

Orbera365™ is an endoscopic product that helps patients lose weight and learn healthy habits when combined with diet, exercise, and behavioral counseling. Orbera365™ helps jump-start patients on a healthier path.

- Straight-forward, endoscopic option
- Tolerated by the majority of patients^{1,2}
- Proven weight loss results^{1,2}
- Encourages portion control

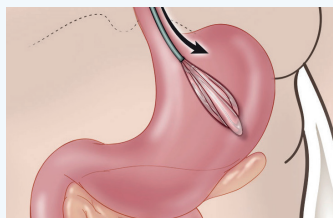


The Orbera365™ Advantage

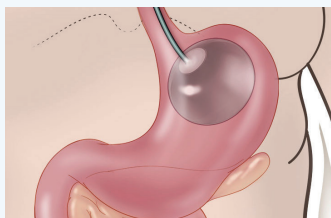
- A reversible, endoscopic weight loss procedure. Future treatment options are preserved.
- Over 400,000 balloons distributed worldwide.⁶
- Over 20 years of clinical history.⁶

Procedure

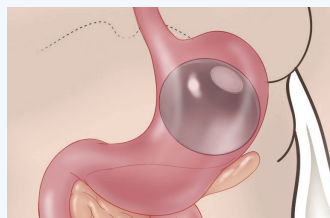
Orbera365™ is placed endoscopically to help fill the stomach and encourage portion control, combined with lifestyle and behavioral modification. Upto 12 months later, the balloon is removed, and the patient should continue their healthy diet and exercise plan.



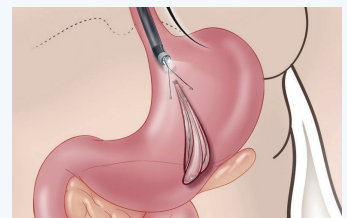
While the patient is under sedation, a trained gastroenterologist or surgeon inserts the deflated Orbera365™ balloon endoscopically.



The balloon is then filled with a sterile saline solution to a volume of 400-700 cc.



The smooth, soft, spherical Orbera365™ balloon takes up space in the stomach and delays gastric emptying, aiding in weight loss.



At maximum 12 months, the Orbera365™ balloon is removed endoscopically. The removal should be scheduled in advance to avoid the chance of prolonged dwell time.



FDA approved

The Orbera365™ Intragastric Balloon System is indicated for use as an adjunct to weight reduction for adults with obesity with Body Mass Index (BMI) of ≥ 30 and ≤ 40 kg/m² and is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of significant long-term weight loss and maintenance of that weight loss. The maximum placement period for Orbera365™ is 12 months.

Designed to be the ideal intragastric balloon

The Orbera365™ balloon was designed to fulfill the consensus criteria of a multi-disciplinary international physician collaboration, which listed the features of an ideal intragastric balloon effective in producing weight loss.^{3,4,5}

- Non-ulcerogenic: smooth, soft, and spherical
- Saline filled to induce satiety
- 400–700 cc variable fill volume
- Precise visualization of position via radiopaque valve

Strong clinical legacy

- Commercially launched outside of the U.S. in 2004 and used in over 80 countries.
- Over 525 peer-reviewed publications around the globe, including data on over 32,000 patients.⁶
- In a US Pivotal Study, patients achieved 3.1x more weight loss than diet and exercise alone.¹



Orbera365™ Intragastric Balloon System

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Supported by a programmatic approach

Educational programs and resources are available for program staff to support optimal pre- and post-procedural care.

Physician training on the Orbera365™ Intragastric Balloon System is an FDA requirement for purchase and use. Training covers placement, removal, pre- and post-procedural management, and adverse event management.

Before placement

Physician and program staff work with patients to ensure appropriate screening, expectation setting, and procedural preparedness.

Placement procedure

Patient should be monitored for accommodative symptom management and any potential adverse events.

Upto 12 months placement

Nutritional and lifestyle coaching supports early weight loss and sustainable behavioral changes.

After removal

Ongoing nutritional and lifestyle coaching should continue 6+ months to support weight loss and long-term success.



Sources

1. Courcoulas et al. Intragastric balloon as an adjunct to lifestyle intervention: a randomized controlled trial. Int J of Obesity. 2017. US FDA Pivotal Study.
2. Moore et al. Safety and effectiveness of an intragastric balloon as an adjunct to weight reduction in a post-marketing clinical setting. Obesity Surgery. 2020.
3. Nieben et al. Intragastric balloon as an artificial bezoar for treatment of obesity. Lancet. 1982.
4. Schapiro, et al. Obesity and the gastric balloon: a comprehensive workshop. Tarpon Springs, Florida, Gastrointest Endosc. 1987.
5. Silva et al. Intragastric balloon. Minim Invasive Ther Allied Technol. 2022.
6. Data on file. Based on sales data as of December 2023.

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