

Device Safety Information



Medicines & Healthcare products
Regulatory Agency

SAMPLE

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).