Orbera365™
managed weight loss system



KICKSTART YOUR **WEIGHT LOSS** WITH **ORBERA**365™

apollo endosurgery

Apollo Endosurgery, Inc.

1. Table of Contents

1. Table of Contents

2. Glossary

3. Introduction

3.1. About the ORBERA365 Intragastric Balloon (IGB)
3.2. Who can receive an ORBERA365?
3.3. Who cannot receive an ORBERA365?

4. Warnings and Precautions

4.1. Warnings
4.2. Precautions

5. Risk and Benefit Information

5.1. Risks Related to Endoscopic Procedures and Sedation
5.2. Possible Risks Related to the ORBERA365
5.3. Benefits of the ORBERA365

6. What to Expect - Procedures for ORBERA365

6.1. Placement of Your IGB
6.2. Living with the ORBERA365
    6.2.1. Week 1
    6.2.2. Week 2
6.3. IGB Removal
    6.3.1 Early IGB Removal
    6.3.2. IGB Removal
    6.3.3. After IGB Removal Recommendations
    6.3.4. Life after ORBERA365

7. Date of Release

8. User Assistance Information

2. Glossary

Anesthesia
A medication that takes away pain from a part of your body or makes you sleep or feel sleepy so that you don't feel pain during a medical procedure.

Anesthesiologist
A doctor specializing in the use of anesthesia for medical procedures. An anesthesiologist gives you the medication and checks your health while the medication is in your body.

Aspiration
The passage of stomach contents into the lungs.

Binge Eating Disorder
A serious eating condition in which you frequently eat unusually large amounts of food and feel unable to stop eating.

Body Mass Index (BMI)
A measure of body fat based upon height and weight which is used to tell if your weight is in a healthy range.

18–25 – healthy
25–30 – overweight
30 or above – obese

Bowel Obstruction
A possibly serious problem with your body where the intestines are blocked and bowel surgery may be required. If they become blocked, food and drink cannot pass through the body.

Cholesterol
A type of fat in your blood. If you have too much cholesterol, it starts to build up in your blood vessels and can cause restricted blood flow, clots, or serious heart problems.

Clinical Study
A scientific trial to test new medicines or medical devices in a controlled way to find out how well they work.

Diabetes
A disease that affects the way your body handles glucose, a kind of sugar, in your blood.

Dietitian
A dietitian is a qualified health professional who helps promote good health through proper nutritional habits.



Endoscope
A long, bendable tube with a tiny camera attached. The doctor moves it down your throat to see inside your stomach.

Endoscopic
Using an endoscope for a medical test or procedure.

Endoscopy
A medical test where your doctors look inside your body using an endoscope.

Esophagus
The tube that carries food and liquids from your mouth to your stomach.

Gallstones
Stones that form in the gallbladder (a small organ where fluid from the liver is stored), which can cause a painful digestive problem.

Hypertension
High blood pressure.

Intragastric Balloon (IGB) Intolerance
Your body does not get used to the IGB and causes stomach upset and throwing up that does not get better with medicine. If this happens, the IGB may have to be removed before the six months.



Nutritionist

A person who helps others plan what foods to eat that are good for their health. A nutritionist may or may not have formal training, license, or certification.

Obesity

A medical condition in which extra body fat builds up to the point that it may be unhealthy. People with a BMI of 30 and above are obese.

ORBERA365 & ORBERA Intragastric Balloon (IGB)

A balloon placed within your stomach that is made of a soft, rubber-like material used to help with weight loss. It is designed to take up space in the stomach and mostly slow down the emptying of food in the stomach. ORBERA365 and ORBERA are identical in manufacturing and are both used to treat health issues associated with obesity and being overweight. The ORBERA balloon was approved by the US FDA in 2015 for 6 months in your stomach. ORBERA365 is available outside the US and is labeled for 12 months in your stomach.

Perforation

A hole in an area of your digestive tract, such as esophagus, stomach or intestines.

Run-in Patients

A group of 35 patients in the US ORBERA® US pivotal clinical study who had their IGB placed in their stomachs and then had it removed right away. After the first IGB was removed, the doctor then placed an IGB that stayed in their stomachs for 6 months. All doctors in the study did this so that they could gain experience with the IGB placement procedure.

Saline

A solution of salt in water. Saline is used to fill the IGB.

Sedation

Medication used to make you feel sleepy and not feel pain during a medical test or procedure.

Side Effect

Something bad or harmful that can happen as a result of a medical treatment that may or may not be expected.



3. Introduction

3.1. About the ORBERA365™ Intragastric Balloons (IGB)

The ORBERA365 Intragastric Balloon (referred to as “IGB” throughout this booklet) is made to help you lose weight. The IGB is made of soft, smooth silicone rubber. The empty IGB is passed through your mouth, down your esophagus, and into your stomach. Once in place, it is filled with saline. It then becomes about the size of a grapefruit. The filled IGB lies in your stomach and takes up space. (Figure 1). The IGB also slows down how fast your food passes through your stomach.

From the time that your IGB is placed and for six months after it is removed, you will follow a healthy diet and exercise program. You may not lose weight if you do not follow the program.

Losing weight and keeping it off is not easy. A group of healthcare professionals, that may include your doctor, dietitians or nutritionists and/or exercise trainers, will help you through your journey. They will help you make, and keep, changes in your eating and exercise habits.

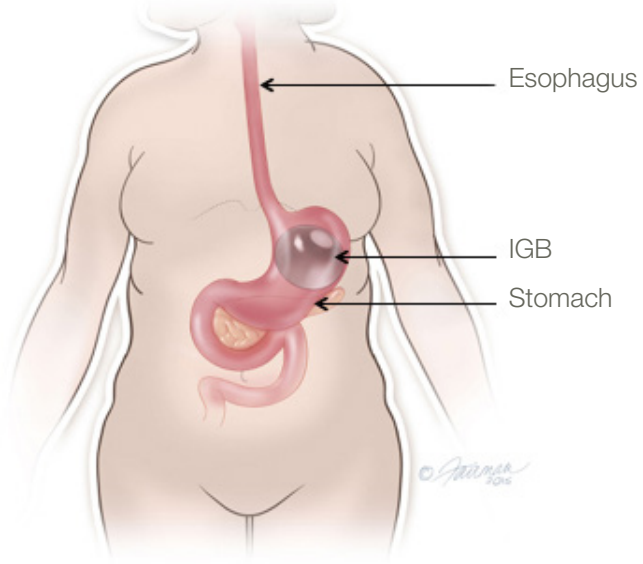


Figure 1: ORBERA365 in the stomach

3.2. Who can receive an ORBERA365?

The ORBERA365 is for adults who are suffering from obesity and have not been able to lose weight and keep it off.

To receive an ORBERA365, you must be willing to follow an 18-month program. The program begins with the use of the IGB and a healthy diet and exercise program for 12 months. That is followed by 6 more months of a healthy diet and exercise program without the IGB in your stomach.

3.3. Who cannot receive an ORBERA365?

- You are not a candidate for ORBER365 if you have severe damage to the liver or if you have digestive issues every day, and especially if your doctor has told you that your stomach empties food slowly.

- You are not a candidate for ORBERA365 if you take prescription aspirin, anti-inflammatory agents, anticoagulants, other gastric irritants, or prescription medicines which slow your stomach emptying daily.

- You are not a candidate for ORBERA365 if you are pregnant or breastfeeding.

There may be other reasons why you cannot have the device. Your doctor will ask for your medical history and will examine you to decide if an IGB is right for you. If your doctor finds stomach problems such as irritation or ulcers, you cannot receive an IGB.



4. Warnings and Precautions

4.1. Warnings



Always tell your health care providers that you have an ORBERA365 and show them your Patient ID Card. If they do not know that you have an IGB, they may not be able to treat you correctly.

Tell your doctor if anything listed in this section happens to you. This will help you get the right care.

After the IGB is first placed, you may not feel well. This should improve steadily over the coming days. If you are improving but start to feel worse again, tell your doctor. Also, tell your doctor if you have severe, steady abdominal pain which makes it difficult for you to take a deep breath or move around. These may be signs that you have a perforation of your stomach, which can cause death.

Tell your doctor if you feel very tired, your stomach hurts, you can't remember things, have trouble sleeping, or you are constipated. These may be signs that you are having a problem with the balloon.

Tell your doctor if you have not been able to drink fluids, if you have become weak, and you are not urinating as much. This may mean your body is low in fluids and you have become dehydrated.

Tell your doctor if you feel severe persistent stomach pain / back pain combined with nausea or vomiting. These may be signs that your stomach is not emptying correctly or that you have an irritation of your pancreas.

Tell your doctor if you no longer feel full after eating, if you are hungrier between meals than before you received an IGB, or if you gain weight. If this happens to you, your IGB may have deflated. A deflated IGB can stop food from passing. This may lead to stomach pain and swelling, throwing up, constipation, or even cause death. Your doctor can check to see if the deflated IGB has moved. If it has, you will need to be watched closely to see if it passes in your stool. Or, you may need an operation to remove it.

Tell your doctor if you feel intense abdominal pain, feel as though your stomach may be swollen (with or without discomfort), difficulty breathing, persistent and untreatable nausea and/or vomiting. These could indicate there may be an issue with your IGB.

Tell your doctor if you have chest pain, painful swallowing, or painful breathing after placement of your IGB or after endoscopy. These may be signs that you have a tear or hole in your esophagus.

Do not use ORBERA365 for more than 12 months. Prolonged IGB placement may increase the risk of the IGB deflating. A deflated IGB can cause the bowels to block, requiring surgery. While it has not yet been reported, it is possible for an unaddressed blockage to cause death.



DO NOT

Do not at or drink anything for 12 hours before your appointment. Food or liquid in your stomach could enter your lungs and cause harm. If you have food in your stomach, your doctor will re-schedule your appointment and give you special instructions. If you take medications, ask your doctor about how they should be taken during that time period.

DO NOT

Do not eat solid foods for 72 hours before your IGB is removed. Also, do not drink liquids for 12 hours before your IGB is removed. Your doctor will provide specific instructions on what type of fluids you should have before removal. If there is food or liquid in your stomach, it can go to your lungs. Food or liquid in your lungs can cause death. If you take medications, ask your doctor about how they should be taken during that time period.

4.2. Precautions

You must follow the diet, exercise, and other directions from your doctor and weight loss team while IGB is in place. If you do not follow directions, you may not lose weight or you may not maintain the weight you have lost already.

Tell your doctor right away if you feel nonstop nausea, or if you cannot stop throwing up. Tell your doctor right away if you were improving after the IGB was first placed but now you feel like you are getting worse. Tell your doctor right away if you have stomach pain that is so bad that you cannot drink any liquids. If you do not tell your doctor about your nausea or vomiting, your body could lose too much water and salts. You may need to go to the hospital to make sure you do not develop problems with your heart and kidneys. Your doctor may give you medicine to take, replace fluids through your vein, or may even remove your IGB.

Some typical symptoms associated with having an IGB in your stomach include: your stomach feeling unusually heavy, nausea and vomiting, acid reflux, burping, heartburn, diarrhea, and pain in your stomach or even into your back or cramping in your stomach. However, you should contact your doctor immediately if these symptoms become unusually severe or worsen significantly.

The safety and effectiveness of the ORBERA365 has not been established during pregnancy or breastfeeding. As soon as you know you are pregnant, tell your doctor so that your IGB can be removed. If you are a breastfeeding mother or planning to become pregnant within the next year, you should not use an IGB.



5. Risk and Benefit Information

5.1. Risks Related to Endoscopic Procedures and Sedation

After you have been given a sedative medication, your IGB will be placed by your doctor using an endoscope that goes down your throat and into your stomach. The IGB is removed in the same way. Endoscopy is very safe, but there are rare risks. The most common risks of endoscopy include bleeding, infection, and tearing of the tissue of your esophagus or stomach (which could lead to a hole forming) and a passage of stomach contents into the lungs. These problems only occur in about 3–5 of every 10,000 endoscopies.

Risks related to sedation during endoscopic procedures are rare, occurring in less than 1 in every 10,000 people. The most common side effects of sedative medications are temporary slowing of your pulse or breathing rate, which can be improved by the doctor giving you extra oxygen or medication to reverse the effect of the sedative.



Patients with heart, lung, kidney, liver, or other chronic diseases are at higher risk for side effects from medications. In order to reduce the chance of having side effects during the IGB procedures, you should follow your doctor's instructions on how to prepare for endoscopy, such as not eating and stopping certain medications.

5.2. Possible Risks Related to the ORBERA365

Your IGB may cause you to feel uncomfortable as your body gets used to it. You can expect to feel some nausea, throwing up, pain, and acid reflux. These may stop on their own, or you may need medicine. Your doctor may give you medicine to help your body get used to the IGB. Some of these medicines may further slow the emptying of your stomach and should be used sparingly and in accordance with your doctor's instructions. If while taking these medications your symptoms become more severe or if they reappear after becoming used to the IGB, contact your doctor as this may be a sign of a serious health issue. Prescribed acid reducing medications (i.e. proton pump inhibitors (PPIs)) should be taken throughout the period of time in which the IGB is implanted, even in the absence of symptoms, to help reduce the risk of ulcers, subsequent stomach perforation and to help to reduce the risk of device deflation.

In a U.S. pivotal clinical study of 160 people (125 patients with the ORBERA IGB placed for 6 months plus 35 run-in patients), 139 reported nausea, 137 reported pain or discomfort, 121 reported throwing up, and 48 reported acid reflux at some time while they had the IGB. Most of the side effects started on the day the IGB was placed in the patient's stomach or the following day. In the U.S. clinical study, a total of 30 people out of 160 had their IGBs removed early (before 6 months).

8 of the 30 people had their balloons removed early because of serious balloon intolerance which resulted in a hospital stay. The serious side effects included non-stop throwing up, nausea, pain and acid reflux that did not get better with medications.

5 of the 30 people that had their balloon removed early because of other serious side effects such as lack of proper hydration, balloon blocking the outlet of their stomach, a hole forming all the way through their stomach, lung infection, and infection due to bacteria growth on the balloon.

2 of the 30 people had their balloons removed early due to other side effects: 1 person had gallstones and 1 person had small hollow pouches in the lining of the digestive system.

15 out of the 30 people asked to have their balloons removed early for unknown reasons and did not need to stay in the hospital.

In a U.S. post-approval study of 258 people, conducted after the IGB was FDA approved, 70 reported nausea, 67 reported throwing up, 63 reported pain or discomfort, and 32 reported acid reflux at some time while they had the IGB. Mose of these side effects started within the first week of the IGB being placed in the patient's stomach and resolved within 2 weeks of starting. In the U.S. post-approval study, a total of 47 people out of 258 had their IGBs removed early (before 6 months).

27 of these 47 people that had their IGB removed early had it removed because of IGB intolerance or serious side effects such as throwing up, nausea, pain and acid reflux that did not get better with medications.

13 of these 47 people that had their IGB removed early requested removal of the IGB due to their schedule or in preparation for an unrelated medical procedure.

4 of these 47 people had their IGB removed early had it removed due to over inflation of the implanted IGB with gas or fluid.

3 of these 47 people had their IGB removed early had it removed due dissatisfaction with treatment or due to reaching their weight loss goal early.



Serious side effects are health problems which:

1. May lead to hospitalization
2. Result in an illness or injury which puts you at risk for death
3. Cause long lasting injury to the body
4. Need quick medical treatment or surgery to prevent bodily injury

Reported serious side effects related to ORBERA seen in the U.S. pivotal study are described in Table 1. Given that this US study involved IGBs placed within the stomach for only 6 months, the risk profile in this tables may be somewhat different for 12 month IGBs. Table 2 includes serious side effects that have occurred in people with weight loss IGBs that were not seen within the US pivotal study, but occurred with commercial use of the device (i.e. both 6 month and 12 month IGBs). Other risks or side effects may not yet be known.

Table 1: Serious side effects with ORBERA IGB that were seen in the U.S. pivotal study, which required hospital stay or were important medical events.

Side Effect	Number of people who had the side effect in the U.S. pivotal study (out of 160)[1]	Harm, or possible harm	Onset
IGB Intolerance.	8 out of 160	Stomach pain, nausea, acid reflux, and non-stop throwing up, which can lead to lack of body water and salts. 8/8 patients had early removal.	Patient 1: Day of IGB placement Patient 2: Day 1 Patient 3: Day 2 Patient 4: Day 6 Patient 5: Day 11 Patient 6: Day 13 Patient 7: Day 18 Patient 8: Day 60
Lack of proper hydration.	2 out of 160	Lack of body water and salts; admitted to hospital; early IGB removal. 1/2 patients had early removal because of lack of proper hydration and 1 patient also had device intolerance as well as lack of proper hydration, which led to early IGB removal.	Patient 1: Day 1 Patient 2: Day 3
IGB blocking the passage of food from the stomach to the intestine.	1 out of 160	Feeling full, nausea, throwing up, stomach pain, and acid reflux; early IGB removal. 1/1 patients had early removal.	Day 24
Sudden closure of the throat during procedure.	1 out of 160	Hard time breathing, which required a breathing tube for a short time.	During the procedure
Injury to the lining of the esophagus.	2 out of 160	Chest pain, fever, and admitted to hospital.	During the procedure
A hole formed all the way through the wall of the stomach.	1 out of 160	Nausea, cramping, throwing up, infection, admitted to hospital, and surgery to remove the IGB. 1/1 patients had early removal.	Day 3
Lung infection caused by breathing in of stomach contents while throwing up.	1 out of 160	Hard time breathing, pain, fever, admitted to hospital, and IGB removal. 1/1 patients had early removal.	Day 74
Stomach cramping and infection caused by bacteria growing on the IGB.	1 out of 160	Cramping, pain, fever, and IGB removal. 1/1 patients had early removal.	Day 154

1. 125 people in the study group plus 35 more people who had 1 IGB inserted and removed and then another IGB inserted on the same day so that doctors could get experience with the procedures.

Table 2: Serious side effects with the IGB that were seen in the U.S. Post-Approval study, which required hospital stay or were important medical events.

Side Effect	Number of people who had the side effect in the U.S. pivotal study (out of 160)[1]	Harm, or possible harm	Onset
IGB Intolerance.	12 out of 258	Stomach pain, throat pain, vomiting, nausea, acid reflux, dehydration, admitted to hospital and early IGB removal. 11/12 patients had early removal.	Patient 1: Day of IGB Placement Patient 2: Day of IGB Placement Patient 3: Day of IGB Placement and Day 3 Patient 4: Day of Placement and Day 77 Patient 5: Day 8 Patient 6: Day 9 Patient 7: Day 11 Patient 8: Day 14, Day 28 Patient 9: Day 17 Patient 10: Day 89 Patient 11: Day 98 Patient 12: Day 125
Delayed Stomach Emptying.	5 out of 258	Stomach cramping/pain, vomiting, nausea, acid reflux, constipation, admitted to hospital and early IGB removal. 5/5 patients had early removal.	Patient 1: Day of IGB Placement Patient 2: Day of IGB Placement Patient 3: Day 28 Patient 4: Day 38 Patient 5: Day 87
Device Intolerance due to over inflation of the implanted IGB (after placement procedure), which prompted early removal.	5 out of 258	Stomach pain, vomiting, nausea, acid reflux, dehydration, admitted to hospital and early IGB removal. 5/5 patients had early removal.	Patient 1: Day 3 Patient 2: Day 10 Patient 3: Day 40 Patient 4: Day 74 Patient 5: Day 166
Stomach swelling due to air or gas (bloating).	1 out of 258	Nausea, discomfort and early IGB removal. 1/1 patients had early removal.	Day 63
Low Potassium Levels in Blood (Hypokalemia).	1 out of 258	Admitted to hospital, Low levels of potassium in the blood due to vomiting and diarrhea, early IGB removal. 1/1 patients had early removal.	Day 98
Diarrhea.	1 out of 258	Admitted to hospital, dehydration, Low levels of potassium in the blood early IGB removal. 1/1 patients had early removal.	Day 98

Table 3: Serious side effects known to occur with weight loss IGBs.

Potential Side Effect	Harm, or possible harm	Occurrence
Deflated IGB causing a bowel obstruction.	A deflated IGB in the stomach can pass through the intestines naturally or it can become stuck (bowel obstruction) and must be removed with surgery. If not treated, it can cause death. Death due to bowel obstruction has not been reported.	Was not reported in the U.S. studies. • US rate for bowel obstruction is 0.01%* (less than 1 case per 10,000 patients) • Global rate for bowel obstruction is 0.01%* (less than 1 case per 10,000 patients)
Did not understand or remember instructions and warning statements about taking acid reducing medications.	Ulcers (sores in the stomach), stomach pain and/or burning, and heartburn. If not treated may lead to a hole in the stomach, which can cause death.	Was not reported in U.S. studies.
Hole forming all the way through the wall of the stomach, caused by the endoscope or other reason.	Ulceration and the endoscope may not be the only causes of a hole forming in the stomach. Other causes are currently not well-understood. If not treated, it can lead to death.	Was reported once in the U.S. pivotal study (0.625%) (1 case per 160 patients) but not in the Post-Approval FDA study. • US rate for hole forming in the stomach is 0.086%* (about 9 cases per 10,000 patients) • Global rate for hole forming in the stomach is 0.030%* (about 4 case per 10,000 cases)
Did not understand or remember instructions and warning statements about use longer than 6 months.	Prolonged IGB placement may increase the risk of the IGB deflating (i.e. collapse or “empty”). If not addressed, a deflated IGB can cause the bowels to block and can cause death, though this has not been reported.	Was not reported in U.S. studies.
A hole forming all the way through the esophagus, caused by the endoscope or other instruments.	Bleeding, pain, infection, surgery to repair injury. If not treated, it can lead to death	Was not reported in U.S. studies • US rate for a hole forming in the esophagus is 0.020%* (less than 3 cases per 10,000 patients) • Global rate for hole forming in the esophagus is <0.01%* (less than 1 case per 10,000 patients)
Heart problems, or heart attack during anesthesia.	Chest pain, fast or slow heartbeat, and a hard time breathing. If not treated, it can lead to death.	Was not reported in U.S. studies.
Allergic reaction to medications, including anesthesia.	Rash, hives, wheezing, hard time breathing, sudden drop in blood pressure, sweating, fast heartbeat, and swelling around the mouth, throat, or eyes. Severe allergic reactions can lead to death if not treated right away.	Was not reported in U.S. studies.
Compression of the Pancreas.	Severe persistent stomach pain / back pain with nausea or vomiting that may be caused by irritation of or injury to the pancreas.	Was not reported in U.S. studies. • US rate for pancreatitis is 0.070%* (about 7 cases per 10,000 patients) • Global rate for pancreatitis is 0.015%* (about 2 cases per 10,000 patients)
Over inflated IGB.	The IGB could over inflate with gas or fluid by itself while it is in a patient’s stomach. The IGB will need to be removed early.	Was not reported in the U.S. pivotal study but was reported in the post approval study (2.3%) (6 cases per 258 patients, 1 of the 6 cases was seen during the patient’s planned removal surgery). Additionally, half of these cases (3 out of 6) were associated with IGB placements from a single study site (1 out of 11 sites). • US rate for over inflated IGB is 0.347%* (about 4 cases per 1,000 patients). • Global rate for over inflated IGB is 0.205%* (about 21 cases per 10,000 patients)

Potential Side Effect	Harm, or possible harm	Occurrence
Death.	Infection and organ failure may occur as a result of a hole in the stomach or esophagus. Severe injury to the lungs may occur after stomach contents have entered the lungs. Bowel obstruction due to the migration of a deflated IGB into the intestines can occur. These events can all lead to death.	Was not reported in the U.S. studies. • US mortality rate is 0.030%* (less than 3 deaths per 10,000 patients) • Global mortality rate is 0.011%* (less than 2 deaths per 10,000 patients)
Did not understand or remember instructions and warning statements about not eating or drinking prior to IGB removal.	If food and liquid are retained in the stomach during removal, there is an increased risk of these stomach contents entering the lungs.	Was not reported in the U.S. studies. • US rate for aspiration is 0.065%* (less than 7 cases per 10,000 patients) • Global rate for aspiration is 0.013%* (about 1 case per 10,000 patients)

*Rate of reported serious side effects that occurred during commercial use of Apollo IGBs; rates are calculated based on number of devices distributed, which may be greater than the number placed. These rates were calculated from post-market data collected during August 05, 2015 to March 31, 2021. Global rates include all Apollo balloons.

The three most common side effects seen in the U.S. pivotal and post-approval study, which did not lead to hospital, stay are nausea, throwing up, and pain. These side effects are shown in Table 4 for the pivotal study.

Side effects seen in more than 1% of patients (at least 2 out of 160) in the U.S. pivotal study, which did not lead to hospitalization, are described in Table 5 and listed in order by most frequent to less frequent (similar rates were seen in the post-approval study). Side effects occurring in less than 1% of the patients (1 out of 160) were not related to the digestive system and are not listed. Only 5% of people had side effects that caused severe pain which made it hard for them to do their usual work or activities.

Table 4: Most common gastric (stomach) side effects seen in the U.S. Pivotal Study

Side Effect	Total number of people with side effect (percent of people with side effect)	Number of people with side effect beginning within 3 days of the IGB being placed (percent of people with side effect)	Number of people with side effect starting within 3 days of IGB being placed and lasting longer than 14 days and less than 30 days (percent of people with side effect)	Number of people with side effect starting within 3 days of the IGB being placed and lasting longer than 30 days (percent of people with side effect)
Nausea	139 out of 160 (86.9 %)	123 out of 139 (88.5%)	6 out of 123 (4.9%)	9 out of 123 (7.3%)
Throwing up	121 out of 160 (75.6%)	103 out of 121 (85.1%)	3 out of 103 (2.9%)	4 out of 103 (3.9%)
Stomach Pain (General)	92 out of 160 (57.5 %)	74 out of 92 (80.4%)	5 out of 74 (6.8%)	4 out of 74 (5.4%)



Table 5: Side effects caused by ORBERA, which were seen in more than 1% of patients in the U.S. pivotal study, but did not lead to hospital stay.

Side Effect	Number of people in the pivotal study who had the side effect	Harm, or possible harm
Nausea.	139 out of 160 (87%)	An uneasy feeling in the stomach, or feeling like you need to throw up.
Pain or discomfort.	137 out of 160 (82%)	An unpleasant feeling in the stomach, chest, or back.
Throwing up.	121 out of 160 (76%)	Throwing up can lead to a lack of body water and salts. It can also cause you to breathe in food or fluids, which can cause a lung infection.
Acid reflux.	48 out of 160 (30%)	Acid coming up from the stomach causes heartburn and chest pain, and may also cause nausea and throwing up. If not treated, it can cause other health problems.
Burping/belching.	39 out of 160 (24%)	None.
Heartburn.	34 out of 160 (21%)	A burning pain in the chest.
Constipation.	32 out of 160 (20%)	Stools that are dry, hard to pass, and may be painful.
Stomach bloating.	28 out of 160 (18%)	Swelling of the stomach.
Lack of body water and salts.	23 out of 160 (14%)	Lack of body water and salts can cause other health problems with your heart or kidneys.
Diarrhea.	21 out of 160 (13%)	Liquid stool multiple times a day can cause a lack of body water and salts.
Gas.	18 out of 160 (11%)	None. Gas can make the belly feel full or bloated and can cause cramps..
Slowed digestion of food.	14 out of 160 (8.8%)	Nausea, throwing up, swelling of the stomach, poor appetite, and inability to eat anything.
Tiredness, weakness, dizziness, or uneasy feeling.	12 out of 160 (8%)	Being tired, weak, or dizzy can due to the lack of fluids and salts and can cause falls..
Headache or migraine.	10 out of 160 (6%)	Pain in the head, which may make it hard to do your usual work or activities and cause nausea.
Device intolerance.	9 out of 160 (6%)	Severe side effects such as nausea, throwing up, pain, inability to eat or drink and worsened acid reflux, all due to poor stomach emptying (not requiring a hospital stay). 5 out of 9 reports lead to early device removal.
Bodily pain after procedure.	8 out of 160 (5%)	A feeling of aches and pains in the body.
Sinus or respiratory infection, nasal congestion, or chills.	6 out of 160 (4%)	Coughing, fever, stuffy or runny nose, body aches and pain, hard to breathe.
Bad breath.	6 out of 160 (4%)	A harmless but bad taste in the mouth and on the breath can be due to food staying in the stomach for a long time..

Side Effect	Number of people in the pivotal study who had the side effect	Harm, or possible harm
Hard to swallow.	5 out of 160 (3%)	Having a hard time swallowing blocks eating food and can cause a lack of body water and salts or poor nutrition.
Irritation of the lining of the esophagus, which may be caused by not taking acid-reducing medication as instructed.	5 out of 160 (3%)	Burning pain in the chest after eating, hard time swallowing, nausea, and throwing up. If not treated, it can cause open sores (ulcers) to form.
Stiff stomach muscles.	5 out of 160 (3%)	The belly is painful to touch and grunting can be painful.
Lack of Vitamin B1.	5 out of 160 (3%)	Weakness, tiredness, loss of appetite, nausea, confusion, difficulty breathing, poor vision, tingling in the hands and feet.
Sore throat.	5 out of 160 (3%)	Pain in the throat, which may make it hard to swallow.
Infection in the stomach.	4 out of 160 (2.5%)	Pain and swelling of the stomach, nausea, and throwing up.
Hiccups.	4 out of 160 (2.5%)	None.
Irritation of the lining of the stomach, which may be caused by not taking acid-reducing medication as instructed.	4 out of 160 (2.5%)	Upper belly pain or burning, nausea, throwing up, feeling of fullness in upper belly after eating.
Food unable to move from stomach to bowel.	3 out of 160 (1.9%)	Nausea, throwing up, upper belly pain, and worsened acid reflux, which may require early removal of the IGB.
Dry heaves.	3 out of 160 (1.9%)	Throwing up without anything coming out. Strong feeling of need to throw up, but does not lead to throwing up of food or liquid.
Lung infection.	3 out of 160 (1.9%)	Cough, fever, hard time breathing.
Fear, worry, or hard time falling asleep.	3 out of 160 (1.9%)	An uneasy feeling which may makes it hard to do your usual work or cause you to not get enough sleep.
Lack of appetite.	3 out of 160 (1.9%)	May lead to poor nutrition and weight loss.
Unable to control bowels.	2 out of 160 (1.3%)	An accidental liquid stool may affect your usual work or activities.
Spasm of the intestine.	2 out of 160 (1.3%)	Pain and cramping can cause difficulties eating and carrying out your usual activities.
Low potassium.	2 out of 160 (1.3%)	If not treated, could lead to heart problem or death.
Low blood count.	2 out of 160 (1.3%)	Weakness, tired, and dizziness.

5.4. Benefits of an IGB

The benefits of ORBERA were tested in a clinical study in the United States. This was the U.S. Pivotal Study. The study looked at people with BMI between 30 and 40. People in the study received an IGB for six (6) months along with diet and exercise and were compared with people who only used diet and exercise. The people who only used diet and exercise are called the Control group. Both groups had regular doctor visits during the study.

After 6 months with ORBERA, patients in the study lost an average of 21.8 lbs (9.9 kg) as compared to patients in the Control group who lost an average of 7.0 lbs (3.2 kg). Three (3) months after the IGB was removed (at 9 months), patients in the ORBERA365 group weighed an average of 19.4 lbs (8.8 kg) less than when they had the IGB placed.

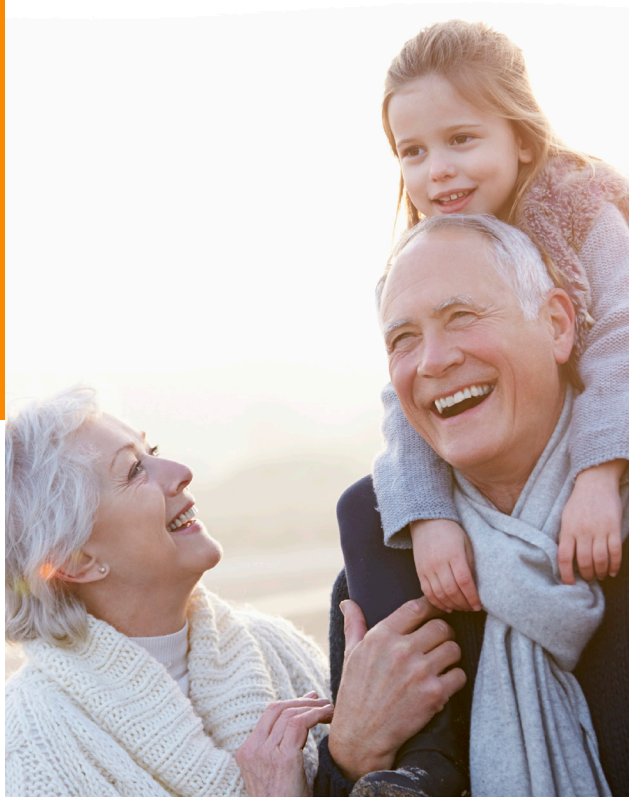
Six (6) months after the IGB was removed (at 12 months), patients in the ORBERA group weighed an average of 16.2 lbs (7.3 kg) less than when they had the IGB. Weight loss for the Control group at 6 months and 9 months was 7.1 and 6.3 lbs (3.2 and 2.9 kg), respectively.



Both groups of patients in the study answered questions about their quality of life at baseline (before treatment) and at 9 months. At baseline the quality of life scores were similar for both the ORBERA and Control groups. By 9 months (3 months after device removal) the scores in the ORBERA group for physical functioning, role functioning, bodily pain, general health, social functioning, and vitality (ability to live and exist) were significantly improved; however, only physical functioning was significantly improved in the Control group.

A second study was conducted in the US after FDA approval of the IGB. This "Post Approval Study" was similar to the U.S. pivotal study in that it included people with BMI between 30 and 40 and study participants received an IGB for six (6) months along with diet and exercise as well as six (6) additional months of diet and exercise after the IGB was removed.

All subjects in the study demonstrated weight loss as early as 2 weeks and weight loss continued to gradually increase while the balloon was in place. After 6 months with the IGB, patients in the study lost an average of 27 lbs (12.2 kg). Three (3) months after the IGB was removed (at 9 months), patients weighed an average of 20 lbs (9.0 kg) less than when they had the IGB placed. Six (6) months after the IGB was removed (at 12 months), patients weighed an average of 17 lbs (7.7 kg) less than when they had the IGB placed.



The benefits described above were reported from the US pivotal study, with the balloon being in the stomach for 6 months. The expected incremental benefits associated with ORBERA365 (12 months in the stomach), include more time to lose weight and adopt health habits. This may help you lose more weight and to keep it off, but this has not been proven yet. These benefits of ORBERA365 are being studied in an ongoing clinical study.

6. What to Expect – Procedures for the ORBERA365

6.1. Placement of Your IGB

Your doctor will set a date for you to have the balloon placed in your stomach.

WARNING: Do not eat or drink anything for 12 hours before your appointment. Food or liquid in your stomach could enter your lungs and cause harm. If this is found the IGB placement will be changed to another time. Your doctor will need to give you special directions to prepare for this. Ask your doctor about how to take medications during that time period.



On the day of placement:

1. Before the doctor places the IGB in your stomach, you will be weighed. Tell your doctor about any changes to your health, illnesses, eating habits, or medicines since your last visit. If you are a woman who could get pregnant, you will have a pregnancy test.
2. You may be given medicine to help with nausea, vomiting, stomach pain, or cramping. These problems are normal. They happen as your stomach gets used to the IGB and it should only last for 1 to 2 weeks. You should make steady progress tolerating the IGB each day after it is placed.
3. You may be given medicine to help with any pain after the balloon is placed.
4. When the balloon is in place, your doctor will fill it with salt solution, saline.
5. After the procedure, the doctor or nurse will watch you for a few hours. They will make sure that you are awake, can swallow, and can take sips of water before you go home.



On the day of placement:

DO NOT drive, use machinery or power tools, or make important decisions for 24 hours. You will have had sedation and your judgment will be affected without you knowing it. You may have accidents and make mistakes.

DO call your doctor if you have pain or redness at the area on your arm where the needle was placed for your IV fluids. This may be due to a clot in the vein where the IV was placed. Your doctor will give you instructions to care for this.

DO call if you don't urinate (pee) for 12 hours after going home from the clinic. This may mean that you are not getting enough fluids.

Your ORBERA365 will stay in your stomach for 12 months (365 days). During this time and for 6 months after the balloon is removed, your doctor and nutritionist will help you change your eating and exercise habits.

6.2. Living with ORBERA365

6.2.1. Week 1

Right Away:

- Your doctor may give you medicine for pain, stomach cramps, nausea, and stomach acid. Have prescriptions filled before you get home. Follow all doctor's orders for taking medicines.

- You should make steady progress tolerating the IGB each day after it is placed. If not, call your doctor.

- DO NOT drive, use machinery or power tools, or make important decisions for 24 hours. You will have had sedation and your judgment will be affected without you knowing it. You may have accidents and make mistakes.

- Keep your Patient ID Card with you at all times when you leave home.



First 24 Hours:

- You should drink clear liquids (broth, gelatin, ice chips, water, apple juice, coffee, tea). Warm liquids, such as broth, may be better than cold drinks. Do not drink carbonated drinks (soda or pop), which can cause gas and bloating.

- Drink at least 8 cups of liquid per day. Drinking liquids keeps you from becoming dehydrated and can drop the risk of constipation. Start by taking small sips. Wait a minute or two between sips. Slowly take more with each sip. Drink only 1/3 cup at a time.

- Sit upright for 3 to 4 hours after drinking. If resting, use a recliner rather than lying flat.

- Do not drink more than one cup of coffee or caffeine drinks per day. Caffeine can cause you to become dehydrated. It can cause cramps or diarrhea.



First 3 Days:

- Rest for 72 hours (3 days) after the IGB is placed if you are experiencing a lot of nausea, vomiting, and stomach discomfort. Walking and other light activities are allowed.

CAUTION: You may have nausea and vomiting as you become more active or begin to eat more. If this happens, cut back on your activities and return to liquids. This is always a useful thing to do if you re-experience difficulties tolerating the IGB. Take medicine as directed by your doctor.

CAUTION: You may feel dizzy if you stand up or move too quickly. Stand up slowly so you do not fall.

First Week:

- Follow your doctor's instructions about what to eat and drink. For the first week, continue the liquid diet. Work with your nutritionist or dietitian and doctor about what to eat and drink. You may drink meal replacement shakes.



6.2.2. Week 2

At the beginning of week 2, start eating pureed foods. Talk to your nutritionist, dietitian, or doctor about what foods to eat and when to introduce new or solid foods.

Eat slowly and chew thoroughly. Each meal should take about 15 to 20 minutes.

Continue to drink at least 8 cups of liquid a day.

Pay close attention to how you feel before, during, and after meals. Stop eating as soon as you feel full or have any stomach discomfort.

This means that you may not need to eat everything on your plate.



WARNING: If you ignore these feelings, you may have heartburn, vomiting, or pain.

WARNING: Call your doctor if you have any concerns about your health or well-being during this time or if you notice:

- Unable to progress each day in tolerating the IGB after placement.
- Nausea that is worse than it was right after the IGB was put in or the inability to eat anything
- Coughing, spitting, or throwing up blood.
- Bloody or black stools, persistent diarrhea, or constipation .
- Stomach pain becoming worse or actual swelling of the belly (Note: It is normal to feel some swelling after the IGB is put in).
- Burping or heartburn that is new or worse than it was right after the IGB was put in.
- No longer feeling full, like you did when the IGB was first put in.
- You are gaining weight instead of losing weight, or you are eating more than usual.
- Severe persistent stomach pain / back pain combined with nausea or vomiting. These may be signs that your stomach is not emptying correctly or that you have an irritation of your pancreas.
- Intense abdominal pain, feel as though your stomach may be swollen (with or without discomfort), have difficulty breathing, persistent and untreatable nausea and/or vomiting. These could indicate there may be an issue with your IGB.
- Chest pain, painful swallowing or painful breathing, which could be signs of a tear or hole in your esophagus.
- Severe, steady abdominal pain which may make it difficult for you to take a deep breath or move around. These could be signs that you have a perforation in your stomach.

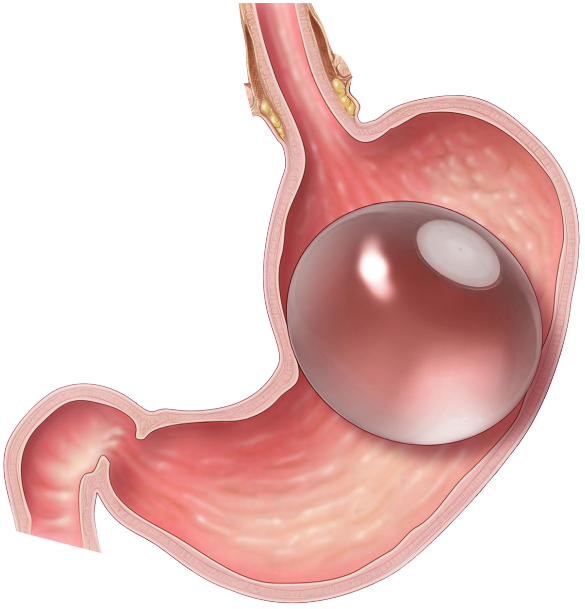
After you can eat solid foods, work with your nutritionist or dietitian to find a diet and exercise plan to follow.

While your IGB is in your stomach, your nutritionist or dietitian and physician will check with you to help you with diet and exercise. It is a good idea to write down what you eat and how much you exercise. This will help them find a plan that works best for you.



6.3. IGB Removal

6.3.1 Early IGB Removal



Your IGB may have to be removed before the planned twelve months of weight loss treatment. The most common reason for the IGB to be taken out of your stomach is because you are unable to tolerate the IGB.

The IGB works by slowing down how your stomach empties food and juices. In some people the stomach stops emptying completely. This will cause you to have an enlarged stomach. It will make it very difficult to eat or drink and cause you to throw up, sometimes after only drinking very small amounts of fluids. If your stomach has stopped emptying, these symptoms will not go away even with advice your doctor has given you. This is a dangerous situation.

If this happens, the IGB must be removed before the planned removal time. Leaving the IGB in your stomach can lead to more serious issues, such as a hole developing in the stomach needing surgical repair. If left untreated, it can be fatal. Your doctors will take special care to remove the IGB in this situation such that any food or fluids remaining in your stomach do not get into your lungs.

Other potential reasons for an early IGB removal may include, but are not limited to, spontaneous hyperinflation (microbes getting into the IGB can cause it to swell), inflammation of the pancreas, and the development of a hole or perforation in the esophagus or stomach.

6.3.2. IGB Removal

YOU MUST have your ORBERA365 removed no later than 12 months (365 days) after it is placed. Prolonged IGB placement may increase the risk of the IGB deflating (i.e. collapse or “empty”). A deflated IGB can cause the bowels to block, requiring surgery. While it has not yet been reported, it is possible for an unaddressed blockage to cause death.

To remove your IGB, your doctor will do an endoscopic procedure or surgery. Call your doctor’s office to schedule this procedure before the IGB is due to be removed.

Before IGB removal you will be given sedative medications to make you feel sleepy and not feel pain during the procedure. Then your doctor will use an endoscopic tool to deflate the IGB. It will be removed through your mouth.

The doctor or nurse will watch you for a few hours. They will make sure that you are awake, can swallow, and can take sips of water. Most people go home the same day the balloon is removed.

WARNING: Your stomach must be empty before your IGB is removed.

Do not eat solid foods for 72 hours or drink liquids for 12 hours before your IGB is removed. Food or liquid in your stomach can enter your lungs and cause life-threatening harm. If you have food in your stomach, your doctor will postpone the removal and give you special instructions.

Ask your doctor about how to take medications during that time period. Note that if you still have retained food or liquid in your stomach, you may require placement of a tube through the nose and into the stomach to empty your stomach prior to IGB removal.



6.3.3. After Balloon Removal Recommendations

DO NOT drive, use machinery or power tools, or make important decisions for 24 hours. You will have had sedation and your judgment will be affected without you knowing it. You may have accidents and make mistakes.

Walking and other light activities are allowed the day that the IGB is removed. If you feel dizzy, stand up slowly so you do not fall.

For the first 24 hours, follow a clear liquid diet (broth, gelatin, ice chips, water, apple juice, coffee, tea). Warm liquids, such as broth, may be better than cold drinks. Do not drink carbonated drinks (soda or pop), which can cause gas and bloating.

Call your doctor if you notice:

- Fever or chills
- Cough and shortness of breath
- Nausea or throwing up that does not stop
- Coughing, spitting, or throwing up blood
- Bloody or black stools (bowel movement)
- Stomach pain which is getting worse
- Pain or redness at the area on your arm where the needle was placed for your IV fluids



6.3.4. Life after ORBERA365

For 6 months after your IGB is removed, you must follow a healthy diet and exercise program. If you do not continue your diet and exercise, you may not lose weight or maintain the weight you have lost already.

While your IGB helps you get started with your weight loss, the habits you form during the 18-month program are the tools to keeping a healthy weight.

With an IGB you get a weight loss tool, and a chance to learn a new way to feel about food and yourself. Losing weight and keeping it off is not easy and can take a team effort. Your doctor, trainer, dietitian or nutritionist will help you through your journey. They will help you with your eating and exercise habits. Be sure to follow up with your doctor and nutritionist to help you maintain your weight loss.



NOTES

Orbera365™
managed weight loss system

7. Date of Release
2023-04

8. User Assistance Information
For any assistance, users should contact:

Apollo Endosurgery Inc.
1120 South Capitol of Texas Highway
Building 1, Suite 300
Austin Texas 78746
USA

Phone: 1.855.MYORBERA
Fax: 512.279.5105

Or go online at www.apolloendo.com

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