The ORBERA365™ Intragastric Balloon System

DIRECTIONS FOR USE (DFU)

apollo endosurgery

ORBERA365 Intragastric Balloon System

1. INTRODUCTION

ORBERA365™ Intragastric Balloon System
(Ref. No. B-50012)

The information below is generalized. Each patient must be individually evaluated for the ORBERA365 Intragastric Balloon (referred to as IGB throughout this document) treatment based on the medical judgment of a qualified bariatric medical team.

Each physician and patient should evaluate the risks associated with endoscopy and IGBs and the possible benefits of a temporary treatment for weight loss prior to use of the IGB.

Physicians placing an IGB must fulfill the following requirements:

- Advanced upper endoscopy skill and experience evidenced by possession of Interventional Endoscopy privileges granted locally by the participating hospital or ambulatory facility.
- Completion of an Apollo Endosurgery sponsored or authorized comprehensive IGB training program.
- Clinical use of the IGB to make it a component of a multidisciplinary weight management practice which provides long-term support and follow-up.
- Have a comprehensive therapeutic weight management patient support program that includes appropriate endoscopy facilities, nutrition and exercise counseling, psychological, general medicine, and radiological support personnel.
- Able to have in-service training for support staff by Apollo Endosurgery trained product specialists.

2. INFORMATION THAT SHOULD BE PROVIDED TO THE PATIENT

IGB placement is an elective procedure and the patient must be well counseled on the risk-benefit relationship. The physician must inform the patient of the warnings, precautions, and adverse events listed in this document. The physician should also advise the patient that early removal of the balloon may be required if serious adverse reactions occur. It is important that the intended balloon placement duration be communicated to the patient, and understood, so that removal can be planned.

The balloon packaging includes a Patient Implant Card and leaflet that instructs the physician on how to complete the card. The card documents the patient name and physician contact information, target removal date, device tracking information, and warnings for related health care providers. Patients should be provided with the completed patient implant card and the leaflet.

3. DEVICE DESCRIPTION

The ORBERA365 Intragastric Balloon (IGB) System (Figure 1) is designed to assist weight loss by partially filling the stomach.

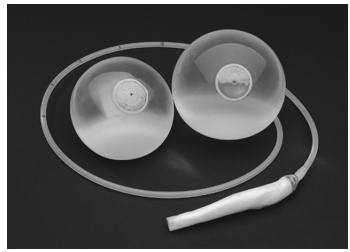

Figure 1: The ORBERA365 Intragastric Balloon (IGB)System filled to 400cc and 700cc with uninflated system in the foreground

The IGB is placed in the stomach and filled with sterile saline, causing it to expand into a spherical shape (Figure 2). The filled IGB is designed to occupy space and move freely within the stomach. The expandable design of the IGB permits a fill volume range of 400cc (minimum) to a maximum of 700cc (refer to the “Filling Recommendations” section). Once filled, the IGB volume is not adjustable. A self-sealing valve permits detachment from a Placement Catheter (see the “Directions for Use” Section).

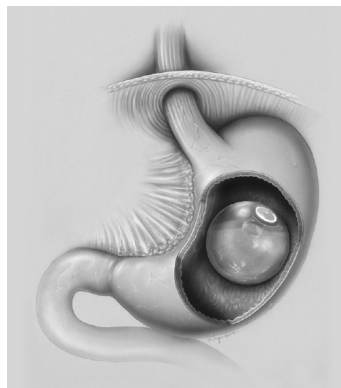

Figure 2. Inflated balloon in the stomach

The IGB is positioned within the “Placement Catheter Assembly” (Figure 3) which consists of a 6.5 mm external- diameter catheter with length markers provided as a reference. One end of the catheter is connected to a sheath which houses the collapsed IGB and the opposite end has a Luer lock connector which allows the catheter to be attached to the “Fill Kit”. The tubing of the placement catheter is made of either silicone or polyurethane. Silicone catheters have a stainless-steel guidewire inserted into the catheter tubing for increased rigidity during placement. A guidewire is not present within polyurethane catheters as the rigidity of the material makes a guidewire unnecessary.

A “Fill Kit”, consisting of an IV spike, fill tube and filling valve, is also provided to assist with the IGB filling process (Figure 4).

Figure 3: Placement Catheter Assembly (i.e. Sheath Assembly)

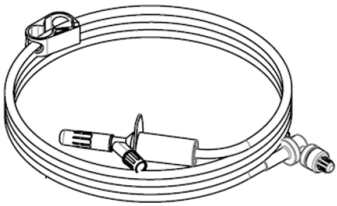

Figure 4: Fill Kit with IV Spike

The expected clinical benefit of the Orbera365 is incremental weight loss and/or delayed weight regain, relative to a 6 month balloon. The US pivotal study of Apollo’s 6 month balloon demonstrated an average of 10.3%TBWL (percent total body weight loss) after 6 months of balloon placement and 7.6%TBWL at 12 months (6 months after removal). A US Post-Approval Study (OPAS-1) verified the pivotal result in a non-randomized study, demonstrating an average of 12.5% TBWL after 6 months of balloon placement and 8.0%TBWL at 12 months (6 months after removal).

Apollo is collecting post market clinical follow up in the form of real-world evidence on Orbera365. Data collected thus far demonstrates that Orbera365 results in average weight loss of 9.6-16.2%TBWL after 12 months of balloon placement.

4. INDICATIONS FOR USE

The ORBERA365 System is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of long-term weight loss maintenance.

The ORBERA365 System is indicated for:

- Temporary use for weight loss in obese patients (BMI 30-50) who failed to achieve and maintain weight loss with a supervised weight-control program.
- Pre-surgical temporary use for weight loss in obese and super obese patients (BMI 40 and above or a BMI of 35 with comorbidities) prior to obesity or other surgery, in order to reduce surgical risk.

The maximum placement period for the ORBERA365™ System is 12 months, and it must be removed at that time or earlier.

5. PRODUCT SPECIFICATIONS

- ORBERA365 System, Reference No. B-50012 (IGB positioned in a Placement Catheter Assembly (i.e. sheath assembly))
- The IGB System contains no latex or natural rubber materials.
- The products are supplied clean, non-sterile and packaged for single use.
- The materials used to fabricate this device (see Table 1) have been tested according to ISO 10993, the international Standard for biological evaluation of medical devices.

Table 1: IGB Product Materials

System Component	Materials
IGB	Silicone elastomer components coated in Sodium Bicarbonate
Placement Catheter Assembly	**Tubing:** • Silicone (assemblies with a PTFE coated stainless-steel guidewire) • Polyurethane (assemblies without a PTFE coated stainless-steel guidewire) **Catheter Tip:** Polypropylene **Sheath:** Silicone elastomer and Silicone adhesive/primer coated in Sodium Bicarbonate

The balloon consists of 17 grams of silicone elastomer, covered with approximately 0.3 grams of sodium bicarbonate to prevent the silicone from sticking to itself during the fill process. Leachable substances have been estimated to be 127 mg/device of sodium, 7.8 mg/device of silicone, 0.9 mg/device of potassium, followed by trace elements consistent with siloxane oligomers.
The balloon is filled with 400-700 cc of sterile saline. Toxicological risk assessment demonstrates exposure is well below reasonable safe exposure limits.

6. 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 associated with 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 12 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.

7. 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, gastrointestinal obstruction, acute pancreatitis, IGB inflation after placement (i.e. spontaneous hyperinflation), ulceration, gastric and esophageal perforation, 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 12 months of placement.
- Patients must be advised that the IGB is intended to be placed for 12 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 are also significantly higher when filled to a larger volume than indicated (greater than 700cc).
- Bowel obstructions have been reported due to deflated IGBs (i.e. collapsed) 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 a 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 an indwelling IGB. 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 IGB. Plain radiographic films will often demonstrate hyperinflation with a large air-fluid level within the IGB 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. IGBs cause delayed gastric emptying which may increase the time typically needed to ensure an empty stomach prior to endoscopic procedures
- Patients should be advised to take the necessary precautions to prevent pregnancy prior to placement and throughout the duration of treatment. Patients should be instructed to inform you as soon as possible if pregnancy is confirmed during treatment, so that removal of the device can be arranged.
- 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.
- The IGB is composed of 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.

8. PRECAUTIONS

- Temporary weight-loss treatments have been shown to have poor long-term success rates in obese and severely obese patients.
- When filling the IGB, the use of sterile saline and aseptic technique, similar to changing IV fluids (e.g. use of clean 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 Assembly 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 Placement Catheter defects, the catheter must remain slack during the filling process. If the Placement Catheter is under tension during this process, the tip of the catheter may dislodge from the IGB and prevent 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 two (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 a silicone elastomer balloon which may be degraded by gastric acid. Physicians have reported 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 IGB has not been studied on 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 who's 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 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.

9. RISK ASSOCIATED WITH RE-USE

The IGB System is for single use only. Removal of the IGB requires that it be punctured in situ to deflate, and any subsequent reuse would result in the IGB deflating in the stomach. This could lead to possible bowel obstruction and may require surgery to remove. Should an IGB be removed from the patient prior to being filled with saline, it still cannot be reused on a new patient as any attempt to decontaminate this device could cause damage resulting again in deflation after implantation.

10. DEVICE LIFETIME

Apollo has established that the maximum balloon lifetime is 12 months. This is based on laboratory testing and validated through clinical experience in the same type of patients/procedures as with the 6-month balloon.

Placement of an IGB for longer dwell times is associated with an increased likelihood of certain events. While post-market surveillance data is prone to underreporting, it provides a source of information that can be used to estimate these incremental risks. Complaint data has shown that the risk of balloon deflation (which can possibly lead to migration or gastric outlet obstruction) increases the most, followed by spontaneous hyperinflation and ulceration when extending balloon dwell time from 6 months to
12 months. Orbera365 is to be removed at
12 months. It is important that the intended balloon placement duration be communicated to the patient, and understood, so that removal can be planned.

The table below demonstrates the estimated increased risks of a longer dwell time, based on complaints received from June 2017 to June 2022. These are estimates and are subject to change with different reporting periods

Risk	Estimate for 6M Balloons	Estimate for 12M Balloons	Risk Multiple Estimate
Inflation	0.233%	0.280%	1-2x
Deflation	0.165%	0.878%	5-6x
Migration	0.019%	0.189%	9-10x
Ulcer	0.014%	0.027%	1-2x
Obstruction	0.073%	0.127%	1-2x
Death	0.015%	0.015%	1-2x

11. COMMENT ON PRACTICE OF SERIAL IMPLANTATION

There are reports on the practice of serial balloon placements (placing a balloon, removing it at the intended dwell time and then placing another balloon for an additional course of balloon therapy). Apollo Endosurgery has not performed studies to evaluate the risk/benefit of this practice. This practice is not promoted by Apollo and such usage is considered off-label.

12. 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.

12.1 Possible Adverse Events

Possible adverse events associated with the use of the IGB include:

- Death due to complications related to aspiration, intestinal obstruction, gastric perforation, or esophageal perforation, is possible.
- Intestinal obstruction by the IGB. An insufficiently filled IGB or a leaking IGB that has lost sufficient volume may be able to pass from the stomach into the small bowel. It may pass all the way into the colon and be passed with stool. However, if there is a narrow area in the bowel or adhesion formation, which may occur after previous surgery on the bowel, the IGB may not pass and could cause a bowel obstruction. If this occurs, surgery or endoscopic removal could be required.
- Esophageal obstruction. When the IGB is being filled in the stomach, the IGB could be inadvertently pulled back into the esophagus. This can cause rupture of the esophagus. If this occurs, surgery or endoscopic removal could be required.
- Gastric outlet obstruction. A partially filled IGB (i.e.,<400cc), or a leaking IGB could lead to gastric outlet obstruction, requiring IGB removal. It is also possible for a fully filled (400-700cc) IGB to impair the gastric outlet, which can produce a mechanical impediment to gastric emptying. Gastric outlet obstruction may require early removal.
- Gastric distention with retained food and fluid due to severely delayed gastric emptying with or without outlet obstruction from displacement of the IGB into the antrum.
- Injury to the digestive tract during placement of the IGB in an improper location such as in the esophagus or duodenum. This could cause bleeding and perforation, which could require a surgical or endoscopic correction for control.
- Insufficient or no weight loss.

- Adverse health consequences resulting from weight loss.
- Gastric discomfort, feelings of nausea and vomiting following IGB placement as the digestive system adjusts to the presence of the IGB.
- Continuing nausea and vomiting. This could result from direct irritation of the lining of the stomach, delayed gastric emptying and/or the IGB blocking the outlet of the stomach. It is even theoretically possible that the IGB could prevent vomiting (not nausea or retching) by blocking the inlet to the stomach from the esophagus.
- A feeling of heaviness in the abdomen.
- Abdominal or back pain, either steady or cyclic.
- Gastroesophageal reflux.
- Influence on digestion of food.
- Blockage of food entering into the stomach.
- Bacterial growth in the fluid which fills the IGB. Rapid release of this fluid into the intestine could cause infection, fever, cramps and diarrhea.
- Injury to the lining of the digestive tract as a result of direct contact with the endoscope, the IGB, grasping forceps, or as a result of increased acid production by the stomach. This could lead to ulcer formation with pain, bleeding or even perforation. Surgery could be necessary to correct this condition.
- IGB deflation (i.e. collapse) and subsequent replacement.
- Acute pancreatitis.
- Spontaneous hyperinflation due to gas production within the IGB

12.2 POSSIBLE COMPLICATIONS OF ROUTINE ENDOSCOPY & SEDATION

Potential risks associated with upper endoscopic procedures include, but are not limited to: abdominal cramping and discomfort if air is used to distend the stomach, sore or irritated throat, bleeding, infection, tearing of the esophagus or stomach that could lead to perforation, and aspiration pneumonia. The risk increases if additional procedures are performed.

According to the American College of Gastroenterology, risks related to sedation during endoscopic procedures are rare, occurring in less than one in every 10,000 people.1 The most common complications involve a temporary decrease in the rate of breathing or heart rate, which can be corrected by giving extra oxygen or by reversing the effect of the sedative medications. Patients with heart, lung, kidney, liver, or other chronic diseases are at higher risk for complications. Drug dosages and airway management should be taken into consideration when treating high risk patients.

13. HOW SUPPLIED

Each IGB System contains an IGB positioned within a “Placement Catheter Assembly” and a “Fill Kit”. All are supplied NONSTERILE and FOR SINGLE USE ONLY. All components should be handled carefully.

Materials Included:

- One (1) Intragastric Balloon (IGB) System consisting of:
  - One (1) Placement Catheter Assembly (i.e. Sheath Assembly) containing the IGB
  - One (1) Fill Kit with IV Spike

Materials Not Included:

- Endoscope
- Surgical Gel
- Sterile Saline
- Sterile 50cc Syringe
- Removal tools (i.e. sheathed needle catheter, long jaw or wire prong grasper)

13.1 CLEANING INSTRUCTIONS

In the event that the product becomes contaminated prior to use, it should not be used but should be returned to the manufacturer.

CAUTION: DO NOT SOAK THE PRODUCT IN A DISINFECTANT because the silicone elastomer may absorb some of the solution which could subsequently leach out and cause tissue reaction.

13.2 DISPOSAL

Dispose of any used or explanted device’s or device components in accordance with any local regulations for medical waste.

14. DIRECTIONS FOR USE

The IGB is supplied positioned within the Placement Catheter Assembly. Inspect the package seal and the Placement Catheter Assembly for damage prior to use. It should not be used if any damage is noted. A back-up IGB should be available at the time of placement.

DO NOT REMOVE THE IGB FROM THE PLACEMENT CATHETER ASSEMBLY.

A Fill Kit is provided to assist with the IGB deployment.

CAUTION: If the IGB becomes separated from the catheter or sheath prior to placement, do not attempt to use the IGB or reinsert the IGB into the sheath

14.1 IGB PLACEMENT AND FILLING

Prepare the patient for endoscopy. Inspect the esophagus and stomach endoscopically and then remove the endoscope. If there are no contraindications, insert the Placement Catheter Assembly containing the IGB gently down the esophagus and confirm that it is below the lower esophageal sphincter and well within the stomach cavity before removing the guidewire (if present) and proceeding. The small size of the Placement Catheter Assembly allows ample space for the endoscope to be reinserted for observing the IGB filling steps.

14.2 IGB FILLING

Using aseptic technique, place the Fill Kit spike into the sterile saline bag. Attach a sterile syringe to the valve of the Fill Kit and prime it. Connect the Luer-Lock connector on the Placement Catheter to the Fill Kit valve. Proceed to deploy the IGB, verifying with the endoscope that the IGB is within the stomach.

CAUTION: Fill the IGB with sterile saline. An 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 microorganisms that may lead to spontaneous hyperinflation.

CAUTION: During the filling process the Placement Catheter must remain slack. If the catheter is under tension during this process,
the tip of the catheter may dislodge from the IGB, preventing further IGB deployment.

WARNING: Rapid fill rates will generate high pressure which can damage the IGB valve or cause premature detachment from the tip of the Placement Catheter.

14.2.1 Filling Recommendations

The expandable design of the IGB permits a fill volume range of 400cc (minimum) to a maximum of 700cc. The IGB should not be under-filled or over-filled with volumes <400cc or >700cc, as under- or over-filling the IGB could cause higher risk for serious side effects, such as migration (under-filled IGB) or gastric rupture/perforation (over-filled IGB). Once filled, the IGB is not adjustable.

To determine ideal IGB size to produce the greatest weight loss effectiveness, two (2) independent reviewers searched PubMed and Embase to identify full-length IGB clinical studies. A total of 80 studies with 8,506 patients were included in this meta-analysis of global data. Figure 5, meta-regression analysis of IGB fill volume correlation with total body weight loss (TBWL), demonstrates fill volume ranges from 500cc to 700cc. Results at 6 months do not seem to differ with volume (p=0.24).1 Therefore, based on this, the recommendation should be filling volume between 500cc to 650cc; however the pivotal clinical study's safety and effectiveness data for this device was only tested with fill volumes of 550cc ± 50cc.

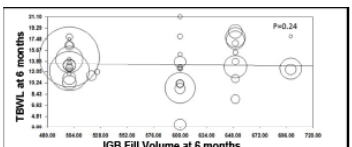

Figure 5: Meta-regression analysis of IGB fill volume correlation with total body weight loss (TBWL).[1]

Note: the size of the circles on the graph corresponds with the study size. Figure courtesy of Dr. Barham Abu-Dayyeh.

The following filling recommendations are provided to avoid inadvertent damage to the valve of the balloon or premature detachment from the Placement Catheter:

- Always use the IGB Fill Kit provided.
- Always use a sterile 50cc syringe to fill the IGB. Use of smaller syringes can result in very high pressures of 30, 40, and even 50 psi, which can damage the IGB valve.
- With a sterile 50cc syringe, each filling stroke should be done slowly (minimum of 10 seconds) and steadily. Slow, steady filling will avoid the generation of high pressure to the valve.

WARNING: Rapid fill rates will generate high pressure which can damage the IGB valve or cause premature detachment from the tip of the Placement Catheter.

- Filling should always be completed under direct visualization (gastroscopy). Integrity of the IGB valve should be confirmed by observing the valve lumen as the Placement Catheter is removed from valve of the IGB.
- An IGB with a leaking valve must be removed immediately. A partially filled IGB can result in a bowel obstruction, which can result in death. Bowel obstructions have occurred as a result of unrecognized or untreated IGB deflation (i.e. collapse).

Note: Any IGB that leaks should be returned to Apollo Endosurgery with a completed product return field note describing the event. Your assistance with our continuing quality improvement efforts is appreciated.

A minimum fill volume of 400cc is required for the IGB to deploy completely from the Placement Catheter. After filling the IGB, remove the Fill Kit from the catheter. When filled, the IGB is released by pulling the Placement Catheter gently while the IGB is against the tip of the endoscope or the lower esophageal sphincter.

Continue to pull the Placement Catheter until it has detached from the IGB's self-sealing valve. Once detached, the placement of the IGB should be visually inspected as well as for the presence of any fluid leaks.

14.3 IGB PLACEMENT AND FILLING (STEP-BY-STEP)

1. Prepare the patient according to hospital protocol for sedation and endoscopy.
2. Perform endoscopic inspection of the esophagus, stomach, and duodenum.
3. Remove endoscope.
4. If there are no contraindications:
   a. Lubricate the sheath of the Placement Catheter ssembly with surgical lube-gel.
   b. Gently insert the Placement Catheter into the esophagus and into the stomach.
5. Reinsert the endoscope while the IGB is in situ to observe filling steps. The IGB MUST be below the lower esophageal sphincter and well within the stomach cavity.

6. If present, remove the guidewire from the placement catheter.
7. Attach the sterile 50cc syringe to the Luer lock of the Fill Kit's 3-way stopcock and then insert the spike of the Fill Kit into a bag of sterile normal saline solution for injection (.9 NS).
8. Slowly fill the IGB with sterile saline, 50cc at a time. Repeat up to a minimum fill volume of 400cc to a maximum fill volume of 700cc (14 strokes).
9. Gently remove the Placement Catheter and inspect the IGB valve for leakage.

14.4 IGB REMOVAL (STEP-BY-STEP)

1. Ensure that the patient has been on a liquid diet for 72 hours and NPO (i.e. nothing by mouth) for a minimum of 12 hours before attempting removal. Whether this regimen has been followed or not (i.e. in the case of an urgent removal), due to the potential for residual gastric contents in some patients, additional precautions for aspiration should be considered. In higher risk patients with signs and symptoms suggestive of severely delayed gastric emptying and/or gastric outlet obstruction, a focused physical examination for abdominal distension and/or succussion splash should be performed, followed by radiographic evaluation if succussion splash is absent and the epigastrium is full or tender. If radiographic evaluation is positive for distended stomach with or without an antral IGB, then nasogastric decompression should be considered, the airway should be secured, and general anesthesia employed.
2. Prepare the patient according to hospital protocol for sedation and endoscopy. Additionally, consider administering a smooth muscle relaxant such as intravenous glucagon to relax the esophageal sphincter.
3. Insert the endoscope into the patient's stomach.
4. Assess for the presence of food. If food is present in the stomach the procedure should be delayed. If emergent removal, the airway should be protected prior to proceeding.
5. Get a clear view of the filled IGB using the endoscope.
6. Insert a sheathed needle catheter down the working channel of the endoscope.
7. Use the advanced exposed needle to puncture the IGB.
8. Push the needle catheter through the IGB shell and well into the IGB.
9. Remove the needle from the catheter.
10. Apply suction to the deeply inserted catheter until all fluid is evacuated from the IGB.
11. Remove the catheter from the IGB and out of the working channel of the endoscope.
12. Insert a long jaw or wire prong grasper through the working channel of the endoscope.
13. Grab the IGB with the grasper (ideally at the opposite end of valve if possible).
14. With a firm grasp on the IGB, slowly extract the IGB up the esophagus.
15. When the IGB reaches the upper esophageal sphincter, hyperextend the head to straighten the passage out of the esophagus and throat, allowing for an easier extraction.
16. Remove the IGB from the mouth.

14.5 IGB REPLACEMENT

If an IGB needs to be replaced, then follow the instructions for IGB Removal and IGB Placement and Filling. Additionally, it is recommended that the same volume of sterile saline that was used during the placement of the previous IGB (i.e. initial fill volume) be used when filling the replacement IGB.

CAUTION: A larger initial fill volume in the replacement IGB may result in severe nausea, vomiting or ulcer formation.

15. MEDICAL IMAGING

The saline filled IGB is considered to be MR Safe.

16. DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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1. Abu-Dayyeh B et al. A Randomized, Multi-Center Study to Evaluate the Safety and Effectiveness of an Intragastric Balloon As an Adjunct to a Behavioral Modification Program, in Comparison With a Behavioral Modification Program Alone in the Weight Management of Obese Subjects. Gastrointestinal Endoscopy 2015: 81(5):AB147.

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