# WARRANTY

# CEREFORM<sup>®</sup> SILICONE GEL-FILLED BREAST IMPLANTS





# EUROMI BIOSCIENCES

Zoning Industriel des Plenesses 11 rue des Nouvelles Technologies 4821 Andrimont (BE) Tel. : +32(0) 87 29 22 22 Fax : +32(0) 87 29 22 23

www.euromi-biosciences.com info@euromi-biosciences.com

#### EUROMI BIOSCIENCES COMMITMENT

Our commitment is expressed by our desire to offer you efficient and reliable products in combination with impeccable service, in compliance with applicable standards and regulations.

It is with this in mind that we developed the range of CEREFORM<sup>®</sup> breast implants.

We express this commitment to you by offering you a **lifetime<sup>1</sup> warranty on CEREFORM<sup>®</sup> silicone gel-filled breast implants upon implantation**.

# Standard CEREFORM<sup>®</sup> WARRANTY

- Access to the program is automatic for all patients who have received a CEREFORM<sup>®</sup> range breast implant.
- CEREFORM<sup>®</sup> implant replacement is guaranteed for the lifespan of the implant (10 years)<sup>2</sup>, whatever the model.
- The implant will be **replaced by an identical implant (profile and volume)**. Switching to a smaller or larger implant is not possible.

### WARRANTY TERMS AND CONDITIONS

- The warranty applies <u>exclusively</u> in the event of a proven rupture of the implant linked to a loss of the integrity of the envelope due to a manufacturing defect.
- The warranty only covers CEREFORM<sup>®</sup> silicone gel-filled breast implants.
- The new implants must be a CEREFORM<sup>®</sup> breast implant.
- The implant must have been fitted in conformity with recognized surgical procedures by a qualified **practitioner of plastic, aesthetic, and reconstructive surgery** in accordance with the documentation supplied with the implant.
- The breast implant must have been purchased and implanted in a country where Euromi Biosciences has authorized distributors.

<sup>&</sup>lt;sup>1</sup> <sup>2</sup> Breast implants are by no means permanent and must be changed after a certain number of years. They have an estimated lifespan of 10 years. (*see chapter " Lifespan of the implant " in our informed consent document*).

#### **EXCLUSIONS FROM WARRANTY**

The warranty does not apply in the following cases:

- Implants damaged during the surgical procedure;
- Replacement of an intact implant on the opposite breast;
- Product from other manufacturers ;
- Infections, hematomas, œdemas, waves, folds, migration of the implant, capsular contracture, adverse reactions consecutive to the rupture, etc...;
- Operative and post-operative complications such as the rupture or the leak that proves to be the direct consequence of a re-intervention (capsulotomy, alteration of the surgery...) or violent trauma (road accident, assault, attack...);
- Patients that are unsatisfied with their implant for purely aesthetic reasons (size or result).

### WARRANTY EXTENSIONS: CEREFORM<sup>®</sup> Comfort and Serenity (OPTION)

- These extensions **supplement the Standard CEREFORM**<sup>®</sup> **warranty** and include the same conditions of application and exclusions.
- Replacement of CEREFORM<sup>®</sup> implant is guaranteed throughout the lifespan of the implant (10 years)<sup>3</sup>, whatever the model.
- The implant will be **replaced by an identical implant** (profile and volume). Changing to a smaller or larger implant is not possible.
- To this, we add **financial assistance** of:
  - € 2,000 maximum for Cereform<sup>®</sup> Comfort warranty, subject to the conditions being met.

This warranty extension must be **validated beforehand by Euromi Biosciences for a single flat-rate amount of € 100 net.** 

- € 4,000 maximum for Cereform<sup>®</sup> Serenity warranty, subject to the conditions being met.

This warranty extension must be validated beforehand by Euromi Biosciences for a single flat-rate amount of € 200 net.

This financial assistance is used to cover all or part of the costs inherent in the intervention for an amount of  $\notin$  2000 or  $\notin$  4000 maximum. It does not in any way constitute the granting of a loan to the patient.

• These warranty extensions are both valid once during the 10 years following the placement of breast implant.

<sup>&</sup>lt;sup>3</sup> Breast implants are by no means permanent and must be changed after a certain number of years. They have an estimated lifespan of 10 years. (*see chapter " Lifespan of the implant " in our informed consent document*).

#### THE PROCEDURE TO FOLLOW

- No action on your part is necessary to benefit from the standard warranty.
- To benefit from the warranty extensions, you must first have **completed the membership form and paid the participation fee** according to the terms specified therein, within a maximum period of 30 days following the placement of the breast implant.
- You must keep the confirmation of your membership in the CEREFORM<sup>®</sup> Comfort or Serenity program.

The explanted and decontaminated implant must be returned to us within a maximum of 30 days following the explantation, after following the procedure in the explantation form.

After receipt and examination of the explanted product and the request for treatment, a report will be drawn up by our quality department and then sent to the surgeon as well as to the competent authorities concerned as soon as possible.

• The warranty will apply if and only if all these conditions are met.

#### SUMMARY OF OUR WARRANTIES

In the event of a proven rupture of the implant linked to a loss of the integrity of the envelope due to a manufacturing defect:

	Cost	Duration	Warranty	Modalities
<b>Standard</b> CEREFORM <sup>®</sup> Warranty	Free	10 years	Implant replacement	Automatic membership
<b>Comfort</b> CEREFORM <sup>®</sup> Warranty	€100	10 years	Maximum € 2000 financial assistance	Membership within a maximum period of 30 days following the placement
<b>Serenity</b> CEREFORM <sup>®</sup> Warranty	€200	10 years	Maximum € 4000 financial assistance	