Allurion
PROGRAM

Allurion Gastric Balloon System
Patient Information Guide

Rx Only
Allurion Technologies

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Glossary

- **Adverse Event:** Any uncomfortable, painful, or distressing medical occurrence experienced by a patient.
- **Allurion Gastric Balloon System (or "Allurion Balloon"):** A balloon-shaped device filled with liquid designed to aid in weight loss by occupying space in the stomach.
- **Anesthesia:** Drugs used to block pain in part of the body or to make you sleepy or feel sleepy, so you don't feel pain during a medical procedure.
- **Balloon Intolerance:** When the body does not adapt to the balloon, leading to ongoing nausea and vomiting that doesn't improve with medication. In such cases, early removal of the balloon may be necessary.
- **Body Mass Index (BMI):** A calculation based on height and weight that helps determine if someone is underweight (BMI less than 18.5 kg/m^2), at a healthy weight (BMI 18.5 to less than 25 kg/m^2), overweight (BMI 25 to less than 30 kg/m^2), or has obesity (BMI 30.0 kg/m^2 or greater).
- **Bowel Obstruction:** A potentially serious condition where the intestines become blocked, preventing food and liquids from moving through the digestive system.
- **Clinical Study:** A structured research trial that evaluates new medications or medical devices to determine their safety and effectiveness.
- **Diet and Exercise Program:** A plan provided by your doctor that includes regular physical activity (like brisk walking) and a nutritious, low-calorie eating routine.
- **Dietitian:** A medical professional trained to guide people in choosing foods that support good health and well-being.
- **Endoscopy:** A medical procedure that lets a doctor view the inside of your esophagus and stomach using an endoscope—a flexible tube with a camera at the tip, which displays images on a video monitor.
- **Esophagus:** The muscular tube that carries food, drinks, and saliva from your mouth down to your stomach.
- **Gastric:** Related to or involving the stomach.
- **Gastric Banding:** A surgical method for weight loss where a rubber-like band is placed around the upper part of the stomach to reduce how much food it can hold.
- **Gastrointestinal (GI) Tract:** The digestive pathway that runs from your mouth to your anus, including the esophagus, stomach, and intestines.
- **Gastroesophageal Reflux:** A condition where stomach contents or acid move backward into the esophagus, often causing irritation, heartburn, and other symptoms.
- **Procedure:** A series of actions or steps carried out to achieve a specific goal, such as losing weight.
- **Proton Pump Inhibitor (PPI):** A type of medication that lowers the amount of acid produced in the stomach.
- **Sedation:** Medicine given to help you feel calm, drowsy, or lightly asleep during a medical procedure or test.
- **Serious Adverse Event:** An adverse reaction to a treatment that causes death, puts someone's life at risk, leads to a hospital stay, causes lasting problems, or affects a baby during pregnancy.

- **Side Effect:** An unwanted or unexpected reaction that can happen because of a medical treatment.
- **Target:** A specific goal you're aiming to reach, like a certain weight loss amount.
- **Ulcer:** An open sore that can develop in the lining of the stomach or small intestine, often caused by irritation from acid or medical devices.

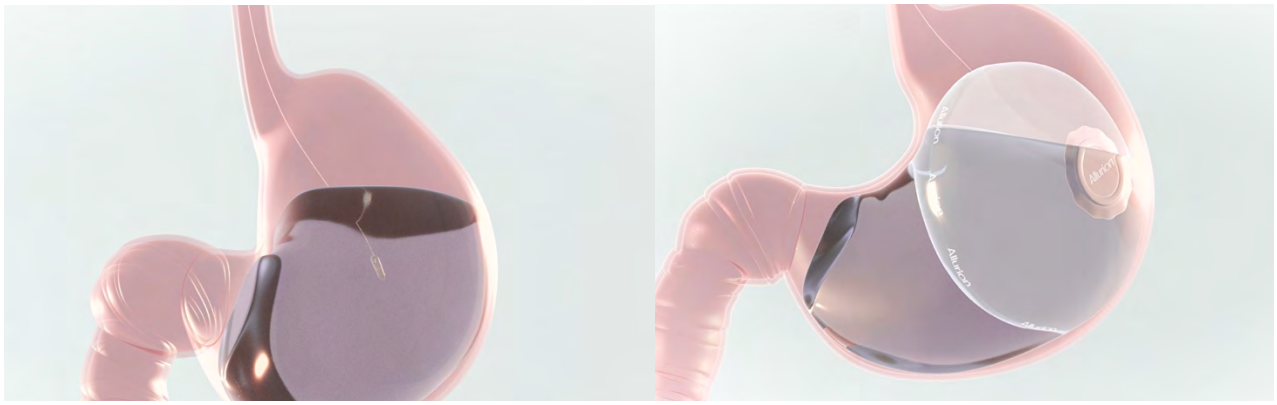
What is the Allurion Balloon?

The Allurion Balloon is a gastric balloon (also known as an intragastric balloon or IGB) that promotes short-term limited weight loss in individuals with obesity. It is made from polyurethane, a material that is much thinner and more flexible than the silicone material in endoscopic balloons. The Allurion Balloon is enclosed in a Capsule that is composed of a vegetarian, non-animal derived, degradable material that encloses the balloon.

The Capsule is swallowed by the patient to introduce the Allurion Balloon into the stomach. The filled Allurion Balloon is designed to remain in the stomach for approximately 16 weeks. During the AUDACITY Study, the balloon remained in the stomach for a little over 15 weeks.

During this time, the Allurion Balloon operates in the same ways as other IGBs to promote satiety and reduce food consumption.

At the end of the treatment period, the Allurion Balloon is designed to automatically open and drain. At this point, the empty Allurion Balloon is designed to transit the gastrointestinal tract and be excreted without further intervention. In some cases, the drained Allurion Balloon may exit the stomach via vomiting.



The Allurion Gastric Balloon System (AGBS) consists of up to 2 Allurion Balloons placed during a 10-month period. The second Allurion Balloon is placed approximately 24 weeks after the initial balloon placement or two months after the initial balloon passes, whichever comes first.

The AGBS is designed to promote short-term limited weight loss as part of a moderate intensity lifestyle modification therapy program that lasts for a minimum of 10 months, to which you must be fully committed to changing your eating habits and increasing your physical activity. You may not lose weight if you do not follow the program.

Who Can Get the Allurion Balloon

The Allurion Balloon is a medical device indicated for short-term limited weight loss treatment in adults between 22 years and 65 years old who live with excess weight or obesity with a body mass index (BMI) from 30 to 40 kg/m^2 who have had at least one unsuccessful attempt at a weight loss program The indwelling time for the AGBS is variable with an average observed time of 15.3 weeks. The Allurion Gastric Balloon System is to be used in conjunction with a moderate intensity lifestyle modification therapy program. The AGBS consists of up to two Allurion Balloons placed during a 10-month period.

If you are interested, discuss it with your doctor to carefully evaluate both the risks and benefits of the treatment and to confirm that this solution is suitable for you.

Eligibility for the placement of an Allurion Balloon will be assessed by a certified doctor after an initial consultation and a careful review of your medical history.

Who Cannot Get the Allurion Balloon (Contraindications)

You are NOT a candidate for the Allurion Program if you have one of these conditions:

Difficulty swallowing (dysphagia):

- Any abnormal swallowing mechanism from an esophageal motility disorder such as achalasia, which is trouble getting food into the stomach,

scleroderma, which is a tight esophagus leading to difficulty swallowing, or diffuse esophageal spasm
- History of any structural esophageal abnormality such as a web, stricture, diverticulum, or para esophageal hernia

Conditions that predispose to bowel obstruction:
- History of perforated appendicitis or any other perforated abdominal viscus
- Crohn's Disease
- Severe GI motility disorder such as severe gastroparesis
- Any history of actual, or suspected, bowel obstructions or small bowel surgery
- Any history of intraperitoneal adhesions, which are bands of scar tissue that cause organs to stick together

Conditions that predispose to gastric perforation:
- History of any previous bariatric, gastric or esophageal surgery
- History of previous laparoscopic band ligation
- History of anti-reflux surgery
- Underlying thrombotic disorder

GI bleeding or conditions that predispose to GI bleeding:
- Recent history of inflammatory conditions such as esophagitis, gastritis, gastric ulceration, or duodenal ulceration
- History of vascular lesions such as esophageal varices, gastric or duodenal varices, or intestinal telangiectasias, which are tiny blood vessels that can bleed easily
- Benign or malignant gastrointestinal tumors
- Inability to discontinue use of non-steroidal anti- inflammatory drugs (NSAIDs) or other gastric irritants during the device period
- Patients receiving anticoagulants
- Patients receiving chronic high dose steroids
- Severe coagulopathy or underlying thrombotic disorder
- Hepatic insufficiency or cirrhosis
- Inability or unwillingness to take prescribed proton pump inhibitor medications in preparation for and/or during device indwelling

Other conditions:
- Serious or uncontrolled psychiatric illness
- Diagnosed bulimia, binge eating, compulsive overeating, or similar eating-related psychological disorders
- Alcoholism or drug addiction
- Pancreatitis
- Symptomatic congestive heart failure, cardiac arrhythmia, or unstable coronary artery disease
- Pre-existing significant respiratory disease such as chronic obstructive pulmonary disease (COPD), severe sleep apnea, or cystic fibrosis
- Cancer, unless in complete remission
- Known or suspected allergies to polyurethane
- Inability or unwillingness to take prescribed anti-nausea medications in preparation for and/or during device indwelling

- Women who are pregnant or nursing
- Placement of a new device when a gastric balloon was in the stomach less than 2 months ago
- An existing gastric balloon that is currently in the stomach

Things you must consider (Warnings and Precautions)

- Always tell your health care providers that you have an Allurion Device and show them your Patient Information Card. If they do not know that you have an Allurion Device, they may not be able to treat you correctly
- Tell your doctor if you experience these sensations before the end of the 4-month balloon indwelling: you no longer feel full after eating, you are hungrier between meals than before you received the Allurion Device, or you gain weight. If this happens to you, your balloon may have deflated early. An early deflated balloon can stop food from passing. This may lead to stomach pain and swelling, throwing up, constipation, or even cause death. Your doctor can check to see if the deflated balloon has moved. If it has, you will need to be watched clo sely to see if it passes in your stool. Or you may need an operation to remove it.
- It is important to note that the Allurion Gastric Balloon may cause adverse events, some of which may require removal by endoscopy. Rare cases of spontaneous hyperinflation, s mall intestine obstruction, stomach dilation, esophagitis, pancreatitis, or stomach perforation have been reported, requiring surgical intervention. Please consult the full list of potential c omplications in the section 'Risks of the Allurion Balloon System'.
- Each patient should be instructed regarding the symptoms of gastrointestinal obstruction, ulceration, and other potentially severe complications, and should be advised to contact his/her physician or health care provider (HCP) immediately upon the onset of such symptoms.
- Patients should be available to follow-up with their physician throughout the therapy period, particularly if they experience symptoms including but not limited to persistent nausea, vomiting, dehydration, and/or abdominal pain.
- The Allurion Gastric Balloon is not suitable for all patients. Pregnant individuals or those with a history of esophageal or stomach surgery, among others, are not eligible for the procedure. The complete list of contraindications can be found in the device's instructions for use provided to doctors. Your doctor will review your medical history and conduct a physical examination to confirm your eligibility for the Allurion Program.
- It is crucial that each doctor and patient carefully assess the risks and benefits of the treatment before using the Allurion device. To learn more about the Allurion Balloon, its effectiveness, and its tolerability, discuss it with your doctor.
- You must be available for follow-up with your doctor throughout the treatment period, especially if you experience the following symptoms, including but not limited to: persistent nausea, vomiting, dehydration, and/or abdominal pain. If you consult other healthcare professionals, inform them that an intragastric balloon is present.
- We encourage you to stay close to modern emergency care facilities during the time the balloon is in place, in case serious complications arise.

How clinical studies were done

A clinical study, called the AUDACITY Study, included 524 Patients at 17 sites in the United States. Patients either had the Allurion Gastric Balloon System, accompanied by a moderate intensity lifestyle modification therapy program or received a moderate intensity lifestyle modification therapy program only, for 10 months. The patients in the Allurion Gastric Balloon System group received up to two balloons, each with an average 4-month indwelling time, placedover a 10-month period. The patients who received the Allurion Gastric Balloon System versus the patients receiving a moderate intensity lifestyle modification therapy program only were assigned to their treatment by chance.

261 patients received the Allurion Gastric Balloon System plus a moderate intensity lifestyle modification therapy program and 263 patients received only a moderate intensity lifestyle modification therapy program. All the balloons lasted for an average 4 months.

The clinical study patients were all between 22-65 years old with a BMI between 30-40 kg/m^2. Patients were not allowed to be in the clinical study if they ever had weight loss surgery or said that they would not or could not follow the moderate intensity lifestyle modification therapy program, or if they were pregnant or breastfeeding. All clinical study patients had 2 to 4-week follow-up visits for 10 months where the doctor's staff collected information on weight loss and side effects. The patients also received a moderate intensity lifestyle modification therapy program to help them eat smaller amounts of food, reduce total calories, and exercise regularly.

Risks of the Allurion Balloon System

It is essential to inform potential patients about the benefits and risks of gastric balloons and the Allurion Device prior to treatment. The physician must communicate all contraindications, precautions, warnings, and complications listed in these instructions.

The physician must make it clear to the patient that treatment with a gastric balloon may result in complications and that severe complications have resulted in interventions, including both endoscopic and surgical interventions, to puncture or remove the device. Complications may occur at any time during treatment and physicians should encourage patients to maintain access to modern emergency healthcare facilities during Allurion Device treatment should serious complications occur.

A serious side effect (serious adverse event) are health problems that:

1. Led to death;
2. Led to serious deterioration in the health or the subject that either resulted in:
    a. A life-threatening illness or injury
    b. A permanent impairment of a body structure or a body function
    c. In-patient or prolonged hospitalization (>24hrs), or

d. Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function; or

3. Led to fetal distress, fetal death or a congenital abnormality or birth defect.

In the US study, there were a total of 15 serious adverse events that were assessed as related to the Allurion Device treatment occurring in 8 patients who received the second balloon. There were no serious adverse events reported with the first balloon.

Serious Side Effect (Serious Adverse Event)	Harm	Number of Patients who had the side effect out of 264 (%)	Number of patients who had their balloon removed because of the serious side effect
Nausea	Uneasy feeling in the stomach or feeling like you need to throw up	3 (1.1%)	3 out of 3
Vomiting	Possible dehydration or chemical imbalance	4 (1.5%)	4 out of 4
Gastric perforation	Injury or hole in the stomach requiring surgery, if untreated, can lead to infection and possible death.	1 (0.4%)	1 out of 1
Gastric ulcer	Pain/Drop in blood count/Weakness	1 (0.4%)	1 out of 1
Hematemesis	Vomiting blood or material that resembles coffee grounds.	1 (0.4%)	1 out of 1
Gastric obstruction	Balloon blocking the stomach leading to food backup and vomiting. Will require endoscopic removal, if untreated, can lead to stomach perforation.	3 (1.2%)	2 out of 3
Metabolic alkalosis	Increase in blood pH that can be caused by vomiting	1 (0.4%)	1 out of 1
Acute kidney injury	Sudden decline in kidney function	1 (0.4%)	1 out of 1

Other, possible serious side effects (serious adverse events) of the Allurion Balloon (including those related to endoscopy or sedation) which were not reported in the clinical study of 264

patients but did occur in other studies or commercial use are listed in the table below. It is unknown what adverse events may develop and how many patients may develop them. In this study, we did not observe some adverse events we thought were possible. The harm possible from them and their frequencies are unknown based on this clinical trial. It is unknown whether they will happen and how often they will happen with more widespread use of the Allurion balloon:

Possible Serious Side Effect (Serious Adverse Event)	Harm
Esophageal obstructions	Balloon blocking the esophagus leading to food backup and vomiting. Will require endoscopic removal, if untreated, can lead to esophagus perforation.
Small bowel obstruction	Balloon causing blockage of small intestine resulting in distention and backup of food. May require surgery, and if untreated, can lead to serious harm including death.
Esophageal or intestinal trauma perforation	Injury or hole in the esophagus or in the lower GI track requiring surgery, if untreated, can lead to infection and possible death.
Pancreatitis	Inflammation of the pancreas, if severe, can lead to death.
Stomach dilation	Poor stomach contraction leading to enlargement of the stomach. If untreated, can lead to stomach perforation, infection, and possible death.
Esophagus or duodenal ulcers and erosions	Disruption of the lining of GI tract can lead to bleeding or perforation. May require endoscopy or surgery and if untreated, can possibly lead to death.
Esophageal tear	Can lead to bleeding or perforation, may require endoscopy or surgery.
GI bleeding	Bleeding in the GI tract from any cause may require endoscopy or surgery. If untreated, can possibly lead to death.
Aspiration	Entry into the respiratory tract of the stomach contents or the balloon can lead to lung infection, respiratory arrest, or death.
Allergic reactions	Allergy to any of the balloon components can cause rash, hives, wheezing, difficulty breathing, a sudden drop in blood pressure, sweating, fast heartbeat, and swelling around the mouth, throat, or eyes. Severe allergic reactions can lead to death if not treated right away.
Cardiac or respiratory arrest	Chest pain, fast or slow heartbeat, difficulty breathing. If untreated, can lead to death.
Migration of device	Before complete deflation of the balloon, it passes into the esophagus or intestine.
Death	N/A

Other procedure or device-related side effects (adverse events) of the Allurion Balloon not leading to hospitalization reported during the clinical study:

Side Effect (Adverse Event)	Number of Patients who had the side effect out of 264 (Rate)	Harm
Gastrointestinal disorders	260 (98.5%)	Nausea, vomiting, reflux, ulcers, or intestinal obstruction
Abdominal discomfort	39 (14.8%)	Cramping, bloating, nausea, or pain from stomach lining irritation
Abdominal distension	43 (16.3%)	Stomach feels full of gas and swollen
Abdominal pain	204 (77.3%)	Unpleasant or painful feeling in the stomach that can prevent you from doing your normal activities.
Abdominal pain upper	11 (4.2%)	Irritation or cramping causing gastric pain
Constipation	73 (27.7%)	Having hard and/or infrequent bowel movements
Diarrhea	71 (26.9%)	Can cause a loss of body water and salts
Indigestion	56 (21.2%)	Stomach feels full of gas, burping, pain or discomfort in the throat
Burping / Belching	48 (18.2%)	None
Hiccups	8 (3.0%)	None
Flatulence	18 (6.8%)	Bloating/Need to pass gas
Gastritis	2 (0.8%)	Stomach lining inflammation, pain, nausea, and risk of ulcers
Gastrooesophageal reflux disease	34 (12.9%)	Acid reflux or esophageal irritation
Nausea	253 (95.8%)	Uneasy feeling in the stomach or feeling like you need to throw up
Retching	97 (36.7%)	Scratchy, painful throat/Possible minor bleeding
Lightheadedness	1 (0.4%)	Can lead to nausea and fainting
Vomiting	142 (53.8%)	Can lead to a loss of body water and salts or liquid going into lungs

There was one case of hyperinflation, which is an increase in volume of the balloon that can cause abdominal discomfort, pain, nausea, vomiting, and if not removed, potentially lead to stomach

perforation. This hyperinflation did not lead to a serious adverse event and was resolved after endoscopic removal of the balloon.

There are other potential occurrences that are not deemed as adverse events but may occur with the Allurion Balloon.

Event	Description
No or insufficient weight loss	None
Early deflation	Balloon passage in less than 90 days

In the clinical study of 264 patients, the most common side effects (adverse events) of the Allurion Balloon were gastrointestinal disorders, vomiting, nausea, and abdominal pain.

If you have nausea and vomiting, it can be treated with anti-nausea medications. If your symptoms are more severe, fluids may be given to you through a needle in your vein. If you have abdominal pain, your doctor will prescribe pain medications as needed to control the pain. If you cannot tolerate your symptoms, you can always choose to have the balloon taken out before 4 months. In the clinical study, 2 out of 261 patients asked to have their first balloon taken out before the 4 months had passed, and 6 out of 185 patients asked to have their second balloon taken out before the 4 months had passed.

Benefits of having the Allurion Balloon

The benefits of the Allurion Balloon were tested in the AUDACITY study in the United States. The study looked at people with a BMI between 30 and 40 kg/m^2. People in the study received the Allurion Balloon along with a moderate intensity lifestyle modification therapy program. They were compared with people who only used a moderate intensity lifestyle modification therapy program. The people who only used a moderate intensity lifestyle modification therapy program are called the Control group. Both groups had regular doctor visits during the study.

The Allurion Balloon was shown to help patients lose weight. On average, patients who received the Allurion Balloon along with a moderate intensity lifestyle modification therapy program lost 2.2 times[1] more weight at Week 48 than patients who just received a moderate intensity lifestyle modification therapy program alone.

The results of the AUDACITY trial demonstrate weight loss at 6 months and 10 months that exceed the 3%-5% reduction in body weight recommended by the American Heart Association /

[1] The AUDACITY Study. 48-week LOCF results in mITT population. Data on File (2025).

American College of Cardiology / The Obesity Society and fall within the range of the 5%-10% sustained weight reduction at 1 year that correlates to more durable long-term health benefits.

Both groups of patients in the study answered questions about their quality of life at baseline (before treatment) and at Week 48. Overall mean score and domain sub-scores increased more in the Allurion Balloon group compared to the Control group, with statistically significant differences in the Overall score and Physical Function and Self-Esteem sub-scores.

Both groups of patients in the study also answered questions regarding their eating behaviors at baseline (before treatment) and at Week 32. In the Allurion Balloon group, there were significant improvements in cognitive restraint and decreases in emotional and uncontrolled eating.

How to decide if Allurion is right for you

Allurion may be right for you if you are between 22 and 65 years old, have a body mass index (BMI) between 30 and 40 kg/m², and have not been able to lose enough weight through diet and exercise alone.

To achieve the best results with the Allurion Balloon and maintain your weight loss after it passes naturally, it's essential to continue following a doctor-recommended moderate intensity lifestyle modification therapy program. Without lasting changes to your eating habits and lifestyle, weight regain is likely. Before choosing the Allurion Program, make sure you're ready to reduce your total calorie intake, eat smaller portions, and exercise regularly.

Be sure to ask your doctor about other weight loss options. The Allurion Program is one of several treatment choices. Others include diet and exercise plans, prescription medications, and — for those who qualify — surgical procedures such as gastric banding, gastric bypass, or sleeve gastrectomy. Discuss your options with your doctor to choose the one that best fits your needs.

What are the first steps to use the Allurion Balloon

Your doctor will review your medical history to help determine whether the Allurion Program is a good option for you. As part of the process, you'll be given a practice capsule that looks and feels like an Allurion Balloon. This test is to ensure you can swallow the capsule that contains the actual balloon. This practice capsule is composed of a vegetarian, non-animal derived, degradable material.

You will also be prescribed medications to help reduce stomach cramps, nausea, vomiting, and stomach acid during treatment. It's recommended that you fill all prescriptions before your procedure.

At this stage, you will also meet with a dietitian to receive personalized guidance on a moderate intensity lifestyle modification therapy program while using the Allurion Balloon System. These recommendations will be tailored to your individual needs.

Before the placement, take the medication prescribed by your doctor as directed. Make sure to drink plenty of fluids throughout the day. Have a light dinner the night before your appointment, ensuring that it takes place at least eight hours prior. Prepare your pantry in advance with foods that align with your post-placement dietary needs—your dietitian can advise you on what to buy and prepare. Plan your travel to the clinic; since no sedation is involved, you can even drive yourself. Finally, arrange for a friend or family member to check in on you after the placement.

How is the Allurion Balloon placed in your stomach

Take the medication prescribed for you by your doctor. You should drink only clear liquids, such as water or herbal tea, up until two hours before your appointment. After that, stop drinking to help ensure you're more comfortable during the placement.

Avoid wearing lipstick, lip balm, or a necklace, as these can interfere with the placement process. Plan to arrive at your clinic 15 minutes before your scheduled appointment and check in at reception. You will then review and sign your consent form.

The Allurion Balloon comes in a capsule with a thin tube. Under your doctor's supervision, you will swallow the capsule, which is attached to a thin tube. You will hold the tube in place, or dressing tape can be applied to the tube and affixed to the face to hold it in place. A quick X-Ray is performed to make sure the balloon is in the stomach. The balloon is then filled with water through the tube, and after X-Ray confirmation the tube is removed, completing the process. Getting the Allurion Balloon takes an average of 12-13 minutes. If the capsule cannot be swallowed, a thin wire called the Allurion Stylet can be used to gently assist during swallowing—still without endoscopy or anesthesia. In rare cases, the Allurion Balloon may require endoscopic or surgical intervention for removal.

Once the capsule is confirmed to be in your stomach, your doctor will use the thin tube to fill the balloon with water. Once the balloon is filled, you will have a second X-Ray to confirm the balloon is filled. The doctor will then gently remove the tube, and the balloon will remain in your stomach.

What happens after the Allurion Balloon is placed in your stomach

If everything goes smoothly with the placement of the balloon, you'll be able to leave immediately and continue with your day. Over the next couple of days, it's normal to feel nauseous and fatigued, but your doctor and dietitian will help you manage any symptoms you experience.

Be sure to take the medication your doctor has prescribed. In the first few days following placement, you'll need to reintroduce food gradually. Your dietitian will guide you through this process and tailor the progression to your needs.

It's important to stay well hydrated, so drink plenty of fluids. Your dietitian can advise you on how much fluid you should aim to drink and what you're likely to be able to manage during this period.

If you feel well and are staying hydrated, gentle walking is fine after placement. However, you should avoid more strenuous physical activity, such as sports, for at least one week—wait until any symptoms have completely resolved. Additionally, avoid flying or traveling long distances for 7 to 10 days after the procedure.

The Allurion Balloon is designed to empty and pass naturally out of your body at around 4 months, although this can sometimes be earlier or later. You may experience stomach cramps and diarrhea when this happens. If so, don't worry. This will pass quickly. Most people don't notice the passing of their Balloon, but in rare cases the Balloon may be vomited.

When to call your doctor

Once your balloon is in place it is important that you tell your doctor if anything listed in this section happens to you. This will help you get the right care. The Allurion Balloon may cause gastrointestinal complications that may require endoscopic or surgical intervention. Contact your placement doctor immediately if you experience any of these adverse effects. These symptoms may indicate a serious complication requiring prompt medical evaluation.

- Persistent nausea
- Severe vomiting
- Constipation with inability to pass gas
- Severe diarrhea
- Lack of urine or signs of dehydration
- Severe stomach or back pain
- Severe cramps or discomfort
- A stomach that feels full and tight, appears swollen or larger than usual
- Fever
- Gastrointestinal bleeding
- Difficulty breathing or moving around
- Any other unexpected symptom

In case of any emergency, consult a doctor as soon as possible. Always tell your healthcare professionals that you have Allurion Balloon and show them your Implant Card. If they do not know that you have the Allurion Balloon in your stomach, they may not be able to treat you correctly.

MRI Compatibility

The Allurion Balloon is MR Safe. You may undergo an MRI if needed. Please talk to your doctor first before getting the MRI.

Patient ID Card

After placement, your healthcare professional will give you an implant card on which the elements identifying the device, and its manufacturer appear. This card may also include a QR code referring to the information available to the doctor concerning the management of your health in the event of an adverse reaction. It is important that you always keep this card with you to inform other doctors and care providers that you have an Allurion Balloon in your stomach.