

OBALON[®]

Balloon System Instructions for Use



**Caution: Investigational Device. Limited by
Federal (or United States) law to investigational
use.**

OBALON® BALLOON SYSTEM- INSTRUCTIONS FOR USE

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INTRODUCTION

The Obalon Balloon System (the "System") is designed to assist weight loss by partially filling the stomach and inducing fullness. The System consists of up to 3 intragastric balloons that are administered via capsule form and are intended to reside in the stomach for up to 6 months.

For administration, a Balloon Kit is used, which includes a balloon and catheter assembly. Each balloon is contained within a USP grade porcine gelatin or cellulose capsule, which is attached to a catheter. The balloon capsule delivers the balloon in a similar manner that a medicinal capsule delivers pharmaceuticals. The catheter comes pre-attached to the compacted balloon's radio-opaque, resealing valve.

The administration (placement) procedure requires no sedation. The catheter/capsule is swallowed by the patient. The catheter is then attached to the EzFill Dispenser that contains an EzFill Can (a can containing nitrogen-sulfur hexafluoride gas mixture) to fill the balloon. After the patient swallows a balloon capsule, radiography must be done prior to inflation to ensure the balloon is in the stomach (visualized by the radio-opaque marker). The preferred radiographic method is fluoroscopy since it provides a real-time image of the balloon using low levels of radiation. The balloon is then inflated.

A fully inflated single balloon is an ellipsoid with a volume of approximately 250cc. When 3 balloons are placed, the total balloon volume is approximately 750cc.

After inflation is complete, the catheter is ejected from the balloon valve and retrieved, leaving the balloon free-floating in the patient's stomach for up to 6 months.

Balloon use requires the concurrent use of Proton Pump Inhibitors for the duration of use. Clinical studies have shown that use of 40 mg/day of omeprazole or an equivalent dosage of similar medications is required over the duration of use. Anti-emetic and spasmolytic agents should be prescribed in conjunction with balloon use. Physicians have used Upper GI procedures to determine a patient's suitability for the procedure.

The balloon helps the patient eat less food at each sitting. The balloon therapy must be used in conjunction with a moderate intensity diet and lifestyle modification program to achieve the appropriate effect.

The balloons are only intended to remain in the stomach for 6 months from the time of placement of the first balloon. There should be no less than 14 days between Balloon placements. All balloons placed must be removed at the end of 6 months using endoscopy per the specified tool dimensions. All placed devices must be removed by a trained healthcare professional proficient in endoscopy.

OBALON BALLOON-EZFILL INFLATION SYSTEM OVERVIEW

The Obalon Balloons must only be inflated utilizing the EzFill Inflation System. The EzFill Inflation system consists of an EzFill Can and EzFill Dispenser. The EzFill Can is intended to provide a gas source for transfer of a fixed volume of inflation gas to the Obalon Balloon and the EzFill Dispenser is intended to serve as a method for transferring the fixed volume of the inflation gas to the Obalon Balloon.

The EzFill Inflation System is prepared prior to balloon administration away from the patient. The Extension Tube from the Accessory Kit is attached on the proximal end to the EzFill Dispenser using a luer connection, while a 3-way stopcock valve on the distal end of the Extension tube remains closed. The green valve on the EzFill Dispenser is turned to the on position and the EzFill Can is inserted into the Dispenser. The lever on the Dispenser is closed to secure the Can in place and actuate a valve in the Can pressurizing the system; the Dispenser audibly releases excess pressure in the Can via its mechanical pressure relief system to ensure a starting pressure appropriate for the altitude at which the system is operated. The Dispenser contains a digital pressure gauge that provides a continuous read-out of the pressure inside the Can. Prior to initiating each step in the inflation process, the pressure gauge value is verified to ensure that it is stable for at least 30 seconds (not changing more than 0.3 kPa) at each decision point to ensure there are no leaks in the system.

After the capsule is swallowed, the EzFill Inflation System is connected to the catheter by way of the Extension tube. All entries and exits within the Dispenser and Catheter connections are sealed and it is imperative that all system connections are fully secured during the procedure to maintain a closed gas pathway between the Can and Balloon. The pressure gauge on the Dispenser should be monitored to ensure there are no leaks in the system during inflation. All decision points require that prior to moving to the next step that the measured value is stable and does not change more than 0.3 kPa in a 30 second period. Any value provided that is not stable or unexpected could indicate that there is a leak in the closed loop system.

FACILITY REQUIREMENTS

The health care setting in which the device is to be used must have access to fluoroscopy or digital x-ray at the time the device is administered in order to ascertain the balloon/capsule placement in the stomach prior to inflation. In addition, the prescribing physician must have access to an endoscopy unit and personnel proficient in endoscopy and foreign object retrieval should problems arise during administration. Endoscopy equipment and persons trained in foreign object retrieval is required for device removal.

INDICATIONS FOR USE

The Obalon Balloon System (the "System") is a swallowable intragastric balloon system indicated for temporary use to facilitate weight loss. Indicated patients include obese (BMI of 30 – 40 kg/m²) adults. The System is intended to be used as an adjunct to a diet and behavior modification program.

A maximum of 3 Obalon Gastric Balloons may be placed in the stomach across a 6-month treatment period based on the individual's weight loss progress and fullness levels. All balloons must be removed 6 months after the initial balloon placement or sooner.

CONTRAINDICATIONS

The following contraindications apply to the Obalon Gastric Balloon System:

- Anatomical abnormalities or functional disorders that may inhibit swallowing or passage through any portion of the entire Gastrointestinal (GI) Tract
- Prior surgeries that may have resulted in intestinal adhesions, narrowing of any portion of the digestive tract or any other condition that may inhibit passage through any portion of the GI tract
- Prior or current bariatric surgery
- Inflammatory and other pathophysiological conditions of the GI tract
- Chronic or acute use of medications known to be gastric irritants or to otherwise alter function or integrity of any portion of the GI tract, including but not limited to NSAIDs and aspirin
- Untreated *Helicobacter pylori* infection
- Untreated hypothyroidism or untreated Cushing's disease or syndrome
- Severe, unstable/uncontrolled medical conditions of major organ systems
- Allergies to products/foods of porcine origin
- Patients diagnosed with bulimia, binge eating, compulsive overeating, high liquid calorie intake habits or similar eating related psychological disorders
- Patients with known history of structural or functional disorders of the stomach including, gastroparesis, gastric ulcer, chronic gastritis, gastric varices, hiatal hernia (> 2 cm), cancer or any other disorder of the stomach
- Potential excessive bleeding is possible at device removal for those patients requiring the use of anti-platelet drugs or other agents that affect the normal clotting of blood.

This should be considered during patient selection prior to administering the product.

- Patients with known cardiovascular disease such as recent acute coronary syndrome or clinically unstable ischaemic cardiac disease including evolving or ongoing myocardial infarction, typical angina at rest, recent coronary intervention, recent deterioration of ECG, laboratory or clinical findings.

WARNINGS

The risk of balloon deflation is significantly higher with balloons that are left longer than 6 months.

Patients reporting a loss of fullness, increased hunger, and/or weight gain should be examined by radiograph, as this may be a sign of balloon deflation. Additionally, any increase in nausea, vomiting and/or cramping after initial symptoms have subsided may indicate a deflated balloon. Endoscopic visualization might be required if the state of inflation cannot be determined radiographically. In the event of balloon deflation, the balloon should be removed as soon as possible.

Each patient should be monitored closely during the entire device therapy period in order to detect the development of possible complications. Patients should be instructed regarding symptoms of deflation, gastrointestinal obstruction, ulceration, esophageal injury, and other possible complications that could occur, and should be advised to contact their physician if these symptoms worsen over time or persist for more than 24 hours.

DO NOT place more than 3 balloons in one patient across the 6-month therapy cycle. Results of more than 750 cc of volume are unknown with the System.

Do not place more than one device simultaneously. There should be no less than 14 days between Balloon placements. Risk of intolerance due to too much initial volume may occur.

Endoscopic retrieval might be required in the event that a capsule is swallowed, but not completely inflated.

Patients must not use gastric irritant medications including but not limited to NSAIDs or Aspirin during use. This can lead to an increase in ulcerations and gastric bleeding events while balloons are in residence.

PRECAUTIONS

To minimize radiation, during administration, if fluoroscopy is utilized instead of digital x-ray, monitoring of the actual swallow process is not required to ensure successful placement and is not recommended. Radiation exposure should be minimized to the lowest possible level during confirmation after swallow and balloon inflation.

Prior to usage of the Obalon Gastric Balloon System, patients should have previously attempted to lose weight unsuccessfully using a medically supervised or non-medically supervised diet.

Use with caution in patients with Type 1 diabetes mellitus or on medications required for Type 2 diabetes. For persons with diabetes weight reduction can reduce insulin resistance and improve response to insulin and oral anti-diabetic medications. Adjustments of insulin/oral medication may be required. The patient should be advised of this potential benefit and should continue to monitor their blood glucose; the patient should

follow-up with their physician before, during and after use of the Obalon Gastric Balloon System.

Patients using medications known to affect weight or who are undergoing chronic steroid immunosuppressive therapy should not use the treatment.

DO NOT place balloons if the patient expects to permanently reside at an elevation greater than 4000 ft from balloon placement elevation or lower than 2500 ft from the balloon placement elevation. The risk of balloon deflation increases with significant change in elevation during balloon use.

Must not undertake scuba diving or travel in an unpressurized airplane cabin.

Must not undergo MRI while balloons are implanted. The Obalon Balloon System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Obalon Balloon System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

SPECIAL PATIENT POPULATIONS

Safety and effectiveness in pregnant women, women who are nursing, and persons under the age of 21 have not been established.

ADVERSE REACTIONS

The most frequently reported events are:

- Abdominal Cramping
- Nausea
- Abdominal Discomfort
- Vomiting
- Gastroesophageal Reflux/Heartburn
- Clinically insignificant esophagogastric bleeding due to removal procedure
- Feeling of fullness, bloating or heaviness in the abdomen
- Additional Endoscopy

Other less frequently reported events are:

- Gastric Ulceration
- Diarrhea
- Sore Throat
- Salivation
- Constipation
- Gastrointestinal Hypermotility

On rare occasions the following events were reported:

- Aspiration of gastric secretions
- Burping
- Clinically insignificant esophagogastric junction redness due to removal
- Dizziness
- Esophageal Dysmotility
- Excessive Gas
- Gastritis
- Halitosis
- Hiccups
- Hyperventilation
- Indigestion
- Esophageal Laceration
- Esophageal Rupture

- Inflation in the esophagus
- Perforation of the esophagus
- Bowel Obstruction Requiring Surgical Removal
- Psychological Intolerance
- Esophageal Hematoma
- Infection
- Esophageal Abrasion
- Fatigue
- Edema

The following events are possible, but have not been reported:

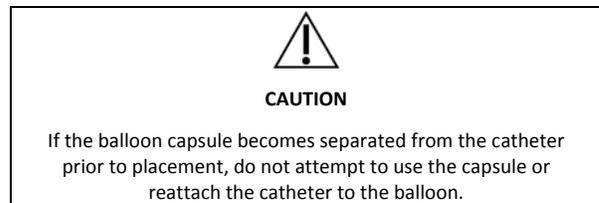
- Discomfort during administration or catheter removal
- Upper GI discomfort during administration
- Airway obstruction
- Perforation or rupture of the stomach
- Gastrointestinal Bleeding

Complications associated with endoscopy include:

- Abdominal cramps or discomfort from the air used to distend the stomach
- Allergic or Adverse reaction to sedation or anesthesia
- Aspiration (of liquid or food if present in stomach during balloon removal procedure)
- Cardiac or respiratory arrest (These are extremely rare and are usually related to severe underlying medical problems)
- Digestive tract injury or perforation
- Excessive Sweating
- Hypotension
- Impaired judgment or reactions after sedation or anesthesia
- Laryngospasm
- Sore or irritated throat following the procedure

HOW SUPPLIED

All components are supplied non-sterile. The Balloon System consists of the following:

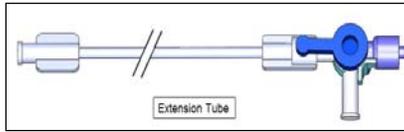


1. Balloon Kit (All components in this kit are for single use only)
- Obalon Balloon Assembly: 1 folded balloon contained in a swallowable Capsule that is attached to 1 disposable, flexible Catheter Delivery System



2. Accessory Kit: (All components in this kit are for single use only)
- 3cc Syringes (QTY: 2)

- Extension tube and stopcock with a 3-way valve



ADDITIONAL ITEMS REQUIRED FOR DEVICE USE



CAUTION

Prior to Balloon Administration you must follow the **Obalon Inflation System Operational Instructions** to prepare the balloon gas delivery devices.

The following accessories are required for use with the Obalon Balloon System but are included in separate packaging:

For Administration:

1. Placebo Capsules (for single use only)
 - Placebo Capsule Assembly: Capsule is the same material, size, shape and weight as the actual device but does not contain a balloon or catheter. The capsule is filled with 4 grams of sugar to simulate device weight.
2. Obalon EzFill Dispenser with Extension Tube attached and Can inserted



3. Additional Items Required for Use with the Obalon Balloon System:

For Balloon Administration:

- Small clean bowl/Room temperature bottled water
- Carbonated, clear beverage
- Timer / clock
- Digital X-Ray or Fluoroscope (set to General Settings)
- 60 cc Syringe

For Balloon Removal:

- Vacuum aspiration source
- Gastroscope
- Gastroscope Injection Needle (minimum suggested length is 6 mm and minimum needle gauge size is 23) compatible with working channel of gastroscop
- Rat Tooth with Alligator Jaws Grasping Forceps (minimum opening width of 15 mm) or other commercially available

endoscopy retrieval tools such as two-prong graspers, compatible with working channel of gastroscop.

PRE-BALLOON ADMINISTRATION

Placebo Capsule Use

Prior to administration of an actual balloon capsule, patients must undergo a placebo capsule test. The purpose of this procedure is to help identify patients who may not be able to swallow the actual device. However, the placebo capsule is not intended to diagnose swallowing disorders, and patient medical history should also be thoroughly reviewed to determine if a history of relevant disorders exists.

To administer the placebo test, provide the patient water and instruct them to swallow the placebo capsule. If the patient complains that the placebo capsule feels “stuck,” they should be instructed to continue to drink copious amounts of room temperature water. The capsule will eventually dissolve and pass through the gastro-esophageal junction.

If the patient has any difficulty swallowing the placebo capsule they may be poor candidates for the actual balloon device. The actual balloon capsule is attached to a catheter and patients experiencing swallowing difficulties with the placebo capsule may have even more difficulty with the actual balloon capsule.

If the patient swallows the placebo capsule without any difficulty, they may proceed with the balloon therapy. Swallowing the actual balloon device should not be done immediately after the placebo test. Wait a sufficient time to ensure that all remnants of the placebo capsule have dissolved and are no longer in the esophagus.

PREPARATION FOR USE

You must follow the **Obalon Inflation System Directions for Use** in their entirety prior to administering the Obalon Balloon. Then you may proceed to preparing the System as discussed below:

3cc Balloon Ejection Syringe (Accessory Kit)

1. Remove the 3cc syringe from its packaging.
2. Fill each 3cc syringe with 1.5ml of room temperature water and set aside.



CAUTION

Do not fill the syringe more than half way (1.5 ml). Doing so may compromise the amount of force needed to push the syringe plunger for detachment of balloon from the catheter.

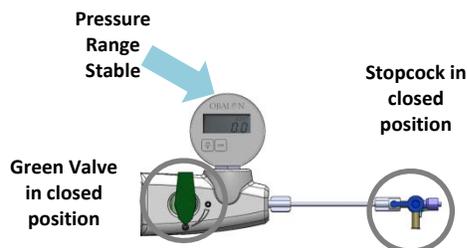
Use the provided syringes. Use of a larger syringe might not create enough hydrostatic pressure to eject the balloon.

Balloon Capsule/Catheter (Balloon Kit)

1. Fill a small, clean bowl half-way with water.
2. Carefully remove the balloon by gently pouring out the components of the package. Trying to pull out the capsule/catheter may cause more tangling. Examine all components for bends, kinks or other damage.

EzFill Dispenser

1. Prior to use, verify that you have an EzFill Dispenser labeled with an operating altitude range (elevation) that you intend to use it in.
2. Verify the proper set-up of the EzFill Inflation System and the green valve is in the closed position




WARNING

Follow the ***Obalon Inflation System Operational Instructions*** in its entirety prior to Balloon Administration.

Do not proceed with Balloon Inflation if any of the following occur:

The Dispenser is not within pressure range or is not stable (within 0.3 kPA for 30 seconds)

The Green Valve is not in the "Closed Position"

BALLOON ADMINISTRATION

The Obalon Balloon Kit capsule is administered to the patient using a normal pill swallowing method. Endoscopy is not required for placement. Fluoroscopy or digital x-ray is required during the placement procedure to verify placement of the balloon in the stomach prior to inflation of the device. Patient must be in the erect position during the administration procedure. Any existing balloons should also be imaged to confirm their integrity prior to placement of an additional balloon. The total placement time is usually less than 15 minutes for each balloon placed. Immediate access to personnel proficient in endoscopy in the event of a failed swallow is also required.

Review the procedure with the patient prior to commencing.

Balloon Placement


WARNING

Use standard radiography methods for balloon placement. You must have patients remove all metal objects including jewelry, clothing with metal or zippers, and/or belts that can affect visualization of the balloon valve.

Have the patient refrain from talking during the procedure and instruct them not to close their mouth tightly or bite down on the catheter at anytime.

Do not allow the patient to grab or hold onto the catheter at anytime.

To minimize radiation exposure, fluoroscopic imaging of the swallow procedure is not required and is not recommended.

1. Ensure that the patient has no lipstick, gloss, or emollients on their lips that could affect the administration process.
2. Have the patient stand (preferable) or sit upright and have the patient drink a small amount of water to prepare for capsule administration.
3. Instruct the patient NOT to hold onto the catheter by hand. It is recommended to have the patient hold something in their hands to avoid his/her grabbing of the catheter.
4. Wet the capsule/catheter by submerging into the bowl of water for no more than 10 seconds.


WARNING

Do Not Use a balloon capsule assembly that has been wetted for more than 10 seconds. This may cause the balloon capsule to dissolve prior to passing through the gastro-esophageal junction and reaching the stomach. If this happens go to the **Troubleshooting Section** of this Instructions for Use.

5. Within 1 minute of submerging the capsule in the water, hand the patient the capsule/catheter and instruct him/her to place the capsule immediately in the mouth and swallow the capsule with another large glass of room temperature water. Hold the Proximal Catheter Port outside of the patient's mouth.
6. Patients should be given additional water (at least 100 ml) after swallow. Patients must remain in an upright sitting or standing position the entire time.
7. Ask the patient to continually drink water or carbonated beverage to facilitate peristalsis of the capsule/catheter if the balloon has not visibly passed into the stomach.
8. If the patient is having difficulty swallowing the capsule (not passing the pharynx) go to the Troubleshooting Section for additional swallowing tips.
9. Once swallowed, the proximal end of the capsule/catheter assembly will remain outside of the patients' mouth until after the balloon is filled.
10. Approximately 1-2 minutes after swallow, **perform digital x-ray or fluoroscopy** with the patient standing (preferred) or sitting upright (if necessary) to determine the location of the radio-opaque balloon marker in the stomach.
11. If the capsule is still in the esophagus, proceed to the Troubleshooting section for [esophageal transit difficulties](#).

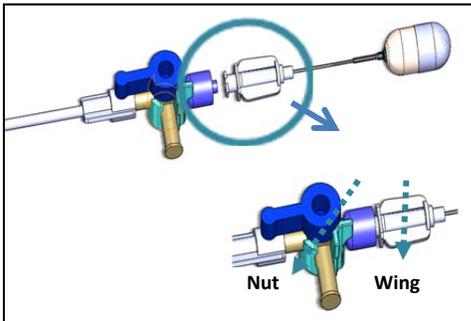
Balloon Placement "Pre-Pulse" Detection


WARNING

Do not connect the balloon catheter before verifying that the Green Valve and the Stopcock Lock are in the CLOSED position.

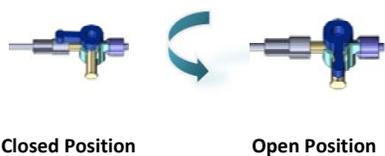
1. Connect the catheter to the extension tube of the accessory kit. Do so by connecting the catheter to the male luer port on the 3-way stopcock of the extension tube as shown in **Figure 1**. Ensure the connection is tight but do not over-tighten. Make sure that the green valve is in the off position.

FIGURE 1. CONNECTING CATHETER TO EXTENSION TUBE



2. 2-5 minutes after swallow, perform a second verification of the device location utilizing the digital gauge read-out:
 - a. Verify the EzFill Dispenser is on. If the EzFill Dispenser is off, turn on the EzFill Dispenser Digital Gauge by pressing the "ON" button.
 - b. Should the Gauge Backlight dim, press the "ON" button on again to restore the Gauge Backlight.
 - c. To release the Pre-Pulse gas volume, turn the blue 3-way valve on the stopcock to the open position (counter clockwise) 90 degrees until the valve stops. **Figure 2** shows the Stopcock with the 3-way valve in the "open" position.

FIGURE 2. TURN STOPCOCK WITH 3-WAY VALVE TO OPEN



Pressure is below 7 kPa

- d. The pressure measurement will decrease approximately **20 kPa** and continue to decrease to a value below **7 kPa**. This should take approximately 45 seconds but no longer than 4 minutes. A value below 7 kPa indicates that the capsule has transited the esophagus and has dissolved. This provides a second confirmation of the x-ray that the balloon is in the stomach. Proceed to [Balloon Inflation](#).

Pressure is between 7.0 kPa and 17.2 kPa

- e. If the pressure is between **7.0 kPa** and **17.2kPa**, then the capsule has not dissolved sufficiently or the

balloon may be in the esophagus. Take another x-ray placement verification. If the x-ray confirms the balloon is in the stomach, the patient should drink more liquid to facilitate capsule dissolution and balloon opening for full inflation.

Pressure is above 17.2 kPa

- f. If the pre-pulse pressure remains above 17.2 kPa for an extended period of time after swallow and the gauge stays constant without significant changes in pressure, the capsule may be constricted in the esophagus. Do not attempt balloon inflation. Continue to observe patient for signs of discomfort and immediately refer to the use of the [60 cc syringe in the Troubleshooting Section](#)
3. Continue to monitor pressure for up to 4 minutes. If after this time the pressure has not dropped below **7 kPa**, then the capsule has not dissolved or may be constricted in the esophagus. **Do not proceed with Balloon Inflation**. Re-confirm placement in the stomach with another x-ray or fluoroscopic viewing.



WARNING

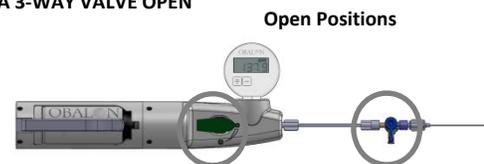
Do not rely solely on the gauge measurement for confirmation of placement in the stomach. You must confirm all pressure measurements with x-ray or fluoroscopy verification.

4. If the gauge reads less than **7 kPa** and you have re-confirmed that the balloon valve is in the stomach by radiographic imaging, you can proceed to [BALLOON INFLATION](#).

BALLOON INFLATION

1. To fill the balloon, rotate the Green Valve on the EzFill Dispenser to the right (open position) as shown in **Figure 3**.

FIGURE 3. BALLOON FILL: GREEN VALVE OPEN & STOPCOCK WITH A 3-WAY VALVE OPEN



2. The balloon will inflate completely approximately 2 minutes after the Green Valve is opened.



WARNING

During inflation, if there is indication of inflation in a constrained space (by pressure readings or patient symptoms), shut off the gas flow by closing the green valve, detach the catheter and evacuate the gas from the balloon with a 60cc syringe. Proceed to the Troubleshooting Section.

Inflation in the esophagus may cause serious injury or death.

Do not disconnect the balloon from the catheter prior to balloon fill completion. In the event of a premature disconnection, retrieve the catheter by pulling it out. Document the gauge pressure measurement and inform and contact Obalon Customer Service immediately. The Balloon may require endoscopic removal.

- Wait a minimum of 2 minutes from when the Green Valve is opened in step 2. Verify that the readout pressure on the digital gauge is stable by monitoring the gauge for at least 30 seconds to assess balloon pressure stability. The balloon pressure is stable if it does not steadily decrease by more than 0.3 kPa within a 30 second period.
- Close the Green Valve and verify that the final readout pressure on the digital gauge reads between **9.0 and 13.0 kPa**. Repeat monitoring the gauge for at least 30 seconds to assess balloon pressure stability. The balloon pressure is considered stable if it does not steadily decrease by more than 0.3 kPa within a 30 second period. **If the balloon pressure is greater than 13.0, refer to "Final Pressure Setting Adjustment" in the Troubleshooting section of these Instructions for Use.**


CAUTION

IF THE GAUGE DOES NOT STABILIZE, the balloon inflation process is not complete or the balloon system may have a leak. If the pressure is not stable or the balloon pressure is below 9.0 kPa, contact Obalon Customer Service. The Balloon May require endoscopic removal.

- Verify the location of all balloons using x-ray or fluoroscopy imaging, in addition to being at a stable pressure between 9.0-13.0 kPa. A fully inflated balloon will look like the x-ray presented in Figure 4. Evaluate the image by examining the shape of each balloon, confirming that the outline appears to be elliptical or circular. Also note if the radiopaque balloon valve appears to be in the stomach. A second x-ray view may be useful in the event that balloons are obscured from each other in a single x-ray view. Note that partial balloon deflations may not be visible on x-ray until a substantial portion of gas has left the balloon.

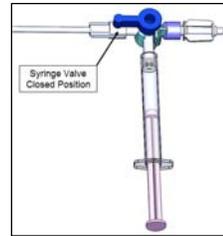
FIGURE 4. EXAMPLE X-RAY SHOWING 3 BALLOONS INFLATED IN THE STOMACH



- Attach the pre-filled Syringe to the Stopcock with the 3-way Valve still open as shown in **Figure 3**.

- Rotate the 3-way Valve back to the closed position (or 90 degrees clockwise) to close the flow of gas from the EzFill Dispenser (see **Figure 5**).

FIGURE 5. STOPCOCK WITH A 3-WAY VALVE CLOSED/SYRINGE ATTACHED




CAUTION

Do not close the 3-way stopcock valve until you have attached the pre-filled syringe. Doing so will reduce the final starting pressure in the balloon, and the balloon may not maintain its volume for the 6-month period.

Catheter Retrieval

- Push the plunger of the 3cc syringe filled with 1.5ml of room temperature water in a single rapid and deliberate motion. The catheter will detach from the balloon valve in the stomach. If the catheter does not detach after the first attempt, a second attempt will be necessary.
- Prior to removing the first syringe, rotate the stopcock valve to open the flow of gas. Attach the second 3cc syringe and rotate the stopcock back to the closed position. Use the second water filled syringe to again attempt to remove the catheter. On the second attempt, ensure that the catheter is straight and has no kinks and that the plunger is pressed in a rapid and deliberate motion.
- If more than two attempts are unsuccessful go to the Troubleshooting Section of this Instructions for Use.
- Slowly pull the catheter out of the patient's mouth. Having the patient put their chin down may facilitate this process with less of a gag reflex.
- Visually inspect the catheter and visualize the needle inside the needle sleeve (which is the white protective hub that came attached to the capsule device) to ensure the needle is intact. If the needle is not inside the needle sleeve, remove the balloon endoscopically.
- Separate the catheter from the Extension Tube by unscrewing the luer lock.

BALLOON USE

Post-Administration Guidelines

Advise patients to drink liquids for the first 24 hours and then transition to soft solids on the 2nd day after administration. Patients should not drink sodas or other "fizzy" or carbonated drinks. On the 3rd day after the administration, patients should be able to return to solid foods and follow the diet and behavior modification program provided to them by their physician.

Patients should be advised that some degree of nausea, vomiting and cramping are normal within the first week of each administration procedure. Patients should also be reminded to take medications intended to help minimize symptoms exactly as prescribed by their physician. Patients should be informed of who to contact in the event that they experience symptoms that are intolerable, new symptoms that start after the first week post-administration, or a sudden loss in fullness or increase in hunger. These symptoms should be further evaluated by the following physician and potential balloon deflations should be ruled out.



WARNING

Patients reporting a loss of fullness, increased hunger, and/or weight gain should be examined by radiograph, as this may also be a sign of balloon deflation. Balloon deflation can be evaluated using radiography (film x-ray, digital x-ray, or fluoroscopy) and endoscopy as appropriate. Evident balloon deflation may require early balloon removal.

Additionally, an increase in nausea, vomiting, and/or cramping after initial symptoms have subsided may indicate a deflated balloon.

Patients should also be advised to contact their physician if the frequency of adverse events experienced is more than anticipated or becomes intolerable.

Patients must not use gastric irritant medications including but not limited to NSAIDs or Aspirin during use. This can lead to an increase in ulcerations and gastric bleeding events while balloons are in residence.

Diet and Behavior Modification Program

The Obalon Balloon System is intended to be an adjunct to weight loss behavior modification program. All subjects will participate in an adjunctive weight loss program focusing on the following principles:

- A balanced low calorie diet
- Education on identifying nutritional content and determining appropriate portion sizes
- Behavior modification techniques to promote healthy eating habits
- Medically appropriate use of physical activity

Additional Balloon Placements

A single Obalon Balloon does not provide enough volume to induce the fullness required for suitable weight loss. Clinical studies have shown that three balloons are required to achieve effective weight loss over the course of the 6-month intended use period. The clinical study demonstrated that placement of a second balloon between 14 and 28 days after first balloon placement and the third balloon between 56 and 91 days provided safe and effective weight loss. It is recommended that there should be no less than 14 days between Balloon placements.



WARNING

DO NOT place more than 3 balloons in one patient across the 6-month therapy cycle. Results of more than 750 cc of volume are unknown with the System.

Do not place more than one device simultaneously. Risk of intolerance due to too much initial volume may occur.

BALLOON REMOVAL

After 6 months of use, all balloons must be removed from the patient.

This procedure should be conducted using a working length endoscope that is less than 1200 mm, and the inner diameter must be compatible with the accessory tools suggested for puncture and retrieval of the balloon.

Suggested Tools:

- A needle instrument: Injector needle in a Teflon Sleeve 23G x 6mm or similar having a lumen for suction
- Rat Tooth Grasper with Alligator Jaws or Two Jaw Grasping Forceps (with a minimum opening width of 15 mm); two prong graspers with same minimum opening may work as well.



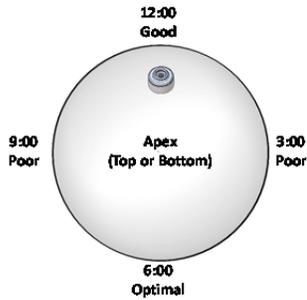
WARNING

Use of tools that are not within the specifications above could result in patient injury.

The above mentioned tools are suggested, but there may be other retrieval tools acceptable for retrieving the balloons. Retrieval procedures in general should be conducted per the gastroscopie manufacturer's instructions for retrieving foreign objects. The endoscopy procedure performed is similar to that of an interventional or therapeutic procedure; however, tailoring the endoscopic approach according to the unique product features is important:

- Balloons should only be punctured once, so that the maximum amount of gas can be aspirated (via vacuum)
- A lesser degree of stomach inflation (less air insufflation) allows for easier puncture of the balloon
- Once deflated and all gas is aspirated, the balloon should be optimally grasped at the 6:00 position as seen below. The image below shows a cross section of an inflated balloon through the balloon seam
- The balloon should be optimally grasped at the 6:00 position **on the seam**, which may result in a more

secure hold on the balloon given the increased strength of the overlapping seam



WARNING

Potential excessive bleeding is possible at device removal for those patients requiring the use of anti-platelet drugs or other agents that affect the normal clotting of blood.

Persons conducting the removal procedure must be a physician trained and proficient in clinical endoscopic technique. Patients should be fasted at least 24 hours or per hospital protocol for gastroscopy procedures to ensure the stomach is empty and the balloon(s) are therefore easily visible.

1. Anesthetize per hospital and physician recommendations for gastroscopy procedures.
2. Insert the gastroscopy into the patient's stomach.
3. Get a clear view of the filled balloons through the gastroscopy.
4. Insert the needle instrument down the working channel of the gastroscopy.
5. Locate the valve of the balloon and puncture the balloon with the needle only once (at the opposite end of the valve if possible for easier removal).
6. Apply suction and aspirate balloon gas using a large 60cc syringe or aspiration tube.
7. Remove the needle from the working channel.
8. Quickly insert the graspers through the working channel.
9. Grab the balloon with the graspers at the opposite end of the valve.
10. With a firm grasp on the balloon, slowly extract the balloon up through the esophagus removing the balloon through the mouth.
11. Repeat for the remainder of the balloons.

TROUBLESHOOTING

Placement of the balloon does not require endoscopy; however, it is highly suggested that a trained Endoscopist be readily available should there be a problem with placement of the balloon. The following should be considered during balloon placement:

Swallowing Difficulties:

- Always use the Obalon Placebo Capsule prior to attempting administration of an Obalon Balloon Capsule.
- Make sure the patient has not had large volumes of liquid prior to the administration procedure. This usually provides them a feeling of "too full" and makes it more difficult to ingest anything else.
- Create a relaxing, calm environment for the patient. Minimize the number of people in the room. Provide calm, confident words of encouragement. Have the patient take a few deep breaths before swallowing. If failure to swallow is due to anxiety, standard methods to reduce the patient's anxiety should be used.
- Guide the patient to place the capsule on the back of the patient's tongue and orient the catheter to the side of the patient's mouth.
- Encourage the patient to drink large gulps of water rather than small sips of water.
- If the patient fails two attempts, you should discuss this issue with the patient and determine if the patient remains a good candidate for the therapy.
- If the device does not pass the pharynx in the patient's mouth after 30 seconds of attempting swallow, the capsule must be removed from the mouth. A new wetted balloon capsule/catheter assembly must be used.
- 4 oz. of a "smoothie" (thick consistency/flavored beverage) can aid in swallowing difficulties. This method helps to mask the flavor and consistency of the device.

Esophageal Transit Difficulties:

- Attempting to remove the balloon by traction on the catheter could lead to separation of the balloon. If this occurs, it could occlude the upper airway requiring emergency procedures to relieve the obstruction.
- Esophageal transit of the device can be facilitated by use of clear carbonated beverages or a small piece of banana.
- When the capsule clears the esophagus, return to the [Balloon Placement](#).
- If the capsule does not clear the esophagus, immediately proceed to endoscopic removal.

60cc Syringe Use:

If radiography or x-ray indicates that the radio-opaque marker has not passed completely into the stomach within 2 minutes after swallow, the patient may be having difficulty transiting the capsule. If pre-pulse has already been administered and the pressure gauge is still above 17.2 kPa, ensure that the green valve is turned to the closed position and proceed below:

- To relieve gas from the balloon, attach the 60cc Syringe to the stopcock. Rotate the stopcock to the closed position. Pull back the syringe and hold the

plunger to maintain the vacuum. Note that the pressure might be strong. This will help constrict the balloon as much as possible.



Closed Position

Open Position

Attempt to use additional beverages or a piece of banana to encourage transit of the balloon into the stomach.



WARNING

Do not use banana more than once to encourage transit.

Catheter Ejection Difficulties:

- Catheter ejection requires a single, rapid push of the plunger. It is recommended to use two thumbs on the plunger. Performing this step in a less forceful manner may lead to a failed ejection. Ensure the 3 ml syringe is always filled to 1.5 ml and perform an additional attempt.
- If the catheter fails to eject there may be a kink in the catheter. Gently tug the catheter to straighten the line and repeat the syringe ejection procedure.

Final Pressure Setting Adjustment:

- If during balloon placement the final balloon pressure reads greater than 13.0 kPa, the balloon pressure must be adjusted. You can do this using the following method:
 1. Ensure the current pressure reading is stable for at least 30 seconds and close the green valve.
 2. Rotate the stopcock to the Closed Position for **2 seconds**.



Closed Position
 3. Then rotate the stopcock back to the Open position.



Open Position
 4. Wait 10 seconds to verify that the pressure is now within a range of 9.0-13.0 kPa. If the pressure does not meet this range, repeat steps 2-3, waiting 10 seconds between attempts until the balloon falls within the required 9-13 kPa pressure range. Once the pressure reading meets the required 9.0-13.0 kPa range, please make sure it remains stable for at least 30 seconds.



CAUTION

If the balloon pressure does not fall within 9.0-13.0 kPa after several attempts, or drops below 9.0 kPa, contact Obalon Customer Service. In the event the balloon pressure does not fall within this range you will have to remove the balloon endoscopically.

Unstable Pressure Measurements:

For each pressure measurement review you must verify that the measurement is “stable”. A stable measurement is one that does not steadily decrease by more than 0.3 kPa for a minimum of 30 seconds. If the gauge measurement is not stable there may be a leak in the System. Please call Obalon customer service. If the expected measurement is not stable or not within the expected measurement range you will have to perform an endoscopic removal of the balloon.

The expected stabilized pressure measurements at balloon placement to be verified during the procedure prior to moving to the next step are as follows:

Instructions for Use Section	Expected Pressure Reading
Preparation for Use	Review Dispenser Label: Operating Altitude xxx-xxx ft Pressure XXX.X – XXX.X kPa City, State
Balloon Administration - Balloon Placement “Pre-Pulse” Detection	Less than 7.0 kPa and approaching 0.0 kPa after Radiographic Confirmation. Re-verify radiographically if pressure exceeds 7.0 kPa
Balloon Inflation	9.0-13.0 kPa

Use of radiography to rule out potential balloon deflation:

It is expected for patients to experience some degree of nausea, vomiting, and cramping within the first week after each balloon administration. Severe symptoms during that time or new symptoms occurring after the first week could indicate a premature balloon deflation. A sudden loss of fullness or a sudden increase in feelings of hunger may also indicate a potential balloon deflation.

In these circumstances, radiographic imaging should be considered to rule out a potential balloon deflation. Balloon valves are radiopaque and the outline of an inflated balloon will have an elliptical or circular perimeter. If all balloons cannot be visualized with a single x-ray view, a second x-ray view should also be evaluated. Endoscopic visualization will be required if the state of inflation cannot be determined radiographically. Balloon deflation will require early endoscopic balloon removal.

If a previously placed balloon is not in the stomach and has not been excreted, patients should be closely monitored for symptoms suggestive of a bowel obstruction. Serial imaging at 24 hour intervals should be considered if the patient is asymptomatic in an effort to ascertain if the balloon is progressing through the digestive tract. Deflated balloons may eventually be excreted and invasive intervention (e.g. colonoscopy, surgery) to remove the balloon should be considered if the physician believes that a bowel obstruction may occur and the benefits of the intervention outweigh the risks.

Clinical Study Design

The Obalon SMART Pivotal Trial was a prospective, sham-controlled, double blinded, randomized multicenter study that treated 387 obese subjects. Subjects had an initial BMI of 30-40. Some subjects had an obesity-related comorbidity, but it was not required to be in the study. Of the subjects that were randomized, 8.3% of subjects exited the study after being unable to swallow the capsule and be treated. The Obalon Balloon Treatment Group subjects received exactly one (n=5), two (n=10) or three (n=183) Balloons over the course of the 24 week therapy with an average administration time of 9.5 ± 4.1 minute administration procedure. The Sham Control Group Subjects received one (n=2), two (n=6), or three (n=181) sham procedures. Approximately 1.5% of subjects were unable or unwilling to swallow a second device, and 3.7% were unable or unwilling to swallow a third device.

Adverse Events

One (1) subject had a total of 1 device- or procedure-related Serious Adverse Event (SAE). The proportion of subjects with any device- or procedure-related SAEs was 0.5% (1/198, 95% CI 0%, 2.8%). There were no deaths, no device migrations out of the stomach and no intestinal obstructions. The Serious Adverse Device Effect (SADE) that occurred was in a subject who had elected to receive a total knee replacement during the therapy period. During that procedure the subject received a high dosage of NSAIDs and Aspirin. The subject presented with peptic ulcer disease (gastrointestinal bleeding) two weeks after the knee surgery occurred. The NSAID therapy was stopped concomitantly with balloon removal.

Table 1. GI System Device Related Adverse Events Occurring in 10% or More of Subjects

ADE Description	OGB Treatment Group (N = 198)	
	Events	Subjects (%)
Abdominal Cramping	214	126 (63.6%)
Nausea	175	104 (52.5%)
Vomiting	37	29 (14.6%)
Abdominal Pain	35	29 (14.6%)
Reflux/Heartburn	28	25 (12.6%)
Bloating	25	23 (11.6%)
Abdominal Discomfort	25	21 (10.6%)

Overall, for the Obalon Treatment Group, 587 (86.3%) of events were mild, causing , 91 (13.4%) were moderate, and 2 (0.3%) events were severe. Mild was defined as subject awareness of

signs or symptoms that were easily tolerated and caused no loss of time from normal daily activities where the symptoms did not require prescription medications to resolve and were treated with homeopathic methods or OTC medications. Moderate events were considered symptoms that caused transient periods of discomfort not always easily tolerated and on occasion interfered with normal daily activities. These symptoms required additional prescription medications but did not require hospitalization or invasive interventions. Severe events were episodes of non-transient discomfort that inhibited the subject's ability to perform normal daily activities. These events could require hospitalization or invasive interventions but did not always. An event was classified if it met one of the requirements within the classification scheme (subject normal daily activity assessment or action taken requirements to stabilize or resolve the event).

Early device deflation occurred in a single balloon (0.17%) in a single subject (0.51%). The deflation was identified when the subject complained of new onset of symptoms of epigastric pain after previous symptoms had resolved (change in baseline symptoms). The deflated balloon did not migrate out of the stomach. No adverse events were associated with the deflation. There were two bit catheters that resulted in the two balloons failing to inflate. The failure to inflate was identified during the administration procedure where the balloon inflation measurement was less than required range (9-13), ~1 KPA. The balloons were removed the same day with no adverse events associated with the failures to inflate.

Demographics and Effectiveness

The SMART Trial baseline physical characteristics and demographics are shown below.

Demographic	Statistic	Treatment (n=198)	Control (n=189)	p-value
Age (years)	Mean ± SD (Median) IQR Range	42.7 ± 9.6 (43.2) [35.0, 50.0] [22.2, 62.9]	42.5 ± 9.3 (43.8) [35.3, 49.0] [22.2, 63.6]	0.8705
Gender: Female	n (%)	171 (86.4%)	170 (89.9%)	0.2762
Ethnicity: Not Hispanic or Latino	n (%)	183 (92.4%)	165 (87.3%)	0.0943
Race: White or Caucasian	n (%)	165 (83.3%)	155 (82.0%)	0.7310
Race: Black or African American	n (%)	21 (10.6%)	29 (15.3%)	0.1648
Other race	n (%)	12 (6.1%)	5 (2.6%)	0.1013
Height (in)	Mean ± SD (Median) IQR Range	65.6 ± 3.3 (65.0) [63.0, 67.2] [57.0, 75.0]	65.6 ± 2.9 (65.5) [64.0, 67.0] [59.0, 77.3]	0.9159
Waist (in)	Mean ± SD (Median) IQR Range	43.1 ± 3.8 (43.0) [40.5, 46.0] [31.5, 52.8]	43.6 ± 4.0 (43.7) [41.0, 45.8] [30.5, 56.0]	0.2453
Enrollment Weight (lbs)	Mean ± SD (Median) IQR Range	215.7 ± 29.3 (211.1) [193.8, 235.2] [156.7, 302.0]	216.8 ± 25.9 (216.4) [199.8, 233.7] [153.2, 305.4]	0.6851

Demographic	Statistic	Treatment (n=198)	Control (n=189)	p-value
Enrollment BMI (kg/m ²)	Mean ± SD (Median) IQR Range	35.1 ± 2.7 (35.0) [32.9, 37.5] [30.0, 39.9]	35.4 ± 2.7 (35.5) [33.0, 37.7] [30.1, 39.9]	0.3452
Initial Administration Weight (lbs)	Mean ± SD (Median) IQR Range	216.3 ± 29.1 (210.1) [195.0, 236.4] [156.8, 301.2]	217.8 ± 26.2 (217.2) [201.3, 232.6] [152.8, 307.8]	0.6013
Initial Administration BMI (kg/m ²)	Mean ± SD (Median) IQR Range	35.2 ± 2.7 (35.1) [33.0, 37.6] [30.0, 40.2]	35.5 ± 2.7 (35.7) [33.3, 37.8] [30.2, 40.3]	0.2557

The study had two pre-defined co-primary effectiveness endpoint criteria: the difference in mean Percent Total Body Loss (TBL) between treatment groups and the percentage of subjects in the OGB Treatment group who lose at least 5% TBL. The Per Protocol Cohort was used in evaluating both co-primary effectiveness endpoints. The Per Protocol Cohort was prospectively defined as subjects who received at least two devices and participated in at least 18 weeks of use. Single balloon therapy is not expected to provide substantial weight loss effectiveness when compared with a sham control and participation for less than 18 weeks is also expected to reduce weight loss effectiveness. This cohort is therefore designed to represent a minimum reasonable use scenario where weight loss effectiveness, albeit diminished from a complete 3-balloon, 24 week period, might reasonably be expected.

The first co-primary endpoint after the 6-month course of therapy was as follows:

The difference in mean % TBL between the Obalon Balloon Treatment Group and the Control Sham Group is greater than or equal to -2.1% after the 6-month therapy period.

The null hypothesis would be rejected if the upper bound of a two-sided 95% confidence interval for the difference in least square means using an Analysis of Covariance (ANCOVA) model with the starting weight as covariate is less than -2.1%.

The second co-primary endpoint after the 6-month course of therapy was as follows:

The percentage of subjects in the treatment arm who lose at least 5.0% TBL after the first 6-month course of therapy will be calculated to determine if at least 35% of subjects are responders.

The null hypothesis would be rejected if the lower bound of a two-sided 95% exact confidence interval for the percentage of subjects in the Obalon Treatment Group who lose at least 5% TBL is greater than 35.0%.

Both primary co-endpoints were met:

Main Analysis of 6-Month %TBL	Least Square Mean		Difference in LS Means (Treatment – Control)			
	Treatment	Control	Estimate	95% LCL	95% UCL	p-value
Per Protocol Cohort	-6.81	-3.59	-3.23	-4.26	-2.19	0.0338

Main Analysis of 5% TBL Responder Rate	Estimate	95% LCL	95% UCL	p-value
Per Protocol Cohort	119 / 185 (64.3%)	57.0%	71.2%	< 0.0001

Weight loss maintenance after removal of the device was not evaluated.

The study was not powered for assessment of changes and did not include a pre-determined endpoint for factors associated with health improvements; however, data was collected to measure changes in co-morbid conditions. Results suggest overall metabolic measurements changed more favorably for the Obalon Balloon Treatment Group with statistically significant differences noted for systolic blood pressure, fasting glucose, LDL cholesterol and triglycerides. Although these changes may not be clinically significant the results suggest that populations with diabetes, hypertension, or hyperlipidemia may also see benefit with weight loss seen with use of the device.

STORAGE and DISPOSAL

Obalon Balloon Kit and Placebo Capsule

- Keep the Obalon Balloon Kit and Placebo Capsule in its packaging until you are ready to use it.
- Do not use the Obalon Balloon Kit or Placebo Capsule past the expiration date printed on the packaging; it must be used before the last day of the month if only the month and year are printed. Storage temperature should be 59° to 77° F (15° to 25° C) for the length of its shelf life.
- Discard the Catheter per standard biohazard methods and instructions after use

Accessory Kit

- Keep the Accessory Kit in its packaging until you are ready to use it.
- Store under normal conditions.
- Discard the Accessory Kit per standard biohazard methods and instructions after use.

PRODUCT SPECIFICATIONS

Obalon Products	Product number
Balloon Kit	7500/ 7600
Accessory Kit	6000
Placebo Capsule	7150/7650
Balloon Kit Assembly	
Storage Temperature	59° to 77° F (15° to 25° C)
Porcine Gelatin Capsule Ingredients	Porcine Gelatin/Water/ Methylparaben/ Propylparaben/ Sodium Lauryl Sulphate
Cellulose (HPMC) Capsule Ingredients	Hydroxy Propyl Methyl Cellulose (HPMC)/ Carrageenan / Potassium Acetate
Balloon Materials*	Nylon/Polyethylene/Silicone/Titanium
Catheter Length	71 cm
*The materials used to fabricate this device have been tested according to ISO 10993, the International Standard for biological evaluation of medical devices. This product is not made with latex or natural rubber materials.	

Additional information	
Single Use Only	
Storage/Operating Temperatures	
Caution/Warning	
Non-Sterile	
Do not use if package is damaged	
Keep dry	
Refer to instruction manual/booklet	
Manufacturer	
Expiration	
Lot number	
Part Number	
Type BF Applied Part	
Batteries not to be placed in trash	
MR Unsafe	
Not made with natural rubber latex.	

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