

MOTIVA USA WARRANTY PROGRAM

This document describes the terms, conditions, and claims procedures of Motiva USA, LLC's ("Motiva") warranty programs entitled, the **Motiva® Health Program** and **Motiva® Health Program Plus** (Motiva® Health Program and Motiva® Health Program Plus collectively referred to herein as the "**Motiva USA Warranty Program**").

A. Effective Date of Coverage

The Motiva USA Warranty Program covers and applies to all Motiva® breast implants that are implanted in patients in the United States or Puerto Rico on or after September 26, 2024 ("**Program Effective Date**").

B. Patient Eligibility

Patients will automatically be enrolled in the **Motiva Health Program** after implantation of Motiva Implants® (free of charge), but should confirm their implant information after their surgeon uploads their respective implant information to the Motivaimagine® app. Once the surgeon uploads the device information to the Motivaimagine app, an e-mail will be sent to patients to confirm the accuracy of their implant details. A patient's e-mail confirmation of their Motiva Implants® will constitute a successful registration of Motiva Implants®.

Patients will only be able to upgrade to the **Motiva Health Program Plus Plan** after (1) completing registration of their Motiva Implants® as described above and (2) after paying a supplemental \$250 one-time fee to Motiva within ninety (90) days of their implantation surgery.

C. Covered Events

Motiva will provide implant replacement and financial assistance under the Motiva USA Warranty Program which will vary based on the patient's program type. Each patient filing a claim will need to meet the terms for each event covered by the Motiva USA Warranty Program below (each an "**Event**" and collectively, "**Events**").

1. **Rupture**: A hole or tear in the shell of the implant that allows silicone gel filler material to leak from the shell resulting in a loss of shell integrity, diagnosed clinically by a patient's surgeon and confirmed by either (i) an MRI, or other acceptable diagnostic imaging method, or (ii) acceptable photographs to Motiva of the implant(s) immediately following explant surgery.
2. **Capsular Contracture**: Baker Grade III or Baker Grade IV capsular contracture forming after the DOS, clinically diagnosed by a patient's surgeon and confirmed by photographs acceptable to Motiva showing the appearance of the breast immediately prior to explant surgery.
3. **Late Forming Seroma**: Clinically significant seroma forming at least one (1) year after the DOS with no intervening surgical procedures performed on the implant between the primary surgery and the development of the seroma. Must be diagnosed by the patient's surgeon and confirmed by photographs, pathology, or other reports acceptable to Motiva.
4. **Double Capsule**: Finding of two separate capsular (scar tissue) layers, separated by a space, around an implant, that has been clinically diagnosed by the patient's surgeon and confirmed by intraoperative photograph(s) acceptable to Motiva.

5. **BIA-ALCL**: Breast Implant Associated-Anaplastic Large Cell Lymphoma, clinically diagnosed by the patient's surgeon and confirmed by (1) immunohistochemistry (IHC) staining or flow cytometry for CD30 and cytology with cell block preparation and (2) confirmation of the patient's surgeon's clinical diagnosis of BIA-ALCL by an independent rheumatologist and psychiatrist.

D. Program Exclusions

Determination of whether an Event is covered by the Motiva USA Warranty Program and not otherwise excluded by this Section D lies in the sole discretion of Motiva.

The Motiva USA Warranty Program will not apply to any of the following:

- Events that occur as result of surgical procedures performed by non-qualified or unlicensed surgeons.
- Any adverse reactions or injury other than an Event covered in Section C (1) – (5).
- Patients with a previous history of textured implants. Textured is defined in this exclusion as a breast implant having a surface roughness of more than 10 microns.
- Rupture resulting from open-capsulotomy or closed-compression-capsulotomy procedures, or any other procedure for which there is a warning, precaution or contraindication in Motiva Implants® “Directions for Use, Motiva SmoothSilk® Round, Ergonomix® and SmoothSilk® Round Silicone Gel-Filled Breast Implants.”
- Removal of intact implant(s) for any reason other than those specified in C (1) – (5) including, but not limited to, Baker Grade I or Baker Grade II capsular contracture, style or size change, wrinkling or rippling.
- Revision surgery patients with previous history of capsular contracture with other non-Motiva brands of breast implants.
- Loss of shell integrity caused by or during re-operative procedures.
- Loss of shell integrity resulting from sharp instrument damage.

E. Motiva Health Program Coverage

Patients implanted with Motiva SmoothSilk® Round Implants and Motiva SmoothSilk Ergonomix® Implants will be enrolled in the Motiva Health Program, free of charge, which provides implant replacement and financial assistance to patients as stated below:

1. **Implant Replacement:**

For a qualifying rupture or BIA-ALCL Event under the Motiva Health Program, Motiva will replace the implant free-of-charge for the lifetime of the patient. For all other qualifying Events (capsular contracture, double capsule, late forming seroma) Motiva will replace the product free-of-charge for up to ten (10) years from the date of the patient's qualifying surgery with Motiva Implants®.

When a patient qualifies for a no-charge replacement implant, Motiva will, at the surgeon's request, also provide a replacement of the contralateral implant free of charge. Replacement

implants provided under the Motiva Health Program may be of any size or style, but in the event the size or style of the Implant selected by the patient is no longer available, replacement implants of the most comparable size and style manufactured by Motiva will be provided. All replacement implants provided under the Motiva Health Program (limited to two (2) per qualifying surgery) shall be shipped at no cost pursuant to Motiva's standard shipping policies, provided that extra charges for expedited shipping shall be payable by the implanting surgeon. All replacement implants provided under the Motiva® Health Program shall be enrolled in the terms and conditions of the Motiva USA Warranty Program in effect at the date of implant surgery. Coverage for revision surgery with replacement Motiva Implants® will be subject to the terms and conditions herein.

2. **Financial Assistance:**

Under the Motiva Health Program, Motiva will provide financial assistance as described herein this Section E (2.) for rupture, capsular contracture and BIA-ALCL. The Motiva Health Program does not provide patients with financial assistance for double capsule and late forming seroma Events.

For a qualifying **rupture** Event that occurs within ten (10) years from the date of the patient's surgery with Motiva Implants®, Motiva will provide a one-time only payment up to a maximum of **\$3,500** to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or waived by the healthcare provider, that are directly related to the rupture Event.

For a qualifying **capsular contracture** Event that occurs within two (2) years from the date of the patient's primary or revision augmentation surgery with Motiva Implants®, Motiva will provide a one-time only payment up to a maximum of **\$2,000** to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or waived by the healthcare provider, that are directly related to the capsular contracture Event.

For a qualifying **BIA-ALCL** Event that occur within the lifetime of the patient after the patient's surgery with Motiva Implants®, Motiva will provide a one-time payment up to a maximum of **\$7,500** to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or waived by the healthcare provider, that are directly related to the BIA-ALCL Event.

The amounts payable under the Motiva Health Program are limited to a maximum of **\$7,500** per qualifying surgery. All claims for monetary reimbursement must be supported by medical invoices, bills or other acceptable forms of proof of payment, and Motiva shall only reimburse the actual out-of-pocket amount up to the maximum amount for the applicable Event.

In addition to the coverage for qualifying Events listed above, Motiva will also provide coverage and financial assistance for late seroma diagnostic testing to rule out BIA-ALCL when suspected, which may include one or more of cell cytology, CD30 immunohistochemistry, or flow cytometry testing. This financial assistance will be rendered by Motiva to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or waived by the healthcare provider. Reimbursement for such testing will be provided by Motiva upon submission of proof of payment.

F. Motiva Health Program Plus Coverage

Patients implanted with Motiva SmoothSilk Ergonomix® Implants and Motiva SmoothSilk® Round Implants will be eligible for the Motiva Health Program Plus upon payment of a one-time plan fee to Motiva of \$250 within ninety (90) days of the date of implantation surgery. Implant replacement and financial assistance for patients enrolled in this program are described below:

1. Implant Replacement:

For all qualifying Events, except capsular contracture, Motiva will replace the implant free-of-charge for the lifetime of the patient. For a capsular contracture Event, Motiva will replace the product free-of-charge for up to ten (10) years from the date of the patient's qualifying surgery with Motiva Implants®.

When a patient qualifies for a no-charge replacement implant, Motiva will, at the surgeon's request, also provide a replacement of the contralateral implant free of charge. Replacement implants provided under the Motiva Health Program Plus may be of any size or style, but in the event the size or style of the implant selected by the patient is no longer available, replacement implants of the most comparable size and style manufactured by Motiva will be provided. All replacement implants provided under the Motiva Health Program Plus (limited to two (2) per qualifying surgery) shall be shipped at no cost pursuant to Motiva's standard shipping policies, provided that extra charges for expedited shipping shall be payable by the implanting surgeon. All replacement implants provided under the Motiva Health Program Plus shall be enrolled in the terms and conditions of the Motiva USA Warranty Program in effect at the date of implant surgery. Coverage for the revision surgery with replacement implants will be subject to the terms and conditions herein.

2. Financial Assistance:

Under the Motiva Health Program Plus, Motiva will provide financial assistance as described herein this section F (2.) for all qualifying Events.

For a qualifying **rupture** Event that occurs within ten (10) years from the date of the patient's surgery with Motiva Implants®, Motiva will provide a one-time only payment up to a maximum of **\$5,000** to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or waived by the healthcare provider, that are directly related to the rupture covered Event.

For a qualifying **capsular contracture** Event that occurs within five (5) years from the date of a patient's **primary augmentation surgery** with Motiva Implants®, Motiva will provide a one-time only payment up to a maximum of **\$2,500** to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or waived by the healthcare provider, that are directly related to the capsular contracture Event. For a qualifying **capsular contracture** Event that occurs within two (2) years from the date of a patient's **revision augmentation surgery** with Motiva Implants®, Motiva will provide a one-time only payment up to a maximum of **\$2,500** to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or waived by the healthcare provider, that are directly related to the capsular contracture Event.

For a qualifying **late forming seroma** Event that occurs within two (2) years from the date of a patient's primary or revision augmentation surgery with Motiva Implants®, Motiva will provide a one-time only payment up to a maximum of **\$2,000** to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or

waived by the healthcare provider, that are directly related to the late forming seroma Event.

For a qualifying **double capsule** covered Event that occurs within two (2) years from the date of a patient's primary or revision augmentation surgery with Motiva Implants®, Motiva will provide a one-time only payment up to a maximum of **\$3,500** to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or waived by the healthcare provider, that are directly related to the double capsule covered Event.

For a qualifying **BIA-ALCL** Event that occurs within the lifetime of the patient, coverage will be provided as follows; (1) up to ten (10) years from the date of a patient's surgery with Motiva Implants®, Motiva will provide a one-time payment up to a maximum of **\$15,000** to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or waived by the healthcare provider, that are directly related to the BIA-ALCL Event, and (2) eleven (11) years and on from the date of a patient's surgery with Motiva Implants®, Motiva will provide a one-time payment up to a maximum of **\$7,500** to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or waived by the healthcare provider, that are directly related to the BIA-ALCL Event.

The amounts payable under the Motiva Health Program Plus are limited to a maximum of **\$15,000** per qualifying surgery. All claims for monetary reimbursement must be supported by medical invoices, bills or other acceptable forms of proof of payment, and Motiva shall only reimburse the actual out-of-pocket amount up to the maximum amount for the applicable Event.

In addition to the coverage for qualifying Events listed above, Motiva will also provide coverage and financial assistance for late seroma diagnostic testing to rule out BIA-ALCL when suspected, which may include one or more of cell cytology, CD30 immunohistochemistry, or flow cytometry testing. This financial assistance will be rendered by Motiva to help the patient offset any fees or costs not paid or payable by any form of insurance, or otherwise covered or waived by the healthcare provider. Reimbursement for such testing will be provided by Motiva upon submission of proof of payment.

3. **Femtech Freedom Program**

Patients who are enrolled in the Motiva® Health Program Plus will also automatically be enrolled in the Femtech Freedom Program. Under the Femtech Freedom Program, patients will be offered a \$2,500 credit towards the explant of Motiva Implants® for up to two years following a primary augmentation surgery. The Femtech Freedom Program was designed for patients who wish to remove their Motiva Implants® for a reason not related to an Event under a Motiva USA Warranty Program. Patients enrolled in the Femtech Freedom Program must adhere to specific terms and conditions to benefit from this program. These terms and conditions can be found at www.motivausa.com and are incorporated by reference.

G. Qualifying Conditions for Motiva USA Warranty Program Claims

The following conditions are required for a Motiva USA Warranty Program claim to qualify for approval from Motiva:

1. The implantation, and all subsequent procedures, must have taken place in the United

States or Puerto Rico on or after the Program Effective Date;

2. The implantation, and all subsequent procedures, must have been performed in accordance with the *Directions for Use Establishment Labs Sterile Silicone Breast Implants Motiva Implant Matrix®* in effect at the time of the procedure and all applicable professional standards of care;
3. For the Motiva Health Program Plus, the patient must have completed implant registration and payment within ninety (90) days after the date of implant surgery;
4. The claims procedure set forth in Section H must have been followed, including obtaining Motiva's pre-authorization and returning the explanted product(s) and other required documentation to Motiva within thirty (30) days of the explant procedure; and
5. The patient must sign a full release releasing Motiva from any further liability related to the explanted product(s) in return for receipt of the benefits provided under the Motiva USA Warranty Program (the "**Release**").

Motiva will retain sole discretion of whether the conditions in this Section G. are fully satisfied to qualify an otherwise covered Event under the Motiva USA Warranty Program.

H. Filing a Claim

In order to obtain the benefits for a qualifying Event under the Motiva USA Warranty Program, the following claim procedure steps are required:

1. The patient's surgeon must initiate the claims process and obtain pre- authorization in advance of any revision or explant surgery by filing the warranty claim at <https://motivausa.com/contact-us>. To obtain pre-authorization, the surgeon must send to Motiva copies of the following:
 - i. A completed and signed FOR-302 "Complaint Notification (Customer)" Document regarding the patient's implant information and the Event description. 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; and
 - ii. A Release, signed by the patient, in return for acceptance of the benefits of the Motiva USA Warranty Program.
 - iii. The patient's medical records (including photographs, diagnostic imaging or pathology testing as applicable) showing the basis for the surgeon's diagnosis of the qualifying Event;
2. After obtaining pre-authorization, the patient's surgeon must complete and return the Motiva Explant Return Kit in accordance with Motiva's instructions. To be considered complete, Motiva must receive at least the following items from the patient or the patient's surgeon.
 - i. The explanted Motiva product(s) involved in the Event (do not return contralateral

- implant if not affected);
- ii. Copies of the operative report for the revision surgery;
 - iii. Copies of relevant bills for operating room, anesthesia and surgical fees or costs incurred in the revision surgery;
 - iv. Copies of all relevant insurance reimbursements, or coverage or waiver of any fees or costs by the healthcare provider.
3. For all covered Events, Motiva will ship any replacement product(s) to the surgeon in accordance with the surgeon's instructions and/or issue payment for the relevant amount to the appropriate party or parties within thirty (30) days of receipt of all items listed in 1 and 2 above. For qualifying rupture covered Events, replacement product(s) and payment shall be issued after receipt of the independent laboratory report confirming the rupture Event.
 4. Motiva will render all financial assistance payments for approved claims under the Motiva USA Warranty Program directly to the applicable patient.

I. Claim Follow-Up

1. Motiva 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.
2. In the case where there is a lack of clinical evidence provided for a Motiva USA Warranty Program claim, Motiva will make up to three attempts to request additional evidence. If no response is received, Motiva is authorized to close the claim.
3. For guidance on providing the necessary information and support documentation BEFORE any implant is explanted, the patient or their surgeon should contact Motiva at uspms@motivausa.com.

J. Disclaimer of Liability:

THE MOTIVA USA WARRANTY PROGRAM AND ITS AFFILIATED PROGRAMS DESCRIBED HEREIN ARE LIMITED WARRANTIES ONLY AND ARE SUBJECT TO THE TERMS AND CONDITIONS OF THIS DOCUMENT. ALL OTHER WARRANTIES, WHETHER EXPRESSED OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS ARE EXCLUDED. THE REMEDIES FOUND IN THIS DOCUMENT ARE THE SOLE AND EXCLUSIVE REMEDIES AVAILABLE. MOTIVA SHALL NOT BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL LOSS, DAMAGE OR EXPENSE ARISING DIRECTLY OR INDIRECTLY FROM THE USE OF THESE PRODUCTS. MOTIVA NEITHER ASSUMES NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH MOTIVA BREAST IMPLANTS.

K. Motiva USA Warranty Program Modifications:

Motiva 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 filed claims already registered and covered under the existing Motiva Warranty USA Program in effect on the date of the patient's implantation surgery. The Motiva USA Warranty Program and its respective programs are non-transferable and non-refundable.

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