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**THE MENTOR<sup>®</sup> LIFETIME PRODUCT  
REPLACEMENT POLICY and THE MENTOR<sup>®</sup>  
PATIENTCARE PROMISE LIMITED WARRANTY  
FOR MENTOR<sup>®</sup> AND PERTHESE™ SILICONE  
GEL-FILLED  
BREAST IMPLANTS, IMPLANTED ON OR  
AFTER MAY 1, 2013<sup>1</sup>,**

**A. Introduction**

(1) This document describes the Mentor Medical Systems C.V.'s ("Mentor") Lifetime Product Replacement Policy and the MENTOR<sup>®</sup> PatientCare Promise Limited Warranty for MENTOR<sup>®</sup> and PERTHESE™ Silicone Gel-Filled Breast Implants described later in this document.

(2) The MENTOR<sup>®</sup> Lifetime Product Replacement Policy and the MENTOR<sup>®</sup> PatientCare Promise Limited Warranty applies automatically to recipients of MENTOR<sup>®</sup> and PERTHESE™ Silicone Gel-Filled Breast Implants implanted on or after May 1<sup>st</sup> 2013 in the countries listed in Appendix 1.

(3) Rupture is among the known risks of Silicone Gel-Filled Breast Implants. The surgeon, as learned intermediary, is responsible for providing the patient with appropriate risk information before surgery, including (but not limited to) the risk of rupture. Mentor makes available to all surgeons and patients a copy of its **Informed Decision Brochure**. Copies can also be

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<sup>1</sup> Any MENTOR<sup>®</sup> or PERTHESE™ Silicone Gel-Filled Breast Implant, implanted prior to May 1st 2013 will be covered by the following respective warranty plans; MENTOR<sup>®</sup> PatientSafe Limited Warranty or Quality Assurance Program of PERTHESE™.

obtained by contacting Mentor directly, or through the Mentor web site. **This document is not intended to, and cannot, take the place of a full and frank discussion between surgeon and patient.**

(4) Provided that the conditions set herein are met, under the MENTOR<sup>®</sup> PatientCare Promise Limited Warranty, Mentor will pay, up to defined maximum amounts, certain uninsured<sup>2</sup>, out-of-pocket costs directly related to revision surgery necessitated by a covered event (qualifying rupture) for the following products: Smooth Round Low Profile Gel, Smooth Round Moderate Profile Gel, Smooth Round Moderate Plus Profile Gel, Smooth Round High Profile Gel, Smooth Round Ultra High Profile Gel, Siltex<sup>®</sup> Round Moderate Profile Gel, Siltex<sup>®</sup> Round Moderate Plus Profile Gel, Siltex<sup>®</sup> Round High Profile Gel, Siltex<sup>®</sup> Round Ultra High Profile Gel, and the Contour Profile<sup>®</sup> Gel Family of products. It will also cover the following PERTHESE™ and PERTHESE™ Esthea Silicone Gel-Filled Breast Implants: TX Low Profile Micro-Textured, MX Moderate Profile Micro-Textured, MP Moderate Plus Profile Micro-Textured, 540 High Profile Micro-Textured, 550 Ultra High Profile Micro-Textured, 700T Low Profile Smooth, 510T High Profile Smooth, ELP Micro-Textured, EHP Micro-Textured, ESHP Micro-Textured, AX Micro-Textured, EFP Micro-Textured and EMP Micro-Textured, EMHP Micro-Textured<sup>3</sup>.

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<sup>2</sup> Not paid or payable partially or wholly by any form of insurance and/or national health care funds

<sup>3</sup> All other MENTOR<sup>®</sup> and PERTHESE™ Breast Implants not specified in section A.4 will only be covered under MENTOR<sup>®</sup> Lifetime Product Replacement Policy. Please refer to "MENTOR<sup>®</sup> Lifetime Product Replacement Policy" document

(5) THIS IS A LIMITED WARRANTY ONLY AND IS SUBJECT TO THE TERMS AND CONDITIONS SET FORTH IN THIS DOCUMENT. ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS ARE EXCLUDED, TO THE EXTENT PERMITTED BY LOCAL LAWS. 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. TO THE EXTENT PERMITTED BY LAW MENTOR NEITHER ASSUMES, NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS

**B. Application of the MENTOR<sup>®</sup> Lifetime Product Replacement Policy and the MENTOR<sup>®</sup> PatientCare Promise Limited Warranty**

1. The MENTOR<sup>®</sup> Lifetime Product Replacement Policy and the MENTOR<sup>®</sup> PatientCare Promise Limited Warranty applies only to MENTOR<sup>®</sup> and PERTHESE™ Silicone Gel-Filled Breast Implants described in section A.4 of this document, and implanted on or after May 1st 2013 in the countries listed in index appendix 1. Implantation must be in accordance with current Mentor and Perthese product literature (including product package inserts, enclosures, data sheets, and other notifications or instructions published by Mentor ) and accepted plastic surgical procedures by appropriately qualified, licensed surgeons.

2. The MENTOR<sup>®</sup> Lifetime Product Replacement Policy and the MENTOR<sup>®</sup> PatientCare Promise Limited Warranty apply only to the following covered events:



2.1 rupture due to wear or delamination (“**qualifying rupture**”) requiring surgical intervention (for all MENTOR® and PERTHESE™ Silicone Gel-Filled Breast Implants described in section A.4 of this document) ;

2.2 Capsular Contracture Baker GRADE III / IV in augmentation, requiring surgical intervention (for all MENTOR® and PERTHESE™ Silicone Gel-Filled Breast Implants described in section A.4 of this document).

3. The MENTOR® Lifetime Product Replacement Policy and the MENTOR® PatientCare Promise Limited Warranty may also apply to other event-related losses of shell integrity not specifically excluded; applicability is subject to Mentor’s sole discretion.

4. The MENTOR® Lifetime Product Replacement Policy and the MENTOR® PatientCare Promise Limited Warranty do not apply to; (a) removal of intact implants for size alteration; (b) removal of intact implants due to wrinkling or rippling; (c) loss of implant shell integrity caused by re-operative procedures; (d) loss of implant shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures; (f) surgery on the opposite breast to replace an intact implant.

### **C. What Mentor will provide under the MENTOR® Lifetime Product Replacement Policy and the MENTOR® PatientCare Promise Limited Warranty**

1. In the event of a qualifying rupture of a MENTOR® or PERTHESE™ Gel-Filled Breast Implant, Mentor will replace the product, free of charge for the lifetime of the patient, provided that eligibility is proven and confirmed by Mentor based on its evaluation of explanted product and assessment of all required documentation. Mentor will provide a replacement by Mentor or Perthese product of any size in the same or

similar style as the originally implanted product. Implantation of the original MENTOR® or PERTHESE™ Gel-Filled Breast Implant, as well as any subsequent procedures, must be in accordance with current Mentor and Perthese product literature and accepted plastic surgical procedures by appropriately qualified licensed surgeons for the product to qualify for replacement under the MENTOR® Lifetime Product Replacement Policy. Should a more expensive style be requested by the surgeon, Mentor will invoice the ordering customer for the list price difference between the confirmed rupture product - and the requested replacement product. Mentor will neither provide nor pay for a non-Mentor or non Perthese product under the terms of this Lifetime Product Replacement Policy, nor in any event provide money for or in lieu of a Mentor or Perthese replacement product. Any replacement MENTOR® and PERTHESE™ Silicone Gel-Filled Breast Implant described in section A.4 of this document automatically includes a new MENTOR® PatientCare Promise Limited Warranty covering the replacement implant only.

Financial assistance: When a replacement surgery due to qualifying rupture occurs within ten years from the date of implantation and provided that eligibility is proven and confirmed by Mentor based on its assessment and evaluation, Mentor will pay uninsured, out-of-pocket costs for operating room, anesthesia and/or surgical expenses directly related to revision surgery up to a maximum aggregate amount of €1000 (£700). Operating room and anesthesia charges shall be given payment priority.

In such cases, the request for financial assistance under the MENTOR® PatientCare Promise Limited Warranty must be made to the local Mentor branch or distributor, as applicable, by or on behalf of patient.

Financial assistance does not imply a loan to the patient.

2. In the event of Capsular Contracture Baker GRADE III / IV in augmentation surgery of a MENTOR® or PERTHESE™ Gel-Filled Breast Implant, Mentor will replace the product, free of charge for the period of 10 years from the date of implantation, provided that eligibility is proven and confirmed by Mentor based on its evaluation of explanted product and assessment of all required documentation. Mentor will provide a replacement Mentor or Perthese product of any size in the same or similar style as the originally implanted product. Implantation of the original MENTOR® or PERTHESE™ Gel-Filled Breast Implant, as well as any subsequent procedures, must be in accordance with current Mentor and Perthese product literature and accepted plastic surgical procedures by appropriately qualified licensed surgeons for the product to qualify for replacement under the MENTOR® PatientCare Promise Limited Warranty. Should a more expensive style be requested by the surgeon, Mentor will invoice the ordering customer for the list price difference between the confirmed capsular contracture Baker III or IV product and the requested replacement product. Mentor will neither provide nor pay for a non-Mentor or non Perthese product under the terms of this Policy, nor in any event provide money for or in lieu of a Mentor or Perthese replacement product. Any replacement MENTOR® and PERTHESE™ Silicone Gel-Filled Breast Implant described in section A.4 of this document automatically includes a new MENTOR® PatientCare Promise Limited Warranty covering the replacement implant only.

**D. Limitation on the MENTOR® Lifetime Product Replacement Policy:** If Mentor’s ability to provide a replacement product 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 under this warranty shall be excused without penalty.

### **Patient Information on the MENTOR® Lifetime Product Replacement Policy and the MENTOR® PatientCare Promise Limited Warranty**

Before implantation surgery, the surgeon should explain the details of the MENTOR® Lifetime Product Replacement Policy and the MENTOR® PatientCare Promise Limited Warranty to the patient, and provide the patient with a copy of this document. In addition to explaining the terms of the MENTOR® Lifetime Product Policy and the MENTOR® PatientCare Promise Limited Warranty, the surgeon should also advise the patient about possible adverse reactions and complications associated with the Silicone Gel-Filled Breast Implants, and review with the patient the Informed Decision Brochure provided by Mentor.

#### **E. Filing a Claim**

1. In case of claimed qualifying rupture, the customer should contact the local Mentor representative to obtain a return kit and instructions to send the following documents to Mentor Product Evaluation Department:

- (a) Authorizations, signed by the patient, allowing release of medical records/patient's file related to breast implant surgery;
- (b) A copy of the patient's file related to breast implant surgery, including the Operative Report for the initial surgery; provided proper consent is given as described under a) above;
- (c) A copy of the Operative Report for the revision surgery (if already performed);
- (d) The removed and decontaminated Mentor or Perthese product;
- (e) Copies of forms showing any relevant insurance reimbursements;

(f) Fully completed FER (Field Experience Report Form) form on paper or in Web Portal.

2. In case of claimed Capsular Contracture Baker GRADE III / IV in augmentation surgery, besides documentation under E 1 a) – f), also picture of Thorax must be provided for eligibility assessment.

For more information on mailing such documentation, please see Mentor's website, <http://www.mentorwllc.eu/warranty-info>

The explanted product and all required documents specified under E.1 and E.2 must be returned to the Mentor Product Evaluation Department within 60 days following the claim is reported to Mentor local affiliate, in order for the claim to qualify for eligibility assessment under MENTOR® PatientCare Promise Limited Warranty and / or MENTOR® Lifetime Product Replacement Policy.

In the event that the explanted product and all required documents are not returned to the Mentor Product Evaluation Department within the above deadline, Mentor reserves the right to consider the claim closed without further assessment.

Provided that eligibility is proven and confirmed by Mentor based on its assessment and evaluation, a replacement product or a returned product credit will be issued to the ordering customer. The replacement product will be sent without shipping charges if the order is received in the Mentor Product Evaluation Department at least three business days prior to scheduled delivery date; otherwise, freight charges will be invoiced to the ordering customer

Replacement products may be ordered before surgery by contacting your local Mentor branch or distributor, as appropriate.

3. Should the Mentor's evaluation based on claim substantiated with complete documentation under E.1 confirm:

- a) the assessed case as qualifying rupture and
- b) that the replacement surgery due to such qualifying rupture occurred within ten years from the date of implantation

Mentor will require the claimant to submit in particularly the following documentation for financial assistance eligibility assessment:

- a copy of bills or receipts associated with the revision surgery

Provided the eligibility for financial assistance is proven, Mentor will pay uninsured, out-of-pocket costs for operating room, anesthesia and/or surgical expenses directly related to revision surgery up to a maximum aggregate amount of €1000 (£700).

Local Mentor affiliate SOP determines the process of payment.

#### **F. Applicable law and Jurisdiction**

This MENTOR® Lifetime Product Replacement Policy and the MENTOR® PatientCare Promise Limited Warranty will be governed by Dutch law and the courts of The Hague, the Netherlands have exclusive jurisdiction to settle any claim arising from or connected with this Lifetime Product Replacement Policy and the MENTOR® PatientCare Promise Limited Warranty.

This provision does not derogate from, and does not intend to limit, the patients' non-waivable essential rights as provided in overriding local law mandatory provisions, if more favorable to same patients

Mentor reserves the right to cancel, change, or modify the terms of the MENTOR® Lifetime Product Replacement Policy and/or the MENTOR® PatientCare Promise Limited Warranty. Any such cancellation, change, or modification will not affect the currently stated terms for those already enrolled therein.

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**Appendix 1: List of Applicable Countries and Warranty Start Dates<sup>4</sup>**

ALBANIA	May. 1, 2013
ARMENIA	May. 1, 2013
AUSTRIA	May. 1, 2013
AZERBAIJAN	May. 1, 2013
BAHRAIN	May. 1, 2013
BELARUS	May. 1, 2013
BELGIUM	Under Revision
BULGARIA	May. 1, 2013
BURKINA FASO	May. 1, 2013
CROATIA	May. 1, 2013
CYPRUS	May. 1, 2013
CZECH REPUBLIC	May. 1, 2013
DENMARK	May. 1, 2013
EGYPT	May. 1, 2013
ESTONIA	May. 1, 2013
FINLAND	May. 1, 2013
FRANCE	May. 1, 2013
GEORGIA	May. 1, 2013
GERMANY	May. 1, 2013
GREECE	May. 1, 2013
GUADELOUPE	May. 1, 2013
GUYANE FRANÇAISE	May. 1, 2013
HUNGARY	May. 1, 2013
ICELAND	May. 1, 2013
IRAQ	May. 1, 2013
IRELAND	May. 1, 2013
ISRAEL	Under Revision
ITALY	May. 1, 2013
JORDAN	May. 1, 2013
KUWAIT	May. 1, 2013
LATVIA	May. 1, 2013

LEBANON	May. 1, 2013
LICHTENSTEIN	May. 1, 2013
LITHUANIA	May. 1, 2013
LYBIA	May. 1, 2013
LUXEMBURG	May. 1, 2013
MACEDONIA	May. 1, 2013
MARTINIQUE	May. 1, 2013
MAYOTTE	May. 1, 2013
MONTENEGRO	May. 1, 2013
MOROCCO	May. 1, 2013
NETHERLANDS	Under Revision
NORWAY	May. 1, 2013
NOUVELLE CALÉDONIE	May. 1, 2013
OMAN	May. 1, 2013
PAKISTAN	May. 1, 2013
PALESTINE	May. 1, 2013
POLAND	May. 1, 2013
POLYNÉSIE FRANÇAISE	May. 1, 2013
PORTUGAL	May. 1, 2013
QATAR	May. 1, 2013
REUNION	May. 1, 2013
ROMANIA	May. 1, 2013
RUSSIA	Under Revision
ST MARTIN	May. 1, 2013
ST PIERRE ET MICLON	May. 1, 2013
SAUDI ARABIA	May. 1, 2013
SERBIA	May. 1, 2013
SLOVAKIA	May. 1, 2013
SLOVENIA	May. 1, 2013
SOUTH AFRICA	May. 1, 2013
SPAIN	May. 1, 2013
SWEDEN	May. 1, 2013
SWITZERLAND	May. 1, 2013
SYRIA	May. 1, 2013
TURKEY	May. 1, 2013
UK	May. 1, 2013
UKRAINE	May. 1, 2013
UNITED ARAB EMIRATES	May. 1, 2013
UZBEKISTAN	May. 1, 2013
WALLIS & FUTUNA	May. 1, 2013
YEMEN	May. 1, 2013

<sup>4</sup> For countries stated "Under Revision" : Applicability of warranty is under assessment from local law – subject to local authority approval