



# **ORBERA®**

## FREQUENTLY ASKED QUESTIONS

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### **WHO IS ELIGIBLE FOR ORBERA?**

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The Orbera weight loss program is designed for obese adults with a Body Mass Index (BMI) of 30 to 40 kg/m<sup>2</sup>, who have been unable to lose weight through diet and exercise.

### **WHO IS NOT ELIGIBLE FOR ORBERA?**

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You are not eligible for Orbera if you have had prior stomach or bariatric surgery, including hiatal hernia repair, lap band, or gastric bypass.

You are not eligible if you use anti-inflammatory medications (such as aspirin or ibuprofen) on a daily basis.

You are not eligible if you are pregnant or breastfeeding.

### **DOES INSURANCE COVER IT?**

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No, insurance does not cover the Orbera balloon, but we offer financing options.

### **WHY DOESN'T INSURANCE COVER IT?**

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At this time, it is considered a “cosmetic” procedure, even though weight loss can be expected to reduce your risk of other serious health issues.

### **WHEN WAS THIS PROCEDURE APPROVED BY THE FDA?**

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August 6, 2015

## **HOW LONG DOES THE PROCEDURE TAKE?**

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Both the balloon insertion and removal take approximately 20 minutes.

## **HOW IS THIS DIFFERENT THAN BARIATRIC SURGERY?**

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Orbera is a completely non-invasive, reversible weight loss treatment. The balloon is removed after six months and does not permanently alter your anatomy. It is performed under sedation but not general anesthesia (no ventilator is required).

## **HOW OFTEN DO I HAVE TO COME IN TO THE OFFICE AFTER THE PROCEDURE?**

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You will be seen by your physician approximately 1-2 weeks after your balloon is placed. You will meet with your dietician once each month for the entire 12-month treatment program. These sessions may be conducted in person, or via video conference (telemedicine) from the comfort of your home. Your physician will be available to see you throughout the treatment period, though we do not require mandatory office visits on a set schedule.

## **WHAT DOES IT FEEL LIKE TO HAVE THE BALLOON IN MY STOMACH?**

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Many people say it feels like they've eaten a large meal immediately after the procedure. You may experience nausea, cramping, and sometimes even vomiting in the first few days after placement, as the stomach is getting used to the balloon. After a few weeks, the ability to "tell" where the balloon is goes away. It is not noticeable during exercise, according to our patients.

## **CAN YOU SEE THE BALLOON IN THERE?**

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No, the balloon is not visible from the outside.

## **HOW MUCH WEIGHT WILL I LOSE?**

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Weight loss is rapid, with most weight loss occurring in the first 3-4 months. It is important for you to understand that the balloon is a tool to aid weight loss and must be used in conjunction with a diet, exercise, and behavior modification program. The amount of weight you lose and maintain will depend on how closely you follow your diet and adopt long-term lifestyle changes. In studies, people lost an average of 13% of their body weight at 6

months, and people with the balloon lost 3 times the weight of those on a diet and exercise program alone. That means that if you weigh 250 pounds, you would be reasonably expected to lose about 32 pounds. The range of weight loss depends on the person and their motivation. In general, patients in our program lose an average of 30-50 pounds.

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### **WILL I KEEP THE WEIGHT OFF?**

Long term success after Orbera will depend on whether you make the appropriate lifestyle and diet changes during the 12-month treatment program. The balloon itself is a very effective tool to promote weight loss, and 6 months is sufficient for most patients to sustain the behavioral changes they make. The overall program is 12 months long, so that we can monitor you and make sure that you continue to succeed after the balloon is removed. Studies show that most patients continue to lose weight for 3 months after the balloon is removed, then maintain their weight loss for the following year. After 1 year, a small percentage of patients may begin to regain weight.

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### **WHAT HAPPENS IF I DON'T LOSE AS MUCH WEIGHT AS I WANT, OR IF MY WEIGHT LOSS IS SLOWER THAN EXPECTED?**

We will closely monitor your progress during the Orbera treatment program to ensure that your weight loss is on track. If, despite optimizing your diet and exercise, you still need further assistance, we may recommend weight loss medications (pharmacotherapy) under the guidance of your treating physician. These medications can greatly enhance your weight loss, when used in conjunction with an Orbera balloon.

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### **CAN I HAVE THE ORBERA BALLOON A SECOND TIME?**

Yes. If for some reason you do not reach your weight loss goals following your initial Orbera treatment, it is possible to be treated again with an Orbera balloon. We would first assist you in addressing any underlying dietary, exercise, or behavioral factors that may have contributed to your insufficient weight loss.

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### **WHAT ARE THE RISKS OF THE PROCEDURE?**

Gastric balloons have been used in the management of obesity for over 20 years. Over this time they have evolved in shape, size, and design, resulting in a modern, durable product, which is now well established as a safe weight loss procedure. Over 300,000 ORBERA® balloons have been placed worldwide. The risk of a serious side effect is about 1 in 10,000. Potential serious side effects include stomach ulceration, balloon deflation, bowel obstruction, intestinal perforation, and death.

## **WHAT IS THE CHANCE THAT THE BALLOON WILL DEFLATE IN THE STOMACH?**

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Balloon deflation is a rare event, typically related to a balloon that has been in the stomach for over 6 months. This event is estimated to occur in 0.3% of patients (3 out of every 1000 patients).

## **CAN I EXERCISE WITH THE ORBERA BALLOON IN MY STOMACH?**

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Yes! Exercise is one of the keys to succeeding. We recommend a minimum of 30 minutes of exercise 5 days each week, and ideally a total of 60 minutes, 5 days a week. You can do any type of exercise you like, including walking, running, swimming, weight training, aerobics, kickboxing, even Crossfit! Our patients do every type of exercise you can think of. There are no restrictions.

## **CAN I TRAVEL OR FLY?**

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Yes, there are no travel restrictions with Orbera. The balloon is not affected by altitude, so it is safe to travel by plane.

## **CAN I SO SIT-UPS AND ABDOMINAL EXERCISES?**

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Yes! The balloon is not affected in any way by abdominal exercises, so feel free to train your core. The balloon is protected by your stomach and abdominal wall and won't be harmed by any type of routine abdominal exercise or activity.

