Table of Contents

What is the Allurion Gastric Balloon?

- **Minimally invasive, swallowable device** for weight loss.
- **Capsule swallowed in clinic**—no surgery, endoscopy, or anesthesia
- **Balloon filled** with 550 ml of a proprietary solution of buffered distilled water and a food grade preservative.
- **Radiography (X-ray) confirms:**
  - Correct capsule placement in stomach
  - Balloon inflation after filling via catheter
- **Balloon induces satiety** (fullness), reducing food intake
- Remains in stomach for **~16 weeks, then passes naturally**
- Supports weight loss as part of a **structured medical program**

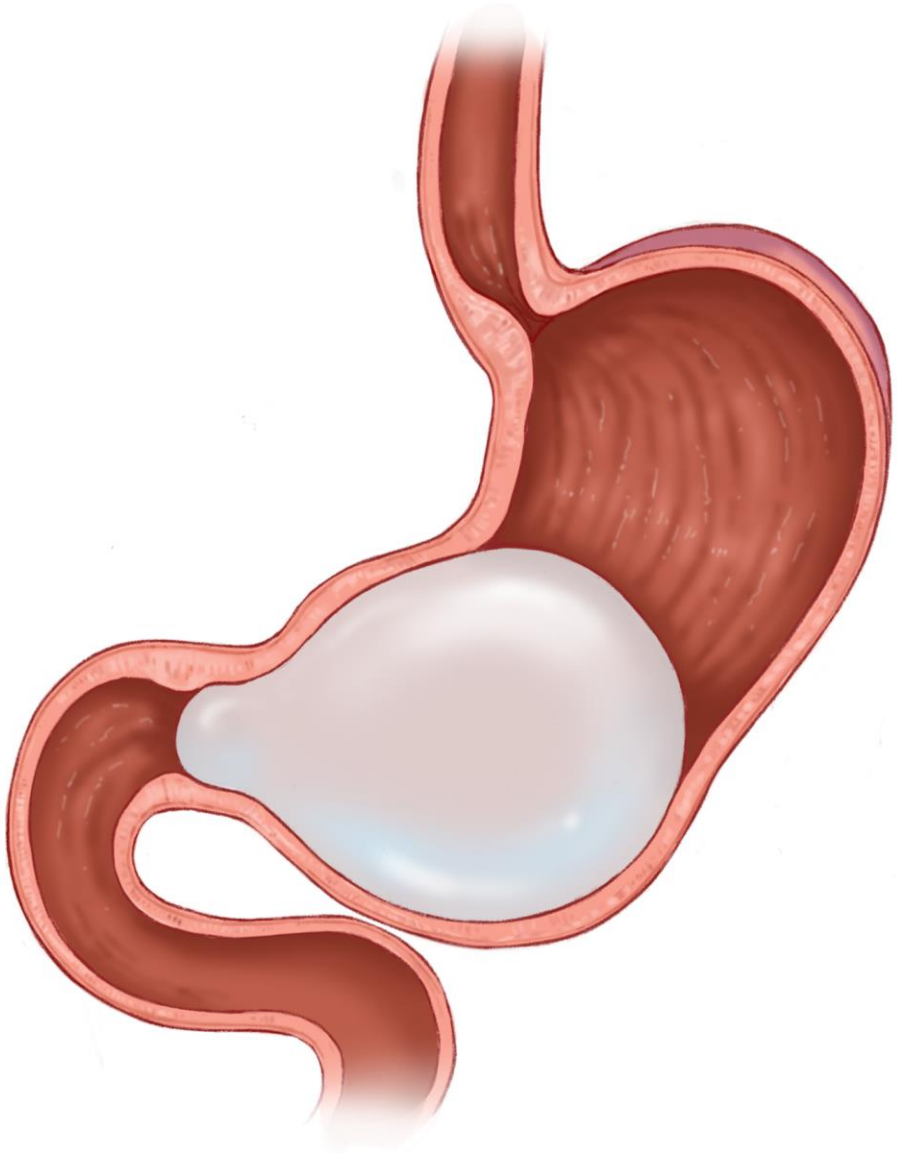
Allurion Balloon Filling

Medical Management of Gastric Outlet Obstruction from the Allurion Balloon

The Allurion Balloon and Gastric Outlet Obstruction:

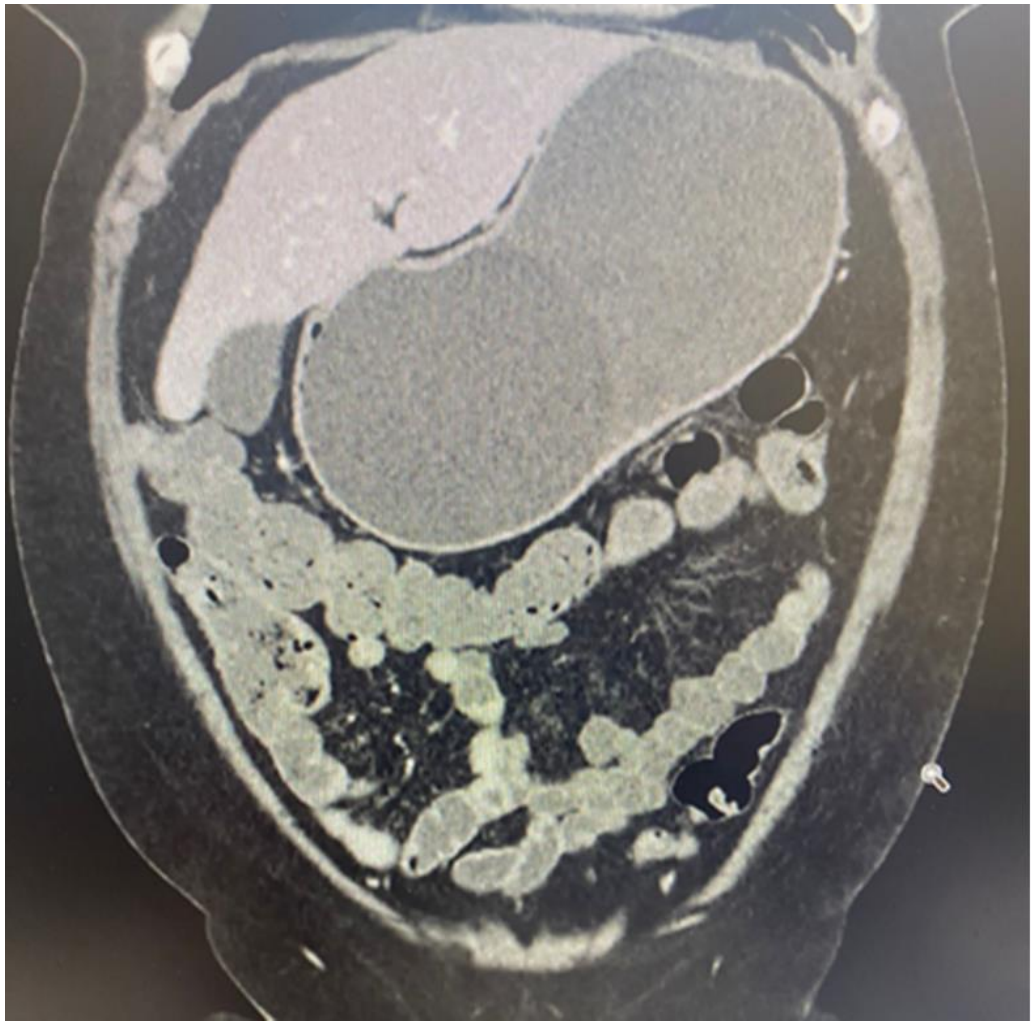
- **The Allurion Balloon may create a blockage at the pylorus that preventing food and liquids from passing into the intestine.**
- **Mild symptoms (nausea, vomiting, cramps, bloating)** are normal in the first few days after Allurion gastric balloon placement as your stomach adjusts.
- **If symptoms persist or worsen beyond the first week**, complications such as GOO should be considered.
- **Symptoms suggestive of GOO:**
  - ✓ Ongoing or severe vomiting
  - ✓ Persistent nausea
  - ✓ Abdominal pain or distention
  - ✓ Inability to tolerate liquids or food
  - ✓ Dehydration (reduced urine, dizziness)
  - ✓ Inability to pass gas or stool

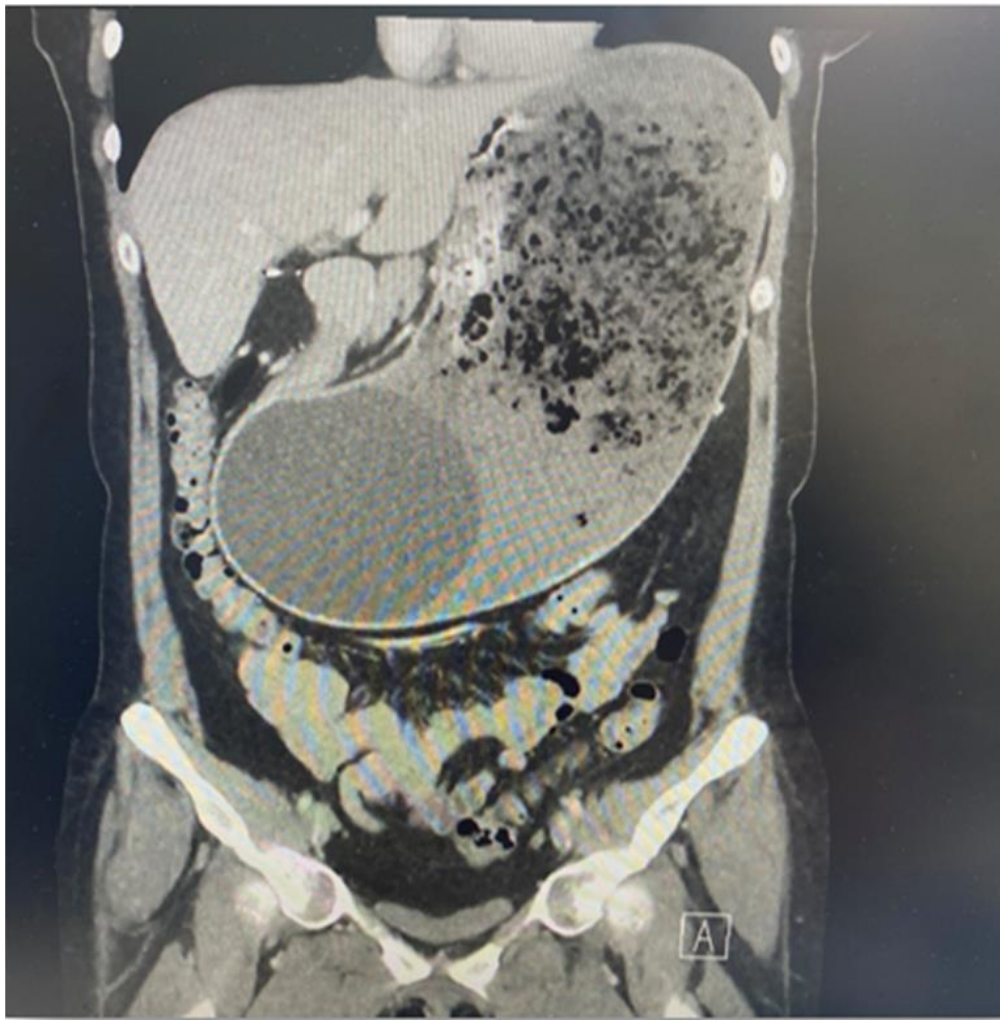
Allurion



The Allurion Balloon and Gastric outlet obstruction:

How do you manage?





Medical management for suspected gastric outlet obstruction by the Allurion Balloon*

First, and most important, if there is significant gastric dilation, place NG tube to decompress the stomach. Secondly, optimize parenteral analgesia while considering opiate exacerbation of suspected dysmotility.

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 If manual dis-impaction fails and the patient remains symptomatic and/or unwell, please seek surgical opinion. If manual dis-impaction is successful, keep patient on clear liquid diet for at least 48 hours.

05 Patient should sleep or rest on the left side for 48 hours post dis-impaction to help prevent re-impaction of the balloon.

06 Following rest, physical movement such as walking may also prevent re-impaction of the balloon.

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.

* This guidance is informed by field experience with both the Allurion Balloon and endoscopic intragastric balloons.

Endoscopic removal of the Allurion Balloon

Allurion Balloon Aspiration and Removal Tools

Standard Upper GI Endoscope

Endoscopic aspiration needle

Endoscopic grasping forceps

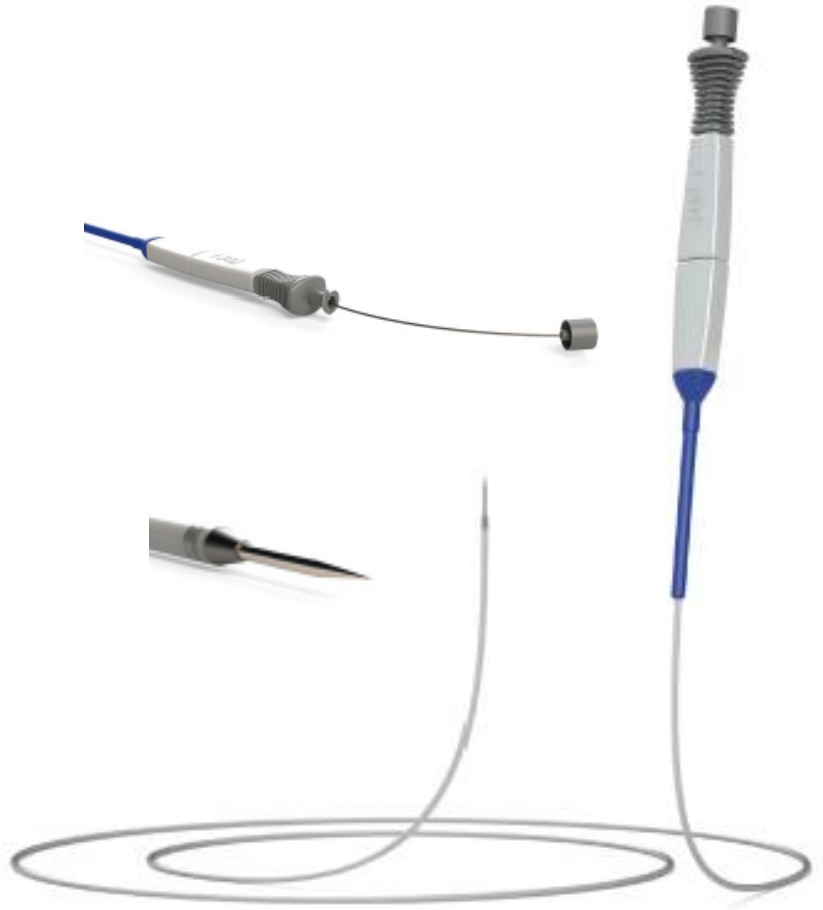
Both tools are designed for removal of intragastric balloons or foreign bodies in the stomach

Endoscopic Aspiration Needle used for the Allurion Balloon

- 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.

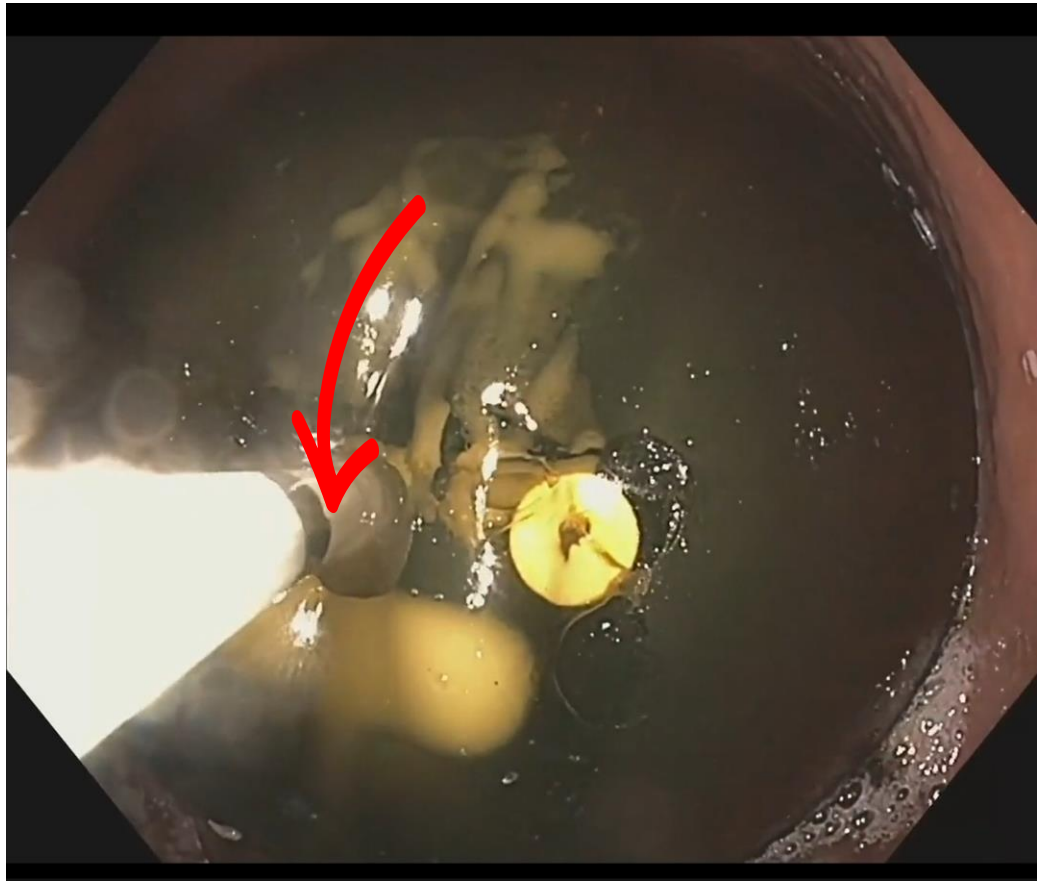
A Steps Using the Endoscopic Aspiration Needle for the Allurion Balloon

1. **Mark the distal end of the endoscopic aspiration needle:** See slide 12 for detail.
2. **Advance the catheter:** Insert a hollow catheter with a puncture needle out of the distal (tip) end through the endoscope and position it adjacent to the target balloon.
3. **Puncture the balloon:** Extend the needle from the catheter to pierce the wall of the balloon.
4. **Withdraw the needle:** Retract the needle back inside the catheter after successful puncture, leaving just the hollow catheter within the balloon.
5. **Aspirate the fluid:** Attach the proximal (external) end of the catheter to either room suction or a luer lock syringe.
6. **Remove balloon fluid:** Use suction or manual withdrawal as appropriate to extract the contents of the balloon through the hollow catheter.
7. **Remove the deflated balloon:** Use endoscopic grasping forceps. See slide 13 for detail.



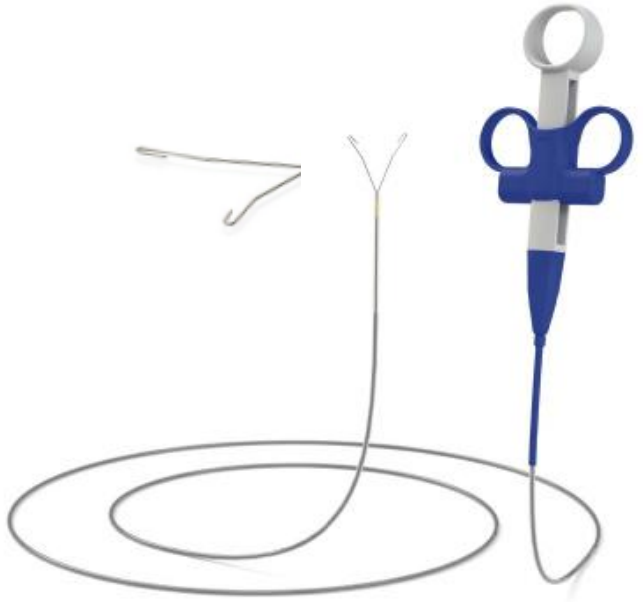
Marking the Endoscopic Aspiration Needle

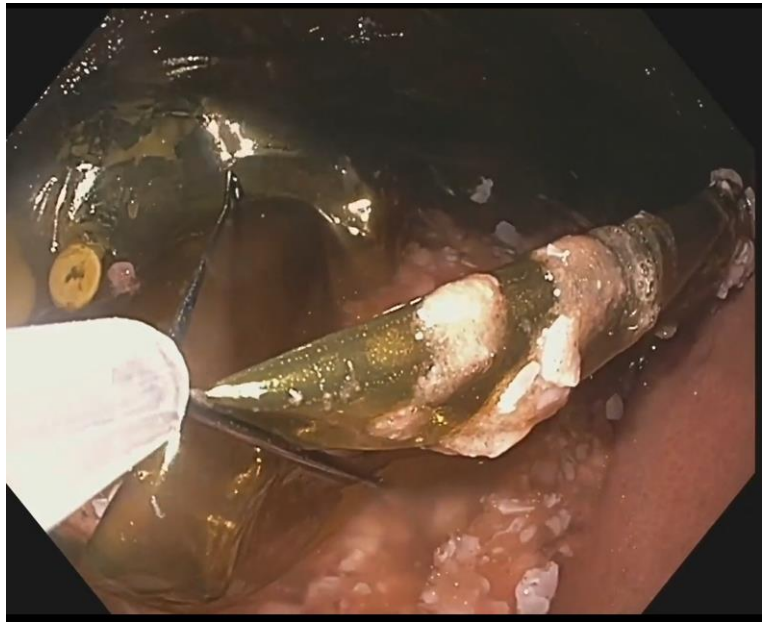
- Mark with a Sharpie at 4cm from distal end.
- Used to visualize depth of needle in the balloon (4 cm = in the middle of balloon).
- Aims to prevent needle from passing through the balloon and penetrating the stomach wall.
- Able to visually maintain depth of needle throughout aspiration of fluid.



Endoscopic Grasping Forceps for the Allurion Balloon

- 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.





Video: Endoscopic Removal of the Allurion Balloon

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

The Allurion Balloon and Small Bowel Obstruction (SBO)

Definition: Where the Allurion Balloon may create a blockage in the small bowel that prevents food, fluids, and gas from moving through the digestive tract.

Clinical Presentation:

Abdominal pain and cramping (often severe)

Nausea and vomiting (possible bilious content)

Abdominal distention (bloated belly)

Inability to pass gas or stool

Signs of dehydration (dry mouth, low urine output, dizziness)

Other symptoms: Fever, rapid heart rate, severe pain, or vomiting blood may indicate complications and require urgent evaluation.

Small Bowel Obstruction due to the Allurion Balloon – Management

Immediate actions:

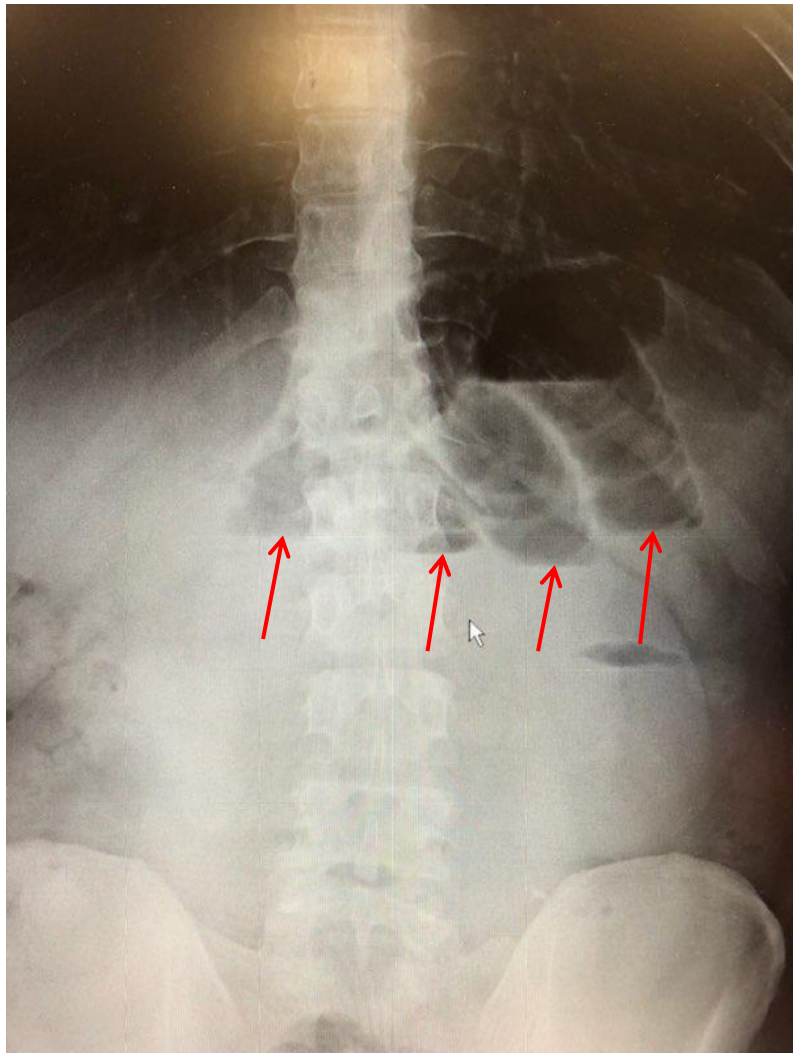
- Hospital admission and close monitoring
- Hospital protocol should be followed. This may include:
  - Resuscitative Management
  - CT Imaging
  - NBM (nil by mouth)
  - Nasogastric tube for decompression if indicated.
  - Surgical review

Definitive management:

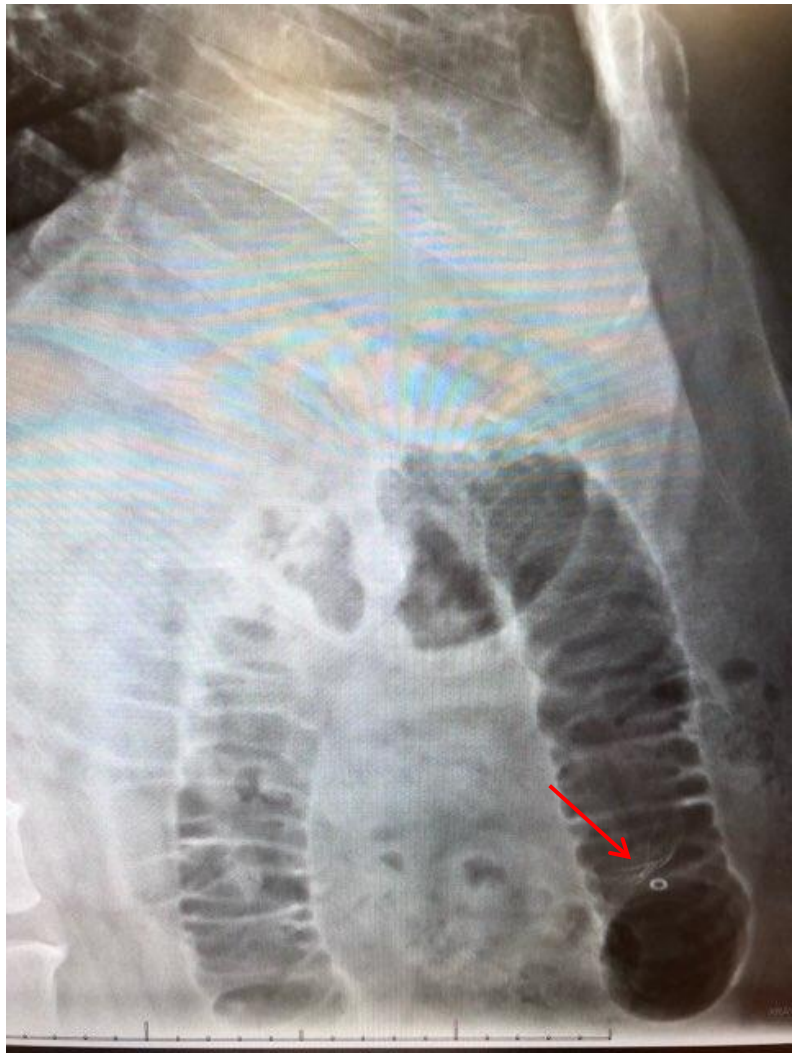
- Surgical intervention is the gold standard especially if there are signs of bowel compromise (perforation, ischemia, persistent obstruction).
- However, in many cases SBO from an Allurion Balloon may be relieved percutaneous (without surgery) by using a long 22-gauge needle under CT or ultrasound guidance, required trained personnel and tools*:
  - An Interventional Radiologist
  - Long 22-gauge fine-needle aspiration needle.
  - CT Scan or Ultrasound.
  - Syringe with luer lock.

***Prompt intervention is critical to prevent serious complications. The use of the CT of Ultrasound needle aspiration technique must be made at the clinician's discretion and if all trained personal and tools are present.**

Typical Images of a Small Bowel Obstruction from an Allurion Balloon



Air fluid levels

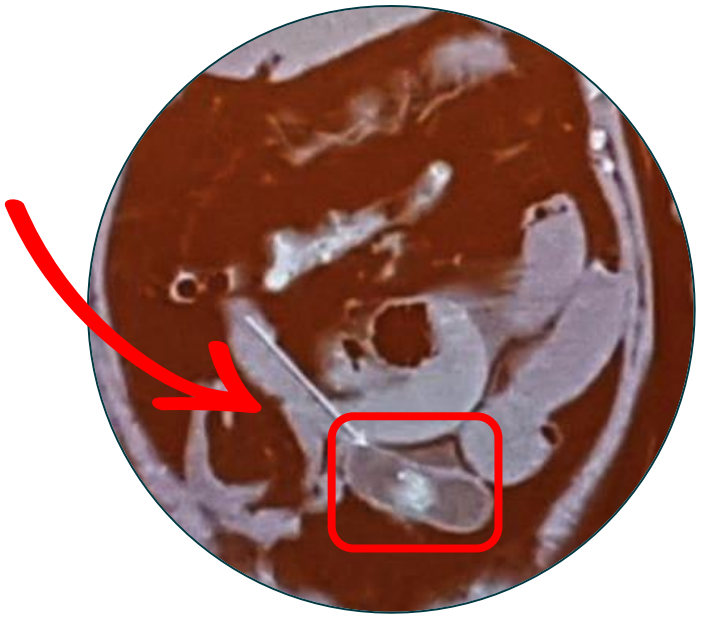


Obstructing balloon causing dilated bowel

SBO from an Allurion Balloon

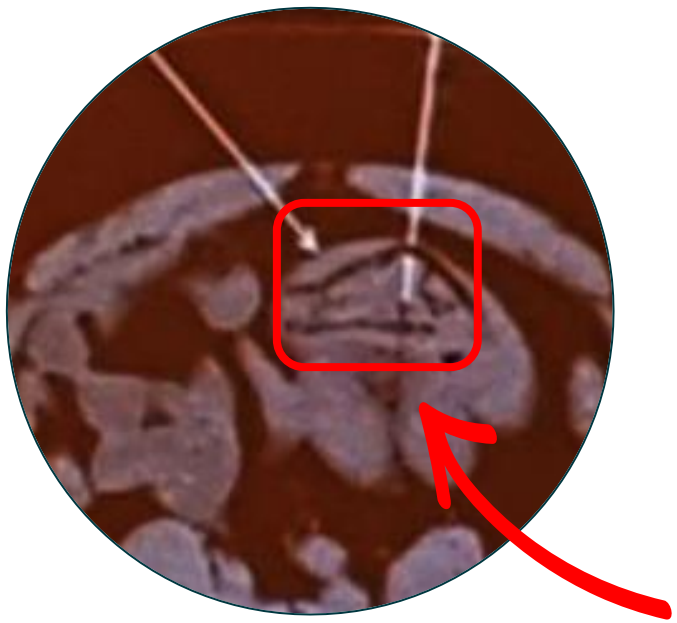
CT scan of obstructing balloon in the small bowel.

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: balloon blocking the ileum, causing obstruction

CT Guided Needle Aspiration: needle inserted into balloon under CT guidance to deflate it



Decompressed balloon: balloon successfully deflated relieving obstruction

The Allurion Balloon and SBO: Symptoms Resolved

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