

THE SAFETY OF SILICONE BREAST IMPLANTS

Science-Based Facts of Silicone Gel Breast Implants

HOW COMMON ARE BREAST IMPLANTS?

VERY!

~35
MILLION

Women worldwide have received implants between 1980-2016¹

>385,000

U.S. IMPLANT PROCEDURES IN 2017²

↑ 2.2%
INCREASE
FROM 2016

DID YOU KNOW?

All U.S. breast implant manufacturers are **required** by the FDA to complete at least one **10-year clinical study** to show the safety of their implants

...AND

Sientra® has the **LARGEST** pivotal study in the U.S.³



1,788
PATIENTS
ENROLLED

GREAT! WHAT DOES THE SIENTRA 10-YR STUDY LOOK LIKE?

2002

Enrollment began



10-YEAR PATIENT FOLLOW-UP FOR COMPLICATIONS & SATISFACTION

- Step 1** Have First Post-Operative Visit
- Step 2** Visit Surgeon Once a Year (for 10 Years)
- Step 3** Magnetic Resonance Imaging (MRI) is required for patients at Years 3, 4, 6, 8 & 10

37 PLASTIC SURGERY SITES



SMOOTH & TEXTURED SURFACE IMPLANTS

2018

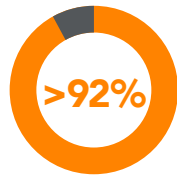
Final Results Published

A LEGACY OF SAFETY

Overall Sientra OPUS® 10-Year Clinical Study Results³

IMPLANT RUPTURE

A hole or tear in the shell of the implant



Rupture Free

13.5%

LOW Capsular Contracture Rate

CAPSULAR CONTRACTURE

A tightening/hardening of the scar tissue around the implant

IMPLANT ROTATION

A cause of asymmetrical appearance

0.1%
Implant Rotation

ZERO
Double Capsules

DOUBLE CAPSULE

The formation of two layers of scar tissue around the implant



PRIMARY AUGMENTATION PATIENT SATISFACTION RATES, POST SURGERY



90% Felt more feminine
91% Felt breasts look natural and soft
79% Felt their clothes fit better

So what we're saying is...we trust in the performance of our implants

To give you the same level of confidence, we offer the **best** warranty in the industry.

LIFETIME FREE implant replacement if your implant ruptures

20 YEAR Up to \$5,000 for uncovered fees and costs due to implant rupture

20 YEAR FREE implant replacement for complications of capsular contracture (Baker Grade III/IV), late forming seroma and double capsule

2 YEAR Up to \$2,000 for uncovered fees and costs due to capsular contracture (Baker Grade III/IV), late forming seroma and double capsule



AND IT'S ALL AT NO COST TO YOU!

For more information about the Sientra Platinum20™ program and Sientra OPUS breast implants visit sientra.com/resources

Important Safety Information: Sientra's OPUS Silicone Gel Breast Implants are indicated for breast augmentation in women at least 22 years old and for breast reconstruction. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of primary breast augmentation surgery. Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the results of a primary breast reconstruction surgery.

Breast implant surgery is contraindicated in women with active infection anywhere in their bodies, with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions and, who are pregnant or nursing.

Key complications include capsular contracture, implant removal, rupture and reoperation. For more detailed information about the risks and benefits of Sientra OPUS breast implants, please visit sientra.com/resources or call Sientra at 888.708.0808. Sientra OPUS breast implants with High-Strength Cohesive silicone gel are only available through board-certified or board-eligible plastic surgeons.

1. Sieber DA, et al. What's your micromort? A patient-oriented analysis of breast-implant associated anaplastic large cell lymphoma (BIA-ALCL). *Aesth Surg J.* 2017;37:1-5. 2. American Society of Plastic Surgeons 2017 Plastic Surgery Statistics Report. 3. Stevens WG, et al. Ten-year core study data for sientra's food and drug administration-approved round and shaped breast implants with cohesive silicone gel. *Plast Reconstr Surg.* 2018;145:7S-19S.