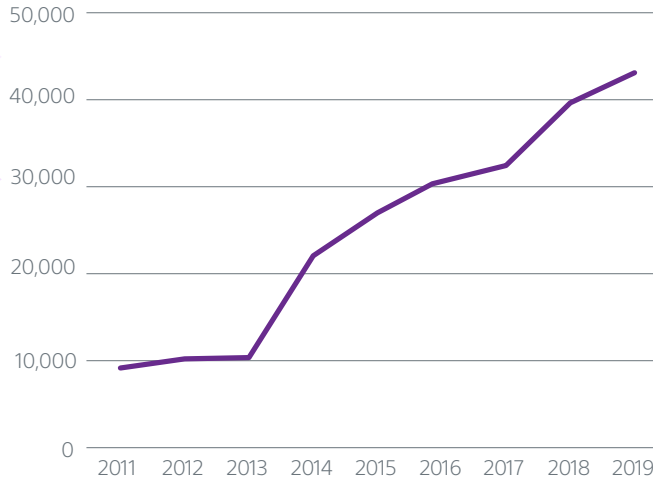


# **TORe: Transoral Outlet Reduction**

Re-envision  
bariatric revisions



## Revisions are the fastest growing segment of the bariatric surgery market<sup>1</sup>.



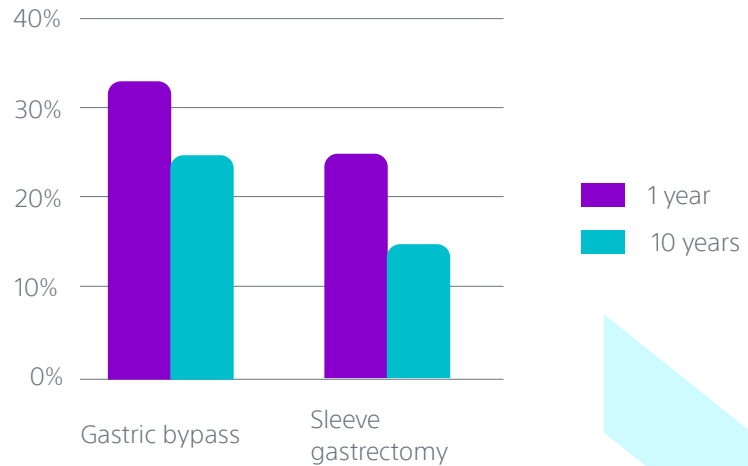
- ~17% of bariatric procedures are revisions
- ~42K revisions were performed in 2019
- Revisions can range from anatomic modifications to complete conversions through to end-stage procedures.



## Weight regain after a primary procedure is increasingly recognized as part of the chronic disease process.

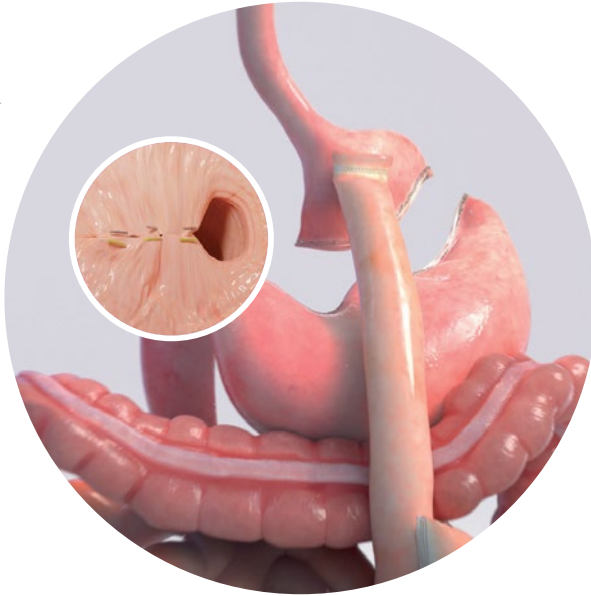


Durability: TBWL at 1 year vs 10 years<sup>2</sup>



# Introducing TORe

Transoral Outlet Reduction (TORe) is an endoscopic procedure to revise a Roux-en-Y gastric bypass. TORe and gastric pouch reduction can address anatomic dilation to induce weight loss. TORe is performed using the OverStitch™ System.



- No incisions or scars
- A same-day procedure for many patients
- Low adverse event rate<sup>3</sup>

## Endoscopic revisions are well studied in the clinical literature.



An estimated 15,000 endoscopic bariatric revisions have been performed worldwide.<sup>4</sup>



>150 papers and abstracts published on the TORe procedure.<sup>5</sup>



The OverStitch™ System is CE-marked for transoral outlet reduction procedure for weight loss.



## How is T0Re performed?

A specially-trained gastroenterologist or surgeon uses the OverStitch™ System to reduce the size of the gastrojejunal outlet back and if needed, can reduce the gastric pouch. T0Re is performed under general anesthesia, often as a same day procedure. Anatomic modifications result in earlier satiety and weight loss.



Interrupted sutures



Purse-string technique

Sutures are placed in an interrupted, running, or circumferential (purse string) pattern to reduce the size of the outlet.



Endoscopic view  
of pouch reduction



Abdominal view  
of pouch reduction

Additional suturing can be performed to reduce the size of the gastric pouch, if required.



# Clinical evidence



6%

## Effectiveness

Large meta-analysis showed an average of 6% total body weight loss (TBWL) at 12 months<sup>6</sup>.



9-12%

## Latest Technique

Latest studies using the purse-string approach report 9-12% TBWL at 12 months.<sup>7,8</sup>



5 & 7  
Years

## Durability

Long-term studies support durable weight loss at 5 and 7 years.<sup>7,9</sup>

## A study showed few adverse events and similar long-term weight loss when compared to laparoscopy.<sup>3</sup>

	TORe n=31	LAP n=31	p-value
Effectiveness at 5 years	11.5% TBWL	13.1% TBWL	0.67
Adverse events	6.5%	29.0%	0.04
Safety profile	0% SAE* rate	19.4% SAE rate	0.024

Dolan, et al; Gastrointestinal Endoscopy. 2021

- Matched cohort population
- Multicentric
- Long follow-up studies: 5yrs

\* Values are n (%). Adverse event rate comparison between endoscopic and surgical gastrojejunal anastomosis revision. Serious adverse events were determined in reference to the American Society for Gastrointestinal Endoscopy lexicon for reporting endoscopic adverse events and the National Surgical Quality Improvement Program. Early events defined as those occurring within 30 days of revision.



## 5 & 7 year data demonstrates durable and clinically meaningful weight loss.



**8.6%**

TBWL maintained  
by TORe patients  
at 5 years<sup>7</sup>

**8.4%**


TBWL for subset  
of patients from same  
study followed to 7 years<sup>9</sup>



**Minimal  
SAEs**

SAEs in both studies,  
evaluating 342 and 443  
patients respectively.<sup>7,9</sup>

In the 5-year data,  
11 of 342 patients experienced  
moderate AEs.



# Endobariatric Solution Portfolio complements a comprehensive endobariatric program



## Orbera365 IntraGastric Balloon System

- Temporary saline-filled balloon
- Placed and removed endoscopically under sedation
- Patients typically return home the same day
- Removal at 12 months
- Future treatment options preserved



## Endoscopic Sleeve Gastroplasty with OverStitch™ System

- CE Marked for Primary Endobariatric Procedures
  - A restrictive, gastric-only procedure targeting 70-80% reduction of stomach volume
  - Performed under general anesthesia
  - Many patients return home the same day
  - Preserves both the fundus and the antrum
  - Future treatment options preserved



## Revisonal Procedures OverStitch™ System

- CE-marked for transoral outlet reduction
  - Revision of prior bypass surgery
  - Performed under general anesthesia
  - Alternative to surgical revision
- Other revisonal procedures:
  - Revision of LSG
  - ESG re-tightening



- 1 ASMBS. 2019 data.
- 2 Sjostrom. Review of the key results of the Swedish Obesity Subjects (SOS) trial – a prospective controlled intervention study of bariatric surgery. 2013.
- 3 Dolan, et al; Endoscopic versus surgical gastrojejunal revision for weight gain in Roux-en-Y gastric bypass patients: 5-year safety and efficacy comparison. Gastrointestinal Endoscopy. 2021.
- 4 Estimates based on Apollo Endosurgery internal sales data.
- 5 Data on file.
- 6 Jarunvongbanich et al. Endoscopic full-thickness suturing plus argon plasma mucosal coagulation versus argon plasma mucosal coagulation alone for weight regain after gastric bypass: a systematic review and meta-analysis. Gastrointestinal Endoscopy. 2020.
- 7 Jirapinyo, et al. Five-year Outcomes of Transoral Outlet Reduction for the Treatment of Weight Regain After Roux-en-Y Gastric Bypass. Gastrointestinal Endoscopy. 2020.
- 8 Meyers, et al. Factors associated with weight loss after endoscopic transoral outlet reduction (TORE). Gastrointestinal Endoscopy. Volume 95, No. 6S. 2022.
- 9 Jirapinyo, et al. Seven-year Outcomes of Transoral Outlet Reduction for the Treatment of Weight Regain After Roux-en-Y Gastric Bypass. Gastrointestinal Endoscopy. 2020. Subset of patients included in study are also represented in 5-year data.

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