

Motiva Warranty Program Terms and Conditions

This document describes the terms, conditions and claim procedures for Motiva Implants® warranty and product replacement programs.

Information for the Patient

Before implantation surgery, the surgeon should explain the details of the Motiva Always Confident Warranty®; the Product Replacement Policy and the 2Y and 5Y Extended Warranty Program, to the patient, and provide the patient with a copy of this document.

In addition to explaining the terms, the surgeon should also advise the patient about possible adverse reactions and complications associated with Breast Implants as well as the benefits and risks of surgery with Motiva Implants® silicone breast implants according to DOC-026 "Breast Augmentation with Motiva Implants® Information for the Patient".

Always Confident Warranty®

All Motiva Implants® silicone breast implants are covered by the Always Confident Warranty® against rupture for the lifetime of the device.

Establishment Labs will replace the products qualified as rupture with the same or similar type as the qualifying product free of charge for the lifetime of the implant. Implantation of the replacement product, as well as any subsequent procedures, must be in strict accordance with current Motiva's product Directions for Use, Sterile Silicone Breast Implants Motiva Implant Matrix (DOC-002 Directions For Use, DFU) and accepted surgical procedures by appropriately qualified licensed surgeons for such product to qualify for replacement.

The explanted product must be returned to Establishment Labs within 10 days of its explantation properly decontaminated and sterilized by the surgeon, following the indications and procedures contained in the Establishment Labs S.A. Explanted Breast Implants Handling Protocol (SID-129), and the laws and regulations regarding biological risk in every country must be taken into consideration. Shipping charges will be covered by Establishment Labs

Failure to abide by these terms will invalidate any claim.

Product Replacement Policy

All Motiva Implants® silicone breast implants are covered by our Product Replacement Policy in the event of capsular contracture Baker grades III and IV for a period of 10 years.

Establishment Labs will replace the products qualified as rupture with the same or similar type as the qualifying product free of charge for ten years since the first implantation surgery. Implantation of the replacement product, as well as any subsequent procedures, must be in strict accordance with current Motiva's product Directions for Use, Sterile Silicone Breast Implants Motiva Implant Matrix (DOC-002 Directions For Use, DFU) and accepted surgical procedures by appropriately qualified licensed surgeons for such product to qualify for replacement.

Qualifying replacement product will be sent without shipping charges. Motiva will neither provide nor

pay for a non- Motiva product, nor in any event provide money for or in lieu of a Motiva replacement product.

Failure to abide by these terms will invalidate any claim.

Extended Warranty Program

To extend the coverage described above Motiva offers an Extended Warranty Program that applies to qualifying Motiva Implants® silicone breast implants, through an additional fee to be covered by or on behalf of the patient during the first 90 days after the initial breast surgery as specified below.

a. First Year Free Coverage

For first year coverage, patients must register their Motiva Implants® silicone breast implants through our website or through the Motiva App within the first 90 days after the initial breast surgery. During this first year since implantation in addition to product replacement, in qualified rupture and capsular contracture Baker grades III and IV cases, patients may also receive financial assistance, according to the implanted device model, applicable to the cost of the revision surgery when complying to this terms, conditions and claim procedures

Qualified Motiva breast implant are the following:

- Round, SilkSurface® Plus™ with Qid™
- Round, VelvetSurface Plus with Qid
- Round, Ergonomix with Qid

b. 2Y Extended Warranty Program

The Motiva 2 year Extended Warranty Program applies only to the qualified SilkSurface® Plus without Q inside and Ergonomix® implants without Q inside registered in the Motiva website and Motiva app when a non-refundable fee of \$100 has been applied to enroll the patient in the program. Patients must register the implanted devices during the first 90 days after the initial breast surgery.

For all registered products with our 2Y Motiva Program™, in addition to the replacement product patient may also receive up to \$1,000 of financial assistance applicable to the cost of the revision surgery in the case of a warranty claim for rupture or capsular contracture Baker grades III and IV when complying to this terms, conditions and claim procedures

Qualified Motiva breast implant are the following:

- Round, SilkSurface® Plus™ without Qid®
- Round, VelvetSurface Plus without Qid
- Round, Ergonomix without Qid

c. 5Y Extended Warranty Program

The Motiva 5 year Extended Warranty Program applies only to the qualified SilkSurface® Plus with Q inside and Ergonomix® implants with Q inside registered in the Motiva website and Motiva app when a non-refundable fee of \$200 has been applied to enroll the patient in the program. Patients must register the implanted devices during the first 90 days after the initial breast surgery.

For Motiva Implants® with Q Inside Safety Technology™, with our 5Y Motiva Program™, in addition to the replacement product customer may also receive up to \$2,500 of financial assistance applicable to the cost of the revision surgery in the case of a warranty claim for rupture or capsular contracture Baker grades III and IV. when complying to this terms, conditions and claim procedures

Qualified Motiva breast implant are the following:

- Round, SilkSurface® Plus™ with Qid™
- Round, VelvetSurface Plus with Qid
- Round, Ergonomix with Qid
- Oval, Ergonomix with Qid

Exclusions

Motiva Implants® silicone breast implants warranty shall not apply to any implantations performed without strict accordance to current product "Directions for Use, Sterile Silicone Breast Implants Motiva Implant Matrix" (DOC-002) and accepted surgical procedures by appropriately qualified licensed surgeons.

Motiva Implants® standard and extended warranty program do not apply to:

- Revision surgery patients
- removal of intact implants for capsular contracture, Baker Grade I or Baker Grade II
- removal of intact implants for size alteration
- removal of intact implants due to wrinkling or rippling
- loss of shell integrity caused by or during 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

**Establishment Labs may exclude from the applicable warranty program patients with previous history of capsular contracture Baker grades III and IV.

Filing a Warranty Claim

To file a claim for any warranty program the patient surgeon should file the warranty claim through Motiva support site at:

<https://professional.motivaimagine.com/support/breast-implants/?ref=screening>

Rupture and Capsular Contracture Baker grades III and IV cases should have been reported Establishment

Labs within the stated eligibility timeframe.

The following information is required to verify eligibility for financial assistance and/or product replacement under the Extended Warranty Program:

- Information to document the patient's implant information and the patient's event description FOR302 – Complaint Notification (Customer) **This document must be completed and signed by the treating surgeon.** This report includes vital information that must be accurately stated, such as the device reference, series and lot numbers, volume, base, projection, expiration date and type. It also must contain a detailed description of the event being reported.
- 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
- For capsular contracture Baker grades III and IV claims: an ultrasound with the correspondent technician report or an MRI scan and photographs of the patient as clinical evidence; and the doctor's report on the case showing the appearance of the breast prior to the explant procedure.
- For rupture claims: the explanted product is required; exceptionally when local applicable laws does not allow it please contact Establishment Labs for assistance. When local applicable laws allow it the patient must require for the surgeon to send the removed and decontaminated product following the Explanted Breast Implants Handling Protocol (SID-129), to: *Establishment Labs S.A., Coyoil Free Zone and Business Park, 0 Street, Building B-25, Alajuela, Costa Rica.*

For guidance on providing the necessary information and support documentation BEFORE any implant is explanted the patient or its surgeon should contact the local representative or Establishment Labs Customer Service Department at customerservice@establishmentlabs.com

Extended Warranty Financial Assistance Application

Motiva will not pay for any re-operative expenses until receipt of the complete form FOR-302 Complaint Notification (Customer). In addition, Motiva require for the claimer to submit a copy of bills or receipts associated with the revision surgery before payment will be made.

Other documentation, such as operative notes, may be required prior to payment. Claim for financial assistance under the "2Y or 5Y Extended Warranty Program" must be made to Establishment Labs through: <https://professional.motivaimagine.com/support/breast-implants/?ref=screening>

Establishment Labs reserves the right to cancel, change or modify the terms established in this document. Any such cancellation, change or modification will not affect the stated terms as of the date of their implantation for those already registered and covered under the existing warranty programs in effect on the date of the applicable implantation.

MOTIVA 2Y and 5Y Extended Warranty Program are non-transferable and non-refundable.