

THE SIENTRA LIMITED WARRANTY AND PRODUCT REPLACEMENT PROGRAM FOR SIENTRA SILICONE GEL BREAST IMPLANTS

This document sets forth the terms, conditions, scope, coverage and claim procedures of the Sientra Limited Warranty and Product Replacement Program (the "LWRP").

1. Effective Date and Applicability

Subject to the terms and conditions set forth herein, the Sientra LWRP automatically applies to all Sientra Smooth or Textured Surface Silicone Gel Breast Implants that are implanted in a patient in the United States or Puerto Rico between April 1, 2012 and April 30, 2018. No action is required on the part of the patient to be enrolled in the Sientra LWRP. For Sientra Smooth or Textured Surface Silicone Gel Breast Implants implanted on or after May 1, 2018, please consult the documentation applicable to your implants available [here](#).

2. Scope of Covered Events

Provided the qualifying requirements of Section 3 are met, and none of the exclusions in this Section 2 apply, the following events, as defined for the purposes of this document (the "Covered Events"), are covered by the Sientra LWRP:

- A. **Rupture:** Any actual or suspected loss of integrity of the implant shell clinically diagnosed by the patient's surgeon and confirmed by either (i) an MRI, or other diagnostic imaging method acceptable to Sientra.
- B. **Capsular Contracture:** Baker Grade III or Baker Grade IV capsular contracture forming at least three (3) months after implant surgery, clinically diagnosed by the patient's surgeon and confirmed by photographs acceptable to Sientra showing the appearance of the breast at the first visit following implant surgery and immediately prior to explant surgery. Covered Events do not include other surgical issues, including but not limited to, any malposition that is present post-implantation, implants that have not settled in their pocket, under-dissected pockets, superior malposition or tight pockets. Any capsular contracture forming prior to the three (3) month anniversary of the implant surgery will not be considered a capsular contracture Covered Event.

Notwithstanding the foregoing, the Sientra LWRP does NOT apply to any of the following:

- Any events, adverse reactions or injury other than a qualifying Covered Event described in Sections 2(A)-(B)
- Removal of intact implant(s) for any reason other than those specified in Sections 2(A)-(B) including, but not limited to, Baker Grade I or Baker Grade II capsular contracture, style or size change, wrinkling or rippling, or dissatisfaction;
- Rupture caused by patient trauma, improper implantation or operative procedures;
- Rupture resulting from open-capsulotomy or closed-compression-capsulotomy procedures, or any other procedure for which there is a warning, precaution or contraindication in Sientra Silicone Gel Breast Implant's Instructions for Use;
- Damage that occurs during, or due to, any re-operative procedure;
- Explanation and subsequent re-implantation of any Sientra Silicone Gel Breast Implant;

- Events or injury covered by insurance, reimbursed by insurance, or for which the healthcare provider has waived any costs or fees.

Determination of whether an event is a Covered Event that is not otherwise excluded by this Section 2 lies in the sole discretion and judgment of Sientra. In the event of any dispute over whether an event is a Covered Event, Sientra shall refer such dispute to its Medical Advisory Board, who shall make the final determination by a majority vote, which determination shall be binding on all parties.

3. Qualifying Covered Events

In order for a Covered Event to qualify under the Sientra LWRP, the following criteria must be satisfied:

- A. For rupture Covered Events the implantation must have taken place between April 1, 2012 and April 30, 2018, and for Capsular Contracture Covered Events the implantation must have taken place between October 1, 2014 and April 30, 2018;
- B. The implantation, and all subsequent procedures (including explanation), must have been performed in the United States or Puerto Rico by licensed physicians who are Board certified in plastic or reconstructive surgery by the American Board of Plastic Surgery ("ABPS"), the American Osteopathic Board of Surgery ("AOBS"), or who are otherwise admissible to be certified in plastic or reconstructive surgery by the ABPS or ABOS (e.g., by virtue of having completed the training and other prerequisites required for permission to take the Board examination);
- C. The implantation, and all subsequent procedures, must have been performed in accordance with the Sientra Silicone Gel Breast Implant Instructions for Use in effect at the time of the procedure and all applicable professional standards of care;
- D. The patient's surgeon must have completed Sientra's Device Tracking and Limited Warranty Enrollment Form;
- E. The claims procedure set forth in Section 6 must have been followed, including obtaining Sientra's pre-authorization and returning the explanted product(s) and other required documentation to Sientra within thirty (30) days of the explant procedure; and
- F. The patient must sign a full release releasing Sientra from any further liability related to the explanted product(s) in return for receipt of the benefits provided under the Sientra LWRP (the "Release").

NOTE THAT IN THE EVENT THAT ANY ONE OF THE ABOVE CONDITIONS (A)—(F) OF THIS SECTION 3 ARE NOT MET, AN OTHERWISE COVERED EVENT WILL NOT QUALIFY FOR BENEFITS PROVIDED FOR IN THE SIENTRA LWRP. DETERMINATION OF WHETHER A COVERED EVENT IS A QUALIFYING COVERED EVENT UNDER THIS SECTION 3 LIES IN THE SOLE DISCRETION AND JUDGMENT OF SIENTRA.

4. Product Replacement Program Coverage

For all qualifying Rupture Covered Events, Sientra will replace the product free-of-charge for the lifetime of the patient. For all qualifying Capsular Contracture Covered Events, Sientra will replace the product free-of-charge for a term of five (5) years from the date of the patient's qualifying surgery.

All no charge replacement implants ("NCRI") shall be provided by way of credit to the implanting surgeon's account. There is no cash benefit to the product replacement program, and no cash is payable to the patient in the event that: (a) they elect not to have a NCRI; (b) the NCRI has a lower list price than the original implant; or (c) the same style or size NCRI is not available for any reason. SIENTRA WILL NEITHER PROVIDE NOR PAY FOR A REPLACEMENT IMPLANT WITH ANY NON-SIENTRA PRODUCT.

When a patient qualifies for an NCRI Sientra shall, at the surgeon's request, also provide a replacement of the contralateral implant free-of-charge.

NCRI provided under the Sientra LWRP may be of any size or style. If the size or style of the replacement products selected by the patient is no longer available, then replacement implants of the most comparable size and style manufactured by Sientra will be provided.

All NCRI provided under the Sientra LWRP (limited to two (2) per patient) shall be shipped at no cost pursuant to Sientra's standard shipping policies, provided that extra charges for expedited shipping shall be payable by the implanting surgeon.

All NCRI provided under the Sientra LWRP shall be automatically enrolled in accordance with the terms and conditions of the Sientra Limited Warranty and Product Replacement Programs (if any) in effect at the date of the revision implant surgery.

5. Limited Warranty Program Coverage

For a qualifying Rupture Covered Event that occurs within ten (10) years from the date of the patient's qualifying surgery, Sientra will provide a one-time only payment up to a maximum of **\$3,600** to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or waived by the healthcare provider, that are directly related to the Rupture Covered Event.

The amounts payable under the Sientra LWRP are limited to a maximum of **\$3,600** per qualifying surgery. All claims for monetary reimbursement must be supported medical invoices, bills or other acceptable forms of proof of payment, and Sientra shall only reimburse the actual out-of-pocket amount up to the maximum amount for the applicable Covered Event. In the event that a patient experiences multiple qualifying Covered Events from a qualifying surgery, either simultaneously or sequentially (as determined by Sientra in its sole discretion), Sientra will only make one payment up to a maximum amount of **\$3,600**.

Under no circumstances will Sientra provide payments under the Sientra LWRP for lost wages, pain and suffering, or any and all other ancillary medical expenses not identified above arising for any reason relating to the Covered Events.

6. Product Replacement and Limited Warranty Program Claims Procedure

In order to obtain the benefits for a qualifying Covered Event under the Sientra LWRP, the following claims procedure must be followed:

- A. The patient's surgeon must initiate the claims process and obtain pre-authorization in advance of any revision or explantation surgery by contacting Sientra's Product Support Team at 888.708.0808 or warranty@sientra.com. To obtain pre-authorization, the surgeon must send to Sientra copies of the following:
 - i. The patient's medical records (including photographs and diagnostic imaging as applicable) showing the basis for the surgeon's diagnosis of the qualifying Covered Event;
 - ii. A completed and signed Request for a NCRI Form (if applicable) within the time period specified on the NCRI Form;
 - iii. Authorizations, signed by the patient, allowing the release of the patient's health and medical records and return of the explanted product(s) to Sientra; and
 - iv. A Release, signed by the patient, in return for acceptance of the benefits of the Sientra LWRP.
- B. After obtaining pre-authorization, the patient's surgeon must complete and return the Sientra Explant Return Kit in accordance with Sientra's instructions within thirty (30) days of explantation. To be considered complete, Sientra must receive at least the following items from the patient or the patient's surgeon

- i. The explanted Sientra product(s) involved in the Covered Event (do not return contralateral implant is not affected);
 - ii. Copies of the Operative Report for the initial implant surgery;
 - iii. Copies of the Operative Report for the revision surgery;
 - iv. Copies of relevant bills for operating room, anesthesia and surgical fees or costs incurred in the revision surgery;
 - v. Copies of all relevant insurance reimbursements, or coverage or waiver of any fees or costs by the healthcare provider.
- C. Upon receipt of all the information required by Sections A and B of this Section 6, Sientra will determine, in its sole discretion and judgment, whether a qualifying Covered Event has occurred. In the event that Sientra determines that a qualified Covered Event has occurred, and that no exclusions apply, Sientra shall, within ninety (90) days of receipt of all information required by Sections A and B of this Section 6, provide any credits for NCRI to the surgeon in accordance with the surgeon's instructions and, if applicable, issue a check for the relevant amount to the appropriate party or parties. If indicated in the signed Release, the check may be made payable to the patient's surgeon, or the provider of the operating room, anesthesia, or the patient, or to a combination of payees.

NOTE THAT IN THE EVENT THAT ANY ONE OF THE ABOVE CONDITIONS (A)—(C) OF THIS SECTION 6 ARE NOT MET, AN OTHERWISE COVERED EVENT WILL NOT QUALIFY FOR BENEFITS PROVIDED FOR IN THE SIENTRA LWRP. DETERMINATION OF WHETHER AN OTHERWISE QUALIFYING COVERED EVENT MEETS THE REQUIREMENTS OF THIS SECTION 6 LIES IN THE SOLE DISCRETION AND JUDGMENT OF SIENTRA.

7. Limitations of Product Replacement and Limited Warranty Program

THE SIENTRA LWRP IS A LIMITED WARRANTY ONLY AND IS SUBJECT TO THE TERMS AND CONDITIONS OF THIS DOCUMENT. ALL OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED, STATUTORY, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF SATISFACTORY QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE (WHETHER OR NOT SIENTRA KNOWS, HAS REASON TO KNOW, HAS BEEN ADVISED, OR IS OTHERWISE AWARE OF ANY SUCH PURPOSE) ARE EXPRESSLY DISCLAIMED AND EXCLUDED. THE REMEDIES SET FORTH IN THIS DOCUMENT ARE, TO THE MAXIMUM EXTENT ALLOWED UNDER APPLICABLE LAW, THE PATIENT'S SOLE AND EXCLUSIVE REMEDY. IN NO EVENT WILL SIENTRA, ITS AFFILIATES, OFFICERS, DIRECTORS OR EMPLOYEES BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OR EXPENSE ARISING, DIRECTLY OR INDIRECTLY, FROM THE USE OF THE SIENTRA OPUS SILICONE GEL BREAST IMPLANTS (SMOOTH AND TEXTURED) REGARDLESS OF THE FORM OF ACTION (WHETHER FROM BREACH OF CONTRACT, BREACH OF WARRANTY, OR FROM NEGLIGENCE, STRICT LIABILITY, BREACH OF STATUTORY DUTY, LIABILITY UNDER INDEMNITIES OR ANY OTHER FORM OF ACTION), EVEN IF SIENTRA HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR EXPENSE. SIENTRA NEITHER ASSUMES, NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THE SIENTRA SILICONE GEL BREAST IMPLANTS (SMOOTH AND TEXTURED).

8. Modification or Termination of the Sientra LWRP

Sientra reserves the right to cancel, change, or modify the terms and conditions of the Sientra LWRP at any time for any reason. Any such cancellation, change, or modification will not affect the terms and conditions for those already enrolled in the Program as provided for in Section 0 as of the date of such cancellation, change or modification.