CE 2797

INFORMED CONSENT
INFORMATION
For the attention of the patient

Would you like to undergo a breast augmentation/reconstruction procedure? This operation is not insignificant.
Carefully read the information below that is addressed to you. It is intended to inform you about the breast augmentation/reconstruction surgery with silicone implants, its risks, constraints and the alternative treatments.
Make sure that you have fully understood the information provided; do not hesitate to take your time to read and understand the document.
Your surgeon is there to answer all of your questions.
Please initial of the pages in the document, then sign the consent form, if applicable, at the end of the document.

1. Introduction

A breast implant is a long-term implantable medical device intended to increase breast volume for aesthetic or reconstructive reasons.
Breast implants of the Monobloc® – Silicone SoftOne® range are made up of an envelope made out of silicone elastomer filled with a filling product: a silicone gel. They are differentiated by:

- The surface condition: smooth (L), microtextured (MT), textured (T)
- The shape: round or anatomical,
- The sizes and filling volumes.

2. Identification of the manufacturer

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3. Information on Monobloc® Silicone SoftOne® breast implants

Breast implants in the Monobloc® – Silicone SoftOne® range are long-term, implantable medical devices.
They are made up of a silicone elastomer envelope filled with cohesive and viscoelastic silicone gel.
Monobloc® – Silicone SoftOne® breast implants are manufactured using medical-grade, biocompatible materials and are appropriate for long-term implantation.
The visco-elasticity of the gel makes it possible for the implants to be similar to the consistency of the mammary glands.
The implants are manufactured as Monobloc, i.e. they are made up of a single envelope that is equal in thickness at all points, without glue, in order to improve their capacity to resist rupture.
Monobloc® – Silicone SoftOne® breast implants are sold sterile and are for single use.

4. Indications for use

Claimed use/indications
The Monobloc® – Silicone SoftOne® devise are surgical implants designed for breast augmentation and reconstruction for women who are at least 18 years old, unless otherwise indicated by a doctor.
The indications are the following:
Aesthetic breast augmentation: augmentation in volume by inserting an implant.
Breast reconstruction: breast reconstruction following the removal of all or part of the damaged mammary gland.

- Breast reconstruction due to cancer treatments, other than a mastectomy.
- Another procedure that caused complications or other adverse results following the previous surgical procedure, leading to a mastectomy or following cancer treatments.
- Post-trauma defined as the total or partial removal of one or more of the breasts via surgery (of any kind) or the results of the damage itself.

Expected performance
Breast implants are inactive surgical implants and the requirements specified in ISO 14630: Article 4 apply. In fact, the performance called for Mononbloc® - Silicone SoftOne® implants correspond to the clinical performance and the preclinical specifications.
The clinical performance includes:

- The aesthetic and psychological benefit of the patient
- The expected life span of ten years

The preclinical specifications are defined by the functional characteristics of the materials and components on the envelope and implant.

Expected benefits
Monobloc® breast implants have excellent safety conditions.
They produce the curves of the natural breast, both in cases of reconstructive and aesthetic surgery. Free of any toxicity, they are an aesthetic solution that corresponds to the image of femininity that makes it possible to reconcile it with one's image of one's self.

Device life span
The breast implants have a limited life span, since implants may need to be removed or replaced, which could involve a new surgical procedure.
Under normal conditions of use, the expected life span is ten years.
The life span pends on certain factors, including the real method of implant, the anatomy and the health condition of the patient, her behaviour and activities, such as violent sports or compression caused by violent passage, for example, as well as foreseeable and unforeseeable external mechanical influences (violent trauma, seat belt)

Contraindications
There are contraindications for breast implants. Check with your surgeon that you do not have any.

5. Information on the procedure

Surgical techniques:
The surgeon, during the surgical procedure, uses one of three following approaches (suture area):

- Areolar approach (around the nipple)
- Axillary approach (in the armpits)
- Submammary approach (in the lower fold of the breast)

The surgeon will position the implant based on two choices:

- In the pre-pectoral region (between the mammary gland and the pectoralis major muscle)
- In the retro-pectoral region (behind the mammary gland and behind the pectoralis major muscle)

Limitations:
A serious investigation of the patient's health condition must be completed before any procedure, in order to evaluate the risks of surgery.
You should choose the shape and volume of your implant(s) with the practitioner, according to your needs and expectations. **Your expectations should be realistic.**
Psychological balance is necessary before all procedures.

Course of the procedure:
The procedure is carried out in a hospital environment or at a clinic, most often under general anaesthesia. An anaesthesia work-up should be carried out.

Postoperative follow-up:
Postoperative follow-up is necessary. It is carried out by the practitioner and should be scrupulously followed by the patient.
Furthermore, the presence of implants does not take away from standard medical monitoring (gynaecological monitoring and breast cancer screening), even if it is necessary to have more exams than those related to this monitoring.
Moreover, it is important to specify to the different doctors that see you that you have breast implants. A check-up consultation, specific to implants, with your plastic surgeon is recommended every two to three years.

Special condition after cancer:
After breast cancer, a tissue extension with an "expander" is sometimes necessary before placing breast implants.

Aesthetic considerations:
Satisfaction with the results depends on one's expectations. These expectations should be evaluated before any procedure.
Obtaining a natural effect is desirable (symmetry of the breast implants, nonvisible scar).

Removal and replacement:
It should be noted that implants are not guaranteed for life. In certain cases, it may be necessary to undergo a surgical revision that may lead to the removal and replacement of the implant.

6. Information on the effects

Breast implants is a non-emergency procedure and you should be aware that there is a certain number of risks and side effects may occur:

Local complications:

- *Capsular contracture:* The natural reaction of the body to the presence of a foreign body consists in surrounding it with a small membrane, called a "capsule," in order to prevent it from moving around. This capsule instantly and undetectably forms. It is produced in all patients. In certain cases, for reasons that have not yet been completely studied, this capsule may tighten around one or both of the implants. This is called capsule retraction or "fibrous capsule"; it may produce at variable degrees (Baker stages). Even though some women may consider a certain firmness of the breasts as desirable, bothersome retraction may occur at any time, between a few weeks after the initial procedure to several years later. There is no way to predict the reaction of the body. There are a certain number of techniques used by surgeons to prevent or correct this problem, notably surgical repair. However, none of these techniques are consistently successful.

- *Visible or silent rupture*: Rupture may be discovered from its clinical signs (decrease in breast volume, palpable mass), but it may also be asymptomatic and, therefore, radiological monitoring is necessary.

Even though there are new silicon gels that are cohesive, the migration of the gel in the body is possible.

Hereafter are presented the cumulated rupture rate* for the Monobloc® - Silicone SoftOne® by texture:

Complication	2 years of implantation	5 years of implantation	10 years of implantation
Rupture %	0,00	0,023	0,046
Survival rate %	100,00	99,98	99,95

Table 1 : Cumulated rupture rate at 2, 5 and 10 years for smooth implants

Complication	2 years of implantation	5 years of implantation	10 years of implantation
Rupture %	0,019	0,027	0,047
Survival rate %	99,98	99,97	99,95

Table 2 : Cumulated rupture rate at 2, 5 and 10 years for microtextured implants

Complication	2 years of implantation	5 years of implantation	10 years of implantation
Rupture %	0,017	0,039	0,060
Survival rate %	99,98	99,96	99,94

Table 3 : Cumulated rupture rate at 2, 5 and 10 years for textured implants

**Calculated from PMS data between 2002 and 2020*

- *Gel transudation*: Very small quantities of silicone may pass through the implant envelope and spread to the surrounding tissue.

- *Appearance of folds or wrinkles*: It is possible that the surface of the implant will fold. This phenomenon may occasionally be seen on the surface of the skin, based on the position of the implant.

- *Sensitivity reactions to the implanted materials:* In rare cases, an inappropriate immunological response (allergy, irritation, redness, anaphylactic shock, etc.) may occur as relates to the silicone, sutures, bands or injected products.

- *Infections*: An infection may occur following the operation. It may appear directly after the operation or later. In rare cases, it may be necessary to remove the implant to correctly treat the infection. In exceptional cases, potentially fatal infections, such as toxic shock syndrome, have been observed.

- *Calcification of surrounding tissue*: In rare cases, calcium deposits may form around the implant, making the breast hard and painful. These deposits weaken the implants.

- *Inflammation*: Inflammation is a reaction of the immune defences of the body to a foreign body. The signs are redness, a hot sensation and/or pain. Immediate inflammation after the operation is related to surgery.

- *Siliconomas/granulomas*: Siliconomas are the result of an inflammation due to the silicon that may have spread via the implant envelope. These are small fibrous capsules that form around the silicone.

- *Hypertrophic/abnormal scarring*: There is a problem with scarring, characterised by an indentation/raised area at the incision site. The results are not aesthetically pleasing and may, in certain cases, require surgical revision.

- *Wound dehiscence/separation:* Surgical incisions are entry sites sutured or held together by a margin approximation dressing or device after an operative procedure. Dehisced surgical wounds are defined by the separation of the incision line prior to complete healing resulting in an open wound.

- *Delayed healing*: A delay in healing is possible for certain regions of the breast and/or nipple skin. This delay may require a more frequent change in dressings, or even surgical revision.

- *Haematoma*: This is an accumulation of blood in the tissue, which may arise following trauma, in this case, surgery.

- *Oedema*: Swelling due to an accumulation of liquid following trauma, in this case, surgery.

- *Accumulation of serious fluid without infection:* This is the accumulation of serious fluid in the region of the implant, following trauma from the implant. Drainage (or puncture, may be required.

- *Lymphorrhea*: This is oozing from the lymph node outside of the lymphatic vessels following trauma, in the case, surgery.

- *Necrosis of the adjacent tissue*: Tissue damage following an abnormal local tissue reaction, in the case, for example, of infection or a treatment of the tissue via radiation therapy before the placement of the implant, etc. Necrosis may also occur when the implant is too large or the tissue is insufficient.

- *Implant rotation (specific to anatomical implants):* While rare in practice, the pivoting of an “anatomical” implant remains theoretically

possible and may affect the aesthetic results.

- *Migration/extrusion of the implant*: In exceptional cases, the implant may create a pathway in the tissue and end up appearing on the surface of the skin. These phenomena only occur when the tissue that was already damaged or that has been damaged under pressure, due to ischaemia (i.e. insufficient blood circulation) caused by an implant, for which the size is too large or for an implant that has been displaced.

- *Implant perceptible to touch*: Several causes exist: poor placement, hard capsule and hardening, inappropriate size, movement of the implant, etc.

- *Implant malposition*: When the implant is placed incorrectly during the initial surgery or when the implant has shifted from its original position. Shifting can be caused by many factors, such as gravity, trauma, poor initial placement, and capsular contracture.

- *Atrophy in pectoralis muscle*: Thinning or diminishing of pectoralis muscle (major muscle of the chest)

- *Erythema/Redness*: any abnormal redness of the skin. Erythema is caused by dilation and irritation of the superficial capillaries; the augmented flow of blood through them imparts a reddish hue to the skin

- *Skin paresthesia:* abnormal sensation of the skin (tingling, pricking, chilling, burning, numbness) with no apparent physical cause.

More general complications:

- *Anaplastic large cell lymphoma (ALCL):* Based on European and FDA safety information and the scientific literature, a possible association has been identified between breast implants and developing anaplastic large cell lymphoma (ALCL), a type of Non-Hodgkin's lymphoma. Women with breast implants may be at a very low, but higher risk of developing ALCL in an area adjacent to the implant. This specific item was added to the WHO 2016 classification under the term "BIA-ALCL*".*

- *Side effects of general anaesthesia:* General anaesthesia has risks. There is the possibility of injury and even death.

- *Cardiovascular reactions*: Venous thrombosis, pulmonary embolism, infarction: these are the inherent risks of any surgery, even in patients without symptoms. Hospitalisation may be necessary.

- *Nerve or blood vessel damage*: This damage may arise during the operation.

- *Immunological reactions*: There is, to date, no proof of a correlation between the onset of auto-immune diseases and breast implants.

- *Neurological reactions*: Some women with breast implants have complained of neurological symptoms. However, to date, there is no proof of this.

- *Psychological disorders*: The patient will make a choice in the shape and volume of her implants with the practitioner, according to her needs and expectations. The expectations should be realistic. Please remember that changing your silhouette also sometimes means changing your image of yourself.

- *Connective tissue disorder (CTD):* A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system. Connective tissue diseases ("CTDs") that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma. There have been a number of published epidemiological studies that have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease.

- *Metastatic disease*: Spreading of cancer cells from the original site to other parts of the body.

- *Staphylococcal toxic shock syndrome*: In rare instances, as with other invasive surgeries, Toxic Shock Syndrome (TSS) has been noted in women after breast implant surgery. It is a life-threatening condition. Symptoms of TSS occur suddenly and include a high fever (38.8°C or higher), vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches and drops in blood pressure which may cause fainting

- *Autoimmune syndrome induced by adjuvants (ASIA) syndrome*: also known as Shoenfeld's syndrome, is a theoretical autoimmune disorder proposed by Israeli immunologist Yehuda Shoenfeld in 2011. Symptoms of ASIA syndrome include : Myalgia, myositis or muscle weakness, arthralgia and/or arthritis, chronic fatigue, un-refreshing sleep or sleep disturbances, neurological manifestations, cognitive impairment, memory loss, pyrexia, dry mouth, Raynaud's phenomenon, headache, alopecia or hair loss, skin abnormalities, gastrointestinal symptoms, night sweats and lymphadenopathy.

- *Breast implant illness (BII):* Term used to refer to a wide range of symptoms that can develop after undergoing reconstruction or cosmetic augmentation with breast implants. BII can occur with any type of breast implant, including silicone gel-filled, saline-filled, smooth surface, textured surface, round, or teardrop-shaped. BII impacts each individual in a unique way. Symptoms can include: joint and muscle pain, chronic fatigue, memory and concentration problems, breathing problems, sleep disturbance, rashes and skin problems, dry mouth and dry eyes, anxiety, depression, headaches, hair loss, gastrointestinal problems, …

- *Unknown risk*: Risks that are currently unknown may be associated with silicone breast implants.

Adverse effects:

- *Pain*: You will experience pain after the operation. This pain normally subsides 15-20 days following the operation. If pain persists, do not hesitate to contact your surgeon.

- *Insufficient aesthetic results* (asymmetry, ptosis, displacement, hypertrophic scars): There is no guarantee on the results that may be obtained. You may be disappointed by the results of your operation and it may then be necessary to revise the surgery.

- *Change in the sensitivity of the nipples and breasts:* Sensation may be affected by the implant. These sensations may be variable in intensity and be temporary or permanent in nature.

- *Ptosis*: Sagging or drooping of the breast.

- *Asymmetry*: Uneven appearance between a woman's left and right breasts in terms of size, shape, or breast level.

7. Precautions to take

Certain precautions must be taken, in particular, when doing violent sports, since all chest trauma may have consequences on the integrity of the implant, as well as strong compression caused by, for example, violent massage or a seat belt, and this may have consequences on the implant and its position. You should consult your surgeon in the case of trauma, in order to check the integrity of the implant.

All constraints or abnormal lesions in the breast may lead to the rupture of the implant.

Patient information on medical follow-up: You must undergo check-ups and visits prescribed by your surgeon. Your surgeon will carry out the check-up and monitor proper postoperative function.
You must:

- Consult a surgeon for medical follow-up.
- Consult a doctor or pharmacist before applying topical medications (such as steroids) on the breasts,
- Consult a doctor for normal follow-up, in order to detect breast cancer,
- Tell a doctor or surgeon about the presence of an implant if a surgical procedure on the breasts is called for,
- Tell the radiologist in the case of a mammogram, so that the mammogram compression can be adapted
- Consult a doctor if you suspect complications, notably in the case of trauma or compression caused, for example, by violent breast massage, sports activities or the use of seat belts,
- Keep the patient card with you at all times, in order to facilitate emergency medical care (for example, in the case of a car accident).

Patient information on the effect of the implant on diagnostic techniques, such as mammograms:
Silicone gel implants are not radio-transparent. In certain cases, the implant interferes with breast cancer screening during mammograms. Tell your radiologist about the presence of implants. The latter should also be familiarised with using special imagery techniques and appropriate diagnostic techniques for patients with breast implants, in order to prevent too great of a compression of the implant and its potential rupture.

Patient information on the possible effect of the implant on breast self-exams:
Standard mammogram screenings are more difficult to carry out when you have breast implants. You should continue to examine your breasts every month to screen for perceptible lesions. However, this procedure risks being difficult to execute. Your surgeon should explain to you how to make the distinction between the implant and the breast tissue, in order to optimize the efficacy of self-exams.

Patient information on possible effect of implant on breast feeding:
After the implant of breast implants, breastfeeding is not considered dangerous. Certain studies suggest, however, that there may be a reduction in milk production of the implants are implanted via an areolar approach.

8. Short- and long-term follow-up and contacts

The check-up visits called for by your surgeon are essential during the weeks and then months following implantation. A check-up consultation, specific for implants, with your plastic surgeon is recommended, but besides this visit, it is essential that you consult your doctor as soon as there is a change in one or both of your breasts or after violent trauma.
You should immediately consult your doctor if you suspect that the prosthesis has ruptured.
It is necessary to consult a doctor to carry out normal follow-up, in order to detect breast cancer.

9. Traceability

Laboratoires ARION has made a patient card available, as well as labels that include information concerning the surgery date, your name and the name of the practitioner, as well as all information necessary for the traceability of the breast implants that have been implanted (commercial reference, series number, lot number). You must keep your patient card with you at all times, in order to facilitate emergency medical care (for example, in the case of a car accident).

10. Alternative treatments

You should know that there are alternative treatments to increase breast size, in particular, treatments that do not require a surgical procedure, such as:

- Using external breast prostheses,
- Stuffing.

Or others require a surgical procedure

- Breast lipofilling (Fat injection)
- Implants with saline/hydrogel solution.

Patient consent:

Increased breast size with silicone implants is a non-emergency surgery.

I have read and understood the information in this document. I declare that I am aware of the fact that the risks related to breast implants are not totally foreseeable, even if these products have been exceptionally designed. I declare that I accept these conditions and limitations. I declare that I have informed the surgeon about my surgical history. I declare that I assume entire responsibility for my choice and agree to have the Monobloc®– Silicone SoftOne® breast implants implanted.

Signature of the patient and date:

Signature of the surgeon and date:

The original will be stored by the doctor, a copy will be provided to the patient.