**THE SIENTRA PLATINUM20™ PRODUCT REPLACEMENT AND LIMITED WARRANTY PROGRAM FOR SIENTRA OPUS™ SILICONE GEL BREAST IMPLANTS (SMOOTH AND TEXTURED SURFACE)**

This document sets forth the terms, conditions, scope, coverage and claim procedures of the Sientra Platinum20 Product Replacement and Limited Warranty Program.

## 1. Effective Date and Applicability

Subject to the remaining terms and conditions set forth herein, the Sientra Platinum20 Product Replacement and Limited Warranty Program automatically applies to all Sientra OPUS Smooth or Textured Surface Silicone Gel Breast Implants that are implanted in a patient in the United States or Puerto Rico on or after May 1, 2018. No action is required on the part of the patient to be enrolled in the Program. For Sientra OPUS Smooth or Textured Surface Silicone Gel Breast Implants implanted prior to 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 Platinum20 Product Replacement and Limited Warranty Program

A. **Rupture:** Any actual or suspected loss of integrity of the implant shell diagnosed by the patient's surgeon and confirmed by an MRI, or other diagnostic imaging method, acceptable to Sientra.

B. **Capsular Contracture**: Baker Grade III or Baker Grade IV capsular contracture diagnosed by the patient's surgeon and, if requested by Sientra, confirmed by photographs acceptable to Sientra showing the appearance of the breast prior to explant.

C. **Double Capsule**: The formation of two layers of fibrous tissue around the implant as a result of separation of the initial capsule of fibrous scar tissue formed during the normal healing process, that has been diagnosed by the patient's surgeon and confirmed by intraoperative photograph(s) acceptable to Sientra.

D. **Late Forming Seroma:** The formation of a clinically significant seroma (typically 50cc's of serous fluid or more) at least twelve (12) months after implant surgery, and with no intervening surgical procedures performed on the breast, that has been diagnosed by the patient's surgeon and confirmed by photographs, pathology, or other reports, acceptable to Sientra.

Notwithstanding the foregoing, the Sientra Platinum20 Product Replacement and Limited Warranty Program 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)-(D)

- Removal of intact implant(s) for any reason other than those specified in Sections 2(A)-(D) including, but not limited to, Baker Grade I or Baker Grade II (as diagnosed by the attending physician), 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;

- Explantation 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.

**3. Qualifying Covered Events**

In order for a Covered Event to qualify under the Sientra Platinum20 Product Replacement and Limited Warranty Program, the following criteria must be satisfied:

A. The implantation, and all subsequent procedures, must have taken place in the United States or Puerto Rico on or after May 1, 2018;

B. The implantation, and all subsequent procedures, must have been performed by licensed physicians who are certified by the American Board of Plastic Surgery ("ABPS"), or who are otherwise admissible to the ABPS (e.g., by virtue of having completed the training and other prerequisites required by the ABPS for permission to take the Board examination);

C. The implantation, and all subsequent procedures, must have been performed in accordance with the Sientra OPUS 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 within sixty (60) days of the implant surgery, 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 Product Replacement and Limited Warranty Program (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 PLATINUM20 PRODUCT REPLACEMENT AND LIMITED WARRANTY PROGRAM. 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 other qualifying Covered Events (capsular contracture, double capsule and late forming seroma), Sientra will replace the product free-of-charge for a term of twenty (20) years from the date of the patient's qualifying surgery.

When a patient qualifies for a no-charge replacement product Sientra shall, at the surgeon's request, also provide a replacement of the contralateral implant free-of-charge.

Replacement products provided under the Sientra Platinum20 Product Replacement Program 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 replacement implants provided under the Sientra Platinum20 Product Replacement Program (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 replacement products provided under the Sientra Platinum20 Product Replacement Program shall be automatically enrolled in accordance with the terms and conditions of the Sientra Platinum20 Product Replacement Program in effect at the date of implant surgery.

**5. Limited Warranty Program Coverage**

For a qualifying rupture Covered Event that occurs within twenty (20) years from the date of the patient's qualifying surgery, Sientra will provide a one-time only payment up to a maximum of **$5,000** 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.

For all other qualifying Covered Events (capsular contracture, double capsule and late forming seroma) that occur within two (2) years of the patient's qualifying surgery, Sientra will provide a one-time only payment up to a maximum of **$2,000** 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 Covered Events.

For qualifying late forming seroma, Sientra will additionally cover the costs of a one-time only complete testing to rule out Breast Implant Associated—Anaplastic Large Cell Lymphoma (BIA-ALCL) for patients who do not have such testing covered by insurance, or whose healthcare provider has not otherwise covered or waived the fees or costs associated with such testing. The costs of testing covered by Sientra will be based on current best practices which presently include one or more of the following: (1) cell cytology; (2) CD30 immunohistochemistry; and (3) flow cytometry.

The amounts payable under the Limited Warranty Program are limited to a maximum of $5,000 per qualifying surgery. 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 $5,000.

Under no circumstances will Sientra provide payments under the Sientra Plaltinum20 Limited Warranty Program 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 Platinum20 Product Replacement and Limited Warranty Program, 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 showing the basis for the surgeon's diagnosis of the qualifying Covered Event as specified in Section 2(A)-(D);

   ii. A completed and signed Request for a No-Charge Replacement Implant ("NCRI") Form (if applicable) within the time period specified on the NCRI Form; and

   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.

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's surgeon

   i. The explanted Sientra product(s);

   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 a completed Sientra Explant Return Kit, Sientra will determine, in its sole discretion and judgment, whether a qualifying Covered Event has occurred. Upon confirmation of a qualifying Covered Event, Sientra will send to the surgeon a Release of Sientra's liability for signature by the patient.

D. Upon receipt of a properly signed Release, Sientra will ship any replacement product(s) to the surgeon in accordance with the surgeon's instructions and/or 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)—(D) OF THIS SECTION 6 ARE NOT MET, AN OTHERWISE COVERED EVENT WILL NOT QUALIFY FOR BENEFITS PROVIDED FOR IN THE SIENTRA PLATINUM20 PRODUCT REPLACEMENT AND LIMITED WARRANTY PROGRAM. DETERMINATION OF WHETHER A COVERED EVENT IS A QUALIFYING COVERED EVENT UNDER THIS SECTION 6 LIES IN THE SOLE DISCRETION AND JUDGMENT OF SIENTRA.

**7. Limitations of Product Replacement and Limited Warranty Program**

THE SIENTRA PLATINUM20 PRODUCT REPLACEMENT AND LIMITED WARRANTY PROGRAM 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 OPUS SILICONE GEL BREAST IMPLANTS (SMOOTH AND TEXTURED).

## 8. Modification or Termination of Product Replacement and Limited Warranty Program

Sientra reserves the right to cancel, change, or modify the terms and conditions of the Sientra Platinum20 Product Replacement and Limited Warranty Program 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 1 as of the date of such cancellation, change or modification.