



# Important Information

when considering breast implants



A Confident Choice for Life™



# It's your body, it's your choice

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There are many reasons why women, just like you, choose to have breast implants. Whether it is 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, you have choices.

Whatever your circumstances, it is important you have as much information as possible to be able to make informed decisions on what's right for you. **Throughout this brochure, you will find the most relevant complications related to breast implants. For full details and a clinical explanation of these complications it is essential you discuss with your surgeon.**

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



# Possible complications related to breast implants

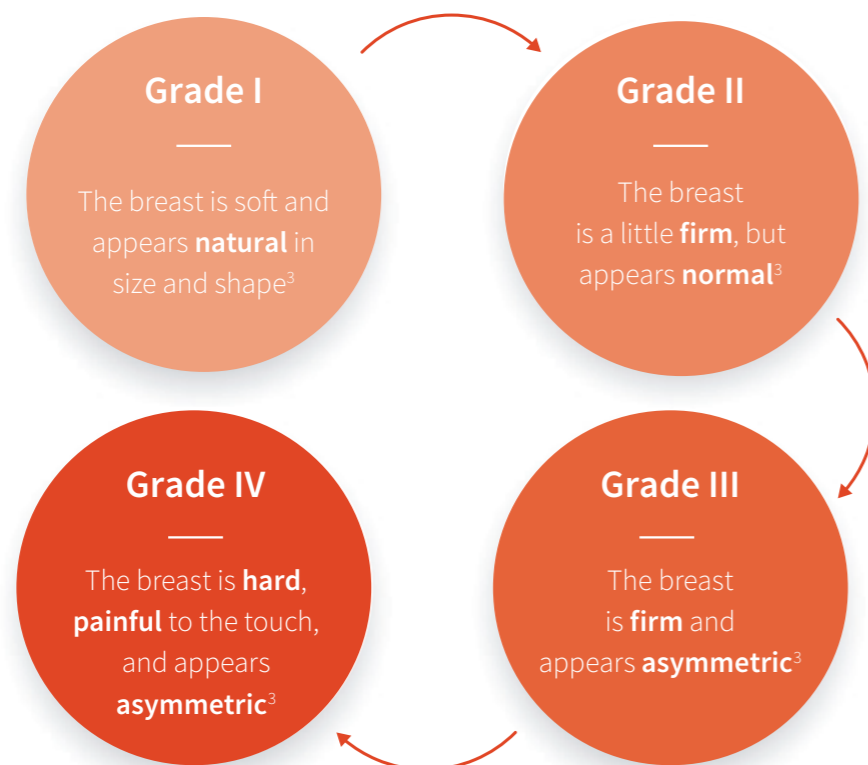


## Capsular Contracture

Once you have your breast implants in place, the healing process begins. During this time, your breast tissue starts to form a collagen-fibre scar around the implant, this is normal and helps keep the implant in place. However, in the case of capsular contracture, the collagen-fibre capsule around the implant shrinks, tightens and

compresses the breast implant. This medical complication can be painful and can distort the aesthetics of the breast implant and the breast itself. The main cause of capsular contracture (mainly in Grade III and Grade IV) is unknown but it is the most common reason for reoperation after breast augmentation<sup>1</sup>.

Degree of incident of capsular contracture is graded using the four-grade Baker Scale<sup>2</sup>. A capsular contracture grade III or IV is considered a complication.



## Reoperation or Reintervention Surgery

There are various reasons why you may require additional surgeries or reoperation some time after your first implant surgery: you may need to replace, correct a problem or resolve a complication. The longer you have a breast implant, the greater the chances of reoperation.

The type of surgical procedure performed during a reoperation depends on the complication involved. You may need to have one or more reoperations over the course of your life due to one complication or a combination of local complications. More than one procedure may be performed in a single reoperation<sup>3</sup>.

### Types of reoperation surgical procedures can include<sup>3</sup>:

- Implant removal, with or without replacement
- Capsule removal or surgical release of the scar tissue around the breast implant
- Scar or wound revision, such as surgical removal of excess scar tissue
- Drainage of a hematoma by inserting a needle or tube through the skin to drain the collection of fluid
- Repositioning of the implant by surgically opening the incision and moving the implant
- Biopsy/cyst removal by inserting a needle through the skin or cutting through the skin to remove a lump

# Possible complications related to breast implants



## Breast Implant Replacement or Removal

Breast implants are not a lifetime device and may need to be removed or replaced<sup>3</sup>. Reasons for removal may include dissatisfaction, an unacceptable cosmetic result, or a complication such as severe capsular contracture. When a breast implant is replaced it is classified as revision surgery. The cost of replacement, including the operating room fee and anaesthesia, may be similar to that of the original surgery.



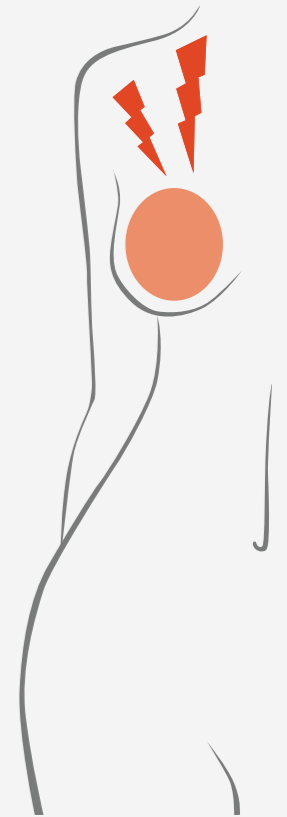
## Implant Rupture

A breast implant rupture is considered as such when, a tear or hole in the outer shell of the implant occurs<sup>4</sup>. The rate of rupture increases over the life of the implant and, if confirmed, would need to be removed or replaced<sup>3</sup>. Due to cohesivity of the gel some ruptures can go undetected (“silent ruptures”) unless surgery occurs for another reason

(e.g. size change or an MRI is performed). Rupture may also be related to force or trauma such as a blow to the chest in a road accident but it is more likely to happen during surgery due to handling or pressure. If an implant ruptures, the silicone gel may be contained within the capsule that has formed around the implant<sup>4</sup>. In these cases removal or replacement of the implant is necessary.

## Main causes of implant rupture<sup>4</sup>:

- The rate of rupture increases over the life of the implant
- Implant damage by surgical instrumentation during implantation
- Too much handling during surgery
- Damage during procedures to the breast, such as biopsies and fluid drainage
- Severe capsular contracture
- History of closed capsulotomy
- Physical stresses such as trauma or intense physical pressure
- Compression during a mammogram



## Breast-implant illness (BII)

More recently, a 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<sup>3</sup>. These symptoms have collectively been called Breast Implant Illness (BII). BII is not currently a recognised medical condition<sup>5</sup>.

Several large epidemiological studies<sup>6</sup> 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<sup>7</sup>. It is also sometimes referred to as autoimmune/inflammatory syndrome induced by adjuvants (ASIA).

# Possible complications related to breast implants



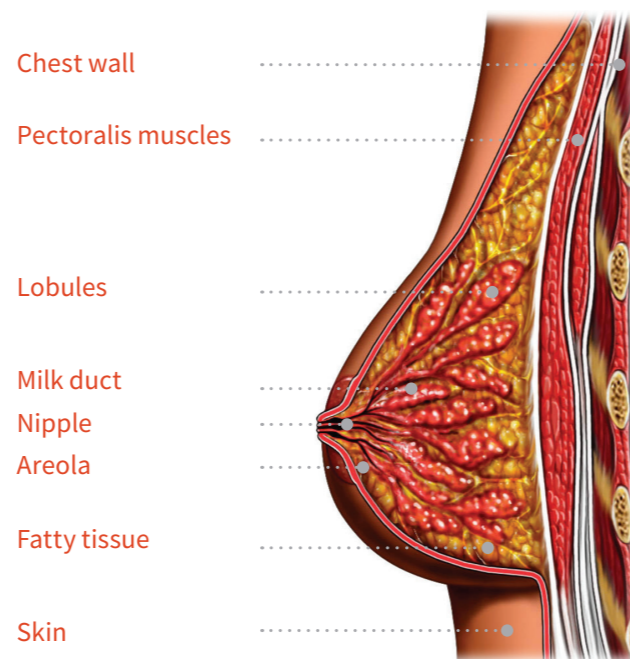
## Breast-Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

### Understanding BIA-ALCL<sup>8</sup>

Breast Implant Associated Anaplastic Large Cell Lymphoma is an uncommon type of lymphoma that has been associated with women who have breast implants. It is not breast cancer.

BIA-ALCL is a rare blood cancer and considered to have low incidence rates. Symptoms may include sudden increase in breast volume. Therefore, part of the diagnosis is the collection of any fluid surrounding the breast implant. If results come back positive, the most common treatment is removal of the implant and scar tissue surrounding the implant.

An individual's risk of developing BIA-ALCL with GC Aesthetics® Breast Implants is very low (0,001%) based on the global rate currently available on the incidence of total cases with textured implants<sup>9</sup>.



Your surgeon will explain the possible risks and treatment options in the unlikely event that BIA-ALCL should occur.

### Additional resources<sup>10</sup>

There are a list of global official regulatory organisations that can provide up to date information and resources about the risk and benefits of breast implant surgery as well as information about BIA-ALCL. These include:

- The U.S. Food and Drug Administration (FDA)<sup>10.1</sup>
- French: National Security Agency of Medicines and Health Products (ANSM)<sup>10.2</sup>
- Australian Therapeutic Goods Administration (TGA)<sup>10.3</sup>
- Medicines & Healthcare products Regulatory Agency (MHRA)<sup>10.4</sup>
- The American Society of Plastic Surgeons (ASPS)<sup>10.5</sup>
- The American Society for Aesthetic Plastic Surgery (ASAPS)<sup>10.6</sup>
- The Plastic Surgery Foundation (PSF)<sup>10.7</sup>
- The International Society of Aesthetic and Plastic Surgery (ISAPS)<sup>10.8</sup>
- The British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS)<sup>10.9</sup>

### Are textured implants safe?

Yes, they are safe. Breast implants carry a reasonable assurance of safety and efficacy in that they perform as they were intended based on the health authorities (SCHEER, UE<sup>8</sup>). For the majority of patients, implants result in high levels of satisfaction. BIA-ALCL is considered to be a rare complication. On the market today there are smooth, smooth opaque, microtextured, macrotextured silicone implants and polyurethane (PU) implants.

Most of the cases of BIA-ALCL have been seen in implants with an intermediate to high surface roughness (macrotextured) but a history of textured breast implants appears to be necessary but not sufficient for the development of BIA-ALCL<sup>8</sup>. Other factors such as genetics can play a role. In the rare event of a BIA-ALCL, advanced surgical removal is recommended as the standard of care treatment, with very good chances of recovery for the patient.



Some specific implants have been shown to be more associated with BIA-ALCL<sup>8</sup>.

Health authorities around the world<sup>3</sup> are advising against the removal of textured implants, especially if there are no complications (please see additional resources above). Women with breast implants, irrelevant of the surface texture type, must undergo yearly check-ups. Those with implants should immediately contact their physicians if they experience symptoms such as excessive fluid retention in the breast, pain, swelling, asymmetry, lumps in the breast or armpit, skin rash or hardening of the breast. **Please discuss with your surgeons which implants are best for you.**

# GC Aesthetics® Breast Implants

## 10 Years of safety and performance<sup>12</sup>

Breast implants have developed significantly over the past several years. Determining which type is best for you depends on the results you desire and your personal preference on feel, costs, and future care.

As a global medical device company with 40 years<sup>11</sup> of cumulative experience, we are focused on aesthetic surgery and patient safety. GC Aesthetics® is fully committed to surgeons and patients to ensure the safety of our products through pre-clinical testing, clinical studies and excellent global post-market surveillance<sup>9</sup>.

We are proud to offer personal and ongoing support in your journey towards the figure you've always wanted and provide a complete service in pre-surgery, surgery and post-surgery. GC Aesthetics® is one of the few companies on the market that can provide robust clinical long-term data proving the low rate of complications over time<sup>12</sup>.

**GCA® is A Confident Choice for Life™, supported by a 10 year large clinical study which demonstrates the short-term and long term safety of products involved in the study<sup>12</sup>.**

### GCA Comfort Plus™ Warranty

We, GC Aesthetics®, are so confident and proud of the proven quality and long-term safety<sup>12</sup> of our products that we go beyond as our warranty covers, without any kind of extension paid programs<sup>11</sup>:

- The lifetime replacement of implants in case of rupture and capsular contracture (Grade III and IV in Baker Scale).
- Reoperation reimbursement in the rare event of BIA-ALCL and free of charge implant replacement.
- No time limitation, it is available for the lifetime of the patient.

To learn more about our warranty, visit:  
[gcaesthetics.com/comfort-plus-warranty](https://gcaesthetics.com/comfort-plus-warranty)



\* Warranty applies to all GC Aesthetics® silicone gel breast implants implanted by an appropriately qualified and licensed Physician in accordance with accepted surgical procedures and techniques, and in strict accordance with the GCA® "Instructions for Use" supplied with the product. Warranty for BIA-ALCL claims is further limited to GC Aesthetics® silicone gel breast implants implanted after January 01, 2009.

For more information about our products or possible complications related to breast implants, please contact your surgeon or [patients@gcaesthetics.com](mailto:patients@gcaesthetics.com)



# GC Aesthetics®

## A Confident Choice for Life™

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For more information about our products please visit: [gcaesthetics.com](https://gcaesthetics.com) or email: [info@gcaesthetics.com](mailto:info@gcaesthetics.com)

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  - 10.3 <https://www.tga.gov.au/>
  - 10.4 <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>
  - 10.5 <https://www.plasticsurgery.org/>
  - 10.6 <https://www.surgery.org/>
  - 10.7 <https://www.thepsf.org/search?q=%7Bkeyword%7D&page=1&site=ps>
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