



# IDEAL IMPLANT<sup>®</sup> Structured Breast Implant

## Basic Protection Plan / Limited Warranty

This document describes the Basic Protection Plan available from Ideal Implant Incorporated (“Ideal Implant”) to patients implanted with IDEAL IMPLANT<sup>®</sup> Structured Breast Implants in Canada on or after August 1, 2018.

**The Basic Protection Plan** is automatically provided at no charge

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

IDEAL IMPLANT PROVIDES ONLY A LIMITED WARRANTY UNDER THE BASIC PROTECTION PLAN, WHICH 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.

Deflation, capsular contracture and insertional scarring are among the known risks of breast implants. Ideal Implant makes available on its web site, [idealimplant.com](http://idealimplant.com), the Patient Information Booklet describing the benefits and risks of surgery with its breast implants.

### A. Application of the Basic Protection Plan

**1. Basic Protection Plan:** The Basic Protection Plan applies to IDEAL IMPLANT Structured Breast Implants implanted in Canada on or after August 1, 2018. The Basic Protection Plans shall not apply to any implantations performed without strict accordance to Ideal Implant Instructions for Use in effect at the time of the procedure and accepted standards of care by appropriately qualified licensed surgeons.

**2. Basic Protection Plan Covered Events:** The Basic Protection Plan applies only to the following covered events (each a “Covered Event”):

- a. Rupture or deflation due to crease fold failure of the shell
- b. Deflation due to manufacturing defect
- c. Deflation from unknown cause
- d. Capsular contracture, Baker Grade 3 or 4, as diagnosed by the attending surgeon and, if requested by Ideal Implant, confirmed by photographs of the breast prior to explant.

**3. Basic Protection Plan Non-Exhaustive List of Events Not Covered:** The Basic Protection Plan excludes events other than the Covered Events listed in A.2 above. The Basic Protection Plan 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
- d. Loss of product integrity due to any operative procedure
- e. Loss of product integrity resulting from open or closed capsulotomy
- f. Other manufacturers' products
- g. Financial reimbursement for a non-Ideal Implant product

## **B. What Will be Provided Under the Basic Protection Plan**

**1. Product Replacement:** If a Covered Event occurs, Ideal Implant will replace the product subject to a Covered Event with another Ideal Implant product, of the same or similar type, free-of-charge for the lifetime of the patient for Basic Protection Plan Covered Events A.2a – A.2c, and for ten (10) years for Basic Protection Plan Covered Event A.2d. Implantation of the replacement Ideal Implant product, as well as any subsequent procedures, must be in strict accordance with Ideal Implant Instructions for Use in effect at the time of the procedure and accepted standards of care 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 product to be replaced and the requested replacement product.

The explanted product must be returned to Ideal Implant within 30 days of explantation along with copies of the operative reports for the initial implant surgery and the replacement surgery in order to qualify for the replacement product under the Basic Protection Plan. In the event that the explanted 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 will be sent pursuant to Clarion Medical 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. For any replacement Ideal Implant product, a new Basic Protection Plan then in effect automatically applies to the replacement implant.

**Limitation on Product Replacement:** If Ideal Implant's obligation to provide a replacement product under the Basic Protection Plan 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, product shortages, 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.

**2. Contralateral Implant:** At the surgeon's request for size change, 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 product, the financial assistance terms of the original Basic Protection Plan continue to apply to the contralateral implant that was not replaced for the remainder of the ten years still available under its original term.

**3. Basic Protection Plan Financial Assistance:** Under the Basic Protection Plan, when a replacement surgery for Covered Events A.2a – A.2c occurs within ten (10) years from the date of implantation, Ideal Implant will pay uninsured out-of-pocket expenses for surgical fees, operating room and anesthesia fees directly related to the IDEAL IMPLANT replacement surgery, up to a maximum aggregate amount of CAD \$3,500. Prior to payment, Ideal Implant requires receipt of the Ideal Implant release form signed by the patient, copies of the operative reports for the initial implant surgery and the replacement surgery, copies of bills for the replacement surgery (e.g., surgical fees, operating room, anesthesia fees) and copies of insurance claims, reimbursements and explanation of benefits. A claim for financial assistance under the Basic Protection Plan must be made to Ideal Implant prior to the date of replacement surgery.

### **C. Filing a Claim**

**1. Product Replacement - Basic Protection Plan:** If a Covered Event occurs qualifying for implant replacement, the surgeon should contact Clarion Medical at (800) 668-5236 for instructions prior to replacement surgery. Replacement products may be ordered by contacting Clarion Medical Customer Service at (800) 668-5236. Return the Protection Plan / Limited Warranty Claim and Release Form signed by the surgeon and copies of the operative reports for the initial implant surgery and the replacement surgery to Clarion Medical by email (consumableorders@clarionmedical.com) or by fax (519) 621-0313. Only if the replacement is for deflation, return the explant along with a copy of the Explant Return Authorization Form to Ideal Implant at the address indicated in the Explant Return Kit. If the replacement is for other reasons, such as capsular contracture or size change, the explant can be discarded.

**2. Financial Assistance - Basic Protection Plan:** If a Covered Event occurs qualifying for financial assistance, send a properly signed Protection Plan / Limited Warranty Claim and Release Form to Clarion Medical by email (consumableorders@clarionmedical.com) or by fax (519) 621-0313. Upon receipt of the returned product and copies of the operative reports for the initial implant surgery and the replacement surgery, copies of bills for the replacement surgery (e.g., surgical fees, operating room, anesthesia fees) and copies of insurance claims, reimbursements and explanation of benefits, a check for any Basic Protection Plan financial assistance will be issued to the appropriate party or parties in accordance with the limitations outlined in the Basic Protection Plan. The check will be made payable to the party or parties indicated by the patient on the release form.

Ideal Implant reserves the right to cancel, change, or modify the terms of the Basic Protection Plan. Any such cancellation, change, or modification will not affect the currently stated terms for those already enrolled. Ideal Implant's obligations under the Basic Protection Plan / Limited Warranty are governed by the laws of the State of Texas.

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