



**GCA Comfort<sup>Plus</sup>**  
Warranty™

**GC Aesthetics®**

offers a comprehensive lifetime warranty on all GCA (Nagor® and Eurosilicone®) breast implants\*

\*This warranty is dated 01 July 2020 and replaces and supersedes any prior GC Aesthetics®, Nagor® or Eurosilicone® guarantee or warranty terms.

# General Comfort Plus Warranty™ Information

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GC Aesthetics® is a manufacturer and seller of medical implants and associated products and does not substitute the expertise and experience of your registered medical physician. You should discuss any medical concerns about your implants with your registered medical physician.

Your Physician is responsible for explaining and making sure that you are fully informed about all the potential risks and complications associated with any medical procedure and in particular with breast implants.

GCA supplies healthcare professionals with detailed instructions for use in relation to its Nagor® and Eurosilicone® products and provides a patient information booklet. Your medical physician will give you a copy of this booklet. However, these materials cannot replace a full and open discussion between you and your medical physician about the procedure, choice of implants, and the risks and benefits of the procedure.

*\* 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.*

## General Warranty details

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### What products are covered?

GC Aesthetics® Silicone gel-filled breast implants.

### What brands are covered?

All GC Aesthetics® breast implants (Nagor® and Eurosilicone®) brands.

### Are previously implanted products covered?

Yes, for Capsular Contracture and Rupture the warranty is fully retrospective and will cover all currently implanted GC Aesthetics® (Nagor® and Eurosilicone®) gel-filled breast implants. For BIA-ALCL the warranty is applicable only to those GCA products implanted after 1<sup>st</sup> January 2009.

### How long does the warranty last?

For the lifetime of the Patient.

### Who can submit a complaint or claim request?

Healthcare professionals. If you are a patient, we invite you to contact your registered medical physician in order to get the appropriate support.

### How can a complaint be registered?

Complaints can be registered by your Healthcare Professional by contacting us at:

Nagor® products email:

[ukvigilance@gcaesthetics.com](mailto:ukvigilance@gcaesthetics.com)

Eurosilicone® products email:

[return@gcaesthetics.com](mailto:return@gcaesthetics.com)

Your healthcare professional can request the GC Aesthetics® Customer Complaint Form for completion.

### What information is required and why?

It is our priority to give customer confidence. We, as a responsible company, follow all regulatory requirements in countries where we trade. As a minimum, the medical physician will need to provide us with: the brand, model, size, lot number and serial number of the explanted product(s), and the reason for the claim as documented in our 'Customer Complaint Form'. We may request additional information depending on your concern in order to provide the best support.

### How long will it take to confirm whether I am eligible to claim under the GCA warranty?

It is our priority to give customer confidence. We deal with all requests as a matter of urgency, so our average response time is 72 hours from receipt of accurate information provided using the GCA 'Customer Complaint Form'.

## Warranty terms in the event of rupture and/or capsular contracture

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Capsular Contracture complications which may occur in connection with breast implants are a recognised and non-fault complication sometimes associated with breast implant surgery and is one of the most common reasons for further surgery.

Implants may rupture for various reasons (through no defect of the implant). All implants have a life expectancy and will eventually need to be replaced.

### What does this warranty cover?

GCA provides free of charge replacement implants in the event of **rupture** of one or both\* implants. GCA provides free of charge replacement implants in the event of **capsular contracture (Grade III or IV only on the Baker Scale)** of one or both\* implants.

\*Contralateral exchange is applicable if deemed necessary by your Physician.

### Which replacements are available?

Any model, size or style from our GCA brands (Nagor® or Eurosilicone®) of breast implants from the current catalogue.

### Does the warranty cover costs of surgery?

No, in the case of rupture or capsular contracture, the warranty applies to the product only and does not cover any costs of surgery.

### How do I claim on the warranty for rupture or capsular contracture?

Your registered medical physician should contact us at the email address provided and should complete the GCA 'Customer Complaint Form' and supply associated evidence. On receipt of adequate information, the complaint will be processed and we will confirm whether or not the application is successful.

## Warranty in the event of BIA-ALCL

BIA-ALCL (Breast Implant Associated-Anaplastic Large Cell Lymphoma) is an extremely rare type of non-Hodgkin's lymphoma. Prior to surgery, surgeons are responsible for informing and educating their patients on the risks and potential adverse effects of breast implant surgery and should advise patients to be aware of potential BIA-ALCL symptoms, such as persistent swelling or pain in or around the breast area.

There are thought to be many different factors that can lead to the development of BIA-ALCL. It is vitally important that a patient discusses any concerns relating to BIA-ALCL with their surgeon or qualified medical professional. To qualify for this warranty BIA-ALCL must be clinically diagnosed by surgeons or other medically qualified professionals and confirmation of such diagnosis should be provided to GC Aesthetics® and take the

form of appropriate diagnostic histopathology / haematology reports and scans, and any other reports deemed acceptable by GC Aesthetics®.

### Medical referral

If you have any concerns about BIA-ALCL in connection with your GCA implants you should discuss those concerns with your surgeon or qualified medical physician.

### Are there any time limitations on the warranty?

The warranty applies to all GC Aesthetics® (Nagor® or Eurosilicone®) implant products, implanted after **January 01, 2009**, 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, but not where symptoms could be linked to non GCA breast implants.

### What does this BIA-ALCL Comfort Plus Warranty™ cover?

GCA offers the following warranty when a BIA-ALCL is confirmed by a qualified medical physician and GCA demonstrates that the patient is eligible for the **Comfort Plus Warranty™**:

- **Reimbursement of up to USD \$3,000** (or Euro or GBP equivalent) towards (a) the cost of necessary medical scan(s) and (b) the cost of necessary surgery to remove the breast implant(s) and associated scar tissue.
- In the event the patient experiences multiple qualified events, **GCA will only make one payment** up to the defined maximum mentioned above and based on submission of supporting incurred expense receipts.
- **Replacement implants:** GCA will replace breast implants with any model, size, or style, from the significant range of GCA breast implants currently featured in our catalogue.

### How is a claim registered by my healthcare physician?

Your healthcare professional should contact us with the required information by emailing us at:

Nagor® products email:  
[ukvigilance@gcaesthetics.com](mailto:ukvigilance@gcaesthetics.com)  
Eurosilicone® products email:  
[return@gcaesthetics.com](mailto:return@gcaesthetics.com)



[www.gcaesthetics.com](http://www.gcaesthetics.com)

#### **DISCLAIMER**

This warranty applies only where there is evidence of rupture or capsular contracture, or BIA-ALCL has been diagnosed under the current recommended guidelines by an appropriately qualified registered medical physician, and in connection with GCA (Nagor® or Eurosilicone®) breast implants.

This is a limited warranty only and is subject to the terms and conditions set forth in this document. All other warranties, whether express or implied, by operation of law or otherwise, including but not limited to implied warranties of merchantability and fitness for a particular purpose, are excluded. The replacement of qualified GCA (Nagor® or Eurosilicone®) breast implants and payment of defined amounts for necessary revision surgery as set forth in this limited warranty are, to the maximum extent allowed under applicable law, the patient's sole and exclusive remedy.

GC Aesthetics® shall not be liable for any incidental, indirect, consequential or special loss, damage, or expense arising directly or indirectly from the use of any of GCA (Nagor® or Eurosilicone®) products. GCA neither assumes, nor authorises any other person to assume for it, any other or additional liability or responsibility in connection with GCA's (Nagor® or Eurosilicone®) products.