Sebbin
PARIS

Patient Information Leaflet

# AESTHETIC OR RECONSTRUCTIVE: ARE YOU CONSIDERING BREAST SURGERY?

## Silicone Gel-filled Round Mammary Implant: A solution to think about

**WARNING : Mammary implants carry a risk of Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL).**
**Please read carefully the explanation and recommendations mentioned in this document.**
**Do not hesitate to ask your practitioner.**
**Regular follow-up by a health care provider is required**

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Dear Patient,

For personal reasons, you would like to reconstruct, modify, remodel or increase the size of your breasts. This desire is of course well founded. It is part of your well-being, self-esteem and confidence which we all need. It is also an issue of femininity and the search for harmony to give you both physical and psychological fulfilment.

Recreating harmonious bodies for a new vision of rebirth. Your surgeon will offer you only the best solutions so that you can once again look favourably at your body and offer your newfound beauty to those around you who you love.

Whatever its purpose, aesthetic or reconstructive surgery is not a trivial matter. Of course, your surgeon is there to support you along the way, in their capacity as a healthcare professional, by answering any questions you may have about the procedure.

This booklet has been produced to help you approach this stage of your life with confidence.

# Content

# GETTING TO KNOW… YOUR BREASTS

Nature does not deal an equal hand when it comes to breasts. Breasts vary from one woman to another in both size and shape depending on differences in glandular and adipose tissue, amongst other things. With age, the breast's hold and its firmness decrease because the glandular tissue is gradually replaced by adipose tissue. Its volume also depends on factors such as age, skin elasticity, past pregnancies and physical activities.

The breasts are attached to the chest muscles (the pectoralis major which also contributes to the movement of the arm) that cover the thorax with connective tissue (fibres). They are supported by both the skin and a suspensory ligament. No one muscle is involved. Breast ptosis, more commonly known as sagging breasts, sometimes occurs with age and is very natural.

The breasts are covered by a multitude of nerves, blood vessels (capillaries) and lymphatic channels, in addition to milk ducts which transport milk to the nipple.

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

## BREAST SURGERY LENDING NATURE A HELPING HAND

In cosmetic surgery, implants are used to correct nature and help you regain your femininity and self-esteem. Your surgeon will talk to you about:

- breast asymmetry: a lack of symmetry between the two breasts (volume and/or shape).
- amastia or aplasia: total lack of development of the mammary gland.
- hypomastia or hypoplasia: insufficient development of the mammary gland.
- breast ptosis: sagging breasts due to having lost their hold (weight loss, pregnancy or age). In this case, breast augmentation is combined with mammaplasty to “lift” the breasts.

But in some cases, such as after breast removal surgery (mastectomy), reconstructive surgery will allow a woman to regain her image and has undeniable psychological benefits (1).

Nevertheless, whether it is:

- breast augmentation for cosmetic reasons,
- the replacement of an implant,
- or reconstruction,

the result is usually much better than placing an external prosthesis in the bra (2).

# REBUILDING TO START AFRESH

*After cancer, any woman can have breast reconstruction. This decision is a personal choice and the different options should be discussed with your doctor.*

## CHOOSING RECONSTRUCTION

Breast reconstruction techniques have evolved considerably in recent years. There are now many options. If subsequent treatments such as radiotherapy, chemotherapy or hormone therapy are needed, this will be reflected in the choice of reconstruction. The result is not instantaneous and several hospitals stays and surgeries may be necessary to achieve the desired result. It will take several months after the surgery for the breast to finally stabilise.

## CHOOSING WHEN TO HAVE RECONSTRUCTION

Breast reconstruction can be performed during the same operation as the mastectomy; this is called immediate reconstruction. The operation time is longer than delayed reconstruction but allows you, on awakening, to have a reconstructed breast, even if it will not take its final form for several months.

If the reconstruction takes place during a second procedure (after the mastectomy), this is called delayed reconstruction. It will require a second operation and you managing without a breast for a longer period of time.

*Some women choose not to go through breast reconstruction and wear an external breast prosthesis in their bra.*

# RECONSTRUCTION

*Your surgeon will explain the advantages and disadvantages of each method. They can be combined depending on your situation.*

## BREAST RECONSTRUCTION USING AN IMPLANT

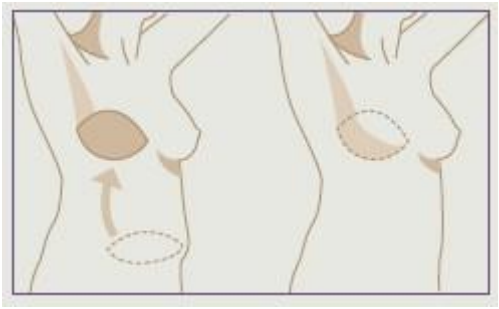
The surgeon inserts a breast implant. More detailed information on reconstruction using an implant can be found on page 12 of this booklet. In some cases, a tissue expander can be used to create the space needed to receive the future implant. It is inserted empty then gradually filled with sterile saline solution over several months. Gradually, the covering tissues stretch and once expansion is complete, the final implant may be inserted. The surgeon will then remove the expander and position the breast implant.

## BREAST RECONSTRUCTION USING BODY TISSUE

The breast can be surgically reconstructed by removing a flap of skin, some fat and muscle and can be combined, depending on the volume missing, with a breast implant. This flap is taken primarily from the abdomen or upper back. The tissue removed will be equal in volume to the breast in order to replace the tissue removed during a mastectomy or after radiotherapy. In some cases, the flap's blood vessels will be retained. When this is not possible, the flap is grafted and microsurgery is used to connect the flap's vessels to those in the breast region. Microsurgery may require a significantly longer operation time.

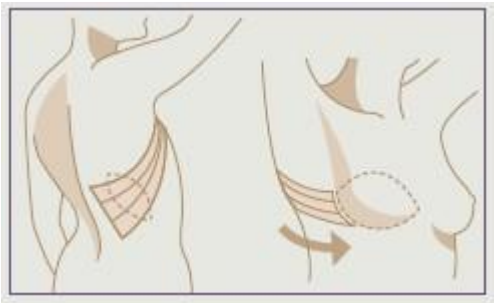
## BREAST RECONSTRUCTION USING BODY TISSUE (DIEP)

The surgeon rotates the abdominal muscle, its fat and skin towards the reconstruction area. The DIEP consists of extracting the fat, skin and vasculature.



Latissimus dorsi flap reconstruction

The surgeon removes almost all of the muscle and the skin necessary to reshape the breast.



## BREAST RECONSTRUCTION USING FAT TRANSFER

Using fat in breast reconstruction after a total mastectomy is an option that can also be considered. Taken from the patient's fatty areas, it is then processed and re-injected into the mammary area to create volume.

The transplanted cells will remain as alive as the surrounding tissue and will adapt to changes in your weight: your breast volume will decrease with weight loss or increase with weight gain.

This procedure is generally carried out during a second operation and lasts for 1-2 hours depending on any additional actions. A special imagining assessment follow-up should be conducted one year after surgery and then regular medical checks should be carried out ideally with the same radiologist.

*The choice of breast reconstruction depends on each patient, her medical condition, general health, lifestyle, emotional state and of course the size and shape of her breasts. Your doctor will help you formulate your goals. Do not hesitate to talk with your loved ones or friends who may have already been faced with this problem. They will help you make the right decision.*

# MAMMARY IMPLANT

Different implants are available on the market. Each manufacturer has its own specificities. Depending on your needs, the surgeon will adapt his choice of implant model.

## ANATOMY OF AN IMPLANT:

An implant consists of a flexible silicone elastomer outer shell which gives its shape to the prosthesis and interfaces with the body. This outer shell is sealed by an occlusion patch (also made of silicone) and can be either sold empty to be filled with saline by the surgeon during surgery (“inflatable” implant) or sold pre-filled with cohesive silicone gel.
The Mammary Implants proposed by Groupe Sebbin are medical devices manufactured from medical grade raw materials, biocompatible and perfectly traceable. They belong to the "polydimethylsiloxane" family.
To date, there are not known manufacturing residuals from gel mammary implant that could pose a risk to patients.

## SHAPE OF BREAST IMPLANT: ROUND OR ANATOMICAL?

The round breast implants are available pre-filled with silicone gel or as inflatable. There are a wide variety of profiles in both cases.
The anatomical breast implants are “teardrops” shaped to mimic natural breasts. They are pre-filled with silicone gel and available in different profiles.

## SURFACE OF BREAST IMPLANT: SMOOTH, MICRO-TEXTURED and MACRO-TEXTURED

The characterization of the envelope of breast implants have been recently normalized. The surface can be smooth, micro-textured or macro-textured. All textures are not available in all countries.
Page 26, you will have a description of products proposed by Groupe Sebbin in Australia.

## STERILITY OF SEBBIN BREAST IMPLANT

Each breast implant is supplied sterile. The sterilization is performed with ethylene oxide. The sterilization cycle is controlled in order to warranty the safety of users and patients.
A breast implant is single used: once explanted, it cannot be re-implanted in a new surgical procedure.

# A SURGICAL PROCEDURE TO REGAIN CONFIDENCE

## Before surgery

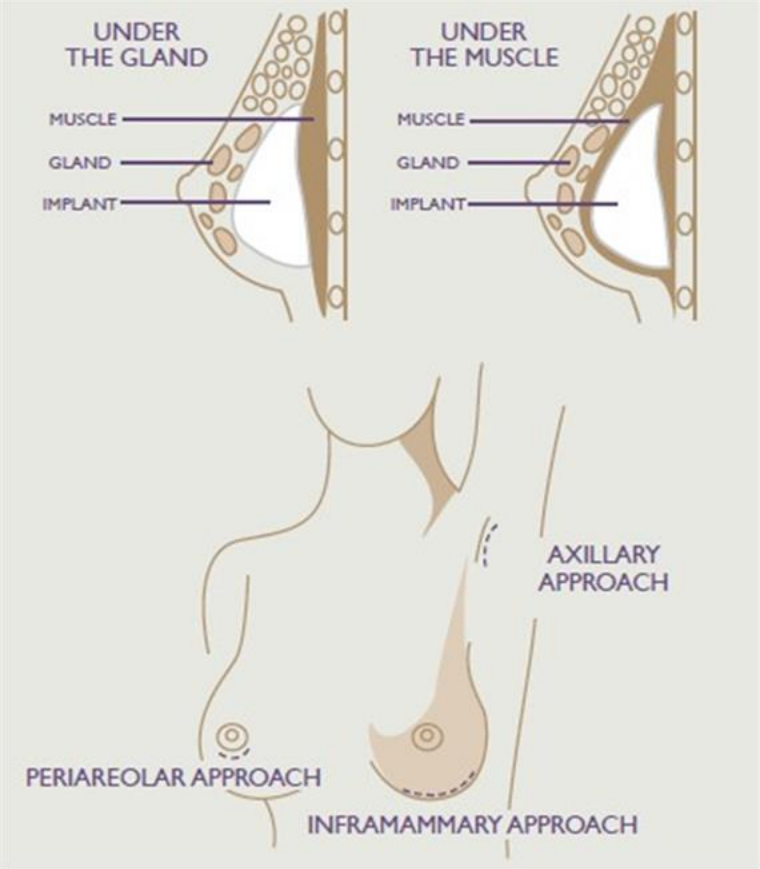
In order to operate confidently, the surgeon and anaesthetist will need to know your medical history. Your surgeon will recommend the insertion approach and to position the implant in line with your body and, as with any operation, they will provide you with the Informed Consent Form that you will have to approve and sign.

## In the operating theatre

In cosmetic surgery, the implant is inserted under the gland (retroglandular position) or under the pectoralis major muscle (submuscular position). The incision is made either in the areola, the armpit or in the groove located under the breast. Scars are concealed on the periphery of the areola.

In most cases, the procedure is relatively short (less than 2 hours) and is performed in the operating theatre under general anaesthesia.

In reconstruction, the surgeon uses the scar left by the mastectomy to insert the implant. This procedure can sometimes take longer.



## Recuperation and Recovery

Recovery takes 1 to 2 hours in the recovery room. The anaesthesia team ensure that you wake up in the best conditions possible. In certain cases, the operation can take place on an outpatient basis (the patient arrives in the morning and leaves later that day), otherwise, 1-2 days of hospitalisation may be required. This is followed by 5-10 days of rest.

# POST-OPERATIVE CARE AND FOLLOW-UP IN COMPLETE TRANQUILITY

## POSTOPERTAIVE CARE

After surgery, a dressing with a pressure bandage or an adapted bra will prevent the prosthesis from moving.

As soon as you leave the operating theatre and for about one month afterwards, your surgeon will advise you to wear a bra with good support both day and night. Some pain may be felt in the days following because the breasts are swollen and can pull on the chest muscle.

Avoid any wide arm movements for at least three days, avoid driving during the first two weeks and do not carry heavy loads from 1 to 2 months. Playing sports is not permitted for a minimum of 4-6 weeks It may last for 3 months according to the location of the implant. Go to swim in a pool or at the sea is not recommended until the end of cicatrisation.

There can be no sun exposure for a month for proper healing! And of course, do not sleep on your stomach...

## BOOK YOUR FOLLOW UP

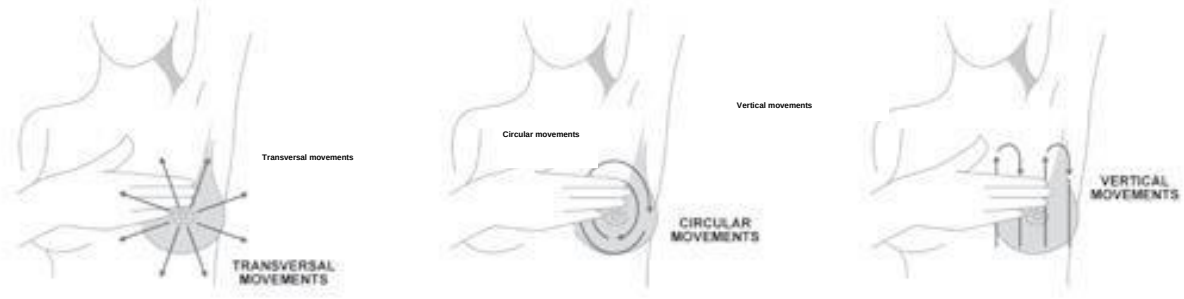
Your surgeon will invite you to a follow-up appointment in the days following the procedure. During the first year after placement of the prosthesis, a consultation is recommended at 3, 6 and 12 months, then annually. Your surgeon will prescribe simple monitoring tests to check that everything is going well, for example, an MRI (Magnetic Resonance Imaging) or ultrasound. A normal follow-up to detect possible breast cancer should then be carried out by a doctor.

## SELF-EXAMINATION OF THE BREASTS

Monthly self-palpation of the breasts is recommended, preferably after the period or on a fixed date for women after menopause, in order to be certain of the absence of swellings.

Perform self-palpation with the arm raised. With the three fingers of the opposite hand firmly flat on the breast, move the hand over the breast:

- from the outside part to the inside part and vice versa (transversal movements)
- by circular movements
- from bottom to top (vertical movements) and vice versa.



Massages of this type may be prescribed by your surgeon after implantation to limit the development of a capsule. Consult your doctor if any change becomes apparent.

## IF YOU SUSPECT A COMPLICATION

In case of changes related to your implant, unusual symptoms, if you suspect complications, including in case of trauma or compression caused, for example, by violent breast massage, sporting activity or a crash (automobile accident, safety belt), you should quickly consult your surgeon.

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the local competent authority.

## HOW WILL YOUR BODY RESPOND?
## *IT'S NORMAL*

**To notice the following :**

- Minimal postoperative pain may be experienced 2-3 days after surgery. This pain can be relieved by taking analgesics.
- Haematoma (swelling of blood) or oedema (excessive accumulation of serum) in the implantation zone: a suitable medical compression on the implantation zone in the weeks following surgery will help reduce postoperative oedema.
- A seroma (collection of fluid) can occur without an infection. It may have to be drained.
- Temporary loss of sensitivity or heightened sensitivity of the nipple is generally observed.

# KEY WORDS USED BY YOUR SURGEON

- ***Approach (Route)***: the part of the body where the implant will be inserted.
- ***Amastia, Aplasia:*** total lack of development of the mammary gland.
- ***Areola:*** pigmented circle around the nipple of the breast.
- ***Axillary***: refers to the armpit.
- ***Breast ptosis:*** sagging of the mammary gland, related to the breast's weight.
- ***Capsule***: tissue which forms in the body around a foreign object.
- ***Capsular contracture***: shrinkage of the fibrous capsule which causes the breast to feel abnormally firm and can cause pain.
- ***Cohesive gel***: compact gel that remains in one piece and has a certain consistency (as opposed to liquid or friable gel).
- ***Congenital***: exists, is present at birth (opposite: acquired).
- ***Contralateral***: concerns the opposite side to the one affected.
- ***Explantation***: opposite to implantation. Removing an implant from the patient's body.
- ***Hypomastia, breast hypoplasia***: underdeveloped mammary gland.
- ***Mammectomy, mastectomy:*** removal of the breast due to cancer or trauma.
- ***Physiological serum:*** saline, can be easily absorbed by the body.

# DO YOU HAVE FURTHER QUESTIONS?

## WILL I BE ABLE TO FEEL MY PROSTHESIS ?

An implant, even if it has been perfectly accepted, may still be generally noticeable, visible or detectable. It may also be possible to feel the implant's peripheral edge. The device's perception varies depending on its position, contents and the thickness of the mammary gland and tissues. In general, it is less visible in cases of implantation behind the muscle.

In reconstructive surgery after a mastectomy, the implant is still palpable whatever the location due to the absence of the mammary gland.

## CAN YOU BREASTFEED WITH BREAST IMPLANTS?

In general, there is no contraindication for breastfeeding after implantation, whatever the type of device; however, this can be compromised if the milk ducts were cut during surgery.

If breast abscesses occur during breastfeeding, the implant may need to be removed.

A study by Semple et al, using silicium (found abundantly in nature and from what silicone is derived) as the unit of measurement, found that the amount of milk present in women with implants is identical to the amount found in women without implants (3).

## AND ABOUT MY FUTURE CHILDREN?

No increase of risk of health problems for the children of mothers fitted with breast implants was confirmed.

## ABOUT THE MAMMOGRAPHY?

Implantation makes it more difficult to read a mammogram; small quantities of breast tissues may remain difficult to analyse.

To limit the risk of rupture, breast compression must not be exaggerated; you must systematically inform the radiologist doctor or the manipulator of the presence of implant(s), but the practitioner remains the sole judge of the technique to be employed.

## ABOUT THE MRI and ULTRASOUND?

All breast implants manufactured from silicone materials are compatible with MRI (magnetic resonance imaging) and detectable by ultrasound facilitating biopsy.

## IS MY IMPLANT COMPATIBLE WITH A PIERCING?

In order to avoid damaging the implant, it is recommended to prohibit any piercing or any other surgical procedure which necessitates the use of a sharp or pointed instrument... in the zone where it is placed.

## CAN I USE DRUG SUBSTANCES?

The use of medicinal substances, such as vitamins, steroids, antibiotics... in the implant area

is contraindicated.

## HOW CAN I KNOW WHICH IMPLANT I HAVE?

A patient card will be communicated to you by your surgeon, at the end of the surgery. It allows you to know what type of implant you have. You should keep this implant card with you at all times to facilitate medical care in case of an emergency.

You have to inform the Healthcare Professionals of the presence of the implant anytime you have a medical visit.

## WHAT IS THE LIFETIME OF THE IMPLANT?

The estimated lifetime of an implant is 10 years, but it is patient -dependent. Annual visit will help your practitioner to plan a revised surgery to remove or replace your implant.

According to a clinical study consisting in the follow-up, over 10 years, of 205 women after implant-based breast augmentation or reconstruction, over 10 years after implantation, the risk of implant rupture is 7.4% in breast augmentation and 21.2% in breast reconstruction. The risk of capsular contracture over 10 years is 3.8% in breast augmentation and 10.5% in breast reconstruction (4).

## GENERAL RISKS RELATED TO MAMMARY IMPLANT SURGERY

*If any of these symptoms occur longer than expected by your surgeon, seek medical advice.*

Although rare, like all surgical and cosmetic procedures there are inherent risks involved, such as:

- Pain
- Haematoma (swelling of blood in tissue spaces or body cavity), bleeding,
- Oedema (excessive accumulation of serum), lymphorrhea (lymph accumulation),
- Seroma (pocket of clear serous fluid),
- Inflammation, redness (rash),
- Infection,
- Fever, hyperthermia,
- Delayed wound healing,
- Potential scarring,
- Tissue necrosis which is promoted by smoking and further treatments such as chemotherapy and radiotherapy.

# CONTRA-INDICATIONS RELATED TO BREAST IMPLANT SURGERY

Contra-indications to breast implant surgery, in relation to the indication for any surgery or more specifically to implant placement.

## CONTRAINDICATIONS RELATED TO THE SURGERY

- Infection or inflammation in progress,
- Pathology impairing blood coagulation, immune defences,
- Diabetes, or any disease having an effect on wound healing,
- Physiological condition that does not allow surgery,
- Pathology or any ongoing drug therapy that may result in a high surgical risk of complications,
- Pregnancy, breast-feeding in progress.

## CONTRAINDICATIONS RELATED TO THE IMPLANTATION OF AN IMPLANT

- Non-stable psychological state, reluctance to surgery, unrealistic expectation of the desired result....
- History of mammary abscess
- In case of autoimmune disease, breast implant placement should be discussed with your surgeon,
- Breast cancer known and not yet treated locally,
- Poor tissue coverage, poor skin quality in the breast area,
- History of sensitivity to foreign bodies or allergy (atopic terrain).

## SPECIFIC SIDE EFFECTS LINKED TO BREAST IMPLANTS IMPLANTATION

*If any of these symptoms occur, contact Health Professionals.*

The lifetime of an implant is not unlimited since it depends on possible complications and individual factors. Furthermore, loco-regional complications may require an implant's temporary or permanent explantation.

An implant will not last forever, it ages, it wears. It will therefore need replacing one day.

The side effects brought to Groupe Sebbin's attention related to breast implants have been listed below:

- A change in nipple or breast sensation: this is usually temporary, but in rare cases there may be a decrease or even complete loss of nipple sensation.
- Galactorrhoea or difficulty breastfeeding.
- Skin breakdown, extrusion of the implant.
- Dissatisfaction because the expected aesthetic result has not been fully achieved (asymmetry, breast tissue thinning, delayed wound healing…).
- Rotation of implant (in the case of an anatomical implant).
- Late onset of periprosthetic effusion, a build-up of fluid around the implant which results in breast swelling.
- Axillary swelling: a swelling of axillary ganglions due to an inflammation reaction may occur temporarily after implantation. Some distance from the operation, it may itself be the sign of inflammation due to rupture of implant.
- Capsular contracture of fibrous scar tissue which forms naturally around the implant. Sometimes this capsule tightens and squeezes the implant, causing your breasts to become hard and painful. The risk of formation of capsular contraction can be increased in the case of radiotherapy and/or chemotherapy.
- Deflation of fluid-filled breast implants. This is hard to predict and generally occurs quite quickly.
- Rupture of the gel-filled implant's outer shell. There is a risk that the gel might slowly migrate outside of the scar tissue, related to the implant ageing or premature. Surgery is required to change the ruptured or suspected ruptured implant. This rupture can occur without any obvious external signs (silent rupture) hence the importance of clinical observation and/ or regular ultrasounds and the need for a consultation in the event of violent trauma.
- Calcification of the periprosthetic capsule: Although rare, this can pose diagnostic problems as they are similar to the calcium deposits observed in breast cancer.
- Interference with standard mammography: the implant can hide part of the breast

tissue (both medium- and long-term). You should inform the radiologist of this.

- Interference with standard mammography: during a standard mammographic screening, the implant may rupture if compression is exaggerated. To minimise the risk of the implant rupturing during this screening, we recommend an ultrasound or an MRI instead.
- Folds, wrinkles, displacement and turning of the implant are signs of wear, and a potential premature rupture. It can also become visible or detectable.
- Breast ptosis : it is a breast sinking. This is a natural phenomenon that manifests itself with age or other individual factors.
- Breast implant associated cancer: breast cancers observed in patients with implants received a prognosis identical to that for patients without implants.
- Inflammation
- Infection
- Pain in breast, chest wall, in the axilla

As regard breast reconstruction with implant after cancer, the retrospective studies conducted do not reveal any deterioration of the prognosis, but instead even an improvement.

All these side effects can arise in the short-, medium- or long-term and may require surgical reintervention. Mammary implants have a limited lifetime and will have to be removed or replaced, which may imply revision surgery.

## BREAST IMPLANT ASSOCIATED – ANAPLASTIC LARGE CELL LYMPHOMA

According to the French Competent Agency (ANSM): Based on European safety information and from the FDA and the scientific literature, an association was identified between the breast implants and the rare development of Anaplastic Large Cell Lymphoma (ALCL), a type of lymphoma. Women with breast implants may have a very low but higher risk of developing an ALCL in an area adjacent to the implant. This specific entity is included in the WHO 2016 classification under the terminology “BIA-ALCL”.

This pathology has to be investigated only in case of proven clinical sign (recurrent periprosthetic effusion, breast redness, increase of breast volume, perceptible mass, tardive seroma). A precise serological and pathological examination must then be made in order to identify the nature of the lesion.

Consumers should remember that implants are not lifetime devices. The longer you have breast implants, the more likely it is that complications will occur and you will need to have them removed. There is no guarantee that you will have a satisfactory cosmetic outcome from any reoperation.

Breast implants with a rough (textured) surface adhere better to the surrounding tissue. This can prevent the implant from moving around, reducing complications such as capsular contracture, rippling, implant displacement and asymmetry.

Based on information reported to global regulatory agencies and in medical literature, an association has been identified between textured breast implants and the development of anaplastic large cell lymphoma (ALCL). People with breast implants may have an increased risk of developing BIA-ALCL in the fluid or scar capsule adjacent to the implant, and there is documented evidence that this can spread and cause death. Most of the cases in the literature reports describe a history of the use of textured implants.

BIA-ALCL is a rare but serious condition. Education and information regarding the risk and benefits of breast implants should be part of the consent process. Your surgeon is responsible for providing this information to you and will often have information in addition to this leaflet for you to read. A patient implant card should also be provided to you following surgery. This card provides you with sufficient information to identify the breast implant(s) you have. It also has contact details for the manufacturer should you want more information or to report any issues.

It is important that you continue to conduct regular breast cancer awareness self-examination and if you notice any swelling, unevenness between breasts, pain or a lump see your doctor immediately. The doctor, if they suspect BIA-ALCL, will order tests that include sampling the fluid around the implant and either an MRI or an ultrasound of your breasts. If the result of these tests indicates that you have BIA-ALCL you will be looked after by a team of clinicians including your surgeon and a specialist in treating cancer.

## FOR AUSTRALIAN PATIENT

Ask your surgeon if they contribute to the Australian Breast Device Registry (ABDR). The ABDR records your contact details and the details of your surgery (including the reason for your surgery).

Including your details in the ABDR helps us to track the long-term safety and performance of breast implants. It also helps in notifying you and other patients of any safety concerns related to breast implants.

Research reports and other publications that use ABDR data will not contain any identifiable information about you. More information about ABDR data privacy is available on the ABDR website.

We encourage you to contribute to the ABDR, but you may choose to opt-out if you wish. You are encouraged to contact the legal manufacturer or the local Regulatory body if you have an issue. Reporting of issues assists in identifying any trends so that action can be taken at the earliest opportunity.

*Australian Breast Device Registry :* www.*abdr*.org.au

All findings respecting cases of BIA-ALCL associated with this device should be reported to the local competent authority and to the legal manufacturer and it is also recommended that surgeons report to pertinent breast device registries. Finally, physicians should keep informed of BIA-ALCL in the literature and provide appropriate therapy to patients as needed.

# ADDITIONAL INFORMATION

## CONCERNING THE AUTOIMMUNE AND CONNECTIVE TISSUE DISEASES

For prudence, implantation is not recommended in patients having personal or family prior history of such pathologies.

Nevertheless, no relationship was confirmed between breast implants prefilled with silicone gel and any of the specified connective tissue disorders (including Sjögren's syndrome) or any other autoimmune/rheumatic disease. It was established that women with silicone breast implants did not present systemic anomalies of the types or functions of immune system cells that could be attributed to silicone.

However, certain recent studies suggest the existence of a risk of "Autoimmune/inflammatory syndrome induced by the adjuvants" (ASIA), which could be caused by incompatibility with silicone, with the following possible main symptoms: myalgia, arthralgia, chronic fatigue, neurological manifestations, deterioration of cognitive faculties and pyrexia.

## AND IF I WOULD LIKE TO KNOW EVEN MORE ?

If you live in the UK:

- British Association of Plastic Reconstruction & Aesthetic Surgeons (BAPRAS): www.bapras.org.uk
- British Association of Aesthetic Plastic Surgeons (BAAPS): www.baaps.org.uk
- Association of Breast Surgery (ABS): www.associationofbreastsurgery.org.uk
- Breast Cancer Care: www..breastcancercare.org.uk
- Macmillan Cancer Support: www.macmillan.org.uk
- English Competent Authority : MHRA (Medicines & Healthcare products Regulatory Agency) - www.gov.uk

If you live in Australia:

- Australian Competent Authority : TGA (Therapeutic Goods Authority) –
- www.tga.gov.au
- Distributor: Unit 2 / 37-39 Green Street

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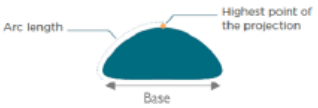
# RANGE OF PRODUCT PROPOSED BY SEBBIN IN AUSTRALIA

## SMOOTH, ROUND, FIRM HIGH COHESIVE GEL, MAMMARY IMPLANTS

## SMOOTH, ROUND, CLASSIC COHESIVE GEL, MAMMARY IMPLANTS


| *Shape* | *Gel* | *Ref* | | *Vol. (mL)* | *Base (mm)* | *Proj. (mm)* | *Arc (mm)* |
|---|---|---|---|---|---|---|---|
| Moderate  | Cohesive gel | LS 50 | min | 80 | 80 | 25 | 54 |
| | | | max | 610 | 147 | 51 | 108 |
| | High Cohesive gel | LSC 54 | min | 90 | 78 | 26 | 54 |
| | | | max | 670 | 142 | 58 | 111 |
| High  | Cohesive gel | LS 51 | min | 85 | 68 | 35 | 52 |
| | | | max | 615 | 134 | 65 | 105 |
| | High Cohesive gel | LSC 55 | min | 90 | 66 | 39 | 55 |
| | | | max | 645 | 132 | 69 | 108 |

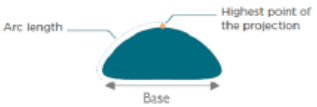
The norm ISO 14 607:2018 has brought new requests on term of analysis and characterization. And it's Groupe Sebbin responsibility to transmit and get available to each user and patient all information to understand and compare our products.

So, Groupe Sebbin opens a new page, modifying its graphic chart, adding a brand name for each range of mammary implant and associating the new designation of shell texture on its labelling.

## SEMI-SMOOTH (ex:MICROTEXTURED), ROUND, COHESIVE GEL, MAMMARY IMPLANTS

## SEMI-SMOOTH (ex:MICROTEXTURED), ROUND, HIGH COHESIVE GEL, MAMMARY IMPLANTS

This surface is offering the advantages of both smooth and textured implants: Its ease of insertion induces less friction in the tissues. Textured implants show disorganisation of the cicatricial reaction minimising the rate of capsular contracture.(1)




| *Shape* | *Gel* | *Ref* | | *Vol. (mL)* | *Base (mm)* | *Proj. (mm)* | *Arc (mm)* |
|---|---|---|---|---|---|---|---|
| Semi-moderate  | Cohesive gel | LS 74 | min | 80 | 82 | 21 | 56 |
| | | | max | 560 | 157 | 42 | 102 |
| | High Cohesive gel | LSC 76 | min | 80 | 82 | 21 | 56 |
| | | | max | 560 | 157 | 42 | 102 |
| Moderate  | Cohesive gel | LS 70 | min | 80 | 80 | 25 | 54 |
| | | | max | 610 | 147 | 51 | 106 |
| | High Cohesive gel | LSC 72 | min | 90 | 78 | 26 | 54 |
| | | | max | 670 | 142 | 58 | 111 |
| High  | Cohesive gel | LS 71 | min | 85 | 68 | 35 | 52 |
| | | | max | 615 | 134 | 65 | 105 |
| | High Cohesive gel | LSC 73 | min | 90 | 66 | 39 | 55 |
| | | | max | 645 | 132 | 69 | 108 |

MICROTEXTURED (ex TEXTURED), ROUND, COHESIVE GEL, MAMMARY IMPLANTS

MICROTEXTURED (ex TEXTURED), ROUND, FIRM HIGH COHESIVE GEL, MAMMARY IMPLANTS

According to clinical study (4), our risk of capsular contracture
with textured implants at 10 years in the augmentation cohort is of 3.8%


| *Shape* | *Gel* | *Ref* | | *Vol. (mL)* | *Base (mm)* | *Proj. (mm)* | *Arc (mm)* |
|---|---|---|---|---|---|---|---|
| Moderate  | Cohesive gel | LS 90 | min | 80 | 80 | 25 | 54 |
| | | | max | 610 | 147 | 51 | 108 |
| | High Cohesive gel | LSC 92 | min | 90 | 78 | 26 | 54 |
| | | | max | 670 | 142 | 58 | 111 |
| High  | Cohesive gel | LS 91 | min | 85 | 68 | 35 | 52 |
| | | | max | 615 | 134 | 65 | 105 |
| | High Cohesive gel | LSC 93 | min | 90 | 66 | 93 | 55 |
| | | | max | 645 | 132 | 69 | 108 |

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*(4) El-Haddad R, Lafarge-Claoue B, Garabedian C, Staub S. A 10-Year Prospective Study of Implant-Based Breast Augmentation and Reconstruction. Eplasty. 2018;18:e7.*