Allurion

INSTRUCTIONS FOR USE
Allurion™ Gastric Balloon System

Introduction

The Allurion Device is a temporary gastric balloon that promotes short-term limited weight loss in individuals with obesity. While weight loss may benefit patients treated with the Allurion Device, use of the Allurion Device also carries risks. Each physician and patient should carefully evaluate both the risks and benefits of treatment prior to use of the Allurion Device.

Physicians or appropriately trained health care professionals (HCPs) under physician supervision placing the Allurion Device must:

- Place the device in the same room as the X-Ray imaging
- Provide the patient with access to an endoscopy facility and an identified endoscopist should intervention be required to puncture or remove the device
- Provide the patient with access to a supervised nutrition program
- Be certified [physician] or trained [HCP] on the use of the Allurion Gastric Balloon System before placement of the Device
- HCPs may only place the Allurion Device under direct physical supervision of a certified physician

Communicating Risks and Benefits to the Patient

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.

Device Description

The Allurion Gastric Balloon System (AGBS) is comprised of the Allurion Device (Figure 1) which becomes the Allurion Balloon (Figure 2) when filled, the Allurion Filler Kit (Figure 3), and the Allurion Stylet (Figure 4). With the exception of the Filler Fluid, which is provided sterile, all components of the Allurion Gastric Balloon System are supplied non-sterile and for single use only. The Allurion Gastric Balloon System has been tested in conjunction with the Merit Medical 500 ml PIB500 Pressure Infusor Bag (Pressure Infusor, Figure 5), which is to be used to aid in filling the Allurion Device and can be re-used if maintained per the manufacturer's instructions for use. The principal component of the Allurion Gastric Balloon System is the Allurion Device (Figure 1). The Allurion Device 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 Device into the stomach. During swallowing, the proximal end of the Delivery Catheter remains outside of the patient's mouth to permit filling. Once the Device position has been confirmed to be in the stomach, the Balloon can be filled with the provided Filler Kit. After filling, the Delivery Catheter is removed from the Device by gently pulling back. The filled Allurion Balloon is designed to remain in the stomach for approximately 16 weeks. During this time, the Balloon operates in the same ways as other IGBs to promote satiety and reduce food consumption. At the end of the treatment period, the Device 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.

The AGBS consists of up to 2 balloons placed during a 10-month period. The second Allurion Device is placed approximately 24 Weeks after the initial Allurion Device placement or two weeks after the initial balloon passes, whichever comes first. The residence time for each AGBS is variable with an average observed residence time of 15.3 weeks. The benefit -risk evaluation for the AGBS consists of up to two Allurion Balloons placed during a 10-month period. The positive benefit-risk determination considered the known risks and benefits of two sequential balloons as a more acceptable duration of benefit in this chronic disease.

The Allurion Device (Figure 1) is comprised of the following items:

- Balloon (Figure 2) constructed from thin film polymers.
- Capsule composed of a vegetarian, non-animal derived, degradable material that encloses the Balloon
- Delivery Catheter with proximal connector, radiopaque shaft, and shaft length markings

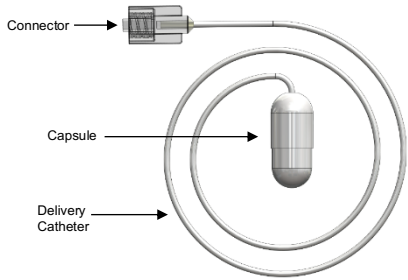

Figure 1: Allurion Device

Figure 2: Allurion Balloon

The Allurion Filler Kit (Figure 3) is comprised of the following items:

- Filler Bag containing sterilized Filling Fluid and a Septum Port to connect to the Extension Hose
- Extension Hose with a Flow Indicator, a Spike to pierce the Filler Bag Septum Port and a Blue Stopcock to connect to the Delivery Catheter
- A Syringe that, if needed, can be connected to the

Delivery Catheter and used to evacuate the Balloon in an emergency

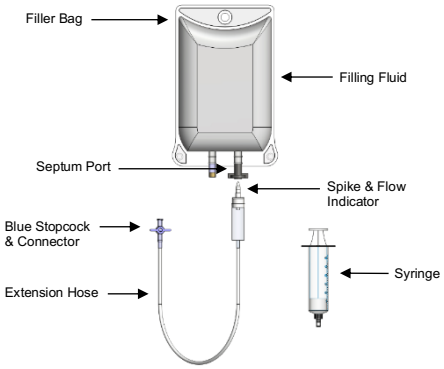

Figure 3: Allurion Filler Kit

The Allurion Stylet (Figure 4) is comprised of the following items:

- A stylet shaft with proximal connector. The Stylet, if needed, can be inserted into the Delivery Catheter to assist patient in swallowing the Device.

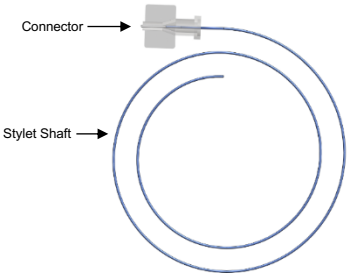

Figure 4: Allurion Stylet

The Pressure Infusor (Figure 5) manufactured by Merit Medical can be re-used per the manufacturer's instructions for use. The Filler Bag slides inside the Pressure Infusor and is hung on a hook prior to pressurization. The Pressure Infusor includes a White Stopcock that can be turned to deflate the Infusor.

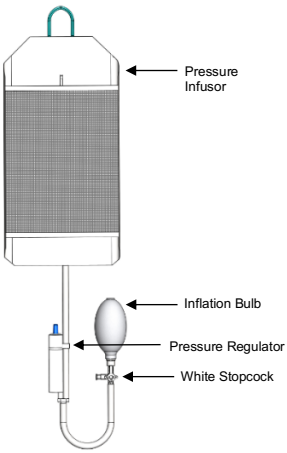

Figure 5: Pressure Infusor

Indications for Use

The Allurion Gastric Balloon System (AGBS) is indicated to promote short-term limited weight loss in adult individuals with obesity between the ages of 22 years and 65 years with a body mass index (BMI) ≥30 kg/m^2 and ≤ 40 kg/m^2 who have had at least one unsuccessful attempt at a weight loss program. The residence time for each AGBS is variable with an average observed residence time of 15.3 weeks. The AGBS 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.

Contraindications

Difficulty swallowing (dysphagia):

- Any abnormal swallowing mechanism from an esophageal motility disorder such as achalasia, scleroderma, 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

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
- 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 residence

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 antiemetic medications in preparation for and/or during device residence
- 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

Adverse Reactions and Complications
Potential adverse reactions and complications include, but are not limited to the following:
- Insufficient or no weight loss
- Adverse health consequences resulting from weight loss
- Nausea and/or vomiting
- Chest pain, Heartburn or GERD
- Esophagitis or esophageal ulcer
- Abdominal distention with or without discomfort
- Abdominal pain
- Gastritis
- Gastric dilation
- Gastric or duodenal ulcers
- Mallory-Weiss tear
- Mucosal laceration
- GI bleeding
- Difficulty breathing
- Dehydration
- Diarrhea
- Constipation
- Fatigue
- Halitosis
- Infection
- Allergic reaction
- Adverse tissue reaction
- Pancreatitis
- Aspiration, aspiration pneumonia
- Esophageal, gastric, intestinal or other organ trauma or perforation
- Esophageal, gastric, small bowel or large bowel obstruction
- Need for endoscopic, radiologic, or surgical intervention to repair organ trauma, perforation, obstruction or other complication
- Cardiorespiratory sequelae, such as anaphylaxis, myocardial infarction (heart attack), arrhythmia, cardiac arrest, and/or bronchial obstruction and respiratory arrest
- Unintended migration of the device
- Detachment of balloon during removal, tracheal aspiration, and respiratory arrest
- Spontaneous hyperinflation of the balloon. This may be asymptomatic or symptomatic. Symptoms may include abdominal pain, abdominal distention with or without discomfort, difficulty breathing, vomiting, or may cause gastric perforation
- Death
- Vasovagal response (feeling faint, lightheaded, and/or dizzy)
- Hiccups

Compatibility
- The Spike of the Extension Hose connects to the Septum Port of the Allurion Filler Bag
- The Blue Stopcock of the Extension Hose connects to the Delivery Catheter
- If needed, the Syringe connects to the Delivery Catheter
- If needed, the Stylet connects to the Delivery Catheter

Accessory Products Not Supplied
These products are not supplied by Allurion but may be used for the procedure based on physician preference and medical judgment:
- Disposable surgical gloves
- IV stand to hang Pressure Infusor
- Endoscope (if Balloon puncture or removal is required)
- Endoscopic aspiration needle and endoscopic grasping forceps designed for removal of intragastric balloons
- Carbonated water (to promote Capsule progression to stomach)

Warnings
- The Allurion Gastric Balloon System must be handled only with gloved hands.
- With the exception of the Pressure Infusor, do not re-use or sterilize devices. Discard after one treatment. Structural integrity and/or function may be impaired through reuse, cleaning, or sterilization.
- Refer to the Pressure Infusor manufacturer's instructions for use for information on the cleaning and care of the Pressure Infusor.
- Do not use more than one Allurion Device simultaneously during a single treatment period. The use of Allurion Devices simultaneously has not been investigated and may increase the risk of complications.
- Only the Allurion brand Stylet can be used with the Delivery Catheter. Use of other Stylets may result in patient injury or device damage.
- To avoid esophageal trauma, do not fill the Balloon until the Capsule is confirmed to be in the stomach with x-ray and/or fluoroscopy.
- Delivery Catheter length markings are approximate and for reference only. They cannot replace x-ray or

fluoroscopy to confirm device location.
- An ultrasound exam will not show the non-inflated device and cannot replace x-ray or fluoroscopy to confirm device location.
- Use only the indicated Pressure Infusor and follow all filling steps included in these instructions to fill the Allurion Device. Use of an alternate pressurization device, or manual pressurization, of the Fluid Bag may result in patient injury or device damage.

The warnings listed above are not the complete list of warnings associated with the Allurion Gastric Balloon System. For additional warnings, see **Recommended Procedure** section.

Precautions
- To reduce the intensity of post-placement symptoms such as nausea, vomiting and abdominal pain, antiemetic, antispasmodic, and anticholinergic drugs may be prescribed. If patients experience unusually severe or worsening symptoms, they should immediately contact their physician or health care provider (HCP).
- To prevent ulcers and gastroesophageal reflux, it is recommended that the patient start a program of oral proton pump inhibitors (PPIs) prior to Allurion placement so a maximal gastric acid suppression effect will be present on the day of placement. A PPI should be continued while the Allurion Balloon is in place.
- The early use of pro-kinetics, such as Domperidone and Metoclopramide, following placement may result in rare instances of gastric outlet obstruction. In addition, routine use of smooth muscle relaxants, such as Buscopan and Hyoscyamine, without a clear history of severe cramps is discouraged as it may precipitate gastric dilation and foot retention.
- Patients should maintain access to modern emergency healthcare during Allurion Device treatment should serious complications occur.
- Each patient should be instructed regarding the symptoms of gastrointestinal obstruction, ulceration, and other potentially severe complications, and should be advised to contact their 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.
- Before placement, inspect ⌛ (Use By) date. Device must not be placed in the patient after ⌛ (Use By) date.
- Store the Allurion Gastric Balloon System indoors at room temperature (approximately 20°C/70°F) in the original packaging. Prolonged exposure to sunlight, heat, or moisture may result in product damage.
- Inspect products for damage before use. Do not use products that have been damaged in any way. Damaged products may cause complications.
- Do not soak products in disinfectant prior to use.
- Do not autoclave products.

Recommended Procedure

1. Device and Patient Preparation

1.1. Confirm patient has not eaten solid food for at least 8 hours and liquids for at least 2 hours prior to the placement. Allurion Device is ready for the patient to swallow after it is removed from the packaging.

1.2. Hang Filler Bag inside Pressure Infusor with Filler Bag Septum Port pointing downward.

1.3. Hang Pressure Infusor on IV stand. See Figure 6.

1.4. Twist to remove the cover over the Septum Port. See Figure 7.

1.5. Confirm Blue Stopcock is closed. Pierce Septum

1.6. Port with Spike of Extension Hose. See Figure 8.

Figure 6: Filler Bag and Pressure Infusor on IV stand

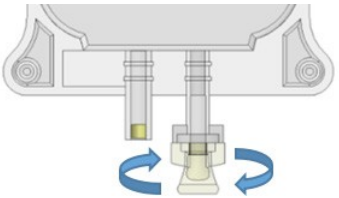

Figure 7: Removal of Septum Port Cover from Filler Bag

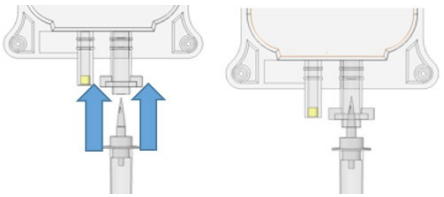

Figure 8: Filler Bag and Extension Hose Assembly

2. Allurion Device Delivery to Stomach

2.1. It is preferable to have patient sitting rather than standing during placement.

2.2. Have the patient take sips of water to lubricate the lips, mouth and throat. Place the Capsule on the very back of the tongue and have the patient swallow with large gulp of water.

⚠ Warning: Never anesthetize the oropharynx prior to swallowing the device. Anesthetizing the oropharynx by a spray or solution can lead to aspiration of water or the device and respiratory arrest.

Warning: Do not lubricate or wet the Capsule prior to swallowing. Lubricating or wetting the Capsule prior to swallowing may result in early capsule opening and patient harm.

2.3. Attempts at swallowing should not extend beyond 3 minutes to maintain integrity of the Capsule. If unable to swallow within this time, use alternative method described in 3.4, otherwise proceed to step 3.8.

2.4. Alternatively, the Allurion Stylet can be inserted into the Delivery Catheter and used to assist patient swallowing by guiding the Allurion Device past the oropharynx as the patient swallows. **Change gloves before touching the Stylet to prevent contamination.**

2.5. Insert the Allurion Stylet into the Delivery Catheter outside the patient with the Allurion Device hanging straight down. Ensure the Allurion Stylet connector is fully engaged and locked into the Delivery Catheter connector. See Figures 10a and 10b for Allurion Stylet assembly.

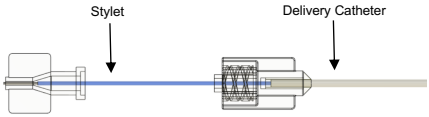

Figure 9a: Allurion Stylet entering Delivery Catheter

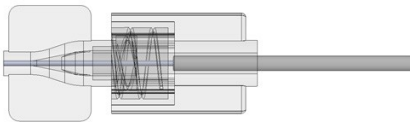

Figure 9b: Allurion Stylet and Delivery Catheter Connectors engaged

Warning: Carefully inspect the Capsule prior to engaging the Allurion Stylet. The Capsule must be fully intact before using the Allurion Stylet. Use of the Stylet with a damaged Capsule may result in Device damage and severe patient harm.

Warning: Do not wet or lubricate the Stylet. Lubricating or wetting the Stylet may result in Device damage and patient harm.

Warning: The Allurion Stylet must be fully inserted and locked into the Delivery Catheter prior to use. Use of a partially inserted Stylet may result in Device damage and severe patient harm.

2.6. The patient now rapidly swallows water and simultaneously the physician or HCP advances the Styleted catheter with the Allurion Capsule down into the esophagus. The capsule may be advanced all the way into the stomach as long as there is NO resistance during the passage. At this point, the three black stripes (see Figure 10) should be near the patient's lips.

Warning: Do not advance the Styleted catheter if there is any resistance during the passage. Use of force during passage may result in Delivery Catheter damage and severe patient harm.

Warning: If using the Stylet to assist the Delivery Catheter, the Delivery Catheter must only be used after the Stylet is completely inserted into the catheter and its hub is locked into the Delivery Catheter Connector. Use of a partially inserted Stylet can lead to severe patient injury.

Warning: Excessive force, indicated by crumpling or buckling of the Delivery Catheter may result in Delivery Catheter damage and severe patient harm.

2.7. Unlock the Allurion Stylet connector from the Delivery Catheter connector.

Warning: To avoid premature detachment of the Delivery Catheter from the Balloon, completely unfasten Stylet connector from Delivery Catheter prior to pulling Stylet out.

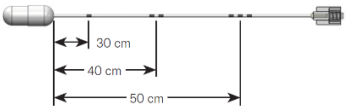

Figure 10: Delivery Catheter length markings (not to scale). Length dimensions are approximate.

2.8. If the stylet was not used during placement, have the patient drink water to facilitate distal esophageal transit of device into the stomach.

2.8.1. If moving the patient once the capsule is swallowed to the x-ray machine, a blue luer cap may be used to temporarily close the catheter to mitigate any catheter contamination during patient transport. After x-ray confirmation is complete remove blue luer cap prior to moving to step 3.

2.9. Confirm that the Capsule has reached the stomach with fluoroscopy and/or abdominal x-ray. Proper position is indicated if the Catheter, Capsule and/or Balloon radiopaque marker is visible in the stomach. The radiopaque catheter should be visible and directed towards the greater curvature of the stomach following removal of the stylet.

Warning: To avoid esophageal or duodenal trauma, do not fill the Balloon until the capsule is confirmed to be in the stomach with x-ray and/or fluoroscopy. Filling the Balloon outside the stomach may result in severe patient harm.

3. Allurion Device Filling

3.1. Remove the protective cap from the Blue Stopcock Connector.

3.2. Connect the Delivery Catheter to the Blue Stopcock Connector.

3.3. Open the Blue Stopcock. See Figure 11A.

3.4. Close the White Stopcock on the Pressure Infusor (Figure 11B). If the Pressure Regulator is in the "down" position (Figure 11C), click the blue button to set to "up" position (Figure 11D).

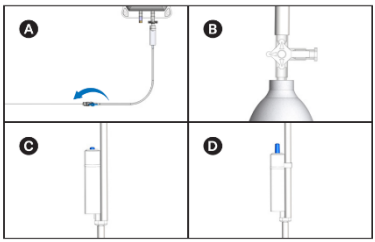

Figure 11: Stopcocks and Pressure Regulator Positions for Filling

3.5. Pump the Inflation Bulb until the pressure regulator indicates a pressure of 300 mmHg.

⚠ Warning: Use only the Filling Fluid provided with the Allurion Filler Kit to fill the Allurion Device. Use of other fluids, including methylene blue, may result in device damage and patient harm.

3.6. Maintain pressure at 300 mmHg until the Flow Indicator chamber shows a constant stream of fluid. Proceed to step 3.9 when flow begins. If the Flow Indicator shows only slow drops of fluid, the Capsule is not fully open. If the Flow Indicator does not show a constant stream of fluid within 10 minutes, proceed to the alternative filling method starting in step 3.7.

⚠ Warning: Lack of flow could be an indication that the Allurion Device is still in the esophagus. Be certain the Capsule is in the stomach before proceeding to alternate filling method in step 3.7. Filling the Balloon in the esophagus may result in severe patient harm.

3.7. Alternatively, under fluoroscopy determine if there is a kink in the Delivery Catheter. If a kink exists, pull back gently to straighten while making certain the Balloon is still in the stomach, and reinitiate filling. If a steady stream starts, continue to 3.9, if no steady stream continue to 3.8.

3.8. Move the Pressure Regulator to "down" position (Figure 11C) and increase pressure to 450 mmHg until the Flow Indicator shows a constant stream of fluid. If a steady stream starts, return the Pressure Regulator to the "up" position (Figure 11D) and continue to 3.9. If no steady stream, the Balloon must be endoscopically punctured, aspirated, and removed (See 5. Endoscopic Allurion Balloon Removal).

⚠ Warning: The syringe must never be used to help initiate or resume filling of the alloon. Use of the syringe during the filling process can damage the Balloon.

3.9. Pump the Inflation Bulb as needed during filling to maintain a pressure in the "green zone" of the Pressure Regulator. Continue filling until the Filler Bag is empty.

3.10. If at any point during filling it becomes necessary to stop filling and empty the Balloon, close the Blue Stopcock. Disconnect the Delivery Catheter from the Blue Stopcock Connector and connect it to the Syringe. Pull back on the Syringe to evacuate Filling Fluid. Partially filled Balloons must be endoscopically punctured, aspirated and removed. (See 5. Endoscopic Allurion Balloon Removal.)

3.11. If at any time filling slows or stops, proceed to directions starting in 3.13.

3.12. Confirm the Pressure Regulator pressure indicates a pressure of 300 mmHg. If the pressure is below 300 mmHg, pump the inflation bulb until 300 mmHg is reached. If Flow Indicator exhibits a constant stream, return to 3.9. If the Flow Indicator does not exhibit a constant stream, continue to 3.13.

3.13. Position the patient such that they are leaning over to the left or the right. If the Flow Indicator exhibits a constant stream, return to 3.9. If the Flow Indicator does not exhibit a constant stream, lean the patient to the other side. If the Flow Indicator does not exhibit a constant stream, continue to 3.14.

3.14. Have the patient take several slow, deep breaths. If the Flow Indicator exhibits a constant stream, return to 3.16. If the Flow Indicator does not exhibit a constant stream, continue to 3.15.

3.15. Physician or HCP should grip the Delivery Catheter close to the patient's mouth and gently pull and hold tension on the Delivery Catheter. If the Flow Indicator exhibits a constant stream, return to 3.9 while maintaining gentle tension. If the Flow Indicator does not exhibit a constant stream, continue to 3.16.

⚠ Warning: To avoid detachment of the Delivery Catheter from the Allurion Balloon, use only gentle tension. Use of rough tension may result in detachment of the Delivery Catheter, which may result in a partially filled Balloon. A partially filled Balloon must be endoscopically punctured, aspirated, and removed.

3.16. Click the blue button to the down position (See Figure 11C). Pump the Inflation Bulb until the Pressure Regulator indicates a pressure of 450 mmHg. If the Flow Indicator exhibits a constant stream, return to 3.9. If the Flow Indicator does not exhibit a constant stream, repeat 3.15 with the Pressure Infusor indicating 450 mmHg. If the Flow Indicator continues to not exhibit any flow, the Balloon must be endoscopically punctured, aspirated, and removed (See 5. Endoscopic Allurion Balloon Removal).

4. Allurion Balloon Detachment

4.1. After Filling Fluid has completely emptied from Filler Bag, close the Blue Stopcock (Figure 12A).

4.2. Rotate the White Stopcock to deflate the Pressure Infusor. Allow the Pressure Infusor to fully deflate (Figure 12B).

4.3. To limit fluid leakage from the delivery catheter a blue luer cap may be attached to the delivery catheter after disconnecting it from the filler kit extension hose.

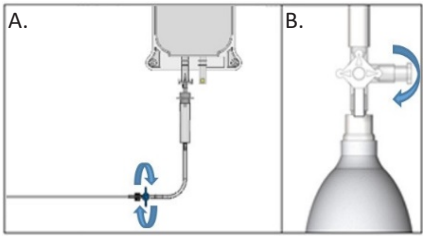

Figure 12: Stopcock Positions for Balloon Detachment

4.4. Confirm Balloon filling and position in the stomach by abdominal x-ray and/or fluoroscopy. The Catheter should remain attached to the Balloon while confirming x-ray is obtained. The radiopaque Catheter aids in locating the filled Balloon.

4.5. Gently but quickly withdraw Delivery Catheter from the mouth. The Catheter distal end will separate from Balloon Fill Valve. To avoid catheter snapping, use a hand-over-hand technique while removing the Catheter. Gripping the catheter close to the mouth prevents the Catheter from overstretching.

⚠ Warning: Do not detach Balloon from Delivery Catheter until complete Balloon filling is confirmed. Incomplete Balloon filling may increase the risk of unplanned migration and/or pyloric or intestinal obstruction.

⚠ Warning: Do not withdraw Delivery Catheter using high force. Movement against resistance may result in Balloon damage or patient harm.

4.6. After Balloon detachment and Delivery Catheter removal from the patient, visually inspect the Delivery Catheter for damage, as well as the presence of two black marks at the catheter tip. If damage is found, inspect for leaks by occluding the distal end of the catheter, filling the included syringe with tap water, connecting the syringe to the catheter hub, and manually compressing the syringe plunger. If leaks are observed or the two black marks are not present, indicating a broken catheter, the balloon must be removed endoscopically per step 5.

5. Endoscopic Allurion Balloon Removal

If required, the Allurion Balloon can be punctured endoscopically, aspirated, and extracted from the stomach. The most common reason for endoscopic balloon removal is balloon intolerance. This endoscopic procedure should be performed under general anesthesia after endotracheal intubation.

Other considerations related to endoscopic Allurion Balloon needle aspiration and removal:

- If a patient presents with, or reports abdominal pain/ discomfort, nausea, vomiting, and/or abdominal distention more than a week after balloon insertion, consider obtaining an abdominal x-ray with the patient standing upright. During normal filling a small amount of air can enter the Balloon. Hyperinflation should be suspected if a significant amount of gas is detected on imaging.
  - Regardless of balloon volume, physicians must use their best clinical judgment when deciding to either intervene or monitor closely.
  - If spontaneous hyperinflation is identified, the balloon will be punctured and aspirated completely via endoscopy using an aspiration needle and then removed from the stomach using forceps; care should be taken to minimize potential contamination with the ambient stomach fluid.
  - The liquid contents will be provided to the Sponsor in a sterile container for analysis.
  - The empty balloon will be removed through the mouth and returned to the Sponsor for investigation. .
- In the event of gastric outlet obstruction, management consists of nasogastric tube decompression of the stomach, followed by manually mobilizing and dis-impacting the balloon by pushing on the mid-abdomen, over the balloon, upwards and towards the patient's left shoulder. This maneuver will often dis-impact the balloon from the stomach antrum and move it into the stomach body. If this maneuver is unsuccessful, the balloon must be removed endoscopically.
- Allurion Balloon needle aspiration and removal is preferably performed after intubation using general anesthesia to minimize the risk of pulmonary aspiration. This approach also eliminates the risk of Balloon aspiration in case the Balloon inadvertently detaches from the grasper/forceps in the upper esophagus during endoscopic removal.

5.1. The preferred technique is to aspirate the fluid inside the Balloon completely and extract the collapsed Balloon through the mouth using an endoscopic aspiration needle and endoscopic grasping forceps designed for removal of intragastric balloons or foreign bodies in the stomach.
  - Any of the dedicated needles and graspers for intragastric balloons may be used, however a variceal injection needle is NOT recommended.
  - The endoscope and the needle must be perpendicular, not tangential, to the Allurion Balloon before puncture is attempted.

The tools and techniques described above are suggestions, but there may be other tools or techniques, including those used for endoscopically removed intragastric balloons, that may be acceptable for Balloon removal. Retrieval procedures in general should be conducted after proper training and per the tool manufacturer's instructions for retrieving foreign objects.

⚠ Warning: Use of endoscopic tools or techniques outside of the tool manufacturer's specifications may result in patient harm.

6. Percutaneous Needle Aspiration of Obstructing Balloon

6.1. Rarely an incompletely empty Balloon may cause obstruction in the small intestine. In some

instances, this has been successfully managed via percutaneous 22-gauge needle aspiration of the obstructing balloon under CT or ultrasound guidance. The physician must use their best clinical judgement when deciding to either intervene or monitor closely.

7. Laparoscopic Removal of Obstructing Balloon

7.1. Laparoscopic removal of an obstructing Allurion Balloon in the small intestine has been successfully performed by locating the Balloon, performing an enterotomy, aspirating and removing the Balloon, and closing the enterotomy. The physician must use their best clinical judgment when deciding to either intervene or monitor closely

8. Human Clinical Data with the Allurion Gastric Balloon System

The safety and effectiveness of the Allurion Gastric Balloon System is supported by data from The AUDACITY Study (AllUrion Device in Adults With Clinical ObesITY) (AUDACITY) (IDE G210294, NCT05368259).

Overview

The AUDACITY Study was designed to evaluate the safety and effectiveness of the Allurion Gastric Balloon System + Moderate Intensity Lifestyle Modification Therapy Program vs. Moderate Intensity Lifestyle Modification Therapy Program for the Treatment of Adults with Obesity. With regards to effectiveness, the AUDACITY Pivotal Trial had two (2) co-primary effectiveness endpoints: Co-Primary Effectiveness Endpoint 1: Treatment Group Responder Rate (RR) dichotomized at 5% TBWL at 48 weeks is significantly greater than 50% and Co-Primary Effectiveness Endpoint 2: Treatment Group mean %TBWL is significantly greater than Control Group mean %TBWL at 48 weeks, with a super superiority margin of 3.0%. The primary safety endpoint of this clinical investigation is the overall incidence of procedure or device-related Serious Adverse Events through 48 weeks.

Study Design:

The AUDACITY Study (AllUrion Device in Adults With Clinical ObesITY) (AUDACITY was a prospective, open-label, multi-center, randomized, pivotal Safety and Efficacy Study of the Allurion Gastric Balloon System + Moderate Intensity Lifestyle Modification Therapy Program vs. Moderate Intensity Lifestyle Modification Therapy Program for the Treatment of Adults with Obesity. The study followed subjects through 48 weeks follow up.

The 550 randomized subjects comprise the ITT population. Of these 550 subjects, 527 subjects (264 AGBS; 263 Control) comprise the Safety Population, having completed a Day 0 visit. Twenty-three (23) subjects (11 AGBS; 12 Control) exited from the study post-randomization, but prior to Day 0, due to reasons such as use of prohibited medications, inability to meet study follow-up requirements, elevated blood pressure leading to exclusion, and undisclosed personal reasons per the patient. These patients were excluded from the safety population.

The primary population for the effectiveness analyses is the mITT population which excludes any subject who was unable to swallow the Allurion device or any subject who was not able to start the MILMTP on Day 0. Three subjects failed to swallow the AGBS capsule on Day 0 and were excluded from the mITT population, leading to an mITT population of 524 subjects (261 AGBS; 263 Control).

The mITT population is the population for determination of benefit. Eleven out of 14 subjects excluded in the mITT population withdrew consent prior to attempting to swallow an Allurion device and only 3 subjects were not able to swallow the device and therefore did not start their assigned therapy.

Of the 397 subjects in both groups who completed through week 24, 367 completed the study through week 48. One hundred and eighty-five (185) AGBS subjects successfully received Allurion Balloon 2, representing 70.9% (185/261) of those receiving Allurion Balloon 1.

Study Population Demographics and Baseline Parameters

A summary of the subject demographics for all screened subjects and in the mITT population is provided in Table 1. There were no significant differences in age, gender, race or ethnicity between the AGBS group and the Control group in either of the analysis populations. Additionally, height and baseline weight and BMI are similar between the treatment groups.

Table 1: Baseline Demographics and Characteristics (mITT Population)

	Total Subjects (N=524)	Randomized to AGBS (N=261)	Randomized to Control (N=263)	P-values
Age				0.4699
N	524	261	263	
Mean	42.9	43.1	42.6	
SD	8.56	8.51	8.62	
Min, Max	22, 63	25, 59	22, 63	
Age, n (%)				1.0000
< 50 Years	386 (73.7)	192 (73.6)	194 (73.8)	
>= 50 Years	138 (26.3)	69 (26.4)	69 (26.2)	
Sex at birth, n (%)				1.0000
Male	46 (8.8)	23 (8.8)	23 (8.7)	
Female	478 (91.2)	238 (91.2)	240 (91.3)	
Race, n (%)				

	Total Subjects (N=524)	Randomized to AGBS (N=261)	Randomized to Control (N=263)	P-values
American Indian or Alaska Native	2 (0.4)	1 (0.4)	1 (0.4)	
Asian	8 (1.5)	7 (2.7)	1 (0.4)	
Black or African American	61 (11.6)	31 (11.9)	30 (11.4)	
Native Hawaiian or Pacific Islander	2 (0.4)	1 (0.4)	1 (0.4)	
White (Caucasian)	396 (75.6)	193 (73.9)	203 (77.2)	
Multiracial	7 (1.3)	4 (1.5)	3 (1.1)	
Not disclosed	2 (0.4)	1 (0.4)	1 (0.4)	
Other	46 (8.8)	23 (8.8)	23 (8.7)	
Ethnicity, n (%)				0.3645
Hispanic or Latino	131 (25.0)	70 (26.8)	61 (23.2)	
Not Hispanic or Latino	393 (75.0)	191 (73.2)	202 (76.8)	
Weight (lbs)				0.9087
N	524	261	263	
Mean	216.51	216.64	216.38	
SD	26.248	25.994	26.545	
Min, Max	156.0, 293.4	156.0, 293.4	159.5, 291.6	
BMI				0.7941
N	524	261	263	
Mean	35.55	35.58	35.52	
SD	2.758	2.772	2.749	
Min, Max	29.4, 41.4	29.6, 40.6	29.4, 41.4	

p-values for continuous outcomes are from an unpaired t-test assuming equal variance; p-values for categorical outcomes are from a Fishers Exact Test

Safety and Effectiveness Results

Safety Results

The adverse events observed in the AUDACITY Study were typical of those associated with gastric balloons, including nausea, abdominal pain, and vomiting (**Table 2**). There were no subject deaths in the trial. The types and severity of non-serious adverse events, including device-related adverse events, are similar to other commercially-available, liquid-filled intragastric balloons, although the rates may be lower than other non-adjustable liquid-filled balloons.

Table 2: Summary of all Adverse Events (Safety Population)

	Total Subjects (n=527)		AGBS Subjects (n=264)		Control Subjects (n=263)	
	Number of Events	Number (%) Subjects	Number of Events	Number (%) Subjects	Number of Events	Number (%) Subjects
Adverse Events (AEs)	2619	408 (77.4%)	2221	261 (98.9%)	398	147 (55.9%)
Procedure- or Device-related AEs	1652	259 (49.1%)	1652	259 (98.1%)	0	0
Procedure-related AEs	41	33 (6.3%)	41	33 (12.5%)	0	0
Device-related AEs	1611	259 (49.1%)	1611	259 (98.1%)	0	0
Unanticipated AEs	11	8 (1.5%)	11	8 (3.0%)	0	0

Serious Adverse Events

With the exception of AEs related to GI disorders and fatigue, the AE profiles were similar in the AGBS and Control groups. Most AEs in the AGBS Group were mild or moderate (97%), indicating that the AGBS was well-tolerated by subjects (Table 3).

Table 3: Severity of Adverse Events (Safety Population)

	Total Subjects (n=527)		AGBS Subjects (n=264)		Control Subjects (n=263)	
	Number (%) Events	Number (%) Subjects	Number (%) Events	Number (%) Subjects	Number (%) Events	Number (%) Subjects
Adverse Events (AEs)	2619	408 (77.4)	2221	261 (98.9)	398	147 (55.9)
Mild AEs	1982 (75.7)	380 (72.1)	1696 (76.4)	260 (98.5)	286 (71.9)	120 (45.6)
Moderate AEs	565 (21.6)	211 (40.0)	459 (20.7)	144 (54.5)	106 (26.6)	67 (25.5)
Severe AEs	49 (1.9)	33 (6.3)	46 (2.1)	30 (11.4)	3 (0.8)	3 (1.1)
Unknown Severity	23 (0.9)	14 (2.7)	20 (0.9)	11 (4.2)	3 (0.8)	3 (1.1)

A total of 21 serious adverse events (SAEs) were reported (18 in AGBS Group and 3 in Control Group) in 13 subjects (10 in AGBS Group and 3 in Control Group).

Of the 18 SAEs reported in the AGBS Group, 15 were device-related and occurred in 8 subjects after placement of Allurion Balloon #2 (Table 4). There were no SAEs reported for Allurion Balloon #1. In one subject, gastric perforation with necrosis in the stomach and small bowel was observed one day after placement of Allurion Balloon #2. Imaging demonstrated occlusion of the left gastric artery and additional necrotic regions were identified in areas not in contact with the balloon. The root cause analysis concluded that an underlying coagulopathy causing thrombosis, ischemia, and multifocal necrosis was the most likely etiology, predisposing the patient to gastric wall weakening and perforation.

The three SAEs reported in the Control Group were bone fracture, ovarian torsion, and appendicitis. Two SAEs in the AGBS Group were not related to the device or the procedure: breast cancer, bulging disk.

. Table 4: Device- or Procedure-Related SAEs by MedDRA term (Site-reported) (Safety Population)

	AGBS (N=264) Number (%) Subjects, Number Events	
System Organ Class / Preferred Term	**Device-Related**	**Procedure-Related**
Gastrointestinal disorders	**8 (3.0), 13**	**0, 0**
Gastric perforation	1 (0.4), 1	0, 0
Gastric ulcer	1 (0.4), 1	0, 0
Haematemesis	1 (0.4), 1	0, 0
Nausea	3 (1.1), 3	0, 0
Obstruction gastric	3 (1.1), 3	0, 0
Vomiting	4 (1.5), 4	0, 0
Metabolism and nutrition disorders	**1 (0.4), 1**	**0, 0**
Metabolic alkalosis	1 (0.4), 1	0, 0
Renal and urinary disorders	**1 (0.4), 1**	**0, 0**
Acute kidney injury	1 (0.4), 1	0, 0

Unanticipated Adverse Device Effects

There were 11 Unanticipated AEs (UAEs) in the AGBS Group: one occurrence of a vasovagal event and 10 occurrences of hiccups in a total of eight subjects. The vasovagal event occurred during balloon placement. Before the balloon was completely filled, the patient developed pre-syncopal symptoms (nausea, lightheadedness). The fill was stopped with only 25 cc of fluid in the filler bag remaining, and the catheter was removed. The patient was moved from the chair to a stretcher and vitals were taken. The initial HR was 54 and BP 119/72. The patient's condition continued to improve with HR increasing into the 70's. The patient sat up and the next blood pressure on sitting was 131/100 with heart rate 71-73. The patient's symptoms completely resolved and a final x-ray image was obtained demonstrating successful balloon administration. All episodes of hiccups were reported as mild and resolved completely.

Display of Adverse Events

It is important to understand the nature, frequency and duration of adverse events that occurred in the study. Although the total number of adverse events in the study is high, this is a phenomenon seen in all liquid filled balloon studies. Nausea and vomiting are almost universal in all subjects receiving a liquid filled balloon due to the accommodation of the stomach to the balloon in the first few days. Most of these mild to moderate symptoms such as nausea, vomiting and abdominal pain resolve following this accommodation period.

Occasionally, there may be recurrence of intermittent nausea or vomiting during the course of the balloon residence on account of advancing or changing the diet. Table 5 displays the more common reported Gastrointestinal AEs.

Table 5: Gastrointestinal Adverse Events by Treatment Group (Safety Population)

	Total Number (%) Subjects, Number Events		AGBS (N=264) Number (%) Subjects, Number Events	
System Organ Class / Preferred Term	**AGBS (N=264)**	**Control (N=263)**	**Device-Related**	**Procedure-Related**
Gastrointestinal disorders	260 (98.5), 1725	42 (16.0), 67	259 (98.1), 1525	20 (7.6), 28
Abdominal discomfort	39 (14.8), 43	1 (0.4), 1	39 (14.8), 42	0, 0
Abdominal distension	43 (16.3), 49	0, 0	40 (15.2), 46	0, 0
Abdominal pain	204 (77.3), 372	1 (0.4), 1	203 (76.9), 354	4 (1.5), 4
Abdominal pain upper	11 (4.2), 12	2 (0.8), 2	11 (4.2), 11	0, 0
Constipation	73 (27.7), 86	9 (3.4), 12	50 (18.9), 55	0, 0
Diarrhea	71 (26.9), 95	14 (5.3), 14	39 (14.8), 47	3 (1.1), 3
Dyspepsia	56 (21.2), 68	2 (0.8), 2	52 (19.7), 60	0, 0
Eructation	48 (18.2), 58	1 (0.4), 1	1 (0.4), 1	0, 0
Flatulence	18 (6.8), 21	0, 0	18 (6.8), 20	0, 0
Gastric perforation	1 (0.4), 1	0, 0	1 (0.4), 1	0, 0
Gastric ulcer	1 (0.4), 1	0, 0	1 (0.4), 1	0, 0
Gastritis	2 (0.8), 2	0, 0	0, 0	0, 0
Gastrooesophageal reflux disease	34 (12.9), 37	2 (0.8), 2	31 (11.7), 33	1 (0.4), 1
Nausea	253 (95.8), 502	10 (3.8), 10	250 (94.7), 46	9 (3.4), 9
Retching	97 (36.7), 128	0, 0	94 (35.6), 122	5 (1.9), 5
Vomiting	142 (53.8), 211	9 (3.4), 9	135 (51.1), 191	6 (2.3), 6

Effectiveness Results

Co-Primary Effectiveness Endpoint #1 for the AUDACITY Study was defined as: Treatment Group Responder Rate (RR) dichotomized at 5% TBWL at 48 weeks is significantly greater than 50%.

In the mITT population using the pre-specified multiple imputation method identified in the Statistical Analysis Plan, Co-Primary Effectiveness Endpoint #1 was met, with 58.0% (95% CI: 51.2% to 64.9%; *p*-value = 0.0102) of AGBS subjects having 5% TBWL or greater at 48 weeks. Results

for the mITT, ITT, and PP populations using various methods of imputation are summarized in Table 6.

Table 6: Co-Primary Effectiveness Endpoint #1 Results

Population	AGBS Group (95% CI)	AGBS Group (95% CI)
	Multiple Imputation	**LOCF**
mITT	58.0% (51.2, 64.9) *p*=0.0102	54.0% (47.8, 60.2) *p*=0.0968
ITT	58.4% (51.7, 65.1) *p*=0.0068	51.3% (45.2, 57.3) *p*=0.3365
PP	57.2% (49.3, 65.1) *p*=0.0363	56.7% (48.6, 64.6) *p*=0.0469

Co-Primary Effectiveness Endpoint #2 for the AUDACITY Study was defined as: Treatment Group mean %TBWL is significantly greater than Control Group mean %TBWL at 48 weeks, with a super superiority margin of 3.0%.

For Co-Primary Effectiveness Endpoint #2, using the MMRM method, the difference between the two groups at 48 weeks was 3.05% (95% CI: 2.09, 4.00). Using the LOCF method, the difference between the two groups at 48 weeks was 3.77% (95% CI: 2.69, 4.86) (Table 7). Using MMRM, the super-superiority margin was 2.09%. While this did not exceed the super superiority margin of 3.0%, the difference in weight loss was clinically meaningful. Results for the ITT and PP populations are also provided in **Table** 7.

Table 7**: Co-Primary Effectiveness Endpoint #2 Results**

Population	Imputation Method	AGBS Group Mean %TBWL (95% CI)	Control Group Mean %TBWL (95% CI)	Difference (AGBS-Control) (95% CI)	p-value
mITT	MMRM	7.15 (6.50, 7.79)	4.10 (3.39, 4.81)	3.05 (2.09, 4.00)	0.4632
	MI	7.39 (6.44, 8.34)	4.30 (3.24, 5.36)	3.09 (1.68, 4.51)	0.4478
	LR/LOCF	6.86 (6.10, 7.63)	3.09 (2.32, 3.86)	3.77 (2.69, 4.86)	0.0805
ITT	MMRM	7.15 (6.50,7.79)	4.10 (3.39, 4.81)	3.05 (2.09, 4.00)	0.4632
	MI	7.46 (6.48, 8.44)	4.31 (3.28, 5.34)	3.16 (1.68, 4.63)	0.4181
	LR/LOCF	6.51 (5.77, 7.26)	2.95 (2.21, 3.70)	3.56 (2.51, 4.61)	0.1479
PP	MMRM	7.43 (6.62, 8.23)	4.13 (3.36, 4.90)	3.29 (2.18, 4.41)	0.303
	MI	7.40 (6.30, 8.49)	4.33 (3.26, 5.40)	3.07 (1.54, 4.59)	0.4666
	LR/LOCF	7.44 (6.37, 8.51)	4.09 (3.09, 5.10)	3.35 (1.88, 4.82)	0.319

Exploratory Analyses

24- and 40-Week Results

In the mITT population using MI at 24 weeks, 58.5% (95% CI: 52.2%, 65.1%) of AGBS subjects were responders.

Evaluating the AGBS endpoints at Week 40 offers important insight into its effectiveness after treatment. This analysis assesses endpoints at the time of excretion of Allurion Balloon #2, aligning with other intragastric balloon studies where primary endpoints were evaluated at the time of device removal.

At Week 40, using LOCF in the mITT population, the mean weight loss in the AGBS group was 7.38% vs. 3.16% in the Control Group; the mean between-group difference was 4.22% (95% CI: 3.18, 5.26). The percent of responders at Week 40 using MI was 63.9% (95% CI: 57.5%, 70.3%).

Responder Rate Analyses

Super-responders were also evaluated. In the mITT population using MI, 25.4% of subjects (95% CI: 19.7, 31.1) and 32.1% of subjects (95% CI: 25.8, 38.5) had greater than or equal to 10% TBWL at 24 weeks and 48 weeks, respectively.

The benefit of receiving two balloons was also evaluated. In subjects receiving two balloons (*n*=185), 58.4% of subjects (95% CI: 51.2, 65.7) had greater than or equal to 5% TBWL at 48 weeks.

Subgroup Analyses

Both co-primary effectiveness endpoints were evaluated across age, sex, race, BMI, and ethnicity. Results are shown in Figure 1 and Figure 2.

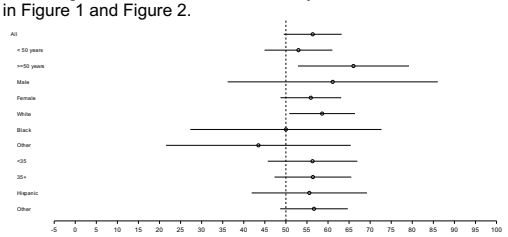

Figure 1: Forest plots for co-primary effectiveness endpoint #1

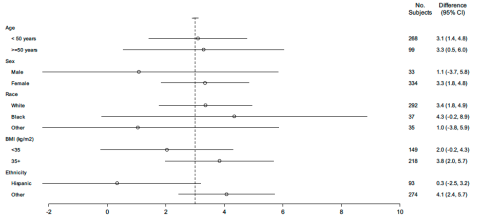

Figure 2: Forest plots for co-primary effectiveness endpoint #2

Symbols

	Caution
	Catalog number
	Consult instructions for use
	Contents
	Do not re-use
	Do not use if package is damaged
	Authorized Representative in the European Community
	Lot number
	Manufacturer
	Non-sterile
	Prescription only - device restricted to use by or on the order of a physician
	Use by
	The Allurion device is MR Safe
	Manufacture Date
	Medical Device
	Keep product dry
	Keep away from sunlight

Patent information: www.Allurion.com/patents

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info@Allurion.com

CS157-01-ART_4

Allurion
PROGRAM

Start your Allurion journey today.

*In rare cases, the Allurion Balloon may require endoscopic or surgical intervention for removal.

What could losing weight mean to you?

I could...

- Feel more confident when I look in the mirror...
- Enjoy my free time more...
- Improve my food and nutritional choices...
- Feel free and happier...
- Improve my physical health...

*In rare cases, the Allurion Balloon may require endoscopic or surgical intervention for removal.

The gastric balloon program for weight loss and healthier lifestyle habits

Simple and safe

No surgery, no endoscopy*, no anesthesia and placed in less than 15 minutes

Passes naturally after approximately 4 months.

A second balloon is placed after a minimum of a 2-month gap, which also passes naturally after 4 months.

Lifestyle modification

Shift towards healthier and sustainable lifestyle habits

The Allurion Program is a new generation weight-loss solution*

Diet and exercise

LOW WEIGHT LOSS

Frustrated with a lack of success?

75% of people trying to lose weight through diet and exercise approaches do not achieve 5% weight loss.[1]

Allurion Program or Weight loss medication

MEDIUM WEIGHT LOSS

Want fast, sustainable results?**

No hormone-impacting medication.

No self-injections at home.

Surgery (Sleeve or Bypass)

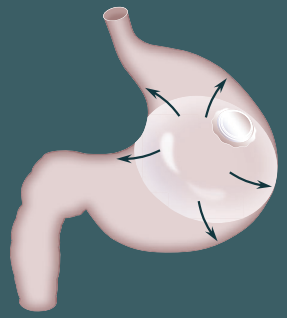
HIGH WEIGHT LOSS

Want to avoid an irreversible procedure that limits your eating choices for life?

*Weight loss treatments are increasingly multimodality, and the Allurion Program can be used in combination with and before / after some other treatments
** Results from common weight loss drugs, are after around 16 months
1. European Association for the Study of Obesity: Three-quarters of adults with obesity have attempted to lose weight in the past year, but most have been unsuccessful. May 2022

How does it work?

- The Allurion Balloon takes up space in your stomach, leaving less room for food. This is designed to help you feel fuller faster and for longer. It reduces your appetite and portion sizes, aiding weight loss.



- The Allurion Smart Capsule is easily swallowed during a 15-minute walk-in appointment

- The balloon and your lifestyle change program work together to help you create healthier habits that last a lifetime

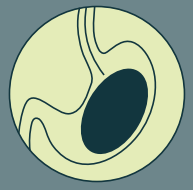
The only gastric balloon requiring no endoscopy for placement or removal*

Scan here to see a video of the Allurion Balloon placement

What happens on placement day

01 - Swallow

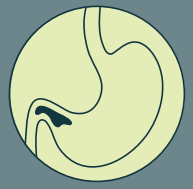
You swallow a Smart Capsule that contains the balloon attached to a thin tube. You will hold the tube in place, or dressing tape can be applied to the tube and affixed to the face to hold it in place. You will have an X-ray to make sure the capsule is in the right position.



02 - Fill

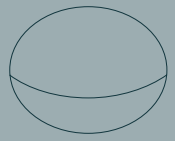
Once in your stomach, your doctor will use the tube to fill the balloon with water.

You will have a second X-ray to confirm the balloon is filled. The doctor will then gently remove the tube and you'll be on your way. With the balloon in your stomach, you can eat less without feeling hungry.



03 - Disappear

At approximately 4 months after placement, the Allurion Balloon self-empties and passes naturally.*



These steps are repeated with each of the two consecutive balloons.

*In rare cases, the Allurion Balloon may require endoscopic or surgical intervention for removal.

Adjusting to life with a balloon

You may experience some discomfort in the days after your placement as your body adjusts to the balloon.

For the first few days after placement you may have nausea, fatigue, abdominal cramping and vomiting. This is completely normal and your nutritionist and doctor can help you manage any symptoms.

You will need to re-introduce food carefully and your nutritionist will support you every step of the way. It is best to not start physical activity (e.g. sports activities) for at least one week after placement, when any symptoms you may have had are gone.

No special diets, fad foods or extreme exercise regimes. Just personalized, achievable and enjoyable goals that are right for you

Your balloon helps you

- **Feel full faster** - eat smaller portions
- **Feel full for longer** - reduce your appetite

Support from your nutritionist helps you

- Kick-start healthier lifestyle habits, shift your mindset and empower you to maintain your weight loss over the long term
- Feel supported throughout your journey

A fully supported program for sustainable long-term weight loss

Smart, simple, and innovative: A balloon redefined by design

01
Unlike endoscopic balloons, the Allurion Balloon conforms to to the shape of the stomach – an oval shape like a grapefruit, with two flat surfaces

02
Made from polyurethane, a material that is much thinner and more flexible than the silicone material in endoscopic balloons

03
Unlike endoscopic balloons, the Allurion Balloon, being malleable, flexes and adapts to the shape of your stomach

04
The release valve is made from thin film with a hole sealed by a degradable filament that weakens in the balloon's internal environment, breaking over time to empty the balloon at a set point.

In the AUDACITY Study, the Allurion Balloon demonstrated a proven safety profile and was well-tolerated.*

96% of all device or procedure-related adverse events were mild or moderate, with the most common being nausea.[1]

MOST COMMON ADVERSE EVENTS

Nausea
Abdominal Pain
Vomiting
Abdominal Discomfort
Diarrhea
Heartburn

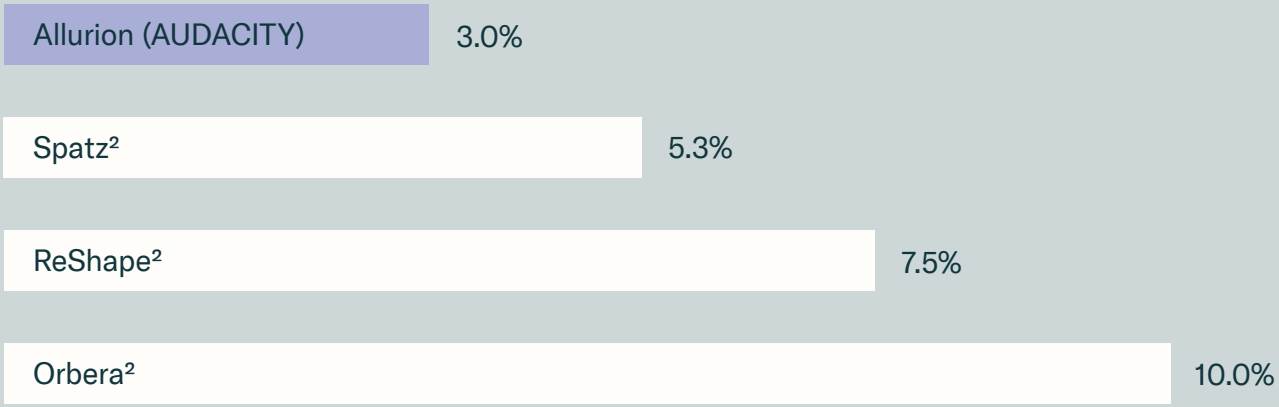
Only 3.0% of subjects had a device or procedure-related serious adverse event.[1]

1 The AUDACITY Study. Data on File (2025).
* In rare cases, the Allurion Balloon may require endoscopic or surgical intervention for removal.

The Allurion Balloon has the lowest rate of serious adverse events compared to FDA approved liquid-filled gastric balloons.*

Allurion subjects were less likely to experience a device or procedure related serious adverse event than subjects treated with another liquid-filled gastric balloon.[1]

Serious Adverse Event Rates for Liquid-Filled Intragastric Balloons



1 The AUDACITY Study. Data on File (2025).
2 Data from SSEDs of the devices.
* In rare cases, the Allurion Balloon may require endoscopic or surgical intervention for removal.

Effective weight loss requires comprehensive care. That's why the Allurion Program offers much more than just a balloon.

10+ month
Allurion Program

Included in the **program**

- **2** balloons
- Medical support
- Nutrition coaching
  10+ months

A Healthier, Happier You*

Allurion subjects reported significant improvements in:

- Overall quality of life
- Physical function
- Self-esteem

Higher scores on the IWQOL-L questionnaire mean a better quality of life. After 48 weeks, people in the study who were in the AGBS Group showed bigger improvements in their overall quality of life and in specific areas like physical function and self-esteem, compared to those in the Control Group. These differences were not just by chance—they were statistically significant.

*The AUDACITY Study. Data on File (2025).

How Eating Patterns Shift During the Program*

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.

*The AUDACITY Study. Data on File (2025).

Allurion is an International Success Story

10+ years

Founded in 2009 with **10+ years** of R&D

200,000+ balloons distributed in over **78 countries** (October 2025)

Extensive body of scientific evidence

Designed and manufactured in the USA

Allurion
PROGRAM

Take the next step in your weight-loss journey

Start your Allurion Program today