



INFORMATION ABOUT THE BREAST IMPLANT PROCEDURE

*The right choice
for me*



Euromi Biosciences wishes to give a fresh perspective on silicone gel-filled breast implants and offers a complete range of implants with a variety of textures and gels to meet your needs.

A new perspective, but also 25 years of experience in medical, aesthetic and plastic surgery.

Euromi Biosciences is part of a group that has specialised in medical devices for the past 25 years. It intends to benefit from the expertise of the French company Cerecare, specialised in compression garments and silicone dressings, and the Belgian company Euromi, specialised in liposuction and lipofilling devices as well as in mesotherapy guns.

Breasts have great symbolic and emotional significance: they represent the very essence of womanhood and are a vital part of a woman's body map. They portray an array of images such as motherhood, comfort and softness but also seduction, aesthetic and sexuality.

Every woman is different, with different aspirations... and for a wide range of personal reasons, a woman may want to reconstruct, alter, remodel or increase the size of her breast. This wish should not be taken lightly, it is legitimate because it contributes to the well-being, self-esteem and self-confidence that everyone needs.

However, inserting breast implants is not a trivial matter and before making a final decision, it is important to weigh up the expected benefits and the risks you are willing to take to achieve the required results.

This booklet is intended to guide you, but cannot under any circumstances replace your doctor's advice.

Your primary contact will be your surgeon. He will help you to make your decision by answering any questions you may have, explaining the procedure and telling you about the potential risks and complications.

You can also talk to your family or friends who already had this type of surgery.



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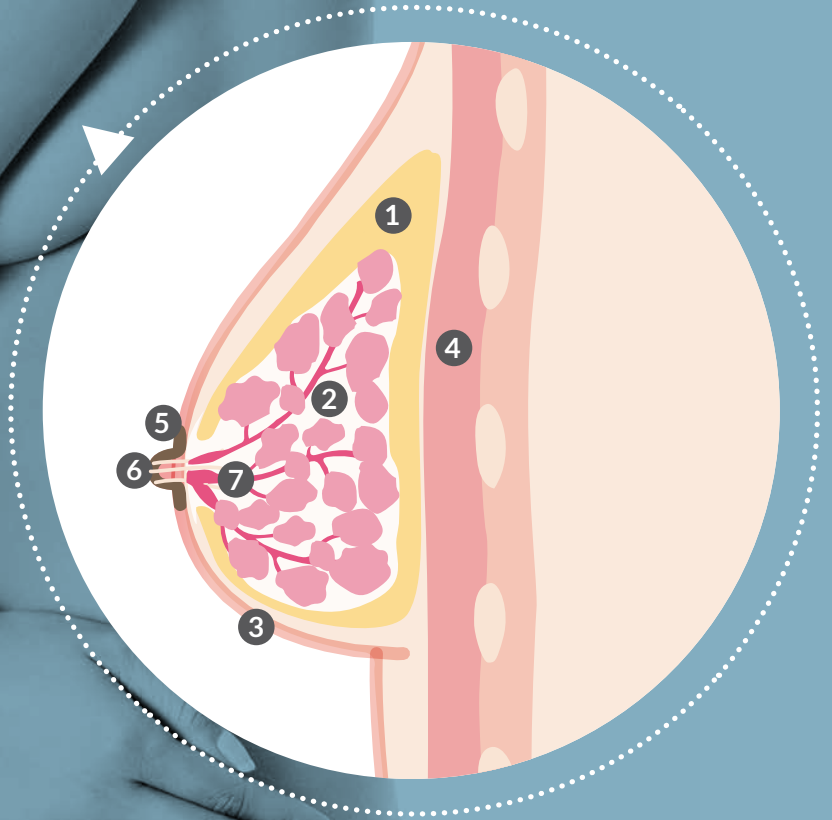
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01

MY Anatomy



BREAST

& biological function

1

2

The shape and size of the breast are determined **by the adipose connective tissue (fat) ①** and **glandular tissue ②**.

1

2

The suppleness of the breast depends on the proportion of **glandular tissue ②**, which, with age, is gradually replaced by **adipose tissue ①**, which is less firm. The breast volume depends on factors such as age, skin elasticity, previous pregnancies, physical activities, etc.

3

4

The breasts do not contain muscles but they have support ligaments which connect the skin **③** to the **pectoral muscles ④**. The pectoralis major muscle is used when we move our arms. They bear their own weight and naturally tend to sag over time (known as breast ptosis).

5

6

The areola ⑤ is the pink or brown area around **the nipple ⑥**.

6

7

Given that the primary natural role of the breast is lactation (the production of milk after childbirth), the role of the mammary ducts **⑦** is to carry the milk to **the nipple ⑥**.

02



BREAST SURGERY

Indications

Breast implant surgery can be indicated for different reasons.

1 BREAST AUGMENTATION FOR AESTHETIC REASONS

To increase breast size. For young women, it is recommended to wait until the end of puberty and to comply with the minimum legal age in the country of the procedure.

2 BREAST AUGMENTATION FOR PLASTIC SURGERY

To correct a congenital malformation:



› **Asymmetry:** lack of symmetry between the two breasts. In most women, the two breasts have a slightly different size and/or shape. When this difference is noticeable, it is known as breast asymmetry.



› **Amastia, aplasia:** complete absence of mammary gland development



› **Hypomastia, hypoplasia:** underdevelopment of the mammary gland.



› **Breast ptosis:** sagging of the breasts due to loss of holding (weight loss, pregnancy or ageing). In this case, breast augmentation is combined with a breast lift to 'raise' the breasts.

3 BREAST RECONSTRUCTION

To restore the shape of the breast after a mastectomy (removal of a breast due to cancer or trauma) or an accident causing the total or partial loss of the breast. The procedure can sometimes be used to correct a congenital malformation.

4 IMPLANT REPLACEMENT

For patients who have undergone a previous augmentation or reconstruction procedure with implants containing silicone gel or saline solution. This involves replacing an implant that is old, faulty or that has caused complications.

For breast reconstruction due to cancer (following a mastectomy), the psychological benefits are extremely important. This is a chance for the woman to recover her body image and forget her disease.

In aesthetic and plastic surgery, breast augmentation with implants generally restores the woman's self-esteem and self-confidence and enhances her sense of womanhood.

Whatever the indication, the psychological benefit is undeniable and makes an essential contribution to the expected results.



good to know

There are alternatives to a breast implant: an external breast prosthesis worn in the bra, breast reconstruction using an abdominal flap or your own fatty tissue (lipofilling).

Contraindications & risks

Breast implants are contraindicated in patients with:

- › a pre-existing pathology in the implant area
- › insufficient tissue (skin expanders should be considered beforehand)
- › a general infection or infection in the implant area
- › a medical history of autoimmune disease (lupus, scleroderma, etc.)
- › non-stabilised breast cancer
- › current treatment using radiation, microwave diathermy or steroids
- › repeated failure of similar implants
- › known hypersensitivity and/or allergy to silicone
- › psychological instability
- › a current pregnancy, breastfeeding or foreseen in the near future
- › if the surgeon deems that the patient is in a poor physiological condition.

It is necessary to consult a doctor or pharmacist before applying topical medications in the breast (such as steroids). CEREFORM® breast implants are not suitable for men (including sex-change cases).

RISKS

Like any surgical procedure, the implantation of breast implants carries risks that you must fully understand before making your decision: this includes the risks inherent to the procedure itself, such as the risks and complications associated with general anaesthesia.



good to know

During the consultations before the surgery, your surgeon will explain in detail the risks and complications of the procedure and the implant insertion. You will be given an informed consent form that you must read and sign to express your agreement.

03

BREAST IMPLANT



Composition

Breast implants all contain the following:



Its role is paramount because it gives the implant its shape and is an interface between the implant and the body (it will be 'colonised' by the adjacent tissue).



Silicone gel; saline solution (salt water); hydrogel (a mixture containing water and a cellulose derivative).

› **The shell can be pre-filled** with one of the fillers: the volume is already decided and cannot be changed.

› **The shell can be filled by the surgeon during the procedure**, after implantation: these are known as 'inflatable' implants: the surgeon determines the final volume of the implant and injects the filler.

Shape

There are mainly two shapes of breast implants that can be adapted to different morphologies:

ROUND IMPLANTS



They provide volume to the upper part of the breast for a more plunging neckline.

They are particularly appropriate for women whose breasts are already slightly formed.

ANATOMICAL IMPLANTS



They are very similar to the dimensions and volume distribution of a natural breast. They gently fit the curves of the bust without any rupture between the top of the breast and the chest.

They are ideal for slender women and women suffering from aplasia or hypoplasia. These implants are particularly recommended for breast reconstruction.



good to know

The most commonly used implants are those pre-filled with silicone gel. They are favoured by many surgeons who appreciate their 'natural' consistency.

Surface

This is the silicone shell enabling the implant to be colonised (accepted by the body).

For most manufacturers, there are **3 types of surface**:



A SMOOTH SURFACE

This enables the implant to be implanted and explanted smoothly, however there are a greater number of capsular contractures.



A MICROTEXTURED SURFACE

This type of surface limits the risk of capsular contracture and improves cell colonisation while enabling easy implantation and explantation.



A MACROTEXTURED SURFACE

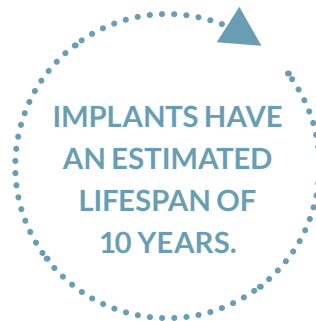
This surface facilitates an optimal implant integration but causes implantation and explantation difficulties.



Lifespan

Breast implants have a limited lifespan. They should never be considered as permanent, because of the constraints they suffer everyday (normal wear and tear of the implant). Implants have an estimated lifespan of 10 years.

The implant may require removal or replacement, that is to say a new surgical procedure. The reasons can be varied: implant replacement, desire for a larger size, ptosis (inevitable and related to the weight of the implant), or possible complications.



good to know

The textured surface was developed to improve the interface between the implant and the body. The shell is slightly rough to facilitate the adhesion of adjacent tissues and the integration of the implant in the body.

The CEREFORM[®] implant

CEREFORM[®] breast implants contain the following:

A SILICONE ELASTOMER SHELL

Due to its technical properties, the shell is very resistant and guarantees maximum safety : it can be smooth or microtextured. A 'barrier layer' integrated into the shell limits silicone gel perspiration through the shell.

THE SHELL IS PRE-FILLED WITH SILICONE GEL

The Cereform[®] implant offers 3 cohesive gels for a more natural touch (Classic gel), better holding (Aptima gel), a suppler touch and excellent shape memory (Ellipse gel).

The implant-filling method **eliminates the risk of silicone leakage**. No perforations that could impair the shell are made during manufacture. Implants are available in a **round** shape (smooth or microtextured shell) and are manufactured using medical-grade silicone.

The CEREFORM[®] implant is dry heat sterilised according to an approved cycle. Intended for single use and for one patient only, these implants are delivered inside a double packaging to ensure an optimal microbiological barrier until implantation.

Each implant has a unique identification number engraved on the occlusion patch for perfect traceability.*

* This number is also given on the labels provided with the implant: one label will be affixed to the patient card which you will be given after your procedure. CEREFORM[®] breast implants are class III medical devices. As such, they have CE marking. Please consult your doctor.

04

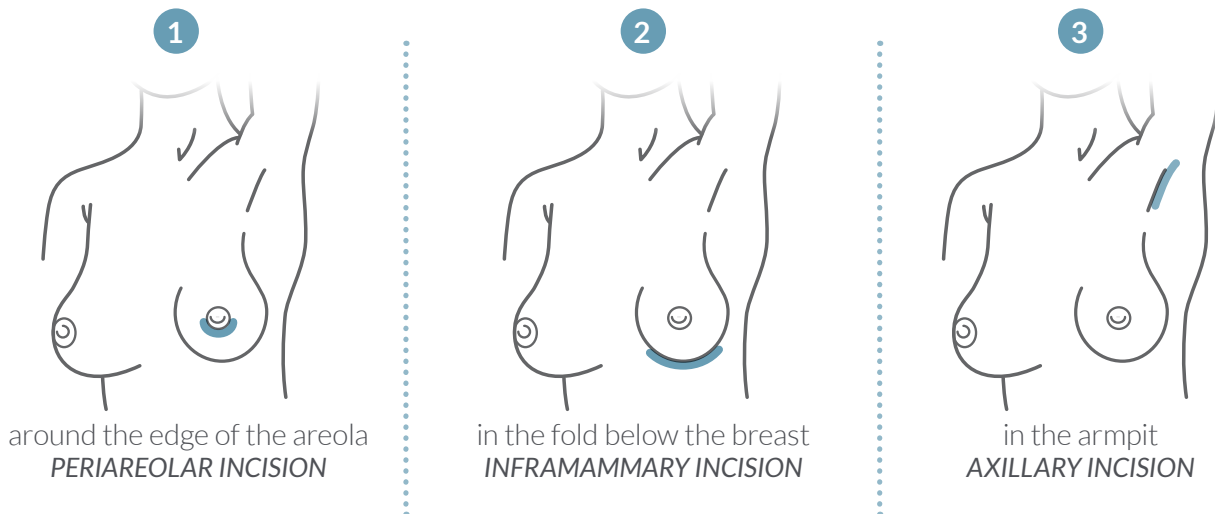
THE SURGERY



Implantation method and scars

The surgical procedure consists in implanting the implant(s) in such a way as to achieve the desired bust: the surgeon will **slide the breast implant through an incision, as small as possible**, to facilitate implantation while minimising post-operative scars.

Before the procedure, the surgeon will discuss this incision with you. The scar will then be concealed in **3 different ways**:



Apart from cases of breast reconstruction, there are no scars other than those left by these incisions: scars are therefore minimal and very discrete.

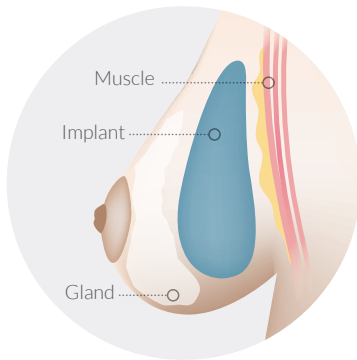
Positioning of the implant

The shape and volume of the implant, your morphology, and the surgeon's approach may determine the type of incision, but the main criterion will be the positioning of the implant. However the implant is positioned, there must be sufficient supple skin to avoid excessive tautness.

The implant can be positioned in **DIFFERENT WAYS**:

1

THE IMPLANT IS INSERTED DIRECTLY UNDER THE MAMMARY GLAND (RETROGLANDULAR INSERTION)



ADVANTAGES:

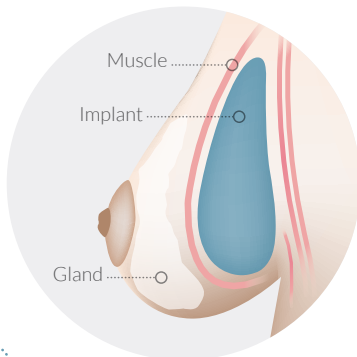
- less immediate post-operative pain
- shorter convalescence
- no friction between the implant and the muscle, which helps to preserve the original shape of the implant

DISADVANTAGES:

- in theory, a greater risk of capsular contracture
- upper part of the implant is noticeable (to the eye and/or to the touch) with normal sagging of the gland

2

THE IMPLANT IS INSERTED UNDER THE PECTORAL MUSCLE (RETROPECTORAL OR RETROMUSCULAR INSERTION)



So that it is less noticeable to the eye and to the touch, with an even more natural appearance:

ADVANTAGES:

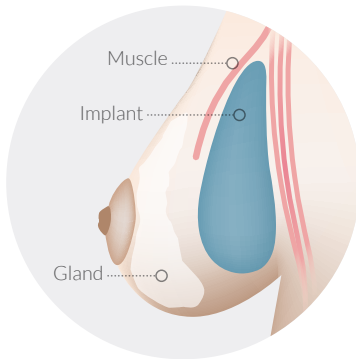
- in theory, less risk of capsular contracture
- better coverage of the implant, which remains unnoticeable

DISADVANTAGES:

- more immediate post-operative pain
- longer convalescence with difficulty raising your arms
- risk of deformation or movement of the implant

3

THE IMPLANT IS INSERTED IN A DUAL PLANE POSITION.



The implant is placed behind the muscle in the upper part of the breast and behind the gland in the lower part.

This dual position **combines the advantages of the two previous techniques**. It has the advantage of interposing the muscle naturally on the upper section and of integrating the implant into the breast in the lower section.

Description of the procedure



The insertion of breast implants is one of the most common aesthetic surgery procedures.

The surgical procedure consists in:

- **Detaching the tissue** to prepare sufficient space (the pocket) for implantation.
- **Inserting the implant** into the chosen incision behind or in front of the pectoralis major muscle, as decided during the previous consultations with your surgeon.

The procedure is performed in the operating theatre, under general anaesthesia, and lasts from half an hour to an hour and a half* for aesthetic procedures. For reconstructive surgery, the procedure may last longer (two hours). At the end of the procedure, the surgeon may leave a drainage system in place for a few days.

*This period of time may vary slightly depending on the surgeon's surgical protocol, the procedure chosen or the need for an additional procedure (ptosis repair). In some cases, the procedure may be performed on an outpatient basis with a very short hospital stay (the patient comes in and leaves the same day).

05



AFTER THE PROCEDURE



RECOVERY

After the procedure, the patient recovers in the recovery room. She stays there for one to two hours*. The anaesthesia team will ensure that the best conditions are in place. The operation requires a short hospital stay of 1 to 3 days*, and a recovery period after the procedure is generally needed (5 to 10 days)*.

*These periods of time may vary slightly depending on the surgeon's surgical protocol, the procedure chosen or the need for an additional procedure (ptosis repair). In some cases, the procedure may be performed on an outpatient basis with a very short hospital stay (the patient comes in and leaves the same day).



USUAL POST-OPERATIVE FOLLOW-UP

Immediately after surgery, **a dressing is applied** with a tight (compressive) bandage to prevent the implants from moving. One or two days after the surgery, the dressing can be changed and replaced by a new one with **a strong support bra*** which should be worn day and night.

The patient will experience breast pain for a few days after the procedure. Although the sutures are removed on the seventh day, it is important to know that the breasts remain very swollen due to oedema and are likely to feel tight on the pectoral muscle.

The patient should avoid extensive arm movements in the first few days. The patient should wait at least three days before resuming normal activities, while taking certain precautions (avoid driving for the first two weeks, avoid carrying heavy loads, avoid sports for 6 weeks).

*Wearing a non-wired, front-fastening compression bra is recommended for approximately 1 month. Your surgeon and you will choose your bra depending on the procedure method and your anatomy.



good to know

It is also recommended to avoid exposing the scars to direct sunlight for one month and to sleep on your back.



FOLLOW-UP

To detect complications as soon as possible, **regular monitoring performed** by a specialist practitioner is advised after the breast implant procedure.

Post-operative follow-up is critical for detecting a damaged or worn-out implant. Your surgeon will schedule a follow-up visit a few days after the procedure and then several consultations during the first year. The recommended consultation frequency is 1 month, 3 months, 6 months and 12 months after the procedure then every year, even if there are no implant-related symptoms.

Some simple tests are able to monitor women's health. Regular breast cancer screening for all women can also detect a breast implant rupture or leak.



MAMMOGRAM

This is **the reference test for monitoring** the breast. The test takes an X-ray image of each breast from the front and the side to view the entire mammary gland. Mammograms are used to detect early stage breast cancer. The test is used to look for anomalies such as opacities or micro calcifications.

It should be performed at any age at the slightest sign or when the breast is too difficult to examine. **The radiology technician must be informed when breast implants are present** because this changes the imaging protocol considerably and the test itself can rupture the implant (by compression).



MAGNETIC RESONANCE IMAGING

MRI uses a magnetic field and non-ionising radiofrequency waves. Due to its precision, it is used **in addition to mammograms** for screening women with implants. It can also check whether breast implants have ruptured or leaked. Once again, the technician must be informed when breast implants are present.



good to know

*It is important to perform a breast self-examination once a month to detect any abnormalities.
It does not replace the opinion of a health professional since the implant can alter the diagnosis.*



POSSIBLE COMPLICATIONS

- › **The intensity of the post-operative pain** may vary and be experienced during 2 to 3 days after the procedure. The patient then experiences discomfort over the following month.
- › **Haematoma or oedema** the implant area: in case of persistent haematoma or oedema, a puncture can be performed by taking all necessary precautions to avoid damaging the implant.
- › **A non-infectious seroma (fluid build-up) may occur.** This will require extensive drainage.
- › **Temporary loss of sensitivity** or, conversely, **exacerbated sensitivity** of the nipple is usually experienced. In rare cases this situation can be permanent.

Although rare, other complications are listed below:

- › a short- or long-term post-operative infection
- › poor scarring
- › wrinkles or ripples on the implant's shell
- › post-operative asymmetry
- › a capsular contracture
- › siliconomas, granulomas
- › tissue necrosis
- › calcification
- › implant rupture/silent rupture
- › implant deflation
- › implant movement/rotation
- › ptosis
- › the Anaplastic Large Cell Lymphoma (ALCL)



good to know

Check with your doctor if you suspect a complication, such as trauma or compression caused by, for example, sports activity or use of seat belts.

FREQUENTLY ASKED QUESTIONS

OUR ANSWERS

How do I choose the right breast implant? Which implants are approved?

› **Your surgeon will help you** to choose the size and shape of your breast implants after a physical examination. He will assess the width and shape of your chest, the height and axis of your breasts and the size of your areola. It is also important to talk to your surgeon about the outcome you want to achieve.

CE marking is mandatory for all medical devices circulating within the European Union. Since 1998, only products with a CE certificate of conformity and for which the manufacturer has provided complete and accurate information proving compliance with current standards and regulations are authorised. Outside the European Union, authorisation is granted by the competent authority.

Is a mammogram possible with breast implants?

› The presence of breast implants does not prevent a mammogram from being performed. However, they do make the test more complicated and the results more difficult to interpret. **It is therefore vital to tell the practitioner that you have breast implants** to take the necessary precautions and adapt the technique (digital images) for the best results without damaging the implant.

From what age can breast implants be considered?

› During puberty, breast size varies with hormonal changes and contraception. The breasts stabilise at the end of puberty. It is therefore **recommended to wait until the end of puberty before having a breast implant procedure, and to comply with the minimum legal age in the country of the procedure, if applicable.**

Is the cost of breast implant procedures covered by the health service?

› You should check with the health service in your country.

When and why must patients have check-ups?

› Like all women, those with implants **must have regular check-ups** to screen for breast cancer (general check-up and breast examination). For women with implants, this check-up is scheduled **each year** with their surgeon or any other appropriate specialist to detect any problem related to the implants. Additional tests (mammogram, ultrasound or MRI scan) may be necessary.

Are there still risks of retractile capsular contracture (fibrous shell) with new generation implants?

› Yes, because the body sees any artificial implant as a foreign body, resulting in the formation of scar tissue around the implant and encapsulating it. This is a **perfectly normal biological process** that occurs after each breast implant procedure. However, in some cases, this capsule can thicken and harden, causing the implant to contract. Retractable capsular contracture generally causes pain and wrinkles on the surface of the breast.

Is there a risk of rupture and what are the consequences?

› Rupturing of a breast implant is a **rare complication** that can occur after an impact, violent trauma or surgical trauma (implant damaged during the procedure). It may also be caused by a retractile fibrous shell or simply by the age of the implant. The greatest risk with a rupture is the migration of silicone gel into the body (leakage through a crack in the shell). Current breast implants use new generation medical-grade silicone. **The silicone gel in the shell is very cohesive, reducing the risk of migration** and complications. However, the breast implant must be removed if it ruptures.

Are any physical activities and sports contraindicated?

› In general, it is recommended **to refrain from any physical activities or sports for 6 weeks after the procedure** to avoid any risk of the implant moving or any other complication. For more intense sports that may cause impacts to the implant (running, weight training, combat sports, etc.), you should be cautious and be aware of the risks of early rupture in case of an impact.

Can breast implants cause autoimmune diseases?

› To date, there is **no proof of a correlation** between systemic complications, cancer or autoimmune diseases and silicone gel-filled breast implants.

Is the use of silicone dangerous for the body?

› Silicone has been used in implants since 1950. It is considered **the most widely tolerated biomaterial**. It has many uses (medical and cosmetic in particular). Nevertheless, it is preferable to prevent the silicone from penetrating the tissues. The gel used for filling breast implants is very cohesive (it has a compact consistency) which minimises the risk of penetration into the body.

Does sensitivity change after a breast implant procedure?

› A decrease in nipple and areola sensitivity is normal whatever type of incision is used. **This feeling is temporary, rarely permanent**, and sensitivity returns after a few months.

Is pregnancy possible after a breast implant procedure?

› From a medical point of view, pregnancy is not contraindicated after a breast implant procedure. However, during this period, there are significant hormonal changes and the size of the mammary gland changes significantly, which can affect the aesthetic result. It is therefore **preferable to delay a breast implant procedure for 6 months to 1 year after giving birth** (or at least 6 months after breastfeeding) for best results.

Can breastfeeding be difficult after a breast implant procedure?

› Breastfeeding is not contraindicated after a breast implant procedure as the mammary glands and ducts are not affected. However, it is **recommended to leave a gap between the procedure and a pregnancy** (you should wait until 3 months after the procedure before becoming pregnant). Breast implants are not likely to be distorted by breastfeeding or a breast pump, but the aesthetic result can be affected by changes in the size of the mammary gland.

What is the informed consent form?

➤ This is a form that the surgeon will ask you to sign after your first consultations and before your procedure. This is not a release form but a **document giving your consent for the procedure**, and acknowledging that your practitioner has described the procedure to you and informed you about the risks.

What is the patient card?

➤ The surgeon will give you the patient card after completing it and affixing the appropriate labels (each label corresponds to one implant). This card **identifies the breast implants** (implant reference, volume, serial number, manufacturer's contact details, procedure date, doctor's name, etc.). You should keep the patient card given to you after the procedure with your medical documents for an unlimited time. In fact, we recommend that you carry it with you at all times to facilitate emergency medical care. We also advise to photocopy and/or scan it in order to keep its traceability in case of lost or damage.

What is the mandatory reflection period before the procedure?

➤ The **legal time** frame between the first consultation and the date of the procedure is **15 days**. This lets you take the time to think about your decision, but also to have two consultations with the surgeon, have a mammogram (mandatory for women over the age of 35) and schedule an appointment with the anaesthetist for a full pre-operative assessment before the procedure. This reflection time is mandatory and is in your own interest.



Any serious incident related to the medical device should be reported to the manufacturer (materiovigilance@euromi-biosciences.com) and to the competent authority responsible for vigilance of the patient's country.



**YOUR PRESCRIBER'S
CONTACT DETAILS**



EUROMI BIOSCIENCES

Zoning Industriel des Plenneses
11 rue des Nouvelles Technologies
4821 Andrimont (BE)

 Tel : +32(0) 87 29 22 22

 Fax : +32(0) 87 29 22 23

 www.euromi-biosciences.com

 info@euromi-biosciences.com

