



## The program:

You are about to make a very personal decision concerning your breast implants. By opting for a SILIMED implant, you are assured of the highest quality and security of the SILIMED Product Replacement Program - SPRP.

## The highest quality:

The whole process of manufacturing at SILIMED complies strictly with national and international standards of quality. Regularly audited by several organizations, the company is always in conformity with the certifications it has been awarded:

- ANVISA - Good Manufacturing Practices;
- ISO 9001 and ISO 13485;
- CE Mark - European Manufacturing
- FDA - Good Manufacturing Practices.

## More security for you:

SILIMED offers you a program of lifetime coverage. In the event of the implant envelope rupturing. A new SILIMED breast implant will be made available to your doctor through our authorized representatives.

The surgery has to be performed by a qualified surgeon in accordance with the instructions for use of SILIMED implants and following current surgical techniques.

This program does not cover the costs of a new operation, but only offers to replace the implant.

## How can you benefit from the program:

After the operation, fill out the personal registration form on our site [www.premiumimplant.eu](http://www.premiumimplant.eu). You will receive a message confirming the registration so that you can print your personal registration card, always carry this with you.

Through the SPRP we document the high quality of our Breast Implant product. Once a year you will be asked to fill out an updated registration on our site. This renewed register will contain some easy questions for you to answer regarding your satisfaction and well-being. On filling out the update, your SPRP will be extended for another year. The program will only be continued after we receive your renewed registration.

Should you want to discontinue participating in the SPRP, you can do so at any time by going to our site and requesting to be removed. Also remember that your participation in the program will be automatically discontinued if you do not renew your registration each year.

By registering personally and voluntarily in the SPRP, you permit SILIMED to use the information for statistical analyses.

SILIMED pledges to treat personal data as strictly confidential and reserves the right to publish statistical analyses of the data.

## What are the benefits:

SILIMED will provide a replacement silicone-gel breast implant free of charge on a lifetime basis if there is proof of damage to the integrity of the envelope in case of rupture.

The implant provided free of charge will be a SILIMED implant of the same type as used in the previous operation, but you will be free to choose a different size.

No request for compensation will be accepted other than the free replacement implant.

SILIMED will replace only implants that have suffered rupture.

## What to do if you suspect that you need to use the SPRP:

Make an appointment immediately with your doctor for him to evaluate the situation.

If it is necessary to ask SILIMED for an implant, follow these instructions:

- After confirming the rupture by examination (MRI or equivalent), use the site to fill out your request for a replacement of the implant and upload the examination and image.
- SILIMED will analyze your request taking into account your personal registration, and the examination. SILIMED will then send you authorization for a replacement implant.

- Following the operation, we request your doctor to return the removed implant to SILIMED through the local representative, within four weeks at most.

The removal operation must be performed by the same surgeon responsible for the original implantation. If it proves impossible to contact the surgeon who did the original operation, another surgeon may be chosen in agreement with SILIMED.

## Attention:

\* SPRP does not cover a new silicone-gel breast implant in the following cases:

- Damage to the implant before or during implantation;
- Damage to the implant due to trauma;
- Damage to the implant during mammography;
- Damage to the implant during open or closed capsulotomy;
- Damage caused during surgical intervention.

SILIMED operates SPRP voluntarily and reserves the right to cancel or modify it at any time. The program is only valid in countries to which SILIMED supplies its products.

Remember that after your replacement surgery, you must register your new implant in the SPRP.

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