



THE MENTOR PRODUCT REPLACEMENT POLICY and THE MENTOR PATIENTSAFE COVERAGE LIMITED WARRANTY FOR MENTOR SILICONE GEL-FILLED BREAST IMPLANTS

This document describes the MENTOR Corporation's Product Replacement Policy and the MENTOR PatientSafe Coverage Limited Warranty for MENTOR Silicone Gel-Filled Breast Implants described later in this document.

The MENTOR Product Replacement Policy and the MENTOR PatientSafe Coverage Limited Warranty applies automatically to recipients of MENTOR Silicone Gel-Filled Breast Implants implanted in Australia, Benelux, Denmark, France, Germany, Italy, Spain, Sweden and the United Kingdom after October 1, 2005.

Rupture is among the known risks of Silicone Gel-Filled 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. 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 PatientSafe Coverage Limited Warranty, MENTOR will pay, up to defined maximum amounts, certain uninsured, out-of-pocket costs directly related to revision surgery necessitated by a covered event for the following products: 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, and the Contour Profile® Gel Family of products.

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 Product Replacement Policy and the MENTOR PatientSafe Coverage Limited Warranty

1. The MENTOR Product Replacement Policy and the MENTOR PatientSafe Coverage Limited Warranty applies only to MENTOR Silicone Gel-Filled Breast Implants described in paragraph four of this document, and implanted in Australia, Benelux, Denmark, France, Germany, Italy, Spain, Sweden and the United Kingdom after October 1, 2005. Implantation must be in accordance with current MENTOR product literature (including product package inserts, enclosures, data sheets, and other notifications or instructions published by MENTOR) and accepted plastic surgical procedures by appropriately qualified, licensed surgeons.
2. The MENTOR Product Replacement Policy and the MENTOR PatientSafe Coverage Limited Warranty apply only to the following covered events:
 - (a) rupture requiring surgical intervention of all MENTOR Silicone Gel-Filled Breast Implants described in the fourth paragraph 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 Product Replacement Policy and the Mentor PatientSafe Coverage 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.

3. The MENTOR Product Replacement Policy and the MENTOR PatientSafe Coverage Limited Warranty do not apply to (a) removal of intact implants due to capsular contracture; (b) removal of intact implants for size alteration; (c) removal of intact implants due to wrinkling or rippling; (d) loss of implant shell integrity caused by re-operative procedures; (e) loss of implant shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures; or (f) surgery on the opposite breast to replace an intact implant.

B. What MENTOR will provide under the MENTOR Product Replacement Policy and the MENTOR PatientSafe Coverage Limited Warranty

1. The MENTOR Product Replacement Policy:

In the event of a qualifying rupture of a MENTOR Gel-Filled Breast Implant, MENTOR will replace the product, free of charge for the lifetime of the patient. MENTOR will provide a replacement MENTOR product of any size in the same or similar style as the originally implanted product. Implantation of the original MENTOR Gel-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 surgeons for the product to qualify for replacement under the MENTOR Product Replacement Policy. Should a more expensive style be requested by the surgeon, MENTOR will invoice the ordering customer for the list price difference between the ruptured product and the requested replacement product. The explanted ruptured product must be returned to the MENTOR Product Evaluation Department within 90 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 90 days of its explantation, the ordering customer will be invoiced for the price of the replacement product. The 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. MENTOR will neither provide nor pay for 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 Silicone Gel-Filled Breast Implant described in the fourth paragraph of this document automatically includes a new MENTOR PatientSafe Coverage Limited Warranty covering the replacement implant only.

- 2. Limitation on the MENTOR Product Replacement Policy:** If MENTOR Corporation's obligation to provide a replacement product 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 PatientSafe Coverage Limited Warranty.
- 3. The MENTOR PatientSafe Coverage 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 €1000 (£700). Operating room and anesthesia charges shall be given payment priority. Financial assistance does not imply a loan to the patient. 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 Patient-Safe Coverage Limited Warranty must be made to the local MENTOR branch or distributor, as applicable, by or on behalf of patient within 3 months of the date of qualifying revision surgery.

C. Patient Information on the MENTOR Product Replacement Policy and the MENTOR Patient-Safe Coverage Limited Warranty

1. Before implantation surgery, the surgeon should explain the details of the MENTOR Product Replacement Policy and the MENTOR Patient-Safe Coverage 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 and the MENTOR Patient-Safe Coverage Limited Warranty, the surgeon should also advise the patient about possible adverse reactions and complications associated with the Silicone Gel-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 Patient-Safe Coverage Limited Warranty, the surgeon should contact local Mentor representative to obtain a return kit and instructions to send
 - (a) a copy of the patient's file related to breast implant surgery, 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 related to breast implant surgery, and return of removed product to MENTOR; and
 - (f) the removed and decontaminated MENTOR product. This information together with the removed product should be sent to the local

Mentor branch or distributor, as applicable. For more information on mailing such information, please see MENTOR's website, www.Mentorcorp.com. Upon receipt of this information together with the removed product, a Mentor representative 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, a 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 or wire transfer will be issued to the appropriate party or parties in accordance with limitations outlined in this document. The check may be made payable to the patient or to the provider of the operating room, anesthesia, and/or surgeon's service(s).

2. When request is solely for a replacement product under the MENTOR Product Replacement Policy, the surgeon should send
 - (a) a copy of the patient's file related to breast implant surgery, 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 together with the removed product should be sent to the local Mentor branch or distributor, as applicable. For more information on returning the explanted product, please see Mentor's website, www.Mentorcorp.com.

Replacement products may be ordered before surgery by contacting your local MENTOR branch or distributor, as appropriate. MENTOR Corporation reserves the right to cancel, change, or modify the terms of the MENTOR Product Replacement Policy and/or the MENTOR PatientSafe Coverage Limited Warranty. Any such cancellation, change, or modification will not affect the currently stated terms for those already enrolled therein.



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