

The global leading* Weight Loss gastric balloon

orbera365™ | Managed Weight Loss
System



*Data on file

Diet & Exercise

Achieving success with diet and exercise alone can be difficult and discouraging.

Pharma

Newer pharmaceutical options have emerged but can be expensive to take long-term or cause rebound weight gain when discontinued.



**Historically,
Weight loss
options for
patients with
obesity have
been limited**

Surgery

Bariatric surgery can be an effective option for patients, but 99% of people with obesity will never receive surgery.¹

The majority have not even considered weight loss surgery.²

Orbera365™ is an effective, endoscopic weight loss option

An endoscopic procedure 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.¹



- Straightforward, endoscopic option
- Well tolerated by the majority of patients²
- Proven weight loss results compared to diet alone^{3,4}
- Helps patients learn healthy eating habits and adopt lifestyle changes for long-term success

¹ Data on file

² Sallet JA, Marchesini JB, Paiva OS et al. Brazilian Multicentre Study of the Intragastric Balloon. Obesity Surgery 2004; 14:991-998.

³ Genco A, Balducci S, Bacci V et al. Intragastric Balloon or Diet Alone? A Retrospective Evaluation. Obes Surg 2007; (DOI 10.1007/s11695-007-9383-9).

⁴ US Pivotal Study

The Orbera365™ advantage



A reversible, endoscopic weight loss procedure. Future treatment options are preserved.



Over 50,000 Orbera365™ balloons distributed worldwide.¹



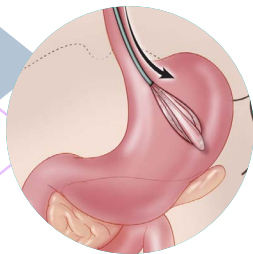
The global leading weight loss balloon in sales with 5 years of clinical history.²

¹ Data on file

² Based on sales data

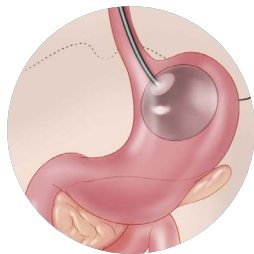
How is Orbera365™ performed?

Orbera365™ is placed endoscopically to help fill the stomach and encourage portion control, combined with lifestyle and behavioral modification. The balloon is removed twelve months later, with the patient continuing to follow their healthy diet and exercise plan.



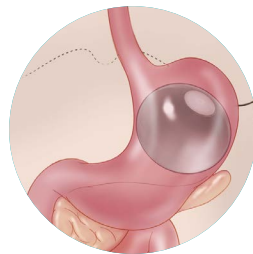
Step 1

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



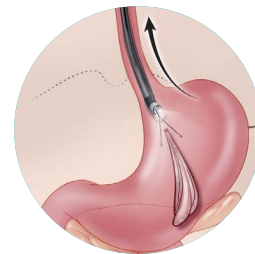
Step 2

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



Step 3

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



Step 4

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

CE-marked

The Orbera365™ Intragastric Balloon System is a weight loss aid for adults living with obesity who have tried other weight loss programmes, such as following supervised diet, exercise, and behavior - modification programmes, but who have been unable to lose weight and keep it off. To be eligible for an ORBERA365, a patient must be willing to follow an 18-month programme. This begins with the placement of the ORBERA365 and continues 6-months after removal, the programme also includes a healthy diet and exercise plan.



Orbera365™ has been CE-marked
under the European MDR
for weight loss in patients with obesity.



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.¹

- Non-ulcerogenic → Smooth, soft, and spherical
- Fluid-filled → Saline-filled to induce satiety
- Variable fill volume → 400-700cc
- Radiopaque valve → Precise visualization of position



¹ Schapiro M et al. Obesity and the gastric balloon: a comprehensive workshop. Tarpon Springs, Florida, March 19-21, 1987. Gastrointest Endosc

Strong clinical legacy



The Orbera365™ was commercially launched outside of the U.S. in 2018 and is used in over 70 countries.



Over 525 peer-reviewed publications on Apollo's gastric balloons around the globe, including data on over 32,000 patients.³



3.1x more weight loss than diet and exercise alone according to the US Pivotal Study.⁴

Supported by a programmatic approach

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

Physician training on the Orbera365™ Intra gastric Balloon System aims to cover placement, removal, pre- and post-procedural management, and adverse event management.

Before Placement

Physicians and programme staff work with patients to ensure appropriate screening, expectation setting, and procedural preparedness.

Placement Procedure

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

12-Month 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 ensure long-term success.

The Orbera365™ Intra gastric Balloon System is a weight loss aid for adults suffering from obesity who have tried other weight loss programmes, such as following supervised diet, exercise, and behavior modification programmes, but who were unable to lose weight and keep it off.

To receive Orbera365™, a patient must be willing to also follow an 18-month programme, beginning with placement of Orbera365™ and continuing for six months after, this includes a healthy diet and exercise plan. If the diet and exercise programme is not followed, patients may not experience significant weight loss results.

After placement, the patient and physician should maintain communication as the patient acclimates to the balloon. Early nausea and vomiting are expected. In cases where the patient experiences severe pain or vomiting, they should contact their physician immediately. In rare cases, severely delayed gastric emptying can lead to perforation. If undetected this can lead to sepsis and death. In such cases, the balloon must be removed immediately.

Potential adverse events include nausea, vomiting, balloon deflation, hyperinflation after the procedure, delayed gastric emptying, perforation and death.

For a full listing of adverse events, refer to the instructions for use at apolloendo.com/dfus.

Orbera365™ is placed for no more than 12 months. Extended dwell time increases the risk of certain adverse events, most notably balloon deflation, which can lead to a blockage in the stomach or intestines. Some patients are ineligible to receive Orbera365™. Patients must not receive Orbera® if they are pregnant or planning to become pregnant within six months or are breastfeeding.

All patients need to review and understand all the complications and risks before undergoing any procedure. Physicians will always act as independent agents and use their independent medical judgement to determine whether any procedure is in the best interest of any particular patient.

Patient information booklet available online at apolloendo.com/dfus.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found at apolloendo.com/dfus. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material is not intended for use in France.

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Individual Weight Loss May Vary

¹ ASMBS. 2019 data.

² Internal patient market research. Nov 2021. n=1,171.

³ Data on file.

⁴ Orbera® US FDA Pivotal Study.

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Advancing science for life™

apolloendo.com/physicians/orbera365