OverStitch™ Endoscopic Suturing System

Boston Scientific
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Endoscopic sleeve gastroplasty: Setting the bar for endobariatrics

- 41% of adults in the United States are living with obesity[1]
- 99% will never receive a surgical treatment[2]

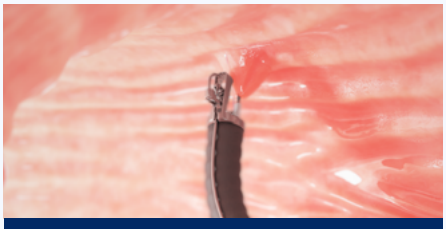
Introducing ESG

Endoscopic sleeve gastroplasty, or ESG, is a weight loss procedure that reduces the volume of the stomach using an endoscopic suturing device. Under general anesthesia, a gastroenterologist or surgeon uses the OverStitch Endoscopic Suturing System to apply 6-8 plications along the greater curve of the stomach.

- No incisions or scars
- Typically a same day procedure
- Organ-sparing, reversible
- Preserves future treatment options

Procedure

A specially trained endoscopist uses the OverStitch Endoscopic Suturing System to create a series of plications in the stomach, forming a sleeve endoscopically. Over time, scarring and bridging tissue maintains the reduced gastric volume. In addition to reducing volume, studies suggest ESG delays gastric emptying, which may alter appetite-related regulatory pathways.[3,4]



6-8 running sutures are placed in a U-shaped pattern along the greater curve of the stomach.

When tightened and secured, the sutures draw together the anterior and posterior walls of the greater curve to shorten gastric length and reduce diameter.

The endoscopic plications result in similar shape to laparoscopic sleeve gastrectomy, but with the fundus and antrum spared.

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The OverStitch Endoscopic Suturing System is intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss by reducing stomach volume through endoscopic sleeve gastroplasty in adult patients with obesity with BMI 30-50 kg/m^2 who have not been able to lose weight, or maintain weight loss, through more conservative measures. Completion of training is an FDA requirement to order the OverStitch Endoscopic Suturing System.

Clinical evidence

The body of evidence supporting the safety, effectiveness, and durability of the ESG procedure has been developed over 10 years and includes both level 1 evidence and large meta-analyses.

- 25,000 ESG procedures performed worldwide
- 10,000 patients included in clinical studies
- More than 250 clinical papers and abstracts published on the ESG procedure, including follow-up out to 5 years[4]

MERIT study

The Multicenter Endoscopic Sleeve Gastroplasty Randomized Interventional Trial (MERIT) evaluated the safety and effectiveness of ESG versus a medically monitored regimen of diet and healthy lifestyle over a 2 year period, n=216.

- 49% excess body weight loss at 12 month
- 68% maintained most of their weight loss out to 2 years
- 2% rate of serious adverse events (Clavien-Dindo Grade III or higher)
- 100% of patients without new or worsening GERD
- 92% of patients with DM Type II experienced clinical improvement according to their physician
- 67% of patients with HTN experienced clinical improvement according to their physician

*As of February 2024.

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Meaningful results

~70-80% stomach reduction
ESG reduces stomach volume and delays gastric emptying, resulting in earlier satiety and weight loss.

Meaningful weight loss
Patients lost an average of 13.6% of total body weight at 1 year, according to a level 1 clinical evidence study.[3]

Fast recovery
In a study, patients went home the same day as the procedure and returned to routine activities in 2-3 days.[3]

As a condition of the FDA De Novo Authorization of the Overstitch NXT and Overstitch Endoscopic Suturing System for endobariatric procedures (formerly referred to as the Apollo ESG and Apollo REVISE Systems), the devices should only be used for Endoscopic Sleeve Gastroplasty (ESG) or to enable transoral outlet reduction (TORe) as a bariatric revision procedure by gastroenterologists and surgeons who have undergone specific training by the device manufacturer.

To fulfill the FDA requirement and special controls for these devices, Boston Scientific is required to independently host courses with consistent training curricula. More information regarding the referenced ESG and TORe revision procedure training courses is available through Boston Scientific.

Sources

1. National Health and Nutrition Examination Survey (NHANES). 2021. https://stacks.cdc.gov/view/cdc/106273.
2. ASMBS. Estimate of Bariatric Surgery Numbers 2011-2020.
3. MERIT Study. The Lancet. 2022, n=216.
4. Sharaiha, et al. CGH. 2020.

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