

SILIMED

connecting science and wellness



Everything you need to
know about

breast implants





Dear patient,

Well-being and safety are two of our main priorities. We know how important it is for you to be happy and feel good in your body.

For more than 40 years, SILIMED has studied and developed breast implants that satisfy the needs of all our patients, improving their health and quality of life.

We always collaborate with medical professionals, studying the most appropriate implants for each body type according to the different needs of each patient and improving their self-esteem and confidence, thus helping them to bring their dreams to life.

It is through this contact with plastic surgeons that we understand the technical specifications of implants in order to obtain the results our patients want.

Breast augmentation is one of the most commonly performed surgical procedures (*), focused on improving the size and shape of the breast. Women decide to have this surgery for many reasons:

- Augmentation due to hypomastia (congenital atrophy or small breasts);
- Breast augmentation or reconstruction due to sagging and ptosis resulting from weight loss or breastfeeding;
- Correction of asymmetrical breasts;
- Breast augmentation or reconstruction after recovering from an illness.

(*) It is important to remember that surgical silicone prosthesis implantation involves more than one surgical operation, because silicone implants are not devices that last a lifetime and there is a risk of adverse effects that may require additional surgery.

Why Silimed?

Silimed is committed to offering high-quality, safe products, always seeking to ensure excellence through strict international production standards:

BRAZIL - Production facilities and processes inspected and products registered/recorded with the National Health Surveillance Agency (ANVISA) and approved, when necessary, by the National Institute of Metrology, Quality and Technology (INMETRO). The environmental conditions and production techniques are in compliance with ANVISA's Good Manufacturing Practices (GMP) for Medical Products.

SILIMED IN EUROPE - Silimed breast implants have the "CE Mark", which is further proof of the international acknowledgement of the quality of Silimed products and is the passport to the return to Europe.

Silimed returned to Europe in 2021, with more product availability after building its new production plant.

OTHER COUNTRIES - Acting in compliance with all the formal requirements of each Ministry of Health in the countries in which the products are distributed, such as, for example, the GMP of the Federal Commission for the Protection against Sanitary Risk (COFEPRIS) in Mexico, the National Institute of Food and Drug Monitoring (INVIMA) in Colombia and the Federal Service for Surveillance in Healthcare (Roszdravnadzor) in Russia, among others.

ISO13485 - Obtained ISO 13485, internationally renowned standard for the quality management system for the industry of medical devices.



FREQUENTLY ASKED QUESTIONS!

1. What is medical grade silicone?

This is a silicone with a high degree of purity and a broad application in the medical field due to its biocompatibility and low risk of causing toxicity or undesired adverse biological reactions. The silicone intended for breast implants is subjected to cytotoxicity tests in accordance with standard ISO 14607.

2. What is breast augmentation?

Breast augmentation is another name for breast enlargement, which can be performed for aesthetic purposes. This is currently one of the most popular plastic surgery operations.

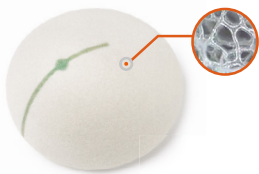
3. What is cohesion?

Cohesion is the property that is related to the distance or proximity of the molecules in the silicone gel. The implant is considered satisfactory for the use intended when this characteristic, which keeps the molecules connected, does not allow the gel to leak if the implant ruptures.

4. Is there more than one type of breast implant?

Yes. Implants come in different shapes and with different coatings to satisfy patients' and surgeons' needs, in order to help each woman get the best possible results for her body. Our breast implants have different profiles and projections, they can be round or oval and have four different types of surface: smooth, textured, soft plus or coated with polyurethane foam. The latter has had a significant volume of sales worldwide in recent years.

PURE POLYURETHANE TRUE TEXTURE

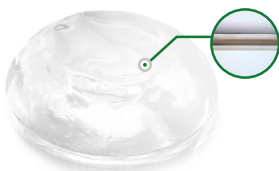


Pure Polyurethane implants give better results in breast augmentation, with a lower rate of capsular contracture, a mere 1% in 10 years.¹



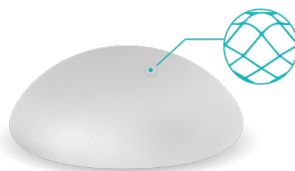
These implants provide excellent results in the reduction of capsular contracture. Silimed developed its own texturing method that creates open pores in the membrane and guarantees excellent implant performance, significantly reducing the occurrence of capsular contracture^{(#), 2}.

SMOOTH SURFACE



SILIMED Smooth Surface implants are made of a mechanically resistant silicone elastomer membrane subjected to a low bleed treatment that helps to reduce rupture and prevent gel transudation. What's more, they are filled with highly cohesive high performance HSC gel.

SOFT PLUS



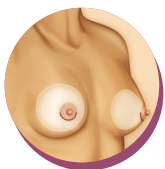
This new implant has additional benefits compared to smooth implants, such as the complete filling of the breasts.

(#) When the organism detects a foreign body, it tries to expel or absorb it. The same applies to implants, and the body's natural reaction is to form a capsule around it. This capsule is formed due to the increase of connective tissue (fibrosis) and is a natural phenomenon after any surgery involving alloplastic materials. The body's defence system goes into action and the immune system develops an internal scar that forms several layers around the prosthesis.

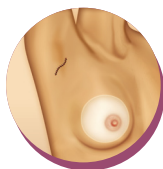
In the capsular contracture, this capsule enveloping the implant loses elasticity. In this case, it is a layer of abnormal scar tissue that sometimes forms around breast implants and can cause discomfort and leave the breasts feeling hard.

5. What types of incision are used in breast augmentation surgery?

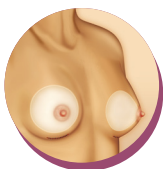
There are three possibilities: periareolar, transaxillary and inframammary. The only one that does not leave a scar on the breast is the transaxillary incision. All of the incisions have the same purpose. Your surgeon will explain which is the best option for your case.



Periareolar



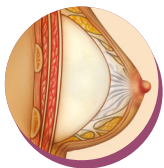
Transaxillary



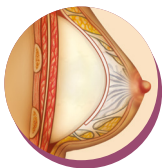
Inframammary

6. What about the position of the implant?

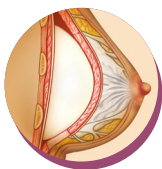
There are three possible positions for the breast implant: behind the mammary gland (retroglandular), behind the fascia of the pectoral muscle (retrofascial) or behind the pectoral muscle (retromuscular).



Retroglandular



Retrofascial



Retromuscular

SPRP

Silimed Product Replacement Programme

Choosing us will guarantee you the peace of mind that comes with opting for a safe, high-quality product, which also offers you a Product Replacement Programme should the breast implant rupture due to a manufacturing defect or due to Baker grades III or IV capsular contracture.

How does the Silimed Product Replacement Programme (SPRP) work?

Silimed will replace silicone gel-filled breast implants with a TRUE TEXTURE micro-textured surface, a surface coated with polyurethane foam (PURE POLYURETHANE), or Soft Plus implants in the following situations:

Rupture of the implant due to a manufacturing defect;

Lifetime replacement will be provided in proven cases of rupture of breast implants due to manufacturing defects.

Capsular contracture;

Although it is a natural response of the body, as explained above, in cases of Baker grades III and IV capsular contracture in primary augmentation surgeries or in the first breast reconstruction surgery, the implant will be replaced considering the following periods counted from the date of surgery. For the Soft Plus implant, the replacement will be exclusively for placement in the submuscular plane.

- Up to 6 years for surgical implantation of breast implants with textured surfaces (TRUE TEXTURE) performed between 1 September 2014 and 3 May 2017, and up to 10 years for surgeries performed on or after 4 May 2017.
- Up to 10 years for polyurethane foam coated breast implants (PURE POLYURETHANE) and breast implants with the SOFT PLUS surface.

For more information about the Silimed Product Replacement Programme, ask your plastic surgeon or visit our website

www.silimed.com/es/psps

Observations:

It is important to remember that the replacement only refers to the product and excludes other costs such as hospital and surgery fees, anaesthesia and pharmaceutical products, for example. The new implant will have the same surface area as the initial implant, but another size can be chosen. If the product is no longer produced, the new implant will be as similar as possible to the original implant. To approve the implant replacement, Silimed will request certain documents for analysis. For more information about the Silimed Product Replacement Programme, ask your plastic surgeon or visit our website www.silimed.com/es/psps



Silimed Indústria de Implantes Ltda.

Rua Figueiredo Rocha, 374
Rio de Janeiro • RJ • Brazil
CEP (postcode): 21240 - 660

Technical Manager:

Marlos de Oliveira e Souza
Chemist - CRQ (III) RJ: 03230137

New Production Plant

Rodovia Washington Luiz, Sítio 20
área A, Sítio 21 área B, Vila Actura,
Duque de Caxias - Rio de Janeiro - Brazil


Technical Manager:

Alexandre dos Santos Zago
Register CRQ-RJ: 032053861

Nordics Subsidiary

Silimed Nordics ApS
CRV: 43824929
C/O: Falkoner Ale 12B 1th
Postal code: 2000 Frederiksberg
Denmark
info@silimed.dk
Tel.: +45 224 201 66

CE Mark: 1434_MDD-083/2020

European Authorized Representative:  SILIMED B.V.

Bond Eindhoven, Luchthavenweg 81,
5657 EA Eindhoven Room 1.11C Floor Atrium B
silimed.bv@silimed.com.nl






Records:

ANVISA Breast Implants:10102180060, 10102180066,
10102180002, 10102180104

AEMPS: PS/2021/0650(D)/ PS/2021/0629(D)/ PS/2021/0634(D)

1. Vázquez G, Pellón A. Polyurethane-coated silicone gel breast implants used for 18 years. Aesthetic Plast Surg. 2007 Jul-Aug;31(4):330-6. doi: 10.1007/s00266-006-0207-4.
2. STEVENS WG, Harrington J, Alizadeh K, Berger L, Broadway D, Hester TR, Kress D, dincelli R, Kuhne J, Beckstrand M. Five-year follow-up data from the U.S. clinical trial for Sientra's U.S. Food and Drug Administration-approved Silimed® brand round and shaped implants with high-strength silicone gel. PlastReconstrSurg. 2012 Nov;130(5):973-81.

www.silimed.com/en

-  Silimed Europe Breast Implants
-  Silimed Europe  @Silimed.Europe
-  Silimed Breast Implants  Silimed.Official