



GC Aesthetics® Breast Implants

# 10 Years

Safety and performance

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Prospective and multicentric long-term proven safety data  
Duteille F, et al. Aesthet Surg J Open Forum. 2019;1(2):ojz012.





# GC Aesthetics®

## A Confident Choice for Life™

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At GCA® we are dedicated to advancing the science of medical aesthetics and delivering **exceptional clinical, operational and commercial performance<sup>1</sup> to be the partner of choice for surgeons and patients across the globe.**

With more than **40 years of experience and 3 million implants fitted<sup>2</sup>** during the last 10 years<sup>5</sup>, GCA® is fully committed with surgeons and patients **in more than 70 countries<sup>3</sup>** with systems in place to ensure the safety of our products through pre-clinical testing, clinical studies and excellent global post-market surveillance<sup>1</sup>.

GCA® is A Confident Choice for Life™ supported by a 10 –year clinical study<sup>5</sup> and **the most comprehensive breast implant portfolio in the industry: different surfaces, gel cohesiveness, fill and projection<sup>4</sup>.**

This brochure summarizes **the evidence to determine the long-term safety and performance of GCA® breast implants.**





GCA® implants approved around the world\*.



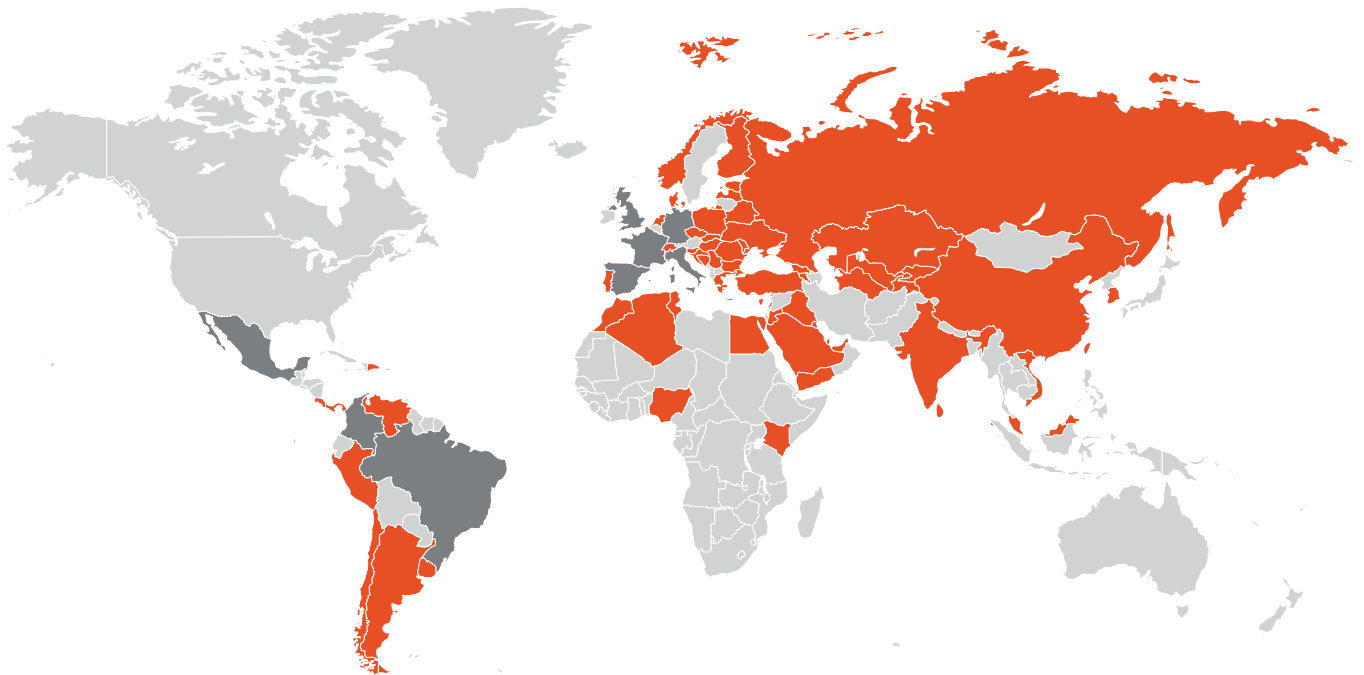
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\*Only some of all regulatory bodies that our product complies with.

# GCA<sup>®</sup> Worldwide presence

GCA<sup>®</sup> breast implants are made with the latest generation NuSil<sup>®</sup> medical grade silicone materials (shell, gel and patch). They are designed, manufactured and sterilized to meet the strictest requirements of the healthcare industry and supported by Master files with the US FDA<sup>1</sup>.

Our products are 100% designed and manufactured in Europe and produced at our ISO13485:2016 certified facilities in France and the United Kingdom. GCA<sup>®1</sup> implants are continually monitored and verified, meaning our products fulfill all standards required for medical devices in Europe and by the health authorities worldwide<sup>1</sup>.



**Headquarters:**  
Dublin, Ireland



**2 State of the Art Manufacturing Sites:**  
Scotland | France



**7 Direct Markets:**  
UK | Spain | France | Germany | Italy | Colombia | Brazil

**+70 Partners**  
from around the globe

- Direct Markets
- Partners



# GCA<sup>®</sup> Breast Implants

At **GC Aesthetics<sup>®</sup>** we are committed and focused on women's breast health. We want to develop best in class solutions serving customers with safety and care.

**GCA<sup>®</sup>** offers breast implants with traditional smooth, smooth opaque, micro-textured and macro-texture surface roughness<sup>1</sup> according to ISO14607:2018.



## ROUND

### Average Surface roughness

ISO 14607:2018 (Sa)



## ANATOMICAL

### Average Surface roughness

ISO 14607:2018 (Sa)

Macro  
(>50 µm)





OPEN



## ORIGINAL ARTICLE

Breast

### Five-year Safety Data for Eurosilicone's Round and Anatomical Silicone Gel Breast Implants

Franck Duteille, MD\*  
Michel Rouif, MD†  
Sophie Laurent‡  
Máirín Cannon, PhD§

**Background:** Multicenter prospective studies assessing the safety and efficacy of silicone gel breast implants are relatively rare. Eurosilicone S.A.S. present their safety and efficacy data herein for the largest European silicone gel breast implant study published to date.



Breast Surgery

### Eight-Year Safety Data for Round and Anatomical Silicone Gel Breast Implants

Franck Duteille, MD; Pierre Perrot, MD;  
Marie-Hélène Bacheley, MSc; and Sharon Stewart, PhD

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**B**reast implants are the leading cause of breast cancer among women. Techniques such as

From the \*Centre Nivolas, France; †Eurosilicone S.A.S., 71 and ‡GC Aesthetics, France. Received for publication February 11, 2019. Copyright © 2019 by the American Society of Plastic Surgeons. All rights reserved. Article distributed under the terms of the Creative Commons Attribution-NonCommercial License.

**Abstract**  
**Background:** Undertaking long-term implant surgery.  
**Objectives:** The Paragel breast implants.  
**Methods:** In this study, 8 years. Descriptive statistics.  
**Results:** Capsules (Baker Grade II/IV) were identified by surgeon examination in all cohorts, was 1.4% for capsular contracture and 0.2% by subject.  
**Conclusions:** This study demonstrates excellent safety and

**Level of Evidence**

Editorial Decision date

Breast implant surgery procedures has been shown to continue to be the most advanced technique which, c

Breast Surgery

### Ten-Year Safety Data for Eurosilicone's Round and Anatomical Silicone Gel Breast Implants

Franck Duteille, MD; Pierre Perrot, MD; Marie-Hélène Bacheley, MSc; Erin Bell, BSc; and Sharon Stewart, PhD

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**Abstract**  
**Background:** Although silicone breast implants have been available for over 60 years, their safety and efficacy continue to be assessed via long-term clinical and vigilance studies. Complications often associated with breast implant surgery include but are not limited to capsular contracture and rupture.  
**Objective:** The authors investigate and evaluate the safety and performance of Eurosilicone's (Eurosilicone SAS, Apt Cedex, France) Crystalline Paragel breast implants at least 10 years postimplantation.  
**Methods:** Nine hundred and ninety-five of Eurosilicone's textured mammary implants were implanted in 526 women undergoing primary (423 patients) and revision surgery (103 patients) at 17 centers throughout France. Complications were recorded at 3 months and annually thereafter for 10 years. Descriptive statistics were used and the Kaplan-Meier method was utilized to analyze key complications.  
**Results:** Seventy-four women (98 implants) experienced capsular contracture across all cohorts. The Kaplan-Meier 10-year cumulative risk of capsular contracture (Baker Grade II/IV) per implant was 11.5% in the primary augmentation cohort and 25.2% in the primary reconstruction cohort. Sixteen implant ruptures were observed by surgeon examination giving a Kaplan-Meier risk of 3.8% per patient and 3.5% per implant. Surgical re-intervention (explantation/exchange) was reported 80 times resulting in a Kaplan-Meier cumulative risk of 13.3% and 31.6% for primary augmentation and primary reconstruction, respectively, per patient. Local complication rates including infection and seroma were low with risk rates of 0.6% and 0.2% by subject.  
**Conclusions:** This multicenter clinical study demonstrates the long-term safety and efficacy profile through 10 years for Eurosilicone round and anatomical silicone gel breast implants.

**Level of Evidence: 3**

Editorial Decision date: April 10, 2019; online publish-ahead-of-print April 27, 2019.



Since the introduction of silicone breast implants in 1962, there have been great advancements in the development and safety of mammary implants.<sup>1</sup> The most advanced silicone technologies have been incorporated into the latest generation of implants utilizing surface texturing. These breast implants are form-stable, filled with a cohesive silicone gel which increases gel stability, minimizing gel bleed. This combined with innovative surgical techniques has contributed to the popularity of breast augmentation amongst women.<sup>2</sup> Breast augmentation with implants is one of the leading aesthetic procedures performed, with an estimated 1.5 million prostheses implanted per annum,

globally.<sup>3</sup> Even with the introduction of alternative breast augmentation techniques such as lipomodelling, breast

Dr Duteille is the Principal Investigator and Dr Perrot is a Clinical Investigator, Centre des Brûlés, Immeuble Jean Monnet, Centre Hospitalier Universitaire, Nantes, France. Ms Bacheley is a Clinical Trial Monitor, Eurosilicone, Apt Cedex, France. Ms Bell is a Clinical Project Associate and Dr Stewart is a Clinical Project Manager, GC Aesthetics (the parent company of Eurosilicone), Glasgow, UK.

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# Key information

## 10-year GCA<sup>®</sup> Safety Data<sup>5</sup>

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### Prospective and multicentric clinical study

#### Round and anatomical breast implants

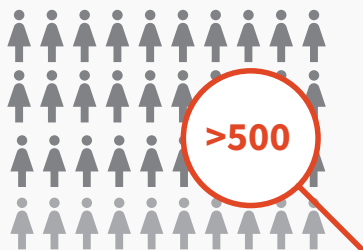


#### A large 10-Year clinical study



Almost **1,000** round and anatomical implants were **monitored** for 10 years in a prospective clinical study.

#### Over 500 women enrolled



423 patients primary  
103 patients revision surgery

#### 17 centers



Multicentric study  
conducted in France

Complications were recorded at 3 months and annually thereafter for 10 years. Well-recognized Kaplan-Meier (KM) method was used to analyse key complications.

# A large 10 year Prospective & Multicentric Clinical Study<sup>5</sup>

~ 1.000 Breast Implants



Methods



Results



Discussion



Conclusions



Rupture

Low

**3.8%**

All cohorts



Re-Intervention

Low

**13.3%**

Primary  
augmentation



Capsular Contracture

(Grade III or IV only on the Baker Scale)

Low

**16.5%**

All cohorts

**31.6%**

Primary  
reconstruction

\* Study conducted with GCA® breast implants: Round Collection™ and The Matrix™.

• GC Aesthetics®: Implant rupture was diagnosed by surgeon examination only (Not MRI cohort).



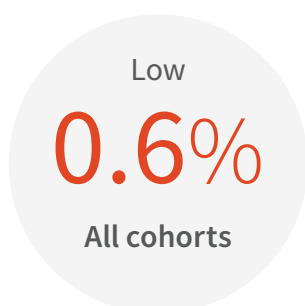
**Silicone gel-filled breast implants have been commercially available for decades and are the most commonly used devices in aesthetic and reconstructive breast surgery.**

Recent challenges in the industry have plastic surgeons and patients expecting devices with long-term data. Over 500 patients were recruited in various clinical studies to prove long term safety and performance of GCA® implants\* in a 10 year prospective & multicentric clinical study cumulative risk<sup>5</sup>.

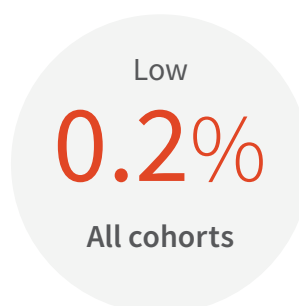


## Complications

### Infection



### Seroma

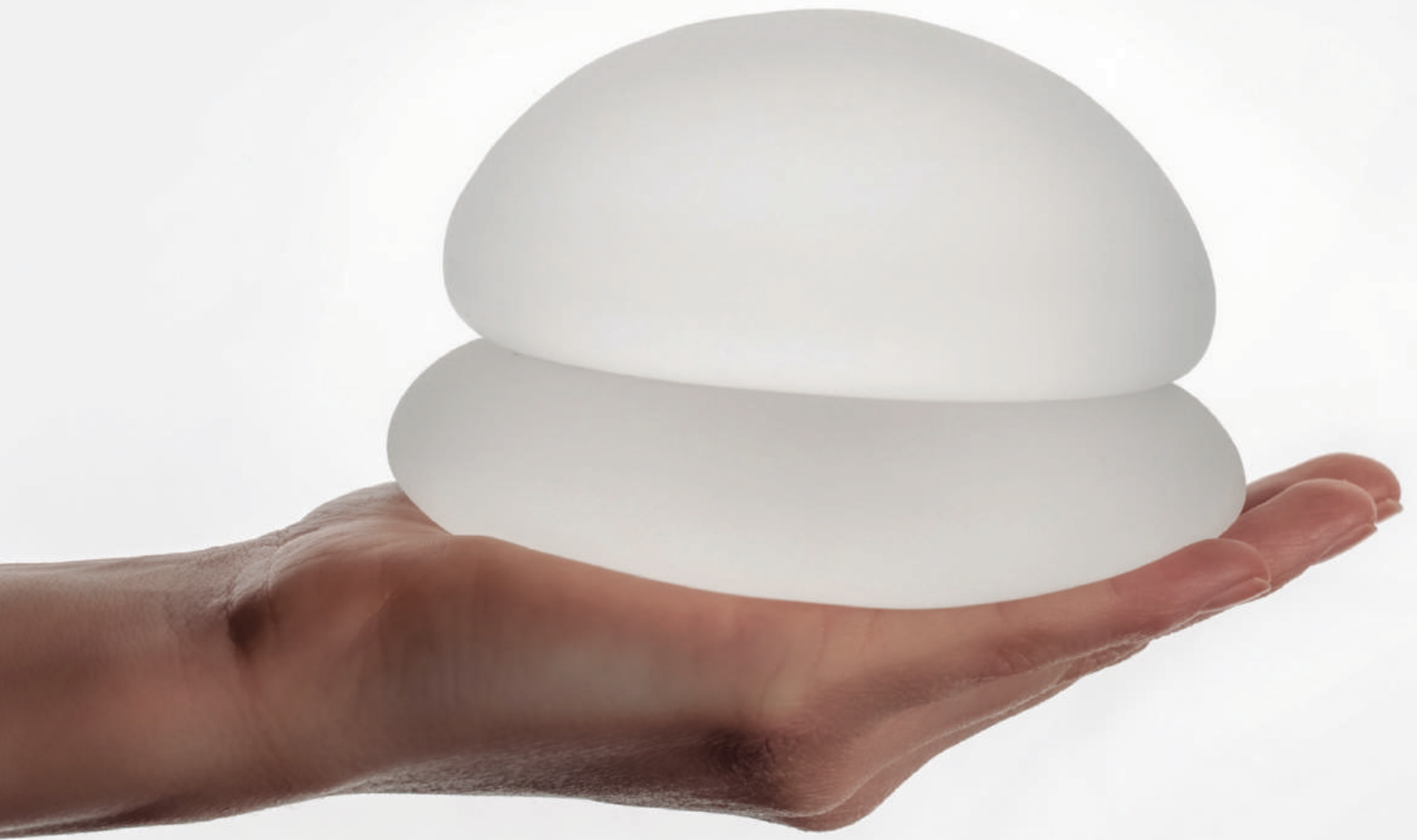


### Autoimmune Disease



### BIA-ALCL






# A Confident Choice for Life™

GCA® 10-year clinical study concludes that there is sufficient evidence to determine the long-term safety and performance<sup>5</sup> of GCA® breast implants\*.

According to **Kaplan-Meier 10-year cumulative risk** estimates for primary augmentation cohort, GCA® implants have **low reported rates of rupture, re-intervention and capsular contracture<sup>5</sup>** (Grade III or IV only on the Baker Scale).

## Results that may empower surgeons & patients to feel confident and secure in their journey

PRIMARY AUGMENTATION COHORT	GCA® <sup>5</sup>	ALLERGAN <sup>6</sup>	SIENTRA <sup>7</sup>	MENTOR <sup>8</sup>	MOTIVA	POLYTECH	SILIMED
	PARAGEL™ (ES)*	NATRELLE™	HSC™, HSC+™	MEMORY GEL™	 NO 10 YEARS LARGE PROSPECTIVE MULTICENTRIC CLINICAL STUDY AVAILABLE		
CC III/IV	13.8	18.9	12.9	12.1			
RUPTURE	4.9	9.3	8.5	24.2			
RE-INTERVENTION	13.3	36.1	24	25.5			

\* Study conducted with GCA® breast implants: Round Collection™ and The Matrix™.

- GC Aesthetics®: Implant rupture was diagnosed by surgeon examination only (Not MRI cohort).
- Not head to head studies. Based on comparison of key complications.
- The third party trademarks used herein are trademarks of respective owners.

# Proven Safety Performance and Clinical Effectiveness

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GCA® has more than 40 years commitment to safety and excellent global post-market surveillance and clinical data<sup>1</sup>. GCA® has collaborated with the medical community to develop new and exciting high quality products to meet both the surgeon and patients need.

## The outcomes of our 10 years data<sup>5</sup> has confirmed\*:

- Re-intervention and rupture rates are low.
- Capsular contracture (Grade III or IV only on the Baker Scale) rates are low and comparable to results obtained by competitors.

GCA® is committed to invest in clinical studies for new products and to continue to be a reliable partner for surgeons and patients.

## GCA Comfort Plus™ Warranty

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All GCA® Breast Implants are covered by the **GCA Comfort Plus™ Warranty**, a comprehensive lifetime warranty<sup>2</sup>. GC Aesthetics® is so confident and proud of the proven quality and long-term safety<sup>5</sup> of our products that we back them with one of the most comprehensive warranty on the market which includes:

- The lifetime replacement of implants in case of rupture and capsular contracture<sup>2</sup> (Grade III or IV only on the Baker Scale).
- Reoperation reimbursement in the rare event of BIA-ALCL and free of charge implant replacement<sup>2</sup>.
- No time limitation, it is available for the lifetime of the patient<sup>2</sup>.



To learn more about the GCA Comfort Plus™ Warranty visit:  
[gcaesthetics.com/comfort-plus-warranty](https://gcaesthetics.com/comfort-plus-warranty)

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\* Study conducted with GCA® breast implants: Round Collection™ and The Matrix™.

# GCA Academy™

We are proud to organize continuous medical education throughout a surgeon career delivering the latest trends and procedures presented at our global GCA Academy™ events.



Find out more about the GCA Academy™ at:  
[gcaacademy.com](http://gcaacademy.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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