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SILIMED
passion inspiring science

INFORMATION FOR PATIENTS
MAMMARY IMPLANTS

“Arrange the time that is necessary to analyze and consider the pertinent information”

Silimed developed this brochure to help you understand the benefits and risks related to augmentation or reconstructive surgery using silicone mammary implants. After having read this brochure carefully, talk to your physician before taking any decision. Arrange the time that is necessary to analyze and consider the pertinent information. However, in cases of revision surgery, your physician may need to anticipate your surgery. If deciding for the procedure, you and your physician must sign the Instrument of clarification before surgery, confirming that you have read and understood the information provided about the benefits and risks of surgery with silicone mammaty implants. The Instrument of Clarification on the use of SILIMED mammary implants is found at the end of this brochure.

DESCRIPTION

SILIMED mammary implants are made of a single external elastomer envelope filled with medical grade silicone gel. May have smooth, textured or polyurethane foam coated surface. All of them are supplied sterile and are designated for a single use.

These implants are available in different sizes and shapes to help every woman to achieve the best result for their bodies. The physician should guide her in choosing the correct implant to achieve the desired aesthetic effect.

INDICATIONS

Indicated for augmenting or correcting the breasts in cases of unilateral or bilateral hypomastia and reconstruction to ensure a natural appearance following surgery.

EXPECTED BENEFITS

The augmentation / reconstruction surgery with mammary implants may bring great benefits, providing reconstruction, augmentation and surgery revision of the breast with high satisfaction. Patients choose surgery for primary breast augmentation to increase the size and proportion of your breast (s). In addition, patients choose to revision surgery (replacement of an existing mammary implant) to correct or improve the results of a primary augmentation surgery.

According to the medical and scientific literature, most women who have undergone surgery with mammary implants reported high levels of satisfaction with the body image, shape and size of the breasts. Additionally, after surgery, patients reported greater self-esteem and felt more feminine and attractive. The reconstruction surgery with mammary implants also results in improved quality of life. Besides this, studies have shown that reconstructing the breast using mammary implants has helped in recuperating from breast cancer, as well as reducing the emotional stress by helping the body to regain a more natural appearance, as opposed to not having reconstructive surgery or using an external prosthesis.

CLARIFICATION AND CONSENT OF THE PATIENT

Considering the risks inherent to a surgery, with or without the use of implants, and the possible related consequences, SILIMED relies on the physicians to clarify their patients as to the existing risk-benefit balance.

Every patient shall be given the Information for SILIMED Patients for Mammary Implants during the initial consultation so that the patient is allowed sufficient time prior to the surgery to suitably read and understand the important risk information, follow-up recommendations and benefits associated to the surgeries for placement of mammary implants. For a successful documentation of the patient´s clarification, the Clarification Term for use of the SILIMED Mammary Implant shall be signed by the patient and by the physician and then attached to the patient´s medical register.

EXPECTED RISKS

The mammary implant surgery offers great benefits. However, any kind of surgery involves risk. There are some local complications (problems near the site of surgery) which can occur following surgery. SILIMED delegates

responsibility to physicians in explaining to patients about the possible adverse effects, consequences and the appropriate treatment. The following are potential risks and complications reported in the literature, associated with surgery with mammary implants of various models and manufacturers, as well as the possible effects related to these risks.

Chest-wall flattening, Allergenicity (skin rash), Tissue atrophy, Calcification, Iatrogenic complications, Capsular contracture, Suture dehiscence, Displacement of the implant, Wrinkling, Erosion, Extrusion, Galactorrhea, Granuloma, Hematoma, Necrosis, Loss of mechanical integrity/Product flaw, Pneumothorax, Inflammatory response, Rupture (including cases of "silent" rupture), Seroma, Symptoms associated with macromastia, and Transudation of gel and thrombosis.

Other risks have been reported in the medical-scientific literature, but until now there is no scientific proof of any possible relation of cause and effect between these events and silicone implants.

Some examples are:

CANCER – Contracting cancer can cause serious irreversible damage and even death. Nevertheless, there has been no proof of any relation between the placement of silicone implants and the occurrence of cancer. Furthermore, the presence of mammary implants seems not to compromise early diagnosis of cancer and consequently the life prognosis of these patients.

IMMUNOLOGICAL RESPONSE – Auto-immune and conjunctive-tissue diseases can cause serious irreversible damage and even death of the patient. Nonetheless, no evidence has been found in the studies carried out so far, that placing silicone implants causes connective or self-immune diseases.

TERATOGENICITY – A review of the medical-scientific literature indicates that studies have demonstrated no signs of teratogenicity associated with mammary implants.

UNDESIRABLE EFFECTS

Altered sensibility of the breast and/or nipple, Pain, Infection (biological contamination), Unsatisfactory aesthetic result (such as ptosis, asymmetry, folds, creases, adherence and hypertrophic scars).

INTERFERENCE IN BREASTFEEDING

The presence of silicone in the mother's milk has been researched in several studies without significant levels of the substance being found in mothers who bear silicone mammary implants when compared with women without implants. There is, however, a possible interference in breast-feeding (reduced production of milk) in women who have undergone surgery with mammary implants. The frequency of interference in breast-feeding is higher in patients in whom the incision route was periareolar.

INTERFERENCE WITH MAMMOGRAPHY: ULTRASSOM E RESSONÂNCIA MAGNÉTICA

Interference occurs when the presence of implants (or artifacts) causes a misreading of the results.

SILIMED points out that the implant may affect the quality of the mammography. For this reason, you shall be orientated and advised to request the services of professionals who are familiar with mammography techniques with implants, to inform the radiologist of the need to adapt the mammographic pressure and not to forget to show the "CARD FOR TRACEABILITY OF SILIMED PRODUCT – FOR THE PATIENT".

Other methods such as ultrasonography and magnetic resonance may be useful together with mammography because they do not require compression and allow examinations to be made from any angle.

INTERFERENCE WITH SELF-EXAMINATION

The breast self-exam is a prevention technique used in an attempt to identify early stages of breast cancer.

The breast self-examination routine o can be more difficult with implants. However, your doctor should advise you on how to distinguish the implant from the breast tissue during the self-examination.

You should perform the self-examination regularly for tracking lumps, swelling, hardening or change in the shape of the implant, which may be signs of rupture. If there is development of any of these symptoms or persistent pain, tell your doctor.

It is worth mentioning that the breast exam done by the woman herself does not replace the

“The presence of silicone in the mother’s milk has been researched in several studies without significant levels of the substance (...)”

“ (...) in order to evaluate the safety and efficacy of SILIMED implants.”

SIENTRA/SILIMED CLINICAL STUDY

The Sientra/SILIMED clinical study was performed in 1788 patients during 3 years, in order to evaluate the safety and efficacy of SILIMED implants.

The most common complications in patients who underwent primary augmentation were reoperation (12.6%) and capsular contracture grade III / IV 6.0%). The most common complications in patients who underwent augmentation revision, primary reconstruction and revision were reoperation (20.3% 34.9% and 42.5%, respectively) and implant removal with or without replacement (11.4 %, 24.8% and 30.3%), respectively).

Safety results of the study are presented below.

Complications Reported in the Sientra Clinical Study
(3 years Follow-up.)

Complication		Primary augmentation (n=1115)	Augmentation Revision (n=362)	Primary reconstruction (n=229)	Reconstruction Revision (n=82)
Reoperation[a]		12.6%	20.3%	34.9%	42.5%
Implant removal with replacement[b]		6.0%	8.7%	19.1%	23.2%
Implant removal without replacement[b]		1.2%	2.9%	7.0%	10.3%
Capsular contracture (III/IV)		6.0%	5.2%	8.8%	6.8%
Rupture	Group that perform IRM[c]	2.5%	0%	2.8%	0%
	Group that did not perform IRMc	0%	0.4%	0%	0%

Complications occurring in 1% or more of patients [d,e]

Complication	Primary augmentation (n=1115)	Augmentation Revision (n=362)	Primary reconstruction (n=229)	Reconstruction Revision (n=82)
Asymmetry	1.1%	1.8%	8.7%	7.1%
Breast cyst / lump	0.3%	0%	1.0%	3.1%
Pain	0.8%	0.9%	2.6%	1.4%
Delayed scarring	0.2%	0.6%	1.9%	0%
Hypertrophic scarring	0.6%	0.7%	2.7%	3.1%
Extrusion	0.1%	0.6%	1.5%	0%
Bad Positioning	1.2%	3.2%	3.0%	5.5%

Complications occurring in 1% or more of patients [d,e]				
Complication	Primary augmentation (n=1115)	Augmentation Revision (n=362)	Primary reconstruction (n=229)	Reconstruction Revision (n=82)
Visualization of the Implant	0.2%	0.6%	1.0%	0%
Infection	0.7%	1.2%	5.1%	1.2%
Alteration of Nipple Sensitivity	3.2%	1.4%	2.0%	0%
Other Complications	0.6%	0.7%	1.1%	0%
Ptosis	1.8%	0.7%	2.0%	0%
Redness	0.3%	0.7%	3.0%	0%
Seroma	0.6%	1.2%	2.4%	1.3%
Edema	0.5%	0.7%	2.0%	0%
Corrugation / Undulation	0.5%	2.4%	1.1%	1.5%

[a] Some reoperations were performed for multiple reasons such as: suspicion of rupture, infection, capsular contracture, extrusion, necrosis, hematoma/ seroma, delayed scarring, irritation/ inflammation, pain, bad positioning, excessive filling of the upper pole, wrinkling, palpability, visibility, asymmetry, ptosis, scarring, complications in the nipple, breast cancer, cyst/ nodule, skin complications, changes in size, trauma.

[b] Reasons for implant removal: suspicion of rupture, infection, capsular contracture, extrusion, necrosis, hematoma/ seroma, delayed scarring, irritation/ inflammation, pain, bad positioning, excessive filling of the upper pole, wrinkling, palpability, visibility, asymmetry, ptosis, scarring, complications in the nipple, breast cancer, cyst/ nodule, skin complications, changes in size, trauma.

[c] IRM – Magnetic Resonance Imaging

[d] Complications following reached index lower than 1% in all groups of patients: contusion, hematoma, implant palpability,irritation, necrosis, rash, changes in skin sensitivity, excessive filling of the upper pole.

[e] The following complications have been reported with the risk rate of 0% in all groups of patients: capsule calcification, lymphadenopathy, linfaedema, complications in the nipples (not related to sensitivity) and pneumothorax.

SILIMED MAMMARY IMPLANTS COATED WITH POLYURETHANE FOAM

SILIMED mammary implants coated with polyurethane foam are effective in sharp decrease in the occurrence of capsular contracture when compared to smooth surfaces and textured implants. Many important articles reported this protective effect provided by the polyurethane foam in the decrease of the capsular contracture in augmentation and reconstruction surgeries, and with few complications. [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12]

The coating with polyurethane foam allows close interaction between the implant and the tissue around it, inducing physiological conditions that depart the fibroblasts of the pocket, slowing, consequently, the synthesis of collagen, precursor of fibrotic capsule. The irregular surface of the polyurethane foam disfavors the formation of a linear fibrotic capsule in favor of the multiplanar formation of the collagen fibrils. The formation of microcapsules around irregularities in the structure of the polyurethane causes the force of contracture to be multi-oriented, rather than having a single orientation. By having multiple vectors, these forces tend to cancel, reducing the capsular contracture. Another benefit of the stable union of the foam coating with the capsule of the implant and the native tissue is the reduce of the risk of displacement or rotation of the implant. [5, 9, 13]

“The coating with polyurethane foam allows close interaction between the implant and the tissue around it (...)”

PRECAUTIONS

The risks of mammary implants surgeries may be higher if you have any of the following specific conditions. Tell your doctor if you develop any of these conditions:

- Autoimmune diseases;
- Recent history of cancer;
- Weakened immune system (immunosuppressants users);
- Conditions that interfere with blood clotting;
- History of severe allergy;
- Cardiovascular diseases;
- Diabetes;

Before surgery, you should have a detailed discussion with your doctor about your medical history.

CARES

In the first month after surgery, some activities can damage the implant and should be avoided, such as the following:

- Exposure to the sun;
- Brusque movements;
- Sports in general.

You should be aware that normal stress or trauma applied to the region of surgery can cause extrusion of the implant.

Wearing an appropriate brassiere and refraining from violent exercises are minimum recommendations to be followed in the post-operative period.

Ask your doctor about the activities he does not recommend in the postoperative period.

You must inform the medical specialist or pharmacist if they are bearers of silicone implants before they use topical medicaments in the region of the breast.

You must continue to consult their medical specialist in order to proceed with routine monitoring to detect breast cancer.

You must inform your physician or surgeon about the presence of the implant if any breast surgery has been scheduled.

In the case of any suspected complication listed in this information, or any other abnormal symptom, contact your surgeon.

DURABILITY

Like all breast implants, the SILIMED Mammary Implants have a limited useful life. This lifetime has not been determined by the scientific community yet. SILIMED establishes a mean period of 10 years as the expected useful life, but such parameter may be altered whenever some reason to justify it is assessed.

The implant may need to be removed or replaced, which may imply in a revision surgery.

An annual clinical follow-up is recommended for these patients.

IMPORTANT FACTORS TO CONSIDER:

1. If you are going to have mammary augmentation or reconstruction, be aware that mammary implants are not considered life-long devices and that mammary implantation may not involve a single operation. It is possible that you may need one or more additional operations, in addition to medical monitoring for the rest of your life. It is also possible that you may need an operation to remove and perhaps substitute the implant.

2. Many of the changes to your breast following implantation surgery cannot be undone. If later on you choose to have your implant(s) removed, you may experience unacceptable folds, drooping or wrinkling, loss of breast tissue or other alterations to the contour of your breasts.

3. Routine mammography evaluation will be more difficult with breast implants and you will need to have additional images, which means more exposure to radiation.

4. All SILIMED mammary implants come with a "SILIMED PRODUCT TRACEABILITY CARD – FOR THE PATIENT", which contains all the information on the surgery. This card is for your security, so you should carry it with you to make medical assistance easier in case of emergency.

This document is available at our site:
www.silimed.com.br

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for physician

Instrument of Clarification

on the use of SILIMED mammary implants

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Termo de Esclarecimento para utilização do Implante Mamário SILIMED

Dear patient,

With a view to lending you support on your decision to avail yourself of a SILIMED mammary implant, we made available on the company website the Information for SILIMED Patients for Mammary Implants, so that you can enjoy access to important matters and to clarify certain doubts with your physician before you have your operation.

Before and after surgery, you should consult your physician and take periodic tests to ascertain your health status.

It is important for you to be aware of the need to follow correctly the orientation provided by your physician so that the operation to place the SILIMED mammary implant is carried out successfully. The useful life of mammary implants is limited and may have to be removed or replaced, which could mean another operation for the purpose of revision.

Both the physician and the anesthesiologist must have your consent in order to take the necessary measures to recover your clinical condition if the need should arise.

Success of the operation with SILIMED mammary implants depends on your commitment to follow the medical recommendations, which will allow the breast to be augmented or reconstructed without any major complications. Breast surgery can improve your self-esteem and quality of life.

Confirmation

I, _____, identity card number _____, have read the INFORMATION FOR SILIMED PATIENTS FOR MAMMARY IMPLANTS provided by SILIMED. I have understood the information on the product and surgical procedures and have had the opportunity to clear up any doubts with my physician in respect to the nature of the product, its benefits, risks and possible complications, procedures and objectives of the surgery. I am aware of the possibility of adverse effects occurring, such as those mentioned in the Information for SILIMED Patients, and that the occurrence of adverse effects does not characterize a defect as far as the guarantee of the product is concerned.

_____ _____/_____/_____
Signature of the patient Date

_____ _____
Witness Identity card

_____
Signature of the Witness

_____ _____
Physician CRM

_____ _____/_____/_____
Signature of the physician Date

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_____ _____/_____/_____
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Witness Identity card

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Signature of the Witness

_____ _____
Physician CRM

_____ _____/_____/_____
Signature of the physician Date

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