

this document. In addition to explaining the terms of the MENTOR® Product Replacement Policy and the MENTOR® Premier Advantage Limited Warranty, the surgeon should also advise the patient about possible adverse reactions and complications associated with the MemoryGel® Breast Implants, **and review with the patient the Important Information for Augmentation Patients about MENTOR® MemoryGel® Silicone Gel-Filled Breast Implants or Important Information for Reconstruction Patients about MENTOR® MemoryGel® Silicone Gel-Filled Breast Implants**, 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 decontaminated product should be sent to:

MENTOR® WORLDWIDE, LLC
Consumer Affairs Department
201 Mentor Drive, Santa Barbara, CA 93111

All explanted and decontaminated product should be sent to:

MENTOR® WORLDWIDE, LLC
Product Evaluation Department
555 Airline Dr., Coppel, TX 75019

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®, 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) or reimbursed to patient, or a combination of payees.

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® WORLDWIDE, LLC
Product Evaluation Department
555 Airline Dr., Coppel, TX 75019

Replacement products may be ordered before surgery by contacting MENTOR®'s Product Evaluation Department at (866) 250-5115. MENTOR® 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 and/or the Mentor Premier Advantage Warranty. Any such cancellation, change, or modification will not affect the currently stated terms for those already enrolled in the Program.



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THE MENTOR® PRODUCT REPLACEMENT POLICY AND THE MENTOR® PREMIER ADVANTAGE LIMITED WARRANTY PROGRAM FOR MEMORYGEL® BREAST IMPLANTS

This document describes MENTOR®'s Product Replacement Policy and the MENTOR® Premier Advantage Limited Warranty Program for MemoryGel® Round Breast Implants described later in this document.

The MENTOR® Premier Advantage Limited Warranty applies automatically to all MENTOR® MemoryGel® round breast implants implanted in the United States or Puerto Rico on or after May 1, 2009. Eligible patients implanted prior to May 1, 2009, remain covered under the terms and conditions stated in, "The MENTOR® Product Replacement Policy and The MENTOR® Advantage Limited Warranty Programs for Saline-Filled and MemoryGel® Breast Implants."

Rupture is one of the known risks of Silicone-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 *Important Information for Augmentation Patients about MENTOR® MemoryGel® Silicone Gel-Filled Breast Implants* or *Important Information for Reconstruction Patients about MENTOR® MemoryGel® Silicone Gel-Filled Breast Implants*. Copies can also be obtained by contacting MENTOR® directly, or through the MENTOR® web site at www.mentorcorp.com. **These documents are not intended to, and cannot, take the place of a full and frank discussion between surgeon and patient.**

Under the MENTOR® Premier 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 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 and Siltex® Round High Profile 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® Premier Advantage Limited Warranty:

The MENTOR® Premier Advantage Limited Warranty applies only to MENTOR® MemoryGel® Round Breast Implants described on the first page of this document, and implanted in the United States or Puerto Rico on or after May 1, 2009. If the surgery falls prior to May 1, 2009, then refer to the Enhanced Advantage Limited Warranty program (program details can be found below and in *The MENTOR® Product Replacement Policy* and *The MENTOR® Advantage Limited Warranty Program For Saline-Filled and MemoryGel® Breast Implants*). 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 the MENTOR® Premier Advantage Limited Warranty 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. Mailing in the warranty form or enrolling online will also help in the event that records are lost or destroyed.

2. The MENTOR® Product Replacement Policy and the MENTOR® Premier Advantage Limited Warranty apply only to the following covered events:

- (a) rupture of a Round MENTOR® Silicone-Filled Mammary Prosthesis;
- (b) loss of shell integrity resulting from patient trauma;
- (c) loss of shell integrity from unknown cause

3. The MENTOR® Product Replacement Policy and the MENTOR® Premier Advantage Limited Warranty program do not apply to
 - (a) any adverse reactions other than rupture;
 - (b) removal of intact implants for capsular contracture;
 - (c) removal of intact implants for size alteration;
 - (d) removal of intact implants due to wrinkling or rippling;
 - (e) loss of shell integrity caused by re-operative procedures; or
 - (f) loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures

4. The MENTOR® Enhanced Advantage Limited Warranty.

The MENTOR® Enhanced Advantage Limited Warranty applies only to MENTOR® MemoryGel® Round Breast Implants implanted in the United States or Puerto Rico after May 1, 2005 and that do not fall within the timeline for the Premier Advantage Limited Warranty on or after May 1, 2009. A non-refundable fee of \$100 to enroll the patient in the program may be required. 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.

B. What MENTOR® will provide under the MENTOR® Product Replacement Policy

1. **The MENTOR® Product Replacement Policy:** In the event of a qualifying of a rupture of a MemoryGel® Breast Implant, MENTOR® will replace the product, free of charge for the lifetime of the patient. Implantation of the MemoryGel® 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 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 explanation, 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® MemoryGel® 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 of MENTOR® MemoryGel® Breast Implant automatically includes a new MENTOR® Enhanced Advantage Limited Warranty covering the replacement implant only.

Limitation on the MENTOR® Product Replacement Policy:

If MENTOR®'s obligation to provide a replacement product under the MENTOR® Product Replacement Policy 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® Premier Advantage Limited Warranty.

C. Patient Information on the MENTOR® Product Replacement Policy and the MENTOR® Premier Advantage Limited Warranty

1. Before implantation surgery, the surgeon should explain the details of the MENTOR® Product Replacement Policy and the MENTOR® Premier Advantage Limited Warranty to the patient, and provide the patient with a copy of