

## **THE MENTOR<sup>®</sup> LIFETIME PRODUCT REPLACEMENT POLICY FOR MENTOR<sup>®</sup> AND PERTHESE<sup>™</sup> BREAST IMPLANTS, IMPLANTED ON OR AFTER MAY 1, 2013<sup>1</sup>**

### **Introduction**

This document describes the Mentor Medical Systems C.V.'s ("Mentor") Lifetime Product Replacement Policy for other MENTOR<sup>®</sup> and PERTHESE<sup>™</sup> Breast Implants (not specified in section A.4 of "THE MENTOR<sup>®</sup> LIFETIME PRODUCT REPLACEMENT POLICY and THE MENTOR<sup>®</sup> PATIENTCARE PROMISE LIMITED WARRANTY FOR MENTOR<sup>®</sup> AND PERTHESE<sup>™</sup> SILICONE GEL-FILLED BREAST IMPLANTS" document)

The MENTOR<sup>®</sup> Lifetime Product Replacement Policy applies automatically to recipients of all MENTOR<sup>®</sup> and PERTHESE<sup>™</sup> Breast Implants implanted on or after May 1<sup>st</sup> 2013 in the countries listed in Appendix 1.

In the event of a rupture or deflation (leaking) due to wear or delamination, 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.

To take advantage of this policy, any MENTOR<sup>®</sup> or PERTHESE<sup>™</sup> Breast Implants that are replaced must be returned to Mentor for eligibility assessment and shall then become the property of Mentor. This replacement policy is limited to replacement of the MENTOR<sup>®</sup> and PERTHESE<sup>™</sup> Breast Implants and

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<sup>1</sup> Any MENTOR<sup>®</sup> or PERTHESE<sup>™</sup> Breast Implant, implanted prior to May 1st 2013 will be covered by the following respective replacement policies; MENTOR<sup>®</sup>Product Replacement Policy or PERTHESE<sup>™</sup>Product Replacement Policy

Mentor shall not be responsible for any incidental or consequential damages of any kind, directly or indirectly, arising from the use of this product, including without limitation, medical, surgical and hospital costs or the reimbursement for the cost of breast implants not manufactured by Mentor. This replacement policy shall only be effective provided that Mentor manufactures breast implants at the time the request for replacement is made. Mentor expressly disclaims all warranties, whether express or implied by operation of law or otherwise, whether written or oral, including without limitation, any implied warranties of merchantability, fitness, or design, to the extent permitted by local laws. Mentor shall have no responsibility for any statements or representations, whether oral or written, made by any other person or entity.

Mentor makes no representation as to the life expectancy of a breast implant. There are conditions which may cause these devices to wear out or malfunction and require replacement. These devices should not be considered lifetime implants.

The MENTOR<sup>®</sup> Lifetime Product Replacement Policy 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; (e) surgery on the opposite breast to replace an intact implant (g) capsular contracture.

### **Filling a Claim**

In case of claimed rupture or deflation (leaking) due to wear or delamination, 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

The explanted product and required documented specified herein 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 this MENTOR<sup>®</sup> 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

For more information on returning the explanted product, please see Mentor's website, <http://www.mentorwllc.eu/warranty-info>

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.

Replacement products may be ordered before surgery by contacting your local Mentor branch or distributor, as appropriate. Mentor reserves the right to cancel, change, or modify the terms of the MENTOR<sup>®</sup> Lifetime Product Replacement Policy. Any such cancellation,



change, or modification will not affect the currently stated terms for those already enrolled therein.

### Applicable Law and Jurisdiction

This MENTOR® Lifetime Product Replacement Policy 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 MENTOR® Lifetime Product Replacement Policy.

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

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### Appendix 1: List of Applicable Countries and Warranty Start Dates<sup>2</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

<sup>2</sup> For countries stated "Under Revision" : Applicability of Lifetime Replacement Policy is under assessment from local law – subject to local authority approval

DENMARK	May. 1, 2013	SLOVENIA	May. 1, 2013
EGYPT	May. 1, 2013	SOUTH AFRICA	May. 1, 2013
ESTONIA	May, 1, 2013	SPAIN	May. 1, 2013
FINLAND	May. 1, 2013	SWEDEN	May. 1, 2013
FRANCE	May. 1, 2013	SWITZERLAND	May. 1, 2013
GEORGIA	May. 1, 2013	SYRIA	May. 1, 2013
GERMANY	May. 1, 2013	TURKEY	May. 1, 2013
GREECE	May.1, 2013	UK	May. 1, 2013
GUADELOUPE	May.1, 2013	UKRAINE	May. 1, 2013
GUYANE FRANÇAISE	May. 1, 2013	UNITED ARAB EMIRATES	May. 1, 2013
HUNGARY	May. 1, 2013	UZBEKISTAN	May, 1, 2013
ICELAND	May. 1, 2013	WALLIS & FUTUNA	May, 1, 2013
IRAQ	May. 1, 2013	YEMEN	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		