Allurion

Urgent- Field Safety Notice

Allurion Device/Elipse Gastric Balloon System

FSN Ref: FSN-01-2024

FSCA Ref: FSCA-01-2024

FSN Type: New

Type of Action: Description of the procedures recommended for management of gastric outlet obstruction and small bowel obstruction; new contraindications, controls, and precautions with the use of the device; and subsequent updates to the device IFU.

Date: 29 February 2024

For Attention of: Physicians in the European Union managing patients on the Allurion Program.

Details of concerned devices:

Name of Device	Reference Number	Lot Number
Allurion Device / Elipse Gastric Balloon System	10D-CE	N/A- no impact to specific lot

Note: there is no recall of current devices.

Dear Customer,

Allurion Technologies is distributing this Field Safety Notice (FSN) to inform physicians about the recommended procedures for managing gastric outlet obstruction (GOO) and small bowel obstruction (SBO); new contraindications, controls, and precautions with the use of the device; and subsequent updates to the device Instructions for Use (IFU). This letter is to identify the affected devices and explain the recommended procedures. This communication includes the key patient management information on the device and the new IFU.

Description of the Issue:

Allurion is aware that in rare instances patients may be admitted to a facility that is different from where the

balloon was placed. Although the clinical staff in the facilities placing the device are trained on the optimal and least invasive management of certain conditions, the clinical staff in the facilities where the patients may seek care may not be trained and may opt for more invasive management.

Allurion has also identified new contraindications, controls, and precautions around the use of the device. These have been incorporated into the updated IFU.

Corrective action being taken by the manufacturer:

Allurion is releasing key patient management information on the Allurion Balloon, including the proper management of certain rare complications, like GOO or SBO, as well as endoscopic removal of the Allurion Balloon, in this FSN.

Allurion is also updating the device IFU to include the following important changes:

- New contraindications:
  - Placement of a new device when a gastric balloon was in the stomach less than 2 months ago
  - Patients receiving chronic high dose steroids
- New controls:
  - Placement of the device must occur in the same room as the X-Ray imaging
  - Patients with BMI ≥ 50 kg/m2 should be assessed and cleared for other cardiac and pulmonary comorbidities that may compromise patient safety in event of complications
  - 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 food retention.
  - The syringe must never be used to help initiate or resume filling of the balloon. Use of the syringe during the filling process can damage the balloon.
  - 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.

Actions the customer should take:

- Review the key patient management information (below) described in this FSN.
- Review the updated IFU attached to this FSN.
- Sign and complete the attached acknowledgment form and send to FSN@allurion.com

Communication with Regulatory Agencies

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Transmission of this Field Safety Notice

- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the Allurion device has been distributed.
- Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

If you have any questions on this Field Safety Notice, please send an email to

FSN@allurion.com or contact your local Allurion representative.

DocuSigned by:
Bill Nadeau
F313CC3B118D40E...

Bill Nadeau

VP Medical Affairs

DocuSigned by:
Joyce Johnson
8AAD9DA1DFF5466...

Joyce Johnson

SVP Regulatory Affairs/ Quality Affairs

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Customer Response/ Acknowledgement

Field Safety Notice

Allurion Device/ Elipse Gastric Balloon System

Product: Allurion Device

Customer Name: _____

I confirm that I have received and read the Field Safety Notice (FSN-01-2024) from my Allurion representative, and I have been made aware of and understand its contents.

Signed: _____ Date: _____

Please complete and return this receipt by e-mail to the following address: FSN@allurion.com

11 Huron Drive, Natick, Massachusetts, 01760, USA

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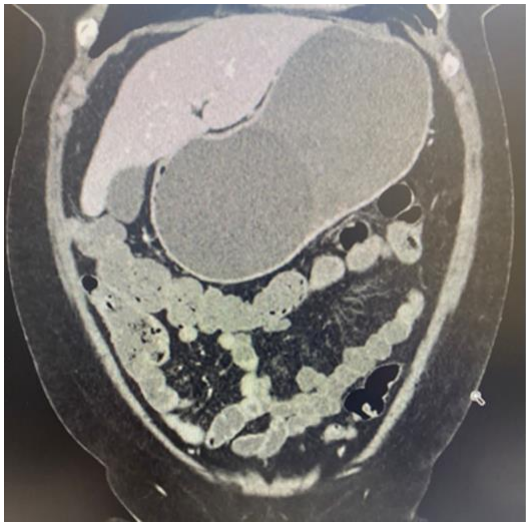
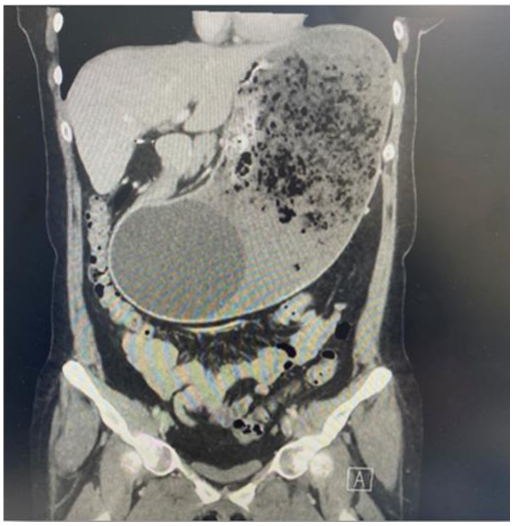
Table of Contents

Medical Management of Gastric Outlet Obstruction from the Allurion Balloon

Gastric outlet obstruction:
How do you manage?





Medical management for suspected gastric outlet obstruction

First, and most important, if there is significant gastric dilation, place NG tube to decompress the stomach

01 Patient lies flat on the back.

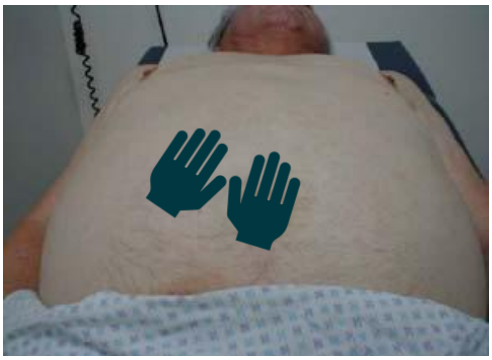
02 Feel the balloon in the mid to lower distended abdomen with both hands.

03 Manually mobilize and dis-impact the balloon by pushing on the balloon upwards and to the left.

04 Have the patient lay down on the left side of body for 48 hours.

05 Keep on clear liquid diet for at least 48 hours.

06 Walk, exercise after balloon has dis-impacted.



If endoscopy is required for balloon removal, must first decompress the stomach via NG tube and intubate before endoscopy to prevent gastric perforation and pulmonary aspiration.

Endoscopic removal of the Allurion Balloon

Balloon Aspiration and Removal **Tools**

Standard Upper GI Endoscope

Endoscopic aspiration needle

Endoscopic grasping forceps

Both tools are designed for removal of intragastric balloons or foreign bodies in the stomach

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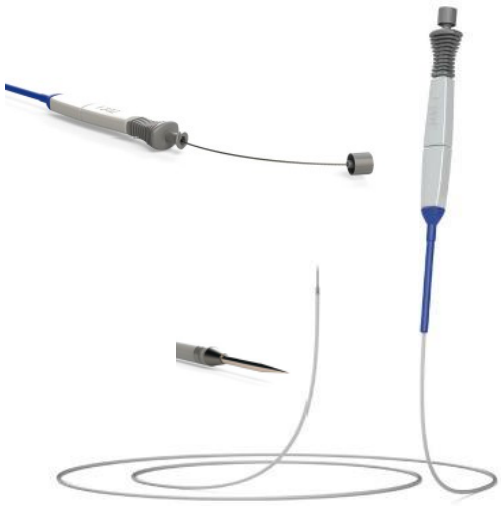
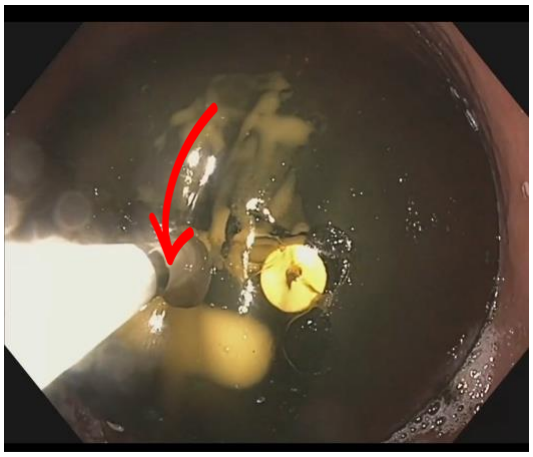
Endoscopic Aspiration Needle

- A hollow catheter with a puncture needle that advances out of the distal end of the catheter to puncture the balloon.
- The needle is withdrawn after the catheter has entered the balloon allowing for a hollow catheter to withdraw the balloon fluid.
- The proximal end of the catheter is attached to room suction or a luer lock syringe.



Marking the Endoscopic Aspiration Needle

- Mark with a Sharpie at 4cm from distal end.
- Used to visualize depth of needle in the balloon (4 cm = in the middle of balloon).
- Aims to prevent needle from passing through the balloon and penetrating the stomach wall.
- Able to visually maintain depth of needle throughout aspiration of fluid.



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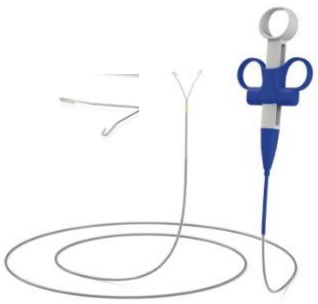
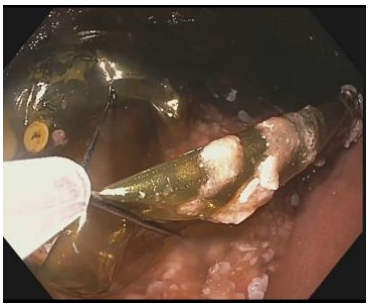
A Endoscopic Grasping Forceps

- Open grasping forceps once in stomach to avoid damaging adjacent tissue.
- Grasp balloon by maneuvering forceps around the edge of the balloon, placing balloon at crotch of forceps, and closing forceps.
- Firmly pull forceps and attached balloon to the head of the scope; maintain it at the head of the scope as the balloon is withdrawn.
- If the balloon is dropped in the esophagus during removal, pull the endoscopic grasping forceps back in the channel, push the balloon back into the stomach with the scope, then regrasp in the stomach.





A

Percutaneous management in the Rare Event of a Small Bowel Obstruction from the Allurion Balloon

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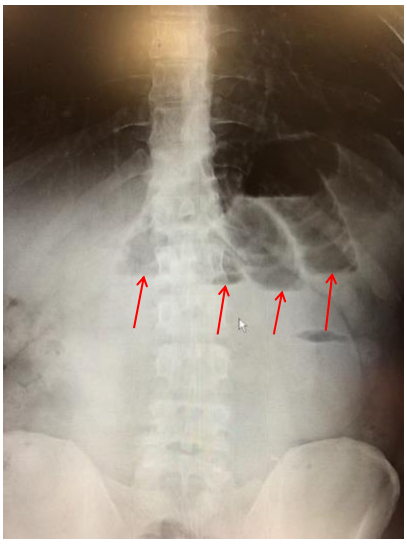
allurion.com

SBO may be relieved without surgery by using a long 22-gauge needle under CT or ultrasound guidance

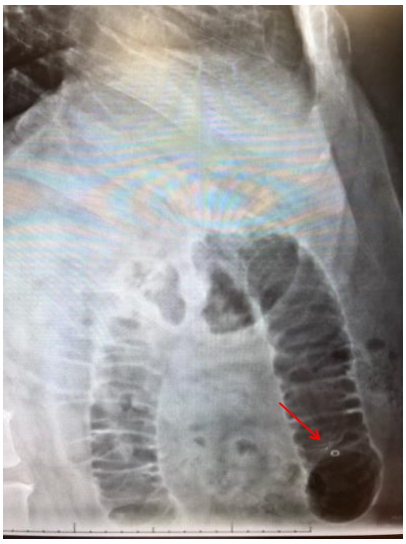
Required Tools

- Long 22-gauge fine-needle aspiration needle.
- CT Scan or Ultrasound.
- Syringe with luer lock.

Typical Images of a Small Bowel Obstruction from an Allurion Balloon



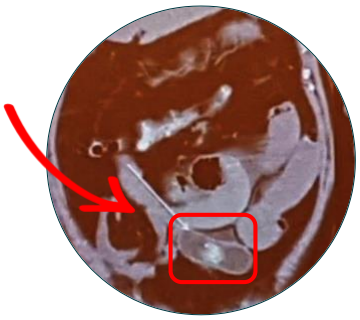
Air fluid levels



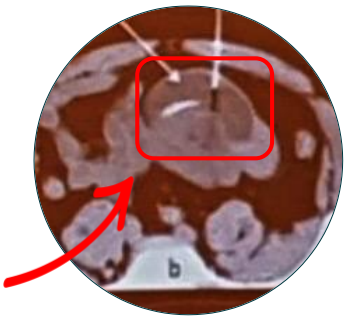
Obstructing balloon causing dilated bowel

Example of CT guided long needle aspiration of the Allurion Balloon in the ileum with subsequent migration of the balloon into the colon

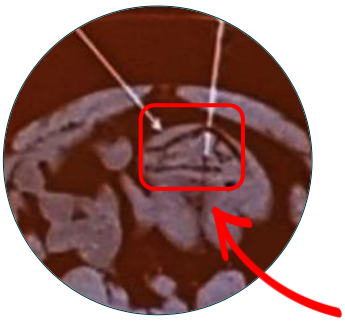
Obstructing balloon



CT Guided Needle Aspiration

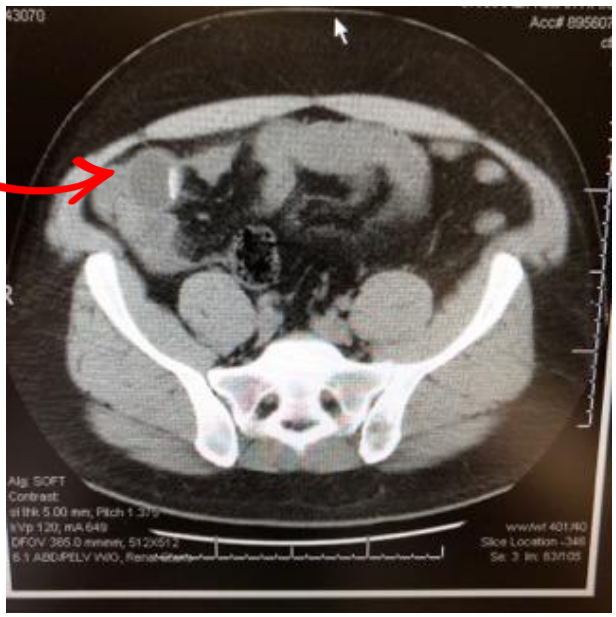


Decompressed balloon



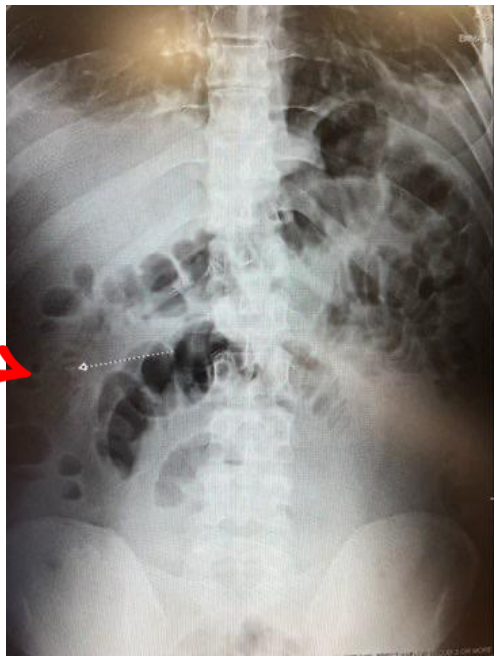
SBO from an Allurion Balloon

CT scan followed by ultrasound guided needle aspiration.



SBO Symptoms Resolved

Decompressed balloon in the transverse colon can be allowed to pass naturally.



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INSTRUCTIONS FOR USE
Allurion™ Gastric Balloon System

Introduction

The Allurion™ Device is a temporary gastric balloon that promotes weight loss in individuals with overweight and 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 is comprised of the Allurion Device (Figure 1) which becomes the Allurion Balloon (Figure 2) when filled, the Allurion Filler Kit (Figure 3), the Allurion Stylet (Figure 4), and the Allurion Practice Capsule (Figure 5). 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 6), 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 Allurion Device (Figure 1) is comprised of the following items:

- Balloon (Figure 2) constructed from thin film polymers. The inflated residence time in the stomach is designed to be 16 weeks but may vary from patient to patient.
- 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.

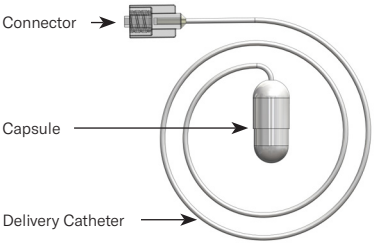

Figure 1: Allurion Device

Figure 2: Allurion Balloon

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

- Filler Bag containing 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.

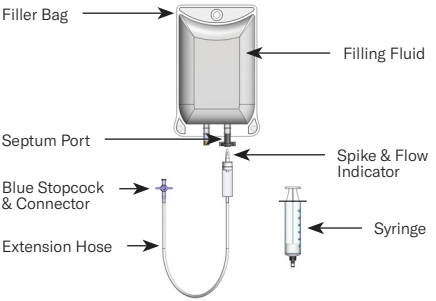

Figure 3: Allurion Filler Kit

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.

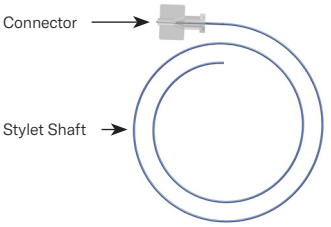

Figure 4: Allurion Stylet

The Allurion Practice Capsule (Figure 5) is comprised of the following items:
- Capsule composed of a vegetarian, non-animal derived, degradable material. The Practice Capsule is approximately the same size and weight as the Allurion Device.

Figure 5: Allurion Practice Capsule

The Pressure Infusor (Figure 6) 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.

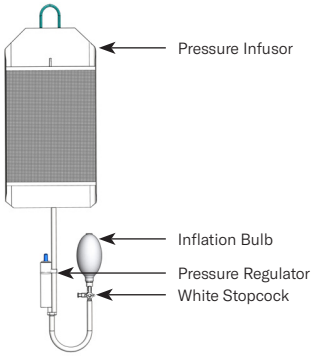

Figure 6: Pressure Infusor

Indications for Use
The indications for use of the Allurion Gastric Balloon System are to promote weight loss in overweight and obese individuals with a body mass index (BMI) of ≥ 27.0 kg/m^2. The Allurion Gastric Balloon System is to be used in conjunction with a supervised nutrition program.

Expected Weight Loss
Clinical evaluation of the Allurion Device suggests that on average, patients will lose approximately 10-15% of their starting total body weight. Individual results vary widely. If weight loss achieved is less than desired and the patient still qualifies and is not contraindicated, a sequential Allurion Device may be placed.

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.

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.
- 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.
- Children younger than 18 years.
- 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
- Fainting/vasovagal reaction during placement
- 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

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 or foreign bodies in the stomach.
- 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.
- Patients with BMI ≥ 50 kg/m² should be assessed and cleared for other cardiac and pulmonary comorbidities that may compromise patient safety in the event of complications.

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 gastroespohageal 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 food 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 the ⌛ (Use By) date. Device must not be placed in the patient after the ⌛ (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. Allurion Practice Capsule

1.1. Allurion Practice Capsule swallowing is recommended prior to Allurion Device placement. The Allurion Practice Capsule is ready for the patient to swallow after it is removed from the packaging.

1.2. Allow the patient to place the Allurion Practice Capsule in mouth and swallow with liquid as needed.

1.3. Reassure the patient that even if the Practice Capsule cannot be swallowed, it is possible to swallow the device with the assistance of a Stylet.

2. Device and Patient Preparation

2.1. 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.

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

2.3. Hang Pressure Infusor on IV stand. See Figure 7.

2.4. Twist to remove the cover over the Septum Port. See Figure 8.

2.5. Confirm Blue Stopcock is closed. Pierce Septum Port with Spike of Extension Hose. See Figure 9.

Figure 7: Filler Bag and Pressure Infusor on IV stand

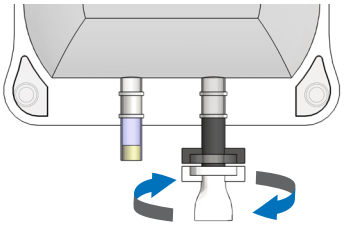

Figure 8: Removal of Septum Port Cover from Filler Bag

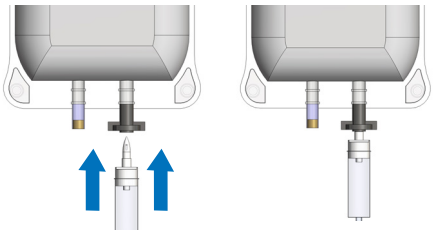

Figure 9: Filler Bag and Extension Hose Assembly

3. Allurion Device Delivery to Stomach

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

3.2. Have the patient take sips of water to lubricate 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.

3.3. 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.

3.4. 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.

3.5. 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.

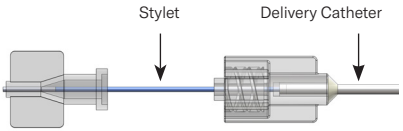

Figure 10a: Allurion Stylet entering Delivery Catheter

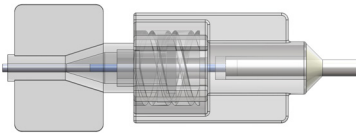

Figure 10b: Allurion Stylet and Delivery Catheter Connectors engaged

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.

3.6. The patient now rapidy swallows water and simultaneously the physician or health care provider (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 11) should be near the patients lips.

Warning: Do not advance the Styleted catheter if there is any resistance during the passage. Use of force durning the 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.

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

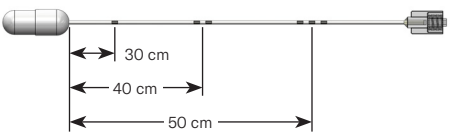

Figure 11: Delivery Catheter length markings (not to scale). Length dimensions are approximate.

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

3.8.1. 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 4.

3.9. 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.

4. Allurion Device Filling

4.1. Remove the protective cap from the Blue Stopcock Connector.
4.2. Connect the Delivery Catheter to the Blue Stopcock Connector.
4.3. Open the Blue Stopcock. See Figure 12A.
4.4. Close the White Stopcock on the Pressure Infusor (Figure 12B). If the Pressure Regulator is in the "down" position (Figure 12C), click the blue button to set to "up" position (Figure 12D).

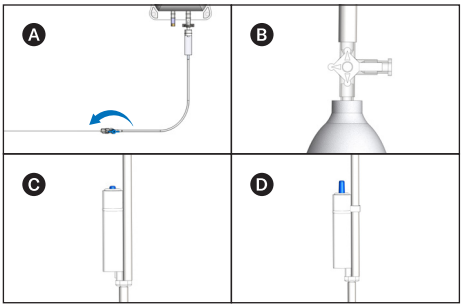

Figure 12: Stopcocks and Pressure Regulator Positions for Filling

4.5. 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.

4.6. Maintain pressure at 300 mmHg until the Flow Indicator chamber shows a constant stream of fluid. Proceed to step 4.9 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 4.7.

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 4.7. Filling the Balloon in the esophagus may result in severe patient harm.

4.7. 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 4.9, if no steady stream continue to 4.8.
4.8. Move the Pressure Regulator to "down" position (Figure 12C) 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 12D) and continue to 4.9 If no steady stream, the Balloon must be endoscopically punctured, aspirated, and removed (See 6. Endoscopic Allurion Balloon Removal).

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

4.9. 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.
4.10. 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 6. Endoscopic Allurion Balloon Removal.)
4.11. If at any time filling slows or stops, proceed to directions starting in 4.13.
4.12. 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 4.9. If the Flow Indicator does not exhibit a constant stream, continue to 4.13.
4.13. 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 4.9. 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 4.14.
4.14. Have the patient take several slow, deep breaths. If the Flow Indicator exhibits a constant stream, return to 4.9. If the Flow Indicator does not exhibit a constant stream, continue to 4.15.
4.15. 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 4.9 while maintaining gentle tension. If the Flow Indicator does not exhibit a constant stream, continue to 4.16.

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.

4.16. Click the blue button to the down position (See Figure 12C). Pump the Inflation Bulb until the Pressure Regulator indicates a pressure of 450 mmHg. If the Flow Indicator exhibits a constant stream, return to 4.9. If the Flow Indicator does not exhibit a constant stream, repeat 4.15 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 6. Endoscopic Allurion Balloon Removal).

5. Allurion Balloon Detachment

5.1. After Filling Fluid has completely emptied from Filler Bag, close the Blue Stopcock (Figure 13A).
5.2. Rotate the White Stopcock to deflate the Pressure Infusor. Allow the Pressure Infusor to fully deflate (Figure 13B).

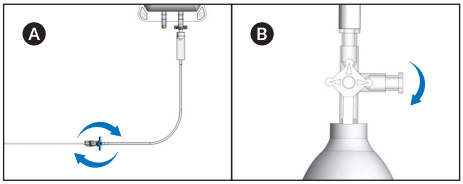

Figure 13: Stopcock Positions for Balloon Detachment

5.3. 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.

5.4. 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.

5.5. 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.

5.6. 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 6.

6. 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.
    - In the event of spontaneous hyperinflation, it is recommended that the balloon be punctured, aspirated, and then removed endoscopically.
- 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-absomen, over the balloon, upwards and towards the patient's left shoulder. This maneuver will often disimpact the balloon from the stomach antrum and move it into the stomach body. If this maneuver is unseccessful, 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.

6.1. 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.

7. Percutaneous Needle Aspiration of Obstructing Balloon

7.1. 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.

8. Laparoscopic Removal of Obstructing Balloon

8.1. 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.

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	Lot number
	Manufacturer
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	Use by
	The Allurion device is MR Safe
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