

Weight loss for patients with obesity

Orbera Balloon is intended for adults with obesity in the 30–40 BMI range who want a minimally invasive way to jump-start weight loss.

The Orbera Balloon is a temporary option designed to help patients adjust to smaller portion sizes and adopt healthier eating habits. The balloon is inserted through the mouth during a quick procedure, filled to take up space in the stomach, and removed after 6 months. With lifestyle changes, it supports effective, proven weight loss.

For the Orbera Balloon, you need to follow a healthy diet and exercise program to lose weight. You may not lose weight if you do not adopt healthy habits. Your doctor's clinical team, including dietitians, nutritionists, and/or exercise trainers, should help you on your weight loss journey.



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* Calculations performed by Boston Scientific based on sales data.

Reference

1. Courcoulas A, Abu Dayyeh BK, Eaton L, et al. Intra-gastric balloon as an adjunct to lifestyle intervention: a randomized controlled trial. US FDA Pivotal Study. *Int J Obes* (Lond). 2017;41:427–433. n=137 Orbera, n=136 control, p<0.001. Most of the patients from the US FDA Pivotal study were female and Caucasian. Because of this, data from this study may not accurately represent the same effectiveness and safety profile in Hispanic, African American, or other ethnic populations.

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CAUTION: U.S. Federal 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.

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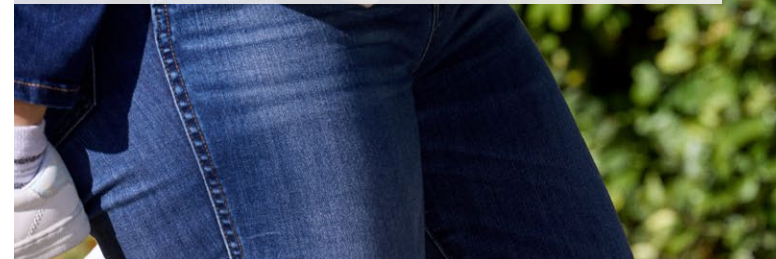
ENDO-2231806-AB NOV 2025

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Weight Loss Solutions

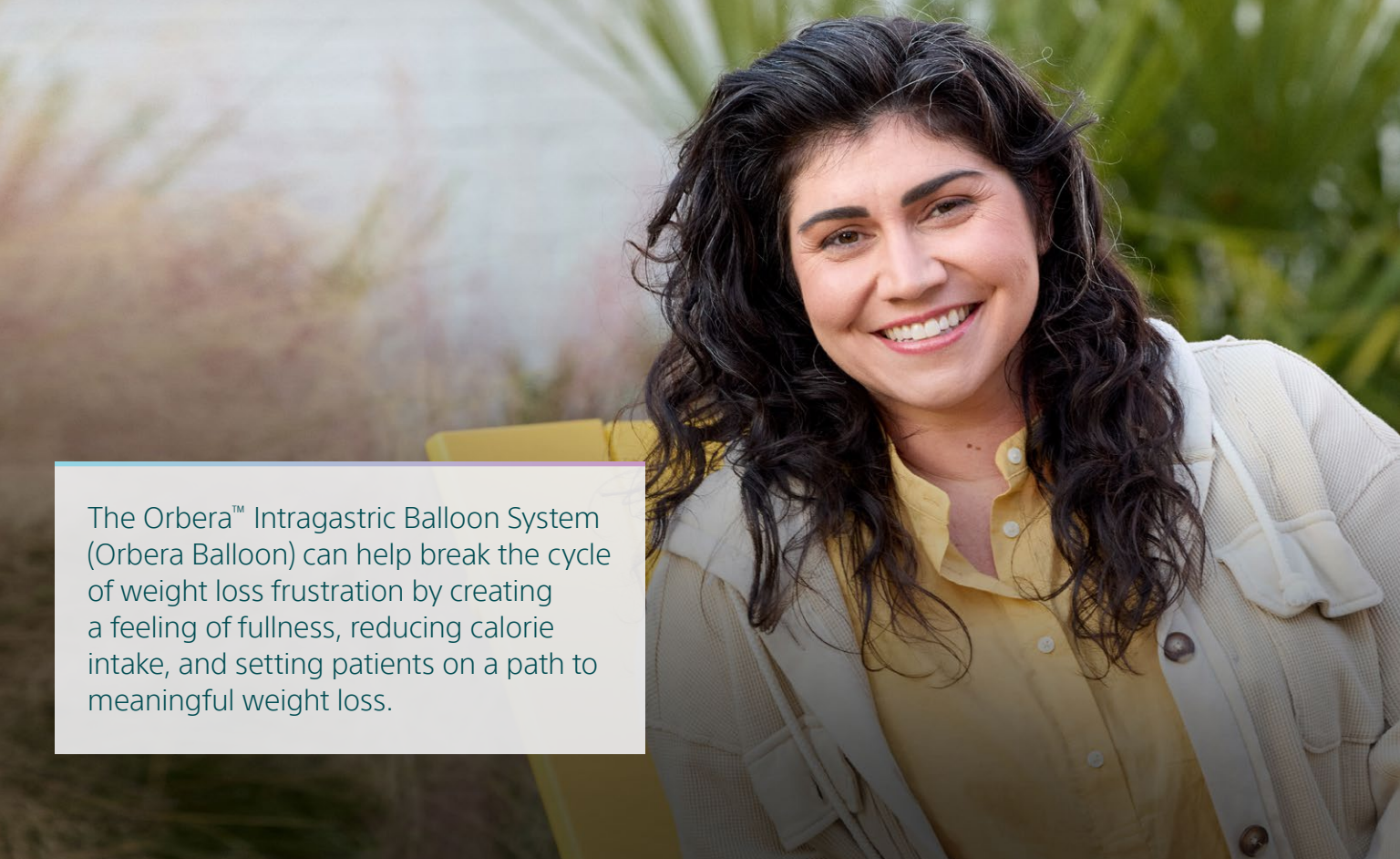


Jumpstart weight loss with the Orbera™ Intra-gastric Balloon System

A temporary option designed to help patients adjust to smaller portion sizes and adopt healthier eating habits



Intra-gastric Balloon (IGB)



The Orbera™ Intra gastric Balloon System (Orbera Balloon) can help break the cycle of weight loss frustration by creating a feeling of fullness, reducing calorie intake, and setting patients on a path to meaningful weight loss.

Minimally invasive weight loss

Placed through the mouth in an outpatient procedure, the Orbera Balloon is filled with saline to about the size of a grapefruit. After 6 months, it's removed in a similar, simple procedure.

Reshape your eating habits to maintain results

A clinical study found that patients maintained 75% of their weight loss 6 months after the Orbera Balloon was removed.¹

During the treatment period, the balloon helps retrain your body to recognize fullness with smaller portions, preparing you to continue healthier eating habits long after removal.

Leading intragastric balloon

With over 500,000* placements worldwide, our intragastric balloon products, including the Orbera Balloon, have helped patients successfully lose weight.

Effective weight loss

In a clinical study, Orbera Balloon patients lost three times more weight than with diet and exercise alone — about 10% of their total body weight.¹

ORBERA™ Intra gastric Balloon System ("ORBERA"): IMPORTANT SAFETY INFORMATION

Talk with your doctor to fully understand all the risks and benefits of using this device. Ask your doctor if this device is right for you.

INDICATIONS FOR USE: ORBERA is for temporary use in weight loss therapy. It is intended for obese adult patients with a Body Mass Index (BMI) of ≥ 30 and ≤ 40 kg/m². It is for those who have failed to achieve and maintain weight loss with a supervised weight-control program.

The maximum placement time for ORBERA is 6 months.

To receive ORBERA, you must be willing to follow a 12-month program. The program begins with the use of ORBERA. You must follow a healthy diet and exercise program for these first six months. After six months, ORBERA is removed. Then, you follow six more months of a healthy diet and exercise program without ORBERA.

CONTRAINDICATIONS: Your doctor will ask you about your medical history and will also perform a physical exam to determine if ORBERA is right for you. At the time of your procedure, the doctor may identify internal issues that prevent you from receiving ORBERA. For example, stomach ulcers or inflammation in the stomach may impact device placement.

You must not receive ORBERA if: you currently have another intragastric balloon implanted; you have had prior surgery involving your food pipe, stomach and/or small intestine or bariatric surgery; you know or suspect you may have an allergic reaction to the materials of ORBERA; you have poor general health or history and/or symptoms of several kidney, liver, heart and/or lung diseases; you have a serious or uncontrolled psychiatric illness or disorder; you have alcoholism or drug addiction; you are unable or unwilling to take prescribed medicine to lower stomach acid for the duration of the device implant; you are unwilling to participate in an established medically supervised diet and behavior modification program, with routine medical follow-up; you take aspirin, anti-inflammatory agents, blood thinners, or other medicines that irritate the stomach that a doctor does not regularly follow up on.; or you are pregnant or breast-feeding.

WARNINGS: Do not use ORBERA for more than six months. Prolonged placement may increase the risk of ORBERA deflating. A deflated ORBERA can cause blockage in the stomach or intestines, requiring surgery.

If you don't feel full, experience increased hunger, and/or weight gain, contact your doctor as this may be a sign of deflation.

You must maintain regular contact with your doctor while ORBERA is in your stomach. Nausea and vomiting are common when ORBERA is first placed. These symptoms typically improve in the first few weeks as you adjust to ORBERA. If you begin to feel intense stomach or back pain, either steady or cyclic, contact your doctor immediately. These may be signs of a major problem with your stomach and could lead to death. After you have adjusted to ORBERA, contact your doctor and seek immediate medical care if you once again begin to have nausea, vomiting, stomach or back pain, swelling of the upper stomach with or without discomfort, difficulty breathing or gastroesophageal reflux.

If you become pregnant at any time while ORBERA is in your stomach, contact your doctor. ORBERA should be removed as soon as it is safely possible.

POTENTIAL RISKS: Inhaling material into the lungs/difficulty breathing; bleeding; lack or loss of fluids leading to loss of normal body functions; bloating of stomach; heartburn/reflux, nausea, vomiting; infection; swelling and redness in the tissue; blockage, hole or tear in the digestive tract; uncomfortable feeling or pain; unintended expansion of ORBERA after placement in the stomach; injury or damage to the tissue; death

MRI SAFETY INFORMATION: ORBERA is Magnetic Resonance Imaging (MRI) safe. The implant can safely be scanned with MRI.