

IDEAL IMPLANT® Saline-Filled Breast Implant Limited Warranty

November 2008

This document describes the IDEAL IMPLANT Saline-Filled Breast Implant Limited Warranty (the "Limited Warranty") provided by Ideal Implant Incorporated (the "Company").

The Limited Warranty applies automatically to IDEAL IMPLANT Saline-Filled Breast Implants implanted in the United States on or after September 1, 2008.

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 deflation. The Company makes available to all surgeons and patients a copy of the Patient Information brochure describing the benefits and risks of surgery with its breast implants. Copies can also be obtained by contacting the Company directly, or through the Company's web site. The surgeon should also advise the patient about possible adverse reactions and complications associated with 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 Limited Warranty, the Company will replace Style 44 IDEAL IMPLANT Saline-Filled Breast Implants, and pay, up to defined maximum amounts, 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. THE REPLACEMENT OF QUALIFIED IDEAL IMPLANT BREAST IMPLANTS AND PAYMENT OF DEFINED AMOUNTS FOR NECESSARY REPLACEMENT SURGERY AS SET FORTH IN THIS LIMITED WARRANTY ARE, TO THE MAXIMUM EXTENT ALLOWED UNDER APPLICABLE LAW, THE PATIENT'S SOLE AND EXCLUSIVE REMEDY. THE COMPANY 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. THE COMPANY 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 AND THIS LIMITED WARRANTY ALLOCATE THE RISKS BETWEEN THE COMPANY AND THE PATIENT; SUCH ALLOCATION OF RISK IS REFLECTED IN THE PRICING OF THE PRODUCTS AND IS AN ESSENTIAL ELEMENT OF THE BASIS OF THE BARGAIN BETWEEN THE COMPANY AND THE PATIENT.

A. Application of the Limited Warranty

1. **Limited Warranty:** The Limited Warranty applies to IDEAL IMPLANT Saline-Filled Breast Implants implanted in the United States on or after September 1, 2008. The Limited Warranty shall not apply to any implantations performed without strict accordance to current Company product literature (including product package enclosures, data sheets, and other notifications or instructions published by the Company) and accepted plastic surgical procedures by appropriately qualified licensed surgeons.

2. **Covered Events:** The Limited Warranty applies only to the following covered events involving an IDEAL IMPLANT Saline-Filled Breast Implant (each a "Covered Event") that require surgical intervention:

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

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

3. **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 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; or (e) loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures.

B. What the Company will provide under the Limited Warranty

1. **Product Replacement:** If a Covered Event occurs that is covered by the Limited Warranty, the Company will replace such product subject to a Covered Event (a "Qualifying Product") with another Company product, of the same or similar type as the Qualifying Product, free-of-charge for the lifetime of the patient. Implantation of the replacement Company product, as well as any subsequent procedures, must be in strict accordance with current Company product literature and accepted plastic surgical procedures by appropriately qualified licensed surgeons for such product to qualify for replacement. Should a more expensive Company product be requested by the surgeon, the Company will invoice the ordering customer for the list price difference between the Qualifying Product to be replaced and the requested replacement product. The customer will not be credited or reimbursed for the list price difference between the Qualifying Product to be replaced and the requested replacement product should the surgeon request a less expensive replacement product.

The explanted Qualifying Product must be returned to the Company within 60 days of its explant in order to qualify for the replacement product under this Limited Warranty. In the event that the explanted Qualifying Product is not returned to the Company within 60 days of its explantation, the ordering customer will be invoiced for the price of the replacement product. Replacement product for a Qualifying Product will be sent without shipping charges. The Company will neither provide a product not supplied by the Company, nor provide money in lieu of a Company replacement product. Any

replacement Company product automatically includes a new Limited Warranty then in effect covering the replacement implant only.

Limitation on Product Replacement: If the Company'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 the Company, the performance of that obligation shall be excused without penalty. For purposes of this provision, excuse of performance shall mean that the Company is neither obligated to provide nor pay for a replacement product, regardless of the product's source. Despite the excuse of the Company's obligation to provide a replacement product under this provision, the Company 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 qualifying replacement surgery for a Covered Event occurs within ten (10) years from the date of implantation of the Qualifying Product, the Company will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to replacement surgery and not covered by insurance, up to a maximum aggregate amount of \$1,200. As a condition to the Company's obligations for such financial assistance, the patient must sign a general release on the form provided by the Company. The Company will not pay for any replacement expenses until receipt of the release signed by the patient. In addition, the Company 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 the Company prior to the date of qualifying replacement surgery.

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 also advise the patient about possible adverse reactions and complications associated with IDEAL IMPLANT Saline-Filled Breast Implants, and review with the patient the Patient Information Booklet provided by Ideal Implant Incorporated 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 the Company 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 the Company at the address indicated in the Explant Return Kit.

Upon receipt of the returned Qualifying Product, and of the 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 the Company at (214) 492-2500.

The Company 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
2445 Gateway Drive
Suite 130
Irving, Texas 75063
(214) 492-2500
www.idealimplant.com