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Advancing science for *life*™

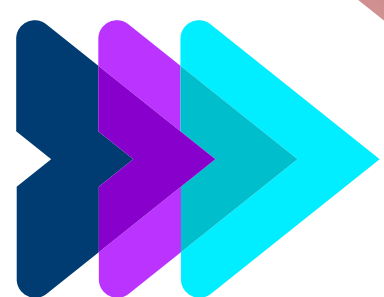
# Orbera365™ Intragastric Balloon System

A Minimally Invasive Option for Effective,  
Proven Weight Loss Results

 [Start](#)

The Orbera365™ Intragastric Balloon System is  
one of the procedures that is part of Endura  
Weight Loss Solutions from Boston Scientific.

**endura**  
Weight Loss Solutions





### **Diet & Exercise**

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



### **Pharma**

Newer pharmaceutical options have emerged, but they can be expensive for long-term use.<sup>1,2</sup>



### **Surgery**

Bariatric surgery can be an effective option for patients, but 99% of people with obesity will never receive surgery.<sup>3</sup> The majority have not even considered weight loss surgery.<sup>4</sup>



**Historically, weight loss options for people living with obesity have been limited.**





## Orbera365™ is a minimally invasive, effective weight loss option

A temporary option designed to help patients adjust to smaller portion sizes and adopt healthier eating habits. With lifestyle changes, Orbera365™ supports effective, proven weight loss.



- Straightforward, endoscopic procedure.
- Well tolerated by the majority of patients.<sup>5,6</sup>
- Proven weight loss results.<sup>5,6</sup>



# The Orbera365™ advantages



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



Over 500,000 Orbera365™ balloons placed worldwide.<sup>7</sup>



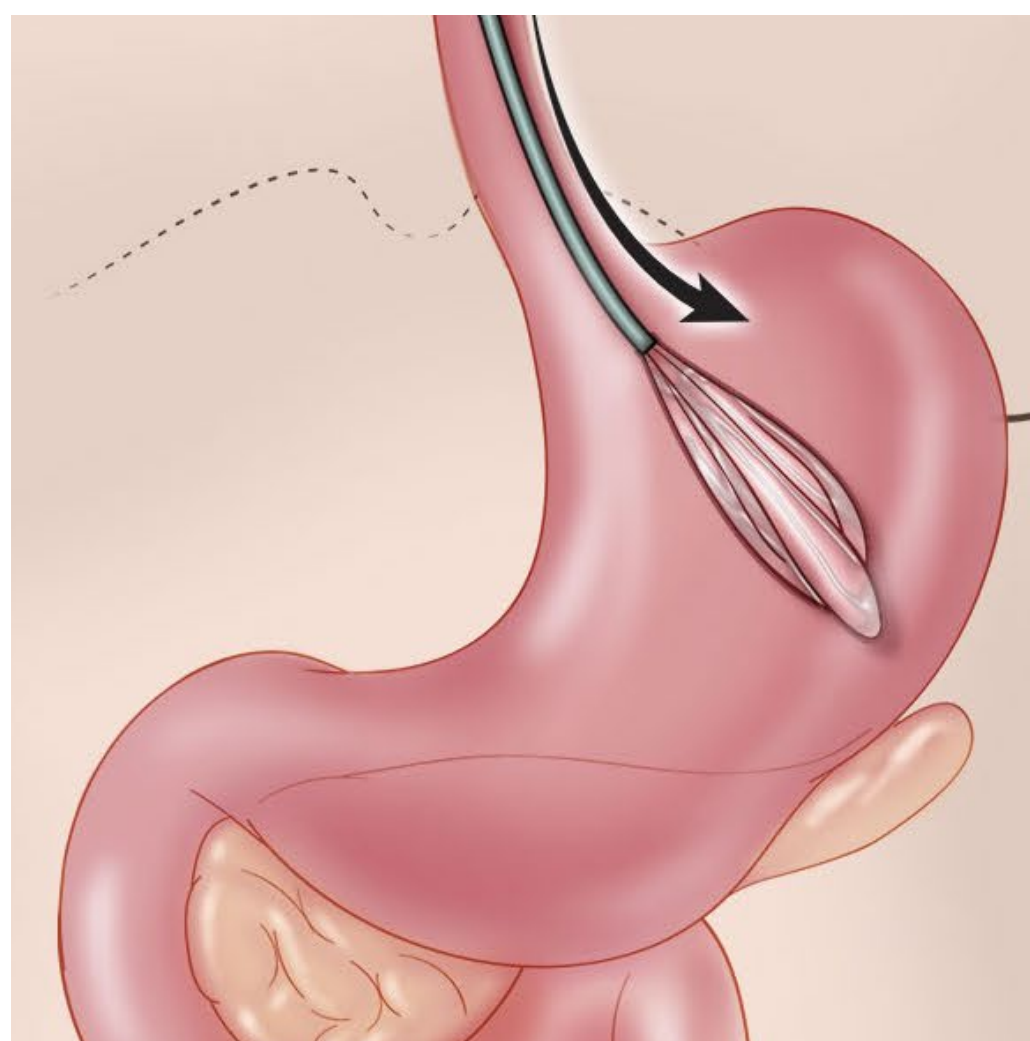
Over 20 years of clinical history.<sup>8</sup>





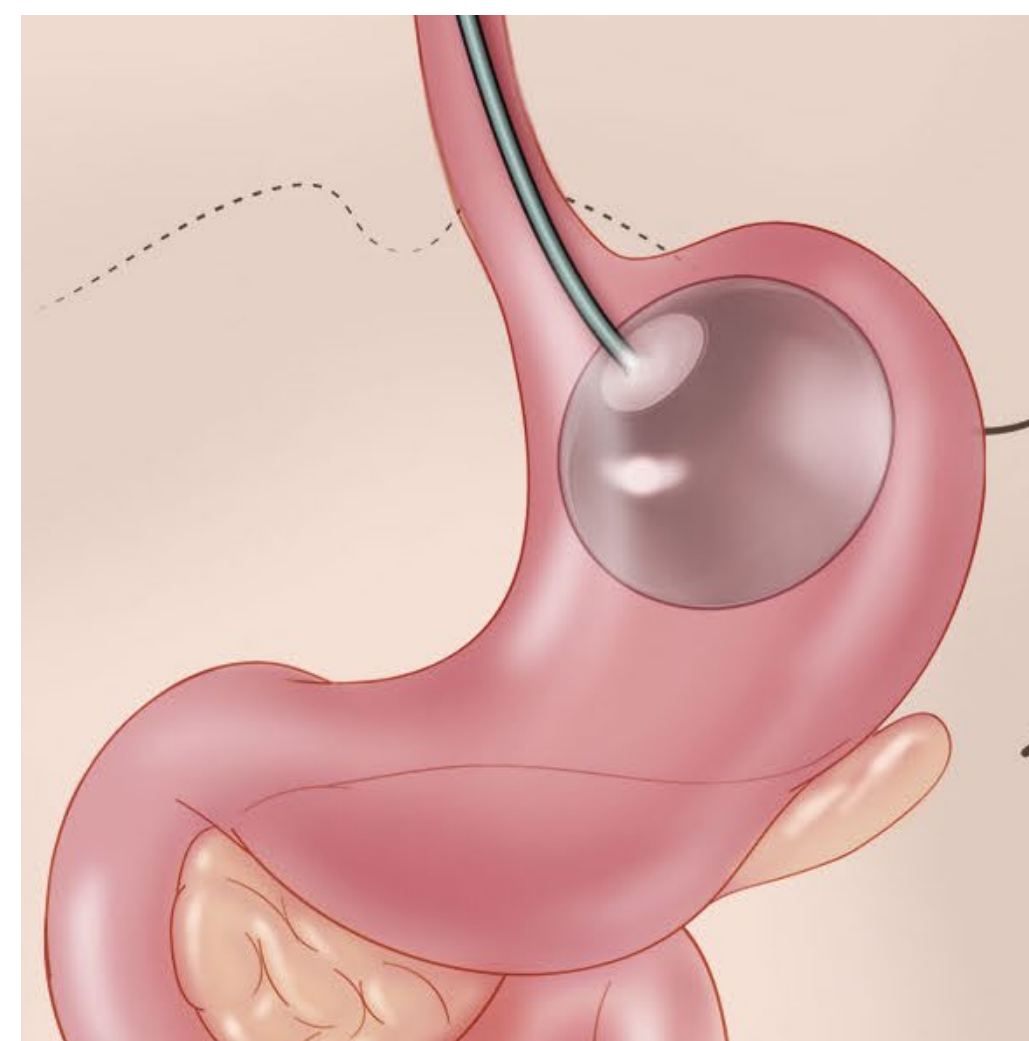
## How is Orbera365™ performed?

The balloon is inserted through the mouth during a quick procedure, filled to take up space in the stomach, and removed after 12 months. With lifestyle changes, it supports effective, proven weight loss.



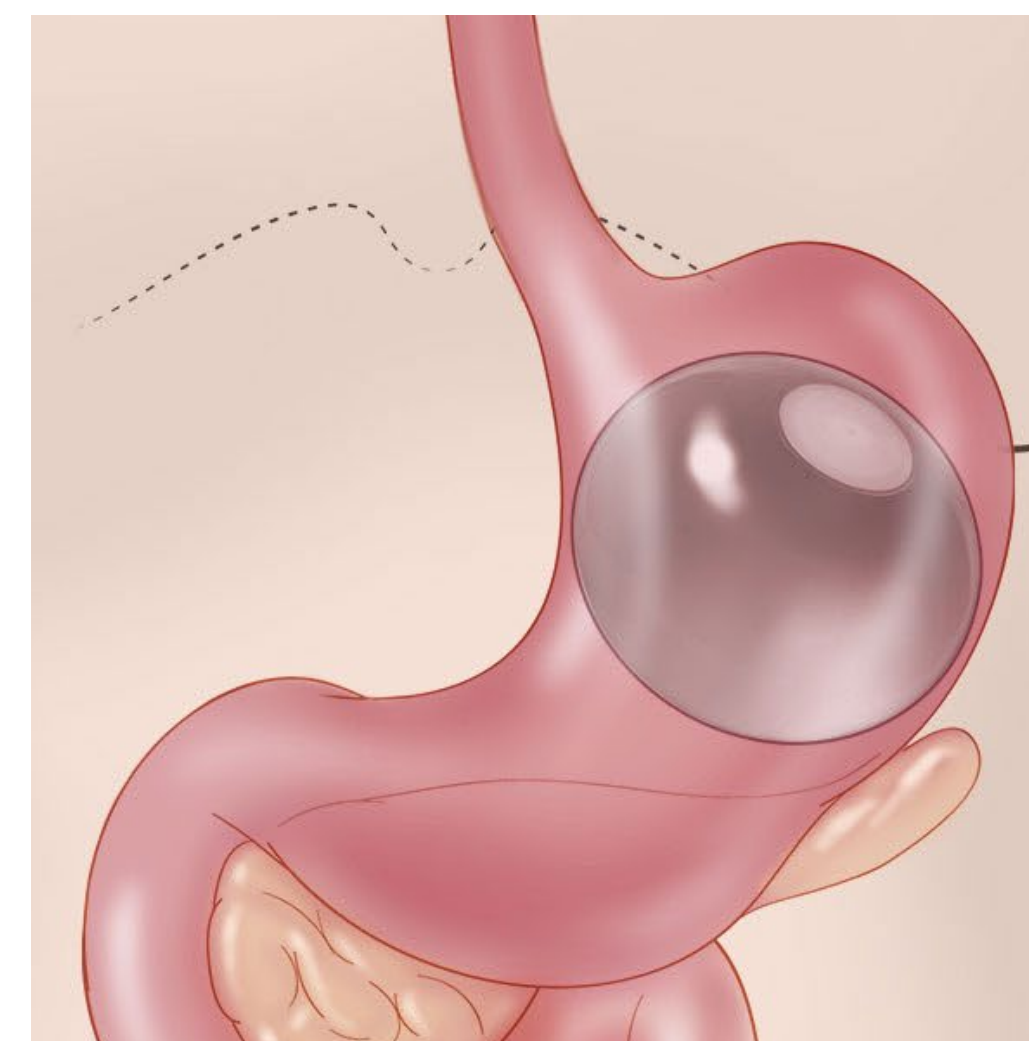
### Step 1

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



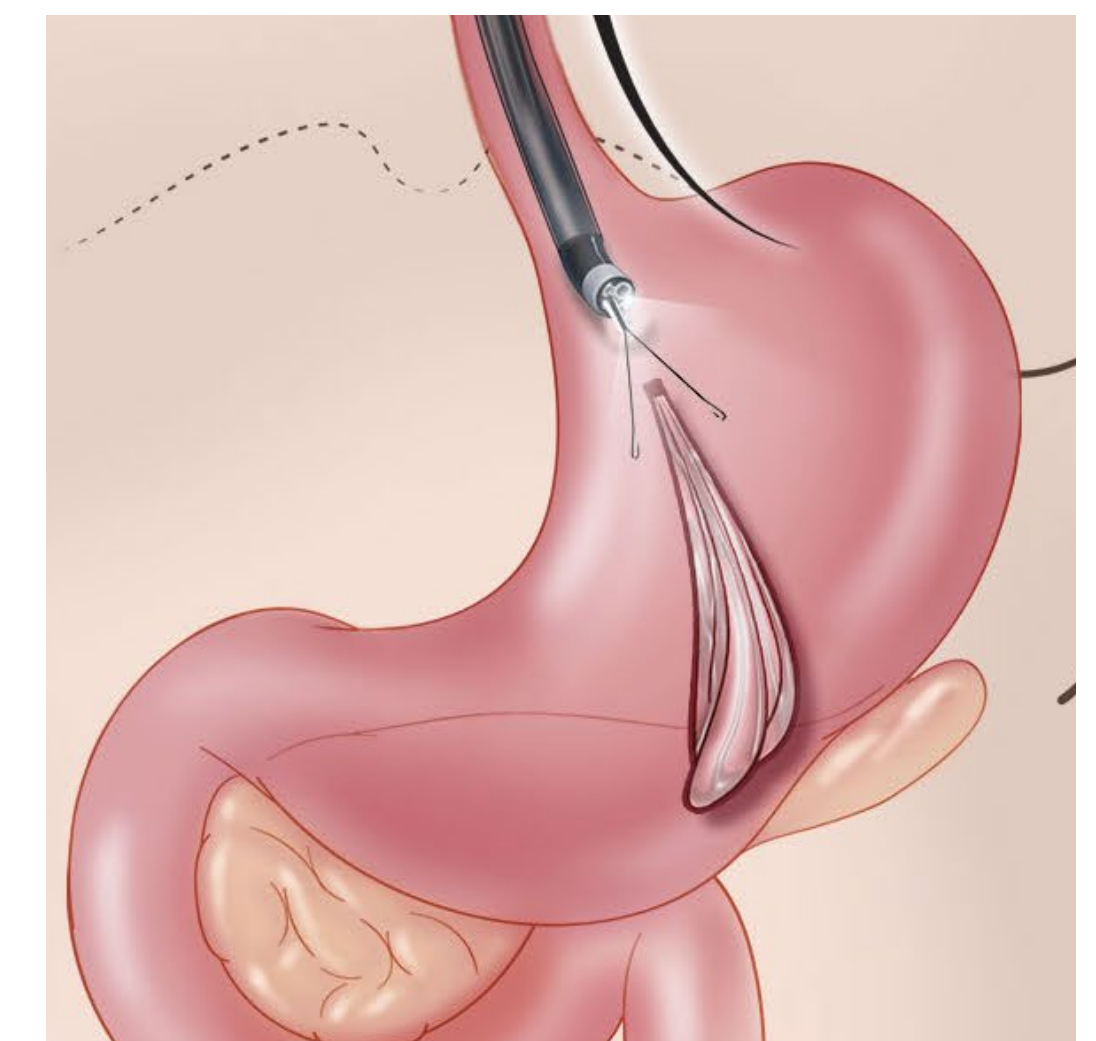
### Step 2

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

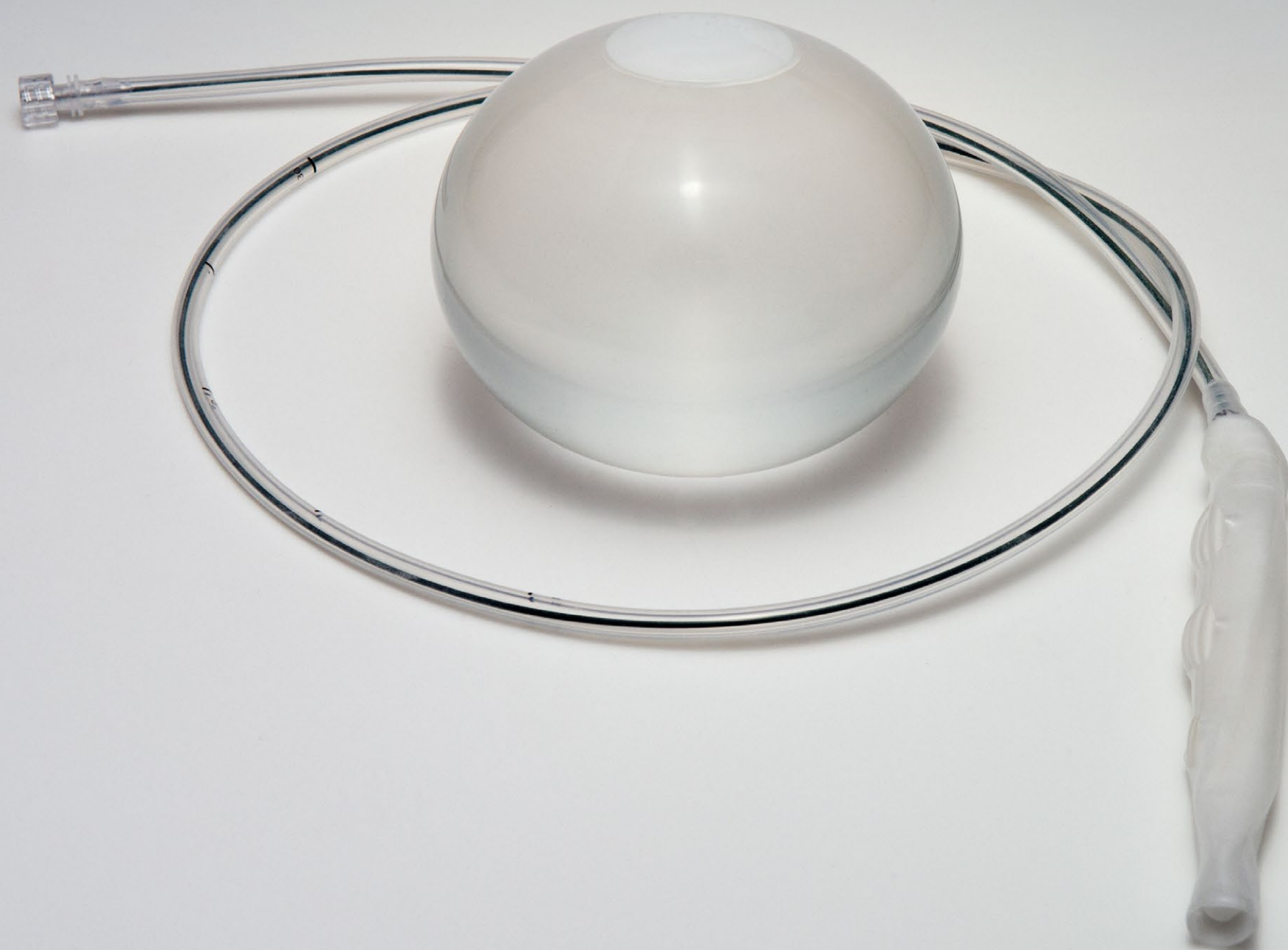
After 12 months, the Orbera365™ balloon is removed endoscopically. The removal should be scheduled in advance to avoid the chance of prolonged dwell time.





## 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.<sup>9</sup>



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



## Proven results



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 the intragastric balloons around the globe, including data on over 32,000 patients.<sup>7</sup>

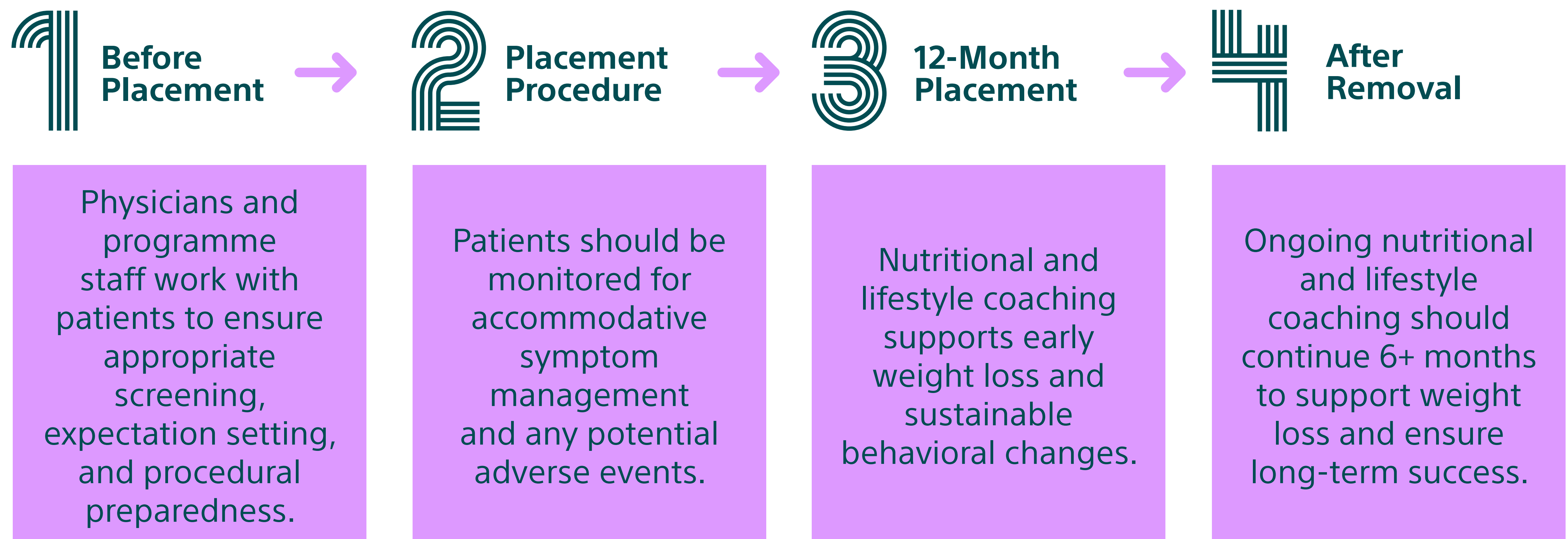


9.6 – 16.2% TBWL in 12 months.<sup>10</sup>



## 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™ Intragastirc Balloon System aims to cover placement, removal, pre- and postprocedural management, and adverse event management.







1. Saumoy et al. 2023. Cost-effectiveness of endoscopic, surgical and pharmacological obesity therapies: a microsimulation and threshold analyses.
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4. Internal patient market research. Nov 2021. n=1,171.
5. Jamal MH, Al-Kanawati N, ElAbd R, et al. A Study Examining the Orbera365 Intra-gastric Balloon Safety and Effects on Weight Loss. clinical. Obes Surg. Dec 2021;31(12):5342-5347. doi:10.1007/s11695-021-05729-8.
6. Wiggins T, Sharma O, Sarfaraz Y, Fry H, Baker J, Singhal R. Safety and Efficacy of 12-Month Intra-gastric Balloon-Series of over 1100 Patients. Obes Surg. Jan 2024;34(1):176-182. doi:10.1007/s11695-023-06953-0.
7. Calculations performed by Boston Scientific. Data on file.
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9. Schapiro M et al. Obesity and the gastric balloon: a comprehensive workshop. Gastrointest Endosc. 1987.
10. Direction for Use
  - ASGE Bariatric Endoscopy Task Force and ASGE Technology Committee, Abu Dayyeh BK, Kumar N, et al. ASGE Bariatric Endoscopy Task Force systematic review and meta-analysis assessing the ASGE PIVI thresholds for adopting endoscopic bariatric therapies. Gastrointest Endosc. 2015
  - Jamal, M. et al (2021). A Study Examining the Orbera365 Intra-gastric Balloon Safety and Effects on Weight Loss. Obesity surgery
  - Wiggins, T. et al (2024). Safety and Efficacy of 12-Month Intra-gastric Balloon-Series of over 1100 Patients. Obesity surgery

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 [www.IFU-BSCI.com](http://www.IFU-BSCI.com).

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 [www.IFU-BSCI.com](http://www.IFU-BSCI.com).

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 [www.IFU-BSCI.com](http://www.IFU-BSCI.com). 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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