Attachment C

Revised Quick Facts about Breast Augmentation and Reconstruction with Sientra Silicone Gel Breast Implants Brochure

QUICK FACTS ABOUT BREAST AUGMENTATION AND RECONSTRUCTION WITH SIENTRA SILICONE GEL BREAST IMPLANTS

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.

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.

COMPLICATIONS

Table 1 below presents the complication rates reported in Sientra's Clinical Study through 3 years.

Table 1
Complication Rates Reported through 3 Years

Complication		Primary Augmentation N=1,115 patients	Revision-Augmentation N=362 patients	Primary Reconstruction N=229 patients	Revision-Reconstruction N=82 patients
Key Complications					
Reoperation		12.6%	20.3%	34.9%	42.5%
Implant removal with replacement		6.0%	8.7%	19.1%	23.2%
Implant removal without replacement		1.2%	2.9%	7.0%	10.3%
Capsular Contracture (Baker Grade III/IV)		6.0%	5.2%	8.8%	6.8%
Implant Rupture	MRI Cohort	2.5%	0%	2.8%	0%
	Non-MRI Cohort	0%	0.4%	0%	0%
Other Complications Occurring in 1% or more of Patients[1,2]					
Asymmetry		1.1%	1.8%	8.7%	7.1%
Breast mass/cyst/lump		0.3%	0%	1.0%	3.1%
Breast pain		0.8%	0.9%	2.6%	1.4%
Delayed wound healing		0.2%	0.6%	1.9%	0%
Hypertrophic/abnormal scarring		0.6%	0.7%	2.7%	3.1%
Implant extrusion		0.1%	0.6%	1.5%	0%
Implant malposition		1.2%	3.2%	3.0%	5.5%
Implant visibility		0.2%	0.6%	1.0%	0%
Infection		0.7%	1.2%	5.1%	1.2%
Nipple sensation changes		3.2%	1.4%	2.0%	0%
Other complications		0.6%	0.7%	1.1%	0%
Ptosis		1.8%	0.7%	2.0%	0%
Redness		0.3%	0.7%	3.0%	0%
Seroma/fluid accumulation		0.6%	1.2%	2.4%	1.3%
Swelling		0.5%	0.7%	2.0%	0%
Wrinkling/rippling		0.5%	2.4%	1.1%	1.5%

[1] The following complications were reported at a risk rate of less than 1% in all patient cohorts: bruising, hematoma, implant palpability, irritation, necrosis, skin rash, skin sensation changes and upper pole fullness.

[2] The following complications were reported at a risk rate of 0% in all patient cohorts: capsule calcification, lymphadenopathy, lymphedema, nipple complications (not related to sensation) and pneumothorax.

IMPLANT REMOVAL

Breast implants may be removed (with or without replacement) in response to a complication or to improve the cosmetic result. In Sientra's Clinical Study, through 3 years, the most common reason for implant removal in all four study cohorts was patient request for an implant size or style change (ranging from 40% to 56% of all implant removals).

Figures 3 through 6 below present the reasons for implant removal in Sientra's Clinical Study through 3 years.

Figure 3. Reasons for Implant Removal through 3 Years
Primary Augmentation Cohort (n=103 implants)

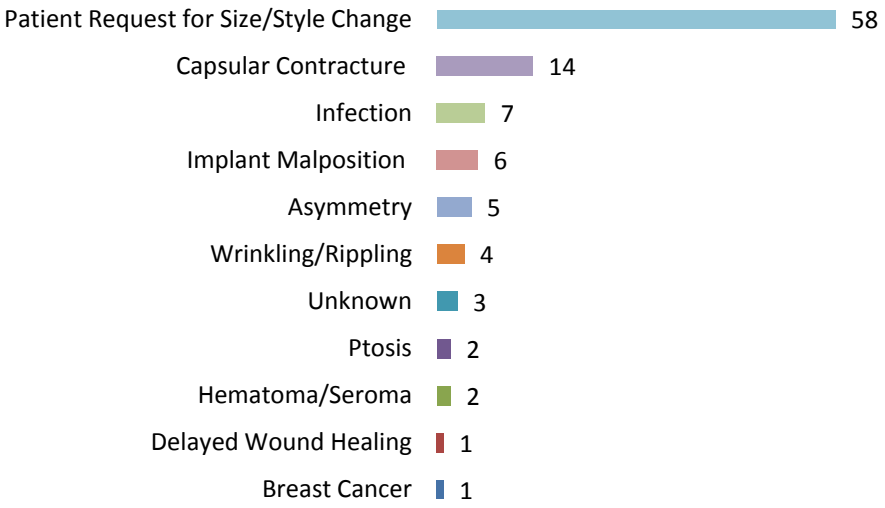


Figure 4. Reasons for Implant Removal through 3 Years
Revision-Augmentation Cohort (n=68 implants)

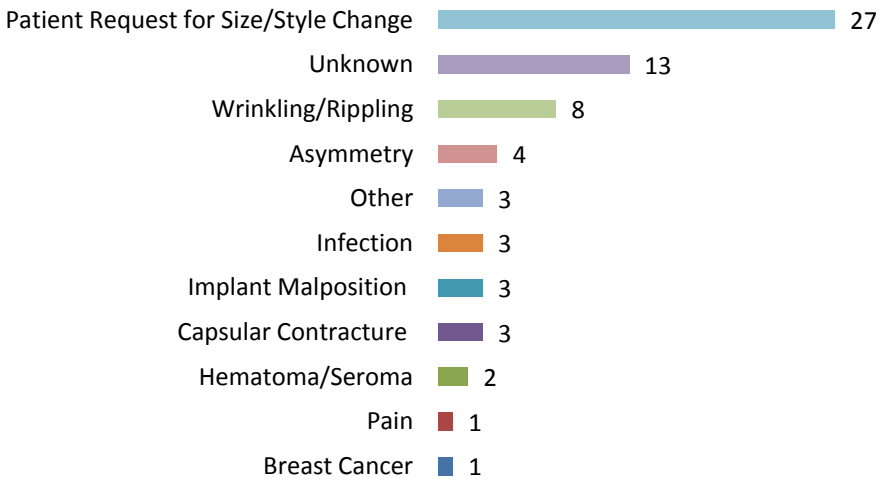


Figure 5. Reasons for Implant Removal through 3 Years
Primary Reconstruction Cohort (n=76 implants)

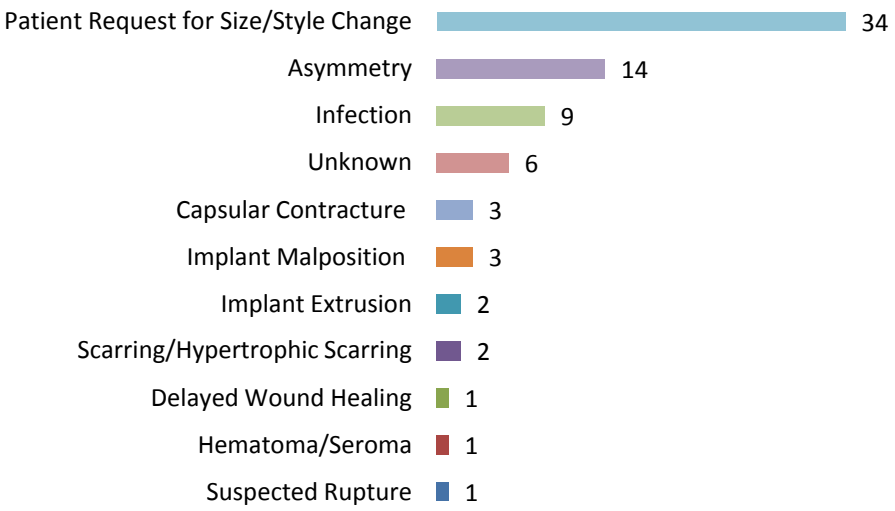
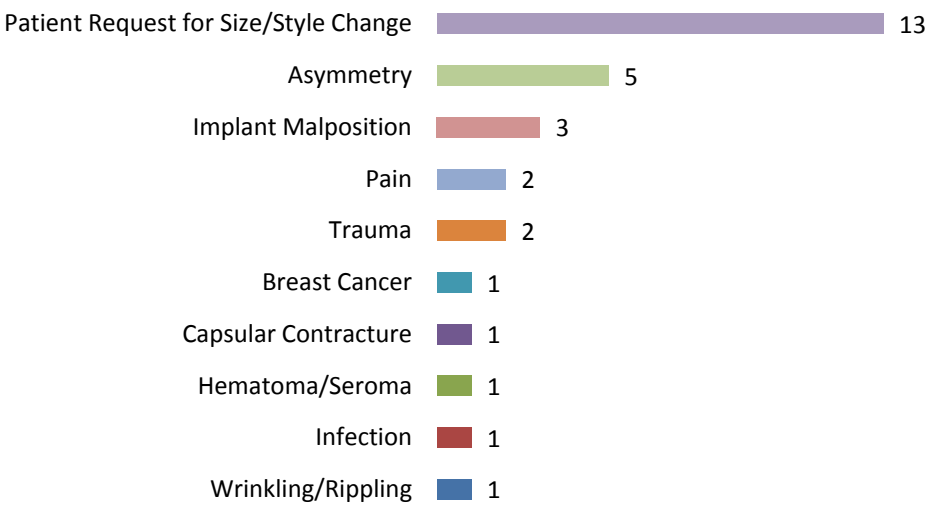


Figure 6. Reasons for Implant Removal through 3 Years
Revision-Reconstruction Cohort (n=30 implants)



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 of your doctors (primary care doctor, surgeon, and any specialists you see) about breast implant surgery in light of your medical history.

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,
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease),
- Conditions that interfere with wound healing and/or blood clotting,
- Reduced blood supply to breast tissue,
- Chemotherapy or radiation to the breast following implantation, 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. For a more detailed review of warnings, please refer to Section 3.4, *Warnings,* of the appropriate *Patient Educational Brochure*.

- 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.
- 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, you should have an MRI 3 years after your breast implant surgery and then every 2 years after that.
- 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*.**

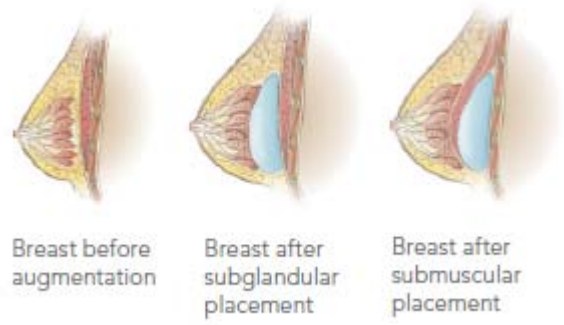
BREAST IMPLANT SURGERY – UNDERSTANDING THE PROCEDURE

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.

IMPLANT PLACEMENT

Your surgeon will consult with you and suggest where the breast implant is to be placed. Implants are placed beneath your breast tissue, either on top of the chest muscle (subglandular placement) or underneath part or all of the chest muscle (submuscular placement).

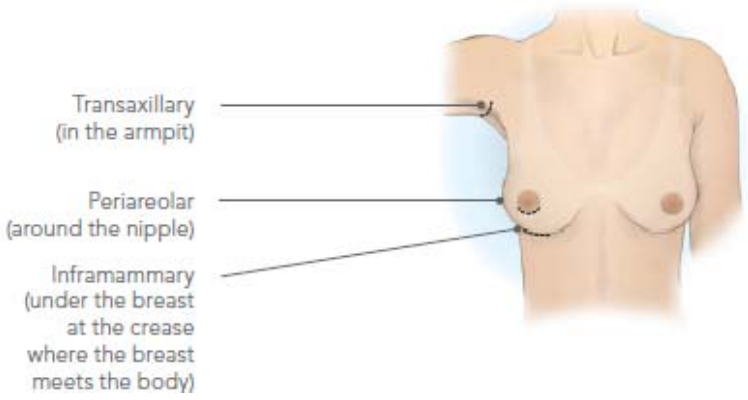
Figure 1: Implant Placement



INCISION SITES

Your surgeon will suggest the best incision site option for your particular surgery. There are three common incision sites to consider:

Figure 2: Incision Sites



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.

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 above.

ADDITIONAL INFORMATION

For additional information or if you have questions regarding the Sientra Silicone Gel Breast Implants, please visit Sientra's website at http://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 http://www.fda.gov/breastimplants.