

The ORBERA™ Intragastric Balloon System

DIRECTIONS FOR USE (DFU)

Rx Only



The ORBERA™ Intra-gastric Balloon System (English)

INTRODUCTION

ORBERA™ Intra-gastric Balloon System (Cat. No. B-50000)

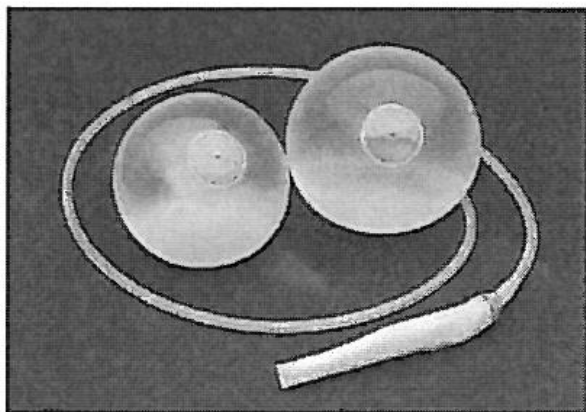


Figure 1. The ORBERA™ Intra-gastric Balloon System filled to 400 cc and 700 cc with uninflated system in the foreground

The ORBERA™ Intra-gastric Balloon System (Fig 1) is designed to assist weight loss by partially filling the stomach and inducing satiety. The ORBERA™ System balloon is placed in the stomach and filled with saline, causing it to expand into a spherical shape (Fig. 2). The filled balloon is designed to act as an artificial bezoar and move freely within the stomach. The expandable design of the ORBERA™ System balloon permits fill volume adjustment at the time of placement from 400 cc to 700 cc. A self-sealing valve permits detachment from external catheters.

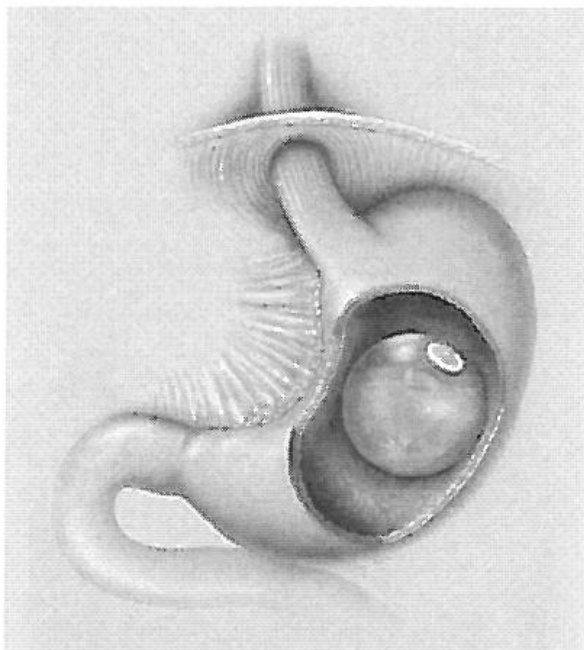


Figure 2. Inflated balloon in the stomach

In the ORBERA™ System, the ORBERA™ System balloon is positioned within the Placement Catheter Assembly. The Placement Catheter Assembly (Fig 3) consists of a 6.5 mm external-diameter silicone catheter, one end of which is connected to a sheath in which the collapsed balloon resides. The opposite end is connected to a Luer lock connector for attachment

to a filling system. Length markers are provided as a reference on the fill tube. A guide wire is inserted into the silicone catheter for increased rigidity.

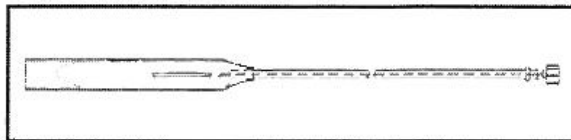


Figure 3. Placement Catheter Assembly

A filling system consisting of an IV spike, fill tube and filling valve is provided to assist in the balloon deployment.

INDICATIONS FOR USE

The ORBERA™ System is indicated for temporary use in weight-loss therapy for obese patients with a Body Mass Index (BMI) 27 kg/m² or greater.

The ORBERA™ 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 maximum placement period for the ORBERA™ System is 6 months, and it must be removed at that time or earlier.

CAUTION: The risk of balloon deflation and intestinal obstruction (and therefore possible death related to intestinal obstruction) is significantly higher when balloons are left in place longer than 6 months. This has already been experienced.

Each physician and patient should evaluate the risks associated with endoscopy and intra-gastric balloons (see complications below) and the possible benefits of a temporary treatment for weight loss prior to use of the ORBERA™ System.

CAUTION: Temporary weight-loss treatments have been shown to have poor long-term success rates in obese and severely obese patients. Patients need to be evaluated and the device removed or replaced every 180 days. Clinical data does not currently exist to support use of an individual ORBERA™ System balloon beyond 180 days.

Physicians have reported the concurrent use of medications which reduce acid formation or reduce acidity. Silicone elastomer is degraded by acid. Moderating the pH in the stomach should prolong the integrity of the ORBERA™ System.

The materials used to fabricate this device have been tested according to ISO 10993, the International Standard for biological evaluation of medical devices.

WARNINGS AND PRECAUTIONS

The risk of balloon deflation and intestinal obstruction (and therefore possible death related to intestinal obstruction) is significantly higher when balloons are left in place longer than 6 months or used at larger volumes (greater than 700 cc).

Deflated devices should be removed promptly

A patient whose deflated balloon has moved into the intestines must be monitored closely for an appropriate period of time to confirm its uneventful passage through the intestine.

Bowel obstructions have been reported due to deflated balloons passing into the intestines and have required surgical removal. Some obstructions have reportedly been associated with patients who have diabetes or who have had prior abdominal surgery, so this should be considered in assessing the risk of the procedure. Bowel obstructions can result in death.

The risk of intestinal obstruction may be higher in patients who have had prior abdominal or gynecological surgery.

The risk of intestinal obstruction may be higher in patients who have a dysmotility disorder or diabetes.

Pregnancy or breast-feeding contraindicates use of this device. Should pregnancy be confirmed at any time during the course of treatment, it is recommended that the device be removed.

Proper positioning of the Placement Catheter Assembly and the ORBERA™ System balloon within the stomach is necessary to allow proper inflation. Lodging of the balloon in the esophageal opening during inflation may cause injury and/or device rupture.

The physiological response of the patient to the presence of the ORBERA™ System balloon 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.

Each patient must be monitored closely during the entire term of treatment in order to detect the development of possible complications. Each patient should be instructed regarding symptoms of deflation, gastrointestinal obstruction, ulceration and other complications which might occur, and should be advised to contact his/her physician immediately upon the onset of such symptoms.

Patients reporting loss of satiety, increased hunger and/or weight gain should be examined endoscopically, as this is indicative of a balloon deflation.

If it is necessary to replace a balloon which has spontaneously deflated, the recommended initial fill volume of the replacement balloon is the same as for the first balloon or the most recent volume of the removed balloon. A greater initial fill volume in the replacement balloon may result in severe nausea, vomiting or ulcer formation.

The ORBERA™ System balloon is composed of soft silicone elastomer and is easily damaged by instruments or sharp objects. The balloon must be handled only with gloved hands and with the instruments recommended in this document.

CONTRAINDICATIONS

Contraindications for use of the ORBERA™ System include:

- Prior gastric or intestinal surgery, including (not exclusively) the following: Nissen Fundoplication, Vertical Banded Gastroplasty (VBG), Gastric Bypass, gastric partitioning,

gastric stapling, gastric resection, gastrectomy, small bowel resection, colon resection, colostomy, gynecological surgery, and placement of the LAP-BAND™ System.

- 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.
- A structural abnormality in the esophagus or pharynx such as a stricture or diverticulum.
- Any other medical condition which would not permit elective endoscopy.
- Major prior or present psychological disorder.
- Alcoholism or drug addiction.
- 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

COMPLICATIONS

Possible complications of the use of the ORBERA™ System include:

- Intestinal obstruction by the balloon. An insufficiently inflated balloon or a leaking balloon that has lost sufficient volume may be able to pass from the stomach into the small bowel. It may pass all the way through into the colon and be passed with stool. However, if there should be a narrow area in the bowel, as might occur after prior surgery on the bowel or adhesion formation, the balloon may not pass and then may cause a bowel obstruction. If this occurs, percutaneous drainage, surgery or endoscopic removal could be required.
- Death due to complications related to intestinal obstruction is possible.
- Esophageal obstruction. Once the balloon has been inflated in the stomach, the balloon could be pushed back into the esophagus. If this occurs, surgery or endoscopic removal could be required.
- Injury to the digestive tract during placement of the balloon in an improper location such as in the esophagus or duodenum. This could cause bleeding or even perforation, which could require a surgical correction for control.
- Insufficient or no weight loss.
- Temporary weight-loss treatments have been shown to have poor long-term success rates (weight-loss maintenance) in severely obese patients.

- Adverse health consequences resulting from weight loss.
- Gastric discomfort, feelings of nausea and vomiting following balloon placement as the digestive system adjusts to the presence of the balloon.
- Continuing nausea and vomiting. This could result from direct irritation of the lining of the stomach or as a result of the balloon blocking the outlet of the stomach. It is even theoretically possible that the balloon 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 balloon. 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 balloon, 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.
- Balloon deflation and subsequent replacement.

COMPLICATIONS OF ROUTINE ENDOSCOPY INCLUDE:

- Adverse reaction to sedation or local anesthetic.
- Abdominal cramps and discomfort from the air used to distend the stomach
- Sore or irritated throat following the procedure.
- Aspiration of stomach contents into the lungs.
- Cardiac or respiratory arrest (these are extremely rare and are usually related to severe underlying medical problems).
- Digestive tract injury or perforation.

HOW SUPPLIED

Each ORBERA™ System contains a balloon positioned in a Placement Catheter Assembly. All are supplied NONSTERILE and FOR SINGLE USE ONLY. All components should be handled carefully.

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.

DIRECTIONS FOR USE

The balloon is supplied positioned within the Placement Catheter Assembly. Inspect the Placement

Catheter Assembly for damage. It should not be used if any damage is noted. A standby ORBERA™ System should be available at the time of placement.

DO NOT REMOVE THE BALLOON FROM THE PLACEMENT CATHETER ASSEMBLY.

A filling system is provided to assist in the balloon deployment.

Note: If the balloon becomes separated from the sheath prior to placement, do not attempt to use the balloon or reinsert the balloon into the sheath.

BALLOON PLACEMENT AND INFLATION

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 balloon gently down the esophagus and into the stomach. The small size of the Placement Catheter Assembly allows ample space for the endoscope to be reinserted for observing the balloon filling steps.

When it has been confirmed that the balloon is below the lower esophageal sphincter and well within the stomach cavity, remove the guide wire.

Fill the balloon with sterile saline. Place the filling system spike into the sterile saline bottle or bag fill tube. Attach a syringe to the filling system valve and prime the filling system. Connect the Luer-Lock connector on the fill tube to the filling system valve. Proceed to deploy the balloon, verifying with the endoscope that the balloon is within the stomach (see filling recommendations below).

Note. During the filling process the fill tube must remain slack. If the fill tube is under tension during the intubation process, the fill tube may dislodge from the balloon, preventing further balloon deployment.

WARNING: Rapid fill rates will generate high pressure which can damage the ORBERA™ System valve or cause premature detachment.

The following filling recommendations are provided to avoid inadvertent valve damage or premature detachment:

- Always use the ORBERA™ System fill kit provided
- Always use a 50 cc or 60 cc syringe. Use of smaller syringes can result in very high pressures of 30, 40, and even 50 psi, which can damage the valve.
- With a 50 cc or 60 cc syringe, each filling stroke should be done slowly (minimum of 10 seconds) and steadily. Slow, steady filling will avoid the generation of high pressure in the valve.
- Filling should always be completed under direct visualization (gastroscopy). Integrity of the valve should be confirmed by observing the valve lumen as the balloon fill tube is removed from the valve.
- A balloon with a leaking valve must be removed immediately. A deflated balloon can result in a bowel obstruction, which can result in death. Bowel obstructions have occurred as a result of unrecognized or untreated balloon deflation.

Note: Any balloons which leak should be returned Allergan with a complete returned product field note describing the event. Your assistance with our continuing quality improvement efforts is appreciated.

A minimum fill volume of 400 ml is required for the balloon to deploy completely from the placement assembly. After filling the balloon, remove the fill kit from the fill tube. Connect a syringe directly to the fill tube Luer-Lock and produce a gentle suction on the placement catheter by withdrawing the plunger of the syringe. You will not withdraw fluid as the valve will seal with the vacuum created.

CAUTION: If more than 5 ml of fluid can be removed from the balloon, replace the balloon. Fluid cannot be removed from the balloon using the fill tube because the tip of the fill tube does not extend to the end of the valve.

When filled, the balloon is released by pulling the fill tube gently while the balloon is against the lip of the endoscope or the lower esophageal sphincter. Continue to pull the fill tube until it is out of the self-sealing valve. After release, the balloon should be visually inspected.

ORBERA™ SYSTEM PLACEMENT AND INFLATION (STEP-BY-STEP)

1. Prepare the patient according to hospital protocol for gastroscopy.
2. Perform gastroscopic inspection of esophagus and stomach.
3. Remove gastroscopy.
4. Where there are no contraindications
 - a. Lubricate the ORBERA™ System placement sheath with surgical lube-gel.
 - b. Move the ORBERA™ System gently down the esophagus and into the stomach.
5. Reinsert the endoscope while the balloon is in situ to observe filling steps. The balloon must be below the lower esophageal sphincter and well within the stomach cavity.
6. Remove the guide wire from the fill tube.
7. Attach the 3-way stopcock and 50 cc syringe to the Luer-Lock. Insert filling kit spike into the saline bag fill tube.
8. Slowly fill the balloon with sterile saline, 50 cc at a time. Repeat up to 700 cc (14 strokes). Recommended full volume is up to 700 cc minimum fill volume is 400 cc.
10. After the last stroke pull back on plunger to create a vacuum in the valve to ensure closure.
11. Gently pull the tubing out and check valve for leakage.

BALLOON REMOVAL (STEP-BY-STEP)

1. Anesthetize per hospital and physician recommendations for gastroscopy procedures.
2. Insert the gastroscopy into the patient's stomach.
3. Get a clear view of the filled balloon through the gastroscopy.

4. Insert a needle instrument down the working channel of the gastroscopy.
5. Use the needle instrument to puncture the balloon.
6. Push distal end of tubing through the balloon shell.
7. Remove the needle from the tubing sleeve.
8. Apply suction to the tube until all fluid is evacuated from the balloon.
9. Remove the tubing from the balloon and out of the working channel of the gastroscopy.
10. Insert a 2-pronged wire grasper through the working channel of the gastroscopy.
11. Grab the balloon with the hooked grasper (ideally at the opposite end of valve if possible).
12. Administer 5 mg of Buscopan to relax esophageal muscles for when the balloon is extracted through the neck region.
13. With a firm grasp on the balloon, slowly extract the balloon up the esophagus.
14. When the balloon reaches the throat, hyperextend the head to allow for a more gradual curve and easier extraction.
15. Remove the balloon from the mouth.

BALLOON REPLACEMENT

If a balloon needs to be replaced, the instructions for ORBERA™ System Removal and ORBERA™ System Placement and Inflation are followed. If the balloon has not lost volume at the time of removal, the replacement balloon may be the same volume as the balloon which is removed. However, if the previous balloon has deflated prior to removal, the recommended fill volume for the replacement balloon is the measured volume of the balloon removed.

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

WARRANTY AND LIMITATION OF WARRANTY

Allergan warrants that reasonable care was used in the design and manufacture of this product. Because Allergan has no control over the conditions of use, patient selection or handling of the device after it leaves its possession, Allergan does not warrant either a good effect or against an ill effect following its use. Allergan shall not be directly or indirectly responsible for any incidental or consequential loss, damage or expenses directly or indirectly arising from the use of this product. Allergan's SOLE responsibility in the event Allergan determines the product was defective when shipped by Allergan, shall be the replacement of the product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including but not limited to any implied warranties of merchantability or fitness for use.

PRODUCT SPECIFICATIONS

ORBERA™ System. Catalog No. B-50000 (Balloon positioned in placement assembly)

Note: The products are supplied clean, non-sterile and packaged for use.

AUTHORIZED TRAINING PROGRAM AND PRODUCT ORDERING INFORMATION

For additional information please contact:

Manufacturer
Allergan
5540 Ekwil Street
Santa Barbara, CA 93111, USA
Tel: (805) 683-6761
Fax: (805) 681-5765

This product is for export only.

The ORBERA™ System contains no latex or natural rubber materials.

The ORBERA™ System and accessories are covered by the following U.S. Patents: 4,930,535; 5,084,061.