

## Warnings, precautions or measures to be taken by the patient or a healthcare professional

### INTERFERENCE IN BREASTFEEDING

The presence of silicone in breast milk has been researched in several studies, with no significant levels of the substance found in mothers with silicone breast implants, when compared to women without implants. However, there is a possible interference in breastfeeding (reduced milk production) in women who have undergone surgery with breast implants. The frequency of interference with breastfeeding is higher in patients in whom the periareolar incision route was used.

### INTERFERENCE WITH MAMMOGRAPHY; ULTRASOUND AND MAGNETIC RESONANCE IMAGING

Interference occurs when the presence of implants (or artifacts) causes an erroneous reading of the result. SILIMED points out that the implant can interfere with the quality of the mammogram. Therefore, you must be guided and instructed to request the services of professionals who have experience with mammography techniques with implant, informing the radiologist of the need to adapt the mammographic compression and not forgetting to show the "SILIMED PRODUCT TRACEABILITY CARD - FOR PATIENT".

Other methods, such as ultrasound and MRI, can be useful in conjunction with mammography because they do not require compression and allow examination from any angle.

According to recent studies, silicone breast implants reduce the image quality of echocardiographic visualizations. More data is needed, however SILIMED advises its patients to inform the technician responsible for the exam about the existence of silicone implants.

### INTERFERENCE WITH SELF-EXAMINATION

Breast self-examination is a preventive technique used in an attempt to identify early stages of breast cancer.

The doctor should guide you on how to distinguish the implant from the breast tissue during self-examination.

You should periodically self-examine for lumps, swelling, hardening, or changes in the shape of the implant, which may be signs of rupture. If any of these symptoms or persistent pain occurs, report it to your doctor.

It is important to note that the breast examination performed by the woman herself does not replace the physical examination performed by a health professional (doctor or nurse) qualified for this activity.

### CAUTIONS

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

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

You should be aware that normal stress or trauma applied to the surgery site can cause the extrusion of the implant. Wearing an appropriate bra and not doing violent exercises are minimum recommendations to be followed in the postoperative period.

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

You must inform the medical or pharmaceutical specialist that you have silicone implants before using topical medications (for example, steroids) in the breast area.

You need to continue to consult with your medical specialist to proceed with routine monitoring for breast cancer.

You should inform the doctor about the presence of the implant if any breast surgery is scheduled.

If you suspect any complications listed in this newsletter or any abnormal symptoms, contact your doctor.

### Durability

Like all breast implants, SILIMED Breast Implants have a limited lifespan. This lifespan has not yet been determined by the scientific community. Several factors can have a significant effect on the lifespan of a device, including the actual implantation procedure, the patient's anatomy and health status, behavior and activities (e.g. sports activities), as well as predictable and unpredictable external mechanical influences. A study conducted with Silimed implants demonstrated a low rupture rate of the devices (5.42%). In addition, the survival calculated by Kaplan-Meier with these devices was 93% at 9 years and 83% at 11 years. Therefore, SILIMED establishes an average period of 10 years as the expected lifespan, but this parameter can be changed when a reason to justify it is raised. The implant may need to be removed or replaced, which may involve revision surgery. Annual clinical follow-up of patients is recommended.

#### References:

- SILIMED. IUP 001-01-T-EC - Implante Mamário - Gel de Silicóne - Superfície Texturizada.
- SILIMED. IUP 001-01-P-E - Implante Mamário - Gel de Silicóne - Superfície Revestida com Espuma de Poliuretano.
- SILIMED. IUP 001-01-L-EC - Implante Mamário - Gel de Silicóne - Superfície Lisa.
- SILIMED. IUP 001-01-LN-EC - Implante Mamário - Gel de Silicóne - Superfície Lisa - Soft Plus.

