



# Your body, your decision.

Learn more about breast surgery using  
Eurosilicone™ breast implants.



# GC Aesthetics™

## Providing choices for you.

GC Aesthetics™ is a leading aesthetic medical device company with over three decades of experience manufacturing silicone implants through our Eurosilicone™ brand.

It's our goal to continually develop high quality products and services that meet both surgeons' and women's needs. GC Aesthetics™ not only provide over 1,100 products across our portfolio, but also deliver services to help you, the patient, make informed choices about your body. Over the following pages, you can learn about breast implant surgery, what to expect and the risks to be aware of.

Remember to discuss all options with your surgeon, who will be able to advise you on the choices available to you.

For more information about GC Aesthetics™ and our Eurosilicone™ implant range visit [www.gcaesthetics.com](http://www.gcaesthetics.com)

# Contents.

5. Your body, your decision.
6. What are breast implants?
7. Selecting an implant and type of surgery.
8. GC Aesthetics.™ Our implants.
9. About your surgery.
11. Anticipated benefits of breast implants.
12. Potential risks and complications related to breast implants.
15. Possible risks & complications related to surgery.
17. Possible long-term issues.
18. Warnings and interactions with other devices.
19. The Australian Breast Device Registry.
20. Contact Us.
21. FAQ.



# Your body, your decision.

There are many reasons why women, just like you, choose to have breast implants. Whether it's to get back to the shape you were before having children; to bring balance to uneven breasts; or simply to feel happier with your figure following mastectomy.

Whatever your circumstances, it's important you have as much information as possible to be able to make informed decisions on what's right for you.

That's why we at GC Aesthetics™, have compiled this brochure to offer an overview of breast implants and breast surgery procedures. You can learn all about what happens during surgery, what to expect and what risks you should be aware of.

Remember to discuss all aspects of your procedure with your surgeon during your consultation. It is your opportunity to ask lots of questions and understand fully what results you can expect based on your individual body type.

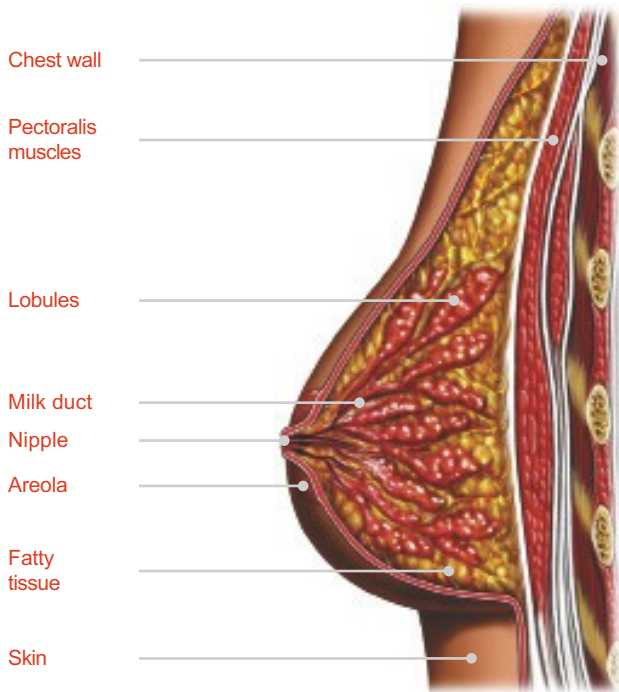
For more information and a comprehensive list of FAQs, please visit [www.gcaesthetics.com](http://www.gcaesthetics.com).

# What are breast implants?

The breast consists of milk ducts and glands surrounded by fatty tissue and covered by skin. The fatty tissue gives the breast its soft feel and shape.

Breast implants can be used for both breast augmentation and reconstruction. They are mainly used on female patients but can also be used for gender reassignment purposes. The implants are designed to alter the size and shape of the breast or correct/improve the result of a previous breast augmentation procedure. Women who have lost breast tissue due to cancer or trauma may also use breast implants to reconstruct the breast.

Silicone gel-filled implants consist of an outer shell constructed from several layers of silicone material. These are filled with medical grade gel silicone, which is clear and cohesive – meaning it's designed to stick together.



# Selecting an implant and type of surgery.

Breast size and shape should be an important focus of discussion with your surgeon. Many women believe they will be too large after surgery and therefore direct their surgeon to choose a smaller size than they really desire. However, you will likely become more comfortable with your new breast shape after surgery.

Some women have wished they had opted for a larger size. Some women desire a larger implant than fits their body proportions. These are all good topics for discussion with your surgeon, who can advise you on your specific concerns and the likely aesthetic improvement attainable.

It may be difficult to visualize your ultimate breast size and shape before surgery. Breast implant manufacturers have improved the shape of implants so it is worthwhile to not only consider size but also the width of your chest and desired projection.

A wider implant may provide more cleavage, but less fullness of the breast. A higher profile implant will provide more projection and fullness but have less width and cleavage.

Once you determine the shape and overall size that you are seeking, talk with your surgeon about which implants will get you as close to your desired shape as possible.

Your body's size and characteristics, along with your desire for a specific shape and size, will usually dictate what is possible. You should be aware that after implant surgery one woman's breasts will be different from another's even though the same implant size and shape were used. Your surgeon will discuss what options are most suitable for you and have the latest tools to show you what you may look like after breast implant surgery.

# GC Aesthetics™

## – our implants.

Backed by years of continuous research and development, Eurosilicone™ offer a range of implants that allows your surgeon to use the most appropriate for you.

Our Round Collection™ breast implants are available in different sizes and profiles to fit with your body characteristics and personal expectations.

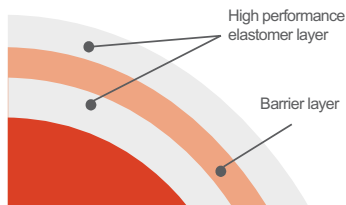
The Round Collection™ breast implants are made with a smooth silicone Shell, which incorporates GC Aesthetics™ barrier layer technology to prevent gel diffusion, promoting strength and longevity.

Your surgeon will explain all options to you in detail. Rely on their knowledge and experience to select the most appropriate breast implant, but do remember that patients who are actively involved in choosing the implant size are more likely to be satisfied with the surgical results.



The Round Collection™

The Round Collection™ PRODUCT CODES	
LOW PROFILE	ES.26 100, 120, 140, 160, 180, 200, 220, 240, 260, 280, 300, 325, 350, 375, 400, 450, 500
MEDIUM PROFILE	ES.261 100, 120, 140, 160, 180, 200, 220, 240, 260, 280, 300, 325, 350, 375, 400, 450, 500, 550, 600, 650, 700, 750, 800
HIGH PROFILE	ES.28 100, 120, 140, 160, 180, 200, 220, 240, 260, 280, 300, 325, 350, 375, 400, 450, 500
EXTRA HIGH PROFILE	ES.281 100, 120, 140, 160, 180, 200, 220, 240, 260, 280, 300, 325, 350, 375, 400, 450, 500, 550, 600, 650, 700, 750, 800





# About your surgery.

## Placement of Implants

Talk to your surgeon about the precise placement of the breast implants in detail. You will want to know what choices you have available to you so that you are ultimately happier with the results. The placement of implants mostly depends on the thickness of your breast tissue.

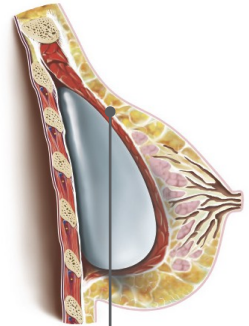
- Implants may be placed either beneath the breast tissue and on top of the pectoralis muscle (subglandular) or beneath the pectoralis major muscle (submuscular).
- There are advantages and disadvantages of each placement. Generally, placement of an implant beneath the muscle gives an extra layer of tissue coverage and may be the choice for patients with minimum breast tissue.

## Subglandular



Mammary gland  
and milk ducts

## Submuscular



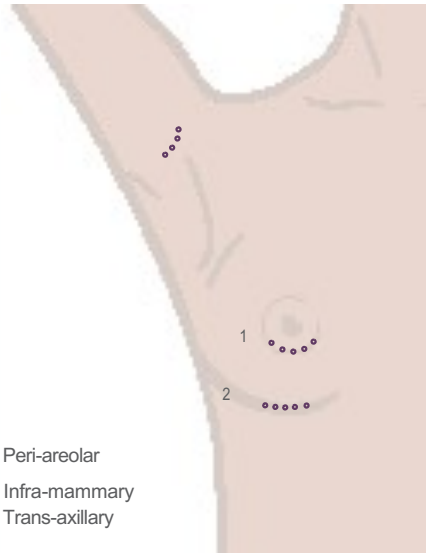
Pectoral  
muscle

## Incision Points

It's important to discuss the exact location of any scars resulting from the operation with your surgeon. During breast augmentation the surgeon will use one of three possible incisions:

- **With a peri-areolar incision**, the scar will be around your areola. This incision is hidden to some extent by the colour change at the edge of the areola.
- **With an infra-mammary incision**, the scar will be located in the inframammary fold below your breast. This incision is hidden by the slight drop of the breast.
- **With a trans-axillary incision**, the implants are inserted through an incision in the armpit.

You should discuss the advantages and disadvantages of the incision site you are considering with your surgeon.



# Anticipated benefits of breast implants.

When opting for either breast augmentation or breast reconstruction surgery, many patients anticipate a number of improvements in their wellbeing. Not surprisingly, these include an improvement in self-esteem and confidence in social settings; improved feelings of sexual attractiveness, both when dressed and undressed; plus a general feeling of physical wellbeing after finally achieving their desired breast shape and size.

However, it should be noted that breast implant surgery, while it has been shown to achieve these aims for the vast majority of patients, cannot be guaranteed to improve quality of life for everyone.

For instance, in the case of physical wellbeing, there have been a few reports of symptoms of unexpected pain or tightness in the breast area, as well as difficulty with mobility and doing some physical activities, such as lifting and running.

Please discuss your expectations of undergoing breast implant surgery with your surgeon, who will give you a professional, realistic view of all the potential benefits and risks associated with breast implant surgery.



# Possible risks and complications related to breast implants.

GCA's gel-filled mammary implants are manufactured in a controlled cleanroom environment in compliance with the applicable regulations and are sterilised prior to shipping to the physician. Every care is taken to remove all manufacturing residues from the implant however there is the possibility of a small level of residual material remaining on or in the implant. These levels have been assessed and have been determined to be at an acceptably low level of risk. However, it is not possible to eliminate all risk associated with the use of medical devices, including breast implants. These 'residual risks' are discussed in this section.

Consult your health professional if concerned about any of the below symptoms/ complications.

## Silicone Bleed and Implant Rupture

Some silicone gel may diffuse or "bleed" through the shell of an intact implant. Implant shell and silicone gel improvements have reduced this bleeding to a minimum. Breast implants may rupture over time and, if confirmed, would need to be removed or replaced. Due to the nature of cohesive gel material (gel material stick together), some ruptures ("silent ruptures") can go undetected unless surgery occurs for another reason (e.g. size change). Rupture may also be related to force or trauma, such as a blow to the chest in a road accident. If an implant ruptures, the silicone gel may be contained within the capsule that has formed around the implant. In these cases removal or replacement of the implant is necessary.

## Capsular Contracture - What is it and what causes it?

As your body heals after the placement of breast implants, it forms a capsule of tissue around the implant. Over time, the capsule may contract or tighten excessively, causing

a change in breast shape and/or discomfort. The appearance of the breast may appear artificially round and/ or feel unnaturally firm to the touch. There are four grades of severity of Capsular Contracture, which your Surgeon can determine using the Baker Grades I-IV scale. Baker Grade III and IV are the most severe and revision surgery may be required along with implant replacement. The severity and appearance associated with each Baker Grade is as follows:

**Grade I** the breast is normally soft and looks normal.

**Grade II** the breast is a little firm but looks normal.

**Grade III** the breast feels firmer than normal and looks somewhat abnormal (change in shape).

**Grade IV** the breast is hard, may be painful and clearly looks abnormal (greater distortion).

Capsular Contracture may occur on one side, both sides or not at all. The degree or severity of tightening may also be different on one side compared to the other. Although both breasts never match exactly, if any of these deformities occur, differences in the two breasts may be more noticeable.

## Visible Skin Wrinkling and Rippling

Underinflated and/or low cohesive gel in certain breast implants may increase the risk of rippling. Additional surgery may be necessary to correct this situation.

## Implant Extrusion

If the skin or breast tissue covering the implant is very thin and/or if there is a problem with wound healing, the implant may break through the skin and become exposed. This will require removal of the implant. Surgery is needed to correct this and can result in permanent scarring or breast tissue loss.

## Change in Nipple and Skin Sensation

Some change in nipple sensation is not unusual immediately following surgery. After several months, most patients have normal sensation. Occasionally, partial or permanent loss of nipple and skin sensation or hypersensitivity may occur in one or both breasts. Changes in sensation may affect sexual response or the ability to breastfeed a baby.

## Malposition

A breast implant may rotate or shift position after initial placement. This may cause discomfort and/or distortion in breast shape, and additional surgery may be necessary to correct this condition.

## Asymmetry

Most women's breasts have at least some asymmetry. Breast implants may improve size differences but may make nipple-areola angle and position more accentuated.

## Breast Tissue Atrophy

Pressure from breast implants may cause the surrounding tissue to thin and shrink. This may also occur normally with aging. Thinning of tissues over the implant may result in it becoming more visible or palpable.

## Breast Implant Associated Anaplastic Large Cell Lymphoma

European safety information, the US FDA and current scientific literature have identified an association between breast implants and the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants rather than smooth implants, and typically develops many years after breast implant surgery. At this time rates of BIA-ALCL are considered to be low.

In most patients, BIA-ALCL is found within the fluid or scar tissue next to the implant. In rare cases, persistent swelling or pain within the breast area can be signs of BIA-ALCL. It is important to obtain medical advice if you suffer from either of these symptoms. Your physician will collect fresh fluid from the breast area for testing and, if positive, the most common treatment is removal of the implant and scar tissue surrounding the implant; however, some patients may require treatment with chemotherapy and/ or radiation therapy. Although treatment is usually successful, some patients have died from BIA-ALCL hence early treatment is essential.

## Palpability

The edges or shell of the implant can sometimes be felt, especially in thin women, after weight loss or after breast reconstruction where there is limited tissue covering the implant.

## Pregnancy

The presence of a breast implant will have no effect on your ability to become pregnant or deliver a baby. Breast implants have not been shown to have an effect on children or future offspring.

## Breastfeeding

Breast implant surgery may affect your ability to breastfeed. Be aware that the surgical approach may influence your ability to breastfeed as scar tissue may interfere with the milk ducts. While this is unlikely, discuss options with your surgeon and be sure to indicate any interest you may have in breastfeeding in the future.

## Breast and Nipple Piercing Procedures

Women with breast implants seeking to undergo body piercing procedures to the breast region must consider the possibility that an infection could develop anytime following this procedure. Treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary.

## Dissatisfaction with Results

Having a full and honest discussion with your surgeon before your surgery about your goals for breast size and shape is really important. Because once the procedure is done, silicone breast implants can't be adjusted. So, for instance, if you're unhappy with the size of the implants you and your surgeon decided on together, this could result in a second operation and additional costs. Besides dissatisfaction with implant size, other complications that may contribute to dissatisfaction include misplaced scar location and hypertrophic scarring - these issues are usually related to surgical technique and are therefore the surgeons' responsibility. It's therefore vitally important to talk about these issues with your surgeon before surgery. You should understand that the female breast will change over time, and your breasts will sag and droop with age and lose some volume over time. Pregnancy and breastfeeding may influence this as well as weight gain or loss. Additionally, you should understand that the breast size that you desire and the implants that you choose today

may not be the same as what you desire at a different stage of your life. So, in the future, you may opt for a change of implant and breast shape to achieve your desired result at that time.

## Calcification

In rare cases, calcium deposits may form following implantation of your prostheses. In extreme cases these deposits may cause breast hardness, discomfort and may require surgical intervention.

## Granuloma

Over time it is possible for silicone to leak from your implant. This is typically the result of an implant rupture. If silicone migrates out of the breast pocket, it can cause a skin condition characterized by the formation of nodules which may require implant removal.

## Phlebitis Superficial

During surgery, damage to a vein wall may occur resulting in inflammation of the vein caused by a blood clot forming under the skin- this is known as phlebitis superficial. This complication is rarely serious and with proper care, usually resolves quickly.

## Ptosis

Time and gravity can have an effect on the natural breast, causing your breasts to sag (ptosis). This may be the reason why you decided to undergo breast augmentation surgery. However, it should be noted that this complication can also occur after placement of your implants. The size, weight and position of the breast implants can have an effect on the degree of sagging. If serious, this complication can lead to re-operation.

## Upper Limb Lymphedema

Women who have previously undergone breast cancer treatment may be at higher risk of developing lymphedema, resulting in swelling of the arm, hand or breast. If you develop this complication it may have an effect on your quality of life due to body image changes, alterations in arm function and the increased risk of developing other complications.

## Breast Deformity After Implant Removal

If breast implants are removed for any reason, the appearance of the breasts may not be desirable or pleasing. Older patients and those with large implants may have more cosmetic deformity if they choose not to replace the implants or to undergo additional surgery. Typical problems include asymmetry and drooping of the breast skin.

## Breast Implant Replacement

If you decide after surgery that your implants are too large or too small, you may decide you want to have the implants replaced with a larger or smaller size. The cost of replacement, including the operating room fee and anaesthesia, will be similar to that of the original surgery.

## Cost Involved with Breast Implant Surgery

Your surgeon should inform you about the cost of implants, surgery, anaesthesia and after care. Be aware of the fact that the cost of treatment of complications might be higher than the initial breast surgery. Ask your surgeon what they would charge for additional surgery. Check with your health insurance company if complication costs are covered before undergoing surgery.

## Post-operative Care

GC Aesthetics™ are not best placed to provide patients with post-operative care details, however, your surgeon will provide specific advice on how to take care of yourself after you have breast implant surgery. These may include recommending that you wear a

supportive bra 24 hours a day, while others may just advise you to change the adhesive bandages when necessary. Your surgeon may also prescribe prophylactic antibiotics. These and other measures are at your surgeon's discretion and are based on their personal experience and overall treatment plan. Not following the surgeon's recommendations may lead to any of the complications mentioned in this brochure.

You should consult your surgeon if you suspect any complications, in particular in the case of trauma or compression caused by, for example, extreme massaging of the breast regions, by some sporting activity or by using seatbelts. Contact sports are not recommended. Tanning at salons or sunbathing can influence scar healing and direct scar exposure to the sun should be avoided for about six months after surgery. It is recommended that you consult a physician or pharmacist before the use of topical medicines (e.g. steroids) in the breast area. If any surgery of the breast area is scheduled, you should inform the physician or the surgeon of the presence of an implant. It is recommended that patients carry the details of the patient record label either attached to the patient consent form or the patient warranty card to facilitate medical care in case of emergency (e.g. in case of a road accident). The presence of breast implants could delay the detection of breast cancer by self-examination. For this reason, please consult a surgeon and/ or doctor for appropriate medical monitoring as well as regular breast cancer screening.

Many surgeons will ask you to return yearly for follow-up visits. These appointments are critical as they give the surgeon a chance to identify changes in your breasts, your implants, or the surrounding tissue. The post-operative care recommendations presented within this section of the patient brochure is not an exhaustive list and your surgeon should provide post-operative care details.

## Self-Examination and auto-palpation

It's recommended that adult women of all ages, perform a breast self-exam at least once a month. A regular breast self-exam will help you to be familiar with how your breasts look and feel so that you can contact a healthcare professional if you notice any changes.

One of the ways you can perform a breast self-exam is in front of a mirror by visually inspecting any changes in contour, any swelling, or dimpling of the skin, or changes in the nipples. You should do this with your arms at your sides and your arms high overhead. Next, rest your palms on your hips and press firmly to flex your chest muscles. Look for any dimpling, puckering, or changes, particularly on one side.

# Possible risks and complications related to surgery.

It is not possible to eliminate all risk associated with the use of medical devices, including breast implants. These 'residual risks' are discussed in this section.

Consult your health professional if concerned about any of the below symptoms/ complications.

## Risks of Anaesthesia

There are three types of anaesthesia used during surgery, all of which carry some level of risk.

### Local Anaesthetic

The lowest level of risk is a local anaesthetic, which involves minimal I.V. sedation with injection of local anaesthetic in the area beneath the breasts. Some patients may have an allergic reaction to the local anaesthetic or experience a rapid heartbeat due to the epinephrine that is used to reduce bleeding. There may be some discomfort intermittently throughout the procedure with a local anaesthetic.

### Sedation

A second method of anaesthesia is I.V. sedation (intravenous medications delivered without a tube in the throat). This carries risks of respiratory distress,

reactions to the medications or medication overdose. It is recommended that a professional trained in the use of I.V. sedation be available to monitor and administer the medications. The cost for this type of anaesthesia is generally higher due to the cost of the medication and personnel to administer them.

### General Anaesthesia

A third method is general anaesthesia in which a patient is asleep during the surgical procedure. The risks of general anaesthesia are the same as those of a general anaesthetic used for other operations and can involve respiratory problems and/or blood clots in the legs. The expense of general anaesthesia is higher because of the anaesthetist needed and the equipment and medications used.

### Infection

Infection may appear shortly after surgery or at any time following the insertion of a breast implant. A low-level infection may be difficult to diagnose. Infection around a breast implant is more difficult to treat than an infection in normal body tissues. If an infection occurs, antibiotics are usually given, and if the infection does not respond to antibiotics, the implant may have to be removed. After the infection is treated, a new breast implant can usually be inserted a few months later.

### Wound Healing Problems or Tissue Necrosis

Some patients experience delayed healing, and for others the incision site may not heal well. It may open from injury or infection. If the implant is exposed, further surgery will be required. Tissue necrosis is the development of dead tissue around the implant. It will delay wound healing, may cause wound infection and may require surgical correction and/ or implant removal. Tissue necrosis has been reported following the use of steroid drugs, chemotherapy, radiation to breast tissue, and smoking, but in some cases, it may occur without any known cause.

### Hematoma

A hematoma is a collection of blood that may occur around a breast implant following surgery. Each woman's experience may be different. In some cases, this is a simple matter that can be handled in the surgeon's office, but more frequently it will require a general anaesthetic and additional surgery to remove the hematoma and stop the bleeding. A hematoma may contribute to Capsular Contracture, infection or other problems. Aspirin, other medications that contain aspirin and anti-inflammatory medications should not be taken for ten days before or after surgery, as their use may increase the risk of bleeding. After a few weeks, the risk of bleeding is low. However, a hematoma can occur at any time following an injury to the breast. Follow your surgeon's advice for post-operative care.

## Seroma

Fluid may accumulate around the implant following surgery, trauma or vigorous exercise. Additional treatment may be necessary to drain the fluid accumulation. A seroma may contribute to infection, Capsular Contracture, or other problems. If one or both breasts seem to increase in size over time or if it seems that there is fluid around the implant, this may indicate a seroma condition and require secondary treatment.

## Scars

All surgery results in scarring - it is nature's way of healing - and the quality of a scar may vary significantly from one person to another. Healing is an individual patient's response to surgery and it is often not within the control of the surgeon. Most scars following breast augmentation are pale thin lines. They may, however, become red, firm and elevated. Scars such as this are called "hypertrophic." They usually fade with time, but may leave more visible, permanent scarring. Another type of scar, which occurs in some surgical patients, is called a keloid. This is an enlarged scar that does not fade or flatten with time. A surgical correction of the scar might be necessary.

## Toxic Shock Syndrome

In extremely rare instances, life-threatening infections including toxic shock syndrome can occur.

## Pain

Pain may develop after breast implant surgery. Some women who did not have pain prior to surgery may have persistent pain after surgery. These pain symptoms are unpredictable and in some patients no cause can be found. Ask your surgeon what pain medication you can take. Your surgeon will be able to confirm the likelihood of the occurrence of the complications related to surgery.



# Possible long-term issues.

## Connective Tissue Disease: Immune System Diseases

A small number of women with breast implants have reported symptoms similar to those of known diseases of the immune system, such as systemic lupus erythematosus, rheumatoid arthritis, scleroderma, and other arthritis-like conditions. The effect of breast implants in individuals with pre-existing immune system and connective-tissue disorders is an area of ongoing clinical research, but there is currently no scientific link associated with these diseases and the presence of breast implants.

## Breast Implant Illness (BII)

More recently, a very small number of women with symptoms which include fatigue, hair loss and brain fog have attributed their symptoms to the presence of their breast implants and have self-diagnosed as having Breast Implant Illness (BII). Several large epidemiological studies of women with and without implants have indicated that there is no scientific evidence that women with silicone gel breast implants have an increased risk of these diseases. These diseases appear no more common in women with implants than in women without implants.

## Product Lifetime

Mammary implants should not be considered as lifetime devices, and you should be aware that they will need to be removed or replaced at some future date. Many surgeons suggest replacement after 10-20 years, but unless there is a problem, this may not be necessary.

The lifespan of your implant can be influenced by several factors. Damage to the implants during or after implantation (as a result of subsequent surgical or medical procedures), can reduce the level of implant safety, performance and lifespan. By informing every treating physician about the presence of your implants, you will ensure that they are not exposed to undue trauma or stress and will remain in place for longer. It is particularly important that towards the end of the expected lifespan of your implant you are aware of changes to your breasts that may indicate your implant needs to be explanted. This includes changes to the size and/ or shape of your breast which may be accompanied by pain and/or swelling. Therefore, it is particularly important towards the end of your implants' lifespan to have regular check-ups with your doctor or surgeon and regular MRI scans if necessary.

GC Aesthetics™ stands behind the quality of our implants and offers a lifetime warranty for rupture and Capsular Contracture.

## Breast Cancer

There is no scientific evidence that silicone gel-filled breast implants increase the risk of breast cancer in women. However, this possibility cannot be completely ruled out. You should continue to consult a physician to carry out routine checks to detect breast cancer.

## Mammography

Women who have breast implants should continue to consult a physician to carry out normal checks in order to detect breast cancer. The implant can interfere with the detection of early breast cancer through mammography by obscuring some underlying breast tissue and/ or by compressing overlying tissue which can 'hide' suspicious lesions in the breast. Please make sure you share all information you know about your breast implants to the personnel so that they can adapt the mammography pressure accordingly. You should request radiologists who are experienced with the most current radiological techniques and equipment for imaging breasts with implants. The presence of a breast implant may make screening mammography more difficult and may lead to additional mammography views.

# Warnings and interactions with other devices.

Breast implants are not lifetime devices, and you are more likely to have complications the longer you have your implants. It is recommended that patients undergo regular (every 2 years) mammograms to monitor the integrity of their implants. This is particularly important the longer the implants have been in place. Eurosilicone's breast implants are manufactured from medical implant grade silicone materials which are compatible with MRI scan.

You should inform any other treating physicians of the presence of your breast implants to minimize the risk of damage to the implants due to interactions with other devices. In particular, your treating physician must be informed about the presence of breast implants in the event of any surgical intervention in the breast area.

It is important to alert other treating physicians to the presence of your breast implants as the use of sharp instruments such as scalpels, needles, forceps and scissors during subsequent surgical procedures is not permitted. Use of excessive force during any subsequent procedure may contribute to the weakening of the

implant shell which may lead to a reduced lifespan of the implant and may require further surgery.

## Biopsy

You should inform your surgeon of the presence of your implants should you require a biopsy, as care must be taken to avoid implant damage.

## Radiation therapy

Radiation therapy may increase the likelihood of certain complications as described on Page 12 and these complications should be discussed with your treating physician.

## X-rays

Both general x-rays and those use in mammograms do not sufficiently penetrate silicone gel-filled implants, therefore, it is important that your treating physician knows you have breast implants before undergoing such procedures as your implants may interfere with the imaging process.

## Dermal fillers

As there is currently no data concerning the concomitant use of these devices with dermal fillers, such use of dermal fillers in the proximity of the device is contraindicated.



### After Surgery

Once breast augmentation surgery has taken place, a follow-up appointment with a surgeon will be scheduled. This is routine and will be to check on your general health after the operation.

Following this, contact with a surgeon should be limited if you continue to feel fit and healthy. However, you should always remember to consult a surgeon, physician or pharmacist before the use of topical medicines (e.g. steroids) in the breast area as well as informing them of the presence of implants should you require any surgery in the future.

## The Australian Breast Device Registry

Recently, the Australian Breast Device Registry (ABDR) was launched to monitor the safety and quality of procedures involving breast devices. The aim of this registry is to capture data on all Australian patients undergoing breast device surgery, that is, surgery with a breast implant or tissue expander. The registry will contribute to the understanding of the long-term safety of implanted breast devices and help improve patient health outcomes.

All individuals having breast device surgery in Australia are eligible for

inclusion in the registry. If your surgeon is already contributing to the ABDR, you will automatically be included in the registry. Your surgeon will discuss the registry with you prior to surgery and provide you with a copy of the ABDR Patient Leaflet. The registry will collect information such as the reason for your surgery, the type of procedure, the type of device and whether you've experienced any complications.

It should be highlighted that you are free to withdraw from the registry at any time.

For more information please see: [www.abdr.org.au](http://www.abdr.org.au)

# Contact us

For any questions you may have in relation to you breast implants please contact our local representative at:

Euro Implants Pty Ltd. / Surgical Supplies Australia Pty Ltd.

9/82 Hutchison Street

Burleigh Heads

Qld. 4220

Tel: 1300-294-649 [sales@surgsa.com.au](mailto:sales@surgsa.com.au)

The product is manufactured by:

EUROSILICONE S.A.S

Z.I de La Peyrolière - B.P. 68

84402 Apt Cédex

France

Tel: +33(0)4900 43030

Customers from Australia and New Zealand should also report serious incidents related to their device to the Therapeutic Goods Authority (TGA): [www.tga.com.au](http://www.tga.com.au)

# Frequently Asked Questions.

## What is breast augmentation?

Breast augmentation is an aesthetic surgical procedure performed to increase the size and alter the shape of breasts using breast implants.

## What is silicone?

It is important to understand the differences between silicon and silicone. Silicon is a common mineral chemical element and the second most abundant element in the earth's crust. Silicone is a man-made polymer containing chains of Silicon-Oxygen-Carbon compounds. The most frequent is Polydimethylsiloxane (PDMS). Depending on their structure, silicones can be liquid, gel or solid.

## Is silicone safe?

All medical devices carry a degree of risk however, since 1992 the Institute of Medicine of the Academy of Sciences has declared the implantation of 'silicone' breast implants to be safe.

## Do GC Aesthetics™ implants contain latex?

GC Aesthetics™ implants are composed of medical grade silicone gel and elastomer. GC Aesthetics™ does not use latex or natural rubber in the manufacturing or primary packaging of its implantable products. However please note we have not performed any testing on our products to confirm that they are latex-free.

## Is breast implant surgery painful?

The pain associated with breast implant surgery depends upon which specific surgery you choose to undertake, whether you choose submuscular or subglandular placement and your individual reaction to the surgery. Generally, post-surgical swelling is to be expected, as well as some pain and

discomfort, which can be managed with pain relief medicine.

## How long will the procedure take?

The procedure is routinely performed under general anesthesia and will last 1 to 2 hours depending on the extent of the breast augmentation surgery. To ensure the highest standard of personalised patient care, you will be required to spend the appropriate time before and after the surgery within the clinic/hospital, allowing time for pre-operative procedures and post-operative care.

## How long will I spend in hospital?

The extent of the surgery will determine the length of stay in the hospital, but you are likely to be discharged the same day as the surgery is performed, depending on your general health and your surgeon's preferences. It is recommended that you arrange for someone to drive you to the clinic/hospital and collect you upon discharge.

## Do breast implants interfere with mammograms?

You should be aware that breast implants may interfere with the detection of cancer and that breast compression during mammography may cause implant rupture. Interference with mammography by breast implants may delay or hinder detection of breast cancer either by hiding suspicious lesions or by making it more difficult to include them in the image (x-ray, ultrasounds). Implants increase the difficulty of both taking and reading mammograms. You should tell the radiological technologist about the presence of implants before mammography is performed.<sup>1</sup>

## What is Breast Implant Illness?

A small proportion of women who have breast implants (for both aesthetic and reconstructive purposes) self-identify as having a number of symptoms they believe arise from the presence of their implants. Whilst not recognised medically, they refer to their symptoms as Breast Implant Illness (BII). Breast Implant Illness is not a medical diagnosis, but rather a term developed by those who have a variety of symptoms they feel are related to their breast implants.

These include tiredness, "brain fog", joint aches, immune-related symptoms, sleep disturbance, depression, hormonal issues, headaches, hair loss, chills, rash, hormonal issues and neurological issues.

## What should I do if I think I might have symptoms I identify with breast implant illness?

If you experience symptoms you feel might be related to your implants such as it is important you see a doctor. It is important to bear in mind that your symptoms might not be related to the implants, and that other medical investigations should not be overlooked or ignored. Therefore, you should involve your GP in the first instance to exclude any other underlying disease processes, such as autoimmune conditions, inflammatory conditions or neurological disease processes.

## What is BIA-ALCL and what signs and symptoms of BIA-ALCL should you be looking for?

BIA-ALCL is a very rare type of blood cancer and there is a small but increased risk of it developing in women who have received textured surface breast implants.<sup>2,3</sup> You should regularly check for redness, itching or any swelling or painful lumps around the implant.<sup>4</sup>

While it remains unlikely that you have developed BIA-ALCL, these symptoms should always be discussed with your surgeon if you have any worries or concerns. It is important that you look after your breast health regardless of having breast implants.

#### **What is the risk of developing BIA-ALCL?**

The risk of developing BIA-ALCL is extremely low and a recent FDA report has highlighted that over 80% of globally reported cases are associated with Allergan textured breast implants. The risk of developing BIA-ALCL with GC Aesthetics textured implants is less than 0.0007% and there are no reported figures for BIA-ALCL with GC Aesthetics' smooth implants (0%)

#### **What should you do if you are concerned about BIA-ALCL?**

It is important to have an annual breast check-up with your doctor.<sup>5</sup> In addition to this, you should regularly check for any redness or itching on the breast, or any swelling or painful lumps around your implant.<sup>4</sup> Should you have any worries or concerns, consult your surgeon immediately. There is no reason for you to have a breast implant removed to prevent BIA-ALCL.<sup>6</sup> The risk of BIA-ALCL is very low and no medical authority is currently recommending that implants should be removed.<sup>7</sup>

#### **What about breastfeeding?**

Women of childbearing age should know that they may not be able to breastfeed after breast augmentation. Some women who undergo breast augmentation can successfully breastfeed and some cannot. It is important to discuss the options of breastfeeding with your surgeon prior to your operation.<sup>8</sup>

#### **What's the difference between round and anatomical (teardrop-shaped) implants?**

Round implants add volume to the upper part of the breast giving a lifted look, while contoured (anatomical) implants give a more

discreet look more in-keeping with the natural shape of the breast.

#### **What is 'profile'?**

This is the 'projection' of the implant - so how far it will stand out. We make a variety of different profiles to fit different women and the looks they want to achieve. High and extra high are the largest, while medium and low are more subtle.

#### **Why are there so many different shapes and sizes?**

Because women are different shapes and sizes, and want to achieve different looks. Whether you're considering a curvy silhouette, would like to create small-but-perfectly-formed breasts, or restore fullness after weight loss; each requires different shapes and sizes. So, we offer physicians an expansive range to choose from to find your perfect fit.

#### **How do I decide the size and shape that's right for me?**

Breast size and shape should be something to talk about with your surgeon. You'll also want to discuss and review the many choices of size and weight available. You'll need to think before your consultation about the shape and overall size that you are seeking, then talk with your surgeon about which implants will get you as close to your desired shape as possible. Your body's size and characteristics, along with your desire for a specific shape and size, will usually dictate what is possible. You should be aware that after implant surgery one woman's breasts will be different to another's even though the same implant size and shape were used - your natural breast tissue, amongst other things, affects the results.

#### **What if they're too big?**

Many women believe they will be too large after surgery and ask their surgeon

to choose a smaller size than they actually want. However, you will likely become more comfortable with your new breast shape after surgery... in fact, many wish they had opted for a larger size after all!

#### **What if I want to go really big?**

It's your body and it's your choice! Some women desire a larger implant than fits their natural body proportions. You'll need to talk about what's practical and possible with your surgeon and trust their judgement - after all, they have performed many procedures, and are true experts in beautiful results.

#### **Will they look fake?**

It depends if you want them to! Each woman's body is different, and before and after photos of women who have had breast implant surgery aren't always representative of what you'll look like. If you want natural-looking results, make it clear to your surgeon from the outset, and they'll advise what's possible.

#### **What if I don't like them?**

If you've carefully researched, checked your surgeon's credentials and taken the time to feel really confident about your decision, it's unlikely you'll be unhappy with the results of your surgery.

#### **How long will my new breasts last?**

Your breast implants will need to be replaced during the course of your life. Implants are not lifetime devices and are subject to wear and tear like any other implant device (e.g. tooth fillings, heart valves, hip joints).<sup>9</sup>

#### **What about the PIP scandal? Are GC Aesthetics™ implants safe?**

PIP implants were made of non-medical grade silicone. Our implants are premium products, and have always been made to the very highest standards. In fact, we have one of the lowest rupture rates<sup>10</sup> on the market, and you're fully protected with our GCA Comfort Guarantee.

# References & Glossary.

## References

1. Brown S.L., J.F. TODD, H.M. LUU. 2004. Breast implant adverse events during mammography: reports to the FDA. J. Womens Health (Larchmt). 13(4):371-8; discussion 379-80 PMID:15195650™
2. Quesada AE, et al. Modern Pathol 2019;32(2):166-88
3. Miranda RN, et al. J Clin Oncol 2014;32(2):114-20
4. Kaartinen I, et al. Eur J Surg Oncol 2017;43(8):1385-92
5. ANSM website. www.ansm.sante.fr/var/ansm\_site/storage/original/application/c459764e5e140856e4e88495f1f84875.pdf (Accessed October 2019)
6. Mercer NSG. Aesthet Surg J Open Forum 2019;1(1):ojz003
7. Dixon JM, et al. BMJ 2018;363:k5054
8. Hurst N.M. 1996. Lactation after augmentation mammoplasty. Obstet. Gynecol. 87:30-4 PMID:8532261™
9. Cohen BE, Biggs TM, Cronin ED, Collins DR Jr. Assessment and longevity of the silicone gel breast implant. Plast. Reconstr. Surg. 1997 May;99(6):1597-601 PMID:9145128®
10. Internal safety and performance data, 2013.

## Glossary

### Areola

The dark skin that surrounds the nipple.

### Axillary

Indicates the location of one of the possible incisions for breast augmentation, namely, under the arm.

### Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

BIA-ALCL is a very rare type of blood cancer and there is a small but increased risk of it developing in women who have received breast implants. <sup>1,2</sup>

### Capsular Contracture

A hardening of the tissue surrounding the breast after breast augmentation.

### Cohesive

The state of uniting or sticking together. As in cohesive silicone of a thick consistency which does not leak in the event of a rupture. Cohesive gel implants are breast implants that have a silicone rubber shell and are filled with cohesive silicone gel material. GC Aesthetics™ offers two types of gel: the more cohesive called "Natural" and a softer gel called "Soft Cohesive".

### Hematoma

A mass of usually clotted blood that forms in a tissue, organ, or body space as a result of a broken blood vessel.

### Inframammary

Also called the "crease" or "fold". Underneath the breast. Indicates the location of one of the possible incisions for breast augmentation, namely, under the breast.

### Mammography

X-ray of the breast.

### Pectoralis Major

The major muscle of the chest or "pecs."

### Peri-areolar

Around the areola, this is the dark area around the nipple on the breast. Indicates the location of one of the possible incisions for breast augmentation, namely, around the lower one-third to one-half of the areola.

### Pocket

A cavity made in the body by dissection and tissue expansion to make way for implant placement.

### Rippling

The appearance of waves or wrinkles in the breast.

### Rupture

The silicone shell of the breast implant may break over time. In most cases, the silicone gel will remain within the shell however, occasionally, the silicone can spread outside of the shell into the breast and migrate to other parts of the body.

### Seroma

A collection of the watery portion of the blood in the tissues due to trauma, surgery, injury or disease. Looks like a swollen area, with no blood, can persist for months and can cause scar tissue.

### Smooth

Type of breast implant, the exterior surface of which is smooth.

### Subglandular

Under the breast tissue or gland. One of the locations for breast implant placement. Also known as above the muscle because placement is above the pectoralis muscle but below the breast tissue.

### Submuscular

Under the muscle. Another location for placement of the implant, i.e. under the pectoralis muscle. Also called subpectoral.

### Textured

Type of breast implant in which the outer surface, or shell, is rough and/or irregular instead of smooth.

# Patient Informed Consent Form.

There are a number of risks associated with breast implants and these will have been discussed with your surgeon to ensure that you are fully informed before consenting to the surgical procedure.

There are certain risks particularly associated with breast implants, including (but not restricted to) capsular contracture and implant rupture, as well as the risks involved in any surgical procedure. It is also important to be aware that some of the risks are longer term, as they may arise some time after the implantation procedure.

The Patient Information Booklet that you were given contains information about the risks and may have formed the basis of your discussion with your surgeon. This document is available in PDF format from our website [www.gcaesthetics.com](http://www.gcaesthetics.com).

**Having considered the risks and discussed these with your surgeon, the purpose of this form is for you to indicate your understanding of the risks and to provide your consent to proceed with the breast implant surgery.**

**You should only provide your consent if you accept ALL of the following statements:**

- I have read the "Patient Information" booklet, discussed it with my surgeon and fully understand all the information contained in the text.
- I accept and fully understand that the risks associated with breast implants and surgery cannot be completely predicted.

- It is my choice to proceed with breast implant surgery as I have concluded that the expected benefits outweigh any potential risks.
- Furthermore, I commit that I have fully informed my surgeon of all details of my past and present medical history including all conditions that could possibly contra-indicate this type of surgery so as not to increase the risks of operative, post-operative or long-term complications.
- My breast implants are not lifetime devices and reoperation will be required at some point.

I intend to have Eurosilicone Implants

(Tick as appropriate)

Name of patient (in capitals)

Date and signature (patient)

Name of surgeon (in capitals)

Date and signature (surgeon)

---





THE BREAST EXPERTS AND  
PARENT COMPANY OF NAGOR™  
AND EUROSILICONE.™

Whether you choose GC Aesthetics™ for your breast implant surgery or not, we hope that this information has given you more understanding and knowledge about the subject.

For more information please visit  
[www.gcaesthetics.com](http://www.gcaesthetics.com)

 /gcaestheticsglobal

 /G\_C\_Aesthetics

Global Consolidated Aesthetics Limited, registered in Ireland with number 450181.  
Registered office: Suite 601, Q House, Furze Road, Sandyford Industrial Estate, Dublin 18, Ireland.  
Nagor™, 129 Deerdykes View, Westfield Industrial Estate, Cumbernauld, Glasgow, G68 9HN, United Kingdom.  
Eurosilicone™ S.A.S., Z.I de la Peyrolière BP. 68, 84402 Apt cedex, France.  
© Copyright 2019 GC Aesthetics.™ A50 - 182 (Nagor); 904502 v01 (Eurosilicone).