Sebbin
PARIS

Instructions For Use

Silicone Gel-filled Gluteal Implant

Class IIb – CE0483

GROUPE SEBBIN SAS 39, Parc d'Activités des Quatre Vents

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www.sebbin.com

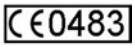
CONTENT

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

GROUPE SEBBIN manufactures the Gel-filled Gluteal Implants medical devices under the brand name Laboratoires SEBBIN.

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

The Gel-filled Gluteal Implants 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

Gluteal 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 is smooth.
- 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 ultra-cohesive, named Extrafirm Gel.

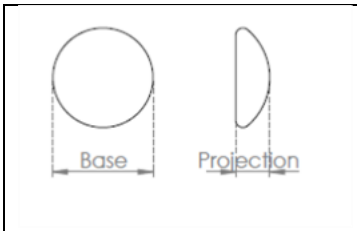
The shape of the implant is either round, biconvex or anatomical.

II.3 Range of products

GROUPE SEBBIN has developed a number of products according to the shape of the implant.

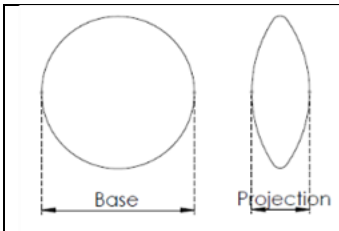
II.3.1 –-Round Gluteal Implant

Each implant is referenced according to the shape, and its dimensions: Vol. (volume), Base (diameter of the base), Proj. (highest point of the projection). Are presented in the table below the minimal and maximal dimensions for the round, smooth gluteal implants filled with Extrafirm Gel.

	***Ref***		***Vol. (mL)***	***Base (mm)***	***Proj. (mm)***
	LS 04	min	200	108	30
		max	440	136	44

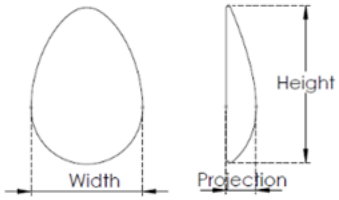
II.3.2 –-Biconvex Gluteal Implant

Each implant is referenced according to the shape, and its dimensions: Vol. (volume), Base (diameter of the base), Proj. (highest point of the projection). Are presented in the table below the minimal and maximal dimensions for the biconvex, smooth gluteal implants filled with Extrafirm Gel.

	***Ref***		***Vol. (mL)***	***Base (mm)***	***Proj. (mm)***
	LS 06	min	370	127	52
		max	530	143	59

II.3.3 –-Anatomical Gluteal Implant

Each implant is referenced according to the shape, and its dimensions: Vol. (volume), Width (diameter of the base), Proj. (highest point of the projection) and height. Are presented in the table below the minimal and maximal dimensions for the anatomical, smooth gluteal implants filled with Extrafirm Gel.

	***Ref***		***Vol. (mL)***	***Width (mm)***	***Height (mm)***	***Proj. (mm)***
	LS 05	min	185	97	139	30
		max	400	129	174	42

III. INDICATIONS

Gel-filled gluteal 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 gluteal implants are intended for:

- Aesthetic correction of hypotrophic buttocks, gluteal ptosis, lateral gluteal depressions;
- Reconstruction: to correct after-effects of gluteal muscle contracture, sarcoma, gluteal abscess, gluteal atrophy, poliomyelitis.

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

Intended target population is women or men, who desire an increase in volume of the gluteal region for aesthetic or reconstruction reason.

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 healing or an additional infectious risk;
- Contra-indications for non-emergency surgery such as unexplored biological, immunological, cardiovascular, respiratory disturbance, etc.;
- Pathologies that 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:

- 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;
- 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
- 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
- Documented cancer developing locally, with ongoing or scheduled chemotherapy and/or radiotherapy.
- 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. INFORMATIONS 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,
- 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.

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

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 gluteal implants are intended in the treatment of:

- Hypotrophic buttocks
- Gluteal ptosis
- Lateral gluteal depressions
- Atrophy of the muscles (after-effects of poliomyelitis)

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;

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 ultrasound monitoring and the necessity of consultation in case of violent trauma.

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 case of limited thickness of the soft tissue covering the implant 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 subcutaneous or subaponeurotic implantation when compared to intramuscular or submuscular 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).

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 pocket, contamination of the suture line, excess pressure over the scar, trauma, etc.

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

Depending on the operative technique used (implant position and choice of incisions), can occur a dehiscence of the incision, which is the main complication and varies from 0 to 14%.

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. 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.

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 or intra-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 rotation able to bring the occlusion patch into an anterior position
- an effect on the sciatic nerve seems to be possible only if the implant is placed between two muscles.

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

Autoimmune and connective tissue diseases

For prudence, implantation is not recommended in patients having personal or family prior history of such pathologies. Published studies were done on patient with mammary implants, but the origin being silicone filled implant, the information cannot be neglected.

"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.

Densitometry

Implantation makes it more difficult to record a radiography; tissues may remain difficult to analyse.

The patient must systematically inform the radiologist doctor or the X-ray technician of the presence of implant(s), but the practitioner remains the sole judge of the technique to be employed.

MRI

Gel-filled gluteal 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 …

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; he/she must keep all means of identification of the implant(s) (implant ID card).

V.4.2 – 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 his/her 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. The patient must also consult a doctor as soon as possible if he/she suspects a complication, especially in case of trauma or compression caused, for example, by violent massage, sporting activity or any accident.
- the patient must carry his/her implant ID card permanently to facilitate emergency medical care.

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

VI – INFORMATION 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, 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,
- 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,
- use the device immediately after the opening of the inner packaging
- 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.
- 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.
- if Betadine® is used, rinse the site carefully with sterile 0.9% physiological saline solution before inserting the implant.
- 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 gluteal implants may have:

- a subcutaneous implantation: the implant is placed in contact with the skin (aponeurotic extensions) and the gluteal aponeurosis.
- a subaponeurotic implantation: the implant is placed in contact with the gluteal aponeurosis and the gluteus maximus muscle.
- a submuscular implantation: the implant is placed in contact with the gluteus maximus muscle and the gluteus medius muscle.
- an intramuscular implantation: the implant is placed inside the gluteus maximus muscle.

Because the gluteal implants are prefilled with silicone gel that is ultra-cohesive and very firm, the surgeon is advised to make an incision of 5 to 7 cm to facilitate the entry of the implant.

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-blister, 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 one to two months to resume a sporting activity.

VI.5 – Explantation

The standard ISO 12891-1 specifies the conditions of removal 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.

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