

## **MENTOR PROMISE AND MENTOR PROMISE ENHANCED PROTECTION PLAN FOR SALINE-FILLED BREAST IMPLANTS**

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This document describes the Mentor Worldwide LLC (“Mentor”) Product Replacement Policy, also known as the MENTOR Promise Protection Plan (“Replacement Policy”), and the for-purchase MENTOR Promise Enhanced Protection Plan (“Enhanced Plan”), for all styles of MENTOR Saline-Filled Breast Implants implanted in the United States (including Puerto Rico) on or after January 1, 2021.

The Replacement Policy applies automatically to all MENTOR Saline-Filled Breast Implants acquired by a valid customer directly from Mentor and implanted in the United States (including Puerto Rico) as of January 1, 2021. Patients implanted on or after January 01, 2021 are eligible to purchase the Enhanced Plan for \$200. Eligible persons choosing not to purchase the Enhanced Plan remain eligible for the Replacement Policy.

Saline-Filled Breast Implants are associated with known risks, including deflation. 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 material entitled “Saline-Filled Breast Implant Surgery: Making an Informed Decision”. Copies are available through the Mentor website at [www.breastimplantsbymentor.com](http://www.breastimplantsbymentor.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® Saline-Filled 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 or the Enhanced Plan. MENTOR® Saline-Filled Breast Implants are defined as part of Mentor’s portfolio of Smooth Round Saline, Siltex® Round Saline, Smooth Round Spectrum®, Siltex® Round Spectrum®, and Siltex® Contour Profile® Saline (moderate and high profile and Spectrum®).

THE REPLACEMENT POLICY AND ENHANCED PROTECTION 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:**

In the event of an unexpected qualifying deflation of a MENTOR Saline-filled Breast Implant, Mentor will replace the product, free of charge, for the lifetime of the patient. Implantation of the MENTOR Saline-filled Breast Implants, 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 outside of the saline implant family, such as a Mentor MemoryGel® Breast implant, Mentor will invoice the ordering customer a flat rate of \$250 per requested replacement product. The explanted deflated 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. If 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.

At the surgeon's request, MENTOR will also provide a replacement of a MENTOR® Saline-Filled 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 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 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 Saline-filled Breast Implant automatically includes new coverage under the Replacement Policy.

### **Limitations 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 Enhanced Plan.

## **2. The Enhanced Plan:**

The Enhanced Plan applies to MENTOR Saline-filled Breast Implants described in this document acquired by a valid customer directly from Mentor and implanted in the United States (including Puerto

Rico) as of on or after January 01, 2021. Patients implanted on or after January 01, 2021, may choose to purchase the Enhanced Plan up to forty-five (45) days from date of 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.

#### **Covered Events under the Enhanced Plan:**

For ten (10) years from the date of implantation, patients implanted on or after January 01, 2021 that have enrolled in the Enhanced Plan are eligible for up to \$2,400 toward unreimbursed, out-of-pocket costs directly related to replacement surgery (whether unilateral or bilateral) for the following events:

- Qualifying deflation of a MENTOR Saline-Filled breast implant (defined as loss of shell integrity)
- loss of shell or valve integrity resulting in deflation of a Mentor Saline-Filled Breast Implant

#### **The Replacement Policy and Enhanced Plan does not apply to:**

- any event other than deflation
- removal of intact implants for capsular contracture
- removal of intact implants for size alteration
- removal of intact implants due to wrinkling or rippling
- loss of shell integrity caused by 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

### **3. Patient Information on the Replacement Policy and Enhanced Plan**

Before implantation surgery, the surgeon should explain the details of the Replacement Policy and the Enhanced Plan to the patient. The surgeon should advise the patient about possible adverse reactions and complications associated with MENTOR Saline-filled Breast Implants, and review with the patient the “Saline-Filled Breast Implant Surgery: Making an Informed Decision” 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 Enhanced Plan. Enrolling online will help document eligibility in the event that records are inadvertently lost or destroyed.

### **4. 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.

The following information is required to verify eligibility for financial assistance or product replacement under the Replacement Policy 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

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

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

Mentor Worldwide LLC reserves the right to cancel, change, or modify the terms of the Replacement Policy, 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.