THE ALLURION GASTRIC BALLOON SYSTEM INFORMED CONSENT

DESCRIPTION

The Allurion Balloon is a temporary gastric balloon that promotes weight loss in overweight and obese individuals. The Allurion Balloon is a gastric balloon (also known as an intragastric balloon or IGB) that is enclosed in a Capsule and is swallowed by the patient to introduce the Balloon into the stomach. During swallowing, the proximal end of the Delivery Catheter remains outside of the patient's mouth to permit filling. Once the Balloon position has been confirmed to be in the stomach via X-ray, the Balloon can be filled with the provided Filler Kit. After filling, the Delivery Catheter is removed from the Balloon by gently pulling back. The filled Allurion Balloon is designed to remain in the stomach for approximately 16 weeks. However, the duration of balloon residence may vary between individuals. During this time, the Balloon operates in the same ways as other IGBs to promote satiety and reduce food consumption. The patient is supervised by a trained dietitian/ nutritionist that will ensure at least 4 follow-up visits during that period. At the end of the treatment period, the Balloon is designed to automatically open and drain. At this point, the empty Balloon is designed to transit the gastrointestinal tract and be excreted without further intervention. In some cases, the drained Balloon may exit the stomach via vomiting.

INDICATIONS

The indications for use of the Allurion Gastric Balloon System are to promote weight loss in overweight and obese individuals. The Allurion Gastric Balloon System is to be used in conjunction with a supervised weight loss nutrition program, provided by a nutrition professional trained by Allurion.

Allurion

KEY CONTRAINDICATIONS

Difficulty swallowing (dysphagia) :

- Any abnormal swallowing mechanism from an esophageal motility disorder (ex: achalasia, scleroderma, diffuse esophageal spasm).
- Any structural esophageal abnormality (ex: a web, stricture, diverticulum, or para esophageal hernia)

Conditions that predispose to bowel obstruction:

- Any history of:
  - Perforated appendicitis or any other perforated abdominal viscus
  - Actual, or suspected, bowel obstruction
- Crohn's disease
- - Small bowel surgery
  - Intraperitoneal adhesions
- Severe GI motility disorder (example: severe gastroparesis)

Conditions that predispose to gastric perforation:

- Any history of:
  - Previous bariatric, gastric or esophageal surgery
  - Laparoscopic band ligation
  - Anti-reflux surgery

GI bleeding or conditions that predispose to GI bleeding:

- History of vascular lesions (ex: esophagial gastric or duodenal varices, intestinal telangiectasias)
- Recent history of inflammatory conditions (ex: esophagitis, gastritis, gastric ulceration or duodenal ulceration)
- Benign or malignant GI tumors
- Inability to discontinue use of NSAIDs (or other gastric irritants) during the device period
- Use of anticoagulants
- Severe coagulopathy
- Hepatic insufficiency or cirrhosis
- Inability or unwillingness to take PPI medication

Other conditions:

- Serious or uncontrolled psychiatric illness
- Diagnosed bulimia, binge eating, compulsive overeating, or similar eating-related psychological disorder
- Alcoholism or drug addiction
- Pancreatitis
- Symptomatic congestive heart failure, cardiac arrhythmia or unstable coronary artery disease
- Pre-existing significant respiratory disease (ex: COPD, severe sleep apnea, cystic fibrosis)
- Cancer
- Known or suspected allergies to polyurethane
- Pregnant or nursing women
- An existing gastric balloon that is currently in the stomach
- Inability or unwillingness to take prescribed antiemetic medications.

OBJECTIVES

To provide weight loss results from the Allurion program, provided by healthcare professionals and adapted to your needs.

FOLLOW-UP

To optimize your weight loss as well as the management of weight-related diseases, you will follow a specific program to help change your life habits and re-equilibrate your daily diet. This program may help achieve long-term results.

RESULTS

Clinical evaluation of the Allurion Balloon suggests that on average, patients lose approximately 10-15% of their starting total body weight. Individual results vary and a small number of patients may not experience any weight loss. If weight loss achieved is less than desired after the first balloon, and the patient still qualifies and is not contraindicated, a sequential Allurion Balloon may be placed.

RISKS AND SIDE EFFECTS

After balloon placement, certain side effects are normal and expected:

Common:	Uncommon:
Nausea	Chest Pain
Vomiting	Constipation
Abdominal pain	Diarrhoea
Abdominal cramps	Fatigue
Esophageal reflux	

During balloon residency, other adverse events and complications may arise:

	Approximate incidence rates based on most recent vigilance reporting
Premature deflation (<90 days)	0.4%
Intolerance (endoscopic removal)	0.18%
Hyperinflation	0.07%
Small bowel obstruction	0.06%
Gastric outlet obstruction	0.02%
Gastric perforation	0.02%
Pancreatitis	0.02%
Dysphagia	0.01%
GI bleed	0.01%
Delayed intestinal transit	0.01%

Other possible adverse events are listed below:
Insufficient or no weight loss, Adverse health consequences resulting from weight loss, Abdominal distention with or without discomfort, Gastritis, Gastric or duodenal ulcers, Mallory-Weiss tear, Mucosal laceration, Difficulty breathing, Dehydration, Halitosis, Infection, Allergic reaction, Adverse tissue reaction, Aspiration, aspiration pneumonia, Death.

This list is non-exhaustive and other adverse events that are not listed here may arise.

WARRANTY

In the event of certain adverse outcomes, Allurion has put in place a best-in-class warranty program.

ALTERNATIVES

Alternative treatment options include the conventional surgical procedures to treat your excess body weight. In addition, there are non-invasive alternative treatments such as endoscope procedures which place devices into the stomach, lifestyle therapy and weight loss medications. Your doctor has advised you on the suitability for other options.

By signing below I acknowledge that I fully understand this consent form, that a provider has satisfactorily explained the proposed Allurion Gastric 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 COMMUNIINCATIVELY 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 Printed Signature	Date	Time