Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 140 **dated** 26/9/2024 **Regarding SFDA Field Safety Corrective Action of Allurion Device / Elipse Gastric Balloon System from (mfr: Allurion Technologies Inc).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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سلطنة عُمان
وزارة الصحة
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مسقط

Circular No. 140 / **2024**

22 -03-1446 H
26 -09-2024

Field Safety Corrective Action of Allurion Device / Elipse Gastric Balloon System from Allurion Technologies Inc.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/114
Product	Allurion Device / Elipse Gastric Balloon System.
Manufacturer	Allurion Technologies Inc.
Local agent	Medical Experts Services-MEDEX.
The affected products	Reference Number: 10D Lot Number: N/A- no impact to specific lot.
Reason	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 the facilities placing the device are trained on the optimal least invasive management of certain conditions, the clinical staff in the facilities where the patient 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 incorporated into the updated IFU.
Action	1. Allurion is releasing key patient management information on the Allurion Balloon, including the proper management of certain rare complications, like GOO or SBOM as well as endoscopic removal of the Allurion Balloon. Allurion is also updating the device IFU to include some important changes. Please refer to the attachment for more information. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

سلطنة عمان - وزارة الصحة - مركز سلامة الدواء
SULTANATE OF OMAN - MINISTRY OF HEALTH
DRUG SAFETY CENTER

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Allurion

Urgent- Field Safety Notice

Allurion Device/Elipse Gastric Balloon System

FSN Ref: SA-28-08-24-574

FSCA Ref: SA-28-08-24-574

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: 18 September 2024

For Attention of: Physicians in the Kingdom of Saudi Arabia managing patients on the Allurion Program.

Details of concerned devices:

Name of Device	Reference Number	Lot Number
Allurion Device / Elipse Gastric Balloon System	10D	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.

Bill Nadeau

VP Medical Affairs

DocuSigned by:
Bill Nadeau
F313CC3B118D40E...

18 September 2024

Joyce Johnson

SVP Regulatory Affairs/ Quality Affairs

DocuSigned by:
Joyce Johnson
8AAD9DA1DFF5466...

18 September 2024

Customer Response/ Acknowledgement

Allurion

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

Allurion

A Table of Contents

A

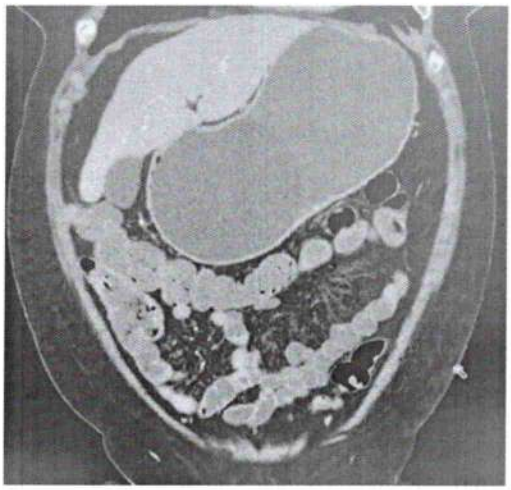
Medical Management of Gastric Outlet Obstruction from the Allurion Balloon

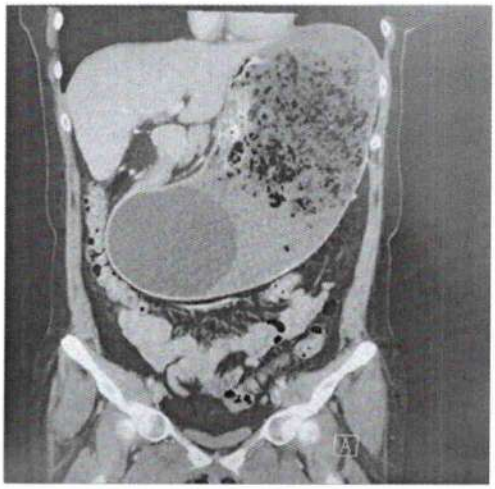
11 Huron Drive, Natick, Massachusetts, 01760, USA

allurion.com

Allurion

A Gastric outlet obstruction:
How do you manage?





A 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.

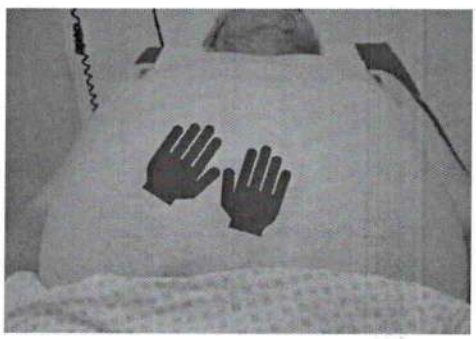
02 Feel the balloon in the mid to lower distended abdomen with both hands.

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.

Allurion

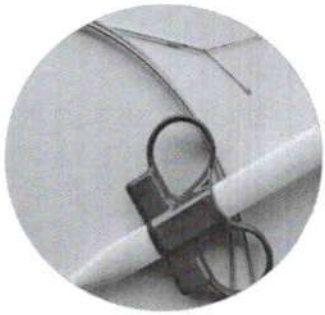
A

Endoscopic removal of the Allurion Balloon

A Balloon Aspiration and Removal **Tools**

Standard Upper GI Endoscope

Endoscopic aspiration needle



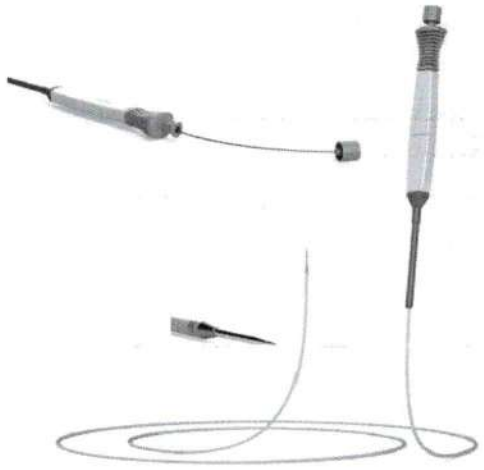
Endoscopic grasping forceps

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

Allurion

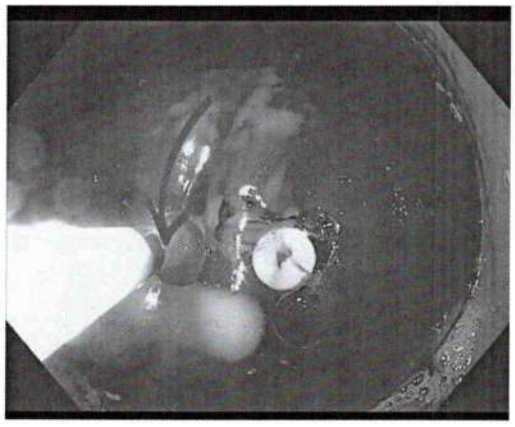
A Endoscopic Aspiration Needle

- 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.



A 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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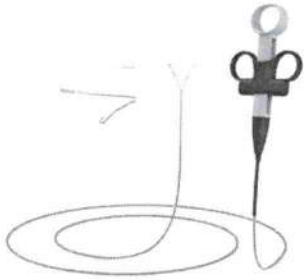
A Endoscopic Grasping Forceps

- 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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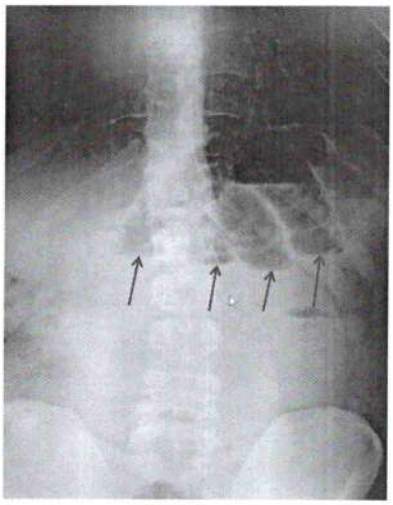
allurion.com

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

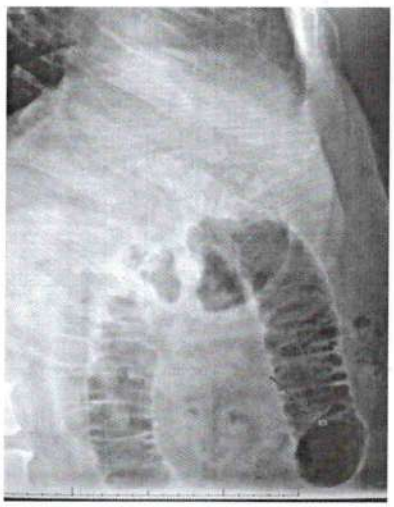
Required Tools

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

A Typical Images of a Small Bowel Obstruction from an Allurion Balloon

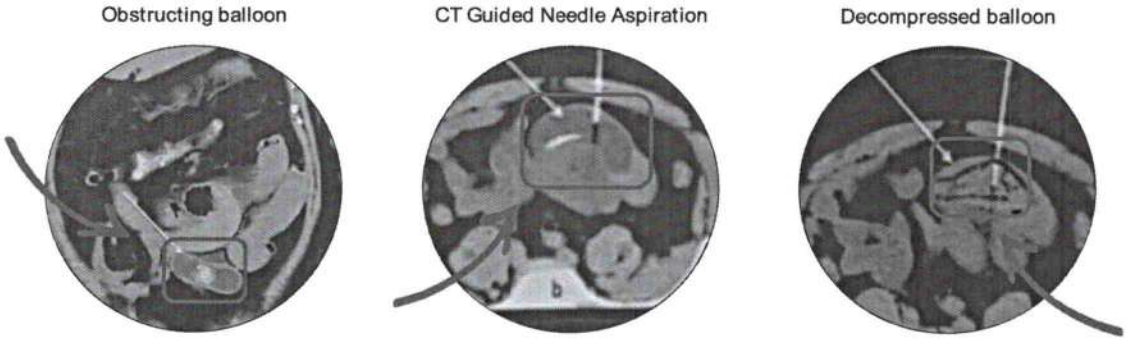


Air fluid levels



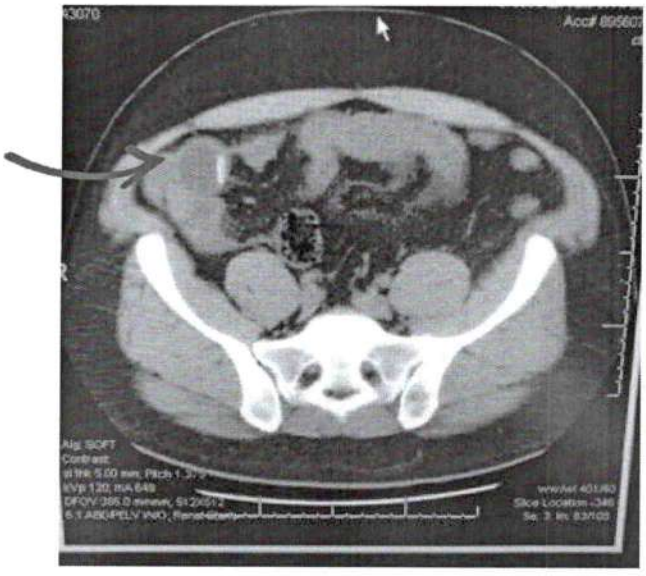
Obstructing balloon causing dilated bowel

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



A SBO from an Allurion Balloon

CT scan followed by ultrasound guided needle aspiration.



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A SBO Symptoms Resolved

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