MENTORPROMISE PROTECTION PLAN FOR MENTOR® BREAST IMPLANTS

A. Introduction

1. This document describes Mentor Medical Systems B.V's ("Mentor")'s MENTORPromise Protection Plan for the MENTOR® Breast Implants and for MENTOR® Breast Tissue Expanders described in this document.

2. The MENTORPromise Protection Plan applies to patients who are implanted with certain MENTOR® Memory Gel Breast Implants on or after July 1st 2017 **[Adjust date as per your country]** and/or MENTOR® CPX™4 Breast Tissue Expander, on or after November 1st 2021. Once a patient receives a MENTOR® Breast Implant or a MENTOR® Breast Tissue Expander as set out in this document, patient is automatically enrolled in the MENTORPromise Protection Plan.

For MENTOR® or PERTHESE™ Breast Implants implanted before July 1st 2017 please refer to Appendix 1.

3. Risks such as rupture and capsular contracture are known risks of breast implants. Likewise, risk of deflation is a known risk of breast tissue expanders. The surgeon ("surgeon" is defined as a physician qualified to practice surgery who is performing the breast implant surgery), as learned intermediary, is responsible for providing the patient with appropriate risk information before surgery, including (but not limited to) the risk of rupture or deflation. Mentor makes available to all surgeons and patients a copy of its Making an Informed Decision - Patient Brochure. Copies can also be obtained by visiting http://www.mentorwwllc.eu/safety-info. This document is not meant to replace or substitute the important and thorough discussion that should take place between a surgeon and the patient. Furthermore, it does not fulfill the legal requirements for patient consent in the specific jurisdictions mentioned in Appendix 3.

Mentor's Product Insert Data Sheet (PIDS) for MENTOR® Breast Implants or MENTOR® Breast Tissue Expanders states that the implants are single use devices. Damage that occurs during or due to a re-operative procedure is not covered under any MENTORPromise Protection Plan. Explantation and subsequent re-implantation also means that the implant can no longer be classified as being used for primary augmentation or primary reconstruction, where – for avoidance of any doubts – "primary augmentation" or "primary reconstruction" are intended as the first time that the patient's tissues come in contact with breast implants. Before implantation surgery, the surgeon should explain the details of the MENTORPromise Protection Plan to the patient, and provide the patient with a copy of the MENTORPromise Warranty document. In addition to explaining the terms of the MENTORPromise Protection Plan, the surgeon should also advise the patient about possible adverse reactions and complications associated with Breast Implants and/or Tissue Expanders (as applicable), and review with the patient the Informed Decision Brochure provided by Mentor. For more information please read the Important Safety Information in Appendix 2.

4. Provided that the conditions set herein are met, under the MENTORPromise Protection Plan, Mentor:

i) will pay an amount equivalent to a maximum aggregate of €1000 based on the exchange rate on the payment date for certain uninsured (not paid or payable partially or wholly by any form of insurance and/or national health care funds) costs directly related to revision surgery necessitated by a Qualifying Rupture (as defined in section B.2.1) for the following MENTOR® Memory Gel Breast Implants: Smooth Round Gel, SILTEX™ Round Gel, and the Contour Profile Gel Family of products (MENTOR® CPG™ Breast Implant).
ii) will provide a replacement expander for MENTOR® CPX™4 Breast Tissue Expander.

5. MENTORPromise Protection Plan represents ~~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 not applicable, 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 MENTOR® Breast Implants or MENTOR® Breast Tissue Expanders, to the extent permitted by local laws. To the extent permitted by local laws Mentor neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with these products. Mentor does not warrant or otherwise assume liability for MENTOR® Products that have not been procured directly from Mentor or from Mentor authorized distributors by the treating physician (or their authorized buying agent), to the extent permitted by local laws.

B. Application of the MENTORPromise Protection Plan

1. The MENTORPromise Protection Plan applies only to MENTOR® Breast Implants and Tissue Expanders set out in this document. Implantation of the original MENTOR® Breast Implant or MENTOR® Breast Tissue Expander as applicable, as well as subsequent procedures, must be in accordance with current MENTOR® 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 for the product to qualify for replacement under the MENTORPromise Protection Plan.

2. Product replacement under the MENTORPromise Protection Plan applies only in case of the following covered events:

2.1 Rupture or deflation (leaking) due to wear or delamination ("Qualifying Rupture") requiring surgical intervention (for all MENTOR® Breast Implants, including MENTOR® Breast Tissue Expanders).

2.2 Capsular Contracture Baker GRADE III / IV in augmentation, requiring surgical intervention (for MENTOR® Breast Implants described in section A.4.i) of this document).

2.3 Double Capsule formation in augmentation, 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 (for MENTOR® Breast Implants described in section A.4.i) of this document).

2.4 Late-Stage Seroma in augmentation, defined for the purposes of this document as clinically symptomatic seroma that develops at least 12 months later 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 (for MENTOR® Breast Implants described in section A.4.i) of this document).

2.5 BIA-ALCL (Breast implant-associated anaplastic large cell lymphoma) in augmentation defined for the purposes of this document as a rare form of lymphoma that can be associated with breast implants. It belongs to the variety of immune system cancer and is not breast cancer.

2.6 At the surgeon's request, Mentor will also provide a replacement of any MENTOR® Breast Implant 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 in this document.

3. The MENTORPromise Protection Plan does not apply to any adverse event other than the ones described in 2.1, 2.2, 2.3, 2.4, 2.5 and 2.6 in this document including without limitation:

(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, before or during operative procedures;
(d) Loss of implant shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures.

C. What Mentor will provide under the MENTORPromise Protection Plan

1. In the event of a Qualifying Rupture of a MENTOR® Breast Implant:

1.1. Product Replacement: Mentor will replace the MENTOR® Breast Implant, free of charge for the lifetime of the patient, provided that eligibility is proven and confirmed by Mentor based on its assessment and evaluation of explanted breast implant and assessment of all required documentation. Mentor will provide a replacement MENTOR® Breast Implant of any size in the same or similar style as the originally implanted product. Should a more expensive style be requested by the surgeon, Mentor will invoice the ordering customer for the list price difference between the confirmed ruptured product - and the requested replacement product. Mentor will neither provide nor pay for a non-MENTOR® Breast Implant under the terms of this MENTORPromise Protection Plan, nor in any event provides money for or in lieu of a MENTOR® replacement Breast Implant. Any replacement of a MENTOR® Breast Implant automatically includes a new MENTORPromise Protection Plan covering the replacement implant only.

1.2. Financial assistance: If a replacement with MENTOR® Breast Implant or removal surgery (without replacement) is required within ten years from the implantation date due to Qualifying Rupture or BIA-ALCL (as defined in section B.2.1. and B.2.5.), Mentor offers financial assistance. This applies in the countries listed in Appendix 3, and eligibility must be proven and confirmed by Mentor through assessment and evaluation of the explanted breast implant and necessary documentation. Under this financial assistance program, Mentor covers uninsured costs for operating room, anesthesia, and/or surgical expenses directly related to the revision surgery, up to a maximum aggregate amount of €1000 (as stated in section 4i). The payment priority is given to operating room and anesthesia charges. In the case of a contralateral MENTOR® Breast Implant replacement (as defined in section 2.6.), the financial assistance amount will not exceed the equivalent of €1000 based on the exchange rate on the payment date.

In such cases, the request for financial assistance under the MENTORPromise Protection Plan must be made to the local Mentor branch or distributor, as applicable, by or on behalf of patient. Alternatively the request for financial assistance can be made to the Mentor branch or distributor in the country where the revision surgery took place. Financial assistance does not imply a loan to the patient. Financial assistance is applicable in eligible countries. Please contact your Mentor representative to know if financial assistance is available in the country of request initiation. No financial assistance will be granted when a breast implant other than a MENTOR® Breast Implant is requested in the surgery by the surgeon or the patient. No financial assistance will be granted in the case of deflation of a MENTOR® CPX™4 Breast Tissue Expander.

2. In the event of Capsular Contracture Baker GRADE III / IV, Double Capsule formation or Late-Stage Seroma (as defined in section B.2.2, B.2.3 and B.2.4) in a surgery of a MENTOR® Breast Implant, Mentor will replace the product, free of charge for the period of ten (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® Breast Implant of any size in the same or similar style as the originally implanted product. 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, Double Capsule or Late-Stage Seroma product and the requested replacement product. Mentor will neither provide nor pay for a non-MENTOR® Breast Implant under the terms of this Policy, nor in any event provides money for or in lieu of a MENTOR® Replacement Product. Any replacement MENTOR® Breast Implant described in section A.4.i) of this document automatically includes a new MENTORPromise Protection Plan covering the replacement implant only.

D. Limitation on the MENTORPromise Protection Plan regarding Product Replacement: 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, pandemic, health emergencies, 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 MENTORPromise Protection Plan shall be excused without penalty. 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 in case of a Qualifying Rupture as per C.1.2 herein above.

E. Patient Information on the MENTORPromise Protection Plan: Before implantation surgery, the surgeon should explain the details of the MENTORPromise Protection Plan to the patient, and provide the patient with a copy of the MENTORPromise Warranty document. In addition to explaining the terms of the MENTORPromise Protection Plan, the surgeon should also advise the patient about possible adverse reactions and complications associated with breast implants, and review with the patient the Informed Decision Brochure provided by Mentor.

F. Filing a Claim

1. In case of claimed Qualifying Rupture: the surgeon should contact the local Mentor representative to obtain a return kit and instructions to send the following documents and medical devices 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® Product or its photos in the event when shipment of the MENTOR® Product is not feasible;
(e) Copies of forms showing any relevant insurance reimbursements;
(f) Fully completed FER (Field Experience Report Form) in Web Portal or e-mailed to the Mentor-PE@its.jnj.com.

Ship to:
Mentor Returns
C .G. Laboratories, Inc.
1410 Southtown Dr.
Granbury, TX 76048
USA

If after the evaluation of the claim and supporting complete documentation Mentor confirms the assessed case as (i) Qualifying Rupture and (ii) 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 a copy of bills or receipts associated with the revision surgery for financial assistance eligibility assessment.

Only in the case the Qualifying Rupture involved a MENTOR® Breast Implant and provided the eligibility for financial assistance is proven, Mentor will pay uninsured costs for operating room, anesthesia and/or surgical expenses directly related to revision surgery up to the amount equivalent to a maximum aggregate of €1000. Local Mentor affiliate SOP determines the process of payment.

2. In case of claimed Capsular Contracture Baker GRADE III/IV, Double Capsule or Late Stage Seroma in a surgery, besides documentation under F.1 (a) – (f), also a picture of the patient's thorax must be provided for eligibility assessment.

The explanted product and all required documents specified under F.1 and F.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 MENTORPromise Protection Plan.

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 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.

At the surgeon's request, Mentor will also provide a replacement of a MENTOR® 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.

Replacement products may be ordered before surgery by contacting your Mentor branch or distributor in the country of the planned revision surgery, as appropriate.

G. Applicable law and Jurisdiction

This MENTORPromise Protection Plan is governed by Dutch law. The courts of The Hague, the Netherlands have exclusive jurisdiction to settle any claim arising from or connected with this MENTORPromise Protection Plan.

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 Promise Protection Plan. Any such cancellation, change, or modification will not affect the currently stated terms for those already enrolled therein.

Appendix 1:

For MENTOR® or PERTHÈSE™ Breast Implants implanted before July 1st 2017, the following MENTORPromise Protection Plan will apply:

a) Lifetime Product Replacement Policy for MENTOR® Breast Implants implanted on or after December 1st 2002;
b) The Mentor PatientSafe Promise Limited warranty for MENTOR® Breast Implants implanted on or after October 1st 2005;
c) The Perthese warranty for PERTHÈSE™ Breast Implants implanted on or after November 10th 2005
d) The Mentor PatientSafe Promise Limited warranty for MENTOR® and PERTHÈSE™ Breast Implants implanted on or after May 1st 2013.

Appendix 2 - Important Safety Information:

MENTOR® Breast Implants are indicated for breast augmentation, in women who are at least 18 years old, or for breast reconstruction. Breast implant surgery should not be performed in those women with active infection anywhere in their body, those with existing cancer or pre-cancer of their breast(s), those who have not received adequate treatment for these conditions or those who are pregnant or nursing. There are risks associated with breast implant surgery. Breast implants are not lifetime devices and breast implantation is not necessarily a one-time surgery. Patients may require additional unplanned surgeries on the breast(s) because of complications or unacceptable cosmetic outcomes. Many of the changes to the breast(s) following implantation are irreversible (cannot be undone) and breast implants may affect the ability to breastfeed, either by reducing or eliminating milk production. The most common complications with MENTOR® MemoryGel™ Breast Implants include re-operation, implant removal, capsular contracture, asymmetry, and breast pain. A lower risk of complication is implant rupture, which is most often silent (meaning neither you nor your doctor will know you have a rupture). The health consequences of a ruptured silicone gel-filled breast implant have not been fully established. Screenings such as mammography, MRI, or ultrasound are recommended after initial implant surgery to assist in detecting implant rupture.

The most common complications with MENTOR® Breast Implants include re-operation, implant removal, capsular contracture, wrinkling, deflation, asymmetry, and breast pain. Patients are reminded to discuss the indications, contraindications, warnings, precautions and the risks and benefits associated with MENTOR® Breast Implants with their surgeon and review the Important Safety Information provided at www.mentorwwllc.eu. It is important that patients understand the risks associated with breast implant surgery when considering MENTOR® Breast Implants.

Appendix 3:
Mentor Medical Systems B.V
Zernikedreef 2
2333 CL Leiden
The Netherlands
www.mentorwwllc.eu

List of countries for which the MENTORPromise Protection Plan on MENTOR® Breast Implants **applies, effective July 1st 2017:**

Albania
Algeria
Armenia
Austria
Azerbaijan
Bahrain
Belarus
Belgium
Botswana
Bulgaria
Burkina Faso
Burundi
Croatia
Cyprus
Czech Republic
Denmark
Egypt & Libya
Eritrea
Estonia
Ethiopia
Finland
France
Georgia
Germany
Ghana
Greece
Guadeloupe
Guyana Française
Hungary
Iceland
Iraq
Ireland
Italy
Ivory Coast
Jordan
Kenya
Kuwait
La Reunion
Latvia
Lebanon
Liberia
Liechtenstein
Lithuania
Luxemburg
Libya
Macedonia
Morocco
Martinique
Mauritius
Montenegro
Namibia
Netherlands
Nigeria
Norway
Nouvelle Caledonia
Oman
Pakistan
Palestine
Poland
Polynesia Française
Portugal
Qatar
Romania
Saudi Arabia
Serbia
Slovak Republic
Slovenia
South Africa
Spain
St. Martin
St. Pierre et Miclon
Sudan
Sweden
Switzerland
Tunisia
Turkey
UAE

Uganda
UK
Uzbekistan
Yemen
Zambia
Zimbabwe

List of countries for which clauses A.4 and C.1.2 do not apply:

Bosnia a. Herzegovina
Central Asia (Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan, Uzbekistan)
Kosovo
Moldova
Russia
Ukraine

List of countries for which clauses A.4, B.2.2, B.2.3, B.2.4, B.2.5, C.1.2, and C.2 do not apply:

Israel

List of countries for which the MENTORPromise Protection Plan on MENTOR® Breast Tissue Expanders applies, effective October 1st 2021

Algeria
Armenia
Austria
Azerbaijan
Bahrain
Belgium
Botswana
Burkina Faso
Burundi
Cyprus
Denmark
Egypt & Libya
Eritrea
Ethiopia
Finland
France
Germany
Ghana
Greece
Guadeloupe
Guyana Française
Iceland
Ireland
Italy
Ivory Coast
Jordan
Kenya
Kuwait
La Reunion
Lebanon
Liberia
Liechtenstein
Luxemburg
Libya
Morocco
Martinique
Mauritius
Namibia
Netherlands
Nigeria
Norway
Nouvelle Caledonia
Oman
Pakistan
Palestine
Polynesia Française
Portugal
Qatar
Russia
Saudi Arabia
South Africa
Spain
St. Martin
St. Pierre et Miclon
Sudan
Sweden
Switzerland
Tunisia
Turkey
UAE
Uganda
UK
Uzbekistan
Yemen
Zambia
Zimbabwe