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## THE MENTOR PRODUCT REPLACEMENT POLICY and THE MENTOR ADVANTAGE LIMITED WARRANTY PROGRAM FOR SALINE-FILLED AND SILICONE-FILLED BREAST IMPLANTS

This document describes MENTOR Corporation's Product Replacement Policy and the MENTOR Advantage Limited Warranty Program for MENTOR Saline-Filled and Silicone-Filled Breast Implants described later in this document. The MENTOR Advantage Limited Warranty consists of the MENTOR Standard Advantage Limited Warranty and the MENTOR Enhanced Advantage Limited Warranty.

The MENTOR Standard Advantage Limited Warranty applies automatically to MENTOR Saline-Filled and Silicone-Filled Breast Implants implanted in the United States or Puerto Rico on or after May 1, 2005, and, with respect to those Breast Implants implanted after that date, supersedes the MENTOR Advantage Limited Warranty Program for MENTOR Saline-Filled Breast Implants, which had become effective as of date of implant October 1, 2000. Eligible patients implanted prior to May 1, 2005, remain covered under the terms and conditions stated in the MENTOR Advantage Limited Warranty Program for MENTOR Saline-Filled Breast Implants.

This MENTOR Enhanced Advantage Limited Warranty applies to MENTOR Saline-Filled and Silicone-Filled Breast Implants implanted in the United States on or after May 1, 2005 when an additional \$100 fee has been paid to MENTOR by or on behalf of the patient.

Deflation or rupture is among the known risks of Saline-Filled or Silicone-Filled Breast Implants, respectively. 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 or rupture. MENTOR makes available to all surgeons and patients a copy of its **Informed Decision Brochure**. Copies can also be obtained by contacting MENTOR directly, or through the MENTOR web site. **This document is not intended to, and cannot, take the place of a full and frank discussion between surgeon and patient.**

Under the MENTOR Advantage Limited Warranty Program, MENTOR will pay, up to defined maximum amounts, certain unreimbursed out-of-pocket costs directly related to revision surgery necessitated by a covered event for the following products: MENTOR Smooth Round Saline, Siltex® Round Saline, Smooth Round Spectrum®, Siltex® Round Spectrum®, Siltex® Contour Profile® Saline (moderate and high profile and Spectrum®), Smooth Round Moderate Profile Gel, Smooth Round Moderate Plus Profile Gel, Smooth Round High Profile Gel, Siltex® Round Moderate Profile Gel, Siltex® Round Moderate Plus Profile Gel, Siltex® Round High Profile Gel, Smooth Round Becker 25, Smooth Round Becker 50, Siltex® Round Becker 25, Siltex® Round Becker 50 and Siltex® Contour Profile® Lumera™ Gel Breast Implants.

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, ARE EXCLUDED. THIS REMEDY IS THE SOLE AND EXCLUSIVE REMEDY AVAILABLE. MENTOR 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. MENTOR 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 MENTOR Advantage Limited Warranties**

1. **The MENTOR Standard Advantage Limited Warranty:** MENTOR Standard Advantage Limited Warranty applies only to MENTOR Saline-Filled and Silicone-Filled Breast Implants described on the first page of this document, and implanted in the United States or Puerto Rico on or after May 1, 2005. Implantation must be in accordance with current MENTOR product literature (including product package enclosures, data sheets, and other notifications or instructions published by MENTOR) and accepted plastic surgical procedures by appropriately qualified licensed physicians.
2. **The MENTOR Enhanced Advantage Limited Warranty:** The MENTOR Enhanced Advantage Limited Warranty applies only to MENTOR Saline-Filled and Silicone-Filled Breast Implants described on the first page of this document, and implanted in the United States on or after May 1, 2005, when a non-refundable fee of \$100 has been received by MENTOR 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. Implantation must be in accordance with current MENTOR product literature (including product package enclosures, data sheets, and other notifications or instructions published by MENTOR) and accepted plastic surgical procedures by appropriately qualified licensed physicians.

With both Mentor Advantage and Mentor Enhanced Advantage it is important to maintain your own records to ensure validation of your enrollment, as it is possible your doctor may not retain your records for the entire duration of the warranty.

3. The MENTOR Product Replacement Policy, the MENTOR Standard Advantage Limited Warranty, and the MENTOR Enhanced Advantage Limited Warranty apply only to the following covered events:
  - (a) deflation of a MENTOR Saline-Filled or Silicone-Filled Mammary Prosthesis described on the first page of this document due to crease fold failure;
  - (b) loss of shell integrity resulting from patient trauma;
  - (c) loss of shell integrity from unknown cause; or
  - (d) loss of valve integrity.

The MENTOR Standard Advantage Limited Warranty and the MENTOR Enhanced Advantage Limited Warranty may also apply to other event-related losses of shell integrity not specifically excluded, subject to review by a physician retained by MENTOR.

4. The MENTOR Product Replacement Policy, the MENTOR Standard Advantage Limited Warranty, and the MENTOR Enhanced Advantage Limited Warranty do not apply to
  - (a) removal of intact implants for capsular contracture;
  - (b) removal of intact implants for size alteration;
  - (c) removal of intact implants due to wrinkling or rippling;

- (d) loss of shell integrity caused by re-operative procedures; or
- (e) loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures.

**B. What MENTOR will provide under the MENTOR Product Replacement Policy, the MENTOR Standard Advantage Limited Warranty, and the MENTOR Enhanced Advantage Limited Warranty**

- 1. The MENTOR Product Replacement Policy:** In the event of a qualifying deflation of a Saline-Filled Breast Implant or rupture of a Silicone-Filled Breast Implant, MENTOR will replace the product, free of charge for the lifetime of the patient. Implantation of the Saline-Filled or Silicone-Filled Breast Implant, as well as any subsequent procedures, must be in accordance with current MENTOR product literature and accepted plastic surgical procedures by appropriately qualified licensed physicians for product to qualify for replacement under the MENTOR Product Replacement Policy. Should a more expensive product be requested by the physician, MENTOR will invoice the ordering customer for the list price difference between the deflated product and the requested replacement product. The explanted deflated or ruptured product must be returned to the MENTOR Product Evaluation Department within 60 days of its explant in order to qualify for the free of charge replacement product. In the event that the explanted product is not returned to the MENTOR Product Evaluation Department within 60 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 if the order is received in the MENTOR Product Evaluation Department at least three business days prior to scheduled delivery date; otherwise, freight charges will be invoiced to the ordering customer. At the surgeon's request, MENTOR will also provide a replacement of a MENTOR Saline-Filled or Silicone-Filled Breast Implant to use to replace the contralateral implant, provided that the contralateral breast implant is a MENTOR product. There will be no charge for this courtesy except as outlined above. MENTOR will neither provide nor pay for a replacement with a non-MENTOR product under the terms of this Product Replacement Policy, nor in any event provide money for or in lieu of a MENTOR replacement product. Any replacement MENTOR Saline-Filled or Silicone-Filled Breast Implant described in paragraph four of this document automatically includes a new MENTOR Standard Advantage Limited Warranty covering the replacement implant only.

**Limitation on the MENTOR Product Replacement Policy:** If MENTOR Corporation's obligation to provide a replacement product under either the MENTOR Standard or Enhanced Advantage 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 MENTOR, the performance of that obligation shall be excused without penalty. For purposes of this provision, excuse of performance shall mean that MENTOR is neither obligated to provide nor pay for a replacement product, regardless of the product's source. Despite the excuse of MENTOR's obligation to provide a replacement product under this provision, MENTOR shall continue to perform its obligation to provide financial assistance for operating room, anesthesia, and surgical fee costs to the extent described under the MENTOR Standard and Enhanced Advantage Limited Warranties.

- 2. The MENTOR Standard Advantage Limited Warranty:** When a qualifying replacement surgery occurs within ten years from the date of implantation, MENTOR will pay uninsured out-of-pocket costs for operating room, anesthesia and/or surgical expenses directly related to revision

surgery up to a maximum aggregate amount of \$1,200. Operating room and anesthesia charges to be given payment priority. In order to qualify for financial assistance, you will need to sign a release form. Upon submission of a qualifying request, MENTOR will provide a general Release in favor of MENTOR Corporation, and other related entities. MENTOR will not pay for any reoperative expenses until receipt of the Release signed by the patient. In addition, MENTOR requires 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 MENTOR Standard Advantage Limited Warranty must be made to the Consumer Affairs Department by or on behalf of patient within 6 months of the date of qualifying revision surgery.

- 3. The MENTOR Enhanced Advantage Limited Warranty:** When a qualifying revision surgery occurs within ten years from the date of implantation, MENTOR will pay uninsured out-of-pocket costs for operating room, anesthesia and/or surgical expenses directly related to revision surgery up to a maximum aggregate amount of \$2,400. This amount is in lieu of, and not in addition to, any amounts otherwise payable under the MENTOR Standard Advantage Limited Warranty. Operating room and anesthesia charges to be given payment priority. In order to qualify for financial assistance, you will need to sign a release form. Upon submission of a qualifying request for financial assistance, MENTOR will provide a general Release in favor of MENTOR Corporation, and other related entities. MENTOR will not pay for any reoperative expenses until receipt of the Release signed by the patient. In addition, MENTOR requires 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 MENTOR Enhanced Advantage Limited Warranty must be made to the Consumer Affairs Department by or on behalf of the patient within 6 months of the date of qualifying revision surgery. MENTOR's obligations under the MENTOR Enhanced Advantage Limited 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 MENTOR Enhanced Advantage Limited Warranty, an additional payment of \$100 is required. When a patient undergoes a unilateral breast implant replacement, and the MENTOR Enhanced Advantage Limited Warranty is purchased for the qualifying replacement implant, the terms of the original MENTOR Enhanced Advantage Limited 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 MENTOR Enhanced Advantage Limited Warranty. Under no circumstances will the MENTOR Enhanced Advantage Limited Warranty continue for more than ten years from the actual date of implantation for any individual implant. When MENTOR has made payment for a unilateral replacement under the terms of the MENTOR Enhanced Advantage Limited Warranty, and the patient does not elect to purchase the MENTOR Enhanced Advantage Limited 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 MENTOR Standard Advantage Limited Warranty. The assistance available under the terms of the MENTOR Enhanced Advantage Limited Warranty and the MENTOR Standard Advantage Limited Warranty is not cumulative. Payment made under the MENTOR Enhanced Advantage Limited Warranty completes any obligations of MENTOR still remaining under the MENTOR Standard Advantage Limited Warranty, and vice versa. The MENTOR Enhanced Advantage Limited Warranty is not transferable except as follows: In the event of product replacement for an event ineligible for

assistance under the terms of the MENTOR Enhanced Advantage Limited Warranty, any remainder of the ten years available under the MENTOR Enhanced Advantage Limited Warranty will transfer to the replacement implant if the replacement implant is described in paragraph four of this document.

**C. Patient Information on the MENTOR Product Replacement Policy, the MENTOR Standard Advantage Limited Warranty, and the MENTOR Enhanced Advantage Limited Warranty**

1. Before implantation surgery, the surgeon should explain the details of the MENTOR Product Replacement Policy, the MENTOR Standard Advantage Limited Warranty, and the MENTOR Enhanced Advantage Limited Warranty to the patient, and provide the patient with a copy of this document. In addition to explaining the terms of the MENTOR Product Replacement Policy, the MENTOR Standard Advantage Limited Warranty and the MENTOR Enhanced Advantage Limited Warranty, the surgeon should also advise the patient about possible adverse reactions and complications associated with the Saline-Filled or Silicone-Filled Breast Implants, and review with the patient the Informed Decision Brochure provided by MENTOR.

**D. Filing a Claim**

1. If a covered event occurs within ten years of the date of an implantation qualifying under the MENTOR Standard Advantage Limited Warranty or the MENTOR Enhanced Advantage Limited Warranty, the surgeon should contact MENTOR's Product Evaluation Department to obtain a return kit and instructions to send
  - (a) a copy of the patient's file, including the Operative Report for the initial surgery;
  - (b) a copy of the Operative Report for the revision surgery (if already performed);
  - (c) copies of bills showing operating room and/or anesthesia and surgical fee expenses incurred for the revision surgery;
  - (d) copies of forms showing any relevant insurance reimbursements;
  - (e) authorizations, signed by the patient, allowing release of medical records and return of removed product to MENTOR; and
  - (f) the removed and decontaminated MENTOR product.All except the explanted product\* should be sent to:

MENTOR  
201 Mentor Drive  
Santa Barbara, CA 93111

Upon receipt of this information, a Consumer Affairs Analyst will send the surgeon or patient a Release for signature by the patient in favor of MENTOR Corporation, and any related persons or entities. Upon receipt of the returned product, and upon confirmation against MENTOR's database, replacement product or a returned product credit will be issued to the ordering customer. Upon receipt of the properly signed Release and copies of bills, a check will be issued to the appropriate party or parties in accordance with limitations outlined in this document. When the patient's revision surgery is covered by Medicare or any similar state program, the check for operating room, anesthesia, and/or surgeon's fees will be made payable solely to patient. Otherwise, the check may be made payable solely to the provider of the operating room, anesthesia, and/or surgeon's service(s).

\*Explanted, decontaminated product to be returned to Irving, Texas, facility.

2. When request is solely for replacement product under the MENTOR Product Replacement Policy, the surgeon should send
- (a) a copy of the patient's file including the Operative Report for the initial surgery;
  - (b) a copy of the Operative Report for the revision surgery (if already performed); and
  - (c) the removed and decontaminated MENTOR product. This information should be sent to:

MENTOR  
Product Evaluation Department  
3041 Skyway Circle North  
Irving, TX 75038-3540

Replacement products may be ordered before surgery by contacting MENTOR's Product Evaluation Department at (866) 250-5115. MENTOR Corporation reserves the right to cancel, change, or modify the terms of the MENTOR Lifetime Product Replacement Policy and/or the MENTOR Standard Advantage Limited Warranty and/or the MENTOR Enhanced Advantage Limited Warranty. Any such cancellation, change, or modification will not affect the currently stated terms for those already enrolled in the Program.



**MENTOR**

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[www.mentorcorp.com](http://www.mentorcorp.com)