

# Motiva<sup>®</sup> Warranty Program Terms and Conditions

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

## Information for the Patient

Before surgical implantation, the surgeon should explain to the patient the details of the Motiva Always Confident Warranty<sup>®</sup>; the Product Replacement Policy; and the 2Y and/or 5Y Extended Warranty Programs, 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 silicone breast implants, as well as the benefits and risks of surgery with Motiva Implants<sup>®</sup> silicone breast implants according to DOC-026 "Breast Augmentation with Motiva Implants<sup>®</sup> Information for the Patient".

## Always Confident Warranty<sup>®</sup>

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

Establishment Labs will replace any implants that experience rupture with the same or similar type as the qualifying implant 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 the current Motiva Implants<sup>®</sup> Directions for Use, Sterile Silicone Breast Implants Motiva<sup>®</sup> Implant Matrix (DOC-002 Directions for Use, DFU), and accepted surgical procedures performed by appropriately qualified licensed surgeons for such implants to qualify for replacement.

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

Failure to abide by these requirements will invalidate any claim.

## Product Replacement Policy

All Motiva Implants<sup>®</sup> 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 qualified products with the same or similar type as the qualifying product free of charge for 10 years following the first surgical implantation. Implantation of the replacement product, as well as any subsequent procedures, must be in strict accordance with the current Motiva Implants<sup>®</sup> Directions for Use, Sterile Silicone Breast Implants Motiva<sup>®</sup> Implant Matrix (DOC-002 Directions for Use, DFU), and accepted surgical procedures performed by appropriately qualified licensed surgeons for such implants to qualify for replacement.

Qualifying replacement product will be sent without shipping charges. Establishment Labs will neither provide nor pay for any non-Motiva<sup>®</sup> implant replacement, nor provide money in lieu of a Motiva<sup>®</sup> implant replacement. Failure to abide by these requirements will invalidate any claim.

## Extended Warranty Program

To extend the coverage described above, Motiva<sup>®</sup> offers an Extended Warranty Program that applies to qualifying Motiva Implants<sup>®</sup> silicone breast implants, through an additional fee. This fee must 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 selected parties, First Year Free Coverage applies to all mammary Motiva Implants<sup>®</sup> with Q Inside<sup>®</sup> Safety Technology when registered on the Motiva<sup>®</sup> website or through the MotivaImagine<sup>®</sup> App within the first 90 days after the surgical implantation. During the first year following implantation, patient may receive in addition to product replacement, for qualified rupture and capsular contracture Baker grades III and IV cases, financial assistance, applicable

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to the cost of the revision surgery for the implanted device model when the patient and surgeon have complied with these required terms, conditions, and claim procedures.

### b. 2Y Extended Warranty Program

For selected parties, the Motiva® 2-year (2Y) Extended Warranty Program covers replacement of all mammary Motiva Implants® without Q Inside® if the implants are registered on the Motiva® website or through the MotivaImagine® App and a non-refundable fee of \$100 has been applied to enroll the patient in the program. Patients must register implanted devices during the first 90 days after the surgical implantation.

Additionally, patients who have registered products with our 2Y Motiva® Program may 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 if they have complied with these terms, conditions, and claim procedures.

### c. 5Y Extended Warranty Program

For selected parties, the Motiva® 5-year (5Y) Extended Warranty Program covers replacement of all mammary Motiva Implants® with Q Inside® if the implants are registered on the Motiva® website or through the MotivaImagine® App and a non-refundable fee of \$200 has been applied to enroll the patient in the program. Patients must register implanted devices during the first 90 days after the surgical implantation.

Additionally, patients who have registered products with our 5Y Motiva® Program may 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 if they have complied with these terms, conditions, and claim procedures.

### Exclusions

Motiva Implants® silicone breast implants warranty will 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 programs do not apply to:

- Revision surgery patients with previous history of capsular contracture with other brands of breast implants
- 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

### Filing a Claim

To file a claim for any warranty program, the patient's surgeon should file the warranty claim on the Motiva® support website at: <https://professional.motivaimage.com/support/breast-implants/?ref=screening>.

Rupture and capsular contracture Baker grades III and IV cases must be reported to Establishment Labs within the stated eligibility time frame.

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

- Document the patient's implant information and the event description in FOR302 – Complaint Notification (Customer). This document must be completed in full and signed by the treating surgeon. This report includes vital information that must be accurately provided, 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.

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- For capsular contracture Baker grades III and IV claims, provide an ultrasound or high-resolution ultrasound or an MRI scan, including the technician's report confirming the diagnosis.
- Provide a clinical report from the surgeon indicating the evolution of the patient after the surgery and the evolution of the complication.
- Provide post-operative and post-complication photographs of the patient (frontal and lateral), showing the appearance of the breast before and after the complication prior to the explant procedure.
- For rupture claims: the explanted product is required; exceptionally, when local applicable laws do not allow it, please contact Establishment Labs for assistance. When local applicable laws allow for the return of the explanted product, the patient must instruct the surgeon to send the removed and decontaminated product following the Explanted Breast Implants Handling Protocol (SID-129), to:  
Establishment Labs, Coyol Free Zone and Business Park, Building B25, Alajuela, Costa Rica.
- Establishment Labs may ask at its own discretion for a copy of the operative report for the revision surgery and/or copies of bills showing operating room, anesthesia, and surgeon fees incurred for the replacement surgery.
- Establishment Labs reserves the right to exclude from the extended warranty programs surgeons with repetitive complaints for capsular contracture Baker grades III and IV whose ratios fall significantly out of range of reasonable and proportional amounts of such claims, considering the number of surgeries performed and known post-market complication rates for Motiva Implants®.
- Establishment Labs reserves the right to investigate and request additional evidence and documentation in the event of repetitive claims from a single patient, from a single surgeon, or from a single clinic or hospital.
- For guidance on providing the necessary information and support documentation BEFORE any implant is explanted, the patient or their surgeon should contact the local representative or Establishment Labs Customer Care Department at <https://motiva.health/support/>.

### Extended Warranty Financial Assistance Application

Establishment Labs will not pay for any re-operative expenses until receipt of the complete form FOR-302 Complaint Notification (Customer). In addition, Establishment Labs may require the claimant 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 in this document. Any such cancellation, change, or modification will not affect claims regarding implants already registered and covered under the existing warranty programs in effect on the date of the applicable implantation. Motiva® 2Y and 5Y Extended Warranty Programs are non-transferable and non-refundable.