

Allergan Breast Implant Warranty Programme

This document describes Allergan's Saline-Filled and Silicone-Filled Breast Implant Warranty Program effective January 1, 2018. The Breast Implant Limited Warranties consist of the *ConfidencePlus®* Warranty and the *ConfidencePlus®* Premier Warranty and are described in the table below:

		<i>ConfidencePlus®</i> Warranty	<i>ConfidencePlus®</i> Premier Warranty
SALINE	Cost of Coverage	Free	\$200 USD
	Terms of Coverage	10 years	10 years
	Financial Assistance* †† Deflation	Up to \$1,200 USD	Up to \$3,500 USD
	Product Replacement & Contralateral Implant (on request)	Lifetime Replacement	Lifetime Replacement
	Round silicone gel upgrade	Yes	Yes
	Rare events coverage for Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)†		
	Product Replacement	Lifetime Replacement	Lifetime Replacement
SILICONE	Financial Assistance* ††	Up to \$5,000 USD	Up to \$5,000 USD
	Cost of Coverage	Free	\$200 USD
	Terms of Coverage	10 years	10 years
	Rupture	10 years	10 years
	Capsular contracture (Baker grade III/IV)	5 years †††	10 years
	Late seroma	10 years ††††	
	Double capsule	5 years	10 years
	Financial Assistance* ††	5 years	10 years
	Rupture	Up to \$3,500 USD	Up to \$3,500 USD
	Capsular contracture (Baker grade III/IV)	\$0	\$0
	Late seroma	\$0	\$0
	Double capsule	\$0	\$0
	Product Replacement & Contralateral Implant (on request)	Lifetime Replacement	Lifetime Replacement
	Rupture		
	Capsular contracture (Baker grade III/IV)	5 years	10 years
	Late seroma	5 years	10 years
	Double capsule	5 years	10 years
	Rare events coverage for (BIA-ALCL)†		
	Product Replacement	Lifetime Replacement	Lifetime Replacement
	Financial Assistance* ††	Up to \$5,000 USD	Up to \$5,000 USD

† for diagnosis after January 1, 2018

†† for out of pocket expenses not covered by insurance

††† for surgeries prior to January 1, 2018

†††† for surgeries after January 1, 2018

* subject to review and approval by Allergan after submission of all required documentation including: PFN complaint form, photo and/or operative note & explant

Deflation, rupture, capsular contracture, late seroma and double capsule 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. Double capsule is defined as the separation of the capsule into 2 layers such that the inner layer is adherent to the implant surface. The inner layer may adhere only partially or circumferentially.

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, 168, 468

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

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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 on or after January 1, 2018, and supersedes any previous Allergan Warranty Program previously applicable. The Allergan Warranty shall govern the Rare events coverage for Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), while the Allergan ConfidencePlus® Warranty shall continue to apply automatically to NATRELLE® Saline-Filled and NATRELLE® Silicone-Filled Breast Implants implanted in Canada on or after January 1, 2015. Eligible

patients implanted during the period April 1, 2002 through to December 31, 2014 remain covered under the terms and conditions stated in the Allergan ConfidencePlus® Warranty Program applicable during the time of implantation.

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® Saline-Filled Breast Implants:

- (i) deflation of NATRELLE® Saline-Filled Breast Implants due to crease fold failure; or
- (ii) loss of shell integrity from unknown cause; or
- (iii) loss of valve integrity;
- (iv) BIA-ALCL diagnosis

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

- (i) rupture of Allergan Silicone-Filled Breast Implants due to crease fold failure; or
- (ii) loss of shell integrity from unknown cause; or
- (iii) removal of implants for capsular contracture Baker grade III/IV (product replacement only within five years of augmentation surgery for surgeries performed prior to January 1, 2018); or
- (iv) removal of implants for capsular contracture Baker grade III/IV (product replacement only within ten years of augmentation surgery for surgeries performed after January 1, 2018); or
- (v) removal of implants for symptomatic double capsule requiring revision (product replacement only within five years of augmentation surgery); or
- (vi) removal of implants for late seroma (product replacement only within five years of augmentation surgery).
- (vii) 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; or

- (d) loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures.

The Allergan Warranty excludes other events outside the covered events listed in section I(A)(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 for the lifetime of the implant. 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 explantation, 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 \$1,200 USD. 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 \$3,500 USD. 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.

(d) 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 National Comprehensive Cancer Network (NCCN) 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 \$5,000 USD. 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 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 Support Department to obtain a return kit and instructions prior to revision surgery at (800) 668-6424 or via email at MR-CanadaProductSupport@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 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:

Allergan Inc.
85 Enterprise Blvd, Suite 500
Markham, ON L6G 0B5

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

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.

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