

IDEAL IMPLANT® Structured Breast Implant

Limited Warranty

This document describes the Limited Warranty provided by Ideal Implant Incorporated (“Ideal Implant”). The Limited Warranty applies automatically to IDEAL IMPLANT Structured Breast Implants implanted in the United States or Canada on or after October 1, 2017.

Rupture or deflation is 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 rupture or deflation. Ideal Implant makes available to all surgeons and patients a copy of the Patient Information Booklet describing the benefits and risks of surgery with its breast implants. Copies are available through Ideal Implant’s web site idealimplant.com. **This document is not intended to, and cannot, take the place of a full and candid discussion between surgeon and patient.**

Under the Limited Warranty, Ideal Implant will replace IDEAL IMPLANT Structured Breast Implants, and may pay, up to a defined maximum amount, certain uninsured out-of-pocket costs directly related to necessary replacement surgery, in each case by reason of a Covered Event and under the terms and conditions as set forth below.

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. THIS REMEDY IS THE SOLE AND EXCLUSIVE REMEDY AVAILABLE. IDEAL IMPLANT 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. IDEAL IMPLANT NEITHER ASSUMES, NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

A. Application of the Limited Warranty

1. Limited Warranty: The Limited Warranty applies to IDEAL IMPLANT Structured Breast Implants implanted in the United States or Canada on or after October 1, 2017. The Limited Warranty shall not apply to any implantations performed without strict accordance to current Ideal Implant product literature (including Instructions for Use, data sheets, and other notifications or instructions published by Ideal Implant) and accepted plastic surgical procedures by appropriately qualified licensed surgeons.

2. Covered Events: The Limited Warranty applies only to the following covered events (each a “Covered Event”) that require surgical intervention:

- (a) rupture or deflation due to crease fold failure of the shell;
- (b) loss of shell integrity from unknown cause;
- (c) loss of valve integrity; or

(d) capsule contracture, Baker Grade 3 or 4, as diagnosed by the attending surgeon. Baker Grade 3: the breast is firm and looks abnormal (visible distortion), Baker Grade 4: the breast is hard, painful, and looks abnormal (greater visible distortion than Baker Grade 3).

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

3. Non-Exhaustive List of Events Not Covered: The Limited Warranty excludes events other than the Covered Events listed in section A.2 above. The Limited Warranty does not apply to (a) removal for capsular contracture other than Baker Grade 3 or Baker Grade 4; (b) dissatisfaction with implant size or aesthetics; (c) adverse reactions other than implant rupture or deflation; (d) loss of product integrity caused by operative procedures; (e) loss of product integrity resulting from open or closed capsulotomy; (f) other manufacturers' products; or (g) financial reimbursement for a non-Ideal Implant product in lieu of an Ideal Implant product.

B. What Ideal Implant will Provide under the Limited Warranty

1. Product Replacement: If a Covered Event occurs, Ideal Implant will replace the product subject to a Covered Event (a "Qualified Product") with another Ideal Implant product, of the same or similar type as the Qualified Product, free-of-charge for the lifetime of the patient for Covered Events A.2(a) – A.2(c), and for ten (10) years for Covered Event A.2(d). Implantation of the replacement Ideal Implant product, as well as any subsequent procedures, must be in strict accordance with current Ideal Implant product literature and accepted plastic surgical procedures by appropriately qualified licensed surgeons for such product to qualify for replacement. Should a more expensive Ideal Implant product be requested by the surgeon, Ideal Implant will charge 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 Qualified Product must be returned to Ideal Implant within 30 days of its explant in order to qualify for the replacement product under this Limited Warranty. In the event that the explanted Qualified Product is not returned to Ideal Implant within 30 days of its explantation, the ordering customer will be charged for the price of the replacement product. Replacement product for a Qualified Product will be sent pursuant to Ideal Implant standard shipping policies, with extra charges for expedited shipping payable by the implanting surgeon. Ideal Implant will neither provide a product that is not supplied by Ideal Implant, nor provide money in lieu of an Ideal Implant replacement product. Any replacement Ideal Implant product automatically includes a new Limited Warranty then in effect covering the replacement implant only.

Limitation on Product Replacement: If Ideal Implant's obligation to provide a replacement product under the Limited 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 Ideal Implant, the performance of that obligation shall be excused without penalty. For

purposes of this provision, excuse of performance shall mean that Ideal Implant is neither obligated to provide nor pay for a replacement product, regardless of the product's source. Despite the excuse of Ideal Implant's obligation to provide a replacement product under this provision, Ideal Implant shall continue to perform its obligation to provide financial assistance for operating room, anesthesia, and surgical fee costs to the extent described under the Limited Warranty.

2. Financial Assistance: Under the Limited Warranty, when a replacement surgery for Covered Events A.2(a) – A.2(c) occurs within ten (10) years from the date of implantation, Ideal Implant will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to the replacement surgery and not covered by insurance, up to a maximum aggregate amount of \$3,500. As a condition to Ideal Implant's obligations for such financial assistance, the patient must sign a general release on the form provided by Ideal Implant. Ideal Implant will not pay for any replacement expenses until receipt of the release signed by the patient. In addition, Ideal Implant may require a copy of bills or receipts associated with the replacement surgery before payment will be made. Other documentation, such as operative notes, may be required prior to payment. Request for financial assistance under the Limited Warranty must be made to Ideal Implant prior to the date of qualifying replacement surgery.

3. Contralateral Implant: At the surgeon's request, Ideal Implant will provide a replacement Ideal Implant product to use to replace the contralateral implant. If a patient undergoes a unilateral replacement of a Qualified Product, the financial assistance terms of the original Limited Warranty continue to apply to the contralateral implant that was not replaced for the remainder of the ten years still available under its original term.

C. Patient Information on the Limited Warranty

Before implantation surgery, the surgeon should explain the details of the Limited Warranty to the patient, and provide the patient with a copy of this document. In addition to explaining the terms of product replacement and financial assistance, the surgeon should advise the patient about possible adverse reactions and complications associated with IDEAL IMPLANT Structured Breast Implants, and review with the patient the Patient Information Booklet provided by Ideal Implant describing the benefits and risks of surgery with its breast implants.

D. Filing a Claim

If a Covered Event occurs qualifying under the Limited Warranty, the surgeon should contact Ideal Implant to obtain an Explant Return Kit and instructions prior to replacement surgery at (214) 492-2500. Once replacement surgery occurs, send (a) a copy of the Explant Return Authorization Form; (b) the patient's completed Limited Warranty Claim and Release Form (if financial assistance is requested); and (c) the removed and decontaminated implant. This information should be sent to Ideal Implant at the address indicated in the Explant Return Kit.

Upon receipt of the returned Qualified Product, and properly signed Limited Warranty Claim and Release Form, a check for any covered financial assistance will be issued to the appropriate party or parties in accordance with the limitations outlined in this Limited

Warranty. 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 Ideal Implant Customer Service at (214) 492-2500.

Ideal Implant reserves the right to cancel, change, or modify the terms of this Limited Warranty. Any such cancellation, change, or modification will not affect the currently stated terms for those already enrolled.

Ideal Implant Incorporated
5005 LBJ Freeway
Suite 900
Dallas, Texas 75244
(214) 492-2500
idealimplant.com

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