

# **ORBERA™ IntraGastric Balloon System (ORBERA™)**

## **Patient Information Booklet**

**Rx Only**



**Apollo Endosurgery, Inc.**

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## 2 Glossary

**Anesthesia:** A medication that takes away pain from 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 medications and checks your health while the medication is in your body.

**Balloon Intolerance:** Your body does not get use to the balloon and causes stomach upset and throwing up that does not get better with medicine. If this happens the balloon may have to be removed before six months.

**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.

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

**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.

**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.

**Nutritionist:** A trained person who helps others plan what foods to eat that are good for their health.

**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.

**ORBERA™ Intra-gastric Balloon:** A balloon made of a soft, rubber-like material used to help with weight loss. It is designed to take up space in the stomach which means there is less space for food.

**Physiologist:** A doctor who studies how different parts of the body work.

**Run-in Patients:** A group of 35 patients in the ORBERA™ Clinical Study who had an ORBERA™ balloon put in their stomachs and then removed right away. After the first ORBERA™ was removed the doctor then placed the ORBERA™ that stayed in their stomachs for 6 months. All doctors in the study did this so that they could gain experience with the ORBERA™ procedure.

**Saline:** A solution of salt in water. Saline is used to fill the ORBERA™ balloon.

**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.

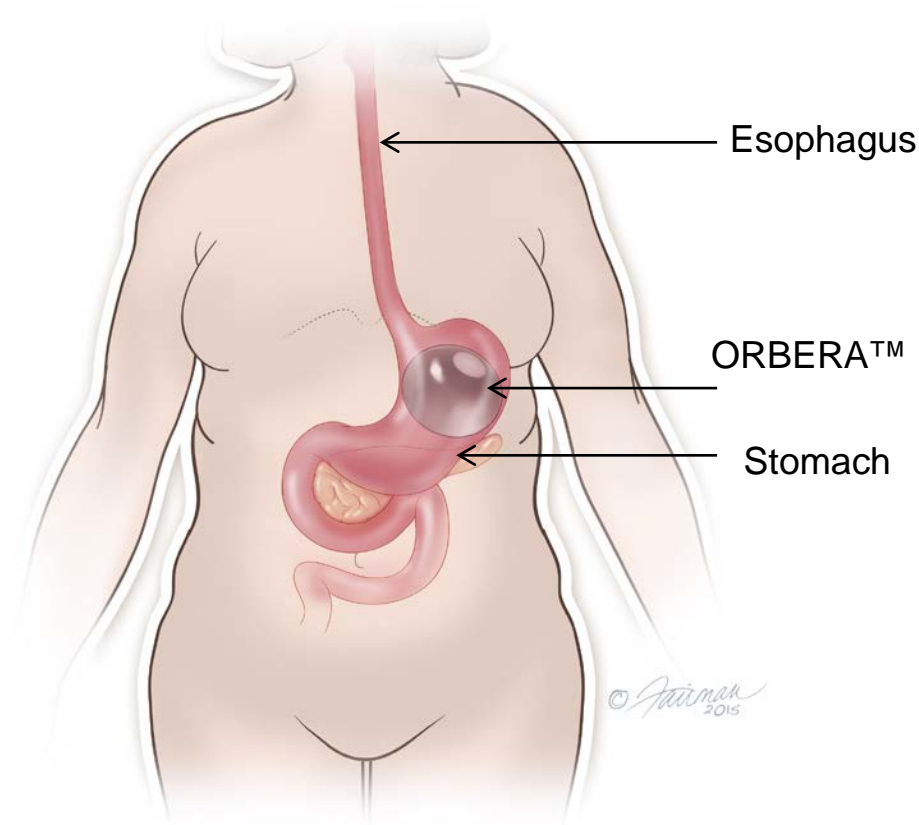
### 3 Introduction

#### 3.1 About the ORBERA™ Intragastric Balloon

The ORBERA™ Intragastric Balloon is made to help you lose weight. ORBERA™ is a balloon made of soft, smooth silicone rubber. The empty balloon 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 ORBERA™ floats in your stomach and takes up space. (Figure 1).

From the beginning and six months after ORBERA™ 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 doctors, physiologists, and nutritionists will help you through your journey. They will help you make and keep changes in your eating and exercise habits.



**Figure 1: ORBERA™ in the stomach**

## **3.2 Who can receive ORBERA™?**

ORBERA™ is for adults suffering from obesity who have not been able to lose weight and keep it off.

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

## **3.3 Who cannot receive ORBERA™?**

- You are not a candidate for the ORBERA™ if you have severe damage to the liver.
- You are not a candidate for the ORBERA™ if you take prescription aspirin, anti-inflammatory agents, anticoagulants or other gastric irritants daily.
- You are not a candidate for the ORBERA™ 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 ORBERA™ is right for you. If your doctor finds stomach problems such as irritation or ulcers, you cannot receive ORBERA™.

# **4 Warnings and Precautions**

## **4.1 Warnings**

Always tell your health care providers that you have ORBERA™ and show them your Patient ID Card. If they do not know that you have ORBERA™, 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.

Tell your doctor if you cannot keep liquids down and cannot swallow, or if you are nauseated or throwing up. You could become dehydrated and your kidneys could shut down.

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

Tell your doctor if you no longer feel full after eating, if you are hungrier between meals than before you received ORBERA™, or if you gain weight. If this happens to you, your balloon may have deflated. A deflated balloon 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 balloon 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.

Do not use ORBERA™ for more than 6 months. The balloon is more likely to deflate and cause the bowels to block if it is left in place longer than 6 months. A blocked bowel can cause death.

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 you have food in your stomach, you will have to wait until you can go 12 hours without food or drink. If you take medications, ask your doctor about how they should be taken during that time period.

Do not eat solid foods for 24 hours before your balloon is removed. Also, do not drink liquids for 12 hours before your balloon is removed. 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 while ORBERA™ 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 have stomach cramps that are 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 have to remove your ORBERA™.

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

## **5 Risk/Benefit Information**

### **5.1 Risks Related to Endoscopic Procedures and Sedation**

After you have been given a sedative medication, ORBERA™ will be placed and removed by your doctor using an endoscope that goes down your throat and into your stomach. Endoscopy is very safe, but there are small risks. The most common risks of endoscopy include bleeding, infection, and tearing of the esophagus or stomach. These problems only occurred 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 a 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 a side effect during the ORBERA™ 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 ORBERA™**

ORBERA™ causes stomach upset as your body gets used to the balloon. 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 as your body gets used to ORBERA™.

In a U.S. clinical study of 160 people (125 patients with ORBERA™ 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 ORBERA™. Most of the side effects started on the day the ORBERA™ 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 balloons removed early (before 6 months).



- 8 of the 30 people had their balloons removed early because of serious balloon intolerance which resulted in a 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 had their balloon removed early because of other serious side effects such as: lack of proper hydration, balloon blocking outlet of stomach, a hole forming all the way through the stomach, lung infection, and infection due to bacteria growth on 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.

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. study are described in Table 1. Table 2 includes serious side effects that can be caused by ORBERA™ that were not seen in the U.S. study, but are known to happen to people with weight loss balloons. The list of side effects in Table 2 is not complete as there are possible side effects that are not yet known.

**Table 1: Serious Side Effects with ORBERA™ that were seen in the U.S. study, which required hospital stay or were important medical events**

Side Effect	Number of people who had the side effect in the U.S. study (out of 160) <sup>1</sup>	Harm, or possible harm	Onset
Balloon 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	Patient 1: Day of balloon placement Patient 2: Day 1 Patient 3: Day 2 Patient 4: Day 6 Patient 5: Day 11

		removal	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 ORBERA™ 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 balloon removal	Patient 1: Day 1 Patient 2: Day 3
Balloon 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 ORBERA™ 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 stomach	1 out of 160	Nausea, cramping, throwing up, infection, admitted to hospital, and surgery to remove balloon  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 ORBERA™ removal  1/1 patients had early removal	Day 74

Stomach cramping and infection caused by bacteria growing on the balloon	1 out of 160	Cramping, pain, fever, and ORBERA™ removal  1/1 patients had early removal	Day 154
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1. 125 people in the study group plus 35 more people who got 1 balloon inserted and removed and then another balloon inserted on the same day so that doctors could get experience with the procedures.

**Table 2: Serious Side effects which were not seen in the study but are known to occur with weight loss balloons**

Deflated balloon prior to 6 months	A deflated balloon can pass through the intestines naturally or it can become stuck and have to be removed with surgery. If not treated it can be cause death	Was not reported in the U.S. study
Did not understand or remember instructions and warning statements about taking acid reducing medications	Ulcers (sores in the stomach), stomach pain and or burning; heartburn. If not treated may lead to a hole in the stomach, which can cause death	Was not reported in the U.S. study
Did not understand or remember instructions and warning statements about use longer than 6 months	Leaving the balloon in for longer than 6 months can lead to a deflated balloon. A deflated balloon can pass through the intestines naturally or it can become stuck and have to be removed with surgery. If not treated it can lead to death	Was not reported in the U.S. study
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 the U.S. study
Heart problems, or heart attack during anesthesia	Chest pain, fast or slow heartbeat, hard time breathing. If not treated it can lead to death	Was not reported in the U.S. study

Allergic reaction to medications, including anesthesia	Rash, hives, wheezing, hard time breathing, a 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 the U.S. study
Death	N/A	Was not reported in the U.S. study

The three most common side effects seen in the U.S. study which did not lead to hospital stay are nausea, throwing up, and pain. These side effects are shown in Table 3.

Side effects seen in more than 1% of patients (at least 2 out of 160) in the U.S. study, which did not lead to hospitalization, are described in Table 4 and listed in order by most frequent to less frequent. 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 that made it hard for them to do their usual work or activities.

**Table 3: Most common gastric (stomach) side effects seen in in the U.S. study**

<b>Side Effect</b>	<b>Total number of people with side effect (percent of people with side effect)</b>	<b>Number of people with side effect beginning within 3 days of balloon being placed (percent of people with side effect)</b>	<b>Number of people with side effect starting within 3 days of balloon being placed and lasting longer than 14 days and less than 30 days (percent of people with side effect)</b>	<b>Number of people with side effect starting within 3 days of balloon being placed and lasting longer than 30 days (percent of people with side effect)</b>
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	103 out of 121	3 out of 103	4 out of 103

	( 75.6%)	(85.1%)	(2.9%)	(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 4: Side effects caused by ORBERA™, which were seen in more than 1% of patients in the U.S. study, but did not lead to hospital stay**

Side Effect	Number of people 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 breath 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 more than 3 times a day can cause a lack of body water and salts
Gas	18 out of 160 (11%)	Gas can cause swelling of the belly and sharp pain
Slowed digestion of food	14 out of 160 (8.8%)	Nausea, throwing up, swelling of the stomach, poor appetite, and acid reflux
Tiredness, weakness, dizziness, or uneasy feeling	12 out of 160 (8%)	Being tired, weak or dizzy can make it hard to do your usual work, and if not treated can cause falls or injury
Headache or migraine	10 out of 160 (6%)	Pain in the head which may make it hard to do your usual work or activities
Device intolerance	9 out of 160 (6%)	Severe side effects such as nausea, throwing up, pain, and acid reflux (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 breath
Bad breath	6 out of 160	A bad taste in the mouth and on the breath

	(4%)	
Hard to swallow	5 out of 160 (3%)	Having a hard time swallowing 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%)	Pain in the chest that happens 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%)	Stomach is hard and painful to touch
Lack of Vitamin B1	5 out of 160 (3%)	Weak and tired
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 stomach pain or burning, nausea, throwing up, feeling of fullness in upper stomach after eating
Food unable to move from stomach to bowel	3 out of 160 (1.9%)	Nausea, throwing up, stomach pain, and acid reflux, which may require early removal of ORBERA™
Dry heaves	3 out of 160 (1.9%)	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 make 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 lack of proper 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
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, dizziness

## 5.4 Benefits of ORBERA™

The benefits of ORBERA™ were tested in a clinical study in the United States. The study looked at people with BMI between 30 and 40. People in the study received ORBERA™ along with diet and exercise. They 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 pounds as compared to patients in the Control group who lost an average of 7.0 pounds. Three (3) months after ORBERA™ was removed (at 9 months), patients in the ORBERA™ group weighed an average of 19.4 pounds less than when they got the ORBERA™ balloon. Six (6) months after ORBERA™ was removed (at 12 months), patients in the ORBERA™ group weighed an average of 16.2 pounds less than when they got the ORBERA™ balloon. Weight loss for the control group at 6 months and 9 months was 7.1 and 6.3 lbs, 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.

## **6 What to Expect – Procedures for ORBERA™**

### **6.1 Placement of ORBERA™**

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 you have food in your stomach, you will have to wait until you can go 12 hours without food or drink. Ask your doctor about how to take medications during that time period.

On the day of placement:

1. Before the doctor places the balloon 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 balloon. They should only last 1 to 2 weeks.
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 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.

**DO NOT** drive, use machinery or power tools, or make important decisions for 24 hours. You will have had sedation and your judgement 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. If you don't you could get a clot or swelling in the vein of your arm which may cause pain.

**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.

ORBERA™ will stay in your stomach for 6 months (180 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 ORBERA™

### 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 doctors' orders for taking medicines.
- **DO NOT** drive, use machinery or power tools, or make important decisions for 24 hours. You will have had sedation and your judgement 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 constipated. 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 balloon is placed. 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. 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 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 or doctor about what foods to eat and when to introduce new or solid foods.

Chew slowly and thoroughly. Each meal should take about 15 to 20 minutes, but no longer than 40 minutes to eat.

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 discomfort at the breastbone (front center of the chest). 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/wellbeing during this time, or if you notice:**

- Nausea or throwing up that is worse than it was right after the balloon was put in
- Coughing, spitting, or throwing up blood
- Bloody or black stools, diarrhea, or constipation
- Stomach pain becoming worse or swelling of the belly (Note: It is normal to feel some swelling after the balloon is put in)

- Burping or heartburn which is new or worse than it was right after the balloon was put in
- No longer feeling full, like you did when the balloon was first put in
- You are gaining weight instead of losing weight, or you are eating more than usual

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

While ORBERA™ is in your stomach, your nutritionist and physiologist 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 the plan that works best for you.

## **6.3 ORBERA™ Removal**

### ***6.3.1 Balloon Removal***

**YOU MUST** have your ORBERA™ removed no later than 6 months (180 days) after it is placed. The balloon can deflate if it is left in place longer than 6 months (a deflated balloon can cause death from bowel obstruction or other health problems).

To remove your balloon, your doctor will do an endoscopic procedure or surgery.

**WARNING:** Do not eat solid foods for 24 hours or drink liquids for 12 hours before your ORBERA™ is removed. Food or liquid in your stomach can enter your lungs and cause harm. If you have food in your stomach, you will have to wait until you can go 24 hours without food. Ask your doctor about how to take medications during that time period.

Before balloon 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 balloon. 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.

### **6.3.2 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 judgement will be affected without you knowing it. You may have accidents and make mistakes.

Rest for 72 hours (3 days) after the balloon is removed. Walking and other light activities are allowed. 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
- Nausea or throwing up which is not stopping
- 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
- No urination (pee) for 12 hours after going home from the clinic

### **6.3.3 Life after ORBERA™**

For 6 months after ORBERA™ 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 the ORBERA™ balloon helps you get started with your weight loss, the habits you form during the 12-month program are the tools to keeping a healthy weight.

With ORBERA™ you get a weight loss tool, and a chance to learn a new way to feel about food. Losing weight and keeping it off is not easy and can take a team effort. Your doctor, physiologist, and 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.

## **7 Date of Printing**

TBD

## **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 <http://apolloendo.com/>