PRODUCT REPLACEMENT POLICY AND WARRANTY FOR MEMORYGEL® BREAST IMPLANTS and CONTOUR PROFILE GEL (CPG™) BREAST IMPLANTS

MENTOR®

This document describes the Mentor* Product Replacement Policy ("Replacement Policy") and the, Mentor Warranty ("Mentor Warranty"), for certain breast implant products that are acquired directly from Mentor and implanted in Australia on or after 1 March 2016.

* Mentor is a business unit of Johnson & Johnson Medical Pty Ltd ABN 85 000 160 403

Rupture, capsular contracture, and other risks are known risks of silicone-filled breast implants. The surgeon, as learned intermediary, is responsible for providing the patient with all appropriate risk information before surgery. In relation to its silicone-filled breast implants, Mentor makes available to all surgeons and patients a copy of its materials entitled "Gel-Filled Breast Implant Surgery: Making an Informed Decision". Copies are available from Johnson & Johnson Medical Pty Limited at the contact details below, or the surgeon. These materials are not intended to, and cannot, take the place of a full and informed discussion between surgeon and patient.

Mentor's Product Insert Data Sheet (PIDS) for MENTOR® Breast Implants state the implants are single use devices. Damage that occurs during or due to a re-operative procedure is not covered under any Mentor Warranty or Mentor Product Replacement Policy. Explantation and subsequent re-implantation also means that the implant can no longer be classified as being used for primary augmentation or primary reconstruction.

THIS DOCUMENT PROVIDES A LIMITED WARRANTY ONLY, AND IS SUBJECT TO THE TERMS AND CONDITIONS SET FORTH IN THIS DOCUMENT. ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, OTHER THAN THOSE THAT CANNOT BE EXCLUDED BY LAW SUCH AS THE ACL GUARANTEES SET OUT BELOW, ARE EXCLUDED. TO THE EXTENT PERMITTED BY LAW, 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. EXCEPT AS SET OUT IN THIS DOCUMENT, MENTOR NEITHER ASSUMES, NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER, OR ADDITIONAL LIABILITY, OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS. TO THE EXTENT PERMITTED BY LAW, MENTOR DOES NOT WARRANT OR OTHERWISE ASSUME LIABILITY FOR MENTOR PRODUCTS THAT HAVE NOT BEEN PROCURED DIRECTLY FROM MENTOR BY THE TREATING PHYSICIAN (OR THEIR AUTHORIZED BUYING AGENT).

OUR GOODS COME WITH GUARANTEES THAT CANNOT BE EXCLUDED UNDER THE AUSTRALIAN CONSUMER LAW. YOU ARE ENTITLED TO A REPLACEMENT OR REFUND FOR A MAJOR FAILURE AND 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. (**ACL GUARANTEES**)

1. The MENTOR Product Replacement Policy:

The Mentor Product Replacement Policy applies to MENTOR® MemoryGel® Breast Implants, Contour Profile Gel (CPG™) Breast Implants and MENTOR® Saline Breast Implants described in this document acquired directly from Mentor and implanted in Australia on or after 1 March 2016. In this document, "Qualifying Rupture" means any unexpected rupture (that is, a loss of shell integrity) of a MENTOR® MemoryGel® Silicone-Filled Breast Implants, Contour Profile Gel (CPG™) Silicone-Filled Breast Implants or MENTOR® Saline Breast Implants EXCEPT FOR the reasons noted in 3 (d) and 3 (e), below.

In the event of a Qualifying Rupture, MENTOR will, without limiting the ACL Guarantees, replace the product, free of charge, for the lifetime of the patient with the same value as the original product. Implantation of the MemoryGel® Breast Implant, Contour Profile Gel (CPG™) Breast Implant or MENTOR® Saline Breast Implant as well as any subsequent revision procedures, must be in accordance with current MENTOR product literature and accepted plastic surgical procedures by appropriately qualified licensed physicians for product to qualify for replacement under the MENTOR Product Replacement Policy. Should a more expensive MENTOR product (than the original) be requested by the physician, MENTOR will invoice the ordering customer for the list price difference between the ruptured product and the requested replacement product. Without limiting the ACL Guarantees, the explanted ruptured product must be returned to the MENTOR Product Evaluation Department within 60 days of its explant in order to qualify for the free of charge replacement product under the Mentor Product Replacement Policy. Without limiting the ACL Guarantees, in the event that the explanted product is not returned to the MENTOR Product Evaluation Department within 60 days of its explantation, the ordering customer will be invoiced for the price of the replacement product. Qualifying replacement product will be sent without shipping charges. At the surgeon's request,

MENTOR will also provide a replacement of a MENTOR® MemoryGel® Breast Implant, Contour Profile Gel (CPG™) Breast Implant or MENTOR® Saline Breast Implant to use to replace the contralateral implant, provided that the contralateral breast implant is a MENTOR product. There will be no charge for this courtesy except as outlined above.

Without limiting the ACL Guarantees, MENTOR will neither provide nor pay for a replacement with a non-MENTOR product under the terms of this Product Replacement Policy, nor in any event provide money for or in lieu of a MENTOR replacement product.

Limitation on the MENTOR Product Replacement Policy:

Without limiting the ACL Guarantees, if MENTOR's obligation to provide a replacement product under the Product Replacement Policy is prevented, restricted, or interfered with by reason of fire, flood, earthquake, explosion, or other casualty or accident, strikes or labor disputes, inability to procure supplies or power, war or other violence, any law, order, proclamation, regulation, ordinance, demand, or requirement of any government agency, or any other act or condition whatsoever beyond the reasonable control of MENTOR, the performance of that obligation shall be excused without penalty. For purposes of this provision, excuse of performance shall mean that MENTOR is neither obligated to provide nor pay for a replacement product, regardless of the product's source. Despite the excuse of MENTOR's obligation to provide a replacement product under this provision, MENTOR shall continue to perform its obligation to provide financial assistance for operating room, anesthesia, and surgical fee costs to the extent described under the MENTOR Warranty.

2. The Mentor Warranty:

The Mentor Warranty applies to MENTOR® MemoryGel® Breast Implants and Contour Profile Gel (CPG™) Breast Implants described in this document acquired directly from Mentor and implanted in Australia on or after 1 March 2016. Implantation (including any subsequent revision procedures) must be in accordance with current MENTOR product literature (including product package enclosures, data sheets, and other notifications or instructions published by Mentor), and accepted plastic surgical procedures by appropriately qualified licensed physicians.

Patients experiencing their primary augmentation or primary reconstruction date of implant on or after 1 March 2016, also automatically have, without limiting the ACL Guarantees, replacement product (with the same value as the original product) covered for ten (10) years from the date of primary implantation, for the following events that are not caused by a Qualifying Rupture:

(a) Capsular Contracture, Baker Grade III or Baker Grade IV as diagnosed by the attending surgeon. Baker Grade III: the breast is firm and looks abnormal (visible distortion) Baker Grade IV: the breast is hard, painful, and looks abnormal (greater visible distortion than Baker Grade III).

(b) Double Capsule, defined as when the initial capsule of fibrous scar tissue around the implant, formed as part of the normal healing process, separates with minor trauma, resulting in two layers of fibrous tissue surrounding the implant.

(c) Late-Forming Seroma, defined for the purposes of this document as a clinically symptomatic seroma that develops at least 12 months after the qualifying primary augmentation or primary reconstruction implant surgery with no intervening surgical procedures performed on the breast between the primary surgery and the development of the seroma.

Should a more expensive MENTOR product (than the original) be requested by the physician, MENTOR will invoice the ordering customer for the list price difference between the explanted product and the requested replacement product. Without limiting the ACL Guarantees, the explanted product must be returned to the MENTOR Product Evaluation Department within 60 days of its explant in order to qualify for the free of charge replacement product under the Mentor Warranty. Without limiting the ACL Guarantees, in the event that the explanted product is not returned to the MENTOR Product Evaluation Department within 60 days of its explantation, the ordering customer will be invoiced for the price of the replacement product. Qualifying replacement product will be sent without shipping charges. At the surgeon's request, MENTOR will also provide a replacement of a MENTOR® MemoryGel® Breast Implant or Contour Profile Gel (CPG™) Breast Implant to use to replace the contralateral implant, provided that the contralateral breast implant is a MENTOR product. There will be no charge for this courtesy except as outlined above.

Without limiting the ACL Guarantees, MENTOR will neither provide nor pay for a replacement with a non-MENTOR product under the terms of this Mentor Warranty, nor in any event provide money for or in lieu of a MENTOR replacement product.

In addition, under the Mentor Warranty and without limiting the ACL Guarantees, Mentor will pay a one-off payment of up to A$1,500 maximum aggregate amount toward operating room, surgeon, and anesthesia fees not paid, or payable by any form of insurance, or waived by the healthcare provider (that is, out of pocket expenses), and that are directly

related to replacement surgery (whether unilateral or bilateral) carried out within ten (10) years of the date of the primary implantation, in relation to a Qualifying Rupture, or the events set out in paragraphs 2(a) to (c) (whether or not caused by a Qualifying Rupture), for the following products: all MENTOR® MemoryGel® Silicone Breast Implants and all MENTOR® Contour Profile Gel (CPG™) Silicone Breast Implants.

3. The Mentor Product Replacement Policy and Mentor Warranty do not apply to:

(a) any adverse event other than the ones described in 2 (a), 2(b), and 2(c) in this document;

(b) removal of intact implants for size alteration;

(c) removal of intact implants due to wrinkling or rippling;

(d) loss of shell integrity caused by or during re-operative procedures; or

(e) loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures.

4. Other Warranty Restrictions

In the case of a Capsular Contracture Baker grade III , Capsular Contracture Baker grade IV, Double capsule or late seroma, the Replacement Product is, without limiting the ACL Guarantees, restricted to primary augmentation and primary reconstruction patients, defined as "first ever" implantation of breast implant(s), regardless of the type of implant or manufacturer of any previously-placed breast implant. A temporary tissue expander for reconstructive purposes will not be considered as a breast implant for an otherwise primary reconstruction.

Without limiting the ACL Guarantees, patients found to have enrolled non-primary implants or implanted prior to eligibility date will not be eligible for replacement product or financial assistance under the Mentor Warranty

5. Patient Information on the Mentor Product Replacement Policy and the Mentor Warranty

Before implantation surgery, the surgeon should explain the details of the Mentor Product Replacement Policy and (if applicable) the Mentor Warranty to the patient. The surgeon should advise the patient about possible adverse reactions and complications associated with MENTOR® Saline Breast Implants, MemoryGel® Breast Implants or Contour Profile Gel (CPG™) Breast Implants, including (as relevant) reviewing with the patient the "Gel-Filled Breast Implant Surgery: Making an Informed Decision," materials provided by Mentor.

It is important for the patient to maintain their own records to ensure validation of eligibility for the Mentor Product Replacement Policy and the Mentor Warranty.

6. Registration for the Mentor Warranty

The Mentor Warranty applies automatically and commences on the date of implantation. There is no need for patients to register their MemoryGel® Breast Implants or Contour Profile Gel (CPG™) Breast Implants.

7. Filing a Warranty Claim

Qualifying events must be reported to Mentor within the stated eligibility timeframe. The patient should contact, or request their surgeon contact either the Johnson & Johnson Medical Pty Limited Product Safety Department on (for Australia) 1800 252 194, (Option 4), or your surgeon's dedicated Mentor product specialist to report the event and organise return of the explanted product. Once notified of a claim, a representative of the Johnson & Johnson Medical Pty Limited Product Safety Department will contact the patient to obtain their consent to contact their surgeon to obtain any necessary medical records which may be required to help determine eligibility for the Mentor Warranty.

The following information may also be required to verify eligibility for financial assistance under the Mentor Product Replacement Policy or Mentor warranty:

(a) Information to document the patient's implant information (catalogue, serial #) and the patient's experience;

(b) the Operative report for the original implantation surgery to document Date of Implant;

(c) a copy of the Operative Report for the revision surgery;
(d) copies of bills showing out of pocket operating room, anesthesia, and surgeon fees incurred for the replacement surgery;
(e) copies of forms showing any relevant insurance Reimbursements (Explanation of Benefits forms);
(f) authorization, signed by the surgeon, allowing release and return of explanted product to MENTOR; and
(g) the removed and decontaminated MENTOR product returned to Mentor Product Evaluation in Irving Texas except where collection is not possible due to hospital policy or other reasons as documented by operating surgeon

All requests for information only should be sent to:

Product Safety Department

Johnson & Johnson Medical Pty Ltd

1-5 Khartoum Road

NORTH RYDE NSW 2113

AUSTRALIA

Email: RA-JNJAU-Complaint@ITS.JNJ.COM

Ph: 1800 252 194 Option 4 (Australia)

Requests for eligible replacement products may be ordered before surgery by contacting Mentor Customer Service on 1800 338 160.

Without limiting the ACL Guarantees, Mentor Worldwide LLC reserves the right to cancel, change, or modify the terms of the Mentor Product Replacement Policy or Mentor Warranty. Any such cancellation, change, or modification will not affect the stated terms as of the date of their implantation for those already enrolled in a Mentor warranty or the ACL Guarantees.

8. Additional Required Claim Information for the Mentor Warranty

Johnson & Johnson Medical's Product Safety team requires a photograph showing the appearance of the breast prior to the explant procedure to support replacement requests for Baker Grade III and Baker Grade IV capsular contracture, a copy of the cytology report to support late-forming seroma requests, or a photograph of intraoperative findings to support double capsule events.