Orbera
Intragastric Balloon System

Indications for Use (Intragastric Balloon)
The ORBERA Intragastric Balloon System is indicated for use as an adjunct to weight reduction for adults with obesity with Body Mass Index (BMI) of ≥ 30 and ≤ 40 kg/m2 and is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of significant long-term weight loss and maintenance of that weight loss. ORBERA is indicated for adult patients who have failed more conservative weight reduction alternatives, such as supervised diet, exercise and behavior modification programs. The maximum placement period for ORBERA is 6 months.

Indications for Use (Removal Tools)
The deflation catheter is intended for use in bariatric and gastric surgical procedures to drain fluid from an Orbera intragastric gastric balloon, so that the empty balloon can be endoscopically removed through the esophagus with a grasper.

Note: The wire grasper is a Class 1 instrument and does not have an indications for use statement.

Contraindications
Contraindications for use of the IGB System include:

- The presence of more than one IGB at the same time.
- Prior surgery involving the esophagus, stomach, and duodenum or bariatric surgery.
- Any inflammatory disease of the gastrointestinal tract including esophagitis, gastric ulceration, duodenal ulceration, cancer or specific inflammation such as Crohn's disease.
- Potential upper gastrointestinal bleeding conditions such as esophageal or gastric varices, congenital or acquired intestinal telangiectasis, or other congenital anomalies of the gastrointestinal tract such as atresias or stenoses.
- A large hiatal hernia of > 5cm or a hernia ≤ 5 cm with associated severe or intractable gastro-esophageal reflux symptoms.
- A structural abnormality in the esophagus or pharynx such as a stricture or diverticulum that could impede passage of the delivery catheter and/or an endoscope.
- Achalasia, symptoms suggestive of delayed gastric emptying, or presence of any other severe motility disorder that that may pose a safety risk during placement or removal of the device.
- Gastric Mass.
- Severe coagulopathy.
- Hepatic insufficiency or cirrhosis involving
    - Acute liver failure and advanced cirrhosis with encephalopathy muscle wasting and anasarca

    - Large esophageal varices with red color signs and gastric varices.
    - Severe portal hypertensive gastropathy with or without gastric antral vascular ectasia
- Patients who are known to have or suspected to have an allergic reaction to materials contained in the IGB
- Any other medical condition that would not permit elective endoscopy such as poor general health or history and/or symptoms of severe renal, hepatic, cardiac, and/or pulmonary disease.
- Serious or uncontrolled psychiatric illness or disorder that could compromise patient understanding of or compliance with follow up visits and removal of the device after 6 months.
- Alcoholism or drug addiction.
- Patients who are unable or unwilling to take prescribed proton pump inhibitor medication for the duration of the device implant.
- Patients unwilling to participate in an established medically-supervised diet and behavior modification program, with routine medical follow-up.
- Patients receiving aspirin, anti-inflammatory agents, anticoagulants, or other gastric irritants, not under medical supervision.
- Patients who are known to be pregnant or breast-feeding.

Warnings

- Proper positioning of the Placement Catheter Assembly and the IGB within the stomach (using measured distance from the incisors via the insertion tube markings) is necessary to allow proper filling. Lodging of the IGB in the esophageal opening during filling may cause serious injury. Failure to confirm proper positioning may cause injury to the esophagus, duodenum, or pylorus.
- When filling the IGB during the placement procedure, avoid rapid fill rates as these will generate high pressure which can damage the IGB valve or cause premature detachment of the IGB from the tip of the placement catheter.
- Each patient must be monitored closely during the entire term of treatment in order to detect the development of possible adverse events. Each patient should be instructed regarding symptoms of deflation (i.e. collapse), gastrointestinal obstruction, ulceration, gastric and esophageal perforation, acute pancreatitis, IGB inflation after placement (i.e. spontaneous hyperinflation) and other adverse events which might occur and should be advised to contact his/her physician immediately upon the onset of such symptoms. Patients need to be evaluated and the device removed at or within 6 months of placement.
- Patients with an IGB that present with severe abdominal pain that have a negative endoscopy and x-ray may additionally require a CT scan to definitively rule out a perforation.
- Patients must be advised that the IGB is intended to be placed for 6 months maximally, at which point removal is required. Longer periods of IGB placement increase the risk of IGB deflation (a reduction in size of the device due to loss of saline) which can lead to intestinal obstruction and risk for death. The risk of these events is also significantly higher when IGBs are filled to a larger volume than indicated (greater than 700cc).
- Bowel obstructions have been reported due to deflated (i.e. collapsed) IGBs passing into the intestines and have required surgical removal. The risk of intestinal obstruction may be higher in patients who have a dysmotility disorder, or who have had prior abdominal or gynecological surgery, radiation therapy, and/or active inflammatory bowel disease, so this should be considered in assessing the risk of the procedure. Bowel obstructions can result in death.
- Deflated devices should be removed promptly. Patients should be advised that IGB deflation may lead to serious adverse events including bowel obstruction and need for emergency surgery.
- Patients should immediately call their physician to receive instructions on preparing for removal of the IGB.
- Patients reporting loss of satiety, increased hunger and/or weight gain should be examined endoscopically as this is indicative of an IGB deflation.

- If it is necessary to replace an IGB that has spontaneously deflated (i.e. collapsed), fill the replacement IGB with the same volume of sterile saline that was used during the placement of previous IGB (i.e. initial fill volume). A greater initial fill volume in the replacement IGB may result in severe nausea, vomiting or ulcer formation.
- Acute pancreatitis has been reported as a result of injury to the pancreas by the IGB. Patients experiencing any symptoms of acute pancreatitis should be counseled to seek immediate care. Symptoms may include nausea, vomiting, abdominal or back pain, either steady or cyclic. If abdominal pain is steady, pancreatitis may have developed.
- Spontaneous hyperinflation of an indwelling IGB with gas has been reported in patients with indwelling ORBERA IGBs. Symptoms of significant IGB over-inflation include intense abdominal pain, swelling of the upper abdomen (abdominal distension) with or without discomfort, difficulty breathing, gastroesophageal reflux, nausea and/or vomiting. Patients experiencing any of these symptoms should be counseled to seek immediate care and should be evaluated for hyperinflation, particularly when persistent abdominal pain, abdominal distension, and food intolerance occur beyond the initial accommodative period of the balloon. Plain radiographic films will often demonstrate hyperinflation with a large air-fluid level within the balloon and an increase in IGB volume compared to the original volume
- Hyperinflation of the IGB often warrants its early removal to prevent serious complications such as gastric outlet obstruction and contact ulceration. Because hyperinflation increases the internal pressure of the IGB (due to accumulated gas) and may increase the fragility of the IGB wall, there is an increased risk of rupture followed by the sudden forceful release of gas and fluid contents when it is punctured or endoscopically manipulated. Therefore, it is suggested that the patient's airway is protected with endotracheal intubation prior to endoscopic removal in order to prevent pulmonary aspiration of the balloon contents. Additionally, in situations in which controlled balloon aspiration is done, it is recommended that mid-stream fluid aspirated from the balloon is sent for bacterial and fungal cultures.
- Pregnancy or breast-feeding contraindicates use of this device. Should pregnancy be confirmed at any time during the course of treatment, the device should be removed as soon as it is safely possible.
- Endoscopic removal of the IGB must be completed in the presence of an empty stomach. Patients should be on a liquid diet for 72 hours and NPO (i.e. nothing by mouth) for a minimum of 12 hours prior to removal. If food is found in the stomach upon endoscopic examination, then measures (aspiration of stomach contents, endotracheal intubation, or delay of procedure) must be taken to protect the airway. The risk of aspiration of gastric contents into the patient's lungs represents a serious risk which can result in death. Intragastric balloons have been shown to cause delayed gastric emptying which may increase the time typically needed to ensure an empty stomach prior to endoscopic procedures.
- The IGB is composed of a soft silicone elastomer and is easily damaged by instruments or sharp objects. The IGB must be handled only with gloved hands and with the instruments recommended in this document.

Precautions

- When filling the balloon, the use of sterile saline and aseptic technique, similar to changing IV fluids (e.g. use of clean or sterile gloves, sterile syringe, etc.), is recommended. Though the cause of hyperinflation is unknown, it may be caused by fungal or bacterial microbes contaminating the balloon. One recommended mitigation is to avoid contaminating the saline within the balloon with micro-organisms that may lead to spontaneous hyperinflation.
- If difficulty with the IGB Placement Catheter is noted during placement (e.g., resistance to IGB filling), then the device should be removed and replaced with a new IGB. To lessen, or prevent catheter defects, the catheter must remain slack during the filling process. If the catheter is under tension during this process, the tip of the catheter may dislodge from the IGB, preventing further IGB deployment.

- Placement of the IGB within the stomach has been shown to produce a delay in gastric emptying. This can create a variety of expected and predictable reactions including a feeling of heaviness in the abdomen, nausea and vomiting, gastroesophageal reflux, belching, esophagitis, heartburn, diarrhea and, at times, abdominal, back or epigastric pain and cramping. Food digestion may be slowed throughout the entire placement duration due to the delay in gastric emptying. Most patients acclimate to the presence of the device within the first 2 weeks. In order to prevent or ameliorate the symptoms most frequently experienced after placement, physicians should prescribe proton pump inhibitors (PPIs) and antiemetics prophylactically and consider prescribing temporarily antispasmodics or anticholinergic medications for cramping due to accommodation of the IGB, and/or prokinetic medications for symptoms due to the delay in gastric emptying. Patients should be advised to immediately contact their physician for any unusually severe, worsening, or recurrent symptoms as these medications can further delay gastric emptying and may lead to stomach distention, perforation and possibly death.
- To prevent ulcers and control gastroesophageal reflux symptoms, it is recommended that the patient start a program of oral proton pump inhibitors (PPIs) for approximately 3-5 days prior to IGB placement so a maximal gastric acid suppression effect will be present on the day of placement. It is recommended that the PPI dose be given sublingually after IGB placement if nausea and/or vomiting are present. A starting full dose daily regimen of an oral PPI should be continued as long as the IGB is in place. Other medications that are started prophylactically should be continued after IGB placement until they are no longer needed. Furthermore, subjects will be directed to avoid medications known to cause or exacerbate gastroduodenal mucosal damage.
- The IGB is made of silicone elastomer which may be degraded by gastric acid. Physicians have reported that the concurrent use of medications, such as proton pump inhibitors, may reduce acid formation or reduce acidity, which can prolong the integrity of the IGB reduce the risk of device deflation) and may help to reduce the risk of gastric ulcers and subsequent perforation.
- The physiological response of the patient to the presence of the IGB may vary depending upon the patient's general condition and the level and type of activity. The types and frequency of administration of drugs or diet supplements and the overall diet of the patient may also affect the response.
- The use of the IGB has not been studied in individuals who have a patulous pylorus, active H. pylori infection, and subjects with either symptoms or a diagnosis of delayed gastric emptying.
- Patients taking anti-cholinergic medications or psychotropic medications should be informed that these medications will delay gastric emptying and should be used sparingly as they may put them at greater risk for stomach distention and perforation. Patients should be advised to immediately contact their physician for any unusually severe, worsening or recurrent symptoms.
- A patient whose deflated (i.e. collapsed) IGB has moved into the intestines must be monitored closely for an appropriate period of time (at least 2 weeks) to confirm its uneventful passage through the intestine.
- In preparation for removal, some patients may have retained contents in the stomach. Some patients may have a clinically significant delay in gastric emptying and refractory intolerance to the IGB, necessitating early removal, and possibly leading to other adverse events. These patients may be at higher risk of aspiration upon removal and/or upon

administration of anesthetic. The anesthesia team should be alerted to the risk for aspiration in these patients.

Adverse Events

It is important to discuss all possible adverse events with your patient. Adverse events that may result from the use of this product include the risks associated with the medications and methods utilized in the endoscopic procedure, the risks associated with any endoscopic procedure, the risks associated with the IGB specifically, and the risks associated with the patient's degree of intolerance to a foreign object placed in the stomach.

NOTE: Any serious incident that has occurred in relation to the device should be reported to Apollo Endosurgery (see contact information at the end of this document) and any appropriate government entity.