

Allergan Breast Implant Warranty Programme

This document describes Allergan’s Saline-Filled and Silicone-Filled Breast Implant Warranty Program effective January 1, 2020. The Breast Implant Limited Warranties consist of the *ConfidencePlus*® Warranty the *ConfidencePlus*® Premier Warranty and are described in the table below:

Adverse Event	Warranty program
BIA-ALCL confirmed	<p>Complimentary product replacement plus financial assistance up to \$7,500USD.</p> <p>Allergan will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of \$7,500USD.</p>
Rupture (Silicone-Filled only)	<p>Complimentary product replacement plus financial assistance up to \$3,500USD.</p> <p>Allergan will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of \$3,500USD. Allergan will pay up to this amount for all silicone implants implanted within the last 10 years.</p>
Deflation (Saline-Filled only)	<p>Complimentary product replacement plus financial assistance up to \$1,200USD.</p> <p>Allergan will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of \$1,200USD. Allergan will pay up to this amount for all saline implants implanted within the last 10 years.</p> <p>* For <i>ConfidencePlus</i>® Premier Warranty, Allergan will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of \$3,500USD. Allergan will pay up to this amount for all saline implants implanted within the last 10 years.</p>
Capsule Contracture	<p>Complimentary product replacement up to 10 years following the date of implantation surgery.</p>
Late Seroma	<p>Complimentary product replacement up to 10 years following the date of implantation surgery.</p>

Deflation, rupture, capsular contracture and late seroma are among the known risks of breast implants. Capsular contracture is defined as the tightening of the tissue capsule around an implant, resulting in firmness or hardening of the breast and squeezing of the implant. Late seroma is defined as a pocket of serous fluid that develops at least 12 months after breast augmentation and presents with clinically evident swelling.

The plastic surgeon, as learned intermediary, is responsible for providing the patient with appropriate risk information before surgery, including (but not limited to) the risk of deflation, rupture and Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Allergan makes available to all plastic surgeons and patients a copy of the device appropriate informed decision brochure describing the benefits and risks of surgery with either its Saline-Filled or Silicone Gel-Filled breast implants. Copies can also be obtained by contacting Allergan directly, or through the Allergan website. The plastic surgeon should also advise the patient about possible adverse reactions and complications associated with Saline-Filled and Silicone Gel -Filled breast implants. **This document is not intended to, and cannot, take the place of a full and candid discussion between plastic surgeon and patient or the informed decision brochure for patients.**

Qualified Allergan Breast Implants are the following (hereinafter referred to as “Allergan Breast Implants”):

Saline-Filled Breast Implants: Style 68, 163, 168, 363, 468

Silicone-Filled Breast Implants: Style 10, 15, 20, 110, 115, 120, 410, INSPIRA

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 ALLERGAN BREAST IMPLANTS AND PAYMENT OF DEFINED AMOUNTS FOR NECESSARY REVISION SURGERY AS SET FORTH IN THIS LIMITED WARRANTY ARE, TO THE MAXIMUM EXTENT ALLOWED UNDER APPLICABLE LAW, PATIENT’S SOLE AND EXCLUSIVE REMEDY. ALLERGAN 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. ALLERGAN NEITHER ASSUMES, NOR AUTHORIZES 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 ALLERGAN 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 ALLERGAN AND THE PATIENT.

I. APPLICATION OF THE ALLERGAN WARRANTIES

A. WARRANTY

- 1. Timeline:** The Allergan Warranty applies automatically to Allergan Breast Implants implanted in all Allergan markets outside the United States of America, where an eligibility claim has been filed on or after January 1, 2020 and supersedes any previous Allergan Warranty Program previously applicable.
- 2. Covered Events:** The Allergan Warranty applies only to the following covered events (each a “Covered Event”) if they require surgical intervention:

- (a) For NATRELLE® Silicone-Filled Breast Implants:
 - (i) rupture of Allergan Silicone-Filled Breast Implants due to crease fold failure;
 - (ii) loss of shell integrity from unknown cause;
 - (iii) removal of implants for capsular contracture Baker grade III/IV (product replacement only within ten years of augmentation surgery);
 - (iv) removal of implants for late seroma (product replacement only within ten years of augmentation surgery); or
 - (v) BIA-ALCL diagnosis.

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

3. **Events Not Covered:** The Allergan Warranty does not apply to:

- (a) removal of implants for size alteration;
- (b) removal of implants due to wrinkling or rippling;
- (c) loss of shell integrity caused by operative procedures;
- (d) loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures; or
- (e) removal of implants due to double capsule

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

4. **Cost:** No cost.

5. **What Allergan will provide under the Allergan Warranty:**

- (a) **Product Replacement:** If patient has a Covered Event, Allergan will replace the qualified Allergan product with another Allergan product, of the same or similar type as the qualifying product, free of charge as per the terms of the relevant Covered Event. Implantation of the replacement Allergan product, as well as any subsequent procedures, must be in strict accordance with current Allergan product literature and accepted plastic surgical procedures by appropriately qualified licensed plastic surgeons for such product to qualify for replacement.

The explanted product must be returned to the Allergan Device Analysis Laboratory within 90 days of its explant in order to qualify for the free of charge replacement product. For claims where both devices are explanted, both explanted devices must be returned. In the event that the explanted product is not returned to the Allergan Device Analysis

Laboratory within 90 days of its explanation, the ordering customer will be invoiced for the price of the replacement product. Qualifying replacement product will be sent without shipping charges. Allergan will neither provide nor pay for a non-Allergan product, nor in any event provide money for or in lieu of an Allergan replacement product. Any replacement NATRELLE® Style, Saline-Filled or Silicone-Filled Breast Implant, automatically includes a new Allergan Warranty covering the replacement implant only.

(b) For NATRELLE® Saline-Filled Breast Implants:

- (i) When a qualifying replacement surgery for a Covered Event occurs within 10 years from the date of implantation, Allergan will pay out -of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of \$1,200USD. Upon submission of a qualifying request, Allergan will provide a general release in favor of Allergan, which is required to be executed by the patient prior to release of any funds related to the foregoing.
- (ii) At the plastic surgeon's request, Allergan will also provide an upgrade replacement Silicone-Filled Breast Implant (round silicone gel only).
- (iii) At the plastic surgeon's request, Allergan will also provide a replacement of a NATRELLE® Saline-Filled or Silicone-Filled Breast Implant (round silicone gel only), as the case may be, to use to replace the contralateral implant. Upon submission of a qualifying request for financial assistance, Allergan will provide a general release in favor of Allergan. The plastic surgeon may also request an upgrade to a round silicone gel upgrade.

(c) For NATRELLE® Silicone-Filled Breast Implants:

- (i) When a qualifying replacement surgery for a Covered Event occurs from the date of implantation within the timelines set out in Table I above, Allergan will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of \$3,500USD. Upon submission of a qualifying request, Allergan will provide a general release in favor of Allergan, which is required to be executed by the patient prior to release of any funds related to the foregoing.
- (ii) Allergan will not pay for any re-operative expenses until receipt of the release signed by the patient. In addition, Allergan may require a copy of bills or receipts associated with the revision surgery before payment will be made. Other documentation, such as operative notes and photos, may be required prior to payment. Request for financial assistance under the Allergan Warranty must be made to the Product Support Department prior to the date of qualifying revision surgery.
- (iii) Should a more expensive Allergan product be requested by the plastic surgeon, Allergan will invoice the ordering customer for the list price difference between the qualified product to be replaced and the requested replacement product.

The customer will not be credited or reimbursed for the list price difference between the qualified product to be replaced and the requested replacement product should the plastic surgeon request a less expensive replacement product.

At the surgeon's request, Allergan will also provide a replacement of a NATRELLE® Silicone-Filled Breast Implant to use to replace the contralateral implant. Upon submission of a qualifying request for financial assistance, Allergan will provide a general release in favor of Allergan.

(c) For BIA-ALCL diagnosis:

- (i) When documentation of a positive diagnosis of BIA-ALCL is provided by a pathology report confirming CD30 positive, ALK negative cytology and/or histology as per the NCCN [National Comprehensive Cancer Network] guidelines, Allergan will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of \$7,500USD. Upon submission of a qualifying request, Allergan will provide a general release on Allergan's standard form.
- (ii) Allergan will not pay for any re-operative expenses until receipt of the release signed by the patient. In addition, Allergan may require a copy of bills or receipts associated with the revision surgery before payment will be made. Other documentation, such as operative notes and photos, may be required prior to payment. Request for financial assistance under the Allergan Warranty must be made to the Product Support Department upon confirmation of a positive diagnosis.
- (iii) Should a more expensive Allergan product be requested by the plastic surgeon, Allergan will invoice the ordering customer for the list price difference between the qualified product to be replaced and the requested replacement product.

The customer will not be credited or reimbursed for the list price difference between the qualified product to be replaced and the requested replacement product should the plastic surgeon request a less expensive replacement product.

At the surgeon's request, Allergan will also provide a replacement of a NATRELLE® Silicone-Filled Breast Implant to use to replace the contralateral implant. Upon submission of a qualifying request for financial assistance, Allergan will provide a general release in favor of Allergan.

B. PATIENT INFORMATION ON THE ALLERGAN WARRANTY

Before implantation surgery, the plastic surgeon should explain the details of the Allergan Warranty, including product replacement, to the patient, and provide the patient with a copy of this document. In addition to explaining the terms of the Allergan Warranty and Product Replacement, the plastic surgeon should also advise the patient about possible adverse reactions and complications associated with Saline-Filled and Silicone-Filled Breast Implants, including the risk of BIA-ALCL, and review with the patient the device appropriate informed decision brochure provided by Allergan, describing the benefits and risks of surgery with either its Saline-Filled or Silicone Gel-Filled breast implants.

C. FILING A CLAIM

If a Covered Event occurs within ten years of the date of an implantation/or at any time for BIA-ALCL coverage under the Allergan Warranty, the plastic surgeon should contact Allergan's Product Surveillance Department to obtain a return kit and instructions prior to revision surgery at (800) 668-6424 or via email at aus-breastinterntionalcomplaints@allergan.com. If revision surgery is planned based on reliance of Magnetic Resonance Imaging (MRI) findings of suspected rupture of an ALLERGAN® Silicone-Filled Breast Implant, a copy of the MRI report must be received by Allergan Product Support in advance of the revision surgery in order for a subsequent claim to be considered for approval. In the case of a claim under a late seroma event for patients with textured implants only, a diagnosis qualifies as > 50 cc of fluid presented at least 12 months after surgery, upon a confirm diagnosis by a surgeon and confirmed by photographs, pathology, or other reports deemed acceptable by Allergan. In the case of a positive diagnosis of BIA-ALCL, the following documents shall be provided: a pathology report confirming BIA-ALCL diagnosis through confirmation of a CD-30 positive, ALK-negative cytology and/or histology. Once revision surgery occurs, send (a) a copy of the Returned Goods Authorization (RGA); (b) the patient's completed general release form; (c) the signed claim form, and (d) the removed and decontaminated Allergan product. This information should be sent to:

UPS SCS, INC.
4150 MAINWAY BUILDING 2
BURLINGTON, ON L7L0A6
CANADA

Paperwork can also be emailed to aus-breastinterntionalcomplaints@allergan.com.

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

Replacement products may be ordered before surgery by contacting Allergan's Customer Care Department at (866) 653-9308.

D. Limitation on Product Replacement

Replacement of Allergan Biocell Breast Implant

Where a patient is eligible for a replacement product under the Warranty Program, Allergan will provide the following support, depending on physician recommendation and patient consent:

- a) An Allergan smooth replacement product will be offered; or
- b) Allergan will reimburse the cost of the Allergan smooth implant back to the doctor/patient.

If Allergan's obligation to provide a replacement product under the Allergan Warranty is prevented, restricted, or interfered with by reason of fire, flood, earthquake, explosion, or other casualty or accident, strikes or labor disputes, inability to procure supplies or power, war or other violence, any law, order, proclamation, regulation, ordinance, demand, or requirement of any government agency, or any other act or condition whatsoever beyond the reasonable control of Allergan, the performance of that obligation shall be excused without penalty. For purposes of this provision, excuse of performance shall mean that Allergan is neither obligated to provide nor pay for a replacement product, regardless of the

product's source. Despite the excuse of Allergan's obligation to provide a replacement product under this provision, Allergan shall continue to perform its obligation to provide financial assistance for operating room, anesthesia, and surgical fee costs to the extent described under the Allergan Warranty.

Allergan reserves the right to cancel, change, or modify the terms of the Allergan Warranty. Any such cancellation, change, or modification will not affect the currently stated terms for those already enrolled in the Program.

NATRELLE® is a trademark of Allergan.

All rights reserved. © 2019 Allergan.