

## NATRELLE™ Breast Implant Limited Warranties

This document describes Allergan's Saline-Filled and Silicone-Filled Breast Implant Limited Warranties. The Breast Implant Limited Warranties consist of the *ConfidencePlus*® Warranty and the *ConfidencePlus*® Premier Warranty.

The Allergan *ConfidencePlus*® Warranty applies automatically to NATRELLE™ Saline-Filled and NATRELLE™ Silicone-Filled Breast Implants, implanted in the United States or Canada on or after April 1, 2002, and supersedes the Allergan *ConfidencePlus*® Program, which became effective as of date of implant June 1, 1993. Eligible patients implanted from June 1, 1993, through March 31, 2002, remain covered under the terms and conditions stated in the Allergan *ConfidencePlus*® Program. The Allergan *ConfidencePlus*® Premier Warranty applies to NATRELLE™ Saline-Filled and NATRELLE™ Silicone-Filled Breast Implants, implanted in the United States or Canada on or after April 1, 2002 when an additional \$100 fee has been paid to Allergan by or on behalf of the patient as specified in Section A(2) below.

Deflation and rupture are among the known risks of breast implants. The 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 and rupture. Allergan makes available to all 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 web site. The 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 surgeon and patient.**

Under the Allergan *ConfidencePlus*® Warranty and the *ConfidencePlus*® Premier Warranty, Allergan will replace qualified NATRELLE™ Breast Implants and pay, up to defined maximum amounts, certain uninsured out-of-pocket costs directly related to necessary revision surgery, in each case by reason of a Covered Event and all as set forth below.

Qualified Allergan NATRELLE™ Breast Implants are the following:

Saline Filled Breast Implants: Style 68HP, 68MP, 68LP, 163, 168, 363LF, 468

Silicone Filled Breast Implants: Style 10, 15, 20, 40, 45, 110, 115, 120, 410 (all cells)

**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.

**A. Application of the Allergan *ConfidencePlus*® and *ConfidencePlus*® Premier Warranties**

**1. The Allergan *ConfidencePlus*® Warranty:** The Allergan *ConfidencePlus*® Warranty applies only to the qualified NATRELLE™ Saline-Filled and Silicone-Filled Breast Implants listed above, implanted in the United States or Canada on or after April 1, 2002. The Allergan *ConfidencePlus*® Warranty shall not apply to any implantations performed without strict accordance to current Allergan product literature (including product package enclosures, data sheets, and other notifications or instructions published by Allergan) and accepted plastic surgical procedures by appropriately qualified licensed surgeons.

**2. The Allergan *ConfidencePlus*® Premier Warranty:** The Allergan *ConfidencePlus*® Premier Warranty applies only to the qualified NATRELLE™ Saline-Filled and Silicone-Filled Breast Implants listed above, implanted in the United States or Canada on or after April 1, 2002 when a non-refundable fee of \$100 has been received by Allergan to enroll the patient in the program. Whether paying by credit card, certified check or money order, the \$100 payment must be either received or postmarked within 45 days of the qualifying implantation surgery. The Allergan *ConfidencePlus*® Premier Warranty shall not apply to any implantations performed without strict accordance to current Allergan product literature (including product package enclosures, data sheets, and other notifications or instructions published by Allergan) and accepted plastic surgical procedures by appropriately qualified licensed surgeons.

**3. Covered Events:** The Allergan *ConfidencePlus*® Warranty, and the Allergan *ConfidencePlus*® Premier Warranty apply only to the following covered events (each a "Covered Event") if they require surgical intervention:

- (a) deflation of NATRELLE™ Saline-Filled Breast Implants due to crease fold failure; or
  - (b) loss of shell integrity from unknown cause; or (c) loss of valve integrity;
- or
- (a) rupture of Allergan Silicone-Filled Breast Implants due to crease fold failure; or
  - (b) loss of shell integrity from unknown cause.

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

**4. Events Not Covered:** The Allergan *ConfidencePlus*® Warranty and the Allergan *ConfidencePlus*® Premier Warranty do not apply to (a) removal of implants for capsular contracture; (b) removal of implants for size alteration; (c) removal of implants due to wrinkling or rippling; (d) loss of shell integrity caused by operative procedures; (e) loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures.

The Allergan *ConfidencePlus*® Warranty and the Allergan *ConfidencePlus*® Premier Warranty exclude other events outside the covered events listed in section A(3) above.

## **B. What Allergan will provide under the Allergan *ConfidencePlus*® Warranty, and the Allergan *ConfidencePlus*® Premier Warranty**

**1. 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 surgeons for such product to qualify for replacement. Should a more expensive Allergan product be requested by the 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 surgeon request a less expensive replacement product.

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. In the event of *ConfidencePlus*® Premier 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 *ConfidencePlus*® Warranty covering the replacement implant only.

**Limitation on Product Replacement:** If Allergan's obligation to provide a replacement product under either the Allergan *ConfidencePlus*® Warranty or *ConfidencePlus*® Premier 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 *ConfidencePlus*® and *ConfidencePlus*® Premier Limited Warranties.

2. **The Allergan *ConfidencePlus*® Warranty:** Under the Allergan *ConfidencePlus*® Warranty, 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. Upon submission of a qualifying request, Allergan will provide a general release in favor of Allergan. 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, may be required prior to payment. Request for financial assistance under the Allergan *ConfidencePlus*® Warranty must be made to the Product Support Department prior to the date of qualifying revision surgery.

3. **The Allergan *ConfidencePlus*® Premier Warranty:** Under the Allergan *ConfidencePlus*® Premier Warranty, 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 \$2,400. At the surgeon's request, Allergan will also provide a replacement of a NATRELLE™ Saline-Filled or 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.

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, may be required prior to payment. If the contralateral side is being replaced, return of both explanted implants is required. Request for financial assistance under the Allergan *ConfidencePlus*® Premier Warranty must be made to the Product Support Department prior to the date of qualifying revision surgery. Allergan's obligations under the Allergan *ConfidencePlus*® Premier Warranty are complete upon full or partial payment of the financial assistance outlined in Section B.3. of this document. For the qualifying replacement implant to be eligible for the Allergan *ConfidencePlus*® Premier Warranty, an additional payment of \$100 is required.

When a patient undergoes a unilateral Breast Implant replacement, and the Allergan *ConfidencePlus*® Premier Warranty is purchased for the qualifying replacement implant, the terms of the original Allergan *ConfidencePlus*® Premier Warranty will automatically continue to apply to the contralateral implant (not replaced) for the remainder of the ten years still available under its original term. This is contingent upon the contralateral implant qualifying under the terms of the Allergan *ConfidencePlus*® Premier Warranty. Under no circumstances will the Allergan *ConfidencePlus*® Premier Warranty continue for more than ten years from the actual date of implantation for any individual implant.

**When Allergan has made payment for a unilateral replacement under the terms of the Allergan *ConfidencePlus*® Premier Warranty, and the patient does not elect to purchase the Allergan *ConfidencePlus*® Premier Warranty for the replacement implant, the assistance available for the contralateral implant (not replaced) is limited to any assistance that may still be remaining under the terms of the original Allergan *ConfidencePlus*® Premier Warranty.**

The assistance available under the terms of the Allergan *ConfidencePlus*® Premier Warranty and the Allergan *ConfidencePlus*® Warranty or the Allergan *ConfidencePlus*® Program (for patients implanted between June 1, 1993 and March 31, 2002) is not cumulative. Payment made under the Allergan *ConfidencePlus*® Premier Warranty completes any obligations of Allergan still remaining under the Allergan *ConfidencePlus*® Warranty and vice versa. The Allergan *ConfidencePlus*® Premier Warranty is not transferable.

C. Patient Information on the Allergan *ConfidencePlus*® Warranty and the Allergan *ConfidencePlus*® Premier Warranty

1. Before implantation surgery, the surgeon should explain the details of the Allergan *ConfidencePlus*® Warranty, and the Allergan *ConfidencePlus*® Premier Warranty, including product replacement, to the patient, and provide the patient with a copy of this document. In addition to explaining the terms of Product Replacement, the Allergan *ConfidencePlus*® Warranty and the Allergan *ConfidencePlus*® Premier Warranty, the surgeon should also advise the patient about possible adverse reactions and complications associated with Saline-Filled and Silicone-Filled Breast Implants, 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 .

D. **Filing a Claim**

1. If a Covered Event occurs within ten years of the date of an implantation qualifying under the Allergan *ConfidencePlus*® Warranty, or the Allergan *ConfidencePlus*® Premier Warranty, the surgeon should contact Allergan's Product Support Department to obtain a return kit and instructions prior to revision surgery at (800) 624-4261 or (805) 683-6761. 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. 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  
Device Analysis Laboratory  
71 S. Los Carneros Road  
Goleta, CA 93117

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 Product Support Department in Santa Barbara, CA at (800) 624-4261.

Allergan reserves the right to cancel, change, or modify the terms of the Allergan *ConfidencePlus*® Warranty and/or the Allergan *ConfidencePlus*® Premier 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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