SIENTRA SILICONE
GEL BREAST IMPLANTS

quick facts

about breast augmentation
and reconstruction

see your skills in
sientra®

Sarita, Actual Sientra Patient

The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Sientra, Inc.

WARNING:

- Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery.
- Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.
- Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

see your skills in sientra®

ABOUT THIS BROCHURE

This brochure is intended to provide you with a high-level overview of the facts about breast implant surgery with Sientra's FDA-Approved Silicone Gel Breast Implants. This brochure is **not** intended to replace consultation with your surgeon. For a complete review of the benefits and risks of breast implant surgery, please read the appropriate Patient Educational Brochure, ***Breast Augmentation with Sientra Silicone Gel Breast Implants or Breast Reconstruction with Sientra Silicone Gel Breast Implants***, available from your surgeon and posted on www.sientra.com. You may also contact Sientra directly at (888) 708-0808 for a copy of the brochure. In addition, a Patient Decision Checklist that highlights key information regarding risks of breast implant surgery is provided in Section 14 of each Patient Educational Brochure mentioned above and is also located at Sientra's "Commitment to Safety" webpage (https://sientra.com/commitment-to-safety/). It is recommended that you review this Checklist with your surgeon. The Checklist will help ensure that you have read and understood the information in the detailed Patient Educational brochure and in the Boxed Warning, and that you have been informed of the benefits and risks of breast implants. Your surgeon will also sign this Checklist indicating that s/he has reviewed all the information in the Patient Educational brochure with you and addressed all of your questions. Make sure all your questions have been answered and you understand the information in the brochure, before you sign the *Patient Decision Checklist*.

You should also be aware that there is a **Boxed Warning** for all breast implants. It is critical for you to understand these warnings. In addition to on the cover page of this Quick Facts, the **Boxed Warning** is located in the Warnings section of this brochure. Additional information regarding the risks listed in the **Boxed Warning** and other risks are briefly discussed below and are discussed in detail in Section 4 of both Patient Educational Brochures: *Breast Augmentation with Sientra Silicone Gel Breast Implants and Breast Reconstruction with Sientra Silicone Gel Breast Implants*.

Revision Date: January 3, 2023

INDICATIONS

Sientra's Silicone Gel Breast Implants are indicated for:

- Breast augmentation for women at least 22 years old. Breast augmentation includes primary breast augmentation as well as revision surgery to correct or improve the result of primary breast augmentation surgery.
- Breast reconstruction. 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.

RISKS ASSOCIATED WITH BREAST IMPLANTS

Undergoing any type of surgery involves risks. There are a number of local complications (problems at or near the breast/surgical incision site) that may occur after your breast implant surgery. See Table 1 "Complication Rates reported through 10 years" for prevalence data from Sientra's 10-Year Clinical Study. Please note, this is not an exhaustive list of complications reported to be related to breast implants. Other, rarer complications include cancer, connective tissue disease (CTD), CTD signs and symptoms, lactation complications, reproductive complications, and suicide.

COMPLICATIONS

Table 1 presents the complication rates reported in Sientra's Clinical Study through 10 years.

In Sientra's CORE Clinical Study, a Magnetic Resonance Imaging (MRI) cohort of patients had scheduled MRIs to look for implant rupture. An MRI is a radiographic examination that has the ability to detect rupture of silicone gel-filled breast implants. The MRI cohort underwent MRI scans at 3, 4, 6, 8, and 10 years after implant surgery. The remaining patients did not have scheduled MRIs to look for implant rupture. These patients are called the non-MRI cohort. Since the overall rate includes both the MRI and non-MRI cohorts, it is usually lower than the MRI-specific rate and underestimates the true rate of rupture. Rupture rates are presented for both the MRI and non-MRI cohorts in the Table 1.

Table 1. Complication Rates Reported through 10 Years

Complication		Primary Augmentation N=1,116 patients	Revision-Augmentation N=363 patients	Primary Reconstruction N=225 patients	Revision-Reconstruction N=84 patients
Key Complications					
Reoperation		24.0%	38.8%	48.2%	56.7%
Implant removal with replacement		12.2%	18.7%	28.8%	40.5%
Implant removal without replacement		4.7%	9.4%	11.1%	18.9%
Capsular Contracture (Baker Grade III/IV)		12.9%	13.7%	15.8%	14.3%
Implant Rupture	MRI Cohort	8.5%	6.8%	16.5%	0%
	Non-MRI Cohort	6.3%	3.5%	6.6%	NR
Other Complications Occurring in 1% or more of Patients[1,2]					
Asymmetry		2.0%	2.7%	11.5%	16.9%
Breast mass/cyst/lump		3.5%	3.7%	2.9%	4.6%
Breast pain		1.2%	2.5%	4.5%	3.1%
Delayed wound healing		0.1%	0.6%	1.9%	0%
Hypertrophic/abnormal scarring		1.0%	1.6%	4.1%	2.9%
Implant extrusion		0.1%	0.9%	2.1%	0%
Implant malposition		2.7%	4.8%	5.1%	11.5%
Implant palpability		0.4%	0.6%	1.3%	0%
Implant visibility		0.7%	0.6%	1.0%	0%
Infection		0.9%	1.5%	5.1%	1.2%
Nipple sensation changes		5.9%	4.7%	2.5%	2.3%
Ptosis		4.6%	3.4%	3.4%	0%
Redness		0.6%	0.6%	2.6%	0%
Seroma/fluid accumulation		1.2%	1.6%	3.6%	1.2%
Skin sensation changes		0.4%	1.0%	0.5%	0%
Swelling		0.9%	0.8%	1.5%	0%
Upper pole fullness		0.1%	0.4%	1.2%	0%
Wrinkling/rippling		1.9%	4.8%	2.3%	2.9%

1. The following complications were reported at a risk rate of less than 1% in all patient cohorts: Bruising, Irritation, Necrosis, Nipple Complication (not related to sensation), Skin Rash and Other Complications.
2. There were no reports of the following complications: Capsule Calcification, Lymphadenopathy, Lymphedema, Pneumothorax or Lymphoma, including Breast Implant Associated - Anaplastic Large Cell Lymphoma or BIA-ALCL

NR: Rate not reported because the number of remaining patients/implants at timepoint is < 10.

As seen in Table 1 above, the most common complications in the Study include:

- **REOPERATION**

It is likely that you will need an additional surgery (a reoperation) at some point after your first breast implant surgery, either to correct a problem with or replace your breast implants. Common reasons for subsequent surgeries include capsular contracture and a woman deciding to change the size or style of her breast implant(s). Some changes to your breast(s) after having breast implants are irreversible (cannot be changed or fixed). These may include dimpling, puckering, wrinkling, or the appearance that the breast is empty or deflated upon implant removal.

- **CAPSULAR CONTRACTURE**

After your implant surgery, your body will begin to heal and to adapt to the presence of the breast implants. A regular part of this process is that the natural breast tissue typically forms an internal scar around the implant. However, in some women, the scar tissue around the implant tightens and squeezes the implant. When scar tissue squeezes an implant and creates a firm feeling, it is called capsular contracture

- **IMPLANT REMOVAL (with replacement)**

Your implants may be removed (and replaced with new implants) at some point during your life. You and your doctor may decide to remove and replace an implant or implants because of a complication or to improve the cosmetic result.

- **IMPLANT REMOVAL (without replacement)**

Your implants may be removed (without being replaced) at some point during your life. You and your doctor may decide to remove an implant or implants because of a complication or based on personal choice.

Figures 1 through 4 below present the reasons for implant removal in Sientra's Clinical Study through 10 years.

Figure 1. *Reasons for Implant Removal through 10 Years Primary Augmentation Cohort (n=283 implants)*

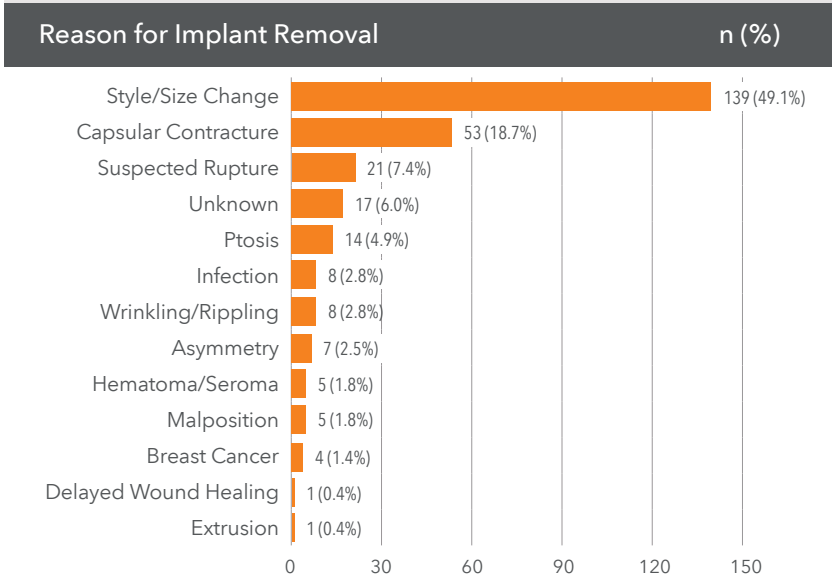


Figure 2. *Reasons for Implant Removal through 10 Years for Revision-Augmentation Cohort (n=144 implants)*

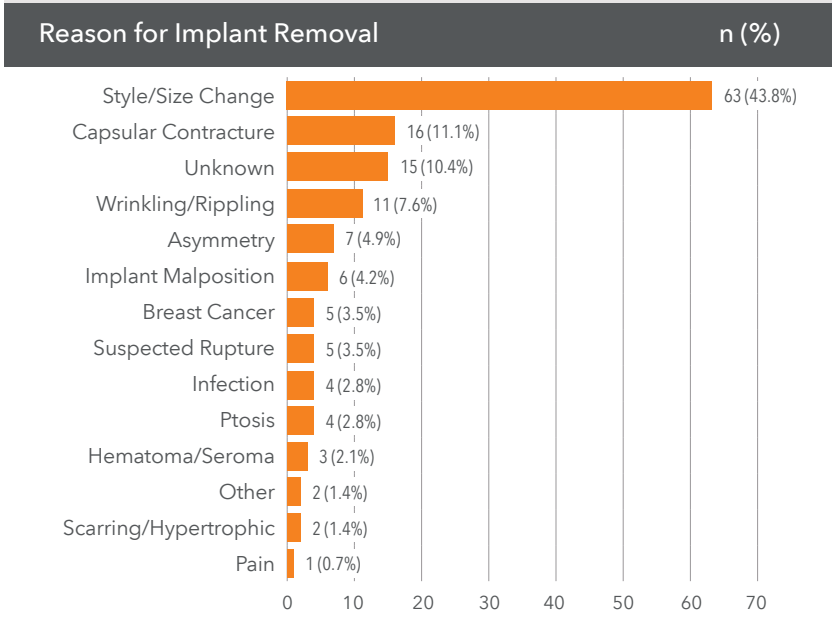
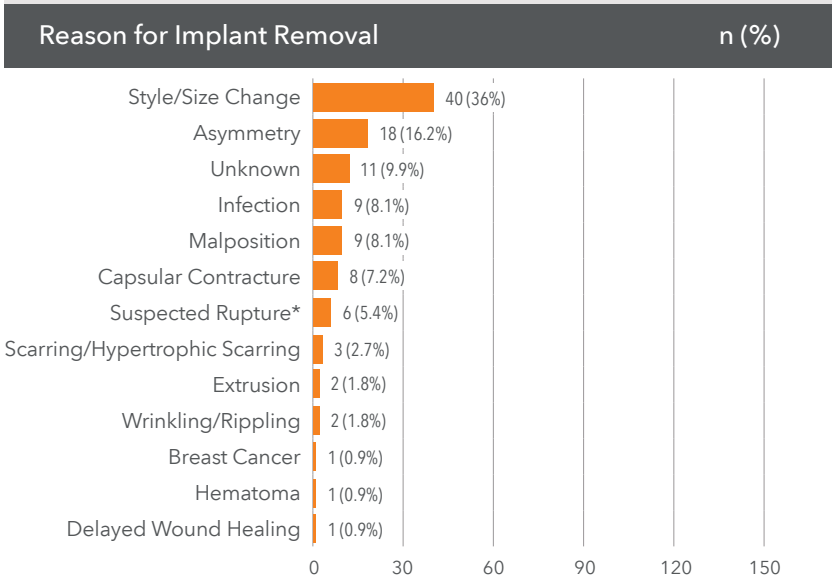
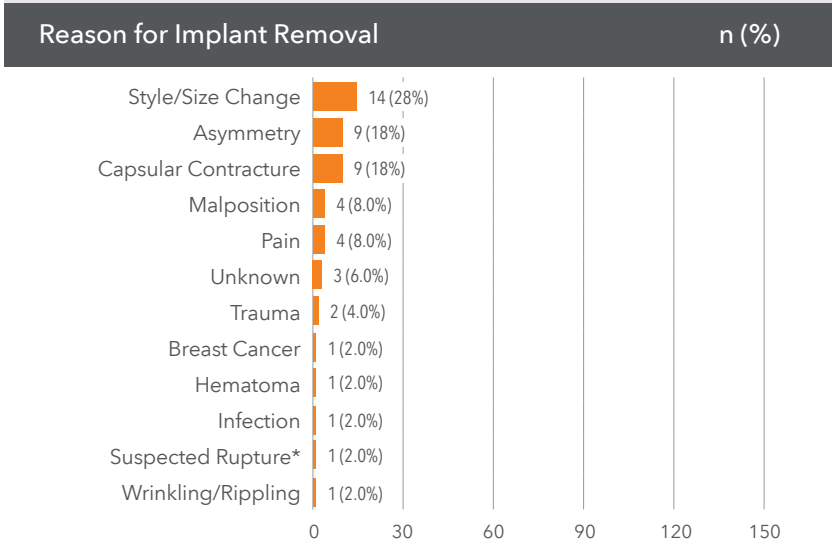


Figure 3. *Reasons for Implant Removal through 10 Years Primary Reconstruction Cohort (n=111 implants)*



*Two of the 6 devices were confirmed not reptured at explantation.

Figure 4. *Reasons for Implant Removal through 10 Years Revision-Reconstruction Cohort (n=50 implants)*



For a more detailed review of potential complications, please refer to Section 4, *Risks Associated With Breast Implants*, of the appropriate Patient Educational Brochure for breast augmentation or reconstruction with Sientra's Silicone Gel Breast Implants.

IMPORTANT FACTORS TO CONSIDER

Before you have surgery, you should have a detailed conversation with all your doctors (primary care doctor, surgeon, and any specialists you see) about breast implant surgery in light of your medical history. In addition, you should also review the applicable Patient Educational Brochure for your situation: *Breast Augmentation with Sientra Silicone Gel Breast Implants or Breast Reconstruction with Sientra Silicone Gel Breast Implants, including the* **Boxed Warning** and Patient Decision Checklist, and discuss with your surgeon prior to deciding to have breast implant surgery.

CONTRAINDICATIONS

Breast implant surgery should **NOT** be performed in:

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

PRECAUTIONS

CAUTION: Notify your doctor if you have any of the following conditions as the risks of breast implant surgery may be higher if you have any of these conditions

- An autoimmune disease, for example, lupus and scleroderma
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease),
- Planned chemotherapy following breast implant placement,
- Planned radiation therapy to the breast following breast implant placement,
- History of radiation therapy to the breast
- Conditions or medications that interfere with wound healing and/or blood clotting,
- Reduced blood supply to breast tissue, or

- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. If you have been diagnosed with or treated for depression, an anxiety disorder, or another mental health condition, you should wait until your condition has resolved or stabilized before having breast implant surgery. Discuss any history of mental health disorders with your doctor(s) prior to surgery.

WARNINGS

WARNING – Below is a list of warnings associated with breast implant surgery including a Boxed Warning for all breast implants. It is critical for you to understand these warnings. For a more detailed review of warnings, please refer to Section 3.4, *Warnings,* of the appropriate *Patient Educational Brochure*.

WARNING:

- **Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery.**
- **Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.**
- **Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.**

- Smoking can make it harder for your body to heal. Do not smoke before your breast implant surgery or while you are recovering.
- Breast implants are not expected to last for the rest of your life, and breast implantation may not be a one-time surgery.

- Many of the changes to your breast that may occur as a result of breast implant surgery will be permanent and cannot be undone.
- Breast implants may interfere with your ability to produce milk (lactate) for breast-feeding.
- Mammography for detecting breast cancer (or cancer recurrence) may be more difficult with breast implants in place. Be sure to notify the technologist that you have breast implants prior to the procedure
- It is recommended that you have periodic imaging (e.g., MRI, ultrasound) of your silicone gel- filled breast implants to screen for implant rupture regardless of whether your implants are for cosmetic augmentation or reconstruction.
- Your implants could rupture without you noticing any change in your breasts (called a "silent" rupture). Because silent ruptures can occur and because they are difficult to detect, even if you have no symptoms, you should have your first ultrasound or MRI at 5-6 years after your initial breast implant surgery and then every 2-3 years thereafter for as long as you have your breast implants
- These recommendations do not replace other additional imaging that may be required depending on your medical history or circumstances (i.e., screening mammography for breast cancer).
- Routine self-examination of your breasts may be more difficult with implants. However, you should still perform an examination of your breasts every month for cancer screening.
- After undergoing breast implant surgery, you may experience changes in your healthcare insurance. Be sure to check with your insurance company about potential issues and understand the complete extent of your health coverage before having breast implant surgery.

For a complete review of the risks and benefits please read the appropriate Sientra patient educational brochure for breast augmentation or reconstruction, ***Breast Augmentation with Sientra Silicone Gel Breast Implants*** or ***Breast Reconstruction with Sientra Silicone Gel Breast Implants*.**

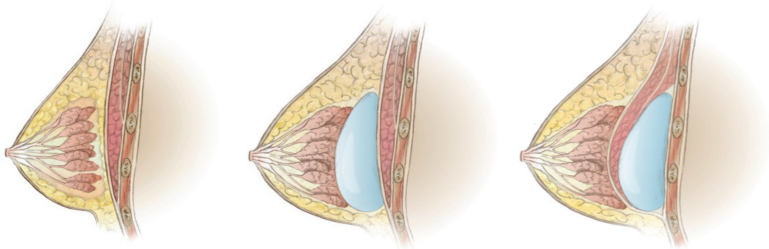
BREAST IMPLANT SURGERY – UNDERSTANDING THE PROCEDURE

Before your breast implant surgery, you and your plastic surgeon will discuss the implant placement and surgical incision options, as well as your expected postoperative care.

AUGMENTATION IMPLANT PLACEMENT

Augmentation patients will have options for the placement of their implant. Your surgeon will discuss the two options with you and suggest where the breast implant is to be placed. Additionally, your surgeon will discuss the pros and cons of each option with you. Your two options are subglandular, where the implant is placed on top of your chest muscle, or submuscular, where the implant is placed underneath part or all of the chest muscle. See Figure 1 for Augmentation implant placement options.

Figure 1. Implant placement



Breast before augmentation

Breast after subglandular placement

Breast after submuscular placement

RECONSTRUCTION SURGICAL OPTIONS

Reconstruction patients will have different options. Your alternatives may include:

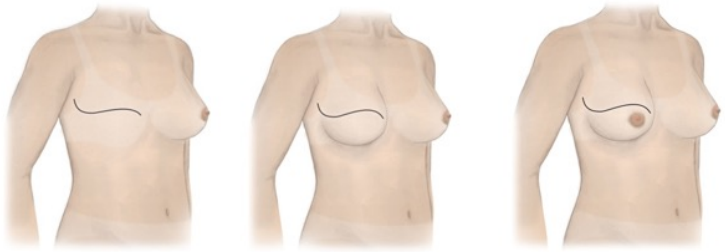
- Deciding not to reconstruct your breast(s) with implants,
- Wearing a padded bra or external prosthesis,
- Having a breast reconstruction surgery using your own tissue (a "flap procedure"), Figures 3 through 5, below or
- Having breast reconstruction with silicone or saline-filled implants.

Patients undergoing reconstruction surgery may want to rebuild the breast. Breast reconstruction with silicone gel breast implant(s) is one option that may be available to you following a mastectomy or to correct a breast abnormality. A breast revision-reconstruction surgery may be appropriate if you have had a breast reconstruction with implants but need to complete, improve upon, or correct a part of that first surgery (called the primary reconstruction).

Breast reconstruction is usually done in stages. It often takes more than one surgery. A primary (first) reconstruction after mastectomy is often started during the same surgery as your mastectomy, but you may need follow-up surgeries to finish and make the reconstructed breast match the other breast. The stages may include:

- Putting in a soft tissue expander, an implanted silicone shell that can be filled with more and more saline solution to slowly stretch your skin enough to allow it to cover an implant, see Figure 2,
- Taking out the tissue expander and putting in a breast implant (silicone gel-filled or saline-filled),
- Surgery to adjust the shape and or size of the opposite breast so it matches the reconstructed breast, and
- Nipple reconstruction (if you have a mastectomy, the nipple is usually removed; usually a new nipple is created later, as an outpatient procedure after the initial reconstruction surgery is finished; a nipple may be created using skin taken from the opposite breast or another part of your body).

Figure 2. Breast Reconstruction Using a Tissue Expander and Breast Implant

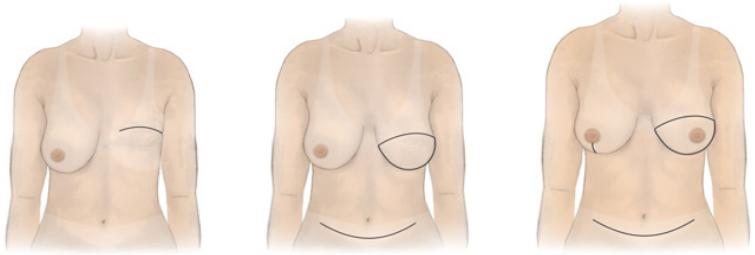


Post-Mastectomy

Stage 1: Tissue Expander Placed and Expansion Under Way

Stage 2: Breast Implant and Nipple/Areola Reconstruction

Figure 3. Breast Reconstruction using a TRAM Flap

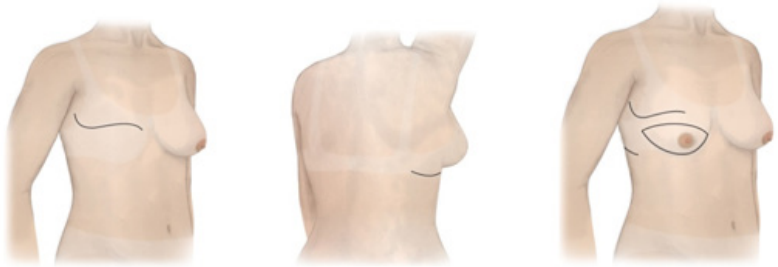


Post-Mastectomy

TRAM Flap

Final Result with Nipple/ Areola Reconstruction (Includes mastopexy to the other breast to improve symmetry)

Figure 4. Breast Reconstruction using a Latissimus Dorsi Flap

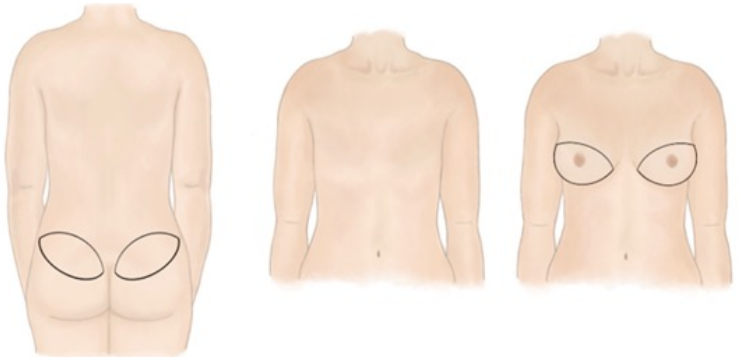


Post-Mastectomy

View showing back scar

Latissimus Dorsi Flap and Nipple/Areola Reconstruction

Figure 5. Breast Reconstruction using SGAP Flap



SGAP Flap Harvesst Location

Front View Pre-Operation

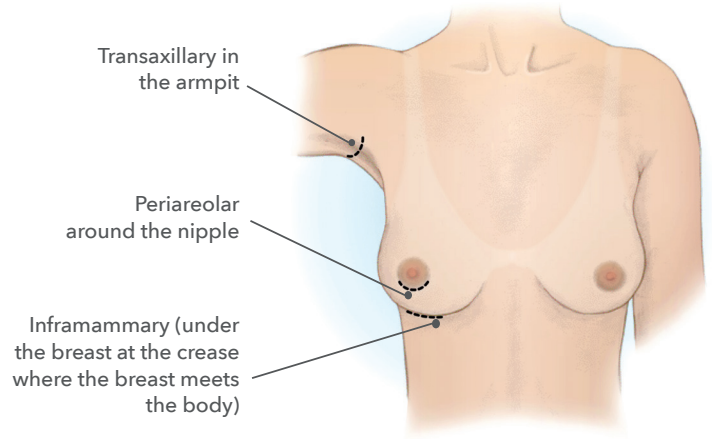
Final Result With SGAP Flap and Nipple/Areola Reconstruction

INCISION SITES

Augmentation patients have three (3) common incision sites to consider. Your surgeon will suggest the best incision site option for your particular surgery and the pros and cons of each incision option with you.

There are three common incision sites to consider:

Figure 6. Augmentation Incision Sites



Reconstruction patients often have multiple surgeries. Your surgeon will explain surgical options and incisions based on the medical plan put forward by your surgeon.

ABOUT SILICONE-FILLED BREAST IMPLANTS

A silicone gel-filled breast implant is a sac (implant shell) made of silicone elastomer (rubber), which is filled with clear silicone gel. Sientra uses implant grade silicone elastomer and implant grade high-strength silicone gel to manufacture its Implants. Sientra's Implants are available in a variety of shapes and sizes, with either a smooth or textured surface. You and your surgeon can choose the Sientra round or shaped implant option that best suits your individual needs. More information about the materials in Sientra's breast implants are presented in Table 2:

Table 2. Sientra Breast Implant Materials

Component	Raw Material
Shell, Inner/Outer Layers	High Strength Silicone Elastomer
Shell, Barrier Layer	Fluorosilicone Elastomer
Spherical Cap	Liquid Silicone Rubber
Patch Sheeting	High Strength Silicone Elastomer
	Fluorosilicone Elastomer
	High Consistency Rubber
Silicone Gel Filler	High Strength Silicone Gel
Titanium Dioxide Pigmented Silicone Ink	Liquid Silicone Rubber
Position Indicator	High Consistency Rubber Titanium Dioxide

The potential toxicity of the chemicals and metals listed in the following tables have been evaluated with both toxicity testing and risk assessments to assess the exposure levels in comparison to the amount determined to likely be safe. However, individual responses to chemicals may vary, and all reactions cannot be predicted. Below are some definitions to help you understand the chemical information:

Volatiles: Chemicals that are released by breast implants as a gas.

Extractables: Chemicals that are released by breast implants following soaking in water and/or organic solvent (liquid).

Table 3. Chemicals Released by Sientra Breast Implants

Cyclic Siloxane	Shell (µg/g)	Gel (µg/g)
D3 Siloxane	0.87	ND
D4 Siloxane	0.60	73
D5 Siloxane	3.92	510
D6 Siloxane	25.39	2119
D7 Siloxane	20.64	2153
D8 Siloxane	14.01	1560
D9 Siloxane	8.29	952
D10 Siloxane	6.11	964
D11 Siloxane	5.05	1107
D12 Siloxane	5.76	1111
D13 Siloxane	6.94	1276
D14 Siloxane	9.0	1808
D15 Siloxane	10.93	2180
D16 Siloxane	14.08	2539
D17 Siloxane	18.0	2563
D18 Siloxane	14.84	2471
D19 Siloxane	15.75	2402
D20 Siloxane	21.79	1447
D21 Siloxane	15.24	ND
Total Extractables (µg/g)	219.45	27,234

ND=Not detected

Information about the heavy metals found in Sientra's breast implants are presented in Table 4:

Table 4. Heavy Metals Found in Sientra Breast Implants

Metal	Shell Concentration (ppm)	Gel Concentration (ppm)
Antimony	ND	ND
Arsenic	ND	ND
Barium	0.27	ND
Beryllium	ND	ND
Bromine	ND	19
Cadmium	ND	ND
Cesium	0.11	ND
Chromium	ND	0.27-0.28
Cobalt	ND	ND
Copper	ND	ND
Germanium	ND	0.07
Lead	ND	ND
Magnesium	ND	2.8-3.2
Manganese	ND	0.04
Mercury	ND	ND
Molybdenum	ND	ND
Nickel	ND	0.07-0.08
Phosphorus	4.0	4.7-5.8
Platinum	1.6-1.7	1.1-8.6
Potassium	ND	22
Selenium	ND	ND
Silver	ND	ND
Tin	0.39-0.95	0.15-0.19
Vanadium	ND	ND
Zinc	ND	0.33-037
Zirconium	0.46	ND

ND=Not detected

POSTOPERATIVE CARE

In the weeks after your breast implant surgery, the skin over your breasts may feel tight as it adjusts to your new breast size. After your stitches are removed, your doctor may tell you to massage your incision site(s) with a cream or lotion to keep the skin from drying out; this may make you more comfortable as well. Use the product(s) he or she recommends.

Your doctor may have special directions about avoiding exercise or activities that compress or put pressure on your breasts during the first weeks after surgery. Follow your doctor's directions. You will be given a Device Identification Card that includes the style and serial number of your breast implant(s) and other information. This card is for your permanent record and should be kept in a safe place. In the event you have a concern or problem with your implant, you can use this card to describe the implant to your health care provider or to Sientra.

BREAST IMPLANTS ARE NOT LIFETIME DEVICES

Breast implants are not expected to last for the rest of your life, and breast implantation may not be a one-time surgery. It is likely that you will need other surgery related to your breast implants over the course of your life. Patients may require a reoperation for a number of reasons, including size and/or style change, implant removal (with or without replacement), capsular contracture procedures, incision and drainage, implant repositioning, scar revision, or to address some of the complications mentioned in Table 1 on page 5.

ADDITIONAL INFORMATION

For additional information or if you have questions regarding the Sientra Silicone Gel Breast Implants, please visit Sientra's website at www.sientra.com or call Sientra at (888) 708-0808.

Additional information about silicone gel breast implants can be obtained from the United States Food and Drug Administration (FDA) at www.fda.gov/breastimplants.

sientra®

Sientra
3333 Michelson Drive, Suite 650
Irvine, CA 92612
Toll Free: 888.708.0808
sientra.com

IMPORTANT SAFETY INFORMATION

Sientra's 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 breast implants, please visit sientra.com/resources or call Sientra at 888.708.0808. Sientra breast implants with high-strength cohesive silicone gel are only available through board-certified or board-eligible plastic surgeons.

MDC-0012 R5