

PATIENT INFORMATION BOOKLET  
**BREAST IMPLANTS**  
OF LABORATOIRES SEBBIN



SEBBIN PARIS  
ESTHETIQUE & RECONSTRUCTION

Recreating harmonious bodies for a new vision of rebirth.



Dear Madam \_\_\_\_\_

For personal reasons, it was your desire to have your breasts reconstructed, modified, remodelled or increased in volume. This desire is of course justifiable. It contributes to your well-being, self-esteem and self-confidence, which everyone has a need for. And the issue here is your femininity. Femininity in search of a harmony entitling you to both physical and psychological fulfilment.

Because recreating harmonious bodies gives a new vision of rebirth, your surgeon will know how to propose the best solutions to you so that you can once again view your body with tranquillity and offer your newfound beauty to those who you love.

But whether it is a matter of aesthetics or reconstruction, fitting breast implants is not a trivial operation. Of course, your surgeon is there to accompany you in your approach by answering, as a health professional, all your questions concerning the choice of possible implants and the surgical procedure.

This booklet was created by Laboratoires Sebbin to help you calmly approach this stage in your life, by explaining to you as simply as possible the reasons why, nowadays, breast implantation is an operation enjoying the advantage of optimal safety.

# BECOME FAMILIAR... WITH YOUR BREASTS



Nature did not give any egalitarian generosity concerning the bust. As much in volume as in shape, the breasts vary from one woman to another due to, among other factors, their glandular and adipose tissue. With age, it is the posture of the breasts which declines, as a result of glandular tissue being progressively replaced by less firm adipose tissue. And their volume also depends on factors such as age, skin elasticity, previous pregnancies, types of physical activities undertaken.

The breasts are attached to the pectoral muscles (the greater pectoral incidentally contributes to arm movement) which cover the thorax in connective tissue (fibres). They are supported both by the skin and by a suspensory ligament. There is no real intervention from any muscles. Drooping of the breasts, as sometimes complained about with age, is a very natural occurrence (it is what your practitioner calls ptosis of the breast).

The breasts are covered by a multitude of nerves, blood vessels (capillaries) and lymphatic vessels, but also by lactiferous ducts, the role of which is to ensure transport of milk to the nipple.

The areola is the pink or brown pigmented zone around the nipple.



A close-up, soft-focus portrait of a woman's face. She has light blue eyes and is looking slightly to the left. Her right hand is raised, with fingers gently touching her temple and ear. The lighting is warm and natural, highlighting the texture of her skin and the subtle contours of her face. The background is a plain, light beige color.

BREAST SURGERY  
COMING TO THE AID OF NATURE )

In aesthetic surgery, implants allow nature to be corrected and enable you to regain your femininity and self-esteem. Your surgeon will speak to you:

- about asymmetry: when lack of symmetry between the two breasts is relatively pronounced (volume and /or shape), the term breast asymmetry is used;
- about amastia, aplasia: total absence of mammary gland development;
- about hypomastia, hypoplasia: the mammary gland is insufficiently developed;
- about mammary ptosis: drooping of the breasts through loss of their support (weight loss, pregnancy or age). In this case, breast enlargement is combined with plastic surgery of the breasts to "lift" the breasts.

But, in certain cases, such as after therapeutic breast ablation (mastectomy), reconstructive surgery will be an opportunity for women to regain their image with undeniable psychological benefits.

Whether it involves:

- a breast enlargement for aesthetic purposes,
- replacement of an implant,
- a reconstruction,

the result will most often be more substantial than placing an external prosthesis in the bra or reconstruction of the breast with tissue from the patient.

*N.B.: This type of surgery may also be recommended in the case of buttock implants known as gluteal implants.*

# FOCUS ON BREAST IMPLANTS.

## IMPLANT ANATOMY:

Implants are made up of a flexible silicone elastomer envelope which gives the prosthesis its shape and interfaces with the body. This envelope, sealed with an occlusion patch, can be sold either empty for filling by the surgeon with physiological saline during the operation in the case of breast implants only or skin expanders, or sold pre-filled with cohesive silicone gel at the time of manufacture.

The improvements in raw materials and in manufacturing processes (which include the barrier in the envelope and the cohesive gel) ensure that bleeding of gel across the envelope and diffusion of the gel in the event of envelope rupture is highly restricted.



## SMOOTH OR TEXTURED?

When breast implantation first began, the envelope had a smooth porous surface which allowed the passage of silicone gel, which was at the time more liquid; this provoked a violent reaction of the body forming a fibrous membrane leading to a capsular contracture. The arrival of texture permitted a significant reduction in these capsular contractures. Nowadays, the improvement in raw materials on the one hand, and in surgical procedures on the other, has caused there to be very little difference in the rate of capsular contracture between smooth or textured implants. The choice between one or the other rests with the surgeon.

By contrast, during implantation of an anatomically-shaped prosthesis, a half-pear-shaped implant mimicking a more natural breast shape, usage of a textured implant is recommended to limit implant rotation (rotation of an anatomical implant results in a visually inaeesthetic effect). In a specific procedure, the envelope is delicately roughened to promote adhesion of neighbouring tissues and to facilitate integration of the implant within the body, thus preventing any rotation of the implant.



SEBBIN IMPLANTS.  
SAFETY FIRST.



For 26 years, Laboratoires SEBBIN have not ceased in the innovation and development of a whole range of high quality breast implants to respond to women's needs. They can be round-shaped or anatomical, always pre-filled with cohesive silicone gel but varying in firmness according to taste, or inflatable with physiological saline, with different projections, available in numerous volumes. They allow women to rebuild themselves, both aesthetically and psychologically...

## MADE IN FRANCE.

Our breast implants are completely manufactured by us, in France, in our factory in Val d'Oise. Our added value resides in the semi-traditional crafting of silicone: production entirely carried out by hand demands a draconian level of quality control on 100 % of our implants, with optimal safety. Each implant is signed by hand by those responsible for successively assuring their soaking, texturing, inspection, sealing, filling and packaging. Each implant is marked by laser and with a unique identification number to allow full traceability.

This number is repeated on the labels accompanying the implant, one of these labels will be stuck onto the patient card that will be given to you after your operation.

## WE DEMAND YOUR SAFETY.

It resides in the use of raw materials registered with the American FDA (Food & Drugs Administration). The application of Standards ISO 9001 and 13485 within the company enables us to fulfil the requirements of the European Directive 93/42. The latter requires an annual inspection of our quality control system by an accredited organisation where examination of product safety is central.

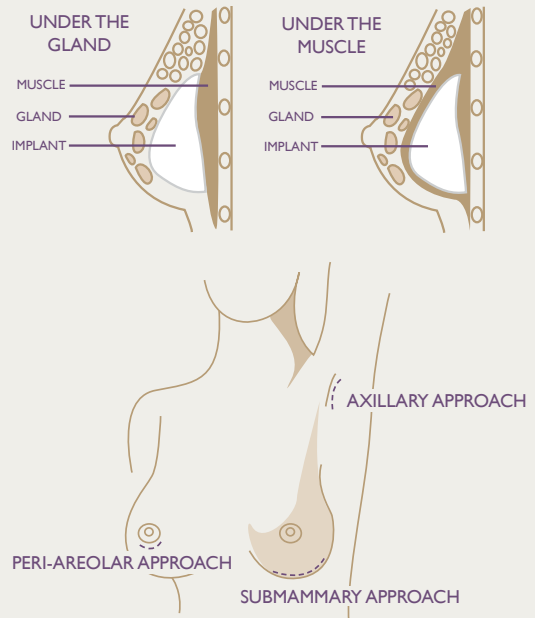
# A SURGICAL INTERVENTION IN COMPLETE CONFIDENCE

## ● BEFORE THE OPERATION.

To be confident to carry out the operation, the surgeon and the anaesthetist must know your medical history. Your surgeon will recommend to you the incision place and the positioning of the implant to suit your morphology and, as with every operation, he will see that you take note of the classic "informed consent form" which you must approve and sign.

## ● IN THE OPERATING THEATRE.

The implant is inserted under the gland (retroglanular position) or under the greater pectoral muscle (retropectoral position) so that the prosthesis will be less palpable, especially in the case of low breast volume, thin skin (risk of seeing the edge of the prosthesis) or after a mastectomy. In aesthetic surgery, the incision will be made either at the level of the areola, or in the axilla, or in the fold under the breast. The incision is limited. Hence, the scars will be very discrete and concealed at the circumference of the areola, in the fold located under the breast or in the hollow of the armpit. In the majority of cases, the intervention is short (1 hour to 1 hour 30). For reconstruction, it may sometimes last longer. It is carried out in the operating theatre, under general anaesthesia.



- **REVIVAL AND RECOVERY.**

Recovery occurs in 1 to 2 hours in the recovery room. The anaesthesia team keeps watch over the recovery process under the best conditions. The operation necessitates 1 to 3 days' hospitalization. It is followed by 5 to 10 days of rest.

## AFTER SURGERY AND FOLLOW-UP IN COMPLETE CONFIDENCE



- **TAKING IT GENTLY, AFTER THE OPERATION.**

After the operation, a dressing with a compressive bandage will prevent the prostheses from moving. After several days and for around 1 month, your surgeon will advise you to replace it day and night with a high-impact bra. Some pain may be felt in the ensuing days as the breasts remain swollen and may pull at the level of the pectoral muscle. Full arm movements should be avoided for at least 3 days, driving for the first two weeks and carrying heavy loads. Sport must be excluded for at least 4 to 6 weeks. No sun exposure for one month to ensure good healing! And of course avoid sleeping on your front...

- **SCHEDULE YOUR FOLLOW-UP.**

Your surgeon will invite you to a check-up consultation in the days following the operation. During the course of the first year, a consultation is recommended every month. Then 3 months, 6 months and 12 months after placement of the prosthesis. Then annually. He will prescribe you some simple monitoring examinations to check that everything is proceeding for the better. For example a MRI (Magnetic Resonance Imaging) or an echography.



## YOUR BODY REACTS? THIS IS NORMAL.

- Minimal postoperative pain can be felt in the 2 to 3 days following the operation. This pain may be relieved by taking analgesics.
- A haematoma or an oedema within the implantation zone: appropriate medical setting in the implantation zone during the weeks following the intervention will allow reduction of postoperative oedema.
- Effusion from a seroma without infection may occur. Drainage may become necessary.
- Temporary loss of sensitivity, or exacerbated nipple sensitivity, are generally observed.



## HAVING GOOD ASSURANCE, IS REASSURING.

Medical device vigilance studies that we have been conducting since 2001 reveal rates of rupture and capsular contracture below 1 % for our breast implants pre-filled with silicone gel (number of complaints received compared with the number of sales between 2001 and 2010 in France).

These rates are confirmed by our current clinical records. Comforted by the integrity and intrinsic quality of our implants and in order to assure you of our long-term commitment we invite you to approach your surgeon to discuss our Guarantee programme.

He will give you your patient card with the identification numbers of your implants and will explain to you how to register on our website ([www.sebbin.com](http://www.sebbin.com)) after your operation, in order to take advantage of it.



THE WORDS OF  
YOUR SURGEON.



- Amastia, Aplasia: total absence of mammary gland development
- Approach: region of the body through which the implant will be inserted.
- Areola: pigmented circle surrounding the nipple of the breast
- Axillary: relating to the armpit
- Breast hypomastia, hypoplasia : insufficiently developed mammary gland
- Breast ptosis: drooping of the mammary gland, due to the weight of the breast
- Capsule: tissue forming within the body, around a foreign body
- Cohesive gel: compact gel, remaining as a single block and having a certain consistency (as opposed to friable or liquid)
- Congenital: existing and presenting at birth (opposite: acquired)
- Contralateral: relating to the side opposite to the affected side
- Explantation: the opposite of implantation. The act of removing an implant from the patient's body
- Mammectomy: ablation of the breast following cancer or trauma
- Physiological saline: saline solution, readily absorbed by the organism
- Steroids: molecules functioning at the hormonal level

# FURTHER QUESTIONS?



- **WILL MY PARTNER BE ABLE TO FEEL MY PROSTHESES?**

Even a perfectly tolerated implant can be noticeable, visible or conspicuous as a whole; it may be possible to palpate its peripheral edge. The conspicuousness of a device varies depending on its position, content and the thickness of the mammary gland and its tissues. Generally, visibility is less if implantation is behind the muscle. In reconstructive surgery following a mastectomy the implant is always palpable wherever it is placed due to the absence of the mammary gland.

- **IS BREAST-FEEDING POSSIBLE WITH BREAST IMPLANTS?**

In a general sense, there is no contraindication for breast-feeding following implantation, whatever the type of device; however, it can be compromised in the event that, at the time of the operation, the lactiferous ducts are sectioned. A breast abscess, more frequent during breast-feeding, may necessitate removal of the implant. One study, carried out by Semple et al, using silicium (very abundant in nature and from which silicone is derived) as a unit of measurement, established that the quantity found in the milk of women with implants is identical to the quantity found in that of women without implants.



## WHAT QUESTIONS WILL THE SURGEON HAVE TO ASK ME IN ORDER TO EVALUATE THE RISKS INHERENT TO THIS TYPE OF OPERATION?

- Are you taking medication?
- Do you smoke?
- Are you allergic or sensitive to certain foods, medications, dressings, rubber... ?
- Have you previously developed red, puffy or broad scars?
- Do you have a tendency (you or one of your ascendants / descendents) to developing nose bleeds or prolonged bleeding following an injury or ecchymoses in the absence of injury?
- Do you (or one of your ascendants / descendents) have any haematological or autoimmune diseases (for example Lupus erythematosus, scleroderma, rheumatoid arthritis, vasculitis)?
- Do you often suffer from swelling or pain in the joints?
- When you are exposed to the cold, do you suffer from severe pain in the hands and/ or do your hands become white in the cold?
- Do you suffer from stiffness in the hands, feet or knees in the mornings?
- Have you already frequently had a strong sensation of tension in your skin, face, arms or legs?
- Is it possible that you are pregnant?
- Have you or are you suffering from any other disease (for example neurological or psychiatric disorder, diabetes, hormonal imbalance, etc...)?



# AND IF I STILL WANT TO KNOW MORE?



Nothing more simple. You can access the internet at different sites of reference that will help you become more familiar with this subject close to your heart:

- French Society of Plastic, Reconstructive and Aesthetic Surgery  
[www.plasticiciens.org](http://www.plasticiciens.org)
- French Society of Plastic Surgeons:  
[www.chirurgiens-esthetiques-plasticiciens.com](http://www.chirurgiens-esthetiques-plasticiciens.com)
- And not forgetting the site of Laboratoires Sebbin :  
[www.sebbin.com](http://www.sebbin.com)
- And that of the French Health Products Safety Agency:  
[www.afssaps.fr](http://www.afssaps.fr)



INFORMED  
CONSENT

## IMPORTANT

You are considering acquiring inflatable SEBBIN breast implants or those pre-filled with silicone gel, and have been designated fit to receive them.

Before signing and giving this informed consent form to your surgeon, you must have taken note:

- of the "instructions for use", of Laboratoires SEBBIN,
- of the alternatives.

N.B.: If your surgeon has not been able to supply you with these documents, you can obtain them from:

GROUPE SEBBIN  
39, Parc d'Activités des Quatre Vents  
95650 BOISSY L'AILLERIE, FRANCE  
Tel.: 33 1 34 42 13 28

These documents will give you all the information known to date concerning the potential risks and benefits of breast implantation. These risks can vary according to your general state of health and the surgical technique used, we advise you to discuss them with your surgeon, and/or your attending physician, gynaecologist, oncologist.

Placement of breast implants necessitates a surgical intervention under general anaesthesia.

The risk/benefit ratio must be carefully evaluated before approving the indication for surgery.

Any implantation of a foreign body in our bodies carries advantages and drawbacks. Here is a reminder of these.



## GENERAL RISKS OF SURGERY

Risks inherent to any surgical procedure and to anaesthesia, although exceptional, can be life-threatening:

- Pain,
- Haematoma, haemorrhage,
- Oedema, lymphorrhoea,
- Inflammation,
- Infection,
- Healing difficulties,
- Resultant scarring,
- Tissue necrosis, promoted by supplementary therapies such as chemotherapy and radiotherapy, and tobacco addiction.



# SPECIFIC RISKS ASSOCIATED WITH BREAST IMPLANTATION

- Change in sensitivity of the nipple or breast: most often temporary, several rare cases of reduction, if not total and permanent loss of nipple sensitivity, must be pointed out,
  - Galactorrhoea or difficulty in breast-feeding,
  - Implant extrusion,
  - Dissatisfaction concerning the aesthetic result expected, but not completely attained.
  - Interference in the standard mammography, the implant may hide part of the breast tissue (also valid in the medium and long term). Hence, inform the radiologist.
  - Late appearance of a periprosthetic effusion, accumulation of fluid around the implant, leading to swelling of the breast.
  - Capsular contracture. A fibrous exclusion membrane will naturally form around the implant. Sometimes, this capsule can harden and compress the implant; thus your breast can become hard and painful.  
A capsular contracture, if considerable, increases the risk of premature wear and rupture.
  - Deflation of an implant with a biodegradable liquid content (our company only authorises physiological saline). This difficult-to-predict phenomenon is generally rapid.
  - Rupture of the envelope of an implant containing a gel (our company uses a cohesive silicone gel of biocompatible medical quality) with the risk of slow migration of the gel, towards the fibrous capsule; if the latter is also

ruptured, the gel can migrate to the exterior of the capsule. An intervention is necessary to change the ruptured implant, or implant suspected of being ruptured. This rupture can occur without any obvious external signs, underlining the importance of regular clinical and/or echographic monitoring and the necessity for consultation in the event of violent injury.

- Calcification of the periprosthetic capsule. Although rare, it can present diagnostic problems due to analogy with the calcium deposits observed in breast cancer.
- Interference in the standard mammography. During standard mammographic screening, the implant can rupture if the compression is too much. In order to minimise the risks of rupture of the implant associated with this technique, we recommend echography or MRI.
- Folds, wrinkles, displacement and rotation can cause wear, and hence premature rupture of the implant. The implant can also become visible or conspicuous.

All these risks can occur in the short, medium or long term and can necessitate surgical reintervention. This phenomenon is likely to be more frequent in the case:

- of implantation in the retroglandular position;
- of an inflatable breast implant.

The lifetime of an implant is not unlimited and cannot be precisely estimated as it depends on the potential occurrence of complications and individual factors. In addition, locoregional complications can necessitate its temporary or permanent explantation.

An implant is not eternal, it ages, it wears out. Thus, one day, it will be necessary to replace it.

### ADDITIONAL INFORMATION:

The existing literature does not show any correlation between cancer, so-called "autoimmune" diseases and implants pre-filled with silicone gel or filled with physiological saline.

### THE BENEFITS:

Breast implants can be of psychological benefit. Patients acknowledge having gained femininity and confidence in themselves, both in the purely aesthetic case, as well as in the case of reconstruction after cancer, or for correction or a morphological anomaly.



PATIENT INFORMED  
CONSENT FORM

## PATIENT'S COPY

- I hereby declare having taken note of and understood the information documents mentioned below informing me of the potential risks and of the benefits associated with having breast implants, mentioned in this form.
- I have fully informed my surgeon of my previous history and ongoing treatments which might contraindicate this intervention, alter the risk assessment or compromise the expected result.
- My surgeon has clearly answered all my questions. He has described the planned surgical procedure to me in my case, the implants which will be inserted, as well as the necessary postoperative follow-up appointments and their dates.
- I am aware that this intervention will oblige me to regular clinical and/or echographic follow-ups, as much for my implants as for my mammary glands.

In awareness of the possible risks associated with this operation, in awareness of the fact that an implant is not eternal and that surgical reinterventions might be necessary, I nevertheless consider that the expected benefits outweigh these risks, which I hereby voluntarily accept.

Consequently, I authorise Doctor..... to proceed with this operation.

Completed at ..... , on ..... , (two copies)

Name, address, tel. of the declarant

Name, address, tel. of the surgeon

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## SURGEON'S COPY

- I hereby declare having taken note of and understood the information documents mentioned below informing me of the potential risks and of the benefits associated with having breast implants, mentioned in this form.
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Name, address, tel. of the declarant

Name, address, tel. of the surgeon

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DECLARATION TO BE KEPT  
BY THE PATIENT

DECLARATION TO BE GIVEN  
TO THE SURGEON

# YOUR IMPORTANT APPOINTMENTS



## BEFORE THE OPERATION.

- 1st consultation
- Following consultations
- Mammography appointment
- Anaesthetist appointment

## ON THE DAY OF THE OPERATION

- Date of operation
- Location of the operation
- Hour of arrival

## AFTER THE OPERATION

- 1st check-up visit
- 2nd check-up visit
- Following visit (                    month)
- Following visit (                    month)
- Following visit (                    month)
- Following visit (                    month)



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