



# A Commitment to Your Well-Being.

Thank you for selecting Mentor Silicone Gel-Filled Breast Implants. Our relationship with you doesn't end with your surgery. We make a long-term commitment to our patients and we stand behind the integrity of our products.

All Mentor Silicone Gel-Filled Breast Implants come with a Lifetime Product Replacement Policy<sup>1</sup> at no additional charge. Also, once you receive Mentor Silicone Gel-Filled Breast Implants, you are automatically enrolled in the Mentor PatientSafe Coverage Limited Warranty.

### Lifetime Product Replacement Policy

- Automatically applies to all recipients of Mentor breast implant products.
- Provides that regardless of the age of the implant, when confirmed rupture occurs, you will be eligible for a no-charge replacement breast implant product of any size in a similar style.

### Additional Benefits of the Mentor PatientSafe Coverage Limited Warranty

The Mentor PatientSafe Coverage Limited Warranty is free of charge to all patients who are implanted with Mentor Silicone Gel-Filled Breast Implant products.

- Automatic enrolment
- Lifetime product replacement policy<sup>1</sup>
- Up to \$1,500AUD financial assistance (in total) for operating room, anaesthesia and surgical charges not otherwise covered by insurance if you require surgery to replace Mentor Silicone Gel-Filled Implants due to a covered event within 10 years from the date of implantation.<sup>2</sup>

### Products Covered

The Mentor PatientSafe Coverage Limited Warranty applies only to Mentor Silicone Gel-Filled Breast Implants that are implanted in Australia after October 1, 2005, that require replacement due to a covered event, provided implants have been (including but not limited to):

- Implanted in accordance with the Mentor package insert, current to the date of implantation, and other notifications or instructions published by Mentor
- Used by appropriately qualified, licensed surgeons, in accordance with accepted surgical procedures

### Events Covered

The Mentor PatientSafe Coverage Limited Warranty applies to the following events:

- Cases of loss of shell integrity resulting in implant rupture that require surgical intervention.

### Events Not Covered

The Mentor PatientSafe Coverage Limited Warranty does not apply to events not noted above including:

- Removal of implants due to capsular contracture, wrinkling, or rippling
- Loss of implant shell integrity resulting from reoperative procedures, open capsulotomy, or closed compression capsulotomy procedures
- Removal of implants for size alteration
- Surgery on the opposite breast to replace an intact implant

### Filing for Financial Assistance

To file a Mentor PatientSafe Coverage claim for product replacement and/or financial assistance the following is required:

1. You should contact Johnson & Johnson Medical Pty Ltd (JJM) prior to your replacement surgery and advise that you would like to submit a claim for the Mentor PatientSafe Coverage Limited Warranty.
2. To determine if you are eligible for the PatientSafe Coverage Limited Warranty the decontaminated explanted Mentor Silicone Gel-Filled breast implants will be collected from your hospital and sent directly to the site of manufacture for analysis. This must be done within 3 months of explantation.
3. The explanted Mentor Silicone Gel-Filled Breast Implants will be analysed within the appropriate Mentor Product Evaluation Department.
4. Once the review has been undertaken and if you are eligible for the PatientSafe Coverage Limited Warranty, you will be asked to complete a patient specific release form (that will be provided by Johnson & Johnson Medical Pty Ltd) and to provide receipts as proof of operating room, anaesthesia and surgical charges not otherwise covered by your insurance.
5. On receipt of the signed general release, financial assistance will be issued.

Mentor reserves the right to cancel, change, or modify the terms of the **Mentor PatientSafe Coverage**.

Any such cancellation, change, or modification will not affect the current stated terms of the **Mentor PatientSafe Coverage** for those already enrolled.

This brochure provides an overview of The Mentor PatientSafe Coverage Limited Warranty for Mentor Silicone Gel-Filled Breast Implants. However, it is not intended to replace any discussion between you and your surgeon.

SUBJECT TO YOUR RIGHTS AS A CONSUMER, AS SET OUT BELOW, 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.

FOR IMPLANTS YOU ACQUIRE AS A CONSUMER, YOU HAVE GUARANTEES THAT CANNOT BE EXCLUDED UNDER THE AUSTRALIAN CONSUMER LAW. YOU ARE ENTITLED TO A REPLACEMENT OR REFUND FOR A MAJOR FAILURE AND FOR COMPENSATION FOR ANY OTHER REASONABLY FORESEEABLE LOSS OR DAMAGE. YOU ARE 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.

YOUR RIGHTS UNDER PATIENTSAFE COVERAGE AND THE LIFETIME PRODUCT REPLACEMENT POLICY ARE IN ADDITION TO YOUR STATUTORY RIGHTS AS A CONSUMER.

SUBJECT TO YOUR CONSUMER STATUTORY RIGHTS, 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, NOT AUTHORISES 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 THE CLAIM.

## For Peace of Mind.

Make sure the breast implants that will become part of your body are made by a company that has over 30 years of experience in the manufacture of breast implants<sup>3</sup> and offers high quality products.

<sup>3</sup> Bondurant S., Ernster V., Herdman R. eds. (1999). Safety of Silicone Implants. Washington, DC: National Academy Press.

# PatientSafe Coverage Limited Warranty

### Thank you for selecting our implant products.

This certifies that Mentor Worldwide LLC will provide a replacement, free of charge, of any Mentor silicone gel-filled breast implant that is removed due to loss of shell integrity resulting in implant rupture during your lifetime. In addition - for a duration of 10 years from date of implantation - Johnson & Johnson Medical will guarantee financial assistance up to the value of \$1,500AUD for operating room, anaesthesia, and surgical charges not covered by insurance.

PatientSafe Coverage is subject to the terms and conditions outlined in the complete Mentor PatientSafe Coverage Limited Warranty.

### Certificate for Mentor Silicone Gel-Filled Breast Implants.

Surgeon Name and Address \_\_\_\_\_

Surgeon Signature \_\_\_\_\_

Date of Surgery \_\_\_\_\_

Mentor Implant Style and Size Used \_\_\_\_\_

Lot # \_\_\_\_\_

Serial # \_\_\_\_\_

After your surgery, obtain above information from your surgeon and keep this document for your personal records.

<sup>1</sup> Lifetime Product Replacement Policy: Mentor will provide replacement Mentor product of any size in the same or similar style as the originally implanted product free of charge for the lifetime of the patient. Upon surgeon's request, a different implant style may be selected (subject to a charge of the difference between product list prices).

<sup>2</sup> Operating room and anaesthesia charges to be given payment priority. In order to qualify for financial assistance, you will need to sign a Release form. Financial assistance does not imply a loan to the patient. Please refer to "Filing for Financial Assistance" contained in this brochure for details about how to submit a claim for financial assistance.

LIMITED WARRANTY

## PatientSafe Coverage

For Silicone Gel-Filled Breast Implants



## PatientSafe Coverage. Reassurance that lasts.

- ✓ Automatic enrolment
- ✓ Free of charge
- ✓ Lifetime product replacement
- ✓ Financial assistance for 10 years from the date of implant, up to AUD \$1,500 (in total) if you require surgery to replace a Mentor Silicone Gel-Filled Breast Implant

### Corporate Headquarters

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### International Operations Australia

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Phone 1800 338 160  
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### Important notice (For Customers in Australia Only).

The PatientSafe Coverage Limited Warranty (Warranty) and Lifetime Product Replacement Policy (Policy) are provided by Johnson & Johnson Medical Pty Ltd:  
Telephone: 1800 338 160 or +61 2 9815 3680  
Address: 1-5 Khartoum Road, North Ryde, NSW 2113  
Email: [mentorcustserv@its.jnj.com](mailto:mentorcustserv@its.jnj.com)

When purchased by a Consumer, Mentor Silicone Gel-Filled Breast Implants come with Consumer guarantees that cannot be excluded under the Australian Consumer Law (ACL). You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are 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.

Your rights under the Warranty and Policy are in addition to your statutory rights as a Consumer.

Johnson & Johnson Medical Pty Ltd ABN 85 000 160 403  
Mentor is a business unit of Johnson & Johnson Medical Pty Ltd (E201303\_38)

Not for distribution in the USA.

LIMITED WARRANTY

## PatientSafe Coverage

For Silicone Gel-Filled Breast Implants

