

WHITE PAPER



# The Round Collection™ round micro-textured breast implants by GC Aesthetics®:

characteristics, patients' performance, safety  
and satisfaction; a short overview.

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## Introduction

Ever since silicone breast implants were introduced in the early 60's, their use and popularity has grown tremendously. Numbers of the International Society of Aesthetic Plastic Surgery (ISAPS) global statistics 2020 suggest that approximately 1.6 million breast prostheses were implanted that year and that breast augmentation is still the number one wanted aesthetic surgical procedure<sup>1</sup>. However, this number of breast implantations in 2020 is 9.5% less than the year before, because of COVID-19 pandemic but also till some extent associated with the increased awareness of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) that can potentially develop in the long run around breast implants, especially around some type of macro-textured ones (most cases associated to Biocell surface) although in a very low incidence rate and with a high cure rate<sup>2-4</sup>.

Thus far, a wide variety of breast implants is available for breast augmentation as well as different surgical techniques; implant shape

(anatomical versus round), implant filling (saline versus silicone), implant surface (smooth versus textured, including from smooth, smooth opaque (also called nanotextured or semi-smooth), micro-textured to macro-textured), location (subglandular versus (partially) subpectoral) and incision location (inframammary versus periareolar versus transaxillary). Despite all these differences, most important characteristics of a breast implant, especially nowadays after the awareness of BIA-ALCL, should be:

1. proven patient safety
2. enhanced performance
3. high patient satisfaction.

The Round Collection™ breast implants by GC Aesthetics® fulfil all these criteria, as based upon well documented published studies<sup>5-7</sup>. A list of implant characteristics & benefits can be found in **Table 1**.

**Table 1.**  
**Summary of the implant characteristics & benefits**  
**The Round Collection™ (TRC)**



### **Cristalline™ Surface- Micro-textured**

Average Implant Surface Roughness (Sa) = 21µm (**microtextured**) is designed to:

- Increase tissue adhesion
  - Minimise rotation/bottoming out/flipping
  - Lower capsular contracture rates (when subglandular placement)
- 



### **ParaGel™ Gel**

- Proprietary GC Aesthetics® formulation
  - Made by long term implantable medical grade silicone
  - Highly cohesive gel for controlling gel distribution
  - Versatility:
    - Two different gel-filled options: 85% and 100% gel-filled implants
    - Available in two types of gels: soft and natural to cover surgeons' and patients' needs
- 



### **The Round Collection™ Shell**

- Rupture resistant: shell elongation at breaking exceeds the requirements by ISO standard (ISO:14607.2018)
  - High performance silicone elastomer to enhance shell strength and elasticity
  - Optimum cross-linking in our exclusive formula for the implant integrity
  - Multiple layers & thickness of safety
  - Provides form stability
  - Incorporate an specific barrier layer: ParaGelGard™ 360° to prevent gel-bleeding
- 



### **ParaGelGard™ 360° Barrier Layer**

- Made of high-performance silicone elastomer to:
    - Reduce silicone leakage
    - Enhance shell integrity
- 



### **The Round Collection™ Patch**

- High performance silicone elastomer to enhance patch strength and elasticity
- ParaGelGard™ 360° formulation (barrier) is also present at the product patch

# Benefits of the micro-texturing of The Round Collection™ breast implants by GC Aesthetics®

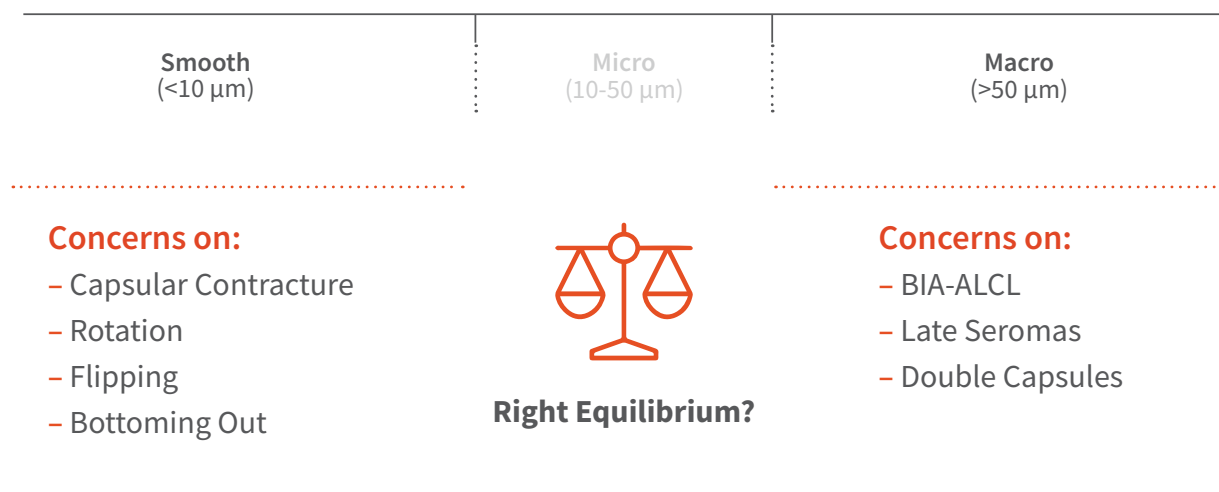
In the literature, smooth breast implants are associated historically with a higher capsular contraction rates (especially in the subglandular plane), more bottoming out and more rotation and flipping over as compared to macro-textured breast implants; however, the latter types of implants have significantly become associated with higher rates of late seroma's, double capsule formation and unfortunately, last but not least with higher rates of BIA-ALCL, which is a potential life threatening disease<sup>2-4</sup>.

The benefit of micro-textured breast implants, which have a texturing status in between smooth and macro-textured breast implants, lies in the fact that they have not the disadvantages the macro-textured implants regarding BIA-ALCL, but still have enough texturing to prevent capsular contraction and rotation as well as flipping over; this nice balance is illustrated in **Figure 1**. Another advantage of the micro-textured round implants might be the significant less shear stress forces in relation to the surrounding tissues, subsequently probably explaining the low rates of implant ruptures after years of implantation.

**Figure 1.**  
The balance of surface roughness & safety of micro-textured breast implants

## Micro-textured: In between smooth and macro-textured

Average Surface roughness of GCA® Round Implants  
ISO 14607:2018 ( $S_a$ )



# Patients' performance, safety and satisfaction reported in literature regarding The Round Collection™ breast implants<sup>5-7</sup>



## Duteille et al. 2014, 2019<sup>5,6</sup>

Duteille et al. was the first to describe the rather long-term safety data employing GCA Aesthetics's (former Eurosilicone) round and anatomical silicone gel breast implants in a prospective study with over 500 patients; overall, Duteille et al. were able to show that round and anatomical silicone

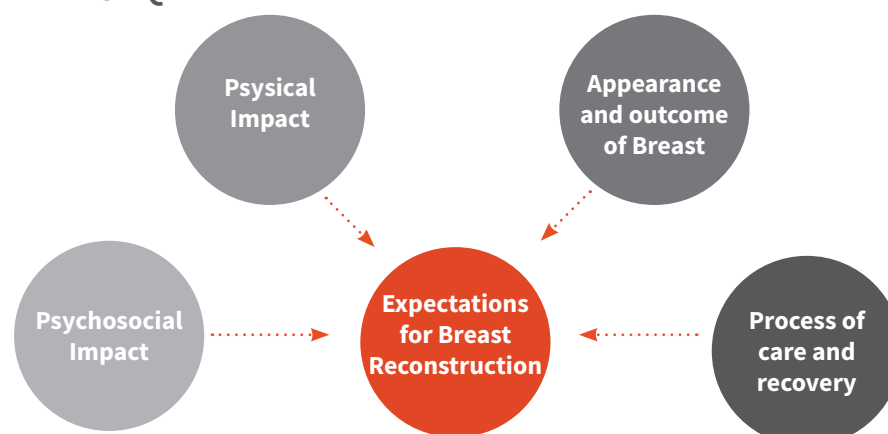
gel breast implants perform excellent and result in high patient satisfaction; their revision rate was only 13.3% at 10 years and the rupture rate was as low as 4.9% at 10 years after primary breast augmentation. No cases of BIA-ALCL or BII were reported in this 10-year follow-up clinical study.

## Kooiman et al. 2022<sup>7</sup>

Kooiman et al. performed a retrospective cohort study on 84 patients who underwent primary breast augmentation with The Round Collection™ implants (round micro-textured Cristalline ParaGel breast implants by GC Aesthetics® (former Eurosilicone), either submuscular (dual plane) or subglandular placed, between 2001 and 2004. All patients were contacted for informed consent, and after approval, the validated BREAST-Q questionnaire was sent and utilized to analyse patient satisfaction. For more information see **Figure 2**. In addition, objective data regarding revisions, including capsular contracture, rupture rate, pain, and/or aesthetic causes needing revision surgery, were analysed.

High BREAST-Q scores (67%-100% for 0-100 scale variables and 66.0%-77.3% of the patients scored "very satisfied" on categorical variables) were found without clinically significant differences between patients with dual-plane-placed implants and subglandular-placed implants. The overall revision rate was 29.8%, also with no significant differences between groups ( $P = 0.317$ ). Overall, it could be concluded that The Round Collection™ breast implants result in high patient satisfaction with relatively low revision rates after 15 to 19 years of follow-up. No cases of BIA-ALCL were reported.

**Figure 2.**  
Domains for BREAST-Q®



# Personal thoughts regarding The Round Collection™ -Surgeon satisfaction



As a plastic surgeon, performing a significant high number of primary breast augmentations every year, my ultimate goal is to achieve a perfect result as demanded by the client. I always stay away from superseding the anatomical borders. Maximum patient satisfaction should be achieved as well as maximum patient safety. In my personal opinion, The Round Collection™ breast implants by GC Aesthetics® fulfil almost all criteria of the ideal breast implants; the implants give a very natural feel, are safe, last long and have a significant long

life-time and last but not least, result in significant high patient satisfaction rates.

The only (theoretical) disadvantage that could be considered is that the implants are not composed of own body tissue (autologous) that would be the best-case scenario in the breast industry, although regarding its proved biocompatibility, feel and safety & performance in daily life, The Round Collection™ implants come very close to it.

## Discussion

The Round Collection™ possesses the ideal characteristics necessary for the ideal breast implant: optimal implant characteristics for safety and security, resulting in a great patient performance, patient safety and very high patient satisfaction rates, as can clearly be deduced from the studies of Duteille et al.<sup>5,6</sup> and Kooiman et al.<sup>7</sup>.

The study of Kooiman et al.<sup>7</sup> analyzing only implants of The Round Collection™ showed a total revision rate of just 29.8% after 15-19 years, evidently significantly higher, but not extreme when considering a follow-up of 15-19 years: this publication is thus far the longest follow-up with a single type of breast implant.

Long-term satisfaction studies after breast augmentation are scarce in literature, with most studies describing a maximum follow-up of approximately 5 years<sup>8,9</sup>. Mundy et al (2017<sup>10</sup>) analyzed patient satisfaction of 1211 women without breast surgery to create normative data. When comparing the data of Mundy et al, with the data of The Round Collection™ of Kooiman et al., significant higher BREAST-Q scores regarding satisfaction with breasts, psychosocial well-being, sexual well-being, and even physical well-being were found<sup>7</sup>.

Literature suggests that subpectoral placement of implants will result in a more natural appearance due to better coverage, less wrinkling and supposedly less capsular contracture<sup>12,13</sup>.

In contrast, patients having glandular ptosis probably benefit more from subglandular placed implants by the possibility of expanding the deflated breast skin envelope without anatomical restrictions of the pectoralis muscle<sup>14</sup>. One of the very few studies analysing and comparing the long-term revision rate of subglandular versus subpectoral placed implants is from Codner et al in 2011<sup>15</sup>. They found an average revision rate of 21% in their study analysing of 812 patients with a follow-up of 6 years, and confirmed that less wrinkling occurred in subpectoral placement, though no difference was found regarding capsular contracture. However, all these breast augmentations were performed by several plastic surgeons and had different incision locations, implant filling, implant trades, shape and surface texture.

Duteille et al (2014 & 2019<sup>5,6</sup>) also described long-term safety data using implants of The Round Collection™ as well as GC Aesthetics® (former Eurosilicone) anatomical breast implants; overall, their revision rate was only 13.3% at 10 years after primary breast augmentation, which is an excellent figure. Other studies, looking at various kinds of implants, suggest a significantly higher revision rate of 19% after already a short-term mean follow-up of 3 years<sup>11</sup>.

# Overall Conclusion

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**The Round Collection™ by GC Aesthetics® fulfil all the criteria of the ideal breast implant: they have proven patient safety<sup>6,7</sup>, enhanced performance<sup>6,7</sup> as well high patient satisfaction on the long-term<sup>7</sup>.**

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