



# DEVICE SAFETY INFORMATION (DSI)

## Allurion Gastric Balloon: Updated safety information due to the risks of gastric outlet obstruction, small bowel obstruction and gastric perforation

DSI/2026/004

*Specialisms: Anaesthesia and intensive care, Critical care, Emergency medicine, General Practice, General Surgery, GI, hepatology and pancreatic disorders, Radiology and imaging*

### DEVICE DETAILS

Allurion Gastric Balloon (formally known as the Elipse Gastric Balloon)

### AFFECTED LOT SERIAL NUMBERS

All lot serial numbers

### MANUFACTURED BY

Allurion Technologies Inc.

## Summary

In rare instances, the Allurion Gastric Balloon has not transited through the stomach or bowel as intended, leading to complications such as gastric outlet obstruction, small bowel obstruction and gastric perforation. Prompt medical intervention is essential to manage these complications.

Allurion Technologies Inc. have updated documentation with new safety information. Field Safety Notice ([FSN-01-2026](#)) provides further details and should be read in conjunction with this Device Safety Information (DSI).

### Advice for Healthcare Professionals:

- remain vigilant and inform patients of the signs and symptoms of gastric outlet obstruction, small bowel obstruction and gastric perforation associated with the Allurion Gastric Balloon
- act promptly to prevent serious complications, including early referral or review for symptomatic patients
- familiarise yourself with the new safety information and materials as described in [FSN-01-2026](#)
- a Patient Information Card should be completed at the initial appointment and given to the patient at the time of device placement
- essential product and safety information can be accessed in the Physician Guidance Document. This document is available through the Allurion mobile app, the QR code on the Patient Information Card or the link in Table 1 below
- ensure any device that has not performed as intended and/or is involved in an adverse event is returned to Allurion Technologies Inc. for evaluation. Please report details of the event to Allurion Technologies Inc. at [FSN@allurion.com](mailto:FSN@allurion.com) and the MHRA via the [Yellow Card Scheme](#)

### Advice for Healthcare Professionals to Provide to Patients:

- seek medical attention immediately if you experience symptoms such as severe or persistent abdominal pain, vomiting, nausea, swollen abdomen, or breathing difficulty, as these could be symptoms of gastric outlet obstruction, small bowel obstruction or gastric perforation
- always carry your Patient Information Card with you. Show it to any healthcare professional who treats you, especially if you are at a different hospital from where the device was placed and you feel unwell
- if you experience any side effects or issue with your balloon, don't throw it away when it has passed and ensure that you return it to your healthcare professional
- if you suspect that you've had a side effect related to the Allurion Gastric Balloon report it to the MHRA via the [Yellow Card website](#)

### Advice for Distributors:

- please ensure that end users are familiar with this DSI, [FSN-01-2026](#) and the relevant documentation updates

### Explanation of identified safety issue

#### Allurion Gastric Balloon

The Allurion Gastric Balloon (formerly known as Elipse Balloon) is an intragastric balloon (IGB) which is intended to assist with weight loss. Removal of the Allurion Gastric Balloon is unique in comparison to other IGBs as it does not require an endoscopic procedure or sedation. Instead, at the end of the approximately 16-week treatment period, the filled balloon is designed to passively open and drain. At this point, the empty balloon transits through the gastrointestinal tract and is excreted without further intervention.

#### Risk of gastric outlet obstruction, gastric perforation, and small bowel obstruction with the Allurion Gastric Balloon

In rare instances the Allurion Gastric Balloon does not transit through the stomach or bowel as designed, leading to complications such as gastric outlet obstruction, gastric perforation, and small bowel obstruction. These are known but serious complications of intragastric balloons and are listed in the Instructions for Use (IFU) for the Allurion Gastric Balloon as potential adverse reactions and complications.

An MHRA review was conducted following an increase in reports of gastric outlet obstruction, gastric perforation, and small bowel obstruction in the UK and EU; and a temporary suspension of the device by the French National Agency for Medicines and Health Products Safety (ANSM). The findings of this review were considered by the UK's independent Interim Devices Working Group (IDWG) who agreed with the recommendations for further risk minimisation measures and advised that the MHRA remind healthcare professionals and patients of the risks of gastric outlet obstruction, gastric perforation, and small bowel obstruction.

The MHRA has received 8 UK reports of perforation and small bowel obstruction, and 13 UK reports of gastric outlet obstruction related to the Allurion Gastric Balloon, occurring between 2018 and 2024. While the number of adverse incidents in the UK is low, there is a potential for serious consequences. In all UK reported cases, additional intervention, such as surgery or endoscopic procedure was required. Following intervention, all patients recovered and no further complications were reported.

#### New advice for managing risk of gastric outlet obstruction, gastric perforation, and small bowel obstruction with the Allurion Gastric Balloon

Following the conclusion of the MHRA review, Allurion Technologies Inc. has strengthened the Allurion Gastric Balloon patient programme to more effectively manage these rare risks. The device remains available for use in the UK.

Details of these updates and associated documents can be found in [FSN-01-2026](#). Additionally, a summary of these updates is provided in Table 1 below.

*Table 1: Summary of updates to the Allurion Gastric Balloon programme*

<b>Updated Document/ Procedure</b>	<b>Summary of Update</b>
Instructions for Use (IFU)	'Section 6: Patient Program' of the IFU has been updated to include information on the patient information card, follow-up appointments (recommended at least once following placement) and device return procedure.
Patient Information Card	The card contains updated fields which healthcare professionals must fill out at placement and a QR code linking directly to the Physician Guidance Document.
Device Return Process	Any device involved in an adverse event or that has not performed as intended must be returned to Allurion for root-cause analysis. Devices should be returned to: Allurion Technologies – Device Returns 11 Huron Drive Natick, MA 01760 United States
Physician Guidance Document	This has been updated with essential safety and product information, and can be accessed through the Allurion mobile app or by scanning the QR code on the Patient Information Card. Alternatively, this can be accessed in the following link: <a href="#">QR Page   Allurion</a>
Informed Consent Template	This has been updated to include all contraindications from the IFU and new information on the patient programme. Please update your informed consent forms accordingly.
Patient Mobile App Articles	Updates have been made to relevant articles to ensure patients receive clearer and more prominent warnings regarding SAEs.

### Reporting advice

Healthcare professionals should report incidents:

- in England and Wales to the [Yellow Card website](#) or via the Yellow Card app
- in Scotland to [Incident Reporting & Investigation Centre \(IRIC\)](#) and their local incident recording system
- in Northern Ireland to the Yellow Card website in accordance with your organisations medical device policies and procedures.

### Additional information:

You can [sign up](#) to receive email updates on alerts and device safety information from the MHRA.

You can [sign up](#) to receive our monthly roundup of safety communications.

For any enquiries, please contact [info@mhra.gov.uk](mailto:info@mhra.gov.uk)

### Stakeholder engagement:

- British Society of Gastroenterology (BSG)
- NHS England National Patient Safety team
- Royal College of Surgeons of Edinburgh (RCSEd)
- Medical Device and Estates Safety (MDES) for Department of Health N. Ireland
- Incident Reporting & Investigation Centre (IRIC) for Scotland
- Welsh Government