

Allurion Assurance Plus Warranty Programme

This document describes the Allurion Assurance Plus Warranty Program for the Elipse Gastric Balloon System effective 1 January, 2021. The warranty is described in the table below:

Covered Event	Warranty program
Spontaneous premature balloon deflation before 90 days	Replacement product sent out to patient's doctor at no charge to patient or doctor. Patient and/or doctor are responsible for any costs associated with placement procedure.
Hyperinflation requiring endoscopic removal	Financial assistance up to \$8,000 USD. Allurion will pay out-of-pocket expenses for procedure fees, X-ray expenses and endoscopic expenses directly related to revision procedure and not covered by insurance, up to a maximum aggregate amount of \$8,000 USD.
Acute Pancreatitis	Financial assistance up to \$8,000 USD. Allurion will pay out-of-pocket expenses for procedure fees, X-ray expenses and endoscopic expenses directly related to revision procedure and not covered by insurance, up to a maximum aggregate amount of \$8,000 USD.
GI Perforation	Financial assistance up to \$20,000 USD. Allurion will pay out-of-pocket expenses for surgical fees, operating room, and anaesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of \$20,000 USD.
Small bowel obstruction	Financial assistance up to \$12,000 USD. Allurion will pay out-of-pocket expenses for surgical fees, operating room, and anaesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of \$12,000 USD.

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Spontaneous premature balloon deflation, hyperinflation, acute pancreatitis, GI perforation and small bowel obstruction are among the known risks of gastric balloons.

The doctor’s medical training, familiarity with the devices and procedures used, and knowledge of the patient and the patient’s medical history, places the doctor in the best position to provide the patient with the risks and benefits of the procedures and the Elipse Balloon. Therefore, the doctor, as learned intermediary, is responsible for providing the patient with appropriate risk information before the procedure, including (but not limited to) the risk of spontaneous premature balloon deflation, hyperinflation, acute pancreatitis, GI perforation and small bowel obstruction, and other possible adverse reactions and complications associated with gastric balloons. The primary source of risk information for patients is through this learned intermediary, though Allurion also makes available to all doctors and patients a copy of the Instructions for Use (IFU) describing the benefits and risks of the Allurion Program with the Elipse Balloon via our website. Copies can also be obtained by contacting Allurion directly. This document is not intended to, and cannot, take the place of a full and candid discussion between doctor and patient, or the important safety information contained in the IFU. A digital copy of the IFU can be found at <https://allurion.com/quality-risk-information>.

Qualified Allurion Program Elipse Balloons are the following (hereinafter referred to as “Elipse Balloons”): Elipse Balloons: REF 10B and 10C part numbers F010-17 and FS010-20

THIS IS A LIMITED WARRANTY ONLY AND IS SUBJECT TO THE TERMS AND CONDITIONS SET FORTH IN THIS DOCUMENT. ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE EXCLUDED. THE REPLACEMENT OF QUALIFIED ELIPSE BALLOONS AND PAYMENT OF DEFINED AMOUNTS FOR NECESSARY REVISION PROCEDURES OR SURGERY AS SET FORTH IN THIS LIMITED WARRANTY ARE, TO THE MAXIMUM EXTENT ALLOWED UNDER APPLICABLE LAW, THE PATIENT’S SOLE AND EXCLUSIVE REMEDY. ALLURION SHALL NOT BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL LOSS, DAMAGE, OR EXPENSE ARISING DIRECTLY OR INDIRECTLY FROM THE USE OF THESE PRODUCTS. ALLURION NEITHER ASSUMES, NOR AUTHORISES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS. THIS SECTION, TOGETHER WITH THIS LIMITED WARRANTY, ALLOCATE THE RISKS BETWEEN ALLURION AND THE PATIENT. THIS ALLOCATION IS REFLECTED IN THE PRICING OF THE PRODUCTS AND IS AN ESSENTIAL ELEMENT OF THE BASIS OF THE BARGAIN BETWEEN ALLURION AND THE PATIENT. SOME LOCALITIES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, OR THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATIONS MAY NOT APPLY TO A GIVEN PATIENT.

APPLICATION OF THE ALLURION WARRANTIES A. WARRANTY

1. **Timeline:** The Allurion Warranty applies automatically to Elipse Balloons placed in all Allurion markets outside the United States of America, where an eligibility claim has been filed on or after 1 January, 2021 and supersedes any previous Allurion warranty Program previously applicable. Claims for spontaneous premature balloon deflation before 90 days inside body must be made within 120 days of initial balloon placement. Claims for Hyperinflation, acute pancreatitis, GI perforation and small bowel obstruction must be made within 180 days of initial placement.

2. **Covered Events:** The Allurion Warranty applies only to the following covered events (each a “Covered Event”) if they require surgical intervention:
 3.
 1. (i) Spontaneous premature balloon deflation before 90 days inside the body entitles patients to (1) no-charge product sent out to the doctor to replace affected balloon. Individual doctors shall determine if any additional charges will be incurred by the patient for the placement procedure, but patient will not be charged for the replacement balloon;
 2. (ii) Hyperinflation with approximately half of the balloon filled with gas requiring endoscopic removal entitles patient to financial assistance up to \$8,000 USD. Allurion will pay out-of-pocket expenses for procedure fees, X-ray expenses and endoscopic expenses directly related to revision procedure and not covered by insurance, up to a maximum aggregate amount of \$8,000 USD;
 3. (iii) Acute pancreatitis requiring endoscopic removal entitles patient to financial assistance up to \$8,000 USD. Allurion will pay out-of-pocket expenses for procedure fees, X-ray expenses and endoscopic expenses directly related to revision procedure and not covered by insurance, up to a maximum aggregate amount of \$8,000 USD;
 4. (iv) GI perforation requiring surgical removal entitles patients to financial assistance up to \$20,000 USD. Allurion will pay out-of-pocket expenses for surgical fees, operating room, and anaesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of \$20,000 USD; or
 5. (v) Small bowel obstruction requiring surgical removal entitles patients to financial assistance up to \$12,000 USD. Allurion will pay out-of-pocket expenses for surgical fees, operating room, and anaesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of \$12,000 USD.

The Allurion Warranty may also apply to other event-related losses of product integrity not specifically excluded, subject to review and approval by Allurion.

Events Not Covered: The Allurion Warranty does not apply to:

1. (a) Though clinical studies have shown that patients lose an average of 10 to 15 kg, Allurion does not guarantee that any individual patient will lose weight, or how much weight any individual will lose, and this warranty does not cover weight loss not meeting this clinical study average and/or patient expectations;
2. (b) Gastric balloons can cause varying degrees of discomfort and other symptoms of intolerance, which at times may result in premature endoscopic removal, but the warranty does not cover endoscopic removal that is not accompanied by another covered claim outlined in 2(a);
3. (c) Adverse events caused by off-label or contraindicated use;

(a) For the Elipse Balloon:

(d) Doctor or patient-related negligence or misuse;

The Allurion Warranty excludes other events outside the covered events listed in section A.2(a) above.

4. Release: Patients must provide a signed, general release to Allurion to obtain reimbursement. **B. PATIENT INFORMATION ON THE ALLURION WARRANTY**

Before the procedure, the doctor should explain the details of the Allurion Warranty, including product replacement, to the patient, and provide the patient with access to a copy of this document. In addition to explaining the terms of the Allurion Warranty and Product Replacement, the doctor should review with the patient the device IFU provided by Allurion, describing the benefits and risks of a gastric balloon procedure. A digital copy of this eIFU can be found at <https://allurion.com/quality-risk-information>.

C. FILING A CLAIM

If a Covered Event occurs, the doctor should contact Allurion's Product Surveillance Department to obtain instructions via email at complaints@Allurion.com.

Required documentation for each covered event includes a signed, general release from the patient and documentation evidencing a covered claim, which includes:

Product arrives damaged:

1. Image of damaged product;
2. Return of damaged product for inspection.

Spontaneous premature balloon deflation before 90 days

1. Endoscopic, X-ray or Ultrasound confirmation showing absence of balloon in the stomach, or passage of the balloon observed by patient and documented with image;
2. Completed complaint report form (SOP13-F1 Product Feedback Report);
3. If possible, return of the passed balloon for inspection. Allurion will provide packaging

materials and cover the return delivery costs.

Hyperinflation requiring endoscopic removal

1. Endoscopic, X-ray or Ultrasound confirmation showing hyperinflation of balloon in the stomach with approximately half of the balloon filled with gas;
2. Completed complaint report form (SOP13-F1 Product Feedback Report);
3. Receipts for patient's out-of-pocket expenses;
4. If possible, return of the balloon fluid for inspection.

Acute pancreatitis

1. Laboratory confirmation of acute pancreatitis;
2. Completed complaint report form (SOP13-F1 Product Feedback Report);
3. Receipts for patient’s out-of-pocket expenses.

GI Perforation

1. X-ray or CT confirmation of the perforation;
2. Completed complaint report form (SOP13-F1 Product Feedback Report);
3. Receipts for patient’s out-of-pocket expenses.

Small bowel obstruction

1. X-ray or CT confirmation of the small bowel obstruction;
2. Completed complaint report form (SOP13-F1 Product Feedback Report);
3. Receipts for patient’s out-of-pocket expenses;
4. If possible, return of the balloon for inspection.

Allurion reserves the right to request additional information to confirm the authenticity of a claim, and the provision of false information is grounds for denial of a claim.

Paperwork can be emailed to Complaints@Allurion.com.

Upon receipt of the required documentation, and of the properly signed release and claim form, replacement product or a cheque will be issued to the appropriate party or parties in accordance with limitations outlined in this document. The cheque will be made payable to the party or parties indicated by the patient on the release form.

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