

MENTOR PROMISE AND MENTOR PROMISE ENHANCED PROTECTION PLAN

FOR MEMORYGEL® BREAST IMPLANTS, MEMORYGEL® XTRA BREAST IMPLANTS AND MEMORYSHAPE® BREAST IMPLANTS

This document describes the Mentor Worldwide LLC (“Mentor”) Product Replacement Policy (“Replacement Policy”), the free Mentor Promise Protection Plan (“Basic Plan”), and the for-purchase Mentor Promise Enhanced Protection Plan (“Enhanced Plan”), for all styles of MemoryGel® Breast Implants, MENTOR® MemoryGel® Xtra Implants, and MemoryShape® Breast Implants, implanted in the United States (including Puerto Rico) on or after May 01, 2017.

The Replacement Policy and Basic Plan apply automatically to all MENTOR® MemoryGel® Breast Implants, MENTOR® MemoryGel® Xtra Breast Implants, and MENTOR® MemoryShape® Breast Implants acquired directly from Mentor and implanted in the United States (including Puerto Rico) as of May 1, 2017. Patients implanted on or after May 01, 2017, are eligible to purchase for \$300 the Enhanced Plan. Eligible persons choosing not to purchase the Enhanced Plan remain eligible for the Basic Plan.

Silicone-filled breast implants are associated with known risks, including rupture and capsular contracture. The surgeon, as learned intermediary, is responsible for providing the patient with all appropriate risk information before surgery. Mentor also 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”, “Important Information for Reconstruction Patients about MENTOR® MemoryGel® Silicone Gel-Filled Breast Implants” entitled “Important Information for Augmentation Patients about MENTOR® MemoryShape® Silicone Gel-Filled Breast Implants”, and “Important Information for Reconstruction Patients about MENTOR® MemoryShape® 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® MemoryGel® Breast Implants and MENTOR® MemoryShape® Breast Implants 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 of the Replacement Policy, the Basic Plan, or the Enhanced Plan. 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 REPLACEMENT POLICY, BASIC PLAN, AND ENHANCED PLAN 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 Replacement Policy:

The Replacement Policy applies to MENTOR® MemoryGel® Breast Implants, MENTOR® MemoryGel® Xtra Breast Implants, and MENTOR® MemoryShape® Breast Implants described in this document and implanted in the United States (including Puerto Rico) as of May 1, 2017.

In the event of a qualifying rupture of a covered product, Mentor will replace the product, free of charge, for the lifetime of the patient.

Mentor will replace covered product, free of charge, for ten (10) years from the date of implantation for the following other qualifying 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 seroma, defined for the purposes of this document as a clinically symptomatic seroma that develops at least 12 months after the qualifying implant surgery with no intervening surgical procedures performed on the breast between the surgery in question and the development of the seroma.

The Replacement Policy does not apply to:

- any adverse event other than a qualifying rupture or the ones described in 1(a), 1(b), and 1(c) in this document
- removal of intact implants for capsular contracture, Baker Grade I or Baker Grade II as diagnosed by the attending surgeon
- removal of intact implants for size alteration
- removal of intact implants due to wrinkling or rippling
- loss of shell integrity caused by or during re-operative procedures
- loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures
- loss of shell integrity resulting from sharp instrument damage per analysis by MENTOR Product Evaluation Department
- product not returned to the MENTOR Product Evaluation Department as per this Replacement Policy.

To qualify for product replacement under the Replacement Policy, implantation of the MENTOR® MemoryGel® Breast Implant, MENTOR® MemoryGel® Xtra Implant, or MENTOR® 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.

Should a more expensive product be requested by the physician outside of the original product family implanted (MENTOR® MemoryGel® Breast Implants, MENTOR® MemoryGel® Xtra Breast Implants, or MENTOR® MemoryShape® Breast Implants), Mentor will invoice the ordering customer for the list price difference between the ruptured product and the requested replacement product. There is no additional charge if the ruptured product and requested replacement product are in the same product family. The explanted ruptured product must be returned to the Mentor Product Evaluation Department within sixty (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 sixty (60) days of its explantation, the ordering customer will be invoiced for the price of the replacement product.

At the surgeon's request, Mentor will also provide a replacement of a MENTOR® MemoryGel® Breast Implant, MENTOR® MemoryGel® Xtra Breast Implant, or MENTOR® 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 this policy.

Qualifying replacement product (limit 2) will be sent without shipping charges if the order is received in the Mentor Product Evaluation Department at least three (3) business days prior to scheduled delivery date; otherwise, freight charges will be invoiced to the ordering customer. All "backup" replacement product requested will be invoiced at customer's established pricing and shipping terms and will follow Mentor's standard return policy.

Mentor will neither provide nor pay for a replacement with a non-Mentor product under the terms of this Replacement Policy, nor in any event provide money for or in lieu of a Mentor replacement product. Any replacement MENTOR® MemoryGel® Breast Implant, MENTOR® MemoryGel® Xtra Breast Implant or MENTOR® MemoryShape® Breast Implant automatically includes new coverage under the Basic Plan.

Limitation on the Replacement Policy:

If Mentor's obligation to provide a replacement product under the 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 Basic Plan and the Enhanced Plan.

2. The Basic Plan:

The Basic Plan applies to MENTOR® MemoryGel® Breast Implants, MENTOR® MemoryGel® Xtra Breast Implants, and MENTOR® MemoryShape® Breast Implants described in this document and implanted in the United States (including Puerto Rico) as of May 01, 2017. 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 Basic Plan, Mentor will pay up to \$3,500 as the 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 any MENTOR® MemoryGel® Breast Implant, MENTOR® MemoryGel® Xtra Breast Implant, and any MENTOR® MemoryShape® Silicone Breast Implant, EXCEPT as stipulated below, for ten (10) years from the date of implantation.

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

The Basic Plan does not apply to:

- any adverse event other than a qualifying rupture
- removal of intact implants for capsular contracture, Baker Grade I or Baker Grade II as diagnosed by the attending surgeon
- removal of intact implants for size alteration
- removal of intact implants due to wrinkling or rippling
- loss of shell integrity caused by or during re-operative procedures
- loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures
- loss of shell integrity resulting from sharp instrument damage per analysis by MENTOR Product Evaluation Department
- product not returned to the Mentor Product Evaluation Department as per Replacement Policy.

4. The Enhanced Plan

Primary augmentation or primary reconstruction patients implanted on or after May 01, 2017, may choose to purchase the Enhanced Plan up to forty-five (45) days from date of surgery. For an enrollment fee of \$300, the Enhanced Plan provides a one-time per patient maximum payment 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 ten (10) years from date of implant, for the events of Baker Grade III or Baker Grade IV capsular contracture, double capsule, or late seroma only.

Primary augmentation or primary reconstruction is 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.

Revision augmentation or revision reconstruction patients implanted with MENTOR® MemoryShape® Breast Implants on or after May 01, 2017, will be eligible to re-enroll in the Enhanced Plan for an additional enrollment fee of \$300 up to forty-five (45) days from date of surgery. Revision augmentation or revision reconstruction patients implanted with MENTOR® MemoryGel® Breast Implants on or after May 01, 2017, will not be eligible to re-enroll in the Enhanced Plan.

Patients enrolling in the Enhanced Plan are automatically enrolled in the Basic Plan for rupture of MENTOR® MemoryGel® Breast Implants, MENTOR® MemoryGel® Xtra Breast Implants, or MENTOR® MemoryShape® Breast Implants. Note that in the event a patient enrolled in the Enhanced Plan 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, MENTOR® MemoryGel Xtra Breast Implant, or MENTOR® MemoryShape® Breast Implant with any Mentor breast implant currently commercially available both for use in the affected breast and to replace the contralateral implant, provided that the contralateral breast implant is a MENTOR product. There will be no charge for any list price differences between explanted device and replacement devices. Shipping charges will remain as outlined in the Replacement Policy.

The Enhanced Plan does not apply to the following events:

- any adverse event other than the ones described in 1(a), 1(b), and 1(c) in this document
- removal of intact implants for capsular contracture, Baker Grade I or Baker Grade II as diagnosed by the attending surgeon
- removal of intact implants for size alteration
- removal of intact implants due to wrinkling or rippling
- loss of shell integrity caused by or during re-operative procedures
- loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures
- loss of shell integrity resulting from sharp instrument damage per analysis by MENTOR Product Evaluation Department
- product not returned to the MENTOR Product Evaluation Department as per the Replacement Policy

Patients found to have enrolled non-primary implants or implanted prior to eligibility date in the Enhanced Plan will have the \$300 enrollment fee credited to the original payment source. In the event of non-eligible enrollment in the Enhanced Plan, no replacement product or financial assistance will be

given for Baker Grade III capsular contracture, Baker Grade IV capsular contracture, double capsule, or late seroma.

7. Patient Information on the Replacement Policy, Basic Plan, and Enhanced Plan

Before implantation surgery, the surgeon should explain the details of the Replacement Policy and the Basic Plan or Enhanced Plan to the patient. The surgeon should advise the patient about possible adverse reactions and complications associated with MENTOR® MemoryGel® Breast Implants or MENTOR® MemoryShape® Breast Implants, and review with the patient the “Important Information for Augmentation Patients about MENTOR® MemoryGel® Silicone Gel-Filled Breast Implants”, “Important Information for Augmentation Patients about MENTOR® MemoryShape® Silicone Gel-Filled Breast Implants”, “Important Information for Reconstruction Patients about MENTOR® MemoryGel® Silicone Gel-Filled Breast Implants”, or “Important Information for Reconstruction Patients about MENTOR® MemoryShape® 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 Basic Plan or the Enhanced Plan. 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 Returns
5314 3rd Street
Analysis Lab -103
Irwindale, CA 91706

The following information are required to verify eligibility for financial assistance or product replacement under the Replacement Policy, the Basic Plan or the Enhanced Plan:

- Information to document the patient's implant information (catalogue, serial #) and the patient's experience
- The operative report for the original implantation surgery to document date of implant
- A copy of the operative report for the revision surgery
- Copies of bills showing operating room, anesthesia, and surgeon fees incurred for the replacement surgery
- Copies of forms showing any relevant insurance reimbursements (explanation of benefits forms)
- Authorization, signed by the patient, allowing release and return of explanted product to Mentor
- The removed and decontaminated MENTOR product returned to Mentor Product Evaluation Department

- For capsular contracture claims: 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
- For late seroma claims: a copy of the cytology report to support late seroma requests
- For double capsule claims: a photograph of intraoperative findings to support double capsule events

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

MENTOR WORLDWIDE LLC Customer Quality Department
33 Technology Drive
Irvine, CA 92618

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 Replacement Policy, the Basic Plan or the Enhanced Plan. Any such cancellation, change, or modification will not affect the stated terms as of the date of their implantation for those already enrolled and covered under the policy or plan in effect on the date of the applicable implantation.