

# MOTIVA IMPLANTS® WARRANTY AND PRODUCT REPLACEMENT POLICY: TERMS AND CONDITIONS



This document (the "Terms & Conditions") describes the terms, conditions, and claim procedures for Motiva Implants® warranties and product replacement policy. It must be understood that any Establishment Labs warranties and product replacements cover only the Motiva Implants® actually implanted.

## Information for the Patient

Before surgical implantation, the surgeon should explain to the patient the details of Establishment Labs' (1) Always Confident Warranty®, (2) Product Replacement Policy, (3) first year free coverage program (the "First Year Free Coverage"), (4) two-year extended warranty program (the "2Y extended warranty program"), and (5) five-year extended warranty program (the "5Y extended warranty program") (collectively, the "Motiva® Warranties"), and provide the patient with a copy of these Terms & Conditions.

In addition to explaining the details of the Motiva® Warranties, 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® according to DOC-026 "Breast Augmentation with Motiva Implants® Information for the Patient."

The patient must be informed by the surgeon that the Motiva® Warranties provided hereunder by Establishment Labs are separate from, and do not limit or exclude, any warranties that apply in the contractual relationship directly between the patient and the surgeon or clinic that entered into the contract for surgical services with the patient.

## Always Confident Warranty®

All Motiva Implants® are covered by the Always Confident Warranty® against rupture for the lifetime of the Motiva® Implant (the "Always Confident Warranty® Period").

Establishment Labs will provide, free of charge, a replacement implant (the same or a similar type of Motiva® Implant) for any Motiva Implants® that rupture, and the patient may, at the surgeon's recommendation, be provided, free of charge, with a replacement implant for the contralateral side Motiva® Implant at the same time even if such contralateral side Motiva® Implant has not ruptured. Implantation of the replacement product(s), as well as any subsequent procedures, must be in strict accordance with the current Motiva Implants® DOC-002 "Directions for Use, Sterile Silicone Breast Implants Motiva® Implant Matrix," and accepted surgical procedures performed by appropriately qualified licensed surgeons.

Any explanted Motiva Implants® must be properly decontaminated and sterilized by the surgeon and returned to Establishment Labs within 10 days of its explantation in accordance with SID-29 "Explanted Breast Implants Handling Protocol" and all applicable laws, rules, and regulations. Shipping charges for both the explanted and replacement Motiva Implants® will be paid by Establishment Labs. To the maximum extent permitted under applicable law, Establishment Labs will neither provide nor pay for any non-Motiva® implant replacement, nor provide money in lieu of a replacement Motiva® Implant. Failure to abide



by any of these requirements will void any claim(s) under the Always Confident Warranty®. If the patient has enrolled in and purchased (as applicable) an Extended Warranty Program, the terms of such Extended Warranty Program will supersede the Always Confident Warranty® and apply during the applicable coverage period. The terms of this Always Confident Warranty® will resume for the remainder of the Always Confident Warranty® Period after such Extended Warranty Program coverage period ends if no rupture or capsular contracture with Baker grades III or IV occurs to trigger coverage under such Extended Warranty Program.

Subject to the foregoing, if any event that triggers the use of the Always Confident Warranty® occurs during the Always Confident Warranty® Period (an "Always Confident Warranty® event"), then the Always Confident Warranty® will be applied to the affected Motiva Implants® and such Motiva® Warranties may only be applied once for a given pair of Motiva Implants®. For clarity, any applicable Motiva® Warranties covering a patient's Motiva Implants® can be applied to only one Always Confident Warranty® event, and all Motiva® Warranties applicable to such Motiva Implants® will be voided for both Motiva Implants® at the time of replacement, even if only one of such Motiva Implants® is replaced at that time. Any replacement Motiva Implants® will have their own separate Always Confident Warranty® and Product Replacement Policy, and such replacement Motiva Implants® will also be eligible for coverage under the Extended Warranties (as applicable and as purchased).

## Product Replacement Policy

All Motiva Implants® are covered by our Product Replacement Policy in the event of capsular contracture with Baker grades III or IV, for a period of 10 years after the surgical implantation of the affected Motiva Implants® (the "Product Replacement Policy Period").

Establishment Labs will provide, free of charge,

the same or a similar type of Motiva® Implant as replacement implant for the affected Motiva® Implant, and the patient may, at the surgeon's recommendation, be provided, free of charge, with a replacement implant for the contralateral side Motiva® Implant at the same time even if the contralateral side Motiva® Implant did not experience capsular contracture with Baker grades III or IV. Implantation of the replacement product, as well as any subsequent procedures, must be in strict accordance with the current Motiva Implants® DOC-002 "Directions for Use, Sterile Silicone Breast Implants Motiva® Implant Matrix," and accepted surgical procedures performed by appropriately qualified licensed surgeons.

Shipping charges for the replacement Motiva Implants® will be paid by Establishment Labs. To the maximum extent permitted under applicable law, Establishment Labs will neither provide nor pay for any non-Motiva® implant replacement, nor provide money in lieu of a replacement Motiva® implant. Failure to abide by these requirements will invalidate any claim under the Product Replacement Policy. If the patient has enrolled in and purchased (as applicable) an Extended Warranty Program, the terms of such Extended Warranty Program will supersede the Product Replacement Policy and apply during the applicable coverage period. The terms of this Product Replacement Policy will resume for the remainder of the Product Replacement Policy Period after such Extended Warranty Program coverage period ends if no rupture or capsular contracture with Baker grades III or IV occurs to trigger coverage under such Extended Warranty Program.

Subject to the foregoing, if any event that triggers the use of the Product Replacement Policy occurs during the Product Replacement Policy Period ("Product Replacement Policy Event"), the Product Replacement Policy and any applicable Extended Warranties (as defined below) will be applied to the affected Motiva Implants® and such Motiva® Warranties may

only be applied once for a given pair of Motiva Implants®. For clarity, any applicable Motiva® Warranties covering a patient's Motiva Implants® can be applied to only one Product Replacement Policy Event, and all Motiva® Warranties applicable to such Motiva Implants® will be voided for both Motiva Implants® at the time of replacement, even if only one of such Motiva Implants® is replaced at that time. Any replacement Motiva Implants® will have their own separate Always Confident Warranty® and Product Replacement Policy, and such replacement Motiva Implants® will also be eligible for coverage under the Extended Warranties (as applicable and as purchased).

## Extended Warranty Programs

In addition to the Always Confident Warranty® and Product Replacement Policy described above, Establishment Labs offers the First Year Free Coverage, 2Y Extended Warranty Program, and the 5Y Extended Warranty Program (each an "Extended Warranty Program" and collectively the "Extended Warranty Programs") for its Motiva Implants®. The First Year Free Coverage is a free one-year program for all Motiva Implants® with Q Inside® Safety Technology, and the other Extended Warranty Programs may be purchased for an additional fee. To enroll in one of the Extended Warranty Programs requiring payment, the applicable fee must be paid by the patient within the first 90 days following the surgical implantation of the Motiva Implants® as specified below.

### a. First Year Free Coverage

First Year Free Coverage is an additional program that only applies to Motiva Implants® with Q Inside® Safety Technology and is free of charge. To enroll, the applicable Motiva Implants® with Q Inside® must be registered by the patient on the Motiva® website or through the Motiva Imagine® app within the first 90 days after the date of surgical implantation of the applicable Motiva Implants®. Coverage will then

be in effect for 12 months from the date of the surgical implantation of such Motiva Implants® (the "First Year Free Coverage Period"). If a patient enrolls in First Year Free Coverage, this coverage is provided instead of the Always Confident Warranty® and Product Replacement Policy during the First Year Free Coverage Period.

First Year Free Coverage provides enrolled patients with replacement implants and up to \$2,500 USD of financial assistance for a First Year Coverage Event (as defined below). Although this First Year Free Coverage supersedes the other warranty programs, the replacement of the affected Motiva Implants® under this Extended Warranty Program (1) due to rupture will be subject to the same terms and conditions as replacement under the Always Confident Program, and (2) due to capsular contracture with Baker grades III or IV will be subject to the same terms and conditions as replacement under the Product Replacement Policy. The financial assistance can be applied to the actual incurred and documented costs of the replacement surgery when the patient and surgeon have fully complied with the First Year Free Coverage terms, conditions, and claim procedures in these Terms & Conditions.

If a rupture or capsular contracture with Baker grades III or IV occurs during the First Year Free Coverage Period (a "First Year Coverage Event"), then the First Year Free Coverage will be applied to the affected Motiva Implants®. Furthermore, all applicable Motiva® Warranties will automatically void after a First Year Coverage Event and may only be applied once for a given pair of Motiva Implants®. For clarity, any applicable Motiva® Warranties covering a patient's Motiva Implants® can be applied to only one First Year Coverage Event, and all Motiva® Warranties applicable to such Motiva Implants® will be voided for both Motiva Implants® at the time of replacement, even if only one of such Motiva Implants® is replaced at that time and/or the full \$2,500 cannot be

claimed. For further clarity, this will also void both the Always Confident Warranty and Product Replacement Policy for such Motiva Implants®. Any replacement Motiva Implants® will have their own separate Always Confident Warranty and Product Replacement Policy, and such replacement Motiva Implants® will be eligible for coverage under the Extended Warranties (as applicable and as purchased). If there is no First Year Coverage Event, then the First Year Free Coverage will void at the end of the First Year Coverage Period and the Always Confident Warranty and Product Replacement Policy will be reinstated for such Motiva Implants® for the remainder of the Always Confident Warranty Period and Product Replacement Policy Period, as applicable.

b.

## 2y Motiva Program Extended Warranty Program

The 2Y Extended Warranty Program is an additional program that only applies to Motiva Implants® without Q Inside®. The 2Y Extended Warranty Program may be purchased for \$100 USD. To enroll, the patient must, within the first 90 days after the surgical implantation of the applicable Motiva Implants®, both (1) register the implanted Motiva Implants® without Q Inside® on the Motiva® website or through the Motiva Imagine® app and (2) pay a non-refundable fee of \$100 USD. The 2Y Extended Warranty Program will then be in effect for 24 months from the date of the surgical implantation of such Motiva Implants® (the “2Y Extended Warranty Coverage Period”). If a patient enrolls in the 2Y Extend Warranty Program, this coverage supersedes the Always Confident Warranty and Product Replacement Policy during the 2Y Extended Warranty Coverage Period.

The 2Y Extended Warranty Program provides

enrolled patients with replacement Motiva Implants® and up to \$1,000 USD of financial assistance for a 2Y Coverage Event (as defined below). Although this 2Y Extended Warranty Program supersedes the other warranty programs, the replacement of the implants under this Extended Warranty Program (1) due to rupture will be subject to the same terms and conditions as replacement under the Always Confident Program, and (2) due to capsular contracture with Baker grades III or IV will be subject to the same terms and conditions as replacement under the Product Replacement Policy. The financial assistance can be applied to the actual incurred and documented costs of the replacement surgery when the patient and surgeon have fully complied with 2Y Extended Warranty Program terms, conditions, and claim procedures in these Terms & Conditions.

If a rupture or capsular contracture with Baker grades III or IV occurs during the 2Y Extended Warranty Coverage Period (a “2Y Coverage Event”), then the Always Confident Warranty and/or the Product Replacement Policy, as applicable, and the 2Y Extended Warranty Program will be applied to the affected Motiva Implants®. Furthermore, all applicable Motiva® Warranties will automatically void after a 2Y Coverage Event and may only be applied once for a given pair of Motiva Implants®. For clarity, any applicable Motiva® Warranties covering a patient’s Motiva Implants® can be applied to only one 2Y Coverage Event, and all Motiva® Warranties applicable to such Motiva Implants® will be voided for both Motiva Implants® at the time of replacement, even if only one of such Motiva Implants® is replaced at that time and/or the full \$1,000 cannot be claimed. For further clarity, this will also void both the Always Confident Warranty and Product Replacement Policy for such Motiva Implants®. Any replacement Motiva Implants® will have their own Always Confident Warranty and Product Replacement Policy, and such replacement Motiva Implants® will be eligible for coverage under the Extended Warranties (as applicable and as purchased). If there is no 2Y Coverage Event, then the 2Y Extended Warranty Program

will void at the end of the 2Y Extended Warranty Coverage Period and the Always Confident Warranty and Product Replacement Policy will be reinstated for such Motiva Implants® for the remainder of the Always Confident Warranty Period and Product Replacement Policy Period, as applicable.

c.

## 5y Motiva Program Extended Warranty Program

The 5Y Extended Warranty Program is an additional program that only applies to Motiva Implants® with Q Inside®. The 5Y Extended Warranty Program may be purchased for \$200 USD. To enroll, the patient must, within the first 90 days after the surgical implantation of the applicable Motiva Implants®, both (1) register the applicable Motiva Implants with Q Inside® on the Motiva® website or through the Motiva Imagine® app, and (2) pay a non-refundable fee of \$200 USD. The 5Y Extended Warranty Program will then be in effect for 60 months from the date of the surgical implantation of such Motiva Implants® (the "5Y Extended Warranty Coverage Period"). If a patient enrolls in the 5Y Extend Warranty Program, this coverage supersedes the Always Confident Warranty and Product Replacement Policy during the 5Y Extended Warranty Coverage Period.

The 5Y Extended Warranty Program provides enrolled patients with replacement implants and up to \$2,500 USD of financial assistance for a 5Y Coverage Event (as defined below). Although this 5Y Extended Warranty Program supersedes the other warranty programs, the replacement of the implants under this Extended Warranty Program (1) due to rupture will be subject to the same terms and conditions as replacement under the Always Confident Program, and (2) due to capsular contracture with Baker grades III

or IV will be subject to the same terms and conditions as replacement under the Product Replacement Policy. The financial assistance can be applied to the actual incurred and documented costs of the replacement surgery when the patient and surgeon have fully complied with the 5Y Extended Warranty Program terms, conditions, and claim procedures in these Terms & Conditions.

[If a rupture or capsular contracture with Baker grades III or IV occurs during the 5Y Extended Warranty Coverage Period (a "5Y Coverage Event"), then the Always Confident Warranty and/or the Product Replacement Policy, as applicable, and the 5Y Extended Warranty Program will be applied to the affected Motiva Implants®. Furthermore, all applicable Motiva® Warranties will automatically void after a 5Y Coverage Event and may only be applied once for a given pair of Motiva Implants®. For clarity, any applicable Motiva® Warranties covering a patient's Motiva Implants® can be applied to only one 5Y Coverage Event, and all Motiva® Warranties applicable to such Motiva Implants® will be voided for both Motiva Implants® at the time of replacement, even if only one of such Motiva Implants® is replaced at that time and/or the full \$2,500 cannot be claimed. For further clarity, this will also void both the Always Confident Warranty and Product Replacement Policy for such Motiva Implants®. Any replacement Motiva Implants® will have their own Always Confident Warranty and Product Replacement Policy, and such replacement Motiva Implants® will be eligible for coverage under the Extended Warranties (as applicable and as purchased). ). If there is no 5Y Coverage Event, then the 5Y Extended Warranty Program will void at the end of the 5Y Extended Warranty Coverage Period and the Always Confident Warranty and Product Replacement Policy will be reinstated for such Motiva Implants® for the remainder of the Always Confident Warranty Period and Product Replacement Policy Period, as applicable.

## Exclusions

Motiva® Warranties will not apply to any implantations performed without strict accordance to the then-current DOC-002 “Directions for Use, Sterile Silicone Breast Implants Motiva® Implant Matrix” and accepted surgical procedures by appropriately qualified, licensed surgeons. Notwithstanding the foregoing, for the Extended Warranty Programs, the patient will still be eligible for financial assistance if he/she can demonstrate that non-compliance with the foregoing directions and procedures did not cause the warranty case at hand. The First Year Free Coverage, 2Y Extended Warranty Program, and 5Y Warranty Program do not apply to:

- Reconstruction surgery patients
- Revision surgery patients with previous history of capsular contracture with other brands of breast implants
- Removal of intact implants for capsular contracture grades I or 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 under any of the Motiva® Warranties, the patient's surgeon should file the warranty claim on the Motiva® support website at:

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

Rupture and capsular contracture Baker grades III and IV cases must be reported to

Establishment Labs within the eligibility time frame defined by the applicable Motiva® Warranty.

The following is required to verify eligibility for implant replacement and/or financial assistance (as applicable) under the Motiva® Warranties:

- Document regarding the patient’s implant information and the event description in FOR-302 “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.
- For capsular contracture Baker grades III and IV claims, provide an ultrasound or high-resolution ultrasound or 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 SID-29 “Explanted Breast Implants Handling Protocol”, to: Establishment Labs, Coyol Free Zone and Business Park, Building B25, Alajuela, Costa Rica.
- Establishment Labs may, at its own discretion, request 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 Motiva® Warranties surgeons with repetitive complaints for capsular contracture Baker grades III and IV whose ratios fall significantly out of the range of reasonable and proportional amounts of such claims, considering the number of surgeries performed and known post-market complication rates for Motiva Implants®. This is without prejudice to the respective patient's right to file a warranty claim based on the Motiva® Warranties through a different surgeon.
- 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.
- Establishment Labs has up to 90 days to solve and close a complaint but will use reasonable efforts to solve a complaint in a shorter time period.
- In the case where there is a lack of clinical evidence provided for a Motiva® Warranties claim, Establishment Labs will make up to three attempts to request additional evidence. If no response is received, Establishment Labs is authorized to close the complaint.
- 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 replacement operation expenses until Establishment Labs has received 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 replacement surgery before payment will be made.

Other documentation, such as operative notes, may be required prior to payment. Claim for financial assistance under the Extended Warranty Programs 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 without notice and without the consent of a patient or surgeon. Any such cancellation, change, or modification will not affect claims regarding implants already registered and covered under the existing Motiva® Warranties in effect on the date of the applicable implantation. The Extended Warranty Programs are non-transferable and non-refundable.

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