Sebbin
PARIS

Instructions For Use

Silicone Gel-filled Round Mammary Implant

Class III – CE0483

GROUPE SEBBIN SAS

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www.sebbin.com

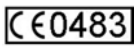
CONTENT

I. PICTOGRAMS

The Instructions for Use are available on the web site: www.sebbin.com.

Please note that healthcare professionals must register prior to getting access to their dedicated portal.

If you cannot access the website, please contact Groupe SEBBIN (+33 1 34 42 13 28) or your distributor, the Instructions for Use will be provided by the quickest method / way (electronic form / fax within 48 hours or postal mail within 3 working days).

	Electronic instruction for use		Do not re-use
	Sterilization method using ethylene oxide		Do not re-sterilize
	Do not use if packaging is damaged		Fragile, handle with care
	Top		Pyrogen-free
	Keep dry		Keep away from sunlight
	Medical Device		Identification of the responsible notified body
	Catalogue reference		Serial number
	Date of manufacture		Use up to
Vol.	Implant volume		MR safe
	General collection Recycling symbol		Caution
QTY	Unit number in the package		Implant sterilization batch number
	Manufacturer		

Instructions for Patient Card

Dr	Name of surgeon who carried out the surgical operation	**Patient**	Name of patient receiving the implant
Date	Date of surgical operation	**Position**	State the location of the implant (right or left)

II. PRESENTATION OF THE MEDICAL DEVICE

II.1 Description

The Gel-filled Round Mammary Implants medical devices are manufactured by GROUPE SEBBIN under the brand name Laboratoires SEBBIN.

The Gel-filled Round Mammary Implants medical devices are manufactured from medical grade raw materials, biocompatible and perfectly traceable. They belong to the "polydimethylsiloxane" family.

The Gel-filled Round Mammary medical devices are presented sterile (sterilization by Ethylene Oxide), single use, and are double wrapped in blister.

The MD has to be stocked with care in appropriate / adequate conditions.

This device is intended for surgeons performing in the operating department in accordance with the prevailing standards.

All manufacturing steps, including sterilization, are duly validated and controlled by our Quality Assurance system.

A technical sheet (or Summary of Product Characteristics or Summary of safety and clinical performance) is available on request from GROUPE SEBBIN.

II.2 Composition

Round mammary implants are medical device prefilled with silicone gel.

These implants consist of:

- a supple shell, made from silicone elastomer obtained by successive dipping of a mould defining the shape, profile and volume of the implant, and comprising, between other layers, an anti-bleeding barrier limiting the risk of diffusion of the gel. The surface of the shell may be smooth, semi-smooth or micro-textured.
- a sealing patch, which is made from silicone elastomer with a defined thickness and diameter, comprising, between other layers, the anti-bleeding barrier, and on which traceability information are inscribed.
- a biocompatible medical grade gel that is defined cohesive, or highly cohesive complying with ISO 14607.

Following to the ISO 14607:2018 standard, GROUPE SEBBIN has re-classified its round mammary implants according to the texture of the shell. The micro-textured implants are classified in smooth texture. To differentiate the both smooth surfaces, GROUPE SEBBIN qualified his microtextured implant as “semi smooth”. In the same time, the shape of the implant and the filling gel have been précised in the device designation.

To facilitate the correspondence to previous information, please see in table 1 below, the denomination used in the document and in full application from March 2020.

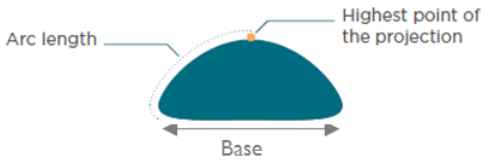
	Previous Name	***New denomination***
Texture	Smooth	Smooth
	Micro-textured	Semi-smooth
	Textured	Micro-textured
Gel	Cohesive	Naturgel 1
	High Cohesive	Naturgel 2
	Integrity	EverlastGel

Table 1: correspondence between denomination

II.3 Range of products

GROUPE SEBBIN has developed a number of products according to the texture of the shell, the shape of the implant and the gel used for filling.

Each implant is referenced according to the shape, the gel property and its dimensions: Vol. (volume), Base (diameter of the base), Proj. (highest point of the projection), Arc (arc length between base and highest point of the projection). Are presented in the tables below the minimal and maximal dimensions for a dedicated texture of the shell, shape and cohesivity of the gel.



II.3.1 –-Purity range: round mammary implant, Smooth Shell

Shape	*Gel*	*Ref*		*Vol. (mL)*	*Base (mm)*	*Proj. (mm)*	*Arc (mm)*
Moderate 	Naturgel 1	LS 50	min	80	80	25	54
			max	610	147	51	108
	Naturgel 2	LSC 54	min	90	78	26	54
			max	670	142	58	111
High 	Naturgel 1	LS 51	min	85	68	35	52
			max	615	134	65	105
	Naturgel 2	LSC 55	min	90	66	39	55
			max	645	132	69	108

II.3.2 – Sublimity range: round mammary implant Semi-Smooth Shell

Shape	*Gel*	*Ref*		*Vol. (mL)*	*Base (mm)*	*Proj. (mm)*	*Arc (mm)*
Semi-moderate 	Naturgel 1	LS 74	min	80	82	21	56
			max	560	157	42	102
	Naturgel 2	LSC 76	min	80	82	21	56
			max	560	157	42	102
Moderate 	Naturgel 1	LS 70	min	80	80	25	54
			max	610	147	51	106
	Naturgel 2	LSC 72	min	90	78	26	54
			max	670	142	58	111
High 	Naturgel 1	LS 71	min	85	68	35	52
			max	615	134	65	105
	Naturgel 2	LSC 73	min	90	66	39	55
			max	645	132	69	108

With a semi - smooth shell, GROUPE SEBBIN has developed a range of mammary implant characterized by the projection, with a unique cohesive gel

Integrity range: mammary implant round matrix, Semi-Smooth Shell

Shape	***Ref***		***Vol. (mL)***	***Base (mm)***	***Proj. (mm)***	***Arc (mm)***
Low projection 	LSM RL	min	80	85	20	53
		max	560	165	38	101
Semi-moderate projection 	LSM RS	min	85	85	22	54
		max	600	155	46	100
Moderate projection 	LSM RM	min	115	85	30	59
		max	670	155	54	105
Full projection 	LSM RF	min	130	85	39	65
		max	650	145	61	106

II.3.3 – Volupty range: round mammary implant Micro-textured Shell

Shape	***Gel***	***Ref***		***Vol. (mL)***	***Base (mm)***	***Proj. (mm)***	***Arc (mm)***
Moderate 	Naturgel 1	LS 90	min	80	80	25	54
			max	610	147	51	108
	Naturgel 2	LSC 92	min	90	78	26	54
			max	670	142	58	111
High 	Naturgel 1	LS 91	min	85	68	35	52
			max	615	134	65	105
	Naturgel 2	LSC 93	min	90	66	39	55
			max	645	132	69	108

III. INDICATIONS

Gel-filled mammary implants are medical devices intended for plastic, reconstructive and aesthetic surgery.

In reconstructive surgery as in aesthetic surgery, silicone implants make it possible to modify the anatomy but do not have any functional role.

On the other hand, they provide a psychological benefit by improving the perceived quality of life and self-confidence.

SEBBIN silicone gel-filled mammary implants are intended in the treatment of:

- Amastia, aplasia: total absence of development of the mammary gland and areola.
- Hypomastia, hypoplasia: the mammary gland is not sufficiently developed.
- Asymmetry: a relatively pronounced lack of symmetry between the breasts (volume and/or shape) is known as breast asymmetry.
- Breast ptosis: sagging of the breasts due to loss of their support (weight loss, pregnancy or age). In this case, breast augmentation is combined with a mastopexy.
- Breast congenital malformations: such as Poland syndrome or tubular breast.
- Breast reconstruction: after mastectomy for breast cancer or other breast pathology.
- Replacement of implant: for medical or cosmetic reason.

The patient selection criteria, the choice of implant type, shape, volume, profile and positioning are the exclusive responsibility of the surgeon.

Intended target population: patient seeking breast augmentation, breast shape correction, or breast reconstruction after mastectomy or lumpectomy. The patient selection criteria are the exclusive responsibility of the surgeon. Use of the implants on minor patients is possible only for medical reasons and with the agreement of its legal representative.

IV. CONTRA-INDICATIONS

Each patient is entitled to a preliminary examination, supplemented if necessary and, in function of age and indication, by all the investigations ultimately deemed necessary, especially radiologic.

The practitioner is responsible at least, of respect for the possible contraindications cited hereafter, except those related to the contemplated method of anaesthesia.

Number of complications relate to the indication of any surgical intervention, since this is not a life-threatening emergency, others are more specific to implant placement.

Contra-indications related to a surgery:

- Any developing infection or inflammation local or systemic;
- Pathologies impairing blood coagulation or immune defences, or any treatment interfering with them;
- Unbalanced diabetes or any disease having an effect on cicatrisation or an additional infectious risk;
- Contra-indications for non-emergency surgery such as unexplored biological, immunological, cardiovascular, respiratory disturbance, etc.;
- Pathologies which generate undue surgical risk and a high risk of complication, as well as any ongoing drug therapy that may result in a high surgical risk and / or significant post-operative complications, including any drug that may interfere with coagulation.

Contra-indications related to the implantation of an implant:

- Disrupted psychological state (instability, lack of understanding or motivation, reluctance to surgery);
- Recent history of mammary abscess;
- Implant placement in a patient with an autoimmune disease such as systemic lupus erythematosus or scleroderma is an indication to be discussed with the therapist;
- Breast cancer known and not yet treated locally. Nevertheless, the implantation of an implant simultaneously with the resection of the lesion is not a contraindication;
- Poor tissue coverage with risk of exposure of the implant due to defects in trophicity and wound healing (multi-cicatricial tissues, ulcerations, vascular abnormalities, acute sequelae or chronic radiotherapy;
- Insufficient integumentary thickness, laxity or flexibility, tissue inadequacy;
- Unrealistic expectation of desired result
- Pathologies affecting blood coagulation, immune defences or any treatment interfering with them.
- Lesions due to radiation ulcerations, vascular abnormalities or histories of circulatory problems able to compromise to some extent the healing of the wound
- Documented cancer developing locally, with ongoing or scheduled chemotherapy and/or radiotherapy
- A physiological condition considered by the surgeon to entail an excessive elevated risk of surgical and/or postoperative complications. Obesity, nicotine addiction, diabetes, chronic pulmonary conditions or cardiovascular diseases can, to varying degrees, affect the capacity of the patient to undergo surgical implantation and/or entail significant postoperative

complications, including those which might interfere with blood coagulation

- Any ongoing infection
- Developing pregnancy or even pregnancy envisaged in the short-term
- Psychological instability, lack of comprehension or motivation, reluctance concerning the operation
- History of sensitivity to foreign bodies or severe allergies or predisposition to the cumulative development of common allergies (atopic terrain)

V. INFORMATION FOR USERS TO BE CONVEYED TO THE PATIENT

It is the surgeon's duty to inform his patients of the following information:

V.1– Generalities

Before scheduling an appointment for intervention, the surgeon must inform his patient objectively of the advantages and risks associated with inserting implant, so that the patient has sufficient time for consideration, after which he/she will give the surgeon the signed informed consent. GROUPE SEBBIN provides you with an informed consent form.

Making the decision to have implants inserted, is to accept the risk of undergoing surgical re-interventions. This decision must take account of potential complications as well as those identified in this manual, but it first requires an awareness and an understanding of the realities:

- the lifespan of an implant is not unlimited and cannot be evaluated precisely, since it depends on possible occurrence of complications and on individual factors,
- The cumulative risks of rupture of the implant and of capsular contracture were assessed according to Kaplan Meier on a cohort of 205 patients over a 10-year period (multicentre observational clinical study conducted by Groupe SEBBIN [I[1]])

Risks	Nature of the intervention		General population % *(SD)*
	Augmentation % *(SD)*	Reconstruction % *(SD)*	
Rupture	7.4 *(4.4)*	21.2 *(9.6)*	10.9 *(4.2)*
Capsular contracture	3.8 *(1.7)*	10.5 *(5.0)*	5.0 *(1.7)*

Table: *Cumulative risk of rupture and capsular contracture according to Kaplan Meier and associated standard deviation (SD)*

- an implant is never indispensable,
- requesting an implant is above all a voluntary act which is never of an unavoidable nature,
- all implantations necessitate a follow-up and regular medical consultations; this is not a definitive surgical operation; throughout a person's life there may be one or several re-interventions:
  - to replace a worn implant,
  - to remedy a complication,
  - to correct a deterioration in the result over time, which is not directly associated with the implant itself but with ageing of the soft tissues, with or without replacement of this latter.

[1] [1] 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.

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The implants have a limited lifespan. The implants will have to be replaced or substituted which will imply revision surgery (a new surgical procedure).

It must be noted that utilisation of medicinal substances in the region of the implant is contraindicated as the effect of certain medications such as vitamins, steroids, antibiotics… in the presence of an implant has not been validated by the manufacturer and therefore GROUPE SEBBIN will not be liable for their utilisation.

V.2 – Advantages

Whether the question is one of reconstruction or breast augmentation for aesthetic purposes, or of replacement of an implant, an external prosthesis may be an alternative to the implantable prosthesis.

Nevertheless, according to the document of the French Health Authority, [Evaluation of breast implants, tissue expander prostheses and external breast prostheses, Revision of the categories registered on the list of reimbursable products and services: "External breast prostheses, breast implant, inflatable skin expander implant"], which appeared in May 2009, the general satisfaction of the patients is on the order of 65% with external prostheses, whereas the satisfaction is good in 90 to 98% of cases with mammary implants.

Also, according to the same studies, the quality of life is 60 on a scale of 1 to 100 with external prostheses, compared with a score of 9 on a scale of 1 to 10 for mammary implants.

The patients feel that they have gained femininity and self-confidence, both in the case of purely aesthetic indication and in the case of reconstruction after cancer, or for correction of a morphological anomaly.

Groupe SEBBIN’s clinical evaluation demonstrates that the use of its silicone gel-filled mammary implants allows for a patient overall satisfaction rate of over 85% for breast reconstruction and over 95% for breast augmentation [1].

V.3 – Complications and adverse effects

Every surgical procedure may be subject to an unforeseen operative or postoperative complication and/or to adverse effects, and it is the surgeon's duty to inform his patient of these, besides the risks specifically associated with anaesthesia, which must be explained by the doctor in charge of anaesthesia and resuscitation.

All risks brought to the attention of Groupe Sebbin have been included in this Instruction for use and are detailed below.

V.3.1 – Complications due to surgical procedure

Certain occurrences, such as wrinkles, weakening or rupture of the implant following excessive stress on introduction or from an instrument, inappropriate scar localisation, inadequate implant size, etc., can result from an inappropriate surgical technique and entail a reintervention.

Other rarer complications that may occur include:

- nerve, motor or sensory trauma associated with the surgical procedure;
- effusion of air into the pleural pocket in the case of intraoperative breach,
- deformity of the chest wall,
- atrophy of the breast tissue.

V.3.2 – Postoperative complications

Ageing – rupture

Patient and implant undergo ageing that is liable to cause rupture of the implant. In fact, all implants are exposed to the risk of rupture with diffusion of the filling product into adjacent tissues. They may cause siliconomas. This requires a reintervention for replacement.

The rupture can be with or without symptoms (silent rupture): this gel may remain confined within the periprosthetic capsule as long as this is intact. This shows the importance of regular clinical and/or echographic monitoring and the necessity of consultation in case of violent trauma.

Axillary swelling

Swelling of axillary ganglions due to a locoregional inflammatory reaction may occur temporarily after implantation. Swelling of axillary ganglions at some distance from the operation may itself be the sign of inflammation due to rupture of the implant. In this case the patient will have to alert her surgeon so that he or she may take the appropriate measures.

Breast-feeding

Breast-feeding is never contraindicated after implantation. Nevertheless, breast feeding may be perturbed or even impossible in case of resection of galactophore channels during the procedure (by areolar incision) or in case of loss of areolar sensitivity. Independently of implantation, a breast abscess is always possible in case of breast feeding; any spread of a possible breast infection may entail removal of the implant.

Calcification of the periprosthetic capsule

In the long term, cases of calcium deposits have been observed in the periprosthetic capsule. Although rare, this calcification can pose diagnostic problems by analogy with the calcium deposits observed in breast cancer.

Capsular contraction

The formation of a fibrous exclusion membrane around an implanted foreign body is a normal response of the body: this capsule may shrink, forming a contractile sheath around the device, potentially causing hardness, deformity and migration.

The aetiology of capsular contraction is poorly understood; it may be unilateral or bilateral.

If a capsular contraction is serious, it may aggravate the risk of premature wear and rupture of the implant. It may necessitate reintervention and the risk of relapse persists.

GROUPE SEBBIN advises against any external manoeuvre (external capsulotomy or squeezing) that attempts to break this capsule, because it may cause folds or even rupture the shell.

Detection – visibility

Even if perfectly tolerated, an implant may be perceptible, visible or detectable in its entirety or by the appearance of cutaneous waves or undulations; it may be possible to palpate its peripheral edge.

The risk of perception of the implant depends on several factors:

- on the patient: greater risk in the case of aesthetic implantation such as in breast reconstruction under a fine integument with a thin glandular thickness;
- on the choice of volume of the implant;
- on the nature of the implant and its consistency (firmness),
- on the implantation site: greater visibility in the case of retroglandular implantation, but deformity and displacement of the implant possible under the effect of contraction of the muscle in the case of retromuscular implantation.

Fever, hyperthermia

As with any surgery, postoperative fever may be observed. This reaction may be unrelated to the surgical procedure. In other cases, it may be caused by a natural and non-infectious inflammatory response to the surgery or it may be indicative of a surgical complication, such as infection. It is up to the surgeon to identify the cause of the postoperative fever and to take appropriate measures if needed.

Gel diffusion

Minute quantities of silicone may diffuse across the intact shell, without it rupturing. Small polymers, the siloxanes, especially the D4 and D5 types, have been identified.

This phenomenon is extremely limited by virtue of the shell containing the anti-bleeding barrier in the Laboratoires SEBBIN implants prefilled with silicone gel.

A chemical analysis was performed: the majority of chemical compound identified was silicon. The concentrations of platinum, which is used as catalyst for the silicone materials, is lower than 1 mg/l of extract (aqueous and ethanolic extracts).

A biological evaluation of the implants was conducted. No particular toxicity in the constitutive raw materials of the mammary implants manufactured by GROUPE SEBBIN was detected during these tests.

Nevertheless, a cell reaction, which is a normal response of the organism in the presence of a foreign body, may occur, causing granulomas or siliconomas.

Gel fracture – Deformation – Gel/shell detachment

This may be caused by manipulation during surgery or by the development of capsular contracture and risks causing distortion of the implant. The aesthetic result obtained might not be pleasing to the patient and surgeon, requiring surgical reintervention.

Haematoma, lymphorrhea, oedema

Effusion of blood or lymph into the cavity, manifested by severe swelling. In all cases, this must be distinguished from possible bruising, which will be reabsorbed spontaneously. Adapted additional drainage may be necessary, while strictly respecting the integrity of the shell of the device (no blind percutaneous drainage).

Healing disorders – Extrusion – Necrosis

Regardless of the incision or how small it is, the occurrence of hypertrophic or keloid scarring (red, swollen scar) is never completely predictable, just as for any surgical procedure. Delays in healing, which are strongly dependent on individual factors, are increased in smoking subjects.

Participation in certain sports and their possible temporary or permanent contraindication must be discussed with the patient.

Wound reopening due to tissue necrosis or loosening of sutures may occur in case of complications such as effusion, infection, overly tight suture, overly large implant relative to the size of the cavity, contamination of the suture line, excess pressure over the scar, trauma, etc and, more particularly in the case of breast reconstruction, if the skin traction is high in irradiated areas; it may also be promoted by local instillation of corticosteroids in the region of the implantation site.

Inadequate tissue coverage and/or interruption of scarring of the wound may entail extrusion or exposure of the device.

Infection

Acute infection is unusual and rarely attributable to the implant if the recommendations for use and asepsis associated with the implantation surgery have been observed. It is less rare in cases of reconstruction, especially in irradiated areas, and if suspected it requires antibiotic treatment, adapted if possible, assuming the pathogen responsible can be identified. Infections that do not react to the treatment may necessitate removal of the device.

Secondary infection is possible by haematogenous route during a serious intercurrent infection, or by lymphatic route.

Cases of contamination without clinical symptoms, due to saprophytic bacteria of the skin, have been reported: they could cause an additional risk of periprosthetic shrinkage; some incisions (axillary, areolar with resection of galactophore channels), where these bacteria are abundant, would theoretically be at greater risk.

Pain

Pain of variable intensity and duration may occur after implantation. This may be related to excessive volume, inappropriate replacement of the implant or inadequate surgical technique. Over the longer term, periprosthetic shrinkage commonly known as "capsular contracture" may cause pain.

A sub-muscular implant may be more painful and, in that case, appropriate medical treatment should be prescribed.

Any unexplained and sudden pain must be investigated immediately.

Ptosis

This is a natural phenomenon that manifests itself with age or other individual factors and which may be promoted by excessive weight, and hence volume, of the implant.

Rotation – eversion –displacement

During dissection of the cavity, very particular attention must be paid to its size and shape, which must be appropriate to those of the implant in order to prevent the following effects as far as possible:

- any displacement of the implant,
- *any eversion that could shift the sealing patch into an anterior position,*

Sensitivity

Loss or local exacerbation of sensitivity of the treated area can occur. This disorder, which is usually transient, generally disappears over a variable period; it is permanent only in exceptional cases.

Seroma, inflammation

A seroma is a mass or swelling caused by the localised accumulation of serum in a tissue or organ. This is a post-traumatic or postoperative reaction, which regresses naturally if the seroma is small or which is treated by aspiration if it is substantial. The seroma is generally sterile but can become infected and develop into an abscess. Inflammation can manifest as redness (rash), swelling, a sensation of heat, pain that appears to pulsate.

Warning to patients concerning the aesthetic results

Scar hypertrophy, asymmetry, displacement, different volume and/or shape from that expected, detection, etc., are phenomena that may occur. A rigorous indication, an appropriate surgical technique as well as detailed information about the risk/benefit ratio may minimise but not eliminate the risk of dissatisfaction. This may lead to reintervention.

Wrinkles

It is possible that ridges or wrinkles appear on the envelope of the implant according to its positioning in the cavity. The folds can promote thinning and erosion of the adjacent tissue and extrusion of the implant. The folds can also promote tearing and rupture of the implant. The folds can be discernible at the surface of the skin; only removal of the implant can correct this phenomenon.

V.3.3 – Patient – Implant interferences

ALCL

According to the French Competent Agency (ANSM): Based on European safety information and from the FDA and the scientific literature, a possible association was identified between the mammary implants and the rare development of anaplastic large cell lymphoma (ALCL), a type of non-Hodgkin's lymphoma. Women with mammary 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.

According to the Australian Competent Agency (TGA) : "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 breast implants and the development of anaplastic large cell lymphoma (ALCL). Patients 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. The surgeon is responsible for providing this information to patients and will often have information in addition to these instructions for use for patients to read.

It is important that the patient continues to conduct regular breast cancer awareness self-examination and if he/she notices any swelling, unevenness between breasts, pain or a lump, doctor must be seen immediately. The doctor, if he/she suspects BIA-ALCL, will order tests that include sampling the fluid around the implant and either an MRI or an ultrasound of the breasts. If the result of these tests indicates that the patient has BIA-ALCL she will be looked after by a team of clinicians including her surgeon and a specialist in treating cancer.

Patient is encouraged to contact GROUPE SEBBIN or the Regulatory Health Agency if he/she has an issue. Reporting of issues assists in identifying any trends so that action can be taken at the earliest opportunity.

All findings respecting cases of BIA-ALCL associated with this device should be reported to GROUPE SEBBIN 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".

Autoimmune and connective tissue diseases

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

"Studies conducted in silicone breast implants"

In a report published in 1998, an American scientific jury (US National Science Panel), appointed by judge Sam Pointer, evaluated the scientific data concerning silicone mammary implants with respect to their relationship with connective tissue disorders and immunological dysfunctions. No relationship was established between mammary 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 mammary implants did not present systemic anomalies of the types or functions of immune system cells that could be attributed to silicone. In 1999, an independent report presented by a committee of the Institute of Medicine in the United States indicated that connective tissue disorders, cancer, neurological diseases and other systemic diseases are no more common in women with mammary implants than in women without. This committee concluded that an examination of toxicological studies on silicones and other substances known to be present in implants did not give any reason for concern about health.

Since then, these results have been confirmed by more recent different studies listed in the literature review compiled by McLaughlin, Lipworth, Murphy and Walker, published in the scientific journal Annals of Plastic Surgery, vol. 59, no. 5, Nov. 2007 under the title: "The Safety of Silicone Gel-Filled Breast Implants: a review of the epidemiologic evidence".

However, certain recent studies, notably those of Colaris et al., published in July 2016 in the journal "Immunologic Research", 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. In the cohort of Colaris et al., an improvement of the symptomatology was observed in 50% of cases after removal of the implants. However, the authors state that experimental and epidemiological data are lacking to confirm the existence of this risk.

Offspring

A literature review of Kjøller et al., combining the results of 4 Scandinavian studies and entitled "Adverse Health Outcomes in Offspring of Mothers with Cosmetic Breast Implants: A Review", published in the journal : "Plastic and Reconstructive Surgery" in December 2007, did not find any increased risk of health problems for the children of mothers fitted with mammary implants, and more particularly no increased risk of oesophageal pathology, rheumatic disorders, congenital malformation, perinatal death or hospitalisation. This analysis of Kjøller was in agreement with that of McLaughlin et al.

Mammography – densitometry

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

To limit the risk of rupture, breast compression must not be exaggerated; the patient 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. We strongly recommend the use of echography or of MRI rather than mammography, which may lead to embrittlement and even rupture of the implant.

MRI

Gel-filled mammary implants are compatible with MRI.

Injections – massages

In order to avoid damaging the implant, prohibit any injection, piercing, etc. in the zone where it is placed. Once the prosthesis has been implanted, excessive distension of the shell during massages may also entail wear and rupture of the shell. In the absence of established scientific data, it is impossible to determine the interaction that may exist between an implant and prior or simultaneous injections of filling product such as hyaluronic acid, collagen …

Nevertheless, the injection of autologous fat is possible when an adapted material is used around an implant. On the other hand, GROUPE SEBBIN recommends using blunt cannulas, the diameter of which must not be smaller than 1.5 mm.

V.4 – Follow up for patient

V.4.1 – Medical follow up

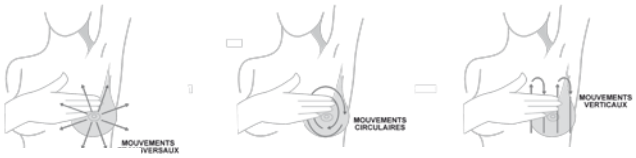
Regular clinical and/or ultrasound monitoring is indispensable. The frequency is left to the evaluation of the surgeon: this follow-up must last as long as the patient has the implant; the patient or the treating doctor must be fully informed of the type of implant; she must keep all means of identification of the implant(s) (implant ID card).

V.4.2 – 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.



Transversal movements | Circular movements | Vertical movements

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

V.4.3 – Information for medical survey

It is the responsibility of the surgeon to alert the patients to the following points:

- the patient is under obligation to inform its physician or surgeon of an implant being present in the region where a surgical intervention is planned,
- the patient is required to inform the practitioner before any check-up, so that the latter may apply the proper technique (compression, Eklund technique, film digitisation technique…). The patient must also consult a doctor as soon as possible if she suspects a complication, especially in case of trauma or compression caused, for example, by violent massage, sporting activity or any accident (automobile accident, safety belt).
- a doctor must be consulted for normal follow-up to detect possible breast cancer,
- the patient must carry his/her implant ID card on her permanently to facilitate emergency medical care.

For more information, go to our website www.sebbin.com.

VI – INFORMATIONS FOR USERS

VI.1 – Precautions before use

VI.1.1 – Purchase order

The following requests are made of the surgeon:

- to schedule his or her order in good time, depending on delivery dates,
- to describe explicitly the type of medical devices desired (reference, volume),
- to order spare devices in case of a handling error such as an error in aseptic procedure,
- to make personally certain of having the necessary medical devices in perfect condition of integrity before beginning the procedure.

VI.1.2 – Storage

The protected units must be stored flat, sheltered from impacts and water and sunlight.

VI.1.3 – Packaging

Hold the outer packaging in such a way that the peelable part of the lid is not pointing toward the person who opens the package. Deposit the contents on a sterile surgical site. Open the inner blister in the same way as for the outer blister.

VI.2 – Protocol of use

It is imperative to:

- verify from the packaging that it indeed contains the desired device (type, reference, and volume),
- verify the use-by date of the implant,
- provide for an incision appropriate for the volume of the implant and for the entry route,
- create an appropriate cavity,
- assure rigorous haemostasis; if necessary, install an aspiration drain before implantation,
- handle the device in an environment appropriate for the surgical procedure,
- use the device immediately after the opening of the inner packaging
- verify the integrity of the implant's individual protective covering as well as its sterilization indicator, then open the protected item,
- verify the change of colour of the indicator of achievement of sterilization under the effect of sterilization with ethylene oxide.

  This indicator adhered on the foot of the inner blister turns from brown to green.
- discard any device with faulty packaging and consult the section on "Materiovigilance"

- open the packaging of the device only at the last instant, to limit as much as possible any risk of contamination; remember that the outer packaging is sterile on the inside but not on the outside, and therefore that it must never be placed on a sterile field; the inner packaging, in contact with the implant, is itself sterile on both the inside and outside; this is why it must be placed on the fluffless sterile field,
- handle the device only with sterile gloves, free of any particles, talc or powder (it is recommended that they be changed just before grasping the implant),
- ~~verify the integrity of the device shell. NOTE: it is possible for bubbles to form in the silicone gel after the manufacturing or sterilization process. These bubbles do not reduce the safety or efficacy of the prosthesis and will dissipate spontaneously. If you observe a detachment of the gel from the envelope or a gel break, please do not implant the device.~~
- verify the integrity of the device shell. NOTE: it is possible for bubbles to form in the silicone gel after the manufacturing. If you observe any bubble or any detachment of the gel from the envelope or a gel break, please do not implant the device.
- never implant a damaged device,
- as the silicone elastomer shell can be easily cut by a scalpel or torn by an excessive strain, prohibit any contact with a sharp-edged or pointed instrument, because any abrasion of the device, even of extremely superficial nature, will make it unusable, and limit any excessive distortion of the device.
  NOTE: any subsequent surgical operation near the implant must be performed with the greatest care, to avoid damaging the implant. If an implant would be damaged, it will have to be removed.
- we caution that the use of an ancillary device of the “Keller funnel” type does not obviate the need to make an incision of sufficient dimensions and adapted to the size of the implant in order to avoid damaging it.
- if Betadine® is used, rinse the site carefully with sterile 0.9% physiological saline solution before inserting the implant.
- position the occlusion patch on the chest wall side,
- fill out the identification labels: patient's name, surgeon's name, date of implantation, location; include one in the patient's dossier and paste the other onto his/her implant ID card,
- issue the patient with the implant ID card where the identification label will be pasted,
- never resterilize an implant. We decline all responsibility if any Laboratoires Sebbin brand medical device is re-sterilised,
- this is a single-use device. There may be risks of contamination, loss of mechanical properties in the event of re-use. We decline all responsibility if any Laboratoires Sebbin brand medical device is re-used.

VI.3 – Surgical technique and position

The surgeon is solely responsible for choosing the indication and the surgical technique.

Gel-filled mammary implants may be inserted by the following main approach routes: inframammary, peri-areolar and transaxillary.

- The inframammary route is the simplest and most direct route for accessing the different anatomical levels. Longer incisions may be made with this route.

- The peri-areolar route is a versatile approach that is compatible with all anatomical levels. However, the diameter of the areola is a limiting factor, and this route could involve more risks of modification of the sensitivity of the nipples.

- The transaxillary route makes it possible to avoid scarring on the breast. It is appropriate for patients with mild ptosis, a poorly defined submammary fold or a too-small areola. However, this approach involves a greater risk of asymmetry or of malposition. This route is inadvisable for large implants with a highly cohesive gel.

The mammary implant may also be placed in different cavities: subglandular, submuscular/subpectoral, subaponeurotic space or in biplanar manner (the top of the implant is underneath the pectoral muscle and the bottom is underneath the mammary gland).

- The subglandular position of the implant is compatible with patients who have tissue that is sufficiently soft to cover the implant and prevent it from being visible. This level is associated with a high incidence of capsular contracture.

- The submuscular position of the implant makes it possible to reduce the visibility and palpability of the implant as well as pseudoptosis, migration and the degree of capsular contracture. However, this method is not as effective in defining the lower pole of the breast.

- Concerning the biplanar or partial submuscular position of the implant: the upper pole of the implant is underneath the muscle and the lower pole is underneath the mammary gland, and so the lower contour is more aesthetic and the degree of capsular contracture is reduced. Precautions must be taken for patients with ptosis, because they tend to develop a "double bubble" malformation corresponding to the visibility of separation between the breast and the implant.

- The position of the implant in the subaponeurotic space is a versatile technique capable of making the implant less visible than in subglandular position, and it avoids the distortions related to contraction of the pectoral muscle. The degrees of capsular contracture are similar to those obtained in submuscular position. However, the dissection of the pocket involves bleeding and therefore a longer operation.

Nevertheless, the approach route used as well as the positioning of the implant are the exclusive responsibility of the surgeon.

VI.4 – Follow up

VI.4.1 – Traceability

Each medical device is supplied sterile, as a single piece and double-bagged, containing the reference and the serial number enabling its traceability, the sterilization batch number and the implant expiry date and is accompanied by:

- seven identification and surgical follow-up labels,
- an implant recipient card and
- the pictogram information sheet with Sebbin contacts.

The surgeon has the obligation of assuring traceability of the medical device all the way to the patient scheduled to receive it, specifically in order to be able to identify it in case of return or recall.

The devices must be implanted without making any modification to them.

VI.4.2 – Medical follow up

Surgical outcomes can sometimes be painful the first few days, especially when the implants are large. An analgesic treatment, adapted to the intensity of the pain, will be prescribed for a few days.

Oedema (swelling), hematoma (bruising) and discomfort are common in the early stages.

The first operative dressing is changed at the time of discharge and renewed when necessary.

It is worth considering a convalescence with interruption of activity for a minimal period of fifteen days.

It is advisable to wait three months to resume a sporting activity.

VI.5 – Explantation

The standard ISO 12891-1 specifies the conditions of retrieval and handling of explanted devices.

- Perform non-invasive examinations of the implantation site and of the implant in situ before removal (ultrasound, MRI…). Remove the device while minimising damage sustained by it and by the tissues. Taking photos of the implant in situ, of the surgical implantation site and of the removed implant, is recommended.
- The arrangement of different parts of the removed implant must be clearly indicated (arrangement of different fragments). Where investigation of tissues and secretion near the implant is likely to aid the analysis, take samples and place them in appropriate storage media. Note the site of implantation and arrangement of the tissue with respect to the device.
- Handling of the device before disinfection and decontamination must be carried out with protective equipment in order to avoid potential contamination of the handler and the explant.

–

– Identify the device: collect it in a state as close as possible to the state in which it is found at the time of removal, clean it and decontaminate it, place it in a labelled and sealed container with the surgeon's initials, date and time of removal, if possible serial number… It is important that the container is sealed in a way that any future opening of the container can be detected.
– Please request the questionnaire on explantation of SEBBIN devices from GROUPE SEBBIN or from your distributor or visit the website (limited access, only for surgeons having registered). This questionnaire will help us afterwards in our research on identification and examination.
– All returned devices must be cleaned and decontaminated, in which case we will not proceed with the analysis of the returned explant. Absence of decontamination must be mentioned on the return packaging.
– If the explantation is not related to a complaint or a case of materiovigilance, the device must be disposed of in accordance with the in-house hospital procedures.

VII – MATERIOVIGILANCE, GUARANTEES

VII.1 – Materiovigilance

Any serious incident, or potential serious incident, must be included in a materiovigilance declaration to the competent health authorities and to GROUPE SEBBIN.

To be of use, this declaration must include:

- The dates of implantation and explantation,
- The date and reason for the incident,
- The type of device (brand, name, reference, article and serial number),
- The description of the incident and the operating report.

It is not necessary to indicate the name of the patient.

Special conditions of the explanted products:

Regardless of the reason, any return of an explanted product is subject to a return authorisation request made to GROUPE SEBBIN. Products returned will have to be accompanied by this authorisation as well as proof that they have been decontaminated and the duly completed explantation questionnaire.

Otherwise, GROUPE SEBBIN reserves the right not to process the return request.

VII.2 – Guarantees – Limit of coverage

GROUPE SEBBIN certifies that all precautions have been taken in the choice of materials and methods of manufacturing its devices. GROUPE SEBBIN delivers, together with its devices, all instructions and information necessary for transport, storage, use and types of operating procedures necessary to guarantee the safety and performance of its implants. These instructions are based on studies and tests that were conducted on the implants and subjected to meticulous evaluation. However, in no case is GROUPE SEBBIN able to guarantee in absolute terms that this information and these instructions will be completely respected once these implants have departed from the storage locations of the company. In this connection, GROUPE SEBBIN promises to replace any product identified as defective by GROUPE SEBBIN at the time of shipping by GROUPE SEBBIN.

Therefore, and in the absence of established scientific data, it is impossible on the basis of the current level of knowledge to anticipate and determine the mechanisms, the effects and the clinical consequences of interactions that may result from previous implantation of an implant of another brand and its subsequent replacement by a Sebbin implant. Consequently, GROUPE SEBBIN declines any responsibility for possible consequences (new adverse effects and/or interactions) considered to be attributable to an interaction between the use of its implants with potential effects and/or complications generated by implantation of the previous device(s). This clause constitutes a guarantee and voids any guarantee not covered in the above text, explicit or implicit according to the provisions of the law, or otherwise, including but not limited to, any implied warranty of merchantability or fitness for purpose. GROUPE SEBBIN accepts no responsibility with regard to any other commitment undertaken in its name by any person relating to its devices and prohibits such activity. GROUPE SEBBIN reserves the use of its devices for physicians trained in the techniques of plastic, reconstructive and aesthetic surgery.

VIII – DESIGNATION

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.

The table hereafter presents the evolution and equivalence of the labelling on the box and card patient.

VIII.1 – PURITY Range

Ref	*Logo*	*Box labelling*
LS 50XXX	SEBBIN PARIS ESTHETIQUE & RECONSTRUCTION	Classic Mammary Implant, Smooth, Moderate Profile Content: Cohesive Naturgel
		Round Mammary Implant, Smooth, Moderate Profile Content: Naturgel I cohesive
LS 51XXX	SEBBIN PARIS ESTHETIQUE & RECONSTRUCTION	Classic Mammary Implant, Smooth, High Profile Content: Cohesive Naturgel
		Round Mammary Implant, Smooth, High Profile Content: Naturgel I cohesive
LSC 54XXX	SEBBIN PARIS ESTHETIQUE & RECONSTRUCTION	Firm Mammary Implant, Smooth, Moderate Profile Content: high cohesive Naturgel
		Round Mammary Implant, Smooth, Moderate Profile Content: Naturgel 2 high cohesive
LSC 55XXX	SEBBIN PARIS ESTHETIQUE & RECONSTRUCTION	Firm Mammary Implant, Smooth, High Profile Content: high cohesive Naturgel
		Round Mammary Implant, Smooth, High Profile Content: Naturgel 2 high cohesive

VIII.2 – SUBLIMITY Range

Ref	*Logo*	*Box labelling*
LS 70XXX	SEBBIN PARIS ESTHETIQUE & RECONSTRUCTION	Classic Mammary Implant, Microtextured, Moderate Profile Content: Cohesive Naturgel
		Round Mammary Implant, Semi-smooth, Moderate Profile Content: Naturgel I cohesive
LS 71XXX	SEBBIN PARIS ESTHETIQUE & RECONSTRUCTION	Classic Mammary Implant, Microtextured, High Profile Content: Cohesive Naturgel
		Round Mammary Implant, Semi-smooth, High Profile Content: Naturgel I cohesive
LS 74XXX	SEBBIN PARIS ESTHETIQUE & RECONSTRUCTION	Classic Mammary Implant, Microtextured, Semi Moderate Profile Content: Cohesive Naturgel
		Round Mammary Implant, Semi-smooth, Semi moderate Profile Content: Naturgel I cohesive
LSC 72XXX	SEBBIN PARIS ESTHETIQUE & RECONSTRUCTION	Firm Mammary Implant, Microtextured, Moderate Profile Content: high cohesive Naturgel
		Round Mammary Implant, Semi-smooth, Moderate Profile Content: Naturgel 2 high cohesive
LSC 73XXX	SEBBIN PARIS ESTHETIQUE & RECONSTRUCTION	Firm Mammary Implant, Microtextured, High Profile Content: high cohesive Naturgel
		Round Mammary Implant, Semi-smooth, High Profile Content: Naturgel 2 high cohesive
LSC 76XXX	SEBBIN PARIS ESTHETIQUE & RECONSTRUCTION	Firm Mammary Implant, Microtextured, Semi moderate Profile Content: high cohesive Naturgel
		Round Mammary Implant, Semi-smooth, Semi moderate Profile Content: Naturgel 2 high cohesive

VIII.3 – VOLUPTY Range

Ref	*Logo*	*Box labelling*
LS 90XXX		Classic Mammary Implant, Textured, Moderate Profile Content: Cohesive Naturgel
		Round Mammary Implant, Micro textured, Moderate Profile Content: Naturgel I cohesive
LS 91XXX		Classic Mammary Implant, Textured, High Profile Content: Cohesive Naturgel
		Round Mammary Implant, Micro textured, High Profile Content: Naturgel I cohesive
LSC 92XXX		Firm Mammary Implant, Textured, Moderate Profile Content: high cohesive Naturgel
		Round Mammary Implant, Micro textured, Moderate Profile Content: Naturgel 2 high cohesive
LSC 93XXX		Firm Mammary Implant, Textured, High Profile Content: high cohesive Naturgel
		Round Mammary Implant, Micro textured, High Profile Content: Naturgel 2 high cohesive

VIII.4 – INTEGRITY Range

Ref	*Logo*	*Box labelling*
LSMRFXXX		Integrity Round Matrix, Microtextured Breast implant Full Profile Content: INTEGRITY gel
		Mammary Implant Round Matrix, Semi smooth, Full Profile Content: EverlastGel
LSMRLXXX		Integrity Round Matrix, Microtextured Breast implant Low Profile Content: INTEGRITY gel
		Mammary Implant Round Matrix, Semi smooth, Low Profile Content: EverlastGel
LSMRMXXX		Integrity Round Matrix, Microtextured Breast implant Moderate Profile Content: INTEGRITY gel
		Mammary Implant Round Matrix, Semi smooth, Moderate Profile Content: EverlastGel
LSMRSXXX		Integrity Round Matrix, Microtextured Breast implant Semi moderate Profile Content: INTEGRITY gel
		Mammary Implant Round Matrix, Semi smooth, Semi moderate Profile Content: EverlastGel

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