ESG in North America

CHRISTOPHER C. THOMPSON MD MSC FAGA FACG FASGE FJGS
DIRECTOR OF ENDOSCOPY, BRIGHAM AND WOMEN'S HOSPITAL
CO-DIRECTOR CENTER FOR WEIGHT MANAGEMENT AND WELLNESS
PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL

IFSO Napoli 2023

Banner Year for ESG in North America

Major studies

FDA activity

Corporate acquisitions

Increasing number of cases

Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial

Barham K Abu Dayyeh, Fateh Bazerbachi, Eric J Vargas, Reem Z Sharaiha, Christopher C Thompson, Bradley C Thaemert, Andre F Teixeira, Christopher G Chapman, Vivek Kumbhari, Michael B Ujiki, Jeanette Ahrens, Courtney Day, the MERIT Study Group, Manoel Galvao Neto, Natan Zundel, Erik B Wilson

RCT (n= 209) ESG (85) and control (124)

Primary outcomes, %EWL at 1 year

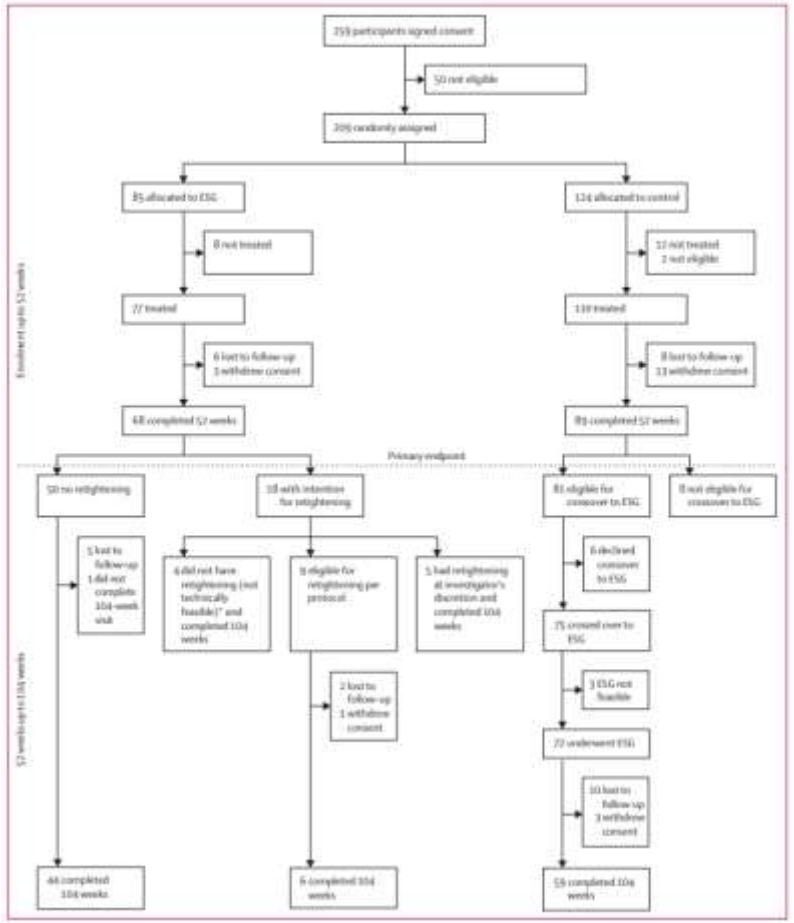
- EWL - 49.2% ESG vs 3.2% Control (p<0.0001)
- TWL - 13.6% ESG vs 0.8% Control (p<0.0001)
- Comorbidities also favorably improved in the ESG group compared to control

Response rate – 25% EWL at 1 year

- ESG 77%
- Control 12%

FDA granted De Novo marketing authorization

- BMI 30-50 kg/m2



Bariatric News

Subscribe →

Search Bariatric News

Latest | All News | Daily Digest | Reports | Events | Directory | Contact

owenhaskins · Jul 14, 2022 · 2 min read

Apollo's ESG and REVISE Systems approved by FDA

Updated: Aug 1, 2022

Apollo Endosurgery has been granted marketing authorisation for its ESG, ESG Sx, REVISE and REVISE Sx through the FDA's De Novo Classification process, a rigorous pre-market review pathway for low-to moderate-risk devices without a predicate. According to the company, these are the first and only devices authorised by the FDA for endoscopic sleeve gastroplasty (ESG) and endoscopic bariatric revision.

ESG is an incisionless procedure that utilises an endoscopic suturing system to reduce the volume of a person's stomach and delay emptying of the stomach, resulting in clinically meaningful, durable weight loss. In a randomised controlled trial, the ESG procedure demonstrated safety and effectiveness with durability out to two years.1 The results from this trial add to a larger body of evidence reporting outcomes in over 10,000 patients receiving ESG. ESG can be performed as a same-day procedure without incisions or scars, and patients typically return to work within a few days.

Bariatric revision procedures are the fastest growing segment of the bariatric surgery market.2 Studies have shown that after ten years, patients who underwent gastric bypass have regained an average of 20-30% of the weight they initially lost. Transoral outlet reduction (TORe) is an endoscopic procedure performed to revise a previous gastric bypass and like ESG, can be performed as a same-day procedure without incisions or scars.

wcg FDANEWS | Simplifying Global Compliance

Drug News | Device News | Books | Training/Events | Resources | CenterWatch | About Us | Advertising

Apollo Endosurgery Endoscopic Devices Get De Novo Marketing Authorization

July 22, 2022

Austin, Texas-based Apollo Endosurgery has received De Novo marketing authorization from the FDA for its Apollo ESG, Apollo ESG Sx, Apollo Revise and Apollo Revise Sx endoscopic devices for treatment of obesity.

The devices are specifically for use in endoscopic sleeve gastroplasty (ESG) and endoscopic bariatric revision surgeries for weight loss.

Currently, less than 0.2 percent of adults with obesity are treated surgically for obesity, leaving a substantial unmet need, the company said.

The De Novo authorization pathway is for low-to moderate-risk devices without an already approved, cleared or authorized reference product. De Novo devices are those for which general and special controls provide a reasonable assurance of the device's safety and effectiveness.

Major Acquisitions

BREAKING NEWS

Boston Scientific to Acquire Apollo Endosurgery for $615M

Expands the company's endoluminal surgery portfolio and adds differentiated technologies for endobariatric procedures.

10-year ESG

A retrospective study of patients who underwent ESG and were eligible for a 10-year follow-up (n=7)

Techniques: technical success of 100% (average suturing time of 97 ± 21 minutes)

- APC at the anterior, posterior and greater curvature
- Bitriangular pattern at the gastric body (9±3 sutures/50±18 stitches)
- Running pattern in the fundus (2±1 sutures/8±4 stitches)
- Medial interrupted pattern for reinforcement (3±1 sutures/7±3 stitches)

Safety: SAE rate of 0%

10-year ESG

Follow-up rates at 1, 5 and 10 years were 100%, 86% and 86%

Weight loss at 10 years: 13.5 ± 7.5% TWL

Out of 5 patients with the 10-year follow-up, 2 underwent sleeve gastrectomy

Weight loss at 10 years after removing these 2 patients: 12.9 ± 10.0% TWL

Increasing Numbers of Cases

Over 2000 ESG cases in the US to date this year with a shift towards private groups

2220 US cases in 2021

1500 US cases in 2020

BREAKING NEWS

FDA OKs Endo Tools' endomina System

Endoscopically places sutures and approximates soft tissue in the GI tract.

FDA U.S. FOOD & DRUG ADMINISTRATION

December 7, 2021

Endo Tools Therapeutics S.A.
Marine Rouyer
International Regulatory Affairs Director
Rue Auguste Piccard 48
Gosselies, 6041
BELGIUM

Re: K211309
Trade/Device Name: endomina system
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCW
Dated: October 25, 2021
Received: October 27, 2021

Dear Marine Rouyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration,

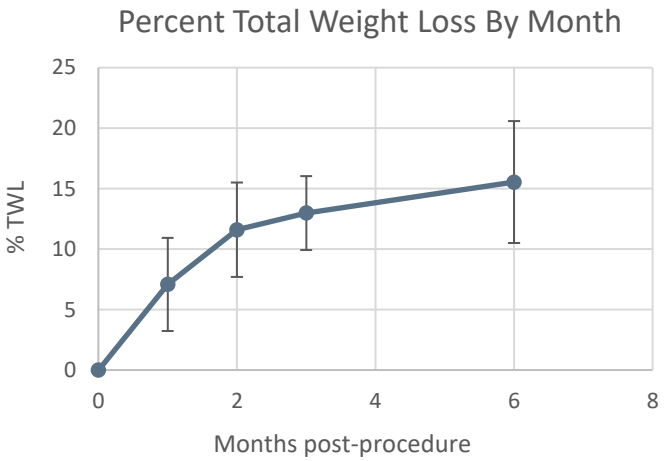
Endomina

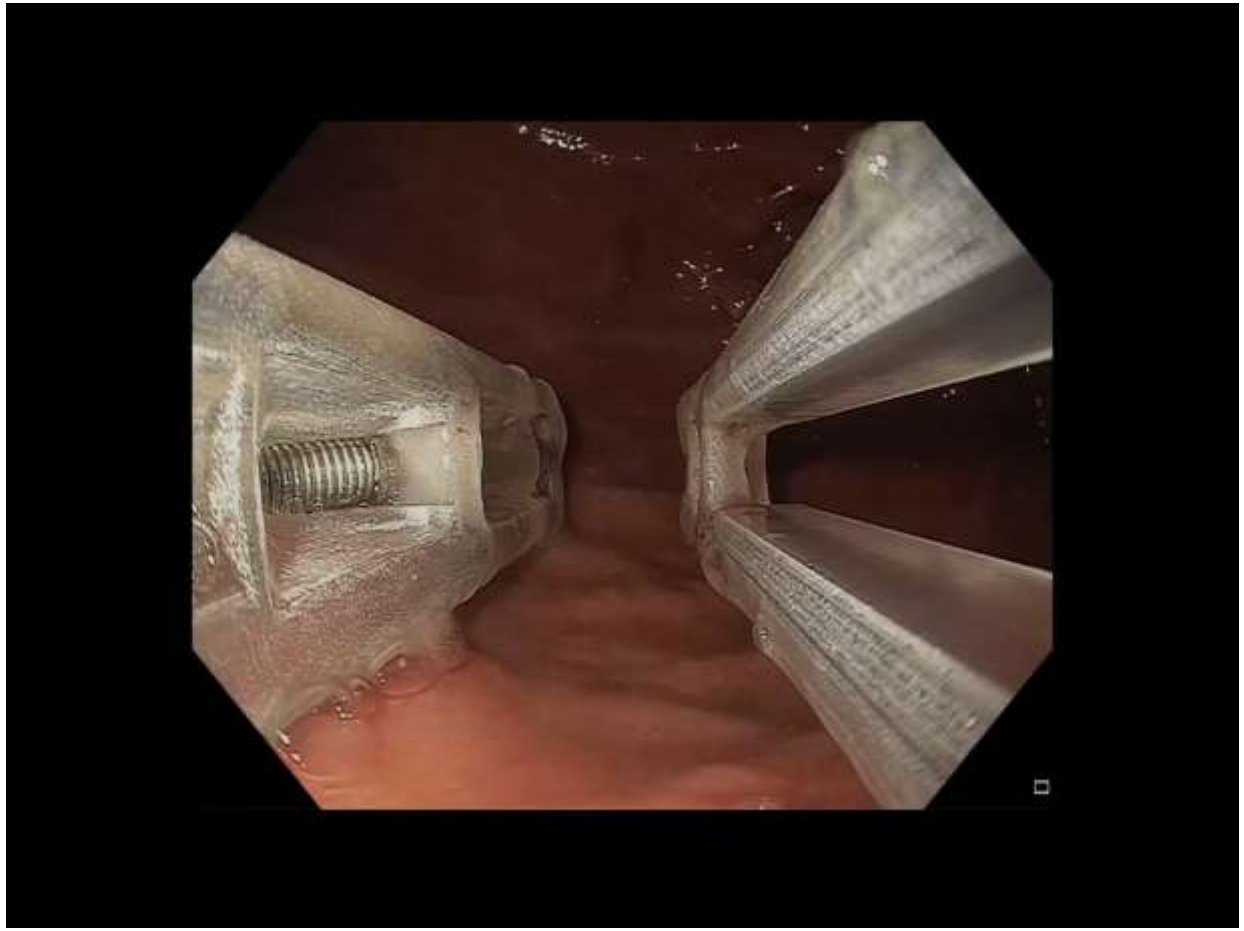
First US cases series, August 2022

N=12, BMI 34 kg/m^2

Results:

Procedural Characteristics	
Procedure time – minutes (SD)	122 (55.2)
Median plications – no. (range)	9 (7-11)
- Distal Belt	3 (2-3)
- Suspender	3 (3-6)
- Medial Belt	2 (2-3)
Gastric shortening – % (SD)	48 (13.5)

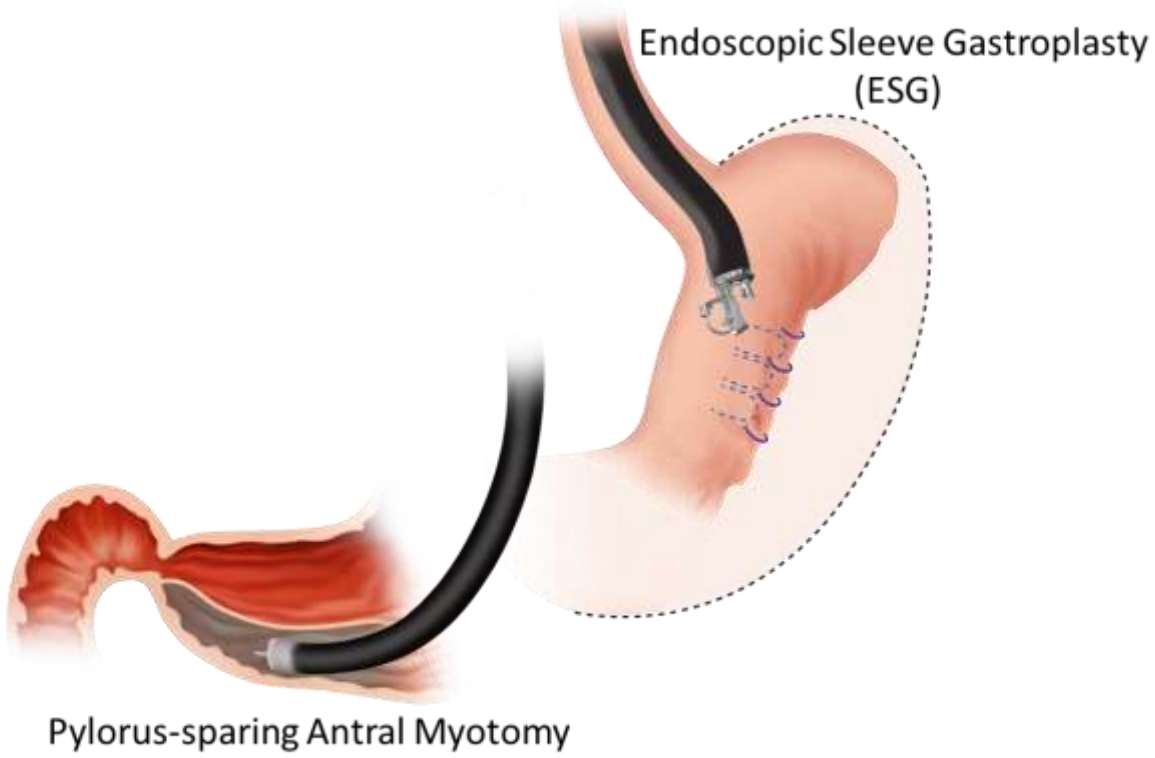




Gastroplasty With Endoscopic Myotomy for the Treatment of Obesity: Preliminary Efficacy and Physiologic Results

Christopher C. Thompson, Pichamol Jirapinyo, Raj Shah, and Cem Simsek

Gastro aga



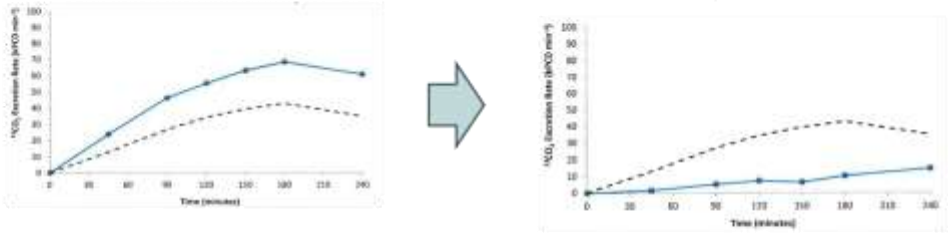
Gastroplasty with Endoscopic Myotomy (GEM)

N=6

At 1, 3 and 6 months, patients experienced 11.5 ± 2.9%, 14.8 ± 2.5% and 19.5 ± 1.4% TWL ($p < 0.0001$ for all)

100% of patients experienced ≥10% TWL

Gastric Emptying Breath Test (GEBT)
- Proportion of patients with delayed gastric emptying: 1/6 (17%) → 6/6 (100%) (p=0.02)
- Average T1/2 increased from 90 ± 58 minutes to 204 ± 18 minutes (p<0.0001)



Gastroparesis Cardinal Symptom Index (GCSI)
- Total GCSI: 0.4 ± 0.4 → 0.6 ± 0.3 (p=0.63)
- Postprandial fullness/early satiety subscale: 0.2 ± 0.3 → 1.0 ± 0.5 (p=0.01)
- Nausea/vomiting subscale: 0 → 0.1 ± 0.3 (p=0.36)
- Bloating subscale: 1.6 ± 1.3 → 0.3 ± 0.4 (p=0.10)

Conclusion

It was a banner year for bariatric endoscopy and obesity management in general with major FDA approvals and M&A activity

New technology is gaining traction and it appears bariatric endoscopy may be here to stay

Reimbursement, training, and credentialing issues must be addressed


You are here

BRIGHAM AND WOMEN'S HOSPITAL

THE HARVARD MEDICAL SCHOOL

Thank you!

@MetabolicEndo