ORBERA™ Managed Weight Loss System

Real Experience. Real Results.
20+ years of extensive global experience.
For many, the weight loss journey leaves them lost in the gap with few options.

Diets can be successful in the short-term, but often fail for many reasons.\footnote{1}

Growing number of pharmaceutical options with modest weight loss.

Most effective approach for long-term weight loss\footnote{1} but rejected by most patients as too invasive.
ORBERA™ is an effective weight loss option that fills the gap

ORBERA™ is a new incision-less, non-surgical option that gives your patients that edge. That boost. That momentum they need to amplify their weight-loss efforts and develop a more confident, healthier lifestyle.
For your patients:
A realistic approach to weight loss

Non-surgical two-part program

1. ORBERA™ Intragastric Balloon
2. Individually tailored support program
Globally proven with real world results

220,000 Devices placed worldwide

20 Years of intragastric balloon experience

FDA Approved
ORBERA™ delivers superior weight loss vs. Diet & Exercise<sup>4</sup>

Orbera is shown to be superior to diet & exercise—with Orbera, 3.1x the weight loss at 6 months

Weight loss is rapid—majority of the weight is typically lost in the first three months

US Pivotal Study—mean weight loss of 22lbs in 6 months
Designed to be the ‘ideal’ intragastric balloon

- Effective: 3.1x the wt. loss of diet & exercise
- Non-Ulcerogenic: Smooth, soft and spherical
- Fluid Filled: Saline filled to induce satiety
- Variable fill volume: 400-700cc range
- Radiopaque valve: Precise visualization of position
ORBERA™ Advantage

Proven to deliver significant weight loss

Straight-forward, non surgical procedure

Takes up space and helps patients eat smaller meals

Custom support provided by a team of experts

Learn eating habits and lifestyle changes for long-term success

Is not a drug or surgical therapy
Non-surgical procedure under mild sedative

Procedure takes 20–30 minutes – typically home same day

ORBERA™ balloon is placed into the stomach

Filled with saline until it’s about grapefruit size
Removal of ORBERA™

+ At six months
+ Non-surgical procedure under mild sedative
Well tolerated by the majority of patients

Adverse effects = nausea and vomiting typically resolve within one to two weeks

Minor complications = reflux oesophagitis & gastric stasis
Important ORBERA™ Intragastric Balloon System Safety Information

• Indications: The ORBERA™ Intragastric Balloon System is indicated for use as an adjunct to weight reduction for obese patients with body mass index (BMI) of \( \geq 30 \) and \( \leq 40 \) kg/m\(^2\). The ORBERA™ Intragastric Balloon System is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of significant weight loss and the maintenance of that weight loss. The ORBERA™ Intragastric Balloon System is intended for adult patients 22 years and older suffering from obesity, who have attempted more conservative weight reduction alternatives, such as supervised diet, exercise, and behavior modification programs. The maximum placement period for the ORBERA™ Intragastric Balloon System is 6 months.

• Contraindications: The ORBERA™ Intragastric Balloon System is not indicated for patients who currently have an intragastric balloon; have had gastrointestinal surgery; gastrointestinal inflammatory disease; potential upper gastrointestinal bleeding conditions; congenital or structural abnormality of the pharynx, esophagus or gastrointestinal tract (e.g., atresias, stenosis, a large hiatal hernia (>5 cm) or patulous pylorus); active H. pylori infection; delayed gastric emptying; gastric mass; or any other medical condition that would not permit elective endoscopy; have a major prior or present psychological disorder; have alcoholism or a drug addiction; who are unwilling to participate in an established medically-supervised diet and behavior modification program with routine medical follow-up; are receiving aspirin, anti-inflammatory agents, anticoagulants, or other gastric irritants, not under medical supervision; or are known to be pregnant or breast-feeding.

• Warnings: If ORBERA™ is not removed within 6 months after placement, there is greater risk of balloon deflation, which can lead to intestinal obstruction and risk for death. The risk of obstructions may be higher in patients with diabetes or dysmotility disorder or in patients who have had prior abdominal/GI surgery. Patients reporting loss of satiety, increased hunger, and/or weight gain should be endoscopically identified potential balloon deflation, and deflated devices should be removed promptly. The ORBERA™ System is composed of soft silicone elastomer and is easily damaged by instruments or sharp objects, so it must be handled only with gloved hands and the instruments recommended in the Directions for Use (DFU). Each patient must be monitored closely during the entire term of treatment in order to detect the development of possible complications, and patients who become pregnant or who are undergoing elective or emergency foregut surgery will require extraction of the ORBERA™ Intragastric Balloon.

• Adverse Events: Complications that may result from the use of ORBERA™ include the risks associated with any endoscopic procedure and those associated with the medications and methods used in this procedure, as well as the patient’s degree of intolerance to a foreign object placed in the stomach. Possible complications include: intestinal or esophageal obstruction by the balloon, insufficient or no weight loss, adverse health consequences resulting from weight loss, gastric discomfort, continuing nausea and vomiting, abdominal or back pain, gastroesophageal reflux, influence on digestion of food, blockage of food entering the stomach, bacterial growth in the fluid filling the balloon, injury to the lining of the digestive tract, gastric or esophageal perforation, and balloon deflation and subsequent replacement.

• Important: For full safety information please visit orbera.com, talk with your doctor, or call Apollo Customer Support at 1-855-MYORBERA.

• CAUTION: Rx only.

References:
2. Data on File: MMO-00256-00R01
3. 20 years – based on global ORBERA® & BIB® experience
4. Directions For Use (DFU). ORBERA™ Intragastric Balloon System (ORBERA™). Austin, TX: Apollo Endosurgery, Inc. © 2015 Apollo Endosurgery, Inc. All rights reserved. Any third-party trademarks used herein are the property of their respective owners.