INFORMED CONSENT

SILICONE GEL-FILLED

BREAST IMPLANTS

CEREFORM®

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Breast implants can be used for breast augmentation, to harmonize breast volume, or simply to replace another implant. However, as with any surgery, a breast implant procedure involves certain risks that must be understood before making your final decision. You must therefore talk to your doctor about the benefits you expect from the procedure and the risks you are willing to take to achieve the results you want.

The indications, types of surgery, information about breast implants, the procedure and what to expect after the procedure are detailed in our booklet « Information about the breast implant procedures » which you have been given. You will also find many answers to questions you may have.

CEREFORM® BREAST IMPLANTS DESCRIPTION

CEREFORM® breast implants are long-term implantable medical devices pre-filled with silicone gel. They come in a **round shape** that provides volume to the upper part of the breast for a more plunging neckline. It is particularly suitable for women whose breasts are already formed. The round shape is available in several profiles (low, medium, intermediate, high and very high) and the volumes range from 100 to 900 cc.

CEREFORM® breast implants are available with two different surfaces:

- **The smooth surface**, to facilitate implantation and explantation.
- **The micro-textured surface**, to improve cell colonisation and reduce the risks of capsular contracture while still facilitating implantation and explantation.

In addition, CEREFORM® breast implants are available with three filling gels: **Classic, Aptima and Ellipse**. The Classic gel is the softest in the range, for a more natural touch, the Aptima gel is firmer for better implant holding and the Ellipse gel offers a softer touch and easier implantation thanks to its shape memory.

You will choose the type of implant (its surface, gel and the projection) with your doctor to meet your needs.

EXPECTED BENEFITS

- **For breast reconstruction after cancer**, the psychological benefits are extremely important. This is a chance for the woman to recover her body image and forget her disease.
- **In aesthetic and plastic surgery**, breast augmentation with implants generally restores the woman's self-esteem and self-confidence and enhances her sense of womanhood.

CONTRAINDICATIONS

CEREFORM® breast implants are contraindicated in the following situations:

- pre-existing pathology in the implant area,
- history or presence of an autoimmune disease,
- if the surgeon deems that the patient is in poor physiological condition,
- psychological instability,
- a general infection of infection in the implant area,
- repeated failure with the implantation of similar implants,
- grossly positive axillary involvement / or chest wall involvement,
- haemoglobin levels >7.5%,
- progressive breast cancer large tumours (>5 cm), late cancer stage and deep tumours,
- high risk of cancer recurrence
- current pregnancy or planned in the near future,
- currently breastfeeding or planned in the near future,
- insufficient tissue or fat,
- obesity or a Body Mass Index >40 kg/m2,
- diabetes,
- smoking,
- known hypersensitivity and / or allergy to silicone,
- history or current treatment using radiation with lower-pole scarring and thin, poorly vascularized skin/tissue / microwave diathermy / or steroids.

CEREFORM® breast implants are not suitable for men (including sex-change cases).

It is necessary to consult a doctor or pharmacist before applying topical medications in the breast (such as steroids).

POSSIBLE COMPLICATIONS

Like any surgical procedure, breast implant procedures involve surgical and post-operative risks. Your practitioner must inform you of the risks associated with the procedure and potential post-operative complications:

Breastfeeding problems
Following breast augmentation, some women may have difficulty breastfeeding their children. Similarly, women who have undergone a mastectomy and breast reconstruction surgery may not be able to breastfeed due to loss of breast tissue and the glands that produce milk.

Asymmetry
Post-operative asymmetry is the result of choosing the wrong implant (size, shape) that is disproportionate to the other breast, or a different tissue reaction between the two breasts. If there is considerable asymmetry and the patient is dissatisfied, the implant can be removed or replaced. Asymmetry appearing several months or years after the procedure suggests capsular contracture or a ruptured implant. In this case, a thorough examination is necessary, and the implant may have to be removed.

Atrophy of the breast tissue / deformation of the chest wall
The pressure exerted by the implant may cause the breast tissue to become thinner and retract, increasing the visibility and palpability of the implant. Atrophy of the breast tissue may potentially deform the chest wall.

Calcification
Calcification is when calcium is deposited in the tissue around the breast implant. These deposits, although quite rare, are painful and can damage the implant, which must then be explanted.

Breast cancer
The number of breast cancer cases in women with (a) breast implant(s) is not related to the number of breast cancer cases in the general female population.

Changes in the sensitivity of the breast or nipple
A breast implant procedure can increase or decrease breast and/or nipple sensitivity. This change in sensitivity can be temporary or permanent.

Delayed healing / hypertrophic scars
When the incision does not heal well this can result in unsightly, hypertrophic or keloid scars. Delayed healing may also occur in the following cases: practice of some sports, an infection, sutures that are too tight, an implant that is too large. If the problem persists, the scars may have to be treated surgically.

Capsular contracture
The fibrous capsule, which forms naturally around any foreign material implanted in the human body, can retract around the latter, causing abnormal compression. This is painful and can deform the breast and rupture the implant. The implant may have to be removed (with or without reimplantation). It is strongly advised not to perform a capsulotomy to treat capsular contractures as this procedure can cause wrinkles or even rupture the shell.

Deflation of the implant
Implants deflate as a result of a rupture. This is rare with silicone gel implants because of the gel's cohesion. Any deflation detected by the patient should be interpreted as a ruptured implant and more thorough examinations will be necessary. If it is established that the implant has ruptured, it must be explanted.

Pain
Post-operative pain due to the surgical procedure can be experienced two to three days after the surgery. The post-operative pain intensity varies according to the patient. The patient then experiences discomfort over the following month. These pains can be treated with analgesics. If there is any persistent or new pain in the area of the implant, the patient should be examined to rule out a complication.

Effects on children
Although there is currently no established method to accurately detect silicone levels in breast milk, a study measuring silicon levels (one component of silicone) did not indicate higher levels in the breast milk of women having silicone gel-filled implants than in women without an implant.

Permanent implant explantation
If multiple implant-related complications occur repeatedly, or if the surgeon deems that the patient's condition requires the explantation of the implant, permanent implant explantation should be considered, meaning that the implant cannot be replaced and leading to unsightly results (sagging breasts, wrinkles).

Extrusion
When there is an excessive pressure on the implant, it can protrude through the incision or the skin.

Gel leakage / silicone migration
Despite its barrier effect, the silicone shell containing the silicone gel is not perfectly impermeable. Small amounts of silicone can therefore diffuse out of the implant and spread into the tissues. Silicone gel is not toxic to the body but local reactions can occur, forming small fibrous capsules.

Galactorrhoea
Galactorrhoea is the flow of milk through the nipple when the woman is not breastfeeding. This can occur on both sides (bilateral) or in one nipple only (unilateral).

Haematoma
To prevent a haematoma in the implant area, meticulous haemostasis must be performed during the procedure. In case of persistent haematoma, a puncture can be performed taking all necessary precautions to avoid damaging the implant. Appropriate medical compression in the implant area for a few weeks following the procedure will reduce postoperative oedema.

Implant noticeable to the touch / visible implant
Improper initial implant positioning, movement of the implant, inappropriate an implant volume, an inappropriate implant type and cohesion are all factors that can make the implant noticeable to the touch and/or visible. If the patient is dissatisfied, a new procedure may be considered.

Infection / Inflammation / fibrosis
Short-term or long-term post-operative infections are only very rarely reported with breast implant procedures. However, any infection should be treated as soon as it occurs. If antibiotics are unable to treat the infection, the implant can be explanted. Inflammation may manifest as redness, swelling, a sensation of heat or a throbbing pain. Fibrosis occurs following substantial tissue degradation or when inflammation develops in an area where tissues are not regenerated.

Lymphoedema or lymphadenopathy
A breast implant procedure can cause swelling or an abnormal reaction in one or more axillary lymph nodes.

Anaplastic large cell lymphoma
Anaplastic large cell lymphoma (ALCL) is a rare type of lymphocytic lymphoma. This type of cancer can very rarely occur in the breasts of women having (a) breast implant(s). The clinical signs that should prompt the patient to see her doctor are: abundant effusion, increased volume, pain, inflammation, a mass or ulceration (skin lesion) in the breast area.

Connective tissue disease
No relation has been established between silicone gel-filled breast implants and connective tissue diseases, breast cancer or reproductive problems but these complications cannot be ruled out as studies on these subjects are not sufficiently relevant.

Poor positioning / movement
The implant may move because of poor initial positioning, trauma in the implant area or significant early slackening of the surrounding tissue, failing to hold the implant sufficiently. This results in loss of functionality of the implant (implant herniation, reversal or a change in breast shape) requiring further surgery.

Mass, lump, cyst, granuloma
A lump or mass of inflammatory cells surrounding a foreign substance may occur due to long-term inflammation.

Necrosis
Tissue necrosis can be caused by:

- soaking the implant in an iodine solution before the procedure,
- an abnormal local tissue reaction possibly due, for example, to infection or treating the tissue with radiotherapy prior to the implant procedure, etc.,
- very taut tissue due to insufficient tissue or an overly large implant.

Additional surgery
In view of the various possible complications related to a breast implant procedure, further surgery is always possible. In addition, the limited lifespan of the implant may result in another procedure to maintain the desired results. The patient must understand and accept the risks of further surgeries before making the decision to have an implant procedure.

Breast ptosis
This phenomenon of sagging breasts normally results from ageing, pregnancy or weight loss. Like natural breasts, a breast fitted with a breast implant may sag over years due to tissue distension in the implant area. Ptosis is not dangerous and can be treated surgically.

Delays in breast cancer diagnosis
Having (a) breast implant(s) can delay the diagnosis of breast cancer. This is because the breast implant hides part of the breast and can therefore hinder the interpretation of mammogram results.

Unsatisfactory results (size, shape, appearance)
After a breast implant procedure, the patient may not be satisfied with the general appearance, depending on the style, shape or size of the implant used.

Wrinkles / creases / ripples
It is possible for the implant shell to wrinkle or undulate, forming ripples depending on how well it is held in the pocket and its position in relation to the pectoral muscle according to the surgical indication. The wrinkles can be noticeable on the surface of the skin. The only solution to correct this is explantation.

Risks of the surgery / iatrogenic Injury, damage
A breast implant procedure involves risks inherent to the procedure itself, such as the risks and complications associated with a general anaesthesia, iatrogenic injury or damage. It is vital to take all these risks into account in the pre-operative assessment and to inform the patient before surgery.

Redness / ecchymosis / bruising
Bleeding during surgery can cause a change in skin colour. This is a symptom expected with surgery and is temporary.

Deep vein thrombosis
Refers to the formation of one or more blood clots.

Rupture
The implant can rupture due to surgical trauma (implant damaged during insertion or by surgical instruments) or post-operative trauma (violent impact, excessive compression in the area of the breasts) or natural ageing. This rupture can be asymptomatic (silent rupture), cause the implant to deflate, or change the shape or the appearance of the breast. If there is any doubt, a diagnostic examination must be carried out (mammogram, ultrasound or MRI) to ensure that the implant is intact. Lastly, regular monitoring enables any rupture to be detected early on. If the rupture is confirmed, the implant must be explanted. To guarantee constant mechanical properties and limit the risk of rupture, regular tests are performed according to current standards.

Seroma
This is the accumulation of lymph around the implant, resulting in a temporary increase in the volume of the breast, which usually resolves itself if it is small, or which can be treated by aspiration if there is a significant increase.

Faced with functional or physical signs (effusion, volume increase, pain, inflammation, mass, ulceration, deterioration of the general state) occurring in particular at a distance from the post-operative phase in a woman carrying breast implant, the diagnosis of anaplastic large cell lymphoma associated with a breast implant must be evoked.

FURTHER INFORMATION

Lifespan of the implant

Breast implants have a limited lifespan. Given the potential complications mentioned above and the natural wear and tear of the implant within the body (daily mechanical stress), the implant may need to be explanted or replaced, involving further surgery.

Given the activities and the many factors that can affect the lifespan of the implants, the lifespan of a breast implant cannot be estimated accurately for any given patient. The lifespan of CEREFORM® breast implants is estimated at 75% after 9 years of implantation (Kaplan Meier method).

You must be informed that if the implant is explanted and not replaced, the result will be unsightly (sagging breasts, wrinkles, etc.).

Alternatives to breast implant procedure

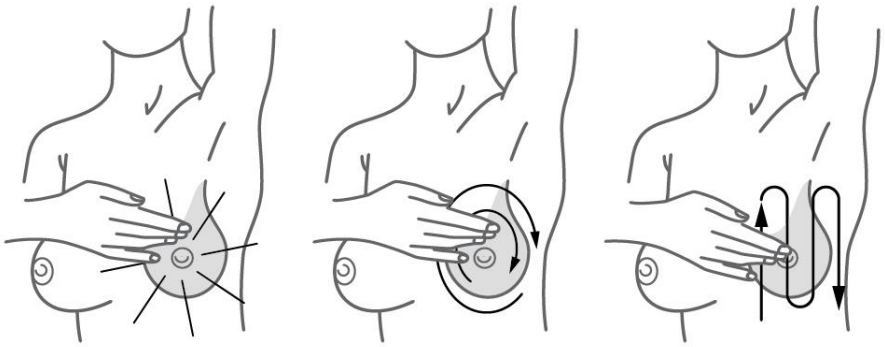
In addition to any potential complications during and after the procedure, your practitioner must inform you of alternatives to a breast implant procedure: external breast prostheses, breast reconstruction using your own tissue, etc.

NECESSARY PRECAUTIONS

The patient must be informed of the following:

- Carry with you the completed **patient card** given by the practitioner at all times to facilitate emergency medical care (for example in case of a road accident).
- Go to **check-up appointments** and report any trauma, deflation or pain in the implant area.
- Consult your doctor for **routine monitoring in order to detect breast cancer**
- **Consult your doctor or surgeon if you suspect a complication**, especially if there has been any trauma or compression (for example, caused by a violent breast massage, sport or the use of a seat belt).
- **Mention the presence of a breast implant in case of imaging examinations** (mammogram, ultrasound, MRI) **or a medical or surgical procedure near the implant area**.
  As silicone is partially radiopaque, the implant can obscure the area underlying the implant during medical imaging. The radiology technician must adapt the technique to choose the most appropriate angles of vision as some areas may be obstructed by the implant. For mammograms, the technique must always be adapted because there is also a risk of the implant rupturing or being weakened.
- Consult your doctor or pharmacist before **applying topical medications** (such as steroids) to the breasts.
- Be cautious concerning **some sports** that may cause impacts to the implant (combat sports, etc.) and be aware of the risks of early rupture in case of an impact.
- Be cautious as to the **use of cold treatments** (e.g. cryotherapy), which can weaken breast implants.
- **Do not have acupuncture** in the breasts.
- Wait at least **3 months after the procedure before becoming pregnant.**

- **Examine your breasts once a month**, preferably one week after the end of your period or on a set date if you are post-menopausal. The purpose of this self-examination is to detect a lump or any change in the appearance of your breasts. The self-examination is carried out as follows:
    - With the arm raised, use the tips of the three middle fingers of your free hand to examine the opposite breast.
    - Make small circular movements without removing the fingers from your skin.
    - Examine the whole breast: from the clavicle to the base of the breast and from the sternum to the armpit.
    - Move upwards and downwards repeatedly.



The self-examination does not replace the opinion of a health professional since the implant can alter the diagnosis.

PATIENT'S COPY

« I acknowledge that I understand the benefits and the surgical and post-surgical risks associated with the breast implant procedure:

- as mentioned in this document,
- as explained in the booklet « Information about the breast implant procedures » that I have been given,
- and after discussing this with my practitioner.

I declare that I have given my practitioner my full medical history and understand that withholding any such information could have serious consequences on my health.

I confirm that I understand that the risks related to the breast implant procedure and the general anaesthesia are not foreseeable.

I confirm that my practitioner has informed me about alternative methods, the importance of clinical postoperative follow up and about the possibility of further surgery. All of my questions have been answered clearly.

By signing this document I confirm that I freely accept the risks related to the insertion of pre-filled silicone gel breast implants and maintain my decision to have this procedure.

I take full responsibility for this decision.

I authorise Doctor ..... to carry out this procedure. »

Hospital stamp *(or name and address)*
+ Date
+ Surgeon's signature

Patient's first and last name
+ Date
+ Signature preceded by "*read and approved*"
(handwritten)

To be signed in duplicate, one copy for the surgeon and the other for the patient

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COPY TO BE KEPT IN THE MEDICAL FILE

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