

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

This document describes the terms, conditions & claim procedures of the Limited Warranty and Product Replacement Programs for Sientra Silicone Gel Breast Implants.

### Background Information

The Sientra Limited Warranty and Product Replacement Programs are available to all patients implanted with Sientra Silicone Gel Breast Implants in the United States after April 1, 2012 and are subject to the terms, conditions, claim procedures, Important Limitations, below, and Exclusions listed in Section 2.

Timely completion of the Device Tracking and Warranty Enrollment Form by the patient's surgeon is required to activate the Limited Warranty and Product Replacement Programs and for the patient and the surgeon to be eligible to receive benefits under either program.

### Summary of Benefits

#### A. Ten-Year Limited Warranty For Certain Ruptures

Under the Sientra Limited Warranty Program, Sientra will reimburse patients (or their designated surgeon) up to \$3,600 of certain out-of-pocket costs that are directly related to revision surgery performed within 10 years from the date of implantation and that were necessitated by a Covered Event (as defined in Section 1.B.).

*See Section 1, below, for Requirements, Sections 2 for Exclusions, Section 3 for Program Specifications and Sections 4 and 6 for Claim Procedures.*

#### B. Lifetime Product Replacement In The Event Of Certain Ruptures

Under the Sientra Product Replacement Program, Sientra will credit qualified plastic surgeons with the cost of replacement breast implants (intended solely as a direct benefit to their patient) when replacement implants are required due to a Covered Event (as defined in Section 1.B.).

*See Section 1, below, for Requirements, Section 2 for Exclusions, Section 5 for Program Specifications, and Section 6 for Claim Procedures.*

### Important Limitations

THIS IS A LIMITED WARRANTY ONLY AND IS 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 FOR A PARTICULAR PURPOSE ARE EXCLUDED. THE REPLACEMENT OF QUALIFIED SIENTRA SILICONE GEL BREAST IMPLANTS AND PAYMENT OF DEFINED AMOUNTS FOR NECESSARY REVISION SURGERY AS SET FORTH IN THIS LIMITED WARRANTY ARE, TO THE MAXIMUM EXTENT ALLOWED UNDER APPLICABLE LAW, THE PATIENT'S SOLE AND EXCLUSIVE REMEDY.

SIENTRA SHALL NOT AND WILL NOT BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL LOSS, DAMAGE, OR EXPENSE ARISING DIRECTLY OR INDIRECTLY FROM THE USE OF THESE PRODUCTS. SIENTRA NEITHER ASSUMES, NOR AUTHORIZES, ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

THE TERMS OF THIS LIMITED WARRANTY IN EFFECT WHEN THE PATIENT'S ORIGINAL IMPLANTATION OCCURS WILL APPLY AT THE TIME OF ANY CLAIM.

Sientra reserves the right to cancel, change, or modify the terms of the Sientra Limited Warranty and/or the Product Replacement Program at any time for any reason. Any such cancellation, change, or modification will not affect the terms for those currently enrolled in the programs as of the date of such cancellation, change or modification.

UNDER NO CIRCUMSTANCES WILL THE SIENTRA LIMITED WARRANTY CONTINUE FOR MORE THAN 10 YEARS FROM THE DATE OF IMPLANTATION FOR ANY INDIVIDUAL IMPLANT.

#### **Additional Patient Information to Be Provided by the Surgeon**

Before implantation surgery, the surgeon must:

- Explain the details of the Sientra Limited Warranty and Sientra Product Replacement Programs to the patient;
- Remind the patient that this document (the Terms, Conditions & Claim Procedures of the Programs) is available at [www.sientra.com](http://www.sientra.com) or by calling 888.708.0808; and
- Advise the patient about all possible adverse reactions and complications (including the risk of rupture and need for replacement/revision surgery) associated with Breast Implants in general and Sientra's Silicone Gel Breast Implants in particular.

If the patient has any questions about the product or the surgery, the patient should discuss these questions with her surgeon. Sientra makes available to all surgeons and patients a copy of patient labeling and physician directions for use. Copies can also be obtained by contacting the Sientra Customer Experience Team at 888.708.0808 or through the Sientra web site at [www.sientra.com](http://www.sientra.com). These documents are not intended to, and cannot and should not, take the place of a full and candid discussion between the surgeon and his/her patient.

#### **1. Requirements For Compensation Under The Sientra Limited Warranty And Product Replacement Programs**

For any compensation or replacement implants to be provided, all of the following requirements must be met:

##### **A. The surgeon must have enrolled the patient in the Limited Warranty and Product Replacement Programs within 90 days of implantation.**

The implanting surgeon will confirm:

- Patient's willingness to participate in Device Tracking and Limited Warranty and Product Replacement Programs;
- Patient's understanding that this voluntary participation authorizes Sientra to collect and retain personal health and medical information about them for device tracking and warranty administration; and
- Patient's oral consent, which allows the surgeon to complete the Device Tracking/Warranty Enrollment Form.

Sientra will use the patient's contact information provided on the Enrollment Form to send the patient a confirmation of enrollment. To ensure that their surgeon properly enrolled them, patients should watch for this confirmation. Patients who do not receive this confirmation within 60 days following surgery should contact their surgeon or Sientra's Customer Experience Team at 888.708.0808 or send an email to [warranty@sientra.com](mailto:warranty@sientra.com). Failure to do so could affect enrollment in the Program.

##### **B. The Sientra Limited Warranty and Product Replacement Programs apply only to "Covered Events."**

**A "Covered Event" is a device rupture (a hole or tear in the implant shell that causes a loss of shell integrity) that is not the result of patient trauma, operative procedure, or contraindicated use.**

##### **C. The implantation as well as any subsequent procedures must be performed under all of these conditions:**

- in the United States, and after April 1, 2012;
- by plastic surgeons who are certified by the American Board of Plastic Surgery or who are Board admissible by virtue of having completed a six-year integrated residency in plastic surgery (or one of the approved alternate routes for board admissibility);
- in accordance with the directions for use in effect at the time of implantation (including product package enclosures, and other notifications or instructions published by Sientra); and,
- in accordance with professional standards of care.

**D. The explanted ruptured product must be returned to Sientra within 30 calendar days of explantation pursuant to the Sientra Explant Return Kit and Instructions, provided at [www.Sientra.com](http://www.Sientra.com).**

In the event that the explanted product is not returned to Sientra within 30 calendar days of its explanation, Sientra will not pay any monetary claim under the Limited Warranty; and the ordering customer will be charged the full price for any replacement implant(s) under the Product Replacement Program.

**E. The patient signs a full release releasing Sientra from any further liability related to the ruptured implant in return for the Warranty Payment and/or for the no-charge replacement implant(s).**

## **2. Exclusions**

The Limited Warranty and Product Replacement Programs do NOT apply to:

- Any events, adverse reactions or injury other than a Covered Event as defined in Section 1.B. above;
- Removal of an intact implant for any reason including capsular contracture, style or size change, wrinkling or rippling, incorrect suspicion of rupture, or dissatisfaction;
- Rupture caused by improper implantation, or by 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 the directions for use; or
- Events or injury covered by insurance or reimbursed by insurance.

## **3. The Sientra Limited Warranty Program:**

In the event that:

- A patient experiences a Covered Event (as defined in Section 1.B.) during the 10 years following implantation, and
- All 5 requirements listed in Sections 1.A. – 1.E. are met, and
- There is no exclusion as listed in Section 2, and
- The surgeon and patient comply with the pre-authorization requirement in Section 4 and the claim procedures described in Section 6 below,

then Sientra will provide up to a maximum of \$3600 of Warranty Payment to help the patient offset any additional out-of-pocket surgical, anesthetic, or operating room fees that are incurred in connection with a revision surgery for which pre-authorization from Sientra was approved and whose primary planned purpose is the confirmation and removal of a suspected rupture and which is confirmed as ruptured by an independent laboratory under contract to Sientra. Sientra will NOT issue any Warranty Payment for lost wages, pain and suffering or any and all other ancillary medical expenses arising for any reason due to implantation of a product that ruptures.

## **4. Required Pre-Authorization for Claims under Sientra's Limited Warranty.**

To qualify for any payment under Sientra's Limited Warranty, the patient's surgeon must initiate the claim process and obtain pre-authorization IN ADVANCE of ANY REVISION SURGERY by contacting Sientra's Customer Experience team at 888.708.0808. To obtain pre-authorization, the surgeon must send Sientra copies of:

- A. The patient's medical records showing a diagnosis of suspected rupture supported by diagnostic imaging, such as an MRI or other method acceptable to Sientra, and a reading confirming the existence of a rupture; and
- B. Authorizations, signed by the patient, allowing release of her health and medical records and return of the explanted product to Sientra.

Sientra will supply an Explant Return Kit and instructions to all surgeons who initiate the claim process.

## **5. The Sientra Product Replacement Program**

In the event that:

- a patient experiences a Covered Event (as defined in Section 1.B.) during her lifetime, and
- all requirements listed in Section 1.A. – 1.E. are met, and
- no exclusions (See Section 2) apply, and
- the patient complies with the claim procedures described in Section 6, below,

then Sientra will provide a replacement device at no charge.

When a patient qualifies for a no-charge replacement device, at the surgeon’s request, Sientra will also provide a replacement of the contralateral implant provided that both of the original implants are returned to Sientra. There will be no charge for this provision except as outlined above.

Replacement product(s) provided under this Program will be sent pursuant to Sientra’s standard shipping policies with extra charges for expedited shipping payable by the implanting surgeon.

Replacement product(s) provided under this Program will be Sientra products of the same size and style as the originally implanted device(s). If the exact same size and style is no longer available, then replacement implant(s) provided will be the most comparable size and style then manufactured by Sientra. If the patient desires a replacement implant that is a different size or style than her original implant, then any additional cost for a more expensive size or style will be charged by Sientra at its then current list prices and must be paid by the surgeon (who may seek payment from the patient). There is no credit or refund if the patient chooses a size or style that is less expensive than her original implants. SIENTRA WILL NEITHER PROVIDE NOR PAY FOR A REPLACEMENT WITH ANY NON-SIENTRA PRODUCT.

Any Sientra Silicone Gel Breast Implants provided as no-charge replacements under this program automatically include eligibility to enroll the replacement implant(s) in the Sientra Limited Warranty and Product Replacement Programs per the terms and conditions applicable at the time of the implantation.

**Limitation on the Sientra Product Replacement Program**

If Sientra’s performance of its obligations to provide replacement product is prevented, restricted, or interfered with by any act or condition whatsoever beyond the reasonable control of Sientra (including fire, flood, earthquake, accident, strikes or labor disputes, inability to procure supplies, war, other violence, any law, order, proclamation, regulation, or requirement of any government agency) then the performance of that obligation shall be excused without penalty. For purposes of this provision, excuse of performance means that Sientra is neither obligated to provide, nor pay for, replacement product from any source. This provision applies only to the Product Replacement Program and not to the Limited Warranty.

**6. Filing a Claim under either the Limited Warranty or Product Replacement Programs**

To file a claim, the surgeon must follow the procedure and provide the documentation indicated in 6.A. – 6.G. in the charts below.

**A. Obtain Pre-Authorization from Sientra as described in Section 4.**

Cash Payment Limited Warranty Claims	Product Replacement Program Claims
X	

All of the following documentation must be sent to Sientra within 30 days of explantation:

**B. Explanted Sientra product returned in an Explant Return Kit following its instructions**

**C. Operative Report for the initial implantation surgery**

**D. Operative Report for the revision surgery**

**E. Relevant bills for operating room, anesthesia and surgical fees incurred for the revision surgery**

**F. All relevant insurance reimbursements**

Cash Payment Limited Warranty Claims	Product Replacement Program Claims
X	X
X	X
X	X
X	
X	

All explanted product should be sent following the procedure, and using the address, indicated in the Explant Return Kit instructions which are available by calling the Sientra Customer Experience Team at 888.708.0808.

All items in 6.C. – F. (but not the explanted product) should be sent to Sientra’s headquarters’ address as listed at [www.sientra.com](http://www.sientra.com).

Upon receipt of all items required by 6.A. - 6.F. Sientra will send the surgeon a Release of Sientra’s liability for signature by the patient. Upon receipt of the properly signed Release, a check will be issued to the appropriate party or parties in accordance with the provisions and limitations outlined in this document.

**G. Release signed by patient**

<b>Cash Payment Limited Warranty Claims</b>	<b>Product Replacement Program Claims</b>
X	X

If indicated in writing in the signed Release, the check may be made payable to the surgeon, or the provider of the operating room, anesthesia, or to the patient or to a combination of payees.