretta is considered appropriate therapy for patients being treated for GERD who are 18 years of age or older, who have had symptoms of heartburn, regurgitation, or both for 6 months or more, who have been partially or completely responsive to anti-secretory pharmacologic therapy, and who have declined laparoscopic fundoplication.
Quality of Evidence: (++++). GRADE Recommendation: Strong

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

LANDMARK STRETТА META-ANALYSIS 2017

LANDMARK STUDY :

**STRETТА 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%

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
Uttley 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 “STRETТА”

수입원: 제이피아이 헬스케어(주)

☞ 서울특별시 구로구 디지털로33길 28, 608호 (우림e-biz 1차)

문의처: ☎ 070-4445-4561~2 ✉ kimjw1@jpi.co.kr

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RF Treatment



