Motiva® Health Warranty Program

(Australia and New Zealand)

Motiva®

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This document describes the terms, conditions, and the process to claim a warranty under the Motiva® Health Warranty Program (**"Motiva Health Program"**). These Terms and Conditions are applicable to all Motiva® implants that are implanted in patients in Australia or New Zealand as of the effective date of 1 March 2026 (for clarity, see ***General Provisions***, section 10).

Prior to the surgical implantation of Motiva® implants, the surgeon must explain to the patient the details of the Motiva Health Program and provide access to these Terms and Conditions. In addition, the surgeon must be a certified professional and follow the guidelines and provisions of the Directions of Use of each Motiva® implant as appropriate. The surgeon must inform the patient that Motiva® warranties are independent of, and do not limit or exclude, any warranties that apply in the contractual relationship directly between the patient and the surgeon or clinic for surgical services.

Motiva® implants also come with guarantees that cannot be excluded under the Australian Consumer Law. A patient is entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. A patient is also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

The Motiva® Health Program operates in addition to all rights and remedies that a patient may be entitled to under the Australian Consumer Law **("ACL")** or any other relevant Australian law. The Motiva® Health Program does not limit, exclude or modify any statutory rights or remedies including those under the ACL. The Motiva® Health Program also operates in addition to all rights and remedies that a patient may be entitled to under New Zealand's Consumer Guarantees Act 1993 (**"CGA"**) and Fair Trading Act 1986 (**"FTA"**). The Motiva® Health Program does not limit, exclude or modify any statutory rights or remedies under the CGA and FTA.

1. Motiva® Health Program

Patients will be automatically covered by the **Motiva® Health Program** after the implantation of Motiva® implants, at no cost and without the need for registration, in accordance with applicable regulations on consumer and user protection.

Products Covered:
Covers all Motiva® implants (excludes Motiva® tissue expanders and sizers).

Events Covered:
- Implant rupture[1]
- Capsular Contracture (Baker Grade III or IV)
- Double capsule
- Late seroma (1 year or more after initial surgery to implant the Motiva® device).
- BIA-ALCL Primary

[1]Coverage of implant rupture under this warranty is provided solely for warranty purposes and does not constitute an admission of liability or confirmation of a manufacturing defect by Motiva. Implant rupture may result from surgical technique, handling, or other external factors beyond Motiva's control, including but not limited to inadequate lubrication of insertion devices, excessive insertion force, or contact with sharp instruments. Such events are not considered product defects.

Benefits:
Without limiting any rights and remedies of patients under the ACL (as applicable in Australia) and the CGA and FTA (as applicable in New Zealand), the following benefits are available to patients enrolled in the Motiva® Health Program:

a. Automatic registration at the time of implantation surgery.
b. Does not require additional payment (free of charge).
c. Product replacement (Motiva® implant)
    i. In the event of a **rupture** the device will be replaced at no cost for the lifetime of the patient, provided that the device remains implanted within the patient's body, from the date of the patient's qualified surgery with Motiva® implants.
    ii. In the event of a **capsular contracture, double capsule, late seroma, or BIA-ALCL**, the device will be replaced at no cost for a period of up to ten (10) years from the date of the patient's qualified surgery with Motiva® implants.
    iii. In cases of a unilateral event affecting only one implant, the patient's surgeon may recommend the replacement of the other implant, in their professional discretion, when deemed necessary to guarantee the safety, functionality or aesthetics of the procedure. The additional implant will be provided free of charge.
    iv. Replacement Motiva® implants provided under the Motiva® Health Program may be of any size or style; however, in the event that the size or style selected by the patient is no longer available, similar Motiva® implants will be delivered. If the patient wishes to upgrade the implant with respect to the original, the corresponding economic difference must be covered by the patient.
    v. All replacement implants provided under the Motiva® Health Program will be shipped at no charge, in accordance with standard shipping policies. However, there may be additional charges for expedited shipping.
    Each replacement request will be evaluated on a case-by-case basis, considering the availability of the product, the specific conditions of the complaint and compliance with the requirements set forth in these Terms and Conditions.
d. Financial Assistance
    i. Rupture Coverage: If a rupture event occurs during the period of up to ten (10) years from the date of the patient's surgery with Motiva® implants, the patient will be entitled to a one-time payment of up to a maximum of **$1,500 USD**** (One Thousand Five Hundred U.S. Dollars) to cover any fees or costs related to the event.
    ii. If any of the other qualifying events **(capsular contracture, double capsule, late seroma, BIA-ALCL)** occur within ten (10) years of the date of the patient's initial implantation surgery with Motiva® implants, the patient will be entitled to a one-time payment of up to a maximum of **$1,500 USD** (One Thousand Five Hundred US Dollars) to cover any fees or costs related to the event.
    iii. Financial assistance shall be granted on a per-claim basis, even if such claim encompasses one or more events contemplated herein.

Table 1. Summary of the Motiva® Health Program

Program	Motiva® Health Program
Covered Product	All Motiva Implants® (Excludes Tissue Expanders and Sizers)
Events Covered	Rupture, capsular contracture Grades III and IV, double capsule, late seroma, and BIA-ALCL
Registration	Automatic, no registration required
Benefits	1. Product replacement FOC. 2. Up to a maximum $1,500 USD in Financial Assistance for 10 years from implantation
Duration of coverage	Rupture, capsular contracture Grades III and IV, double capsule, late seroma, and BIA-ALCL
Additional cost	None (FOC)

This information is provided for illustrative purposes only and is not a substitute for a full reading of the applicable Terms and Conditions. The Motiva® Health Program operates in addition to all rights and remedies that a patient may be entitled to under the ACL (as applicable in Australia) or the CGA or FTA (as applicable in New Zealand) or any other relevant Australian or New Zealand law.

2. Motiva® Health Program Exclusions

The Motiva® Health Program applies only to surgeries performed in strict accordance with the product's directions for use, and implanted through surgical procedures performed by duly qualified and licensed surgeons, and does not cover the following cases:

- Patients undergoing revision surgery with a history of capsular contracture with breast implants of brands other than Motiva®.
- Removal of intact breast implants due to grade I or II capsular contracture.
- Removal of intact breast implants to modify the size.
- Removal of intact breast implants due to rippling.
- Loss of implant integrity resulting from open capsulotomy or closed compression capsulotomy.

Any exclusions under the Motiva® Health Program do not limit or impact a patient's rights or remedies under the ACL (as applicable in Australia) or the CGA or FTA (as applicable in New Zealand).

3. Steps to activate the Motiva® Health Program Warranty.

To activate the warranty under the Motiva® Health Program, the patient or their surgeon must follow the steps indicated in Sections 4 through 7 (as applicable to the event).

4. Filing the complaint

The complaint can be made through the official support website https://motiva.health/documents/surgeons-digital-complaint/ or through your local LifeHealthcare Representative (as applicable to the surgeon filing).

5. Notice Period

Covered events (rupture, Baker grade III and IV capsular contracture, double capsule, late seroma, and BIA-ALCL) must be reported within the eligibility period defined by the Motiva® Health Program.

Any eligibility period under the Motiva® Health Program does not limit or impact a patient's rights or remedies under the ACL (as applicable in Australia) or the CGA or FTA (as applicable in New Zealand).

6. Required Documentation

To verify eligibility for implant replacement and/or financial assistance, the following must be provided:

a. Form FOR-302 "Notice of Complaint (Customer)" with implant information and description of the event, found at https://motiva.health/documents/surgeons-digital-complaint/ or requested from your local LifeHealthcare representative (as applicable to the surgeon filing).
b. Surgeon's clinical report detailing the patient's evolution and complication.
c. For ruptures: Explanted product (unless prohibited by local regulations; in which case, please contact Establishment Labs for instructions). When permitted, the surgeon should send the implant removed and decontaminated following protocol SID-129 to: *Establishment Labs, Coyol Free Zone and Business Park, Building B25, Alajuela, Costa Rica.*
d. For grades III and IV capsular contracture only: Visual tests (photographs and/or videos) showing the appearance of the patient's breasts before and after the reported complication.
e. For BIA-ALCL only: (1) Negative ALK immunohistochemical staining (IHC) or flow cytometry for CD30 and cytology with cell block preparation and (2) confirmation of clinical diagnosis from the patient's surgeon and oncologist of BIA-ALCL.
f. For Double Capsule and late forming Seroma: Imaging testing may be required.

7. Special Conditions

For complaints related to double capsule, late seroma, or BIA-ALCL, additional testing may be required as per protocol. This will be communicated to the patient when necessary.

8. Resolution Deadlines

Establishment Labs has up to 90 days to resolve the complaint, with the intention of completing such resolution sooner whenever possible. If clinical evidence is not provided, it will be requested up to three times; if no response is received, Establishment Labs is entitled to close the complaint. In the event the complaint is closed due to non-response Establishment Labs will reopen the case if the patient or their surgeon responds or contacts Establishment Labs with the requested evidence at a later date.

9. Contact & Support

Establishment Labs has up to 90 days to resolve the complaint, with the intention of completing such resolution sooner whenever possible. If clinical evidence is not provided, it will be requested up to three times; if no response is received, Establishment Labs is entitled to close the complaint. In the event the complaint is closed due to non-response Establishment Labs will reopen the case if the patient or their surgeon responds or contacts Establishment Labs with the requested evidence at a later date.

10. General Provisions

The effective application of the benefits described herein are subject to any applicable local regulations in force, including the ACL (as applicable in Australia) and the CGA and FTA (as applicable in New Zealand). The conditions and benefits described herein apply only to implant surgeries performed on or after **1 March 2026**. Patients who have undergone surgery prior to that date will be subject to the Terms and Conditions of the Motiva® warranty program in effect at the time of their procedure. Any inquiries regarding the applicability of the Motiva® Health Program should be directed to the Establishment Labs Warranty Department at globalwarranty@establishmentlabs.com Subject to the ACL, CGA and FTA, Establishment Labs reserves the right to modify the terms and conditions of the Motiva® Health Program at any time without notice. Any such modification will not affect patients already enrolled under the existing Motiva® Health Program Terms & Conditions and any claim filed prior to the effective date of a modification will be subject to the Motiva® Health Program Terms & Conditions in effect at the time of their implantation procedure.

Warranty coverage is provided on a per-event basis only. Any financial contribution or coverage granted under this warranty for a specific event shall not be cumulative with, or combined with, any other coverage, contribution, or compensation, whether related to the same or a different event. Only one form of coverage may apply per event.