<mark>Men</mark>tor Warranty Program

CANADA

A Limited Breast Implant Warranty Program for Peace of Mind

This warranty applies for any MENTOR[®] Saline or Silicone Gel-Filled Breast Implant, implanted on or after June 1st, 2014.

Any MENTOR* Saline or Silicone Gel-Filled Breast Implant, implanted prior to June 1st, 2014 will be covered by the following respective warranty plans:

- Mentor Advantage Program
- Mentor limited Warranties



A Personal Commitment to Your Well-Being

Thank you for selecting MENTOR® Breast Implants.* Mentor is a global leader in the design and manufacturing of a broad range of innovative and science-based aesthetic products. Our breast implants have been successfully used for over 20 years by millions of women worldwide.

Our relationship with you doesn't end with your surgery. We're committed to supporting you throughout your decision making journey, providing educational resources for each step of the way. More importantly, we are there with you after your surgery with a long-term commitment —the Mentor Warranty Program. Mentor is proud to be the first breast implant manufacturer in the industry to offer a limited warranty on all our breast implants.

Our warranty demonstrates the confidence we feel in the quality of our products. All MENTOR[®] Breast Implants come with a free, limited warranty that offers lifetime product replacement and limited financial assistance^{***} if needed; because your peace of mind comes first.



- * A copy of Saline-Filled Breast Implant Surgery: Making an informed decision & Important Information for Augmentation Patients about MemoryGel[™] Implants should be provided and discussed with you by your surgeon. This guide also may be obtained at www.mentorcanada.com or by calling 1-800-668-6069.
- ** Financial assistance does not imply a loan to the patient.

The Mentor Warranty Program

Our limited warranty program is available free of charge to all patients who receive MENTOR® Saline-filled or Memory-Gel[™] Silicone Gel-filled Breast Implant products in Canada.

To be eligible, the implants must be:

- Implanted in accordance with MENTOR[®] product literature, current to the date of implantation, and other notifications or instructions published by Mentor; and,
- Used by appropriately qualified licensed physicians and surgeons, in accordance with accepted plastic surgical procedures

As with any warranty program, it is important to maintain your own records to ensure validation of your enrollment. It is possible your surgeon may not retain your records for the entire duration of the warranty. Please fill out and keep the MENTOR[®] patient implant ID card that you will receive from your surgeon for your records.

xample Im	plant ID Card		
PatientNa	ame:		
Date of Si	urgery:		
DoctorsN	lame:		
Breast Im	plant Size:		
<u>Final Fill V</u>	olume: (saline implants only)		
	Implant ID Card - This device in This may be the only record of the implant kept in a secure and accessible place for fu Mentor at 1-800-MENTOR8 whenever you	ed device so the card should be uture reference. Please notify	

The Mentor Warranty Program is made up of two parts:

1. Product Replacement

- All recipients of MENTOR[®] Breast Implant products are automatically eligible.
- Regardless of the age of the implant, if a confirmed rupture or deflation occurs, you are eligible for a FREE replacement breast implant product of any size in same or similar style.

NEW

 In the event of a confirmed capsular contracture Baker grade III/IV (as confirmed by your surgeon) in augmentation surgery within ten (10) years of the date of the original implant, you are eligible for a FREE replacement breast implant product of any size in same or similar style.

2. Financial Assistance**

In addition to the Product Replacement described above, if a confirmed rupture or deflation occurs, recipients of MENTOR[®] Breast Implant products are also eligible for Financial Assistance.

• Available for any revision surgery carried out within 10 years of the date of the original implant

NEW

- Available for operating room, anesthesia, and surgical charges of up to \$3500 that are not covered by insurance**
- Free contralateral (opposite side) implant product replacement upon surgeon request
- Non-cancelable terms^{****}
- Product Replacement Policy: In the event of a <u>qualifying</u> deflation or rupture of a MENTOR* Breast Implant during the lifetime of the patient, or a <u>confirmed</u> capsular contracture Baker grade III/IV within ten (10) years of the date of original implant in an augmentation surgery. Mentor will replace the product, in any size, in the same or similar style as the original implant, free of charge. To confirm capsular contracture, surgeon must submit a photograph of the patient's chest/thorax prior to surgery/explantation to Mentor for review and validation. Upon surgeon's written request, a different implant style may be selected (subject to a charge for the difference between product list prices.)

^{**} Operating room and anesthesia charges to be given payment priority. In order to qualify for financial assistance, you will need to sign the Patient Release form found in this booklet. Financial assistance is not available for events involving capsular contracture Baker grade III/IV in augmentation. Financial Assistance applies for any MENTOR* Saline or Silicone Gel-Filled Breast Implant, implanted on or after June 1st, 2014. Any MENTOR* Saline or Silicone Gel-Filled

Implant, implanted on or after June 1st, 2014. Any MENTOR* Saline or Silicone Gel-Filled Breast Implant, implanted prior to June 1st, 2014 will be covered by the following respective warranty plans: • Mentor Advantage Program • Mentor limited Warranties

*** Although Mentor reserves the right to cancel, change or modify the Mentor Warranty Program at any time, any such cancellation, change, or modification will not impact patients enrolled prior to the date of the change, cancellation or modification.

The Mentor Warranty Program

Financial Assistance - Events Covered

The Mentor Warranty Program applies to the following events:

- Deflation due to crease fold failure, patient trauma, or unknown cause
- Loss of valve integrity

Other qualified loss-of-shell-integrity events also may be covered by this program. Mentor reserves the right to determine if specific, additional events should be covered.

Financial Assistance - Events Not Covered

The Mentor Warranty Program does not apply to the following:

- Removal of intact implants due to wrinkling or rippling
- Loss of implant shell integrity resulting from reoperative procedures, open capsulotomy, or closed compression capsulotomy procedures
- Removal of intact implants for size alteration
- Events involving capsular contracture Baker grade III/IV in augmentation

Submitting for Financial Assistance as Part of the Mentor Warranty Program

The Mentor Warranty Program requires that your surgeon submit (for validation) the claim for financial assistance on your behalf and notify Mentor (Canada) in writing of the Explant. To file a claim for financial assistance, your surgeon must follow the instructions in the Surgeon Submission Form found at the back of this brochure.

The Mentor Warranty Program financial assistance will be issued via a cheque payable to the Healthcare Provider identified by you in your Patient Release Form within two (2) weeks of the receipt by Mentor (Canada) of both (1) the completed documentation (items 1 – 5 below), and (2) the explanted decontaminated MENTOR[®] breast implant(s).

- 1. Field Experience Report (FER) and Authorization Form
- 2. Explant Operative Report
- 3. Itemized Bill
- 4. Signed Patient Release Form
- 5. Signed Surgeon Submission Form

Documentation maybe faxed or mailed along with the explants to:

Mentor (Canada)

200 Whitehall Drive Markham, Ontario L3R 0T5 Fax # (for documentation): 905-946-2050 Attention: Product Quality Services

Note: Mentor (Canada) reserves the right to cancel, change, or modify the terms of the Mentor Warranty Program at any time without notice. Any such cancellation, change, or modification will not impact patients enrolled prior to the date of the change, cancellation or modification. In addition, all claims submitted for Financial Assistance must be validated by Mentor Worldwide LLC to ensure that they meet the requirements of the warranty. Should your claim not be validated, your surgeon will be contacted.

Mentor Warranty Program

This brochure provides an overview of The Mentor Warranty Program for breast implants. However, it is not intended to replace any discussion between you and your surgeon.

www.mentorcanada.com

THIS IS A LIMITED WARRANTY ONLY AND IS SUBJECT TO THE TERMS AND CONDITIONS SET FORTH IN THIS DOCUMENT AND EXPLAINED IN GREATER DETAIL IN THE APPLICABLE MENTOR LIMITED WARRANTY. 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.

THIS REMEDY IS THE SOLE AND EXCLUSIVE REMEDY AVAILABLE. MENTOR 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. MENTOR NEITHER ASSUMES, NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

THE TERMS IN EFFECT WHEN ORIGINAL IMPLANTATION OCCURS WILL APPLY AT THE TIME OF CLAIM.



Mentor Warranty Program Instructions and Patient Release Form^{*}

All recipients of MENTOR[®] Breast Implant products are automatically eligible for the Product Replacement Warranty. Regardless of the age of the implant, up to two (2) no-charge replacement MENTOR[®] Breast Implant products of any size in a similar style, when a qualifying deflation or rupture occurs.

In addition, financial assistance is available for operating room, anesthesia, and other surgical charges of up to \$3500 that are not covered by insurance when a qualifying deflation or rupture occurs. The financial assistance is available for any revision surgery carried out within 10 years of the date of the original implant

Instructions:

Please read these instructions, and the Patient Release Form that follows, thoroughly before detaching and completing the form and returning it to your surgeon.

Notes:

- The terms of the Mentor Warranty Program, as outlined in this brochure, represent a business decision and are not to be construed as an admission of liability on the part of Mentor Worldwide LLC, Johnson & Johnson Inc., or any of its affiliates.
- 2. In order for Mentor to validate your claim for Financial Assistance, the explanted MENTOR[®] Breast Implant must be returned to Mentor for evaluation and Mentor may retain or discard it as deemed appropriate.

- No payment will be made by Mentor to your surgeon on your behalf until the required documentation (as outlined in this brochure) as well as the explanted product has been received.
- 4. Any alternation made to the terms of the Patient Release Form without specific written approval from Mentor will void the Patient Release Form.
- Signing this Patient Release Form does not affect your ability to make a future request under the terms of the Lifetime Product Replacement Policy for a MENTOR[®] product not designated in the attached Patient Release Form.
- Mentor (Canada) is part of Johnson & Johnson Medical Products, a division of Johnson & Johnson Inc., with its head office at 200 Whitehall Drive, Markham, Ontario L3R 0T5.
- If you have any questions regarding this Patient Release Form, please have your surgeon contact his/her local Mentor (Canada) Sales Representative.
- 8. For the most up to date terms and conditions please refer to www.mentorcanada.com





PATIENT RELEASE FORM for Financial Assistance

In consideration of the Mentor (Canada) payment of actual operating room and/or anesthesia expenses not paid or payable by any form of insurance in the maximum aggregate amount of \$3,500.00 (Three Thousand Five Hundred Canadian Dollars 00/100) by means of cheque payable directly to my Healthcare Provider as defined below, I, the undersigned Patient do hereby release and forever discharge Mentor Worldwide LLC, Mentor (Canada) part of Johnson & Johnson Medical Products, a division of Johnson & Johnson Inc.. and any related persons, entities, and affiliates (together the "Releasees") from any and all claims arising out of the use of MENTOR® Breast Implant(s) placed in my breast(s) on the Implantation Date and removed on or about the Removal date.

I, the undersigned Patient further understand and agree that neither the payment of any sum of money nor the execution of this Patient Release Form shall constitute or be construed as an admission of any liability whatsoever by the Releasees who have consistently taken the position that they have no liability whatsoever to the undersigned Patient. IN WITNESS WHEREOF, I have hereunto set my hand on the date of signing of this Patient Release Form.

Please clearly print the following:

Patient Name:

Street Address:

City / Province:

Postal Code:

Healthcare Provider:

Implantation Date:

Removal Date:

Product Identification Number:

Witness to Signature of Patient

Signature of Witness

Print Name of Witness

Signature of Patient

Signature of Patient

Print Name of Patient

Patient Release Form Date of Signing

SURGEON SUBMISSION FORM for Financial Assistance

Instructions: Please read this Surgeon Submission Form thoroughly before detaching and completing this form and returning it, along with the items in the checklist below to Mentor (Canada).

As you know, the Mentor Warranty Program requires that you submit for validation the claim for financial assistance on behalf of your patient and notify Mentor (Canada) in writing of the Explant.

The approved financial assistance will be issued via a cheque payable to the Healthcare Provider identified by your patient in her Patient Release Form within two (2) weeks of the receipt by Mentor (Canada) of both (1) the completed documentation (items 1 - 5 as outlined), and (2) the explanted decontaminated MENTOR® device(s).

For your ease we have created the following checklist of items required by Mentor (Canada) in order to validate the claim:

Field Experience Report (FER) and Authorization Form

Explant Operative Report



Itemized Bill



Signed Patient Release Form



Signed Surgeon Submission Form

Decontaminated MENTOR* Breast Implant(s)

continued on reverse

All items on the checklist must be sent to Mentor (Canada) at the address below. Documentation maybe faxed or mailed along with the explants(s).

Mentor (Canada) 200 Whitehall Drive Markham, Ontario L3R 0T5 Fax # (for documentation): 905-946-2050 Attention: Product Quality Services

Acknowledgement: By signing below and submitting this SURGEON SUBMISSION FORM I acknowledge that all claims submitted for Financial Assistance under the Mentor Warranty Program must be validated by Mentor Worldwide LLC to ensure that they meet the requirements of the warranty. Should the claim not be validated as resulting from a qualifying deflation or rupture, any Financial Assistance received by me/my healthcare facility in association with the non-validating claim must be returned to Mentor (Canada).

Witness to Signature of Surgeon

Signature of Witness

Print Name of Witness

Signature of Surgeon

Signature of Surgeon

Print Name of Surgeon

Surgeon Submission Form Date of Signing:

Street Address:

City/Province:

Postal Code:



Mentor CANADA

A unit of Johnson & Johnson Medical Products A division of Johnson & Johnson Inc.

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