Patient Identification Label

Name: _____

MRN: _____

DOB: _____

Date of Service: _____

INFORMED CONSENT
Administration of Obalon Balloon System Treatment

Consent: I voluntarily authorize _____as my physician and other designated health care providers, to provide me with the Obalon Balloon System therapy for weight loss.

A: Obalon Balloon System Regimen: Treatment with the Obalon Balloon System will consist of swallowing a capsule along with the distal portion of a inflation catheter that is pre-attached to a self-sealing valve on the balloon. A portion of the catheter remains outside of the mouth. The capsule begins to dissolve once it becomes exposed to water and gastrointestinal (GI) fluids in the stomach. As the capsule dissolves, the balloon begins to unfold. Balloon location is then confirmed using radiography (fluoroscopy or digital x-ray) to ensure that it is in your stomach. Once balloon location is confirmed, the Obalon inflation system is connected to the catheter and a compressed gas mixture is passively transferred to the balloonthroughout the process. Balloon inflation is generally accomplished within two minutes, and checks for potential leaks are performed. After balloon inflation, the catheter is ejected from the balloon and the catheter is withdrawn. The inflated balloon remains free-floating within the stomach. You will not need transportation assistance after the procedure. Three balloons will be administered within the first 12 weeks of the 6 month therapy.

Six months after administration of the first balloon, you must return to your physician's office to have all three balloons removed. To have them removed, the balloons will be deflated and removed during an endoscopic procedure. You will undergo an upper endoscopy with direct visualization of the upper digestive tract with a lighted instrument called a endoscope. An IV will be inserted to give you sedation for the procedure. You will be placed on your left side on the examining table. A bite block will be placed in your mouth to prevent damage to your teeth and our endoscope. Sedation will be given through the IV to make you sleepy before the procedure. A flexible lighted tube will be inserted into your mouth, your esophagus (swallowing tube), stomach, and into the duodenum (the first part of your small intestines). A needle will be used to puncture each balloon and aspirate all of the gas out of the balloon. A grasping tool will then be used to grab the balloon and pull it through your esophagus out through your mouth. This process will be repeated for the second and third balloons. After the third balloon is removed, the scope will be reinserted into your esophagus and stomach to evaluate for any damage in your stomach or esophagus. You will need transportation assistance after the procedure.

B: The following medications may be prescribed for prevention of stomach ulceration and prevention of symptoms after balloon administration: Omeprazole, Levsin or Bentyl, Carafate and Zofran

C: Details of, Goal(s) of, and Alternatives to the Obalon Balloon System: A provider has explained to me the purpose of, duration of, and the details related to the Obalon Balloon System Treatment that I will receive. A provider has also explained to me the risks associated with not receiving the Obalon Balloon System and alternative treatments. These alternative treatments include, but are not limited to lifestyle therapy, weight loss medications, and if I meet certain criteria, bariatric surgery.

A provider has explained to me the goals of my Obalon Balloon System Treatment, which may include: weight loss and weight loss maintenance. A provider has also explained to me that I must participate in a weight loss program with use of the Obalon Balloon System to support my weight loss.

D: Risks and Side Effects: I understand not receiving the Obalon Balloon System has risks and that the Obalon Balloon System treatment plan also has risks, including possible side effects. I understand that complications of the Obalon Balloon System could require other interventions and that the risks associated with the Obalon Balloon System may include, but are not limited to, those listed below:

Patient Identification Label

Name: _____

MRN: _____

DOB: _____

Date of Service: _____

Most Frequent (>50%)	**Les Common (1-10%)**	**Extremely Rare** (less thank 0.05%)
• Abdominal Pain/Cramping • Nausea	• Burping/Belching • Diarrhea or constipation • Esophageal abrasion or esophagogastric junction bleeding • Difficutly Sleeping • Excessive gas • Esophagitis • Headache • Hypoxemia during removal	• Balloon deflation that leads to a bowel obstruction requiring surgery to remove
Common (10-20%)	**Rare (Less than 1%)**	Extremely Rare (Less than 0.01%)
• Vomiting • Reflux/Heartburn • Bloating	• 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 • Bad breath • Catheter bite resulting in endscopic removal during placement	• Esopphageal rupture requiring surgery (Europe) • Esophageal rupture resulting in sepsis and ultimately death (Mexico) • Other: _____

E: Extension of Consent: I understand that I must return to my phscian's office to have the balloons removed 6

Patient Identification Label

Name: _____

MRN: _____

DOB: _____

Date of Service: _____

months after the first balloon is placed or there are increased risks of serious injury. I understand that I must contact my physician immediately if I plan to change my permanent residence elevation of 4,000 feet higher than my physician's office or an elevation of 2,500 ft lower than my physician's office. I understand the increased risks of the device if I become pregnant during the balloon therapy and I do not intend to become pregnant in the next 6 months. I understand that I must not bite the catheter during the balloon administration procedures and doing so would require an early endoscopic removal. I understand that in the course of my Obalon Balloon System treatment, my provider may discover other or different conditions, which may require modification of the planned Obalon Balloon System regimen. I authorize my health care providers to modify my Obalon Balloon System regimen, as they deem necessary and advisable in their professional judgment, if the reason for such change is discussed with me prior to the change. I also understand that my physician may stop Obalon Balloon System treatment if he/she determines that it is not benefiting me or that the risks of continued treatment outweigh the benefits.

F: No Guarantee: I understand that even though the Obalon Balloon System is being given to help me, Obalon Balloon System affects different people differently and may not work for me as planned. I acknowledge that no warranty or guarantee has been made to me about the results of the Obalon Balloon System.

By signing below I acknowledge that I fully understand this consent form, that a provider has satisfactorily explained the proposed Obalon Balloon System treatment to me, that I have been given the opportunity to ask questions and have had all of my questions answered to my satisfaction, and that I have all of the knowledge I currently desire. I am legally competent and have sufficient knowledge to give this voluntary and informed consent.

Patient's Name	Signature of Patient or Legally Authorized Representative	Date	Time
Provider Printed Name	Provider's Signature	Date	Time

IF PATIENT SPEAKS A LANGUAGE OTHER THAN ENGLISH OR IS COMMINCATIVELY DISABLED:

I have translated information on this form and explanation given orally by the physicians, using a language understood by this patient. To the best of my knowledge he/she understood this translation.

Interpreter's Printed Name	Interpreter's Signature	Date	Time