

This document describes the Mentor Worldwide LLC (“Mentor”) Product Replacement Policy (“Replacement Policy”), free Mentor Warranty (“Mentor Warranty”) and the for-purchase Mentor Enhanced Warranty (“Enhanced Warranty”), for all styles of MemoryGel® Breast Implants and MemoryShape® Breast Implants, implanted in the United States (including Puerto Rico) on or after October 6, 2014.

The Mentor Warranty applies automatically to all MENTOR® MemoryGel® Round Breast Implants and MemoryShape® Breast Implants acquired directly from Mentor and implanted in the United States (including Puerto Rico) as of October 06, 2014. Patients implanted on or after October 06, 2014 are eligible to purchase for \$200 the Enhanced Warranty. Eligible persons choosing not to purchase the Enhanced Warranty remain eligible for the Mentor Warranty.

Rupture, capsular contracture, and other risks are known risks of silicone-filled breast implants. The surgeon, as learned intermediary, is responsible for providing the patient with all appropriate risk information before surgery. Mentor makes available to all surgeons and patients a copy of its materials entitled “Important Information for Augmentation Patients about MENTOR® MemoryGel® Silicone Gel-Filled Breast Implants” and “Important Information for Reconstruction Patients about MENTOR® MemoryGel® Silicone Gel-Filled Breast Implants”. Copies are available through the Mentor website at www.mentorwwllc.com. These materials are not intended to, and cannot, take the place of a full and frank discussion between surgeon and patient.

Mentor’s Product Insert Data Sheet (PIDS) for MENTOR® Breast Implants state the implants are single use devices. Damage that occurs during or due to a re-operative procedure is not covered under any Mentor Warranty or Enhanced Warranty. Explantation and subsequent re-implantation also means that the implant can no longer be classified as being used for primary augmentation or primary reconstruction.

THE MENTOR WARRANTY AND ENHANCED WARRANTY ARE LIMITED WARRANTIES ONLY, AND ARE 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. MENTOR DOES NOT WARRANT OR OTHERWISE ASSUME LIABILITY FOR MENTOR PRODUCTS THAT HAVE NOT BEEN PROCURED DIRECTLY FROM MENTOR BY THE TREATING PHYSICIAN (OR THEIR AUTHORIZED BUYING AGENT).

1. The MENTOR Product Replacement Policy:

In the event of a qualifying rupture of a MemoryGel® Breast Implant or MemoryShape® Breast Implant, MENTOR will replace the product, free of charge, for the lifetime of the patient. Implantation of the MemoryGel® Breast Implant or MemoryShape® 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 or ruptured 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 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® MemoryGel® Breast Implant or MemoryShape® 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 Breast Implant or MemoryGel® Breast Implant described on page one 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's obligation to provide a replacement product under the 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 Warranty and Enhanced Warranty.

2. The Mentor Warranty:

The Mentor Warranty applies to MENTOR® MemoryGel® Breast Implants and MemoryShape® Breast Implants described in this document, and implanted in the United States (including Puerto Rico) as of October 06, 2014. 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.

Under the Mentor Warranty, Mentor will pay up to \$3,500 maximum aggregate amount toward unreimbursed, out-of-pocket costs directly related to replacement surgery (whether unilateral or bilateral) necessitated by an unexpected rupture (defined as loss of shell integrity) of the following products: all MENTOR® MemoryGel® Silicone Breast Implants and all MENTOR® MemoryShape® Silicone Breast Implants.

Covered Events under the Mentor Warranty:

Unexpected rupture (loss of shell integrity) of a MENTOR® MemoryGel® Silicone-Filled Mammary Prosthesis or MemoryShape® Silicone-Filled Mammary Prosthesis EXCEPT FOR the reasons noted in 3 (e) and 3 (f), below.

Patients experiencing their primary augmentation or primary reconstruction date of implant on or after October 6, 2014, automatically have replacement product covered for three (3) years from the date of implantation for the following events:

- (a) Capsular Contracture, Baker Grade III or Baker Grade IV as diagnosed by the attending surgeon. Baker Grade III: the breast is firm and looks abnormal (visible distortion) Baker Grade IV: the breast is hard, painful, and looks abnormal (greater visible distortion than Baker Grade III).
- (b) Double Capsule, defined as when the initial capsule of fibrous scar tissue around the implant, formed as part of the normal healing process, separates with minor trauma, resulting in two layers of fibrous tissue surrounding the implant.
- (c) Late-Forming Seroma, defined for the purposes of this document as a clinically symptomatic seroma that develops at least 12 months after the qualifying primary augmentation or primary reconstruction implant surgery with no intervening surgical procedures performed on the breast between the primary surgery and the development of the seroma.
- (d) At the surgeon's request, MENTOR will also provide a replacement of a MENTOR® MemoryGel® Breast Implant or MemoryShape® 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 in the Product Replacement Policy.

3. The Mentor Warranty does not apply to:

- (a) any adverse event other than the ones described in 2 (a), 2(b), and 2(c) in this document
- (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 or during re-operative procedures
- (f) loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures

4. The Mentor Enhanced Warranty

Primary augmentation or primary reconstruction patients implanted on or after October 6, 2014 may choose to purchase an enhanced version of the Mentor Warranty. For an enrollment fee of \$200, the Mentor Enhanced Warranty extends the

Replacement Policy time limit from three (3) years from date of implant to ten (10) years from date of implant, for the events of Baker Grade III capsular contracture, Baker Grade IV capsular contracture, double capsule, and late-forming seroma, described above. The enrollment fee includes a one-time per patient maximum of \$3,500 toward operating room, surgeon, and anesthesia fees not paid, or payable by any form of insurance, or waived by the healthcare provider, for 10 years from date of implant, for the events of Baker Grade III or Baker Grade IV capsular contracture, double capsule, or late-forming seroma.

Patients enrolling in the Mentor Enhanced Warranty are automatically enrolled in the Mentor Warranty for rupture of MemoryGel® Breast Implants or MemoryShape® Breast Implants. Note that in the event a patient enrolled in the Mentor Enhanced Warranty simultaneously experiences a qualifying rupture with another qualifying event such as Baker Grade III or IV capsular contracture (for illustrative purposes only), Mentor will make only one payment up to the maximum aggregate amount of \$3,500 regardless of whether patient experiences more than one event simultaneously, and also regardless of whether replacement surgery is performed unilaterally or bilaterally.

At the surgeon's request, MENTOR will also provide a replacement of a MENTOR® MemoryGel® Breast Implant or MemoryShape® 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 in the Product Replacement Policy.

Replacement product or financial assistance for Baker Grade III and Baker Grade IV capsular contracture, double capsule, or late-forming seroma is limited to a maximum of one replacement product per breast for the patient's lifetime whether the patient experiences one or all of these events. Similarly, there is a limit of one payment up to the maximum aggregate amount of \$3,500 for Grade III and Grade IV capsular contracture, double capsule, or late forming seroma. Because a replacement implant does not qualify as a primary implantation, no re-enrollment in the Mentor Enhanced Warranty for that implant is available.

5. The Mentor Enhanced Warranty does not apply to the following events:

- (a) any adverse event other than the ones described in 2 (a), 2(b), and 2(c) in this document
- (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 or during re-operative procedures
- (e) loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures

6. Other Warranty Restrictions

In the case of a Capsular Contracture Baker grade III , Capsular Contracture Baker grade IV, Double capsule or late seroma, the Replacement Product and the Enhanced Warranty are restricted to primary augmentation and primary reconstruction patients, defined as "first ever" implantation of breast implant(s), regardless of the type of implant or manufacturer of any previously-placed breast implant. A temporary tissue expander for reconstructive purposes will not be considered as a breast implant for an otherwise primary reconstruction.

Patients found to have enrolled non-primary implants or implanted prior to eligibility date in the Enhanced Warranty will have the \$200 enrollment fee credited to the original payment source. No replacement product or financial assistance will be given for Baker Grade III capsular contracture, Baker Grade IV capsular contracture, double capsule, or late-forming seroma.

7. Patient Information on the Mentor Warranty and Mentor Enhanced Warranty

Before implantation surgery, the surgeon should explain the details of the Mentor Product Replacement Policy and the Mentor Warranty or Mentor Enhanced Warranty to the patient. The surgeon should advise the patient about possible adverse reactions and complications associated with MemoryGel® Breast Implants or MemoryShape® 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," materials provided by Mentor.

It is important for the patient to maintain their own records to ensure validation of eligibility for (or enrollment in) the Mentor Warranty or the Mentor Enhanced Warranty. Enrolling online will help document eligibility in the event that records are inadvertently lost or destroyed.

8. Filing a Warranty Claim

Qualifying events must be reported to Mentor within the stated eligibility timeframe. The surgeon should contact Mentor Customer Quality Department at 866-250-5115 to report the event and obtain a return kit for return of the explanted product.

Send the removed (and decontaminated) product to:

MENTOR WORLDWIDE LLC
Product Evaluation Department
3041 Skyway Circle North
Irving, TX 75038

The following information may be required to verify eligibility for financial assistance under any Mentor warranty:

- (a) Information to document the patient's implant information (catalogue, serial #) and the patient's experience
- (b) the Operative report for the original implantation surgery to document Date of Implant;
- (c) a copy of the Operative Report for the revision surgery
- (d) copies of bills showing operating room, anesthesia, and surgeon fees incurred for the replacement surgery.
- (e) copies of forms showing any relevant insurance Reimbursements (Explanation of Benefits forms);
- (f) authorization, signed by the patient, allowing release and return of explanted product to MENTOR; and
- (g) the removed and decontaminated MENTOR product returned to Mentor Product Evaluation in Irving Texas.

All requests for information only (ie, no delivery of explanted product) should be sent to:

MENTOR WORLDWIDE LLC
Customer Quality Department
301 Mentor Drive
Santa Barbara, CA 93111

Requests for eligible replacement products may be ordered before surgery by contacting Mentor's Customer Quality Department at (866) 250-5115.

Mentor Worldwide LLC reserves the right to cancel, change, or modify the terms of the Mentor Warranty and/or Enhanced Warranty. Any such cancellation, change, or modification will not affect the stated terms as of the date of their implantation for those already enrolled in a Mentor warranty.

9. Additional Required Claim Information for the Mentor Enhanced Warranty

Mentor's Customer Quality Department requires a photograph showing the appearance of the breast prior to the explant procedure to support replacement requests for Baker Grade III and Baker Grade IV capsular contracture, a copy of the cytology report to support late-forming seroma requests, or a photograph of intraoperative findings to support double capsule events.
