# Obalon Balloon System with Navigation and Touch Instructions for Use

**Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.**

**Rx Only**

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# INTRODUCTION

The Obalon Balloon System is designed to assist weight loss by partially filling the stomach. Each balloon is contained within a USP grade capsule, which is packaged pre-attached to a catheter. The balloon capsule is swallowed by the patient without sedation. Three gas-filled intragastric balloons are administered typically within the first 3 months of the 6-month therapy. A fully inflated single balloon is an ellipsoid with a volume of approximately 250 cc. When 3 balloons are placed, the total balloon volume is approximately 750 cc. All 3 balloons are removed 6 months after the first balloon was placed.

The Obalon Balloons are administered using the Navigation System. The Navigation System is used for administration visualization and the Obalon Touch™ Dispenser transfers the nitrogen-sulfur hexafluoride gas to the balloon. The Touch Dispenser must be set-up prior to conducting the patient swallow procedure. The dispenser must be powered on, the dispenser lever is lifted and the can is inserted into the shuttle prior to use. The lever on the dispenser is closed to actuate the can valve and pressurize the system. The dispenser performs a series of electrical, software, and hardware tests to ensure that the inflation system is working properly. Once these tests are complete, the dispenser displays a screen to indicate that the system is ready for use. The dispenser will not allow the user to proceed if any of the system checks indicate that a procedure could be compromised.

The balloon capsule is packaged pre-attached to the distal end of the Touch-compatible Navigation catheter. The catheter incorporates an electromagnetic sensor (inductor) at the distal tip that produces current when in the presence of the Navigation Console's electromagnetic field. During the swallow procedure, the currents generated are fed into a processor located on the Navigation Console that interprets the induced current and determines in 3D space the relationship between the sensor and the electromagnetic field. Prior to the swallow procedure a Reference Sensor is placed on the patient's Xiphoid process of the sternum (breastbone) and is calibrated. The information generated by the sensors is fed into a software application embedded in the computer on the console that displays the real-time position of the Balloon Capsule in 3D space as it relates to the Reference Sensor. The operator then uses this visual information to determine when the balloon has transited past the gastro-esophageal (GE) junction and is in the stomach based upon the occurrence of four known indicators provided in these Instructions for Use. The indicators are representative of signal characteristics of the catheter transitioning from the esophagus into the stomach. The catheter has three reference marks at 30, 40, and 50 cm from the distal end that are intended to provide the physician with a general reference while the capsule is descending into the stomach during the swallow. The method to confirm proper balloon placement prior to inflation is with the Navigation Console capsule trace.

Once a determination that the balloon capsule is in the stomach is made, the catheter is connected to the Obalon Touch Dispenser. The dispenser is controlled via the touchscreen interface. All of the dispenser and catheter connections are sealed and it is imperative that the catheter connection is fully secured during the procedure to maintain a closed gas pathway between the can and balloon. The Touch Dispenser automates and monitors the balloon inflation process to the correct balloon pressure, detects potential leaks in the system, and minimizes the probability of mucosal damage in the case of an inflation in a constrained space (e.g. esophagus, hiatal hernia or other anatomical abnormality). Throughout the procedure the dispenser screen displays pressure readings, images, and touchscreen buttons to facilitate the inflation process.

During the balloon inflation process the dispenser goes through multiple pressure check scenarios. There are two pressure checks conducted during balloon inflation. The first is a Pre-Pulse check and the second check is a Constrained Space Check. The first pressure check is conducted once the physician presses the Start Procedure button once the balloon has been confirmed to be in the stomach. A small bolus of gas is transferred to the balloon to facilitate capsule separation and to detect any unexpected high pressures associated with constrained space placement.

Once the Pre-pulse check is complete the dispenser transitions to the Pre-Fill stage where additional pressure checks are conducted as the gas is transferred to the balloon in small increments. If at any time during the procedure either of these pressure checks exceed 14 kPa, an error screen will appear and the dispenser depressurizes the balloon to less than 5 kPa. The physician is instructed to review the Navigation Console capsule trace indicators again to confirm the location and to perform esophageal transit troubleshooting steps provided in these Instructions for Use if needed. The Touch Dispenser makes a total four constrained space pressure checks

after pre-pulse, on the fourth incidence of higher than expected pressure (greater than 14 kPa), a system error will be displayed and the dispenser will not be able to proceed with the balloon administration and the device may require endoscopic removal.

During the entire balloon fill process, the dispenser displays the current balloon pressure in the top status bar and any high pressures which have triggered pressure errors in the lower section of the display. The balloon pressures provided are associated with different color schemes (green = expected, red = unexpected) to facilitate the physician's understanding of whether the pressure is an expected pressure or a concerning pressure is identified that requires additional troubleshooting. If a patient presents unanticipated symptoms the physician may pause or exit the procedure at any time using the Pause Button on the screen. Any gas that has been transferred to the balloon will be vented to less than 5 kPa when the pause button is used similarly to the pressure checks discussed above.

After inflation is complete, the catheter is ejected from the balloon valve and retrieved, leaving each balloon free-floating in the patient's stomach. Balloon use requires the concurrent administration of proton pump inhibitors for the duration of implantation. Clinical studies have shown that use of 40 mg/day of omeprazole or an equivalent dosage of similar medications is recommended over the duration of use. Anti-emetic and anti-spasmodic medication is recommended at least 24 hours prior to administration and should be prescribed in conjunction with balloon use for up to 5 days beyond balloon administration.

Pre-existing GI abnormalities must be ruled out prior to administration of any balloons by conducting a comprehensive and complete medical history, *Helicobacter pylori* screening, and upper GI to determine a patient's suitability for the procedure and to ensure the patient is not contraindicated for device use and could result in serious injury. The balloon therapy must be used in conjunction with a moderate intensity diet and behavior modification program to achieve weight loss. The components of the program that are necessary to ensure device effectiveness are provided in more detail in the following sections. The balloons are 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 each balloon placement. All balloons placed must be removed at the end of 6 months after placement of the first balloon using endoscopy. All placed balloons must be removed by a credentialed physician trained in endoscopy and foreign object retrieval.

The physician should provide the Patient Identification Card to all patients to be used in the event of an emergency department visit related to the balloons or symptoms related to balloon treatment such that the prescribing physician can be contacted.

## FACILITY REQUIREMENTS

The prescribing physician must have access to an endoscopy suite and a physician credentialed in endoscopy and foreign object retrieval should problems arise during administration. Endoscopy equipment and credentialed physicians trained in endoscopy and foreign object retrieval are required for device removal.

The facility should 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 the event that the physician is unable to determine the location of the balloon capsule using the Navigation Console.

## INDICATIONS FOR USE

The Obalon Balloon System (the "System") is a swallowable intragastric balloon system indicated for temporary use to facilitate weight loss in adults with obesity (BMI of 30 – 40 $kg/m^2$) who have failed to lose weight through diet and exercise. The System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed 6 months after the first balloon is placed.

## CONTRAINDICATIONS

The following contraindications apply to the Obalon Balloon System with Navigation and Obalon Touch:

- 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.
- Persons whom have undergone any bariatric surgery procedure.
- 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.
- Patients who are unable or unwilling to take prescribed proton pump inhibitor medication for the duration of the device implant.
- 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.
- Patients requiring the use of anti-platelet drugs or other agents affecting the normal clotting of blood.
- Pregnant or lactating women, or women with an intention to become pregnant.
- Known history of duodenal ulcer, intestinal diverticula (diverticulitis), intestinal varices, intestinal stricture/stenosis, small bowel obstruction, or any other obstructive disorder of the gastrointestinal tract.
- Known history of irritable bowel syndrome, radiation enteritis, or other inflammatory bowel disease, such as Crohn's disease.
- Patients taking medications on specified hourly intervals that may be affected by changes in gastric emptying, such as anti-seizure or anti-arrhythmic medications.
- Alcoholism or drug addiction.
- Individuals with active implantable devices, for example pacemakers or defibrillators, or with metal implants in the thoracic region.

## WARNINGS

- Radiography (digital x-ray or fluoroscopy) is recommended to confirm placement prior to balloon inflation when the balloon cannot be ascertained to be in the stomach or the capsule image is not displaying the expected balloon behavior as described in the Balloon Administration Procedure section and as observed by a qualified physician.
- 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 radiographic confirmation if required after swallow and balloon inflation. The balloon must not be inflated until the capsule can be clearly identified to be in the stomach by the Navigation Console or radiographic verification.
- The risk of balloon deflation is significantly higher with balloons that are left longer than 6 months. Balloon deflation could lead to serious injury such as bowel obstruction requiring surgical repair.
- Death due to intestinal obstruction is possible and has been reported with other intragastric balloons.
- 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. Patients should be evaluated by radiograph and 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 or perforation, gastric perforation, 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.
- 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.
- Do not place more than 3 balloons in one patient across the 6-month therapy cycle.
- 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. A foreign body retriever should be immediately available in the endoscopy suite.
- 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, gastric bleeding events, and gastric perforations which could lead to death.
- 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.
- Underinflated balloons have also resulted from catheter breaches from bitten tubing. If the balloon is not properly inflated and not identified as underinflated, there is a risk for small bowel obstructions. If you suspect damage to the catheter the balloon must be removed endoscopically.
- An earlier than expected endoscopic removal may be required if there is a new onset of symptoms or ongoing gastrointestinal symptoms where an x-ray has ruled out balloon deflation or obstruction, but the patient's symptoms remain unresponsive to other medical management methods.
- No modification of the Touch Dispenser is allowed.
- To avoid the risk of electrical shock, the Navigation Console must only be connected to a supply mains with protective earth.
- No modifications to the Navigation Console are allowed, unauthorized changes may impact performance and/or patient safety.
- Do not use the Navigation Console if any of the hardware components or connectors are damaged. Such damage may affect system functions and/or contribute to inaccuracy and possible patient/user injury.
- Do not use cables or accessories other than those provided with the Navigation Console. Doing so may result in increased emissions and/or decreased electromagnetic immunity of the console.
- Do not operate the console field generator within 10 m of another operating field generator. Doing so may contribute to inaccuracy and possible patient/user injury.
- Do not operate the console field generator within 200 mm of patients with an implanted pacemaker or defibrillator. The magnetic field produced by the field generator may interfere with the operation of these devices. This interference may result in patient/user injury.
- Disconnect power to the Navigation Console before cleaning, failure to do so may cause personal injury.

# PRECAUTIONS

- The Obalon Balloon System procedure should only be conducted by trained physicians.
- Prior to use of the Obalon System, patients should have previously attempted to lose weight unsuccessfully using a medically supervised or non-medically supervised diet.
- Patients using medications known to affect weight or who are undergoing chronic steroid immunosuppressive therapy should not use the treatment.
- Patients should be advised not to undertake scuba diving or travel in an unpressurized airplane cabin as these activities might cause the balloons to deflate.
- The safety and effectiveness of the Obalon Balloon System has not been established in patients with:
    - Type 1 diabetes.
    - Type 2 diabetes requiring insulin or other hypoglycemic oral agents.
    - Uncontrolled hypothyroidism or Cushing's disease or syndrome.
    - Severe, unstable/uncontrolled medical conditions of major organ systems.
    - Patients with known cardiovascular disease such as recent acute coronary syndrome or clinically unstable ischemic cardiac disease including evolving or ongoing myocardial infarction, typical angina at rest, recent coronary intervention, recent deterioration of ECG, laboratory or clinical findings.
    - Poorly controlled hypertension (≥ 160 mm Hg Systolic and ≥ 100 mm Hg Diastolic).
    - End stage renal disease or requiring hemodialysis within the past 6 months.
- Do not use aerosol sprays near the Navigation Console as these sprays can damage the internal circuitry.
- Do not use any solvents to clean the Navigation Console. Solvents may damage the finish and remove labeling.
- Pull console connections apart by gripping the connector only. Do not pull them apart by tugging on the cable as this can damage the connecting cable. Never force a connection or a disconnection.
- Do not track in an untested application environment, as it may contain elements that affect Navigation Console functions. For example, the system can be adversely affected by electromagnetic field disturbances from other electronic objects in the room (such as cell phones), the proximity of metal, or the proximity of another Field Generator. Failure to test for such disturbances will increase the possibility of inaccurate transformations and possible patient injury.
- Do not expose sensors to a high magnetic field, such as a Magnetic Resonance Imaging (MRI) scanner, as they may become magnetized. Tracking with a magnetized sensor may result in incorrect transformations and result in possible patient injury.
- The sensors and console must be at least one foot (12 inches) away from any motor driven devices, ultrasound devices, diathermy equipment, cauterization equipment, mobile radiofrequency devices, or any other significant metal objects that may interfere with the sensors.

# ADVERSE REACTIONS

The following patient complications are associated with use of the Obalon Balloon System:

Most frequently occurring events (> 50%):

- Abdominal Pain
- Nausea

Frequently occurring events (10-20%):

- Vomiting
- Indigestion/Heartburn
- Bloating

Less frequently reported events (1%-9.9%):

- Burping/Belching
- Diarrhea
- Gastric Irritation
- Gastric Bleeding/Abrasion
- Esophageal Bleeding/Abrasion
- Esophagastric Bleeding/Abrasion
- Constipation
- Difficulty in Sleeping
- Excessive Gas
- Esophagitis
- Headache
- Oxygen Desaturation

Rarely reported events include (<1%):

- Chest Pain
- Gastric Ulcer
- Hypersalivation
- Device Intolerance
- Shortness of Breath
- Sore Throat
- Vocal Cord Spasm
- Allergic Reaction
- Asthma
- Coughing
- Dizziness
- Dry Heaving
- Fatigue
- Food Passage Difficulty
- Fullness
- Hiccups
- Hypertension
- Peptic Ulcer Disease
- Retaining Food & Fluid
- Shoulder Pain
- Swollen Lips
- Syncope
- Halitosis - bad breath

The following reported events have been observed in global experience and are reported at the following estimated patient rates[l]:

**Table I. Device-Related Serious Adverse Events Through 12/31/2019**

| Device-Related Serious Adverse Events | US Number of Events/ Rate | Global Number of Events/ Rate[1] |
|---|---|---|
| Bowel obstruction with surgical repair (Total) | 3 / Less than 0.05% | 10 / Less than 0.05% |
| ● Balloon deflation and bowel obstruction with surgical repair with balloons implanted within indicated duration | 0 / 0% | 0 / 0% |
| ● Balloon deflation and bowel obstruction with surgical repair with balloons implanted beyond indicated duration[5] | 3 / Less than 0.05% | 8 / Less than 0.04% |
| ● Incorrect inflation during administration resulting in migration and bowel obstruction with surgical repair[4] | 0 / 0% | 2 / Less than 0.01% |
| Esophageal Rupture | 0 / 0% | 2 / Less than 0.01% [2] |
| Gastric perforation | 3 / Less than 0.05% | 3 / Less than 0.02% |
| Death | 0 / 0% | 1 / Less than 0.005% [2, 3] |

[1] Includes US data January 1, 2017 – December 31, 2019, Outside US data of a prior generation 3-month balloon not approved in the US (July 1, 2012 – December 31, 2016), and Outside US data of the 6-month device (May 1, 2017 – December 31, 2019)

[2] Administration of prior generation 3-month balloon with EzFill Inflation System

[3] Esophageal rupture (listed above) during EzFill balloon administration resulting in surgical repair/sepsis/death (Mexico)

[4] Administration with EzFill Inflation System

[5] Off Label Use – Balloon not removed by duration therapy per indications for use (approximately 58 - 145 days beyond 6-month balloon use and 15 - 45 days beyond 3-month balloon use)

[l] Rates are estimated based on balloon distribution data (not actual patient data) and the average number of balloons per patient from US clinical trial data and Outside US Post Market Study data. The assumed average number of balloons per patient for the 3-month balloon is less than the 6-month balloon per study data.

Acute pancreatitis as a result of injury to pancreas by balloon has not been reported in the US with the 6-month Obalon Balloon System to date. A single event of acute pancreatitis was reported in the literature with the prior Obalon 3-month international balloon not approved in the US, but could not be confirmed during the investigation. Acute pancreatitis has been reported with other fluid-filled intragastric balloons.

Additional complications that can be 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
- Sore or irritated throat following the procedure
- Excessive Sweating
- Hypotension
- Impaired judgment or reactions after sedation or anesthesia
- Laryngospasm
- Bleeding
- Infection

# WEIGHT LOSS PROGRAM REQUIREMENTS

The Obalon Balloon System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. To produce weight loss with the system patients that are prescribed the Obalon System must also participate in a diet and behavior modification program that focuses 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

The program should be, at a minimum, a Moderate Intensity program where the intensity of a program is defined as the number of patient contacts/interactions per AHA/ACC/TOS 2013 Guidelines for the Management of Overweight and Obesity. Per the 2013 Guidelines, a moderate intensity program is defined as 1-2 patient interactions per month for at least 25-30 minutes each visit. The designated weight loss behavior modification program must be directed by a "Qualified Practitioner" or Physician. At a minimum, the Qualified Practitioner is required to have a Registered Dietician certification or Medical Doctor that possesses a degree with adequate training to prescribe caloric adjustments based upon subject age, starting weight, gender, activity levels, and weight loss progress as delineated in Table 1.

Programs utilized with the Obalon Balloon System should be consistent with AHA/ACC/TOS 2013 Guidelines for the Management of Overweight and Obesity. At each visit, at a minimum, calorie and protein recommendations should be reviewed and adjusted when necessary and diet and behavior education should be conducted. Diet and behavior education should include elements inclusive of topics related to diet, exercise, and behavior change, as well as provide a mechanism for delivering individual lifestyle therapy based on subjects' unique barriers to weight loss.

An example starting calorie prescription recommendation for a 5'5" woman with a BMI 30-40 with a goal of losing 1.5-2 lbs./weeks is listed in Table 1:

**Table 1: Sample Starting Calorie Recommendation**

| **150-199 lbs.** | | **200-249 lbs.** | | **250-320 lbs.** | |
|---|---|---|---|---|---|
| Kcal | Protein (g) | Kcal | Protein (g) | Kcal | Protein (g) |
| 1200-1300 | 60 | 1300-1500 | 70 | 1500-1800 | 70-80 |

*To be adjusted based upon age, sex, and activity level

The qualified practitioner should use his/her judgment based on weight loss and hunger or fatigue issues to adjust the calories up or down. In general, if a subject is not losing 1.5 lbs. per week the calorie prescription can be lowered by 100-200 kcal/day. Decreasing calories below the recommendations listed above can be considered if a patient is not losing 1.5 lbs./week at 1200 kcal/day and the patient is not exhibiting symptoms (fatigue) that interfere with activities of daily living. Exercise goals should also be included in the weight loss and behavior modification program. An exercise program based upon the 2013 American Heart Association/American College of Cardiology/The Obesity Society Guideline for the Management of Overweight and Obesity in Adults recommends ≥ 150 minutes per week of moderate intensity (e.g. brisk walk) exercise per week for weight loss. The exercise program should have an emphasis on aerobic exercise which is associated with weight loss and weight loss maintenance. Additionally, it is suggested that if a subject has plateaued, re-evaluating the exercise regimen should facilitate additional weight loss.

# HOW SUPPLIED

All components are supplied non-sterile. Do not use if the package is opened or damaged.

| | |
|---|---|
| CAUTION | If the balloon capsule becomes separated from the catheter prior to placement, do not attempt to use the capsule or reattach the catheter to the balloon. |

PN 7410 Navigation Balloon Kit (for single use only)

- Obalon Balloon Assembly: 1 folded balloon contained in a swallowable HPMC capsule that is attached to 1 disposable, flexible catheter delivery system with an electromagnetic sensor built into the distal end of the catheter.
- PN 6200 Accessory Kit (components are for single use only): 3 cc ejectors with integrated catheter adapter (QTY: 2)

Obalon Balloon in Capsule

***Note:*** *Only the Obalon NTS Balloons are compatible with the Navigation Console and Touch Dispenser. Other Obalon balloon systems will not provide capsule tracking required to determine balloon placement and may not be compatible with the Touch Dispenser connection.*


Touch Dispenser

PN 9300 Touch Dispenser Kit

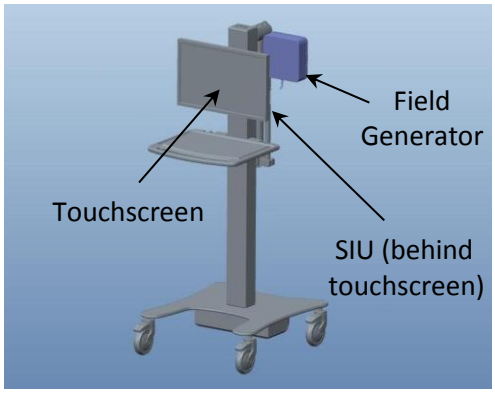
- Obalon Touch Dispenser – a non-sterile, reusable device. (PN 4300)
- 60 cc Balloon Evacuator (PN 6300)
- 8 AA Alkaline Batteries (only all new alkaline batteries should be used when replacements are needed)
- Phillips Screwdriver

Balloon Evacuator

PN 7402 Obalon Navigation Console

- Field Generator
- Sensor Interface Unit (SIU)
- Reference Sensor (PN 7404)
- Touch Screen
- Navigation Software
- Navigation Recalibration Tool (PN 7405)

The Obalon Navigation Console is installed and verified to be functional by a qualified Obalon Representative.




Navigation Console

| | |
|---|---|
| CAUTION | The Navigation Console tray is designed to contain spillage of up to 155 ml of water. Spilling water on the PC or electrical connectors may result in electric shock and personal injury. |

# ADDITIONAL ITEMS REQUIRED FOR DEVICE USE

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

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 actual device weight.*


2. Obalon Inflation Can (for single use only)
3. Additional equipment and materials **required for use but not supplied** include:

   **<u>For Balloon Administration:</u>**
   - Small clean bowl/room temperature bottled water
   - Carbonated, clear beverage
   - Electrode Adhesive Tape

   **<u>For Balloon Removal:</u>**
   - Vacuum source
   - Endoscope
   - Endoscope Injection Needle (minimum 23 Gauge and minimum 6 mm (0.236 in) length)
   - 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 endoscope.

# ABOUT THE OBALON TOUCH DISPENSER

## Preparation for Use

There are no batteries installed in the dispenser as supplied. Before use, remove the battery cover on the back of the dispenser with a Phillips screwdriver and insert 8 new AA batteries. Replace the cover and tighten the screws.


Before first use, remove the shipping plate (shown at right) from the shuttle.

## Powering On and Off

To turn on the dispenser, press and release the power button to the left of the touchscreen. To turn off the dispenser, press the blue power off button displayed on the touchscreen (displayed only on select screens). The dispenser may also powered off by pressing and holding the power button to the left of the touchscreen for 5 seconds. Note that the dispenser will turn off automatically after extended inactivity to preserve battery life.

## Inserting an Inflation Can

Lift the lever on the dispenser. Take the cap off the can and insert the can straight (not at an angle) into the Dispenser shuttle. Close the lever to begin pressurization.

## Screen Brightness

The dispenser will dim the screen automatically to conserve battery life after a period of inactivity. To restore screen brightness, touch the screen.

### Attaching the Catheter

Screw the catheter port onto the dispenser until a hard stop is reached.

### Touchscreen Buttons

Cancel Button | Continue/Resume Button | Pause Button | Power Off Button | Start Procedure Button

### Battery Life

If the dispenser battery power is low on startup, the low battery screen will display (this screen may be dismissed by pressing the cancel button). A low battery indicator will also display at the bottom of the Procedure Summary Screen. When a low battery indicator is visible on the screen, replace the batteries as soon as possible.

When the dispenser battery power is depleted, the dead battery screen will display on startup and the dispenser will shut off automatically. Batteries will typically require replacement after approximately 100 procedures. New AA alkaline batteries (eight) must be inserted before starting a new procedure.

### Product Usable Life

The dispenser has been evaluated for a maximum of 5,000 uses. Use of the dispenser beyond this number of uses has not been evaluated. The device will track and display the number of times it has been used (the "cycle counter") on the start new procedure screen and procedure summary screen.

## 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 that 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, 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 drink 8-10 ounces of room temperature water. The capsule will eventually dissolve and pass through the gastro-esophageal junction.

If the patient has 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.

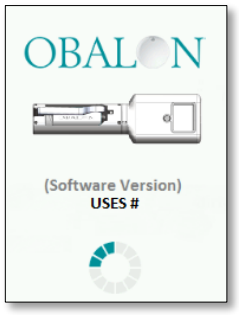
If the patient swallows the placebo capsule without any difficulty, they may proceed with the balloon therapy. **Swallowing the balloon should not be performed immediately after the placebo test. The placebo test should be completed at least 8 hours prior to balloon placement.**

# PREPARATION FOR USE

All pressures displayed on screen images in this document are for reference only. Actual pressures displayed on the Touch Dispenser during a balloon administration may differ.

## Prepare Touch Dispenser

Splash Screen




1. Press and release the power button to the left of the screen to turn on the dispenser. The **Splash Screen** will be displayed as the system boots up.

Insert Can Screen


2. Once the dispenser has powered up, it will prompt the user to insert an Obalon Inflation Can. Remove the cap from the can and insert the can into the dispenser as displayed on the **Insert Can Screen**.

3. Close the dispenser lever to pressurize the system. The dispenser will display the Splash Screen and perform an automatic pressure check.

Start New Procedure Screen


4. When the system pressure check is complete, the dispenser will display the **Start New Procedure Screen**. The dispenser is now ready for inflation.

   **Note:** The dispenser will display the pressure in the inflation can in the top left corner of the screen on the **Start New Procedure Screen**.

5. Do not press the green Start Procedure button until ready to begin the balloon inflation procedure.

| | |
|---|---|
| CAUTION | Check expiration dates for single-use components. Do not use if the expiration date has passed. Do not use if tamper evident seal has been broken or the packaging is damaged. |

## 3 cc Balloon Ejector (Accessory Kit)

1. Remove the 3 cc ejector from its packaging.
2. Fill each ejector with 2.0 cc of room temperature water and set aside.

## Navigation Console Preparation

1. Plug the Navigation Console power cord into an electrical outlet. Ensure that the locks on the 2 front caster wheels of the Navigation Console are engaged by pushing down on the locking tabs.

   ***Note:*** *Ensure that position of console does not limit access to the power cord or power switch at bottom of console.*

2. Turn on the monitor by pressing the power button icon (located on the bottom right of the front-side of the monitor).

   ***Note:*** *Refer to* ***Table 2: Navigation Console Error Codes*** *in the* ***Troubleshooting Section*** *for descriptions and potential mitigations for console onscreen error codes that may occur during console preparation or balloon tracking.*

3. Swipe in an upward motion on the Welcome touch screen to prompt the login screen.
4. Select “ObalonUser” Account.

   ***Note:*** *An “ObalonAdmin” account exists on the login screen. This is a privileged account accessed only by qualified Obalon representatives to perform management and administrative tasks.*

5. Enter password “obalon” using touch screen keyboard.
6. Launch the Obalon Navigation software by double pressing the icon on the touch screen. The software will display the home screen.
7. To start a new balloon administration, press the New Patient Administration button.

## Patient Navigation Preparation

1. Ensure the patient is clothed to allow access to the sternum.
2. Clean the skin of the patient’s sternum with an alcohol prep pad.
3. Attach electrode tape to the reference sensor and remove backing to expose adhesive.
4. Attach Reference Sensor to patient at the midline of the sternum at the Xiphoid process, refer to **Figure 1**.

Reference Sensor

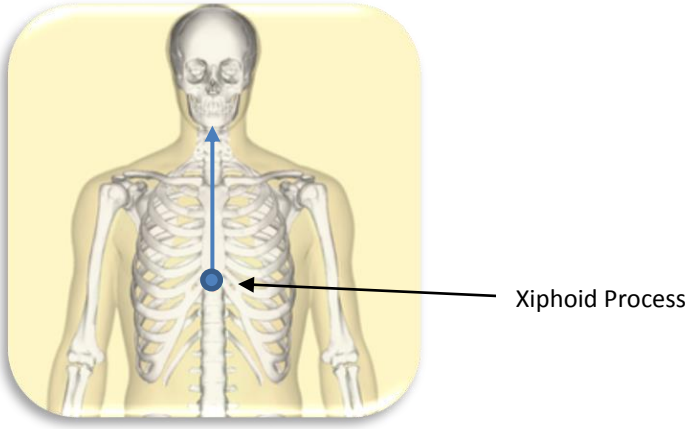



**Figure 1: Reference Sensor Placement**

***Note:*** *It is very important to align the reference sensor over the vertical center of the sternum, this will ensure that the tracking of the catheter can be visualized in alignment with the vertical location of the esophagus.*

Field Generator

5. Have the patient stand with their back within 12 inches of the Field Generator.

   ***Note:*** *Physical contact with the generator is not necessary but the patient should remain near the generator when using the navigation system.*

6. Using the flexible arm of the Field Generator, place the generator over the spine and between the distal third of the scapula, such that the center of the generator posteriorly aligns with the distal aspect of the sternum or Xiphoid process.

7. Plug the reference sensor cable into the Sensor Interface Unit (SIU) port. The reference sensor cable is compatible with any of the three available black SIU ports (see figure to the right).

Reference Sensor Ports

Sensor Interface Unit

## Navigation System Icons

| | |
|---|---|
| **Global System Activities** | |
|  | New patient administration/Enter Patient ID |
|  | Accept |
|  | Cancel |
|  | Exit current screen or Application |
|  | Go to Home Screen |
| **Navigation Tracking** | |
|  | Calibrate Navigation System and start tracking |
|  | Clear tracking on screen |
|  | Stop recording tracking |
|  | Resume recording tracking |
| **Accessing Saved Files** | |
|  | Video Archive |
|  | Open file to browse for saved patients |
|  | Play saved tracking file |
|  | Pause video |
|  | Replay saved tracking file |
| **Troubleshooting** | |
|  | Sensing error within sensing field |
|  | System Error |


**Figure 2: Obalon Navigation System Home Screen**

8. After the New Patient Administration button is touched, the navigation tracking screen will display (**Figure 3**).

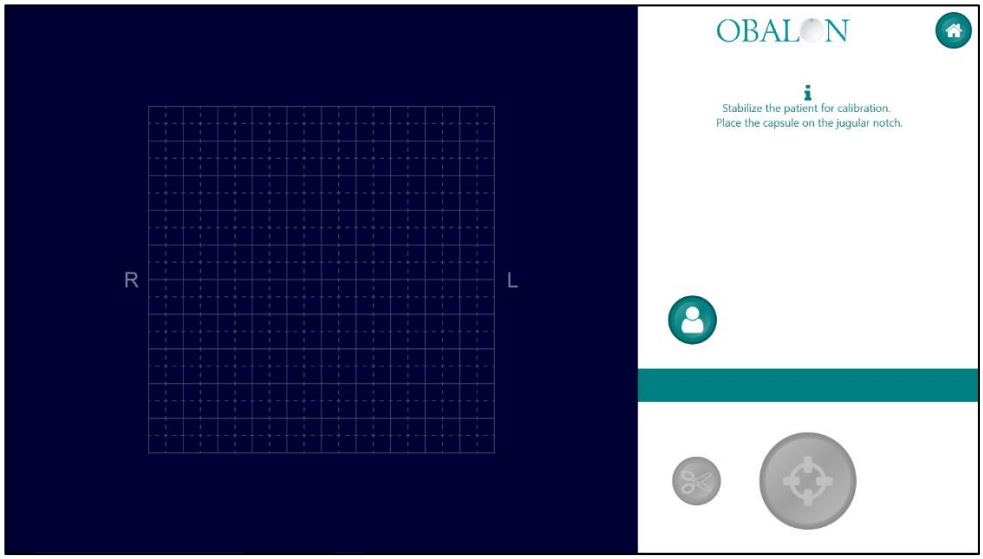



**Figure 3: Navigation Tracking Screen**

9. Touch the New Patient button. The buttons in the control field will remain grayed out until the a patient identifier has been entered.

10. Enter unique Patient ID using the touch screen keyboard and press the Accept button. Patient IDs can be a combination of alphanumeric characters and up to 16 characters in length.

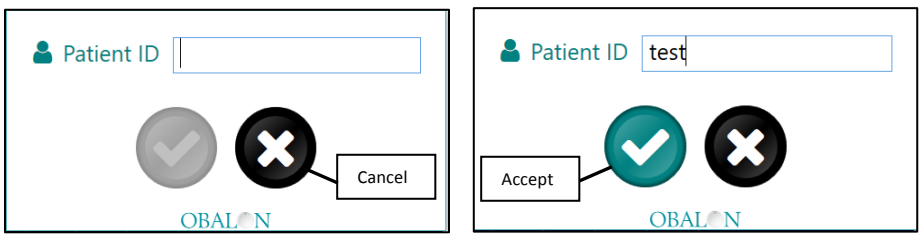



**Figure 4: Cancel and Accept Buttons**

## Navigation Balloon Console Setup & System Calibration

1. Carefully remove the balloon kit by slowly pulling straight up on the blue connector to unwind the catheter from the tray grooves.
2. Examine all components for damage.
3. Ensure that the patient has removed all metal objects such as jewelry, watches, etc. and is in the correct position in front of the Field Generator.
4. Attach the blue catheter connector to the blue port on the Sensor Interface Unit (SIU).
5. Hold the capsule to the patient's jugular notch.

6. Instruct the patient to remain still and press the calibrate button.

**Note:** The calibration process could take up to 30 seconds. While the system is calibrating, the status bar will indicate "Calibrating".

7. After calibration is complete, the status bar will indicate that the system is "Recording". All catheter motion within the sensing volume will be recorded by the console and will be displayed in the Tracking Window. To stop the recording at any time, press the stop button.

**Note:** During or after calibration, the system may display the *Catheter Missing, Catheter Sensor Out of Volume, or Missing Reference Sensor* error when the capsule is moved outside of the sensing field of the field generator. These messages will go away once the capsule is back within the field

Touchscreen Error Message Example

8. If the software does not complete calibration within 30 seconds verify that the patient is not moving. If the patient is not moving and the software will not calibrate, the catheter may be defective and cannot be used.

| | |
|---|---|
| WARNING | Do not proceed to **Balloon Administration** until the catheter is confirmed to be calibrated. |

9. Once calibrated and while the balloon remains in the sensing field of the console field generator, the console displays a representation of the current relative position of the capsule and a representation of the path or track followed by the capsule from the beginning of the administration procedure. At any time during the procedure if the catheter moves outside of the sensing volume, an error message will appear and the image of the capsule path or track will stop displaying until the catheter is brought back into the sensing volume.

| | |
|---|---|
| CAUTION | If the Navigation System needs to be recalibrated after the capsule is in the body, refer to the **Navigation System Recalibration Troubleshooting** section to recover the calibration and continue the administration procedure. |

# BALLOON ADMINISTRATION

The Obalon Navigation Balloon Kit capsule is administered to the patient using a normal pill swallowing method, Endoscopy is not required for placement. The patient must be in an upright position during the administration procedure. The total placement time is typically less than 15 minutes for each balloon placed. Access to fluoroscopy or digital x-ray is recommended; at a minimum, the prescribing physician must have access to an endoscopy suite and physicians credentialed in endoscopy and foreign object retrieval in the event the capsule fails to transit into the stomach or the balloon location cannot be identified during placement prior to inflation. Review the procedure with the patient prior to performing the balloon administration.

## Balloon Capsule/Catheter (Balloon Kit) Prep

| | |
|---|---|
| WARNING | 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 any time.<br><br>Do not allow the patient to grab or hold onto the catheter at any time. |

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 them 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 grabbing the catheter.

| | |
|---|---|
| CAUTION | Do not wet the capsule or have the patient swallow the capsule until the Navigation Console and Touch Dispenser set up is complete and the console calibration is successful. |

4. Touch the clear track button (depicted to the right) to clear the tracking information captured after calibration on the screen before the capsule enters the patient's mouth.

5. Wet the capsule/catheter by submerging into the bowl of water for no more than 10 seconds.

| | |
|---|---|
| WARNING | Do not use a capsule assembly that has been wetted for more than 10 seconds. This may cause the balloon capsule to dissolve prior to passing through the gastroesophageal junction and reaching the stomach. |

## Balloon Capsule/Catheter Swallow Procedure

1. Within 1 minute of submerging the capsule in the water for no more than ten seconds, hand the patient the capsule and instruct the patient to place the capsule immediately in their mouth and swallow the capsule with another large glass of room temperature water. Hold the proximal ends of the catheter outside of the patient's mouth.
2. An image of the capsule will appear in the tracking window once the capsule is in the sensing field.
3. Patients should be given additional water (at least 100 ml) after swallowing the capsule. Patients must remain in a standing (preferred) or in an upright sitting position during the entire procedure. If the patient has trouble swallowing the capsule (not passing the upper esophageal sphincter), go to the **Swallowing Difficulties Troubleshooting Section** for additional swallow tips.

| | |
|---|---|
| WARNING | If the capsule tracking is no longer displayed or the system becomes inoperative before the capsule is confirmed in the stomach, confirm placement in the stomach with digital radiography (digital x-ray or fluoroscopy) or evacuate the gas from the balloon and **proceed to endoscopic removal.** |

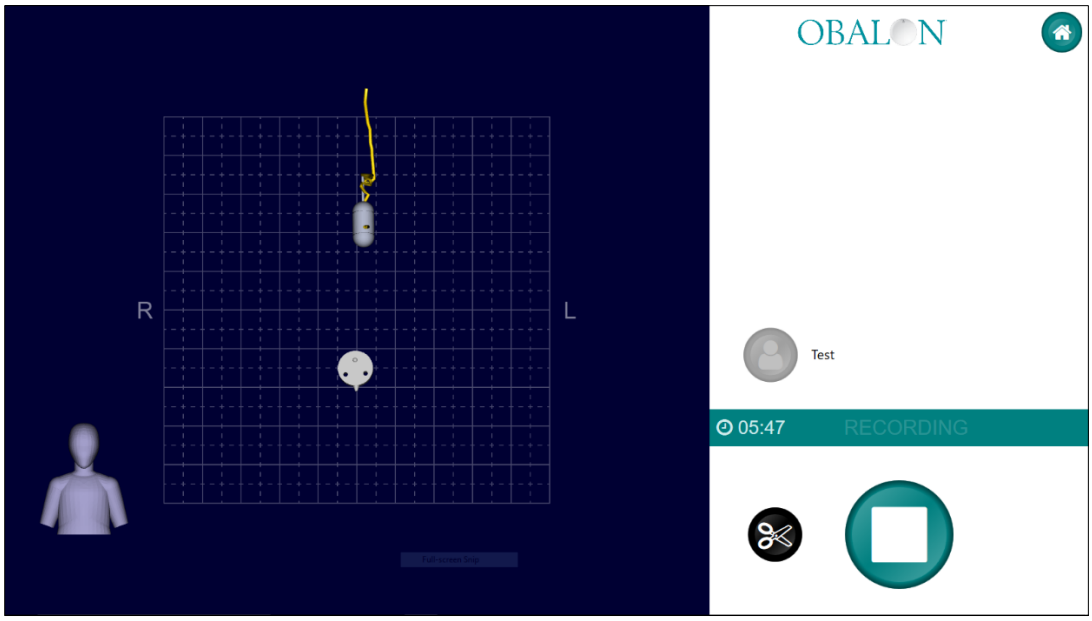



**Figure 5: Initial Screen Image of Balloon Capsule Tracking**

| | |
|---|---|
| WARNING | If capsule has not passed the upper esophageal sphincter after one minute of exposure inside the mouth, replace the balloon to ensure the capsule does not dissolve before completing transit to the stomach. Calibration must be repeated with the new balloon capsule prior to administration. |

4. Once swallowed, the proximal ends of the catheter assembly will remain outside of the patient's mouth until after the balloon is filled.
5. Closely observe the capsule as it moves down the tracking window on the touch screen.
6. If the capsule display on the touch screen does NOT progress down the tracking window, ask the patient to continue to drink water or a carbonated beverage to facilitate peristalsis of the capsule/catheter if the balloon has not visibly passed into the stomach.
7. Approximately 1-2 minutes after the patient swallows the capsule it is expected that the capsule image in the tracking window will exhibit some or all the following behaviors after it passes through the gastroesophageal (GE) junction and into the stomach. Please refer to the Clinical Study Section **Location Indicator Assessment** in this IFU for information on the frequency of the indicators observed in the clinical study.
    a. **Capsule significantly offsets left of lateral from initial vertical track.** This would indicate movement from the esophagus through the GE junction into the stomach.
    b. **The capsule track suddenly accelerates left of lateral.** This would indicate the capsule passing rapidly from the constrained space of the esophagus to the more open stomach space.
    c. **The capsule rotates from a vertical to a horizontal configuration.** When traveling down the esophagus the capsule generally presents itself in a vertical orientation. However, after entry into the stomach the capsule rotates as it rests on the stomach fluid. The rotation of the capsule when in the stomach is more than 45 degrees.
    d. **Vertical movement aligned with respiration.** Once the capsule has entered the stomach it is more susceptible to deep respiratory movements. With deep patient respiration, the capsule is more likely to bob up and down on the stomach fluid compared to when respiration occurs when the capsule is still in the esophagus. **NOTE: All four indicators may NOT always be present.**

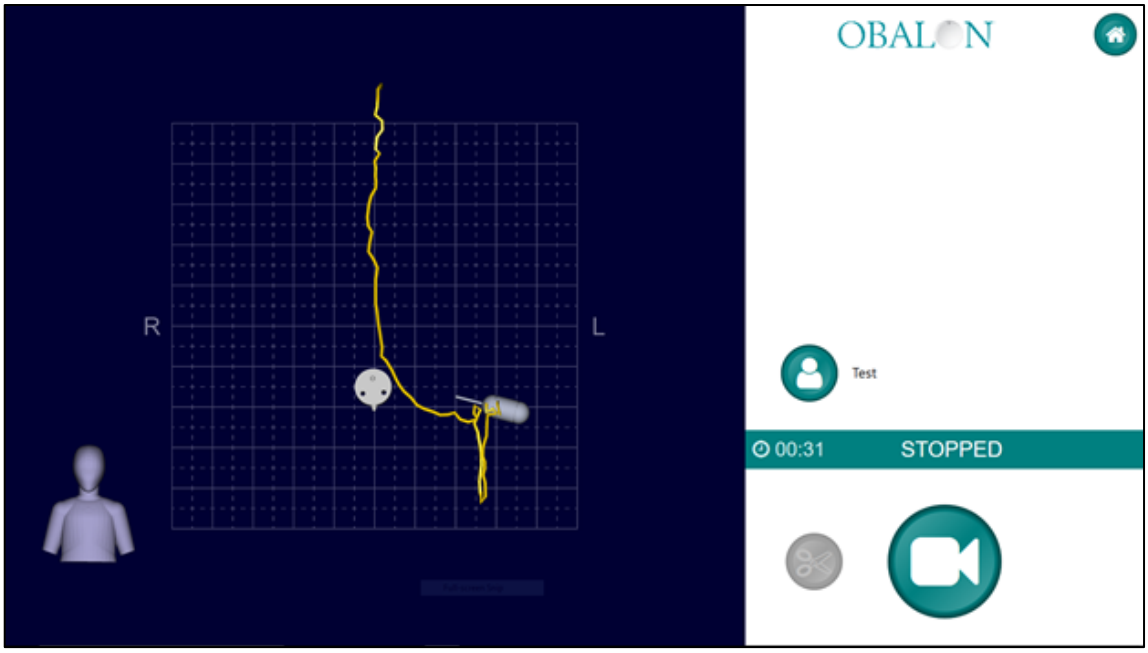



**Figure 6: Screen Image of Balloon Capsule Tracking**

8. If the image does not represent any of the four expected characteristics or the capsule location is not clear, instruct the patient to continue drinking fluids or ingesting soft foods to encourage further transit and monitor the capsule track for the anticipated characteristics of the track described in the previous step.

| | |
|---|---|
| WARNING | Digital radiography (digital x-ray or fluoroscopy) is recommended to confirm balloon placement prior to balloon inflation when the Navigation Console image is not displaying the expected behaviors that would indicate that the balloon is in the stomach as described and observed by a qualified physician. If digital imaging is not accessible, then an endoscopy must be performed to remove the balloon from the patient. |

9. If the image continues to indicate that the capsule is in the esophagus, proceed to the **Troubleshooting Section** for esophageal transit difficulties. If the image is representative of being in the stomach, then the procedure may continue.

10. Press the "Stop" button on the touch screen to finish recording the session after the capsule tracking exhibits behavior indicating it is in the stomach if desired. A balloon administration may be replayed at any time by following the **Replay Balloon Administration** instructions. If the recording has been stopped, it can be resumed by pressing the resume button.

11. Proceed with balloon inflation when the balloon has been properly identified in the stomach and the balloon is ready for inflation.

## Balloon Inflation

| | |
|---|---|
| CAUTION | If for any reason during the balloon administration an error is displayed on Touch Dispenser, go to the troubleshooting section for the applicable error code. |

| | |
|---|---|
| WARNING | Location in the stomach must be confirmed using the Navigation Console prior to inflation. Do not rely solely on the dispenser prompts for confirmation of placement in the stomach. **Inflation in the esophagus can cause serious injury or death.**<br><br>Digital Radiography (Digital x-ray or Fluoroscopy) is recommended to confirm placement prior to balloon inflation when the Navigation Console image is not displaying the expected behavior as described in the **Balloon Administration Procedure** and as observed by a qualified physician. If radiography is not available and location cannot be identified, then endoscopic retrieval of the balloon is required. |

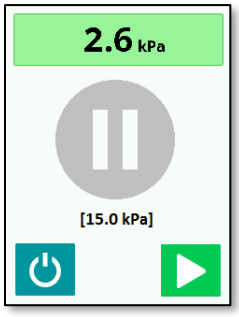
Start New Procedure Screen


1. Once Navigation Console verification is complete and the capsule is confirmed to be in the stomach, attach the catheter to the dispenser.

2. Press the green start inflation button on the start new procedure screen to begin the inflation process.

| | |
|---|---|
| WARNING | If there are any signs of inflation in the esophagus (such as patient symptoms), press the blue pause button immediately and reassess the location of the balloon. Do not rely solely on the dispenser for confirmation of placement in the stomach. |

Pause Screen




*Pause Button:*

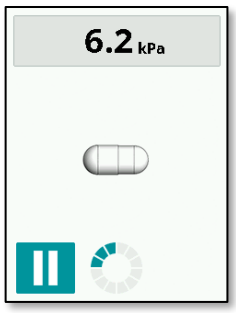
Inflation may be paused at any time by pressing the blue pause button. This will shut off gas flow to the balloon, relieve balloon pressure, and the **Pause Screen** will be displayed. To restart balloon inflation, press the green start inflation button. The dispenser may also be shut down at any time by pressing the blue power button to end the procedure from the Pause Screen.

3. Until the capsule has separated, the image displayed on the inflation screen will depict a capsule. The dispenser will automatically detect when capsule separation occurs.

   While the capsule image is displayed, the dispenser is conducting an automated pressure check known as Pre-pulse. If the pre-pulse value is within acceptable limits (< 14 kPa), the Touch Dispenser will emit an audible beep and move to the next stage of inflation.

   If the pre-pulse pressure is above acceptable limits (> 14 kPa), the dispenser will beep and the screen will change to the appropriate error screen. Go to the **Troubleshooting Error Code #005 Esophageal Pressure Check High** for more information.

Inflation Screen (with capsule)

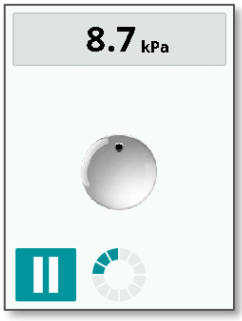



4. Once the capsule has separated, the image displayed will change to a balloon. The dispenser will automatically continue the inflation process.

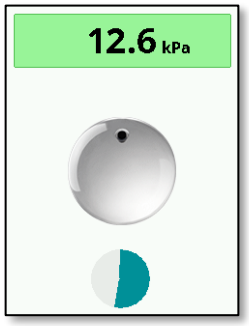
   While the balloon is inflating, the dispenser conducts additional automated pressure checks for possible location in anatomically constrained spaces such as the esophagus or a hiatal hernia. If the system detects a pressure value indicating a possible constrained space, there will be an audible beep and the screen will change to the appropriate error screen.

   Go to **Troubleshooting Error Code #006 Constrained Space Pressure Check High** for more information.

Inflation Screen




Leak Check Screen (with timer)

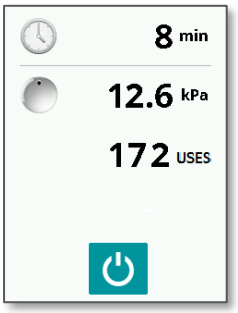



5. Once the pressure stabilizes, the dispenser will perform an automatic 30 second leak check (as indicated by the blue timer icon).

| | |
|---|---|
| WARNING | If the pressure is unstable at the completion of inflation or the final balloon pressure is less than 12.2 kPa, an **Unstable Pressure Error Screen (Troubleshooting Code #007) or Pressure Instability Error Screen (Troubleshooting Code #008)** will be displayed. Go to the Troubleshooting section for further instructions. |

6. When balloon inflation is complete, the dispenser will display the Procedure Summary Screen. Power down the dispenser by holding the power button for 5 seconds or by pressing the power button on the touchscreen and proceed to balloon ejection and catheter retrieval.

Procedure Summary Screen




## Balloon Ejection and Catheter Retrieval

1. Disconnect the catheter from the dispenser.

   Note: A valve in the catheter will prevent any gas from escaping from the inflated balloon when disconnected.

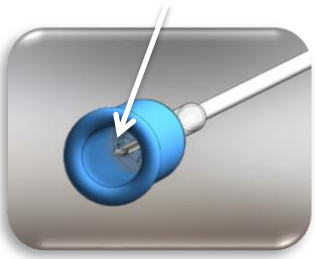
2. Promptly attach a 3 cc ejector (filled with 2.0 cc water) to the catheter.

| | |
|---|---|
| CAUTION | Do not fill the ejector with more than 2.0 cc of water. Doing so may compromise the amount of force needed to push the syringe plunger for detachment of balloon from the catheter.<br><br>Use the provided ejectors. Use of a larger syringe will not create enough hydrostatic pressure to eject the balloon. |

3. Depress the ejector plunger in a single rapid and deliberate motion. The water pressure generated by this motion will detach the catheter from the balloon valve in the stomach. If the catheter does not detach after the first attempt, a second attempt will be necessary.

   If more than two attempts are unsuccessful go to the **Balloon Ejection Issues Troubleshooting Section**.

**Check the Needle**



4. Once the catheter has been ejected from the balloon, slowly pull the catheter out of the patient's mouth. Having the patient put their chin down during this process may reduce the patient's gag reflex.
5. Visually inspect the catheter. Ensure that the needle at the distal end of the catheter is still in place, then discard. **If the needle is not inside the needle sleeve, remove the balloon endoscopically.**

# REPLAYING A PREVIOUSLY RECORDED ADMINISTRATION

1. On the Home screen, touch the Video Archive button, this will open a viewing screen.

2. When the viewing screen appears, touch the folder button to open Windows Explorer.

3. Navigate to the desired Patient ID, select the file, and touch the open button – the viewing screen will appear.
4. Touch the play button to begin the replaying the previously recorded session.

5. The session can be replayed again by touching the replay button.

# TURNING OFF THE NAVIGATION CONSOLE

1. Press the exit button on the Home Screen to exit the Obalon Navigation Application.
2. Press Accept.
3. After the application closes, press the power button icon (located on the bottom right of the front-side of the monitor) to shut down the PC if desired.

**Note:** The console should not be unplugged for an extended period of time, doing so may drain the PC battery and cause the operating system time to reset. If this occurs, contact an Obalon representative to reset the time on the PC prior to the next case to ensure correct video timestamp information is captured.

# 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 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 whom to contact in the event that they experience symptoms that are intolerable, new symptoms start after the first week post-administration, or a sudden loss in fullness or increase in hunger occurs. These symptoms should be further evaluated by the physician and potential balloon deflations should be ruled out.

## 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 physical activity

Additional detail on the recommended program elements is provided in **Weight Loss Program Requirements** section.

| | |
|---|---|
|  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/or endoscopy as appropriate. **Evidence of balloon deflation requires early balloon removal.**<br><br>An increase in nausea, vomiting, and/or cramping after initial symptoms have subsided may indicate a deflated balloon.<br><br>Patients should be advised to contact their physician if the frequency of discomfort experienced is more than anticipated or becomes intolerable.<br><br>Patients must not use gastric irritant medications including but not limited to NSAIDs or Aspirin during balloon use. This can lead to an increase in ulcerations, gastric bleeding events, and gastric perforations which could lead to death. |

### Additional Balloon Placements

A single Obalon Balloon does not provide enough volume for maximum weight loss. Clinical studies have shown that three balloons help achieve more effective weight loss over the course of the 6-month intended use period.

| | |
|---|---|
| WARNING | DO NOT place more than 3 balloons in one patient during the 6-month therapy cycle.<br>DO NOT place more than one device simultaneously. Risk of intolerance due to too much initial volume may occur.<br>DO NOT place balloons with less than 14 days between balloon placements. |

## BALLOON REMOVAL

**After 6 months from the first implantation, all balloons must be removed from the patient.**
This procedure should be conducted using the following recommended tools:

- An endoscope that is less than 1200 mm in working length with an inner diameter that is compatible with suggest needle and grasper for balloon retrieval.
- 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 these specifications could result in patient injury. |

These tools are recommended but there may be other acceptable retrieval tools for removing the balloons. Retrieval procedures in general should be conducted per the endoscope manufacturer 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 recommended.

- 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 in **Figure 9**. The image includes a cross section of an inflated balloon through the balloon seam.
- The balloon should be optimally grasped **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. |

The removal procedure must be conducted by a physician credentialed in endoscopy and foreign object retrieval. Patients should fast at least 24 hours or per hospital protocol for endoscope procedures to ensure the stomach is empty and the balloon(s) are easily visible.

1. Anesthetize per hospital and physician recommendations for endoscope procedures.
2. Insert the endoscope into the patient's stomach.
3. Get a clear view of the filled balloons through the endoscope.
4. Insert the needle instrument down the working channel of the endoscope.
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 60 cc 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 if possible.
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.

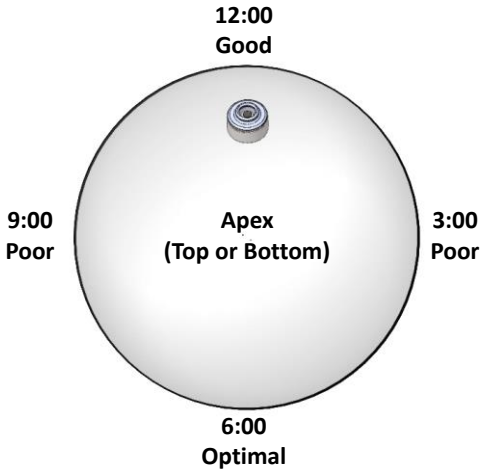



Figure 9: Grasping Sites for Balloon Removal Site

# 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. Physicians should contact Obalon Customer Support for technical support with device operation or to report an issue. The following should be considered during balloon placement.

## Swallowing Difficulties

1. Always use the Obalon Placebo Capsule prior to attempting administration of an Obalon Balloon Capsule.
2. Ensure that the patient has not ingested 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 liquids during balloon administration.
3. 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.
4. Guide the patient to place the capsule on the back of their tongue and orient the catheter to the side of their mouth.
5. Encourage the patient to drink large gulps rather than small sips of water.
6. If the patient fails two swallow attempts, discuss this issue with the patient and determine if the patient remains a good candidate for the therapy.

7. **If the device does not pass the upper esophageal sphincter 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**.
8. 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

Esophageal transit of the device during initial visualization using the Navigation System can be facilitated by use of clear carbonated beverages, a small amount of applesauce and/or a small piece of banana. When the capsule clears the esophagus, continue with **Balloon Swallow Procedure** and review the capsule trace on the Navigation Console screen for the presence of the four indicators to determine when the capsule has transited into the stomach.

If Error screens **#005** and/or **#006** appear indicating the balloon capsule may still be in the esophagus or other constrained space, then proceed with the following steps:

1. Detach the catheter from the dispenser.
2. Attach the 60 cc Balloon Evacuator to the catheter.
3. Pull plunger until fully extended (or as far as possible) and lock.
4. Wait 20 seconds with the evacuator locked.
5. Unlock the evacuator and observe the plunger:
   a. If the plunger stays fully extended the balloon is not yet fully evacuated. Detach from the catheter and push the plunger in to discard the gas, then repeat steps 2-5 again as necessary.
   b. If the plunger moves forward from the locked position, the balloon is fully evacuated.
6. Lock the evacuator.
7. Have the patient swallow a soft viscous food (smoothie, yogurt, mashed banana). This may help push the capsule into the stomach.

| | |
|---|---|
|  WARNING | If multiple swallow aids are used there is the potential for an increased incidence of aspiration in the event that the balloon must be endoscopically removed. Additional precautions should be taken during the endoscopic removal procedure to avoid aspiration of any swallow aids that may remain in the esophagus. |

8. Detach Evacuator from catheter.
9. Review navigation track for indicators that the balloon has transitted into the stomach:
   a. The capsule should be significantly offset left lateral from the initial vertical track.
   b. It is expected that the capsule is in a horizontal orientation (not vertical).
   c. Ask the patient to take a deep breath. With the deep breath, monitor the capsule track for significant vertical (up and down) movemnet aligned with the respiration.
10. Repeat steps 3-9 as necessary until the capsule reaches the stomach.

    Once in the stomach, remove the 60 cc Syringe and attach the catheter to the Touch Dispenser. Resume Balloon Fill by pressing the Green Button and continue with Step 6 of **Balloon Inflation**.

    If the Error #006 is displayed again, repeat steps 1-10 until successful transit and balloon inflation is acheived. If transit/inflation is not successful proceed to endoscopy. The dispenser will shut down automatically after four Error #006 screens are displayed and endoscopy is required at that time.

If unable to transit the capsule to the stomach, disconnect the catheter and power down the dispenser. Evacuate the balloon and **proceed to endoscopic removal.**

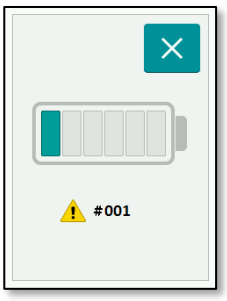
| | |
|---|---|
| WARNING | Do not try to retrieve the balloon by pulling the catheter. Attempting to remove the balloon by traction could lead to separation of the balloon from the catheter. If this occurs, the balloon could occlude the upper airway requiring emergency procedures to relieve the obstruction. |

## Possible Esophageal/Constrained Space Inflation

During inflation, if there is an indication of inflation in a constrained space (by patient symptoms or pressure readings), turn off the inflation gas flow by pressing the Pause button, detach the catheter and evacuate the gas from the balloon using the 60cc Balloon Evacuator. Proceed to the Esophageal/Constrained Space Pressure High Troubleshooting instructions.

## Low Battery (#001)

Low Battery Screen



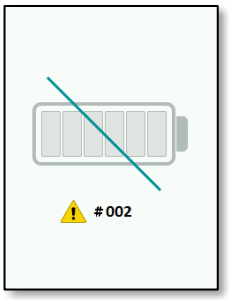

If the Low Battery screen (Troubleshooting Code #001) appears on startup, or if the Low Battery icon is displayed at the top right of the screen, battery power is low.

Replace the batteries as soon as possible.

To replace the batteries, remove the battery cover on the back of the Dispenser with a Phillips screwdriver and insert 8 new alkaline AA batteries. Replace the cover and tighten the screws.

## Depleted Battery (#002)

Depleted Battery Screen




If the depleted battery screen (Troubleshooting Code #002) appears on startup, battery power is depleted.

Replace the batteries and restart the dispenser.

To replace the batteries, remove the battery cover on the back of the dispenser with a Phillips screwdriver and insert 8 new alkaline AA batteries. Replace the cover and tighten the screws.

## Remove Can (#003)

Remove Can Screen


If the remove can screen (Troubleshooting Code #003) appears, the can must be removed since either a low-pressure can was inserted or a can was inserted before startup.

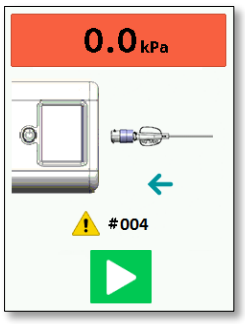
Lift the lever and remove the can. When prompted, insert a new can.

## Attach Catheter (#004)

If the Attach Catheter screen (Troubleshooting Code #004) appears, check the catheter connection. Attach the catheter to the Dispenser and press the start inflation button to continue.

If the catheter is already attached, reattach the catheter to ensure that the connection is properly sealed.

Attach Catheter Screen



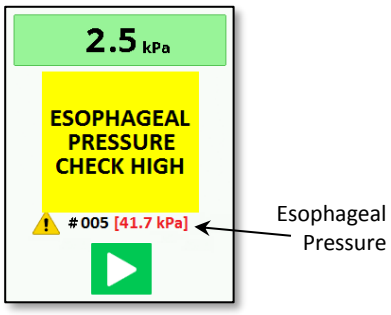

## Esophageal Pressure Check High (#005)/Constrained Space Pressure Check High (#006)

If the Esophageal Pressure Check High Error Screen (Troubleshooting Code #005) or the Constrained Space Pressure Check High Error Screen (Troubleshooting Code #006) appear during inflation, the capsule may be located in the esophagus or another constrained space.

**If the pressure is above 14.0 kPa then the capsule has not dissolved sufficiently or the balloon may be in the esophagus or a constrained space.**

The pre-pulse pressure or constrained space pressure value will be displayed adjacent to the error code in brackets. The pressure display at the top of the screen will decrease as the dispenser depressurizes the balloon.

Esophageal Pressure Check High Screen



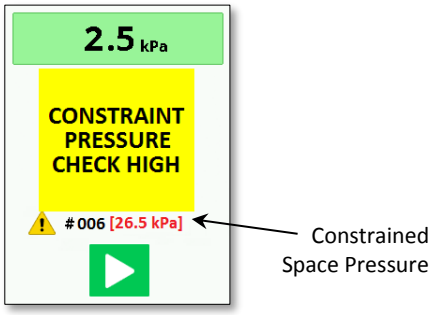

### Balloon is Confirmed to be in the Stomach

If radiography continues to indicate the balloon is in the stomach the patient should drink more liquid to facilitate capsule dissolution and balloon opening for inflation.

### Balloon Location Cannot be Determined to be in the Stomach

If the pressure is above 14.0 kPa for an extended period of time after the patient has swallowed the capsule and it cannot be confirmed in the stomach via radiography the capsule may be constricted in the esophagus or a constrained space. **Do not attempt balloon inflation.** Continue to observe the patient for signs of discomfort and follow the steps to transit the capsule into the stomach outlined in the **Esophageal Transit Troubleshooting** section.

Constrained Space Pressure Check High Screen




## Unstable Pressure Error (#007)

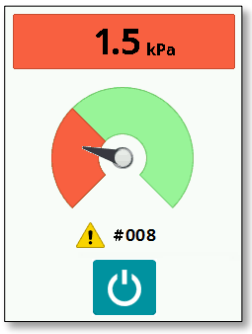
If the **Unstable Pressure Error Screen (Troubleshooting Code #007)** is displayed, the Dispenser has not passed the 30 second leak check at the end of the procedure and detected a potential leak in the catheter or balloon.

To ensure pressure stabilization, check the dispenser catheter connection and ensure that the inflation can is properly engaged in the dispenser prior to proceeding with inflation. Once the dispenser catheter connection and inflation can engagement have been checked, resume inflation by pressing the resume inflation button.

Unstable Pressure Screen

## Pressure Instability Error (#008)

Pressure Instability Screen

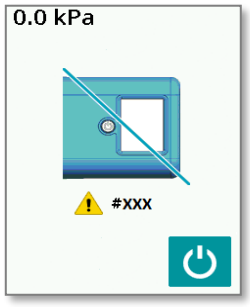



If the **Pressure Instability Screen (Troubleshooting Code #008)** is displayed, the dispenser has detected a potential leak in the catheter or balloon.

Disconnect the catheter from the dispenser, power down the dispenser, and evacuate the balloon per the instructions in the **Esophageal Transit Difficulties** section. **Proceed to endoscopic removal**.

## System Error (#XXX)

System Error Screen




If the System Error Screen (Variable Troubleshooting Codes) is displayed there may be a dispenser malfunction.

If a system error screen appears during dispenser preparation (prior to balloon swallow), turn the dispenser off and on again. If the error appears again, do not continue to use the dispenser. If no new errors are observed, proceed with the balloon administration.

If a system error screen appears during the procedure:

<u>If the patient has swallowed the balloon but inflation is not yet complete</u>:

1. Power down the dispenser.
2. Go to the **Unanticipated Dispenser Shutdown Troubleshooting** and follow the steps to continue balloon inflation.
3. If the System Error is unrecoverable after restarting the dispenser, do not continue to use the dispenser. The balloon may not inflate correctly. Disconnect the catheter from the dispenser and power down the dispenser. Evacuate the balloon per the instructions on the **Esophageal Transit Difficulties** section. **Proceed to endoscopic removal.**

<u>After the balloon is successfully inflated and the catheter is ejected</u>:

Complete the procedure manually (the dispenser is no longer necessary). Turn the dispenser off and on again. If the error appears again, do not continue to use the dispenser.

## Balloon Ejection Issues

If the catheter does not detach from the balloon after the first attempt to eject, use a second ejector prepared with 2.0 cc of water as follows:

1. Detach the used ejector from the proximal end of the catheter and attach the new water filled ejector.
2. Ensure that the ejector is securely screwed onto the end of the catheter, such that no water will leak from the port and so that the luer activated valve in the catheter port is fully opened.
3. Ensure that the catheter is as straight as possible, with no kinks that may restrict the flow of water.
4. Depress the ejector plunger forcefully and completely, in one rapid and deliberate motion. The water pressure generated by the plunger push is what causes the catheter to detach from the balloon. If insufficient pressure is created, the catheter will not detach.

Take care not to bend or crumple the plunger itself; if the plunger becomes bent, replace the ejector with a new one.

5. If the catheter has not detached from the balloon, repeat from step 1 above.
6. **If the catheter does not eject after the fourth attempt, proceed with endoscopic removal**.

| | |
|---|---|
| WARNING | DO NOT attempt to eject the Navigation Balloon more than four times. If four ejection attempts have been made and the balloon remains attached to the catheter, the balloon must be removed endoscopically. |

## Unanticipated Dispenser Shutdown

In the case that the Touch Dispenser is powered down during balloon administration the following steps should be followed to resume the case:

1. Remove the Inflation Can from the Dispenser.
2. Detach the catheter from the dispenser and attach the 60 cc Balloon Evacuator to the catheter.
3. Pull plunger until fully extended (or as far as possible) and lock.
4. Wait 20 seconds with the evacuator locked.
5. Unlock the evacuator (do not press the plunger forward) and observe the plunger.
    a. If the plunger stays fully extended the balloon is not yet fully evacuated. Detach from the catheter and push plunger to discard gas, then repeat steps 2-5 as necessary.
    b. If the plunger moves forward from the locked position, the balloon is fully evacuated.
6. Lock the evacuator.
7. Restart the Touch Dispenser by pushing the power button, reinsert the can when prompted.
8. Once the New Procedure Screen is displayed on the dispenser, unlock the evacuator and release the plunger gently, without forcing the gas back into the balloon (by depressing the plunger), and detach the evacuator from the catheter.
9. Reattach the catheter to the dispenser and press the Start Procedure Button restart the balloon administration.

## Navigation System Recalibration

After capsule tracking has begun, if the reference sensor becomes disconnected from the Navigation Console, a tracking session is inadvertently discontinued, or the Navigation Console loses power, the following steps should be followed to recover the balloon administration:

1. Power up the Navigation Console if applicable.
2. Ensure the Reference Sensor is plugged into one of the three appropriate SIU ports.
3. Disconnect the catheter of the swallowed capsule from the SIU port.
4. Connect the Recalibration Tool to the blue catheter SIU port.
5. Hold the Recalibration Tool vertically to the patient's jugular notch and press the calibrate button.

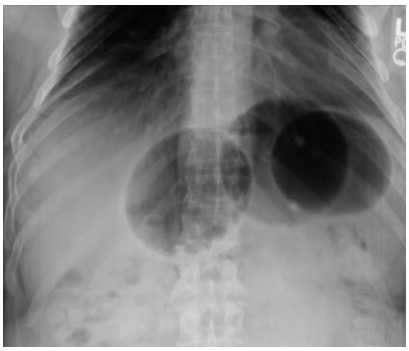
6. After recalibration is complete, disconnect the recalibration tool from the SIU and reconnect the swallowed capsule catheter to the blue SIU port. Continue the procedure.

| | |
|---|---|
| ⚠ CAUTION | After recalibration the capsule track will begin from the current capsule location, the previous tracking information is not recoverable. If the capsule is believed to be in the stomach, ensure that the capsule is significantly offset left of lateral from the center of the screen and/or that the capsule has rotated from a vertical to a horizontal orientation. Have the patient take a deep breath and monitor the capsule track for vertical movement aligned with respiration. |

## 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.



Sample X-Ray of 3 Inflated Balloons

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.

## Table 2: Navigation Console Error Codes

| Error condition | Symbol | Text Color | Text Displayed | Resolution |
|---|---|---|---|---|
| Catheter sensor disconnected from the SIU during session |  | Red | Catheter sensor disconnected or defective. Please check the port. | Until catheter sensor detected |
| Catheter sensor not connected to the SIU at startup |  | Red | Catheter sensor disconnected or defective. Please check the port. | Until catheter sensor detected |
| Reference sensor disconnected from the SIU during session |  | Red | Reference Sensor disconnected. Please check the port. | Until all sensors are detected |
| Reference sensor disconnected from the SIU at startup |  | Red | Sensor disconnected. Please check the port. | Until all sensors are detected |
| Catheter sensor is defective |  | Red | Catheter sensor disconnected or defective. Please check the port. | Until a functional catheter sensor is detected |
| Reference sensor is defective |  | Red | Reference Sensor defective. Please replace. | Until a functional reference sensor is detected |
| Catheter sensor moves outside of tracking volume |  | Orange | Catheter Sensor out of volume. | Until the sensor is detected in the tracking volume |
| Reference sensor moves outside of tracking volume |  | Orange | Reference Sensor out of volume. | Until the sensor is detected in the tracking volume |
| Power is removed from the SCU at application startup |  | Red | Hardware not detected. Please check the power. | Until power is resumed |
| Power is removed from the SCU during session |  | Red | Hardware not detected. Please check the power. | Until power is resumed |
| USB is removed from computer before or during the session |  | Red | USB not detected, please check the cable. | Until USB is detected |
| Calibration attempted while patient not parallel to the field generator |  | Orange | Patient not parallel to the field generator. | Only during calibration, until the patient is in the correct position |
| Calibration attempted with flipped reference sensor |  | Orange | Reference sensor is flipped. | Until the sensor is positioned correctly |

# CLEANING, STORAGE, DISPOSAL, TRANSPORT

## Obalon Navigation Balloon Kit and Placebo Capsule

- Keep the balloon kit and placebo capsule in the original packaging until ready for use.
- Do not use the balloon kit or placebo capsule past the expiration date printed on the packaging.
- Storage temperature should be 59-77 °F (15-25 °C) for the duration of the product shelf life.
- Discard the balloon and catheter per standard biohazard methods and instructions after use.

## Obalon Accessory Kit

- Keep the accessory kit in original packaging until ready for use.
- Store under normal conditions.
- Discard the accessory kit components per standard biohazard methods and instructions after use.

## Obalon Navigation Console

| | |
|---|---|
|  WARNING | Disconnect power to the Navigation Console prior to cleaning. Do not immerse the Navigation Console to liquids or allow fluids to enter the equipment. Exposing the console to liquids may result in equipment damage, produce a fire or shock hazard. Failure to do so may cause personal injury. |

**TO CLEAN:**

- If visible soil is present on the Navigation Console (i.e. Touch Screen or console tray), wipe the console and surrounding areas with a 70% Isopropyl alcohol wipe or equivalent. If visible soil remains on the console after cleaning, the cleaning procedure should be repeated. Wipe off dust with a dry, soft cloth.
- **Reference Sensor**: After each patient use, wipe the reference sensor with a 70% isopropyl alcohol wipe or equivalent. If visible soil remains on the reference sensor after cleaning, the cleaning procedure should be repeated. Ensure that the proximal reference sensor connector remains dry during the cleaning procedure.

| | |
|---|---|
|  CAUTION | Do not use aerosol sprays near the equipment as these sprays can damage circuitry.<br>Do not use any solvent to clean the Navigation Console, solvents may damage the finish or labeling.<br>Do not autoclave any console components as they may be damaged. |

**Storage Conditions**

- Temperature: 50-122 °F (10-50 °C)
- Relative Humidity: 10-90% non-condensing
- Atmospheric Pressure: 50-106 kPa (0-6000 meters)

**Transport**

- Unplug the power cord from the wall.
- Fold the field generator arms to their vertical positions.
- Unlock the caster wheels.
- Grasp the handle cutout on the shelf to pull console into position.
- Navigation Console weight: 125 lbs.

## Obalon Touch Dispenser

- Keep the dispenser clean and protected when not in use.
- The dispenser should be stored in the following conditions: 0-40 °C at 30-85% RH, 0-3000 m.
- The dispenser has been evaluated for a maximum of 5,000 uses. Use of the device beyond this number of uses has not been evaluated.
- Used batteries and electrical waste should be disposed of per local regulations.
- **TO CLEAN:** Wipe the dispenser with a 70% Isopropyl alcohol wipe or equivalent between uses. If visible soil remains on the dispenser, repeat the cleaning procedure.

| | |
|---|---|
|  WARNING | Do not expose or immerse the Touch Dispenser in liquids or allow fluids to enter the equipment. Exposing the Dispenser to liquids may result in equipment damage and cause the device to become non-functional. |

## Obalon Inflation Can

- Each can must be used on or before the expiration date specified on the label.
- Storage conditions should be between 0-40 °C at 30-85% RH, 0-3568 m.
- Dispose of each can after use. DO NOT REUSE.

# SERVICING

The Touch Dispenser has been validated to a limit of 5000 procedures (balloon administrations) and the sensor calibration is good for two years. The dispenser provides a procedure count such that the user may monitor the number of procedures performed. Once 5000 procedures have been completed or current date is greater than two years from the labeled calibration, Contact Obalon Customer Service so that the dispenser can be returned to Obalon for servicing.

# CLINICAL STUDY DESIGN

# SMART TRIAL (OBALON BALLOON SYSTEM)

The SMART Trial was a prospective, multicenter, double-blinded, randomized sham-controlled trial designed to generate safety and effectiveness data for the Obalon 6-Month Balloon System. The trial was conducted from March 9, 2015 to May 19, 2016. The trial was designed to evaluate the effects of a six-month course of balloon therapy in subjects with a starting BMI in the range of 30 – 40 kg/m$_2$ and who participated in a moderate intensity weight loss behavior management program. Treatment Subjects were then followed in an observational portion of the Study (Phase II) for 6-months and previously assigned Sham subjects were provided an elective option to receive the Obalon Balloon for a 6-month period if they still met the BMI qualification criteria. Males and females (22 – 64 years old) with a baseline BMI of 30 – 40 kg/m$_2$ meeting all study inclusion/exclusion criteria were eligible for participation. Those with a history of gastrointestinal abnormalities, previous gastrointestinal surgery, prior use of a weight loss device, were excluded as well as other exclusions such as Type 1 diabetes, uncontrolled hypertension and chronic use of NSAIDs and other gastric irritants. 387 subjects were treated with the Obalon Balloon (198) or sham device (189) in Phase I of the Study. After completion of Phase I, 170 subjects of those previously treated with the balloon (Treatment Subjects) had at least 1 visit in Phase II and 138 sham device subjects meeting the BMI criteria, elected to have the balloon therapy and successfully swallowed a balloon capsule in Phase II. Safety data is based on the 336 subjects who had at least one device placed in Phase I or Phase II of the study.

## Adverse Events

One (1) subject had one (1) Device-Related Serious Adverse Event (SAE). Therefore, the Device-Related SAE rate for the study was 0.3% (1/336) with 95% confidence interval of 0.0% to 1.6%.

**Table 3: Device-Related Serious Adverse Events (Safety Population, n=336)**

| Device-Related Serious Adverse Event* | Safety Population (n=336) | | |
|---|---|---|---|
| | # of Events | Subjects % (n) | Device Removed Due to SAE # Subjects (% Subjects) |
| Peptic ulcer disease | 1 | 0.3% (1) | 1/1 (100%) |

**Device-Related Serious Adverse Events (SAE) were defined as any adverse event that: resulted in death; was life-threatening; required hospitalization (initial or prolonged); caused a substantial disruption of the subject's ability to conduct normal life functions; required intervention to prevent permanent impairment or damage; resulted in a congenital anomaly or birth defect; may require medical or surgical intervention to prevent a serious medical event.*

The SADE was peptic ulcer disease that resulted in gastrointestinal bleeding 6 weeks after receiving three balloons and two weeks after an outpatient total knee replacement that required concomitant use of medications contraindicated with use of the Obalon Balloon System. The balloons were removed as a result of the SADE. There were no deaths, no device migrations out of the stomach and no intestinal obstructions in the pivotal study.

In the initial Treatment Group (n=198 subjects), 90.4% of the subjects experienced a total of 719 device or procedure related adverse events (ADE) in the first 24 weeks of the study. Of the control group (n=138 subjects) that subsequently elected to have balloon therapy, 91.3% of the subjects experienced 493 adverse device effects. Therefore, 90.8% of subjects who received the balloons (Safety Population) experienced 1,212 ADEs. Most of the ADEs, 997 (82.3%), were mild in severity. Of the remainder of the events 210 (17.3%) were moderate, and 5 (0.4%) severe. The 5 severe events are: (1) ulcer, (1) gastric erosion, (1) abdominal pain, (1) device intolerance leading to request for removal and (1) gastric bleeding. Overall, 10.4% of the subjects had an ADE identified at removal that was device related and the ulceration rate was less than 1% of all subjects treated.

Table 4 below includes the most common events such as Abdominal Pain and nausea that are related to the device or procedure, time of onset, and associated durations of the events.

**Table 4: GI-System Device Related Adverse Events Occurring in 10% or More of Subjects treated (Safety Population, n=336)**

| Device Related Adverse Event | Events | Subjects (%) N=336 | Mild* #Events/ %Events | Moderate** #Events/ %Events | Severe*** #Events/ %Events | Onset**** (Days) | Event Duration (Days) #Events (% of Events) |
|---|---|---|---|---|---|---|---|
| Abdominal Pain | 494 | 244 (72.6%) | 414 (83.8%) | 79 (16.0%) | 1 (0.2%) | Median: 0<br>Mean: 10<br>Range: 0-112 | 0-7: 323 (65.4%)<br>8-14: 37 (7.5%)<br>>14: 134 (27.1%) |
| Nausea | 311 | 188 (56.0%) | 261 (83.9%) | 50 (16.1%) | 0 (0.0%) | Median: 0<br>Mean: 11<br>Range: 0-90 | 0-7: 225 (72.3%)<br>8-14: 25 (8.0%)<br>>14: 61 (19.6%) |
| Vomiting | 71 | 58 (17.3%) | 56 (78.9%) | 15 (21.1%) | 0 (0.0%) | Median: 1<br>Mean: 14<br>Range: 0-134 | 0-7: 59 (83.1%)<br>8-14: 5 (7.0%)<br>>14: 7 (9.9%) |
| Indigestion/ Heartburn | 69 | 57 (17.0%) | 48 (69.6%) | 20 (30.4%) | 0 (0.0%) | Median: 5<br>Mean: 15<br>Range: 0-67 | 0-7: 22 (31.9%)<br>8-14: 4 (5.8%)<br>>14: 43 (62.3%) |
| Bloating | 54 | 49 (14.6%) | 49 (90.7%) | 5 (9.3%) | 0 (0.0%) | Median: 2<br>Mean: 14<br>Range: 0-61 | 0-7: 22 (40.7%)<br>8-14: 3 (5.6%)<br>>14: 29 (53.7%) |

**Mild: Subject has an awareness of signs or symptoms, which are easily tolerated and causing no loss of time from normal daily activities; symptoms do not require prescription medications, other than those previously specified; actions taken are limited to clinical observations or diagnostic tests.*

*** Moderate: Subject is experiencing transient periods of discomfort, interfering with normal daily activities; actions taken may include prescription medications beyond what is pre-specified; actions taken do not require hospitalization or invasive interventions.*

**** Severe: Subject is experiencing non-transient discomfort inhibiting performance of normal daily activities; actions taken require hospitalization or invasive interventions.*

***** Onset: Number of days from the time of balloon administration or removal that the Adverse Event began.*

Of the abdominal pain events, no additional treatment beyond the use of the daily PPI and first 5 days of antispasmodic was necessary for treatment for 72.6% of the events. Thirty-three (33) events (6.7%) were treated with natural antispasmodics such as foods containing peppermint oil (e.g. Altoids or Peppermint Tea). Five events (1.0%) were treated with narcotics and 14.0% of events were treated by extending the use of the prescription antispasmodic. Similar to the abdominal pain events, 75.6% of the nausea events were not treated beyond the antiemetic prescribed for five days post each balloon placement, 9.0% of events utilized chamomile tea for soothing the symptoms, and 13.2% of events required the extension of the use of the anti-emetic and/or antispasmodic to alleviate the symptoms. One event was prescribed a narcotic. For vomiting, 78.9% of events required no additional medications other than the 5-days of use of the antiemetic post-each balloon placement. In 12.7% of events, the anti-emetic was extended beyond the 5-days of use. No injectable anti-emetics were used to treat nausea or vomiting at any point in the study. For indigestion/heartburn events, the majority (58.0%) did not require any medical intervention, and about a quarter of the events (27.5%) were prescribed an increase in the PPI medication from 40 mg to 80 mg.

Table 5 below presents the adverse event frequency by number of balloons placed (after 1st, 2nd, and 3rd) and identified at removal, the severity of events and number (%) of subjects that required a device removal as a result of the symptoms experienced during balloon residence. None of the balloon removals were emergent but were due to a request by the subject usually as a result of the symptoms.

**Table 5: All Device Related Adverse Device Effects with Severity by Balloon Placement and Early Removal as a Result of Event for all Subjects in the Control and Treatment Cohorts that received a Balloon (Safety Population, n = 336 Subjects)**

| Device Related Adverse Event | Safety Population (n= 336) | | | | 1st Balloon (n=336) | | 2nd Balloon (n=328) | | 3rd Balloon (n=315) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Events * | Subjects* (%) | Severity of Events % of Events | Subjects w/ Early Removal (%) | Events | Subjects (%) | Events | Subjects (%) | Events | Subjects (%) |
| **ALL Gastrointestinal Events** | **1,146** | **300 (89.3%)** | **Mild: 82.7% Moderate: 16.9% Severe: 0.3%** | **11 (3.3%)** | **442** | **256 (76.2%)** | **293** | **167 (50.9%)** | **373** | **173 (54.9%)** |
| Abdominal Pain | 494 | 244 (72.6%) | Mild: 83.8% Moderate: 16.0% Severe: 0.2% | 4 (1.2%) | 211 | 192 (57.1%) | 128 | 112 (34.1%) | 154 | 117 (37.1%) |
| Nausea | 311 | 188 (56.0%) | Mild: 83.9% Moderate: 16.1% Severe: 0.0% | 2 (0.6%) | 138 | 135 (40.2%) | 79 | 70 (21.3%) | 94 | 71 (22.5%) |
| Vomiting | 71 | 58 (17.3%) | Mild: 78.9% Moderate: 21.1% Severe: 0.0% | 4 (1.2%) | 29 | 27 (8.0%) | 19 | 17 (5.2%) | 23 | 21 (6.7%) |
| Indigestion/ Heartburn | 69 | 57 (17.0%) | Mild: 69.6% Moderate: 30.4% Severe: 0.0% | 0 (0.0%) | 18 | 18 (5.4%) | 20 | 17 (5.2%) | 30 | 29 (9.2%) |
| Bloating | 54 | 49 (14.6%) | Mild: 90.7% Moderate: 9.3% Severe: 0.0% | 0 (0.0%) | 14 | 14 (4.2%) | 19 | 19 (5.8%) | 21 | 21 (6.7%) |
| Burping/ Belching | 37 | 31 (9.2%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 10 | 10 (3.0%) | 9 | 9 (2.7%) | 18 | 18 (5.7%) |
| Diarrhea | 30 | 28 (8.3%) | Mild: 96.7% Moderate: 3.3% Severe: 0.0% | 0 (0.0%) | 9 | 9 (2.7%) | 5 | 5 (1.5%) | 15 | 14 (4.4%) |
| Gastric Irritation** | 25 | 24 (7.1%) | Mild: 48.0% Moderate: 48.0% Severe: 4.0% | 0 (0.0%) | N/A | N/A | N/A | N/A | N/A | N/A |
| Constipation | 10 | 9 (2.7%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 1 | 1 (0.3%) | 5 | 5 (1.5%) | 4 | 4 (1.3%) |
| Difficulty in Sleeping | 9 | 9 (2.7%) | Mild: 66.7% Moderate: 33.3% Severe: 0.0% | 0 (0.0%) | 3 | 3 (0.9%) | 1 | 1 (0.3%) | 5 | 5 (1.6%) |

| Device Related Adverse Event | Safety Population (n= 336) | | | | 1st Balloon (n=336) | | 2nd Balloon (n=328) | | 3rd Balloon (n=315) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Events * | Subjects* (%) | Severity of Events % of Events | Subjects w/ Early Removal (%) | Events | Subjects (%) | Events | Subjects (%) | Events | Subjects (%) |
| Excessive Gas | 8 | 8 (2.4%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 3 | 3 (0.9%) | 0 | 0 (0.0%) | 5 | 5 (1.6%) |
| Esophagitis** | 6 | 6 (1.8%) | Mild: 33.3% Moderate: 66.7% Severe: 0.0% | 0 (0.0%) | N/A | N/A | N/A | N/A | N/A | N/A |
| Hypersalivation | 4 | 3 (0.9%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 1 | 1 (0.3%) | 2 | 1 (0.3%) | 1 | 1 (0.3%) |
| Chest Pain | 3 | 3 (0.9%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 1 | 1 (0.3%) | 1 | 1 (0.3%) | 1 | 1 (0.3%) |
| Gastric Ulcer** | 3 | 3 (0.9%) | Mild: 0.0% Moderate: 66.7% Severe: 33.3% | 1 (3.3%) | N/A | N/A | N/A | N/A | N/A | N/A |
| Device Intolerance | 2 | 2 (0.6%) | Mild: 0.0% Moderate: 50.0% Severe: 50.0% | 0 (0.0%) | 0 | 0 (0.0%) | 1 | 1 (0.3%) | 1 | 1 (0.3%) |
| Hiccups | 2 | 1 (0.3%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 0 | 0 (0.0%) | 1 | 1 (0.3%) | 1 | 1 (0.3%) |
| Sore Throat | 2 | 1 (0.3%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 2 | 1 (0.3%) | 0 | 0 (0.0%) | 0 | 0 (0.0%) |
| Dry Heaving | 1 | 1 (0.3%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 1 | 1 (0.3%) | 0 | 0 (0.0%) | 0 | 0 (0.0%) |
| Food Passage Difficulty | 1 | 1 (0.3%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 0 | 0 (0.0%) | 1 | 1 (0.3%) | 0 | 0 (0.0%) |
| Fullness | 1 | 1 (0.3%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 0 | 0 (0.0%) | 1 | 1 (0.3%) | 0 | 0 (0.0%) |
| Retaining Food & Fluid** | 1 | 1 (0.3%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | N/A | N/A | N/A | N/A | N/A | N/A |

| Device Related Adverse Event | Safety Population (n= 336) | | | | 1st Balloon (n=336) | | 2nd Balloon (n=328) | | 3rd Balloon (n=315) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Events * | Subjects* (%) | Severity of Events % of Events | Subjects w/ Early Removal (%) | Events | Subjects (%) | Events | Subjects (%) | Events | Subjects (%) |
| Syncope | 1 | 1 (0.3%) | Mild: 0.0% Moderate: 100.0% Severe: 0.0% | 0 (0.0%) | 1 | 1 (0.3%) | 0 | 0 (0.0%) | 0 | 0 (0.0%) |
| Upper Body Injury/ Pain | 1 | 1 (0.3%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 0 | 0 (0.0%) | 1 | 1 (0.3%) | 0 | 0 (0.0%) |
| **ALL Metabolic/ Nutritional Events** | **9** | **8 (2.4%)** | **Mild: 66.7% Moderate: 33.0% Severe: 0.0%** | **0 (0.0%)** | **5** | **5 (1.5%)** | **2** | **2 (0.6%)** | **2** | **2 (0.6%)** |
| Headache/ Migraines | 7 | 6 (1.8%) | Mild: 71.4% Moderate: 28.6% Severe: 0.0% | 0 (0.0%) | 4 | 4 (1.2%) | 2 | 2 (0.6%) | 1 | 1 (0.3%) |
| Dizziness | 1 | 1 (0.3%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 1 | 1 (0.3%) | 0 | 0 (0.0%) | 0 | 0 (0.0%) |
| Fatigue | 1 | 1 (0.3%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 0 | 0 (0.0%) | 0 | 0 (0.0%) | 1 | 1 (0.3%) |
| **ALL Respiratory Events** | **3** | **3 (0.9%)** | **Mild: 66.7% Moderate: 33.3% Severe: 0.0%** | **0 (0.0%)** | **0** | **0 (0.0%)** | **0** | **0 (0.0%)** | **3** | **3 (0.9%)** |
| Shortness of Breath | 2 | 2 (0.6%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 0 | 0 (0.0%) | 0 | 0 (0.0%) | 2 | 2 (0.6%) |
| Asthma | 1 | 1 (0.3%) | Mild: 0.0% Moderate: 100.0% Severe: 0.0% | 0 (0.0%) | 0 | 0 (0.0%) | 0 | 0 (0.0%) | 1 | 1 (0.3%) |
| **ALL Other Events** | **1** | **1 (0.3%)** | **Mild: 100.0% Moderate: 0.0% Severe: 0.0%** | **0 (0.0%)** | **1** | **1 (0.3%)** | **0** | **0 (0.0%)** | **0** | **0 (0.0%)** |
| Allergic Reaction | 1 | 1 (0.3%) | Mild: 100.0% Moderate: 0.0% Severe: 0.0% | 0 (0.0%) | 1 | 1 (0.3%) | 0 | 0 (0.0%) | 0 | 0 (0.0%) |
| **ALL** | **1,159** | **300 (89.3%)** | **Mild: 82.6% Moderate: 17.1% Severe: 0.3%** | **11 (3.3%)** | **448** | **256 (76.2%)** | **295** | **167 (50.9%)** | **378** | **175 (55.6%)** |

**Total Events/%Subjects include 1st, 2nd, 3rd balloon placements as well as those identified at removal.*

***ADE onset date is not known*

Adverse events identified at removal due to the removal procedure were also captured and the corresponding severity was assigned using the same Mild, Moderate, Severe and Serious definitions presented in Table 4.

Table 6 presents the frequency of ADEs identified at balloon removal due to the removal procedure. Overall, 13.4% of the subjects had an ADE related to the removal procedure. More than three quarters of procedural related events (75.5%) were mild and required no treatment. Moderate events typically required PPI therapy for an additional period. The Gastric Mucosal damage in these cases was determined to be caused by the balloon removal procedure. Table 7 presents all ADEs in the study and by severity.

**Table 6: All Removal Procedure Related Adverse Device Effects with Severity for all Subjects in the Control and Treatment Cohorts that received a Balloon (Safety Population, n = 336 Subjects)**

| Device Related Adverse Event | Safety Population (n=336 Subjects) | | | | |
|---|---|---|---|---|---|
| | Events | Subjects (%) | Mild | Moderate | Severe |
| Gastric Bleeding/ Abrasion | 17 | 17 (5.1%) | 15 (88.2%) | 1 (5.9%) | 1 (5.9%) |
| Esophageal Bleeding/ Abrasion | 14 | 14 (4.2%) | 11 (78.6%) | 3 (21.4%) | 0 (0.0%) |
| Esophagastric Bleeding/ Abrasion | 12 | 12 (3.6%) | 9 (75.0%) | 3 (25.0%) | 0 (0.0%) |
| Oxygen Desaturation | 4 | 4 (1.2%) | 2 (50.0%) | 2 (50.0%) | 0 (0.0%) |
| Vocal Cord Spasm | 2 | 2 (0.6%) | 0 (0.0%) | 2 (100.0%) | 0 (0.0%) |
| Hypertension | 1 | 1 (0.3%) | 0 (0.0%) | 1 (100.0%) | 0 (0.0%) |
| Coughing | 1 | 1 (0.3%) | 1 (100.0%) | 0 (0.0%) | 0 (0.0%) |
| Sore Throat | 1 | 1 (0.3%) | 1 (100.0%) | 0 (0.0%) | 0 (0.0%) |
| Swollen Lips | 1 | 1 (0.3%) | 1 (100.0%) | 0 (0.0%) | 0 (0.0%) |

**Table 7: Total Number of ADEs With Severity (Safety Population, n = 336 Subjects)**

| | Events | Subjects (%) (n=336) | Severity of Events |
|---|---|---|---|
| **Device Related ADEs** | 1,159 | **300 (89.3%)** | Mild: 82.6%<br>Moderate: 17.1%<br>Severe: 0.3% |
| **Removal Procedure Related ADEs** | 53 | 45 (13.4%) | Mild: 75.5%<br>Moderate: 22.6%<br>Severe: 1.9% |
| **ALL** | **1,212** | **305 (90.8%)** | **Mild: 82.3%**<br>**Moderate: 17.3%**<br>**Severe: 0.4%** |

Early device deflation occurred in a single balloon (0.1%) in a single subject (0.3%). The deflation was identified at removal after the subject was experiencing a new onset of epigastric pain. The deflated balloon did not migrate out of the stomach. There were four (4) bit catheters where the subjects bit the catheter during the swallow process that resulted in the four balloons failing to inflate properly and required early removal. In three of the four subjects the balloons were replaced and the subjects continued with the balloon therapy.

**Table 8: Product Performance - Deflation**

| Observation | Percentage of Balloons | Percentage of Subjects |
|---|---|---|
| Failed to inflate balloon (Bit Catheter) | 4 / 985 (0.4%) | 4 / 336 (1.2%) |
| Early Balloon Deflation | 1 / 981 (0.1%) | 1 / 336 (0.3%) |

The percentage of subjects who were unable to swallow a 1st, 2nd or 3rd balloon is included in Table 9 below. The highest failure rate was 8.3% for the first balloon during the blinded Phase I portion of study.

**Table 9: Subjects unable to Swallow 1st, 2nd and 3rd Balloons**

| Device Number | Treatment Group Subjects Unable to Swallow Balloon (%) | Control Group Subjects Unable to Swallow Sham (%) | Total Subjects Unable to Swallow Balloon or Sham Device (%) |
|---|---|---|---|
| 1st | 18 / 216 (8.3%) | 14 / 203 (6.9%) | 32 / 419 (7.6%) |
| 2nd* | 1 / 195 (0.5%) | 1 / 188 (0.5%) | 2 / 383 (0.5%) |
| 3rd* | 1 / 185 (0.5%) | 1 / 182 (0.5%) | 2 / 367 (0.5%) |

**The denominator represents those subjects that attempted placement of a device (balloon/sham). A 2nd and 3rd device attempt was conducted on only those subjects eligible for placement (e.g. had not exited the study or did not have an on-going adverse event that the investigator felt could be worsened by placement of another device).*

Six subjects (1.8%) were unable to receive all three balloons due to on-going abdominal pain or nausea that the investigator felt would be worsened by placing an additional balloon. Ten additional subjects (3.0%) did not receive three balloons due to unwilling to have another balloon placed (7) or unable to swallow another balloon (3). This is summarized in Table 10 below.

**Table 10: Subjects with Less than 3 Balloons**

| Reason | No 2nd Balloon | No 3rd Balloon | Combined |
|---|---|---|---|
| Device Failed Effectiveness* | 5 (1.5%) | 5 (1.5%) | **10 (3.0%)** |
| Device Intolerance** | 2 (0.6%) | 4 (1.2%) | **6 (1.8%)** |
| **ALL** | **7 (2.1%)** | **9 (2.7%)** | **16 (4.8%)** |

**Device Failed Effectiveness – Unwilling or unable to swallow additional balloons*

***Device Intolerance – Abdominal Pain or Nausea*

## Demographics and Effectiveness

The SMART Trial baseline physical characteristics and demographics are included below in Table 11.

**Table 11: Study Demographics by Treatment and Control Cohorts**

| Demographic | Treatment (n=198) | Control (n=189) | p-value |
|---|---|---|---|
| **Age (years) Mean SD (Median) Min, Max** | 42.6 ± 9.6 (43.2) [22.1, 62.9] | 42.5 ± 9.3 (43.8) [22.2, 63.6] | 0.8707 |
| **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%) | 0.1130 |
| **Race: Black or African American N (%)** | 21 (10.6%) | 29 (15.3%) | |
| **Other race N (%)** | 12 (6.1%) | 5 (2.6%) | |
| **Height (in) Mean SD (Median) Min, Max** | 65.6 ± 3.3 (65.0) [57.0, 75.0] | 65.6 ± 2.9 (65.5) [59.0, 77.3] | 0.9159 |
| **Waist (in) Mean SD (Median) Min, Max** | 43.1 ± 3.8 (43.0) [31.5, 52.8] | 43.6 ± 4.0 (43.7) [30.5, 56.0] | 0.2453 |
| **Baseline Weight (lbs) Mean SD (Median) Min, Max** | 216.3 ± 29.1 (210.1) [156.8, 301.2] | 217.8 ± 26.2 (217.2) [152.8, 307.8] | 0.6049 |
| **Baseline BMI (kg/m²) Mean SD (Median) Min, Max** | 35.2 ± 2.7 (35.1) [30.0, 40.2] | 35.5 ± 2.7 (35.7) [30.2, 40.3] | 0.2599 |

The study had two pre-defined co-primary effectiveness endpoint criteria: the difference in mean Percent Total Body Loss (TBL) between the Treatment and Control Groups and the percentage of subjects in the Treatment Group who lost at least 5% TBL. The mITT and Per Protocol Cohort were used in evaluating both co-primary effectiveness endpoints. The mITT Cohort is defined as subjects who received at least one device. The Per Protocol Cohort was prospectively defined as subjects who received at least two devices and participated in at least 18 weeks of using the mITT cohort, 181 out of 189 Subjects had 3 balloons and ≥18 weeks of participation. Seven subjects had fewer than 3 balloons and less than 18 weeks of therapy. In the Per Protocol cohort, 179 out of 185 Subjects had 3 balloons and ≥18 weeks of participation.

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 ≤ -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:

**Table 12: Primary Effectiveness Endpoint at 24 Weeks – Mean % TBL Difference from Sham**

| 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 Treatment=185 Control=181 | -6.86 | -3.59 | -3.28 | -4.32 | -2.24 | **0.0261** |
| Modified Intent to Treat (mITT) Treatment=198 Control=189 | -6.60 | -3.42 | -3.18 | -4.19 | -2.17 | **0.0354** |

**Table 13: Primary Effectiveness Endpoint at 24 Weeks - % Responder Rate (% of Subjects with 5% TBL or more)**

| Criteria (≤) | Per Protocol Cohort (n=185) | | Modified Intent to Treat (n=198) | |
|---|---|---|---|---|
| | Estimate | 95% Confidence Interval | Estimate | 95% Confidence Interval |
| **-5% TBL** | **120 (64.9%)** | **(57.5 %, 71.7%)** | **123 (62.1%)** | **(59.2%, 73.2 %)** |
| -6% TBL | 98 (53.0%) | (45.5 %, 60.3%) | 101 (51.0%) | (47.1%, 61.9%) |
| -7% TBL | 81 (43.8%) | (36.5 %, 51.3%) | 83 (41.9%) | (37.6%, 52.3%) |
| -8% TBL | 68 (36.8%) | (29.8 %, 44.1%) | 69 (34.8%) | (30.3%, 44.7%) |
| -9% TBL | 55 (29.7%) | (23.2 %, 36.9%) | 56 (28.3%) | (23.7%, 37.4 %) |
| -10% TBL | 49 (26.5%) | (20.3 %, 33.5%) | 49 (24.7%) | (20.3%, 33.5%) |

Additional weight loss parameters at week 24 for the mITT and Per Protocol populations are presented in the table below including %EWL, absolutely weight loss (lbs), and BMI change from baseline. An additional analysis evaluated weight loss maintenance on treated subjects with a measured and negative %TBL at 24 weeks. Of the mITT cohort, there were 171 subjects with a measured negative TBL at Week 24 and 168 subjects in the Per Protocol population had a measured negative TBL at week 24 value to assess weight loss maintenance at Week 48. On average, subjects re-gained ≈2lbs of their total weight lost. These additional weight loss parameters at Week 24 and Week 48 are presented in Table 14 below.

**Table 14: Weight Loss Parameters - Week 24 and Weight Loss Maintenance at Week 48**

| | Treatment | | | | | Control | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Cohort** | **n** | **% TBL Mean SD (Median) Min, Max** | **% EWL Mean SD (Median) Min, Max** | **Pounds Mean SD (Median) Min, Max** | **BMI Change Mean SD (Median) Min, Max** | **n** | **% TBL Mean SD (Median) Min, Max** | **% EWL Mean SD (Median) Min, Max** | **Pounds Mean SD (Median) Min, Max** | **BMI Change Mean SD (Median) Min, Max** |
| mITT at 24 weeks | 198 | -6.6 ± 5.1 (-6.1) [-19.3, 9.5] | -24.1 ± 19.2 (-21.8) [-80.7, 28.8] | -14.4 ± 11.7 (-12.6) [-49.7, 21.1] | -2.3 ± 1.8 (-2.1) [-7.1, 3.6] | 189 | -3.4 ± 5.0 (-2.8) [-18.7, 9.6] | -12.2 ± 18.8 (-10.2) [-104, 30.4] | -7.4 ± 11.2 (-5.8) [-52.4, 21.8] | -1.2 ± 1.8 (-1.0) [-7.1, 3.5] |
| Per Protocol at 24 weeks | 185 | -6.9 ± 5.0 (-6.2) [-19.3, 9.5] | -25.2 ± 19.2 (-22.7) [-80.7, 28.8] | -15.0 ± 11.7 (-13.2) [-49.7, 21.1] | -2.4 ± 1.8 (-2.2) [-7.1, 3.6] | 181 | -3.6 ± 5.0 (-3.1) [-18.7, 9.6] | -12.8 ± 18.9 (-11.2) [-104, 30.4] | -7.8 ± 11.3 (-6.2) [-52.4, 21.8] | -1.3 ± 1.8 (-1.0) [-7.1, 3.5] |

| | Treatment | | | | | Control | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Cohort** | **n** | **% TBL Mean SD (Median) Min, Max** | **% EWL Mean SD (Median) Min, Max** | **Pounds Mean SD (Median) Min, Max** | **BMI Change Mean SD (Median) Min, Max** | **n** | **% TBL Mean SD (Median) Min, Max** | **% EWL Mean SD (Median) Min, Max** | **Pounds Mean SD (Median) Min, Max** | **BMI Change Mean SD (Median) Min, Max** |
| mITT Week 48 – Week 24* Weight Change | 171 | 0.9 ± 4.1 (1.1) [-14.4, 12.0] | 3.2 ± 14.9 (3.6) [-46.4, 43.2] | 1.8 ± 9.3 (2.6) [-41.6, 27.8] | 0.3 ± 1.4 (0.4) [-5.2, 4.2] | N/A | N/A | N/A | N/A | N/A |
| Per Protocol Week 48 – Week 24* Weight Change | 168 | 0.9 ± 4.1 (1.2) [-14.4, 12.0] | 3.3 ± 15.0 (3.7) [-46.4, 43.2] | 1.9 ± 9.4 (2.6) [-41.6, 27.8] | 0.3 ± 1.5 (0.4) [-5.2, 4.2] | N/A | N/A | N/A | N/A | N/A |

*171 out of the 198 mITT Subjects had a measured negative %TBL at Week 24 and evaluated for weight change at Week 48.
** 168 out of the 185 Per Protocol Treatment subjects had a measured negative %TBL at Week 24 and evaluated for weight change at Week 48.
N/A: Control Group weight loss maintenance was not evaluated

# COBALT (NAVIGATION/TOUCH SYSTEM)

The COBALT study design was an open label, multi-center (minimum of 8 and up to 18 centers), prospective single-arm study and was conducted from April 6, 2018 to July 13, 2018. The objective of the study was to generate safety and effectiveness data for use of the Obalon Navigation-Touch System to administer the Obalon Balloon without the use of radiography.

There were 159 subjects that attempted to swallow at least one NTS capsule in the study, of which 155 successfully swallowed at least one NTS Balloon. One hundred nine (109) out of the 155 treated subjects or 70.3% received three balloons administered with the NTS. The other 46 treated subjects were split equally (23) receiving either 1 or 2 NTS Balloons. Across the 159 subjects, there were 406 total attempted NTS Balloon administrations across all balloon types (Balloon 1, 2, or 3) of which 396 administrations successfully transited into the stomach (97.5%) and were inflated. 327 out of the 396 balloons administered (82.6%) were in subjects that received only NTS Balloons (3 NTS balloons). Overall there were 131 first balloons attempted, 137 second balloons attempted, and 138 third balloons attempted. The successful balloon administration results by balloon number are included in Table 15. Table 16 contains the distribution of balloon administration number across the study subjects.

**Table 15: Balloon Administration Success by Balloon Number**

| Balloon # | Overall Success (%) |
|---|---|
| 1 | 127 / 131 (96.9%) |
| 2 | 135 / 137 (98.5%) |
| 3 | 134 / 138 (97.1%) |
| **ALL** | **396 / 406 (97.5%)** |

**Table 16: Balloon Allocation by Subjects**

| # of NTS Balloons/Subject | Subjects (%) n=155 | Balloons (%) n=396 |
|---|---|---|
| 1 | 23 (14.8%) | 23 (5.8%) |
| 2 | 23 (14.8%) | 46 (11.6%) |
| 3 | 109 (70.3%) | 327 (82.6%) |

## Study Results

There were no unexpected inflations in the esophagus that could lead to esophageal injury during the study and all procedures were a success. Therefore, the unexpected inflation in the esophagus that could lead to esophageal injury was 0.0% with a 97.5% one-sided upper confidence bound of 0.92%. The Navigation-Touch success estimate is 100.0% with a 97.5% one-sided lower confidence bound of 99.08%. Table 17 presents the aggregate balloon data in addition to assessment data by balloon number.

**Table 17: Co-Primary Endpoint Results**

| Balloon # | Esophageal Injury Endpoint (ALL) ≤ 1% | | Navigation-Touch Success Endpoint (ALL) ≥ 97% | |
|---|---|---|---|---|
| | Estimate | 97.5% UCB | Estimate | 97.5% LCB |
| 1 | 0 / 127 (0.0%) | 2.86% | 127 / 127 (100.0%) | 97.14% |
| 2 | 0 / 135 (0.0%) | 2.70% | 135 / 135 (100.0%) | 97.30% |
| 3 | 0 / 135 (0.0%) | 2.70% | 135 / 135 (100.0%) | 97.30% |
| **ALL** | **0 / 397 (0.0%)** | **0.92%** | **397 / 397 (100.0%)** | **99.08%** |

## Navigation-Radiography Balloon Location Agreement

An evaluation of Navigation-Radiography location agreement was conducted. There was 100% agreement across all location determinations as applicable between the Navigation Console and radiographic imaging. Because one balloon capsule did not transit to the stomach during the study, the device location assessment agreement between Navigation and radiography is based on 396 balloon administrations. The device location assessment agreement is 100.0% with a 99.07 one-sided 97.5 lower confidence bound of 99.07%. Table 18 contains the device location agreement analysis.

**Table 18: Navigation-Radiography Balloon Location Agreement**

| Balloon # | Navigation-Radiography Assessment Agreement | |
|---|---|---|
| | Estimate | 97.5% LCB |
| 1 | 127/127 (100.0%) | 97.14% |
| 2 | 134/134* (100.0%) | 97.28% |
| 3 | 135/135 (100.0%) | 97.30% |
| **ALL** | **396/396 (100.0%)** | **99.07%** |

## Location Indicator Assessment

An analysis of the study results examined the use of the four indicators provided in the IFU that contributed to the investigator decision of balloon location in the stomach. Table 19 includes the balloon administration number and the number of indicators documented as contributing to the balloon location decisions. Using a 0.15 critical value and the Freeman-Halton Test, the percentage distribution for the number of Navigation assessment indicators present was statistically different (p=0.1277) by balloon number. Although investigators documented that the majority of balloon administrations (at least 84.3% per balloon number) had all four indicators present, the percentage for the 1st balloon (91.3%) with four indicators present was higher compared to the 2nd and 3rd balloons (85.2% and 84.3%, respectively). Thus, 2nd and 3rd balloons had higher percentages of administrations with 3 and 2 indicators present compared to 1st balloons that had all four indicators present. The results also suggest that that more than 97.2% of the time the investigators identified at least 3 indicators prior to making their decision that the device was in the stomach.

For individual indicators, their percentage of presence was statistically different (p <0.15) by balloon number for only the left lateral offset indicator (p=0.1423). The left lateral offset indicator was present in 93.3% of the 3rd balloons compared to 97.6% and 98.5% for 1st and 2nd balloons, respectively. The left lateral offset indicator had a higher percentage of being marginally present in the 3rd balloon compared to the 1st and 2nd balloons. The presence of left lateral acceleration, capsule rotation and up/down movement with deep breath were not statistically different (p>0.15) by balloon number. Tables 20-23 contain the percentages for each indicator being present.

Based on the investigator assessments, the data suggests that the up/down movement of the device capsule when a deep breath is taken was the leading indicator present with at least 98.5% per balloon number, while, the acceleration offset indicator was the lowest but still at least 88.9% per balloon number.

**Table 19: Indicator Use for Navigation Location Decisions in the Stomach**

| Balloon # | # of Indicators Present | | | | Freeman-Halton p-value |
|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | |
| 1 (n=127) | 0 (0.0%) | 0 (0.0%) | 11 (8.7%) | 116 (91.3%) | 0.1277 |
| 2 (n=135) | 0 (0.0%) | 4 (3.0%) | 16 (11.9%) | 115 (85.2%) | |
| 3 (n=134*) | 1 (0.7%) | 6 (4.5%) | 14 (10.5%) | 113 (84.3%) | |

* One swallowed 3rd balloon administration did not transit into the stomach

**Table 20: Left Lateral Offset**

| Balloon # | Left-Lateral Offset Indicator | | | Freeman-Halton p-value |
|---|---|---|---|---|
| | Present | Marginally Present | Not Present | |
| 1 (n=127) | 124 (97.6%) | 2 (1.6%) | 1 (0.8%) | 0.1423* |
| 2 (n=135) | 133 (98.5%) | 1 (0.7%) | 1 (0.7%) | |
| 3 (n=134) | 125 (93.3%) | 7 (5.2%) | 2 (1.5%) | |

*The left lateral offset was less likely to be seen with a 3rd balloon than with a 1st or 2nd balloon administration

**Table 21: Acceleration Offset**

| Balloon # | Acceleration Offset Indicator | | | Freeman-Halton p-value |
|---|---|---|---|---|
| | Present | Marginally Present | Not Present | |
| 1 (n=127) | 122 (96.1%) | 3 (2.4%) | 2 (1.6%) | 0.2046 |
| 2 (n=135) | 120 (88.9%) | 7 (5.2%) | 8 (5.9%) | |
| 3 (n=134) | 120 (89.6%) | 6 (4.5%) | 8 (6.0%) | |

**Table 22: Capsule Rotation**

| Balloon # | Capsule Rotation Indicator | | | Freeman-Halton p-value |
|---|---|---|---|---|
| | Present | Marginally Present | Not Present | |
| 1 (n=127) | 125 (98.4%) | 2 (1.6%) | 0 (0.0%) | 0.6412 |
| 2 (n=135) | 130 (96.3%) | 4 (3.0%) | 1 (0.7%) | |
| 3 (n=134) | 129 (96.3%) | 5 (3.7%) | 0 (0.0%) | |

**Table 23: Up/Down Movement with Deep Respiration (Breath)**

| Balloon # | Up-Down Movement w/ Deep Respiration Indicator | | | Freeman-Halton p-value |
|---|---|---|---|---|
| | Present | Marginally Present | Not Present | |
| 1 (n=127) | 126 (99.2%) | 1 (0.8%) | 0 (0.0%) | 0.6172 |
| 2 (n=135) | 133 (98.5%) | 2 (1.5%) | 0 (0.0%) | |
| 3 (n=134) | 133 (99.3%) | 0 (0.0%) | 1 (0.7%) | |

## POST APPROVAL STUDY

Effectiveness of the Navigation-Touch System in correctly determining the swallowed capsule location within the GI tract is paramount to patient safety, especially when used without radiographic confirmation. The COBALT study used to support FDA approval revealed no events of intra-esophageal inflation within the 155 subjects studied. Due to the limited size of the COBALT study, a post-approval study is forthcoming to further support the safety and effectiveness of the Navigation-Touch System.

# GLOBAL PRODUCT EXPERIENCE

Global device/procedure related adverse events or complaints are presented in Table 24. The data includes the Obalon six-month balloon available in the US and Middle East from January 1, 2017 to December 31, 2019 and the prior generation Obalon three-month balloon which was not approved in the US but was available Outside the US (Europe, Mexico, and Middle East) from July 1, 2012 to December 31, 2016. Some events have not been directly attributed to Obalon and non-device related events are not included. This data has not been scientifically validated and may include duplication of some events. Rates are estimated based on balloon distribution data (not actual patient data) and the average number of balloons per patient from US clinical trial data and Outside US Post Market Study data. The assumed average number of balloons per patient for the 3-month balloon is less than the 6-month balloon per study data.

**Table 24. Global Obalon 3-month and 6-month balloon device and procedure related adverse events and complaints reported between July 1, 2012 and December 31, 2019**

| Events | Patient Count | Patient Rate[1] |
|---|---|---|
| Abdominal Pain | 219 | 0.89% |
| Nausea | 151 | 0.61% |
| Early Removal or Device Intolerance | 89 | 0.36% |
| Vomiting | 84 | 0.34% |
| Ulcer or erosion | 65 | 0.26% |
| Bit Catheter[2] | 51 | 0.21% |
| Dyspepsia | 44 | 0.18% |
| Total Deflations (6-Month Balloon) | 37 | 0.12% |
| - Deflations when system use is beyond indications for use | 24 | 0.08% |
| - Early Balloon Deflation | 13 | 0.04% |
| Total Deflations (3-Month Balloon)[3] | 83 | 0.60% |
| - Deflations when system use is beyond indications for use | 71 | 0.51% |
| - Early Balloon Deflation | 12 | 0.09% |
| Abdominal distension | 33 | 0.13% |
| Failure to transit to stomach during administration[2] | 25 | 0.10% |
| Gastric Irritation | 22 | 0.09% |
| Constipation | 22 | 0.09% |
| Failure to eject catheter from balloon valve during administration[2] | 22 | 0.09% |
| Difficulty sleeping | 20 | 0.08% |
| Eructation | 15 | 0.06% |
| Retching | 10 | 0.04% |
| Hunger | 10 | 0.04% |
| Intestinal obstruction | 10 | 0.04% |
| Diarrhea | 9 | 0.04% |
| Anxiety | 4 | 0.02% |
| Headache | 4 | 0.02% |
| Shoulder Pain | 3 | 0.01% |
| Stomach perforation | 3 | 0.01% |
| Failure to Inflate balloon during administration[2] | 3 | 0.01% |
| Intermittent gastric outlet obstruction | 3 | 0.01% |
| Hypersalivation | 3 | 0.01% |
| Gastric outlet obstruction | 2 | 0.01% |

| Events | Patient Count | Patient Rate[1] |
|---|---|---|
| Dark stool | 2 | 0.01% |
| Esophagitis | 2 | 0.01% |
| Syncope | 2 | 0.01% |
| Dehydration | 2 | 0.01% |
| Esophageal perforation during endoscopic scope placement | 2 | 0.01% |
| Esophageal perforation during administration with EzFill Inflation System resulting in surgical repair/sepsis/death (Mexico) | 1 | 0.00% |
| Acute Pancreatitis[4] | 1 | 0.00% |
| Esophageal laceration at removal | 1 | 0.00% |
| Halitosis | 1 | 0.00% |
| Candidiasis | 1 | 0.00% |
| Chest pain | 1 | 0.00% |
| Disorientation | 1 | 0.00% |
| Esophageal Ulcer | 1 | 0.00% |
| Gastric abrasion/bleeding | 1 | 0.00% |
| Oxygen desaturation | 1 | 0.00% |

[1]For results reported as 0.00% actual rate is 0.004%

[2]Event results in unanticipated endoscopic removal during administration

[3] 3-Month balloon approved outside of the United States with differences in design from US-approved 6-month balloon

[4]Not reported in the US with the 6-month Obalon Balloon System to date. A single event of acute pancreatitis was reported in the literature with the prior Obalon 3-month international balloon not approved in the US, but could not be confirmed during the investigation.

# PRODUCT SPECIFICATIONS

| Products | Product Number |
|---|---|
| Balloon Kit | 7410 |
| Accessory Kit | 6200 |
| Placebo Capsule | 7650 |
| Navigation Console | 7402 |
| Replacement Reference Sensor | 7404 |
| Touch Dispenser | 4300 |
| Touch Dispenser Kit | 9300 |
| Balloon Evacuator | 6300 |
| Recalibration Tool | 7405 |

| Balloon Kit Assembly | |
|---|---|
| Storage Conditions | 15-25 °C (59-77 °F) |
| Operating Conditions | 15-25 °C, 30-85% RH, 0-2438 m |
| Capsule Ingredients | Hydroxypropyl Methyl Cellulose |
| Balloon Materials* | Nylon/Polyethylene/Silicone/Titanium |
| Catheter Length* | Working Length: Greater than 27 in (68.6 cm)<br>Total Length: 56.9 ± 1.5 in (144.5 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 contains no latex or natural rubber materials. | |

| | |
|---|---|
|  <br>WARNING | The use of accessories and cables other than those supplied may result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2.<br><br>The equipment should not be used adjacent to or stacked with other equipment. If necessary, the equipment operation should be observed and verified in the manner in which it will be used. |

## Navigation Console Simplified EMC

Wireless equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations can affect the Navigation Console and should be kept away from the it.

Examples of tested distance for safe operation are:

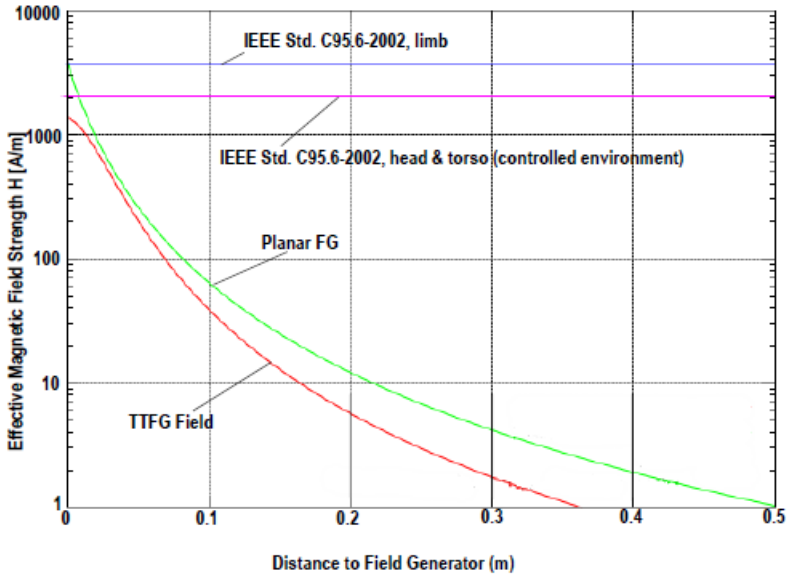
- Cell phones – 3.3 m
- Laptop – 0.18 m
- Cordless phone (900 MHz) – 2.33 m

Safe distances for other equipment not listed will need to be calculated per the electromagnetic environment.

## Navigation Console Detailed EMC

This equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

This equipment is intended for use by healthcare professionals only. This equipment intentionally emits a 800 Hz magnetic field. The power of the field appears in the following graph:




The equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the cart and its cables or shielding the location.

Portable and mobile RF communications equipment can affect *Medical Electrical Equipment*.

Only by using the approved system accessories does this system comply with the *Medical Electrical Equipment* requirements.

<table>
<tr><td colspan="4">The Obalon Balloon Navigation System is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.</td></tr>
<tr><td colspan="2">Emissions test</td><td>Electromagnetic environment– guidance</td><td>Notes</td></tr>
<tr><td colspan="2">RF emissions CISPR 11</td><td>Group 1</td><td>The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment</td></tr>
<tr><td colspan="2">RF emissions<br>CISPR 11</td><td>Class A</td><td rowspan="3">The Navigation Console is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies power to buildings used for domestic purposes.</td></tr>
<tr><td colspan="2">Harmonic emissions<br>IEC 61000-3-2</td><td>Not Applicable (no defined limits for system as rated power is ≤ 75 W and system is not lighting equipment.)</td></tr>
<tr><td colspan="2">Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3</td><td>N/A</td></tr>
</table>

| **The Obalon Balloon Navigation System equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment should assure that it is used in such an environment.** | | | |
|---|---|---|---|
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – Guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact<br>±8 kV air | ±2 kV, ±4 kV, ±6 kV contact<br>±2 kV, ±4 kV, ±6 kV, ±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines | ±2 kV for power supply lines input/output lines not applicable (< 3 m so no testing required) | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV line(s) to line(s) ±2 kV line(s) to earth | ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 230 Vac | <5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles<br><5 % UT (>95 % dip in UT) for 5 sec | 0 % UT (100 % dip in UT) for 0.5 cycle<br>40 % UT (60 % dip in UT) for 5 cycles<br>70 % UT (30 % dip in UT) for 25 cycles<br>0 % UT (100 % dip in UT) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m. | 3 A/m (50 Hz & 60 Hz) | Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment. |
| NOTE $U_T$ is the a.c. mains voltage prior to application of the test level. | | | |

<table>
<tr><td colspan="4">The Obalon Balloon Navigation System is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Conducted RF<br>IEC 61000-4-6</td><td>3 Vrms<br>150 kHz to 80 MHz</td><td>3 Vrms<br>150 kHz to 80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d = [\frac{3,5}{V_1}]\sqrt{P}$ 150 kHz to 80 MHz<br>$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz<br>$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz<br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]<br>Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol:<br>  </td></tr>
<tr><td>Radiated RF<br>IEC 61000-4-3</td><td>3 V/m 80 MHz to 2,5 GHz</td><td>3 V/m 80 MHz to 2,5 GHz</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the Navigation in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.<br>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
<tr><td colspan="4">Recommended separation distances between portable and mobile RF communications equipment and the Obalon Balloon Navigation System.</td></tr>
<tr><td colspan="4">The Obalon Balloon Navigation System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Obalon System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ONS as recommended below, according to the maximum output power of the communications equipment.</td></tr>
<tr><td rowspan="2">Rated maximum output power of transmitter<br>W</td><td colspan="3">Separation distance according to frequency of transmitter (meters)</td></tr>
<tr><td>150 kHz to 80 MHz<br>$d = [\frac{3,5}{V_1}]\sqrt{P}$</td><td>80 MHz to 800 MHz<br>$d = [\frac{3,5}{E_1}]\sqrt{P}$</td><td>800 MHz to 2.5 GHz<br>$d = [\frac{7}{E_1}]\sqrt{P}$</td></tr>
<tr><td>0.01</td><td>0.12</td><td>0.12</td><td>0.24</td></tr>
<tr><td>0.1</td><td>0.37</td><td>0.37</td><td>0.74</td></tr>
<tr><td>1</td><td>1.17</td><td>1.17</td><td>2.34</td></tr>
<tr><td>10</td><td>3.69</td><td>3.69</td><td>7.38</td></tr>
<tr><td>100</td><td>11.67</td><td>11.67</td><td>23.33</td></tr>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Touch Dispenser EMC

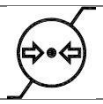
The Touch Dispenser/Inflation Can are intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

| Electromagnetic Immunity | Compliance Level |
|---|---|
| Electromagnetic Environment Guidance Electrostatic Discharge (ESD) IEC 61000-4-2 | ±8 kV Contact<br>± 15kV Air<br>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% |
| Electromagnetic Environment Guidance<br>Power frequency<br>(50/60Hz)<br>Magnetic field<br>61000-4-8 | 30 A/m<br>Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment |
| Electromagnetic Environment Guidance<br>Radiated RF<br>61000-4-3 | 3 V/m<br>Portable and mobile RF communications equipment should be used no closer to any part of the Touch Dispenser, than 30 cm (12 inches)<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

The Touch Dispenser needs special precautions regarding EMC and needs to be put into service according to the EMC information provided in this document.

Portable and mobile RF communications equipment can affect the Touch Dispenser. Portable and mobile RF communications equipment (cell phones, computers with WiFi, etc. and their peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Touch Dispenser. Otherwise, degradation of the performance of Touch Dispenser could result.

The Touch Dispenser should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the Touch Dispenser should be observed to verify normal operation.

| Symbol Definitions | | | |
|---|---|---|---|
| Single Use Only |  | Expiration date |  |
| Atmospheric Pressure Limit |  | Lot number |  |
| Storage/Operating Temperatures |  | Reference number |  |
| Caution |  | Serial Number |  |
| Non-Sterile |  | Type BF Applied Part |  |
| Do not use if package is opened or damaged |  | Humidity Limitation |  |
| Keep dry |  | MR Conditional |  |
| Refer to Instruction manual/booklet |  | MR Unsafe |  |
| Consult Instructions for Use |  | Do Not Push |  |
| Manufacturer |  | Do Not Step |  |
| No pacemakers |  | Pinch Point |  |
| Non-ionizing electromagnetic radiation |  | | |

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Patents. www.obalon.com/patents

Document released: April 07, 2020

**Obalon Balloon MR Safety Information**

Non-clinical testing demonstrated the Obalon Balloon is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3 Tesla or less
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the Obalon Balloon is expected to produce a maximum temperature rise of less than 3 °C after 15 minutes of continuous scanning.

**Artifact Information**

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the Obalon Balloon when imaged with a gradient echo pulse sequence and a 3 Tesla MRI System.

Catheter, Console, and Dispenser MR Safety Information

- The Navigation Catheter (including the electromagnetic sensor) 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 Navigation Catheter in the MR environment is unknown. Scanning a patient who has swallowed the Navigation Catheter may result in patient injury. The Navigation Catheter (including the electromagnetic sensor) should be fully removed from the patient prior to exposure to an MRI field.
- The Obalon Navigation Console and Touch Inflation System (dispenser and can) are MR unsafe and are known to pose hazards in all MR imaging environments.