Dear Patient,

Welcome to a new journey with SILIMED!

Silimed Indústria de Implantes Ltda. has been in the market for 39 years, being globally famous for the quality and safety of its products, its partnership with the surgeons - in order to manufacture implants that better answer the individual needs of patients - as well as the experience, science and technology involved in the whole process, from product design to manufacturing. Our main interest is your satisfaction and your well-being.

Your choice of SILIMED will provide you with the tranquility of acquiring a quality and safe product, and it will also offer you a product replacement program in case of the rupture of mammary implants due to manufacturing defects or capsular contracture Baker degrees III or IV.

After placement, the silicone implants are naturally involved by a tissue capsule, which is a normal reaction of the organism. In some patients, this capsule becomes strong enough to harden the breast and even modify its shape, providing it with an anti-aesthetic, toughened, and sometimes, painful aspect. It is, therefore, a reaction of the organism to the presence of a foreign body, isolating it through a tissue layer formed around it, known as the fibrous capsule or fibrotic capsule. This reaction of the organism is known as capsular contracture. There are four degrees of capsular contracture, according to the Baker classification, and our program covers degrees III and IV.

The success of a breast augmentation surgery occurs based not only on the quality and characteristics of the product chosen - the implant -, but also the instructions provided by the plastic surgeon, both in the pre and post operative period.

Important:

SILIMED offers the program voluntarily and reserves the right to cancel or modify it at any time. The program is only valid in countries for which SILIMED has the registration of its products and provides them according to local legislation. No claim can be made by other countries.

In moments of some kind of suspension of certification or other relevant facts which are out of our control, such as a fire or any other damage caused to our plants, the program will be automatically suspended.

SILIMED
connecting science and wellness

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PSPS

Silimed Product Replacement Program

1. How does the Silimed Product Replacement Program (PSPS) work?

SILIMED will replace silicone gel filled mammary implants coated with textured (TRUE TEXTURE) or polyurethane surfaces (PURE POLYURETHANE) in the following situations:

RUPTURE OF IMPLANTES DUE TO MANUFACTURING DEFECTS

Lifetime replacement in the cases of proved rupture of mammary implants due to manufacturing defects;

CAPSULAR CONTRACTURE

Even though it's a natural demonstration of the organism, as explained above, there will be a replacement in cases of capsular contracture Baker degrees III or IV for primary augmentation surgery or for the first mammary reconstruction surgery, considering the following periods, counted from the date of the surgery:

- **Period of up to 6 years** (for surgeries performed between September 1st 2014 and May 3rd 2017) and **up to 10 years** (for surgeries performed from May 3rd 2017), in the case of mammary implants with textured surface (TRUE TEXTURE).

- **Period of up to 10 years** in the case of mammary implants with polyurethane foam coated surface (PURE POLYURETHANE).

Observations:

Please note that it is only a replacement of product. The program does not include any other type of expenses, such as: hospital, surgeon, anesthesia or medication.

Your implant will be replaced by the same surface model and shape purchased, but it may, however, vary in size. In case the product is no longer being manufactured, it will be replaced by a product with characteristics which are most similar to the previous product, and it will be informed by SILIMED.

For the replacement request to be analyzed, some documents must be provided according to the description in item 2.

2. How to request?

Follow the instructions below to guarantee the easy replacement of your product in the cases mentioned in item 1:

- See your physician immediately for an evaluation.

- Your physician must contact SILIMED through our local distributor/representative or another person formally assigned by us to present the imaging exam (IRM or equivalent) and a medical report suggesting the occurrence of rupture or the diagnosis of contracture Baker degrees III or IV.

- After the evaluation, in case the replacement is confirmed, the implant will be made available to your physician through our authorized distributors/representatives. The surgery must be carried out with a qualified surgeon, who follows the instructions for SILIMED implants according to the updated surgical techniques.

In case you still have doubts, contact SILIMED through our e-mails: **ask@silimed.com.br**

Silimed in connection with you.

The products of SILIMED are always monitored, even after their commercialization.

In order to keep in touch with you, we request you to fill out the personal registration form available at this link: **www. silimed.com.br/registroonline.** Through this channel, we will be able to keep you informed about our Company and products, and also carry out surveys and collect information to improve our processes and products, always aiming at better assisting our physician clients and patients.

Do not forget to keep your patient card with you at all times. It is submitted with the product and it will be delivered to you during or after surgery by your surgeon.

3. When is PSPS not applicable?

- The expenses with the surgery, including medical services, medications or any other item, are not covered by the Silimed Product Replacement Program;

- Dissatisfaction with the size of the implant or aesthetic result;

- Implant rupture caused by other reasons which are not related to manufacturing defects, such as: rupture caused by accident during surgery, rupture caused during mammography, among others;

- Capsular Contracture Baker degrees I or II;

- When the case of rupture happens due to manufacturing defects, or the capsular contracture Baker degree III or IV is not demonstrated through imaging exams/photographs and medical reports;

- When the requesting patient does not display a physical copy of the patient card provided to her during or after surgery;

- In cases of non-primary surgeries, that is, in cases of augmentation revision surgeries, seroma or any other reoperation reason.