



ABOUT THE ORBERA™ INTRAGASTRIC BALLOON

- The ORBERA™ IntraGastric Balloon is a soft yet durable silicone balloon that is designed to assist adult patients with obesity, in losing and maintaining weight. It is intended for adult patients with a Body Mass Index (BMI) of 30 to 40 who have attempted more conservative weight reduction alternatives.
- The balloon is part of the ORBERA™ Managed Weight Loss System - a comprehensive, non-surgical two-part program that starts with the durable balloon filling space in a patient's stomach to reinforce proper portion control.
 - In a non-surgical procedure typically done under a mild sedative, the thin and deflated ORBERA™ balloon is placed into the stomach. It is then filled with saline until it's about the size of a grapefruit. The procedure normally takes about 20-30 minutes and people can generally go home the same day.
 - Once the balloon is in place, the 12-month coaching program begins.
 - At six months, the balloon is removed in the same way it was placed. Through a non-surgical procedure done under a mild sedative, it is deflated and then removed.
- Data on ORBERA™ collected in the U.S. clinical trial has shown the average person lost 3.1 times the weight as compared with diet and exercise alone within six months.
- ORBERA™ is an incision-less, non-surgical solution for patients who are not appropriate for or considering invasive surgery, but for whom diet & exercise or pharmaceutical interventions have not worked.
- For many, the weight loss journey leaves patients with little support or options in the gap between diet & exercise and surgery.
- ORBERA™ is a safe and effective weight loss solution™ with over 220,000 placements worldwide.
- With over 20 years of global experience from the makers of ORBERA™, ORBERA™ is an FDA approved weight loss solution that focuses on developing sustainable, healthy habits that will help you keep the weight off over time.
- ORBERA™ is manufactured by Apollo Endosurgery Inc., a leader in minimally invasive endoscopic surgical products for bariatric and gastrointestinal procedures.

GLOBAL MARKET/DATA

- ORBERA™ is the number one global market leader for gastric balloons with more than 220,000 ORBERA™ balloons distributed worldwide in over 80 countries.
- For more than 20 years, the global medical community has been using gastric balloons from the makers of ORBERA™ to help thousands of people lose weight.
- ORBERA™ has been evaluated in over 230 published papers worldwide.

ORBERA™ CLINICAL RESULTS

- At month six, the ORBERA™ group achieved a mean of 38.4 percent Excess Weight Loss (EWL).
- Mean Total Body Weight Loss (TBWL) at six months was 10.2 percent for the treatment group compared to 3.3 percent TBWL for the control group.
- The ORBERA™ group lost 3.1 times as much weight as the control group at six months.
- The ORBERA™ group also lost significantly more weight than the control group over the course of the study, and was able to maintain significant weight loss through month 12, six months after removal of the device.

WHAT IS THE COST?

For those interested in ORBERA™, they should speak to an ORBERA™ Specialist in their area about pricing. They can assist the individual in understanding their costs and financing options.

Important ORBERA™ Intra-gastric Balloon System Safety Information

The ORBERA™ Intra-gastric Balloon System is a weight loss aid for adults with obesity, with a body mass index (BMI) ≥ 30 and ≤ 40 kg/m², who have tried other weight loss programs, such as following supervised diet, exercise, and behavior modification programs, but who were unable to lose weight and keep it off.

To receive ORBERA™ you must be willing to also follow a 12-month program, beginning with the placement of ORBERA™ and continuing for 6 months after, that includes a healthy diet and exercise plan. If the diet and exercise program is not followed, you will not experience significant weight loss results; in fact, you may not experience any weight loss.

Losing weight and keeping it off is not easy, so you will be supervised throughout this program by a team of physicians, physiologists, and nutritionists. This team will help you make and maintain major changes in your eating and exercise habits.

ORBERA™ is placed for no more than six months. Any time that the balloon is in the stomach for longer than six months puts you at risk for complications, such as bowel obstruction, which can be fatal.

Some patients are ineligible to receive ORBERA™. Your doctor will ask you about your medical history and will also perform a physical examination to determine your eligibility for the device. Additionally, at the time of placement, the doctor may identify internal factors, such as stomach irritation or ulcers, which may prevent you from receiving ORBERA™.

You must not receive ORBERA™ if you are pregnant, a woman planning to become pregnant within six months' time, or breast-feeding.

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 your ability to tolerate a foreign object placed in your stomach. Possible complications include: partial or complete blockage of the bowel by the balloon, insufficient or no weight loss, adverse health consequences resulting from weight loss, stomach discomfort, continuing nausea and vomiting, abdominal or back pain, acid reflux, influence on digestion of food, blockage of food entering the stomach, bacterial growth in the fluid filling the balloon which can lead to infection, injury to the lining of the digestive tract, stomach or esophagus, and balloon deflation.

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

CAUTION: Rx only.

Reference: Directions For Use (DFU). ORBERA™ Intra-gastric Balloon System (ORBERA™). Austin, TX: Apollo Endosurgery, Inc.

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Sources:

1. Ideal weight based on BMI 25.