THE MENTOR PRODUCT REPLACEMENT POLICY, MENTOR WARRANTY AND MENTOR ENHANCED WARRANTY FOR INVESTIGATIONAL ULTRA HIGH PROFILE (UHP-L) BREAST IMPLANTS

This document describes the Mentor Worldwide LLC ("Mentor") Product Replacement Policy ("Replacement Policy"), Mentor Warranty ("Mentor Warranty") and the Mentor Enhanced Warranty for Investigational MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L) implanted in the United States.

The Mentor Product Replacement Policy and Warranty applies automatically to all Investigational MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L) acquired by a health care professional directly from Mentor and implanted in the United States. The Mentor Enhanced Warranty applies automatically to Investigational Ultra High Profile (UHP-L) Breast Implants implanted as the primary first-ever implant used.

The Investigational MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L) are not approved products. The FDA has not approved these gel-filled breast implants as safe and effective because additional scientific evidence needs to be collected. 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 the Informed Consent Form for each investigative clinical study. These materials are not intended to, and cannot, take the place of a full and candid discussion between surgeon and patient.

Mentor also makes available to all participating surgeons in the clinical study specific Product Insert Data Sheet (PIDS). Mentor's Product Insert Data Sheet (PIDS) for Investigational MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L) 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 of an Investigational MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L) means that the newer implant can no longer be classified as being used for primary reconstruction.

THE MENTOR WARRANTY AND ENHANCED WARRANTY FOR INVESTIGATIONAL MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L) 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

A. For Primary and Revision Reconstruction: In the event of a qualifying rupture of an Investigational MENTOR® MemoryGel® Breast Implant Ultra High Profile (UHP-L), Mentor will replace only the medical device, free of charge, for the lifetime of the patient. Implantation of an Investigational Ultra High Profile (UHP-L) Breast Implant, as well as any subsequent procedures, must be in accordance with the Clinical Study Protocol, the Clinical Study PIDS, and accepted plastic surgical procedures by appropriately qualified licensed physician to qualify for free replacement MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L) under the Mentor Product Replacement Policy.

B. For Primary Reconstruction Only:

Primary (first ever) reconstruction may include subjects with previous tissue expander placement, but does not include subjects who were previously implanted with saline or gel filled breast implants. Study subjects having primary reconstruction with Investigational MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L) are entitled to receive replacement for ten (10) 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 reconstruction implant surgery with no intervening surgical procedures performed on the breast between the primary surgery and the development of the seroma.

A primary reconstruction patient is limited to receiving a patient lifetime total of one replacement product per breast per patient for events outlined in 1B(a) through 1B(c) and occurring within ten (10) years of date of implant.

C. Additional terms and conditions of the Mentor Replacement Policy (Applies to both 1A and 1B)

Requests for replacement product must be made by the surgeon.

Should a more expensive product be requested, Mentor will invoice the ordering customer for the list price difference between ruptured product, or the eligible product experiencing Baker Grade III or Baker Grade IV capsular contracture, double capsule, or late-forming seroma and the requested replacement product. The explanted ruptured product or eligible primary reconstruction product experiencing events listed in 1B(a) through 1B(c) must be returned to the MENTOR® Product Evaluation Department within 60 days of its explantation 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.

When requested by the surgeon, Mentor will also provide a replacement of the MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L) 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 Implants Ultra High Profile (UHP-L) described on page one of this document automatically includes a new Mentor Warranty covering the replacement implant only.

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 for Primary and Revision Breast Reconstruction:

The Mentor Warranty applies to MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L) described in this document, and implanted in the United States. Implantation must be in accordance with Mentor Clinical Study Protocol, the Clinical Study PIDS, 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) for up to 10 years from date of implant for Investigational MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L).

Covered Events under the Mentor Warranty:

Unexpected rupture (loss of shell integrity) of a MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L) EXCEPT FOR ruptures outlined in 3(e) and 3(f), below.

3. The Mentor Warranty does not apply to:

a. any adverse event other than unexpected rupture (loss of shell integrity) of a MENTOR® MemoryGel® Ultra High Profile (UHP-L) Breast Implant.
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 available for Primary Reconstruction Only:

Primary reconstruction patients experiencing surgeon diagnosed events of:

a. Baker Grade III or Baker Grade IV capsular contracture
b. double capsule
c. late-forming seroma

Primary reconstruction patients are eligible to receive 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.

Patients eligible for the Mentor Enhanced Warranty are automatically enrolled in the Mentor Warranty for rupture of MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L). Note that in the event a patient eligible for the Mentor Enhanced Warranty simultaneously experiences a qualifying rupture with another qualifying event such as Baker Grade III or IV capsular contracture (used 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.

Replacement product or financial assistance for Baker Grade III or Baker Grade IV capsular contracture, double capsule, or late-forming seroma is limited to a maximum of one replacement product per breast for up to 10 years from date of implant 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 per patient toward unreimbursed, out-of-pocket costs directly related to replacement surgery for Grade III or Grade IV capsular contracture, double capsule, or late forming seroma.

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

a. any adverse event other than the ones described in 4(a), 4(b), and 4(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-forming seroma, the 10 year Replacement Product and the Enhanced Warranty are restricted to 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.

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 MENTOR® MemoryGel® Breast Implants Ultra High Profile (UHP-L), and review with the patient the information provided in the study Informed Consent Form and relevant information from the study PIDS provided by Mentor.

It is important for the patient to maintain her own records to ensure validation of eligibility for (or enrollment in) the Mentor Warranty or the Mentor Enhanced Warranty.

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. A copy of 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.
h. A patient and event specific Release prepared by Mentor must be signed by the patient before any payment for financial assistance or financial reimbursement described in this document will be made to or on behalf of the patient.

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

Mentor Worldwide, LLC
Customer Quality Department
33 Technology
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 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.