

## Informed Consent for Orbera Intra-gastric Balloon Administration

Patient Name \_\_\_\_\_  
DOB \_\_\_\_\_  
MRN \_\_\_\_\_

Please read this form carefully and ask about anything you may not understand.

I request that my physician perform an endoscopic placement of an **Intra-gastric Balloon** for the purposes of helping me to lose weight. I request that my physician and/or staff under his or her supervision perform the procedure, and direct my care during the procedure.

I understand that obesity is associated with early death and significant medical problems such as hypertension, diabetes, obstructive sleep apnea, high cholesterol, infertility, cancer, gastroesophageal reflux, arthritis, chronic headaches, gout, venous stasis disease, liver disease and heart failure, among other problems.

I understand that placement of an Intra-gastric Balloon, when combined with appropriate healthy behaviors including diet and exercise, can assist with weight loss and improve medical problems such as hypertension, diabetes, obstructive sleep apnea, high cholesterol, infertility, cancer, gastroesophageal reflux, arthritis, chronic headaches, venous stasis disease, liver disease and heart failure. I understand there are no specific guarantees that any one of these conditions will improve or resolve as a result of the procedure.

I understand the alternatives to Intra-gastric Balloon administration, which include both surgical and non-surgical options. The opportunity to discuss other surgical options such as the Roux-en-Y gastric bypass, sleeve gastrectomy, and duodenal switch has been made available to me. I also understand that non-surgical options including dieting and exercise are an important component of treatment following intra-gastric balloon placement in order to accomplish weight loss.

There are several types of Intra-gastric Balloons on the market currently.

I have chosen, in consultation with my surgeon, to request placement of the following balloon.  
\_\_\_\_ ORBERA balloon (endoscopically placed and removed)

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Date: \_\_\_\_\_

I understand the procedure as follows:

The intragastric balloon is placed endoscopically. The balloon is placed into the stomach and inflated. It is designed to help me to eat less and therefore lose weight. The intragastric balloon must be removed 6 months after placement. Removal of the balloon requires an additional endoscopic procedure. I will be compliant with my physician's determined time period for removal and further understand the risks associated with failure to remove the intragastric balloon. \_\_\_\_\_ (initials)

**I understand the risk of complications may be dependent on my particular medical history as well as my surgeon's level of training and experience. I have discussed these issues specifically with my surgeon.** \_\_\_\_\_

**I understand that the Orbera intragastric balloon is FDA approved for individuals with a Body Mass Index (BMI) between 30 and 40. If my BMI falls outside of this range, I understand that the balloon is being placed outside of FDA indication, and may pose additional risk to me.** \_\_\_\_\_

**I understand the risks of the Intragastric Balloon administration include, but are not limited, to the following:**

**Endoscopy-Related Risks:**

**Aspiration:** Regurgitation of stomach juices or food into the lungs can occur during balloon placement or removal. Severe aspiration is unlikely and the risk is decreased by fasting before the procedure. Severe aspiration can cause pneumonia, respiratory failure requiring support with a breathing machine, and even death. \_\_\_\_\_

**Significant Bleeding:** Significant bleeding after an endoscopic procedure is uncommon. Bleeding may occur during endoscopy or immediately afterwards. A blood transfusion may be necessary in these rare circumstances. Repeat endoscopy or surgery to stop bleeding may be necessary. \_\_\_\_\_

**Stomach or Esophageal Injury:** Injury to the stomach or esophagus is a rare complication that can cause life-threatening complications and may require emergency surgery for treatment, a prolonged hospital stay, a long period of nothing to eat, prolonged antibiotic requirements, organ failure and even death. \_\_\_\_\_

**Organ Failure:** In rare circumstances, organ failure may occur following intragastric balloon placement. This may include failure of the kidney, heart, lungs or liver. \_\_\_\_\_

**Prolonged Hospital Stay:** Complications may result in a prolonged hospital stay. In some cases surgery may be necessary to treat a problem or complication from the intragastric balloon.

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**Deep Vein Thrombosis (DVT)/Pulmonary Embolism:** Blood clots after endoscopic procedures are uncommon. Blood clots that form in the legs, or elsewhere, and break off and travel to the heart and lungs may cause death. \_\_\_\_\_

**Other Complications that may be common:** Allergic reactions, headaches, itching, medication side-effects, damage or irritation of the vein where intravenous medications were given, heartburn/reflux, anesthetic complications, injury to the bowel or vessels, gas bloating, aspiration of gastric contents into the lungs. \_\_\_\_\_

**Death:** The mortality rate of the upper endoscopy procedure is extremely low, estimated at 1 in 10,000. \_\_\_\_\_

**Balloon-Related Risks:**

**Post-Procedure Symptoms:** After balloon placement, patients may experience stomach cramps, stomach pain/discomfort, nausea, vomiting, acid reflux with heartburn / indigestion, minor bleeding in the esophagus, and a feeling of fullness or bloating. Rarely, patients may additionally have symptoms of diarrhea, sore throat, excessive salivation, gas or burping, hiccups, constipation, gastrointestinal hypermotility, esophageal dysmotility, aspiration, hyperventilation, gastritis, halitosis (bad breath), indigestion, or dizziness. \_\_\_\_\_

Patients can form an ulcer in the stomach after intragastric balloon placement and need to be treated with acid suppression medication while the balloon in place. \_\_\_\_\_

Some patients may become dehydrated after balloon placement and need to have intravenous fluids administered. \_\_\_\_\_

**Balloon Deflation:** The balloon could deflate at any point after administration. In some cases, it can pass through the intestines and be expelled with the stool. In rare cases, it can cause an obstruction in the stomach or in the intestines, requiring surgery for removal. \_\_\_\_\_

**Gastrointestinal Injury:** The balloon may rub against the esophagus and/or stomach causing bleeding or a tear (perforation) or hole. Endoscopy and/or surgery, with removal of the balloon, and repair of the area of bleeding or injury may be required for treatment. \_\_\_\_\_

**Balloon Removal:** Early removal (within 6 months) of the gastric balloon may be needed to treat complications. The procedure to remove the intragastric balloon may itself be associated with complications. **The intragastric balloon must be removed after the time-period specified by the balloon manufacturer and by my surgeon**, typically at 6 months. This will require an additional endoscopic procedure for its removal. Complications related to exceeding this time- period can be serious and life-threatening. \_\_\_\_\_

PATIENT INITIAL EACH PAGE: \_\_\_\_\_

Date: \_\_\_\_\_

**Poor Weight Loss:** I have discussed with my physician the average weight loss that is seen with patients after Intra gastric Balloon placement. I understand that there is no way to predict my own weight loss after the procedure. Weight loss resulting from various surgical weight loss procedures can be variable and unpredictable. \_\_\_\_\_

**Weight regain:** Weight regain may occur. This may occur for a number of reasons. No weight loss method is foolproof. \_\_\_\_\_

**Psychiatric Complications:** Although most people experience improvements in their mood, some will have worsening states of depression, which could lead to suicide. Some patients also experience anxiety from the foreign body within their stomach. Patients taking psychiatric medications should have the dosage and effectiveness of these medications monitored carefully by their prescribing physician. \_\_\_\_\_

**Procedure Abortion:** Under very rare circumstances, the physician may determine that the procedure should be aborted all together. This is most often due to diagnosis of medical problems such as severe liver disease with varices or tumors under endoscopy. \_\_\_\_\_

**Unlisted Complications:** I understand that it is not possible to list every complication that could occur during and after the Intra gastric Balloon placement. \_\_\_\_\_

(Intentionally blank)

I confirm that:

I have had the opportunity to read these materials, speak with my attending physician, and have my questions answered to my satisfaction.

I will actively engage in managing my own health care by following physician orders, communicating directly with my physician or practice representative with any questions, concerns or needs. I have been given contact information for both my physician and practice representative and know how to contact them in case of an emergency.

I understand that unforeseen events may occur that could result in the last minute cancellation or postponement of my procedure. If, for any reason, I cancel my procedure with less than a 7 day notice, or fail to present for my procedure, I will incur a nonrefundable charge of \$1,000 for failure to provide adequate notice of cancellation.

I have reviewed all of the information in this consent form and related consent materials. I have also discussed this information with my immediate family and I have clearly stated to my closest family members that I fully understand the risks of surgery and accept such risks.

I have read, or had read to me, the contents of this consent form and related consent materials and have no further questions.

I request to proceed with Intra gastric Balloon treatment.

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness to signature only

\_\_\_\_\_  
Date