

OBALON [®]

***Obalon*[®] Balloon**

System Level Information Manual

Please review this information before your procedure.
Please talk to your doctor if you have any questions or do not understand any of
this information.

**Caution: Federal law restricts this device to sale by
or on order by a Physician.**

Rx Only

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Glossary

- **Adverse Event:** Any painful, uncomfortable, or troublesome medical episode in a patient.
- **Anesthesia:** Medications that take away pain from part of your body or make 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.
- **Body Mass Index (BMI):** Is a measure of body fat based upon a person's height and weight, which is used to tell whether a person is overweight or obese.
 - 18-25 – healthy
 - 25-30 – overweight
 - 30 or above – obese
- **Bowel Obstruction:** A potentially serious condition where the intestines are blocked. If blockage occurs, food and drink cannot pass through the body.
- **Diet and Exercise Program:** A program given to you by your doctor to exercise (brisk walk) regularly and follow a healthy, low calorie diet
- **Endoscopy:** A procedure that allows a doctor to see the inside of your esophagus and stomach. This examination is performed using an endoscope (a tube that can bend and has a video camera on the end). The camera is connected to a video screen.
- **Esophagus:** The tube that allows passage of food, liquids, and saliva from your mouth to your stomach.
- **Gastric:** Referring to the stomach.
- **Gastric Banding:** A surgical weight loss procedure in which a band made from rubber-like material is placed around the outside of the stomach to limit the amount of food that can be eaten at one time.
- **Gastric Bypass:** A surgical weight loss procedure in which the stomach is divided to make a small pouch (about 1 oz.) to limit the amount of food that can be eaten at one time. This small stomach pouch is connected to a part of the intestines that is lower than the place where the stomach normally connects to the intestinal tract. This increases the feeling of fullness and also allows food to bypass the upper part of the intestines, which changes the way food is absorbed.
- **Gastro-intestinal (GI) Tract:** This includes the path from your mouth to your anus that includes the esophagus, which allows food and liquids to pass, the stomach and the intestines.
- **Gastroesophageal Reflux:** When stomach acid or stomach content flows back into the food pipe (esophagus). Reflux can irritate the esophagus, causing heartburn and other symptoms.
- **Procedure:** A set of steps taken to accomplish a result, such as weight loss.
- **Proton Pump Inhibitor (PPI):** A group of drugs that helps to reduce stomach acid production.
- **Nutritionist:** A trained person who helps others plan what foods to eat that are good for their health.
- **Obalon Balloon:** A balloon-like device used to help with weight loss. It works by taking up space in the stomach.
- **Sleeve Gastrectomy:** A surgical weight loss procedure in which the stomach is reduced to about one

quarter of its original size by taking out a large part of the stomach. The result is a sleeve or tube-like shape. The procedure permanently reduces the size of the stomach.

- **Sedation:** Medication used to make you feel sleepy and relaxed 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.
- **Target:** A thing you aim for, such as a certain amount of weight you are trying to lose.
- **Ulcer:** A sore that can be found in the stomach lining or small intestines. They can occur when there is irritation from acid or mechanical devices.

What is the *Obalon*[®] Balloon

The *Obalon* Balloon is not a cure for obesity. It helps with weight loss. Placing the *Obalon* balloons in your stomach takes up space. During the procedure, you will have the chance to develop new lifestyle skills as recommended by your physician. Working hard on these new habits will help you lose weight and keep it off.

Swallowable Capsule



Gas-Filled Balloon



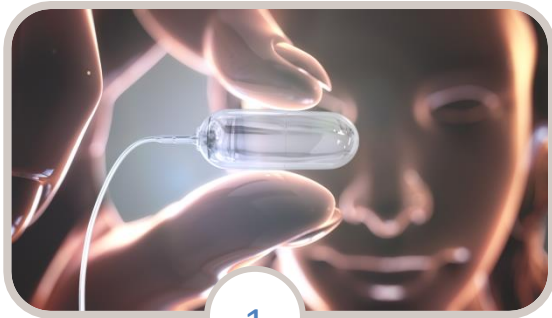
The *Obalon* Balloon is delivered to your stomach by having you swallow a large capsule that is connected to a small bendable tube. This capsule is made with a vegetable based material. The balloon is made of plastic that is folded neatly into a capsule that is slightly larger than a vitamin pill that you might take. When the capsule reaches your stomach, your doctor will either take an x-ray or use the *Obalon* Navigation Console to make sure it is in the right place in your stomach. The doctor will inflate the balloon with gas by connecting the bendable tube to an inflation system. The gas is a nitrogen sulfur-hexafluoride mixture. These gases are used in other medical devices such as surgical devices for eyes. You will get up to three balloons, but not at the same time. Each balloon inflated to 250cc in volume, which is about the size of a small orange. Once the balloon is filled, the doctor will disconnect the bendable tube from the balloon and then will gently pull the tube out of your mouth. The balloon will be free floating and will move inside your stomach.

The first balloon will be in your stomach for 6 months. Your doctor will usually have you swallow a second balloon capsule 1 month after the first balloon and a third balloon capsule within 2 months after the second balloon. These balloons will take up more space in your stomach to help you lose weight. All balloons must be removed 6 months after the first balloon capsule is swallowed.

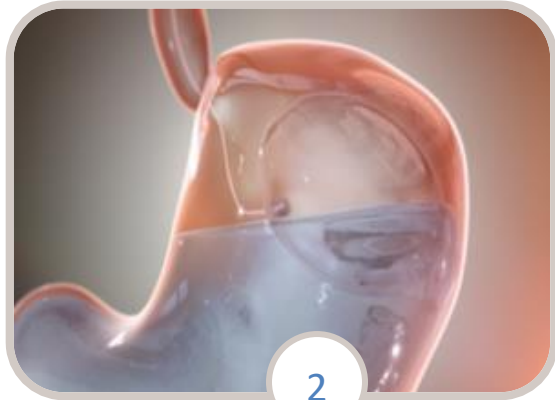
To help understand the size of the Balloon capsule, a picture of a Vitamin E Gel Capsule next to the *Obalon* Balloon Capsule is provided here (scale is in inches).



Swallowing the Obalon® Balloon



You will swallow a capsule



Once in the stomach, the Balloon is inflated with gas.



Over the course of 6 months, you will receive 2 additional Balloons for a total of 3.

Why doctors use *Obalon*

For many people, diet and exercise alone may not be enough to make your weight loss goal. Losing weight and keeping it off is not easy. From the beginning, you will follow a healthy diet and exercise program. You may not lose weight if you do not follow the program. Continuing this program after the balloons are removed is encouraged for the best chance to keep off the weight that you may lose with the Obalon Balloon System. Bariatric surgery can be used for those who qualify, but many people are afraid of the surgical risks. Others want to avoid permanent changes to their body. Obalon may be a nonsurgical choice for you if you are older than 22 years old, with a body mass index (BMI) from 30 to 40 kg/m² and have not been able to lose weight with a diet and exercise program alone.

Who Can Get the *Obalon Balloon*

You are a candidate for the Obalon Balloon if you have a body mass index (BMI) from 30 to 40 kg/m² and are 22 years or older. You must be willing to follow a 12-month program. The program begins with the placement of the Obalon Balloons in your stomach for up to six months. The program includes a healthy diet and exercise program during the time that you have the balloons and for six months after the balloons are removed.

Who Cannot Get the *Obalon Balloon* (Contraindications)

You are NOT a candidate for Obalon if:

- You have any problems with swallowing, any or prior surgeries that would make it difficult to swallow the Obalon balloon capsule.
- You take prescription aspirin, anti-inflammatory agents (such as Advil or Motrin), anticoagulants (blood thinner) or other gastric irritants daily. Taking these drugs on a daily basis increases the possibility of gastric irritations, ulcers, or small perforations (holes) in your stomach when you have the balloons in your stomach. Perforations in your stomach can lead to serious injury and even death.
- You have had prior surgeries or condition that may have led to a narrowing or blockage of your gastrointestinal (GI) tract. If 1 or more of the balloons deflates and passes into your intestines, it will cause a blockage also known as an obstruction and must be surgically removed. This bowel obstruction can lead to serious injury and even death.
- You have ever had weight loss surgery such as a gastric sleeve or lap-band. This does not include the other stomach balloons. Failure to follow this warning may result in damage to your stomach or intestines that may require surgery to repair.
- You have an untreated *Helicobacter pylori* infection. Having this infection increases the possibility of gastric irritations and ulcers.
- You are unable or unwilling to take prescribed proton pump inhibitor medication (examples: Prilosec, Nexium) for the duration of the device implant. Not taking these medications increases the possibility of gastric irritations, ulcers, or small perforations (holes) in your stomach. Perforations in your stomach can lead to serious injury and even death.
- You have been diagnosed including but not limited to bulimia, binge eating disorder, compulsive overeating disorder, or your daily diet includes very high calorie liquids. The balloons may not help you lose weight if you have these eating disorders or these habits.
- You have a history of structural or functional disorders of the stomach including, gastroparesis (stomach emptying disorder), gastric ulcer, chronic gastritis (stomach irritation), gastric varices (veins in your stomach that bleed), large hiatal hernia (> 2 cm), cancer or any other disorder of the stomach. If you have one of these disorders you may not be able to swallow the Obalon Balloon capsule, or the balloon may not inflate properly or you will have increased risk of gastric irritations, ulcers, or small perforations (holes) in your stomach. Perforations in your stomach can lead to serious injury and even death.
- You require the use of anti-platelet drugs or other agents affecting the normal clotting of blood. Use of these drugs may cause you to bleed more during the removal process of the balloons.
- You have a history of irritable bowel syndrome, Crohn's disease, or other diseases of your bowel system. If 1 or more of the balloons deflates and passes into your intestines, it will cause a blockage also known as an obstruction and must be surgically removed. This bowel obstruction can lead to serious injury and even death.
- You are taking medications on specified hourly intervals that may be affected by changes in gastric emptying, such as anti-seizure or anti-arrhythmic medications. Placement of the balloons in your stomach may further affect gastric emptying and motility.
- You have untreated or unstable alcohol or illicit drug addiction.

- You are pregnant or nursing.
- If your doctor is using the Navigation system during your balloon administrations you cannot have a pacemaker, defibrillator, or a large metal implant device in your chest region.

Speak to your doctor for information on other conditions that may prevent you from having the *Obalon* System. Additional reasons why you should not get the Obalon Balloon (contraindications) may not be known until the time of your medical history and physical with your doctor.

Things you must do to avoid serious harm (Warnings and Precautions)

- **WARNING: RETURN** at 6 months to have the Obalon Balloons taken out. If you wait until after 6 months, 1 or more of the balloons may deflate and move from your stomach into your intestines and may cause a blockage also known as an obstruction and must be surgically taken out. This bowel obstruction can lead to serious injury and even death.
- **WARNING: CALL** your doctor immediately if you start experiencing a new stomach pain that is different from the stomach pains that you felt when the balloon was put in, or if the pain does not go away. If you do not, one or more of the balloons may have deflated and moved from your stomach into your intestines and cause a blockage also known as an obstruction and must be surgically taken out. This bowel obstruction can lead to serious injury and even death.
- **WARNING: CALL** your doctor immediately if you have a sudden loss of feeling of stomach fullness. If you do not, one or more of the balloons may have deflated and moved from your stomach into your intestines and cause a blockage that must be surgically taken out.
- **WARNING: CALL** your doctor immediately if you experience a new onset of nausea, vomiting or stomach pain for more than 24 hours. These symptoms may be due to a stomach ulcer that if left untreated can lead to a small perforation (hole) in your stomach. This perforation in your stomach can lead to serious injury or even death if untreated.
- **WARNING:** Gastric perforation adverse events have been reported in patients with Obalon intragastric balloons. Some associated symptoms and findings noted in subjects who have gone on to have perforations are: New onset abdominal pain and/or back pain that persists beyond 24 hours, and persistent nausea and vomiting. PPI use may reduce the risk for ulcerations and subsequent perforations if untreated.
- **WARNING: TAKE** daily acid-blocking medicine prescribed by your doctor (examples: Prilosec, Nexium) while the Balloon(s) are in your stomach. If you do not take this medicine daily, there is a higher risk of developing a stomach ulcer or small perforation (hole) in your stomach. This perforation in your stomach can lead to serious injury and even death if untreated.
- **WARNING: DO NOT** take any stomach irritating medicines like non-steroidal anti-inflammatory drugs (NSAIDs) or Aspirin while the balloons are in your stomach. Some examples of NSAIDs are Motrin or Advil. Please read the warnings on any medicines that you might take to see if they can hurt your stomach. You might get ulcers or bleeding if you take these kinds of medications while the balloons are in your stomach.
- **WARNING: DO NOT** have the balloons placed if you plan to live in a place that is at an altitude of more than 4000 feet higher or 2500 feet lower than where your doctor places your balloons. Based on laboratory testing, changing where you live might cause the balloon to deflate. If the balloons deflate you may need to have an endoscopy to have them removed early from your stomach. If one or more of the deflated balloons moves from your stomach into your intestines and cause a blockage also

known as an obstruction, they must be surgically taken out. This bowel obstruction can lead to serious injury and even death.

- **WARNING: DO NOT** have the balloons placed if you plan on embarking on air travel in non-commercial aircraft. Based on laboratory testing, this type of travel might cause the balloon to deflate. If the balloons deflate you may need to have an endoscopy to have them removed early from your stomach. If one or more of the deflated balloons moves from your stomach into your intestines and cause a blockage also known as an obstruction, they must be surgically taken out. This bowel obstruction can lead to serious injury and even death. There are no restrictions for commercial airplane travel.
- **WARNING: DO NOT** SCUBA dive while you have balloons in your stomach. SCUBA diving might cause the balloons to deflate. If the balloons deflate you may need to have an endoscopy to have them removed early from your stomach. If one or more of the deflated balloons moves from your stomach into your intestines and cause a blockage also known as an obstruction, they must be surgically taken out. This bowel obstruction can lead to serious injury and even death.
- **WARNING: DO NOT** bite the tubing that inflates the balloon. This might cause the balloon not to inflate. If the balloon does not inflate completely, you will require an endoscopy to have them taken out of your stomach early.
- **CAUTION: DO NOT** have the balloons placed if you have Type 1 Diabetes or Type 2 Diabetes using insulin or other oral agents. The effects of this condition with use of the Obalon balloon are not known.
- **CAUTION: DO NOT** have the balloons placed if you have severe coronary artery (blood vessels that supply the heart with blood) disease. The effects of this condition with use of the Obalon balloon are not known.
- **CAUTION: DO NOT** have the balloons placed if you have uncontrolled hypothyroidism, Cushing's disease or syndrome, end stage renal disease or requiring hemodialysis within the past 6 months, or uncontrolled hypertension. The effects of these conditions with use of the Obalon balloon are not known.
- **CAUTION: DO NOT** have the balloons placed if you have severe, unstable/uncontrolled medical conditions of major organ systems. The effects of these conditions with use of the Obalon balloon are not known.

How clinical studies were performed

A clinical study, called the SMART Pivotal Trial, was performed at 15 hospitals in the United States. This study included 387 Patients who had a BMI of 30-40 kg/m². Patients either had the Obalon Balloon System placed for 6 months and received diet and exercise coaching for 12 months or just received diet and exercise coaching for 6 months. The patients who received the Obalon Balloon System and the diet and exercise coaching were chosen by chance (like flipping a coin). By chance, 198 patients received the Obalon Balloon System plus diet and exercise coaching and 189 patients received only diet and exercise coaching. Patients who just received diet and exercise coaching for 6 months were given the choice to have the Obalon Balloon System put in after they completed the first 6 months of diet and exercise coaching. 138 of these patients chose to have the Obalon Balloon System and had another 6 months of diet and exercise coaching. Therefore, a total of 336 study patients had the Obalon Balloon System. All of the balloons lasted for 6 months except for 1 balloon that was found deflated at the time of removal.

The clinical study patients were all at least 22 years old with a BMI between 30-40 kg/m². Patients were

asked if they ever had weight loss surgery or if they could promise to stay on a diet and exercise program. They were not allowed to be in the clinical study if they ever had weight loss surgery or said that they would not or could not follow the *Obalon* diet and exercise program, or if they were pregnant or breastfeeding. The balloons were put in and taken out in the clinical study in the same way and on the same times that your balloons will be put in and taken out. All clinical study patients had three-week follow up visits for 12 months where the doctor’s staff collected information on weight loss and side effects. The patients also got the diet and exercise program to help them to eat smaller amounts of food, reduce total calories and exercise regularly.

Risks of the *Obalon* System

The information in this section is based on a study of the *Obalon* balloons in 336 patients.

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.

In a clinical study of 336 patients, there was one serious adverse device event (SADE). This was not reported with the procedure but rather with the device:

Serious Side Effect (Serious Adverse Event)	Number of Patients who had the side effect (out of 336)	Harm	Number of Patients who had their balloon removed because of the serious side effect
Bleeding Gastric Ulcers	1 out of 336 Patients (0.3%)	Abdominal pain, significant blood loss. (Can increase risk by using NSAIDs and Aspirin)	1 out of 1

Possible serious side effects (adverse events) of the *Obalon* System (including those related to endoscopy or sedation) which were not reported in the clinical study of 336 patients, but did occur in other studies or commercial use are listed in the table below

Possible Serious Side Effect	Harm (Possible Serious Adverse Event)
Patient had a balloon that deflates and moves into the intestines	Any of the balloons could deflate and move from your stomach into your intestines, causing a blockage (also called intestinal obstruction), requiring surgery to remove the balloons and relieve the blockage.
Patient had decreased feeling of fullness or some abdominal pain and did not inform their doctor	Any of the balloons could deflate and move from your stomach into your intestine (also called balloon migration causing blockage, or intestinal obstruction), requiring surgery to remove the balloons and relieve the blockage.
Tear in the wall of the esophagus	The balloon is inflated in the esophagus instead of the stomach during the placement of the balloon causing a tear or hole in the esophagus and possibly death.

Possible Serious Side Effect	Harm (Possible Serious Adverse Event)
Tear in the wall of the stomach	Any of the balloons could cause an ulcer that leads to a tear or perforation (hole) requiring surgery to repair the stomach and possibly death.

Other, possible serious side effects (adverse events) of the *Obalon* System (including those related to endoscopy or sedation) which were not reported in the clinical study of 336 patients and did not occur in other studies or commercial use of the 6-month balloon system. Events that have occurred in the use of other intragastric balloons are listed in the table below. It is unknown what adverse events may develop and how many patients may develop them. In this study, we did not observe some adverse events we thought were possible. The harm possible from them and their frequencies are unknown based on this clinical trial. It is unknown whether they will happen and how often they will happen with more widespread use of the Obalon balloon:

Possible Serious Side Effect	Harm (Possible Serious Adverse Event)
Acute pancreatitis ¹	The balloons could place pressure on the pancreas causing inflammation requiring removal in order to relieve the pressure.
Life threatening allergic reaction (anaphylaxis)	You will need medications and/or need to have a tube placed in your airway to help you breathe during the procedure to take out the balloon.
Heart attack (myocardial infarction)	Your heart muscle becomes temporarily or permanently damaged.
Blood circulation stops (cardiac arrest)	You need to have your heart restarted with medications or an electrical shock through your chest.
Airway obstruction (respiratory distress)	Total blockage of the airway by the balloon when it is being taken out.

¹A single pancreatitis event was reported in the literature in a prior generation 3-month Obalon Balloon System but could not be confirmed during investigation.

Other procedure and balloon-related side effects (adverse events) of the *Obalon* System reported during the clinical study:

Side Effect (Adverse Event)	Number of Patients who had the side effect (out of 336)	Harm
Abdominal Pain	244 out of 366 Patients (72.6%)	Unpleasant or painful feeling in the stomach that can prevent you from doing your normal activities
Nausea	188 out of 336 Patients (56.0%)	Uneasy feeling in the stomach or feeling like you need to throw up
Vomiting	58 out of 336 Patients (17.3%)	Possible dehydration/Chemical imbalance

Side Effect (Adverse Event)	Number of Patients who had the side effect (out of 336)	Harm
Indigestion/ Heartburn	57 out of 336 Patients (17.0%)	Stomach feels full of gas, burping, pain or discomfort in the throat
Bloating	49 out of 336 Patients (14.6%)	Stomach feels full of gas and swollen
Burping / Belching	31 out of 336 Patients (9.2%)	None
Diarrhea	28 out of 336 Patients (8.3%)	Possible dehydration/Chemical imbalance
Scratch or scrape of the stomach by the balloon	24 out of 336 Patients (7.1%)	Discomfort in stomach; Hard to eat or drink
Scratch or scrape of stomach during removal	17 out of 336 Patients (5.1%)	Bleeding or discomfort in stomach; Hard to eat or drink
Scratch or scrape of Esophagus during removal	14 out of 336 Patients (4.2%)	Discomfort in the throat; Hard to eat or drink
Constipation	9 out of 336 Patients (2.7%)	Having hard and/or infrequent bowel movements
Difficulty Sleeping	9 out of 336 Patients (2.7%)	Difficulty sleeping during nighttime causing fatigue
Excessive gas	8 out of 336 Patients (2.4%)	Bloating/Need to pass gas
Abnormal Function of the Esophagus	6 out of 336 Patients (1.8%)	Difficulty swallowing; discomfort while eating
Headache/Migraines	6 out of 336 Patients (1.8%)	Head hurts such that it is hard to do your normal daily activities. In the case of a migraine you could have nausea and dizziness.
Drop in oxygen levels during the removal	4 out of 336 Patients (1.2%)	Unable to catch breath / Difficulty in breathing or catching breath
Stomach ulcer or sore (no bleeding)	3 out of 336 Patients (0.9%)	Pain that is caused by a sore inside your stomach
Increased amount of saliva in the mouth	3 out of 336 Patients (0.9%)	Having excess saliva in the mouth / drooling
Chest pain	3 out of 336 Patients (0.9%)	Pain in the chest
Device Intolerance	2 out of 336 Patients (0.6%)	Doesn't like the feeling of the balloon in the stomach

Side Effect (Adverse Event)	Number of Patients who had the side effect (out of 336)	Harm
Vocal cord spasm during the removal	2 out of 336 Patients (0.6%)	Hard to breath or speak; might need to have a tube put in to help you breath
Shortness of breath	2 out of 336 Patients (0.6%)	Can't catch breath / difficulty breathing
Bleeding Stomach ulcer or sore	1 out of 336 Patients (0.3%)	Pain/Drop in blood count/Weakness
Hiccups	1 out of 336 Patients (0.3%)	Discomfort for a short time. Difficulty breathing
Asthma	1 out of 336 Patients (0.3%)	Wheezing, tightening of the chest and shortness of breath
Fatigue	1 out of 336 Patients (0.3%)	Feeling tired, shortness of breath
Syncope	1 out of 336 Patients (0.3%)	Weakness/Difficulty performing tasks
Allergic Reaction	1 out of 336 Patients (0.3%)	Rash, itchy eyes, runny nose, trouble breathing
Dizziness	1 out of 336 Patients (0.3%)	Feeling dizzy or faint
Dry heaving	1 out of 336 Patients (0.3%)	Scratchy, painful throat/Possible minor bleeding
Food passage difficulty	1 out of 336 Patients (0.3%)	Difficulty in swallowing causing discomfort and hunger
Fullness	1 out of 336 Patients (0.3%)	Unable to tolerate meals
Upper body wound / pain	1 out of 336 Patients (0.3%)	Discomfort in the upper body such as arms, stomach, shoulders
High blood pressure (also called hypertension) at the removal procedure	1 out of 336 Patients (0.3%)	Headache/Blurred vision/Difficulty concentrating/Stomach pain
Coughing at removal procedure	1 out of 336 Patients (0.3%)	Hard to eat or drink
Sore Throat at removal procedure	1 out of 336 Patients (0.3%)	Hard to eat or drink
Swollen Lips at removal procedure	1 out of 336 Patients (0.3%)	Difficulty eating/Mild discomfort

In the clinical study of 336 patients, the most common side effects (adverse events) of the *Obalon* System were vomiting, nausea, and abdominal pain:

Side Effect (Adverse Event)	Number of patients who had side effect happen at any time during the study	Number of patients who had side effect lasting for up to 7 days	Number of patients who had side effect lasting between 8 to 14 days	Number of patients who had side effect lasting for longer than 14 days
Abdominal Pain	244 out of 336 (72.6%)	203 out of 336 (60.4%)	31 out of 336 (9.2%)	106 out of 336 (31.5%)
Nausea	188 out of 336 (56.0%)	158 out of 336 (47.0%)	21 out of 336 (6.3%)	55 out of 336 (16.4%)
Vomiting	58 out of 336 (17.3%)	48 out of 336 (14.3%)	5 out of 336 (1.5%)	7 out of 336 (2.1%)
Indigestion/Heartburn	57 out of 336 (17.0%)	22 out of 336 (6.5%)	4 out of 336 (1.2%)	39 out of 336 (11.6%)
Bloating	49 out of 336 (14.6%)	20 out of 336 (6.0%)	3 out of 336 (0.9%)	28 out of 336 (8.3%)

If you have nausea and vomiting, it can be treated with anti-nausea medications. If your symptoms are more severe, fluids may be given to you through a needle in your vein. If you have abdominal pain, your doctor will prescribe pain medications as needed to control the pain. If you cannot tolerate your symptoms, you can always choose to have the balloon taken out before 6 months. In the clinical study, 5 out of every 100 Patients asked to have their balloon taken out before the 6 months had passed.

Weight Loss Benefits of having *Obalon*

The *Obalon* Balloon was shown to help patients lose weight. Patients who received *Obalon* balloons along with a diet and exercise program lost more weight than patients who just got the diet and exercise program alone. On average, the *Obalon* Balloon patients lost about twice as much weight as the patients who only got the diet and exercise program. Study patients who received the *Obalon* Balloon along with diet and exercise program lost an average of 14.4 lbs. when the balloon was taken out at 6 months while study patients who did not receive the *Obalon* balloon lost an average of 7.4 lbs. with only the diet and exercise program alone (7.0 lbs. less than the *Obalon* balloon patients).

On average, patients in the SMART Clinical study of the *Obalon* Balloon who received balloons and who lost weight during the first 6 months only regained 2 lbs in the 6 months after the balloon was removed. The following table provides a summary of how much weight you might expect to lose with *Obalon*:

Number of Balloons	# Of Patients with number of Balloons	Average Pounds Lost
Patients with 1 Balloon	5	-2.4
Patients with 2 Balloons	10	-3.5
Patients with 3 Balloons	183	-15.4
ALL PATIENTS	198	-14.4

Good things about the *Obalon System*

- You can swallow a capsule and have the doctor inflate a balloon in the doctor’s office on average in 10 minutes
- Does not require sedation for swallowing of or inflation of balloon
- Does not require endoscopy or surgery for placement of device
- Balloons can be taken out if not tolerated
- You can continue to eat the foods you like, just smaller amounts
- Support to help change your eating habits and keep weight loss long-term

How to decide if *Obalon* is right for you

Obalon might be right for you if you are older than 22 years old with a body mass index (BMI) from 30 to 40 kg/m² and you have not been able to lose enough weight with a diet and exercise program alone.

During treatment with the *Obalon* Balloons and after it is taken out, you must continue to follow your doctor-recommended diet and exercise program to have the most weight loss. Without changes to your eating habits and lifestyle, weight regain is likely. Make sure you are ready to reduce your total number of calories, eat smaller amounts of food, and exercise regularly before choosing the *Obalon System*.

Be sure to ask questions about other weight loss treatments. The *Obalon System* is not the only treatment choice. Other choices include diet and exercise programs or prescription medications, and — for patients who qualify - surgery (gastric band, gastric bypass, sleeve gastrectomy). You should talk with your doctor to pick the one that best fits your needs.

The table below can help you tell if your BMI is within the approved BMI range for the *Obalon System*. To use the table, find your height in the left-hand column. Then move across the top and find your weight (with clothes on but without shoes). The number in the box where your height and weight come together is your BMI. If your BMI is blue, your BMI is within the BMI range approved for the *Obalon System*. Your doctor can also help you to find out your BMI.

		Weight (lbs.)																	
		160	170	180	190	200	210	220	230	240	250	260	270	280	290	300	310	320	330
Height (in.)	5'0"	31	33	35	37	39	41	43	45	47	49	51	53	55	57	59	61	63	65
	5'1"	30	32	34	36	37	39	42	44	45	47	49	51	53	55	57	59	61	63
	5'2"	29	31	33	34	36	38	40	42	44	46	48	50	51	53	55	57	59	61
	5'3"	28	30	32	33	35	37	39	41	43	44	46	48	50	52	53	55	57	59
	5'4"	27	29	31	32	34	36	38	40	41	43	45	46	48	50	52	53	55	57
	5'5"	26	28	30	31	33	35	37	38	40	42	43	45	47	48	50	52	53	55
	5'6"	25	27	29	30	32	34	36	37	39	40	42	44	45	47	49	50	52	53
	5'7"	25	26	28	29	31	33	35	36	38	39	41	42	44	46	47	49	50	52
	5'8"	24	25	27	28	30	32	34	35	37	38	40	41	43	44	46	47	49	50
	5'9"	23	25	26	28	29	31	33	34	36	37	39	40	41	43	44	46	47	49
	5'10"	23	24	25	27	28	30	32	33	35	36	37	39	40	42	43	45	46	47
	5'11"	22	23	25	26	28	29	31	32	34	35	36	38	39	41	42	43	45	46
	6'0"	21	23	24	25	27	28	30	31	33	34	35	37	38	39	41	42	44	45
	6'1"	21	22	23	25	26	27	29	30	32	33	34	36	37	38	39	41	42	44
	6'2"	20	21	23	24	25	27	28	30	31	32	33	35	36	37	39	40	41	42
	6'3"	19	21	22	23	24	26	28	29	30	31	33	34	35	36	38	39	40	41
6'4"	19	20	21	23	24	26	27	28	29	31	32	33	34	35	37	38	39	40	

What are the first steps to use *Obalon*

Your doctor will ask about your medical history and perform an exam to help determine if this System may be a good choice for you. Then your doctor will give you a practice pill that looks and feels just like an *Obalon* Balloon but it is filled with table sugar. This is to see if you are able to swallow the same capsule with the balloon inside. If you are able to swallow this sugar pill, your doctor may recommend that you have the *Obalon* Balloons placed. You will also be told about prescription medicines you must take to help reduce the stomach cramps, nausea, vomiting, and reduce the acid in your stomach while you have the balloon. It is recommended that you fill all prescriptions before the procedure. At this time, you will also meet with a dietician to receive information on nutrition and exercise while you use *Obalon*. This nutrition and exercise will be different for each person. Some nutrition examples are including more healthy options such as lean proteins and vegetables and focusing on smaller plates. An example of exercise is brisk walking for 30 minutes, 5 days per week.

How are the *Obalon* Balloons put in and taken out of your stomach

On the day each *Obalon* Balloon is put in your doctor will inflate the *Obalon* Balloon in your stomach during a short office visit that does not require any sedation or anesthesia. Talk with your doctor before the procedure to learn about any dietary rules before coming in to have the first balloon put in. You will be instructed to not eat anything, and not drink a lot of liquids for at least 8 hours before your visit. Upon your visit, your doctor will ask you to swallow the *Obalon* Balloon. Then you will either have an x-ray taken or your doctor will use the *Obalon* Navigation Console to make sure that the balloon is in the stomach (Fig. 1). The doctor will then inflate the balloon with a gas mixture (Fig. 2). You might feel a slight tickling sensation as the balloon is being inflated. Putting in an *Obalon* balloon typically takes less than 10 minutes.



Figure 1. Uninflated *Obalon* Balloon still in the capsule



Figure 2. Inflated *Obalon* Balloon

During the first couple of days that the balloon is put in, you will likely have abdominal (belly) cramping/pain and nausea, and may also have vomiting, bloating and diarrhea. Not all of these may happen, but they are all common and should be expected. Sometimes these symptoms may be severe and your doctor can provide medicine and advice to help. Make sure that you take your medications as the doctor has told you.

If you tolerate the first balloon, your doctor will make an appointment to have your next two *Obalon* Balloons put in. This will usually take place between weeks 3 and 4 and weeks 9 and 12 after your first balloon was placed. Talk with your doctor before the procedure to learn about any dietary rules before coming in to have the next balloons placed.

What happens after *Balloons* are put into your stomach

An important part of the *Obalon* System is the support and supervised coaching. Learning how to eat differently and exercise will be an important part of your *Obalon* experience. You will be asked to follow moderate diet and exercise program during the six months the *Obalon* Balloon is in place and it is recommended that you continue the diet and exercise program to keep the weight off. This diet and exercise program means that you will be asked to have healthy eating habits and meetings with a dietician every 3 to 4 weeks as well as taking brisk walks for 15 to 20 minutes for 3 to 4 times a week.

You should expect that at least once per month, you will meet with the staff at your weight loss center. During the clinical study of the *Obalon* Balloon System, patients had weight measurements and reviewed their diet and exercise program with the staff at each visit. The staff gave clinical study patients suggestions for changes or improvements as needed. This timing and these activities are the same as what the *Obalon* Balloon System clinical study patients received. At each meeting, you will receive that treatment and more, including:

- Customized suggestions based on your progress
- Educational support
- Body composition and weight measurements
- Review of your targets and online support
- Behavioral and emotional support in one-on-one or group sessions as needed

It is important that you follow the diet and exercise program to reach the best weight loss. You may also want to use other tools like calorie counting apps or a diary to help track what you are eating and how much you are exercising. If you do not reduce your total calories, eat smaller amounts of food and exercise regularly, you may not benefit from *Obalon*.

On the day the *Obalon* Balloons are taken out

Talk with your doctor before the procedure to learn about any dietary rules.

Your doctor will take the *Obalon* Balloon out of your stomach during a short outpatient procedure. First, you will be made comfortable with a medication in your vein that causes conscious sedation (light anesthesia). Then your doctor will use a tube that can bend and has a camera on the end to view the balloons. The doctor will puncture the balloons one by one to deflate them. Once your doctor deflates the balloons, they are taken out of your stomach (Fig. 3). Taking all three balloons out of your stomach typically takes less than 20 minutes.

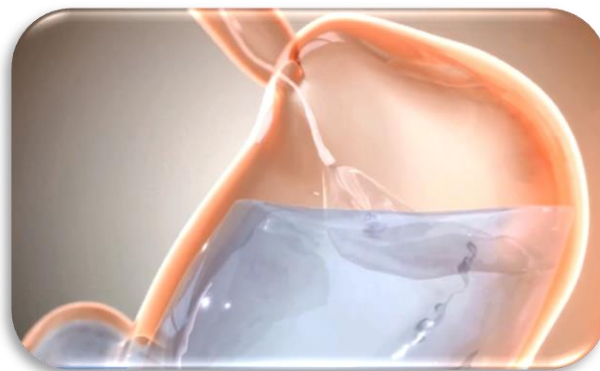


Figure 3. Deflated *Obalon* Balloon Removal

When to call your doctor

After the Obalon balloon is put in, your doctor will tell you when to call. Please review the “Things you must do to avoid serious harm (Warnings)” in this System Level Information Manual (SLIM) for other times when you must call your doctor.

Where you can find out more

Please talk with your doctor to find out more about your condition and whether *Obalon* is right for you. You may also call Obalon Customer Service: +1.844.3OBALON (+1.844.362.2566) to find out more or have more questions.

MRI Compatibility

The Obalon balloons are MR Conditional. You may undergo an MRI if needed under certain conditions. Please talk to your doctor first before getting the MRI.

Patient ID Card

You will receive an *Obalon* ID Card following your first procedure. Carry your *Obalon* ID Card with you at all times. Use this card to contact your prescribing physician in the event of an emergency department visit related to the balloons or for symptoms related to balloon treatment. This card can be used to show other doctors and care providers that you have *Obalon* balloons as well as airport security purposes if needed. If you lose this card, please call your doctor’s office to get a new card.



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