



**Always Confident Warranty®**

**MOTIVA IMPLANT MATRIX® Breast Implants Limited Warranty**

This document describes the terms of the Always Confident Warranty® Program.

The Always Confident Warranty® applies to all MOTIVA IMPLANT MATRIX® Silicone Breast Implants, implanted on or after September 20, 2010, and supersedes any other warranty or offering existing prior to such date.

Establishment Labs S.A. provides all surgeons and patients, prior to surgery, with information regarding the risks involved in any implantation surgery.

The Product Insert document provided with the implants, as well as the document “Breast Augmentation with MOTIVA Implant Matrix®: Information for the Patient” includes important and detailed information regarding the adverse effects and risks that are possible when the products are used.

Patients and surgeons shall openly discuss such risks to facilitate an informed decision of the patients.

Establishment Labs S.A., under the Always Confident Warranty®, will replace qualifying Motiva Implant Matrix® breast implants whenever an Exception Event takes place, as shall be defined below. All Motiva Implant Matrix® breast implants with a valid serial number shall qualify for the Always Confident Warranty®.

**THIS IS A LIMITED WARRANTY SUBJECT TO THE TERMS AND CONDITIONS SET FORTH HEREIN. 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 EXPRESSLY EXCLUDED. THE REPLACEMENT OF QUALIFYING MOTIVA IMPLANT MATRIX® BREAST IMPLANTS IS, TO THE MAXIMUM EXTENT ALLOWED UNDER APPLICABLE LAWS, THE PATIENT'S ONLY AND EXCLUSIVE REMEDY. ESTABLISHMENT LABS S.A. SHALL NOT BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL LOSS, DAMAGE, OR EXPENSE ARISING DIRECTLY OR INDIRECTLY FROM THE USE OF THE MOTIVA IMPLANT MATRIX® BREAST IMPLANTS, AND SHALL NOT ASSUME OR AUTHORIZE ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.**

1. Employment of the Always Confident Warranty®
  - a. The warranty applies only to MOTIVA IMPLANT MATRIX® Silicone Breast Implants, manufactured on or after September 20, 2010, in absolute accordance with the products literature made available by Establishment Labs S.A., as included with the products or published by Establishment Labs S.A., and implanted by licensed and duly qualified surgeons in accordance with accepted and sound surgical procedures.
  - b. The Exception Events covered under the Always Confident Warranty® are defined only as: Rupture of MOTIVA IMPLANT MATRIX® Silicone Breast Implants.
  - c. Exceptions on coverage. The Always Confident Warranty® does not cover:
    - i. Exchange of implants for size changes
    - ii. Exchange or removal of implants due to wrinkling or rippling
    - iii. Ruptures due to open or closed capsulectomy
    - iv. Ruptures caused by surgical procedures
    - v. Exchange of implants in case of capsular contracture (for this effect refer to *Establishment Labs S.A. Product Replacement Policy*).
  - d. In any Exception Event, during the lifetime of the implants, Establishment Labs S.A. will replace under this warranty any qualifying MOTIVA IMPLANT MATRIX® Silicone Breast Implant, with



another Establishment Labs S.A. product of the same or similar kind as the replaced product. There shall be no other compensation or benefit in favor of the customer or the surgeon different to this. No credits or reimbursements shall be given to any customer and only Establishment Labs S.A.'s products shall be given in replacement of the warranted products. Establishment Labs S.A. will not pay, cover, compensate or participate in any way in the costs that may be incurred by the patient or by the surgeon to extract and/or replace any implant from/on the patient.

- e. Establishment Labs S.A. will not replace under warranty, or by any other reason, any product which has not been claimed, dully documented and proven to constitute an Exception Event, BEFORE it is explanted.
  - f. All explanted products shall be returned to Establishment Labs S.A. or their representative within 10 days of being explanted, otherwise the charge for the replacement implant price shall be invoiced to the customer.
  - g. If by reason of force majeure or any other act or condition beyond its reasonable control, Establishment Labs S.A., shall not fulfill the replacement here guaranteed, Establishment Labs S.A. shall have no further obligation or responsibility towards the customer.
  - h. The Always Confident Warranty® does not cover the replacement of the contralateral implant if such implant is not suffering of an Exception Event.
  - i. The Always Confident Warranty® is not transferable.
2. To file a claim under this warranty, the customer or surgeon should contact the local representative or Establishment Labs S.A. Customer Support Department at [customerservice@establishmentlabs.com](mailto:customerservice@establishmentlabs.com), for instructions on providing the necessary information and support documentation BEFORE any implant is explanted. The customer or surgeon shall submit the Warranty Notice form to Establishment Labs S.A. as soon as the Exception Event is verified and before any explantation procedure is performed. In the event of a rupture it will be necessary to provide either a Magnetic Resonance Imaging (MRI) or an Ultrasound report that validates and backs up the surgeons report. The documents which shall be provided either by Establishment Labs S.A. Customer Support Department or by the local representative, and which comprise the claim shall be submitted following explantation are the following:
- a. Always Confident Warranty® Claim Form. This form includes a list of additional documents that will need to be provided by the customer or surgeon.
  - b. Incident Report Form.
- Establishment Labs S.A. will give notice to the customer of the decision made on the claim within a 30- day period after receiving all necessary submittals.
3. All documentation or packages regarding the Always Confident Warranty® shall be sent to Establishment Labs S.A. to the following address:
- ESTABLISHMENT LABS S.A.  
B15, Zona Franca Coyol, San José de Alajuela.  
20113, Alajuela, Costa Rica
4. Replacement products shall be ordered to Establishment Labs Customer Support Department or to the local representative.
  5. Establishment Labs reserves the right to modify or cancel the terms of this Always Confident Warranty® at any time. In no case such modifications or cancelations shall affect the warranty terms for warranty holders at such time.