



Breast
Augmentation
With **Sientra**
Silicone Gel
Breast Implants

PATIENT EDUCATIONAL BROCHURE

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Glossary

Abdomen	The part of the body between the upper chest (breasts) and the pelvis (hips); often called the stomach.
Anaplastic Large Cell Lymphoma (ALCL)	ALCL is not breast cancer; it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system).
Areola	The pigmented or darker colored area of skin surrounding the nipple.
Asymmetry	Uneven appearance between a woman's left and right breasts in terms of their size, shape, or breast level.
Atrophy	Thinning or diminishing of tissue or muscle.
Autoimmune Disease	An autoimmune disease is a disease in which the body's immune system attacks its own cells or tissues by mistake, causing damage and dysfunction. Autoimmune diseases can affect connective tissue in the body (the tissue that binds together body tissues and organs). Autoimmune diseases can affect many parts of the body, like nerves, muscles, glands and the digestive system.
Biocompatible	The ability to exist along with living tissues or systems without causing harm.
Biopsy	The removal and examination of tissue, cells, or fluid from a living body.
Body Dysmorphic Disorder (BDD)	A psychological condition characterized by excessive worry about an imagined or minor physical flaw to the point that it can interfere with normal daily activities.
Body Esteem Scale	A series of questions asking about a person's feelings about his or her body.

Breast Augmentation	<p>A surgical procedure to increase breast size and to treat such conditions as sagging or drooping of the breast (ptosis) or breasts of different size, shape, or placement (asymmetry).</p> <p>The first time a breast implant is placed to increase breast size or treat such conditions as ptosis or asymmetry, it is referred to as “primary augmentation.” Any time there is another surgery to replace the implant, it is referred to as “revision-augmentation.”</p>
Breast Implant	<p>Any surgically implanted artificial device intended to replace missing breast tissue or to enhance a breast.</p>
Breast Mass	<p>A lump in the breast.</p>
Breast Reconstruction	<p>A surgical procedure to replace breast tissue or reconstruct a breast after tissue was taken out because of cancer or injury. Breast reconstruction also includes the surgical correction of a breast that has failed to develop properly due to a severe abnormality or congenital defect.</p> <p>The first time a breast implant is placed to replace breast tissue is referred to as “primary reconstruction.” Any time there is another surgery to replace the implant, it is referred to as “revision-reconstruction.”</p>
Calcification/ Calcium Deposits	<p>The process of a soft tissue hardening when the mineral calcium builds up in a certain place.</p>
Capsular Contracture	<p>Tightening of the scar tissue (also called a capsule) that normally forms around the breast implant during the healing process after surgery. In some women, the scar tissue (capsule) squeezes the implant. When this occurs, it is called capsular contracture. This results in firmness or hardening of the breast. Capsular contracture is classified by a scale named Baker Grade.</p>

Capsule	Scar tissue that forms around the breast implant.
Capsulotomy (Closed)	An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but may rupture the implant and is contraindicated (meaning that the procedure is improper and should not be performed).
Capsulotomy (Open)	A surgery to create an incision or opening in the capsule (scar tissue).
Chest Wall	The system of structures outside the lungs that move as a part of breathing, including bones (the rib cage) and muscles (diaphragm and abdomen).
Congenital Anomaly	An abnormal body part that existed at birth. Also called a congenital malformation or congenital deformity.
Connective Tissue Disease/Disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system. Connective tissue diseases (“CTDs”) that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.
Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
CORE Clinical Study	The major clinical study that supports the approval of a medical product (such as breast implants). For Sientra’s breast implants, the CORE study includes augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients. Information on the safety and effectiveness of the implants are collected every year for 10 years after study participants get their implants.
Delayed Wound Healing	Unusually slow progress in the healing of a wound; surgical incision site fails to heal normally or takes longer to heal.

Displacement	Movement of the implant from the usual or proper place.
Extrusion	Skin breakdown with the implant pressing through the skin or surgical incision.
Fibrocystic Breast Disease	Common, benign (noncancerous) changes in the tissues of the breast. The term "disease" is misleading, and many doctors prefer the term "change." The condition is so commonly found in breasts, it is believed to be a variation of normal. Other related terms include "mammary dysplasia," "benign breast disease," and "diffuse cystic mastopathy."
Fibromyalgia	A chronic condition characterized by widespread pain in muscles and joints. It may include fatigue, difficulty sleeping, and morning stiffness.
Fibrous Tissues	Connective tissue composed mostly of fibers (for example, tendons).
Gel Bleed/Gel Diffusion	When silicone gel leaks or "bleeds" or "diffuses" through the implant shell.
Granuloma	Noncancerous lumps that can form around foreign material, such as silicone. Like any lump, it should be evaluated to distinguish it from a lump that might be cancerous.
Groin	The fold where the lower abdomen meets the inner part of the thigh.
Hematoma	A collection of blood inside the body, for example in skin tissue or other body space.
Hypertrophic Scarring	An enlarged scar that remains after a wound heals.
Infection	The growth in the human body of microorganisms such as bacteria, viruses or fungi. An infection can occur as a result of any surgery.
Inflammation/Irritation	The response of the body to infection or injury resulting in swelling, redness, warmth and/or pain.

Inframammary Fold	The crease under the breast where the breast and chest meet.
Inframammary Incision	An incision made in the fold below the breast.
Lactation	The production and secretion of milk by the breast glands.
Local Complications	Complications that occur in the breast or chest area.
Lymph Nodes	Lymph nodes are glands that play an important part in the body's defense against infection. They produce lymph, which travels throughout the body in the lymph system, and filters impurities from the body. Common areas where the lymph nodes can be felt with the fingers include: groin, armpit, neck, under the jaw and chin, behind the ears, and on the back of the head.
Lymphadenopathy	Enlarged lymph node(s).
Malposition	When the implant is placed incorrectly during the initial surgery or when the implant has moved/shifted from its original position. Shifting can be caused by many factors, such as gravity, trauma, poor initial placement, and capsular contracture.
Mammary	Pertaining to the breast.
Mammography	A type of x-ray examination of the breasts used for detection of cancer.
Mammoplasty	Plastic surgery of the breast.
Mastopexy	Surgical procedure to raise and reshape sagging breasts.
Migration/Gel Migration	Movement of silicone material outside the breast implant to other areas of the body.
MRI (Magnetic Resonance Imaging)	MRI uses a magnetic field to create a 3-dimensional picture of a body part or organ. MRI is the imaging method that currently has the best ability to detect rupture of silicone gel breast implants.

Necrosis	Death of cells or tissues.
Palpability/Visibility	Palpability is when the implant can be felt through the skin. Visibility is when the implant can be seen through the skin.
Pectoralis	Major muscle of the chest.
Periareolar	The areola is the pigmented or darker colored area of skin surrounding the nipple. Periareolar refers to the area just around the areola.
Periumbilical	Around the belly button.
Plastic Surgery	Surgery intended to enhance or improve the appearance of the body.
Platinum	A metallic element used to help make both silicone elastomer (the rubbery material of the breast implant shell) and silicone gel.
Postoperative	After surgery.
Precautions	Information that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
Prosthesis	Any artificial device used to replace or represent a body part.
Ptosis	Sagging or drooping of the breast.
Redness/Bruising	Bleeding at the surgical site that causes discoloration and varies in degree and length of time. This is expected following breast implant surgery or other breast procedures.
Removal	Removal of the implant, with or without replacement using another implant.
Reoperation	Any additional surgery performed to the breast or chest area after the first breast implantation.
Risks	The chance or likelihood that an undesirable effect will occur.

Rosenberg Self-Esteem Scale	A questionnaire that measures overall self-esteem.
Rupture	A hole or tear in the shell of the implant that allows silicone gel filler material to leak from the shell.
Saline	Saltwater (A solution made of water and a small amount of salt).
Scar Revision	A surgical procedure to improve the appearance of a scar.
Scarring	Formation of tissue at an incision site; all wounds heal by the formation of a scar.
Seroma	Similar to a bruise, a seroma occurs when the watery portion of the blood collects around a surgical incision or around a breast implant.
SF-36 Scale	The Short Form 36 Health Scale; a questionnaire intended to measure physical, mental, and social health.
Sientra Clinical Study	The clinical Study that supports the approval of a medical product (such as breast implants). For Sientra’s breast implants, the Study includes augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients. Information on the safety and effectiveness of the implants are collected every year for 10 years after Study participants get their implants.
Silent Rupture	A breast implant rupture without symptoms or a visible change. Silent rupture cannot be felt by the woman or detected by a doctor through physical examination. Silent rupture can only be discovered through appropriate imaging techniques such as MRI.
Silicone	Silicone is a man-made material that can be found in several forms such as oil, gel, or rubber (elastomer). The exact make-up of silicone will be different depending on its use.

Silicone Elastomer	A type of silicone that has elastic properties similar to rubber.
Silicones - Low Molecular Weight (“Low Molecular Weight [LMW] Silicones”)	Small silicone molecules that may be present in gel bleed/gel diffusion.
Subglandular Placement	When the implant is placed under and within the breast glands (breast tissue) but on top of the chest muscles.
Submuscular Placement	When the implant is placed underneath the chest muscles.
Surgical Incision	A cut made to body tissue during surgery.
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Symptomatic	Experiencing symptoms; any evidence or sign of disease or disorder.
Symptomatic Rupture	A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape).
Systemic	Pertaining to or affecting the body as a whole.
Toxic Shock Syndrome (TSS)	A rare, but life-threatening bacterial infection that may occur after surgery. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment if TSS is suspected.
Transaxillary	Under the arm.
Warnings	A statement that alerts the reader about a situation which, if not avoided, could result in serious injury or death.
Wrinkling/Rippling	Wrinkling of the implant that can be felt or seen through the skin.

1. How To Use This Educational Brochure

Sientra, the company that sells these Silicone Gel Breast Implants, has designed this educational brochure to help you understand breast augmentation and to help you talk with your doctor(s) about breast augmentation. Sientra sponsored a large clinical study of these breast implants (also referred to in this brochure as the "Study") that gathered data about these breast implants. The Study collected data from the primary augmentation and revision-augmentation cohorts of the CORE study, as well as pooled data from Sientra's CORE and Continued Access studies for the primary reconstruction and revision-reconstruction cohorts. There are 1,788 patients participating in the Study. A total of 1,115 patients had primary augmentation and 362 patients had revision-augmentation. Of the 229 patients who had primary reconstruction, 156 patients were from the CORE study and 73 were from the Continued Access study. Of the 82 patients who had revision-reconstruction with Sientra Silicone Gel Breast Implants, 50 were from the CORE study and 32 were from the Continued Access study. Results from the Study are presented in Section 8 of this brochure.

After you receive this information, give yourself time to read and think about the information. Because breast implants will require monitoring and care for the rest of your life, you should wait 1-2 weeks after reviewing and considering this information before deciding whether to have the surgery. If you are having revision-augmentation surgery, your surgeon may advise you to have the surgery sooner.

If you decide to have the surgery, you will be asked to sign a statement before the surgery. The statement says you have read and understood the information in this brochure and that you have been informed of the benefits and risks of breast implants. This statement is called the "Acknowledgement of Informed Decision," and there is a copy of it at the end of this brochure. Make sure all of your questions have been answered and you understand the information in this brochure, before you sign the "Acknowledgement of Informed Decision."

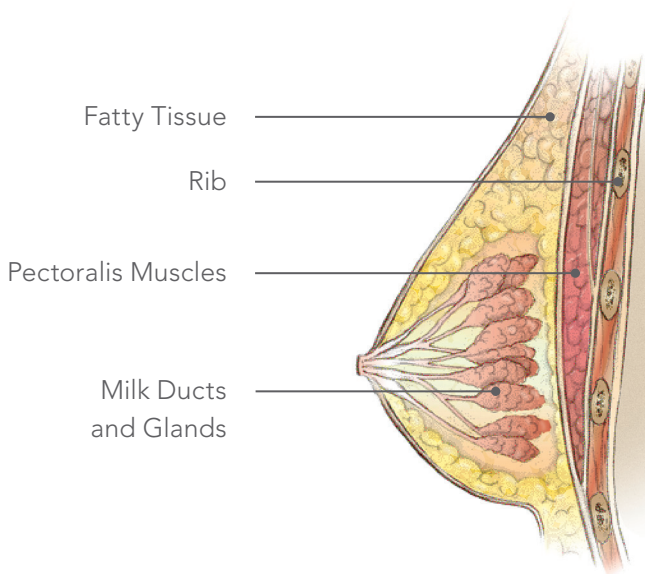
2. General Information About Breast Augmentation With Breast Implants

The information in this section provides some general information about breast augmentation with breast implants.

2.1 What Gives The Breast Its Shape?

As shown in Figure 1, your breast consists of milk ducts, glands, blood vessels, and nerves that are surrounded by fatty tissue. Glandular tissue is firm and gives the breast its shape. The fatty tissue gives the breast its soft feel. The chest muscle (the pectoralis major muscle) is located underneath all this breast tissue but does not have much effect on the shape or feel of the breast.

Figure 1. *Anatomy of the Breast*



2.2 What Is A Silicone Gel Breast Implant?

A silicone gel 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 designed to resemble the human breast in shape, weight and feel.

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. Round implants provide volume in the upper breast area (called upper pole area). Shaped implants are intended to match the anatomy of your chest wall. Depending on your needs, shaped implants can also provide more or less volume in the upper pole area.

Refer to Section 6.3 - *CHOOSING THE RIGHT IMPLANT FOR YOU*, for more information on the different silicone gel breast Implants available from Sientra.

2.3 How Do Breast Implants Work In Breast Augmentation?

Breast implants are used to make the breasts larger or to restore or replace breast tissue. They are surgically implanted beneath your breast tissue, either on top of the chest muscle (subglandular placement) or underneath part or all of the chest muscle (submuscular placement).

3. Deciding Whether To Have Breast Augmentation Surgery With Implants

The answers to the questions in this section will help you to decide whether breast augmentation surgery with implants is right for you.

3.1 Am I Eligible For Augmentation With Silicone Gel Breast Implants?

Breast implants have been approved for use in augmentation in two cases:

- **Primary augmentation** to increase the size and proportions of the breast(s) in women at least 22 years old.
- **Revision-augmentation** surgery to correct or improve the result of primary augmentation. Revision-augmentation includes replacing an existing breast implant.

Women who have lost breast tissue to cancer or injury or want to correct a congenital anomaly may also use Sientra Silicone Gel Breast Implants (also referred to as Implants). This is considered breast reconstruction with implants. A different educational brochure that describes breast reconstruction with Sientra Implants is available for you to read if appropriate to your situation.

3.2 Contraindications

A contraindication is a condition or circumstance that, if present, means a procedure should not be done. Contraindications for breast implant surgery are discussed in this section.

Silicone Gel Breast Implants are contraindicated in the following circumstances because the risk of undergoing breast augmentation with implants outweighs the benefits:

- 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.

Surgery in general is not recommended in patients with an active infection, existing cancer or pre-cancer, and existing pregnancy (unless the surgery is to treat the infection, cancer or pregnancy as recommended by your doctor), as it may interfere with the treatment of the infection or the cancer and safety of the pregnancy/nursing. In addition, these conditions may interfere with the healing after surgery.

Adequate studies have not been performed to demonstrate the safety of breast implant surgery in women with these conditions or under these circumstances; therefore, if you have any of the above conditions or circumstances, breast augmentation surgery with implants should not be performed at this time. Failure to take into consideration these contraindications may increase the risks involved with the surgery and could cause harm.

3.3 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.

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.

CAUTION: In order to avoid possible injury or damage to your incision site(s), you should avoid the following for the first month after your surgery:

- Sun exposure,
- Jerky movements or activities that stretch the skin at your incision site(s),
- Participating in sports or other activities that raise your pulse or blood pressure, and
- Unnecessary physical or emotional stress.

3.4 Warnings

Read this entire brochure before having breast implant surgery so that you will understand the risks and benefits and have realistic expectations of the outcome of your surgery. Breast implants are associated with many short-term and long-term risks.

WARNING – Smoking can make it harder for your body to heal. If you smoke, your doctor will probably have told you to stop before your surgery. Do not smoke while you are recovering from breast implant surgery.

WARNING – The following is a list of possible complications associated with breast implant surgery. Make sure you read and understand these before deciding whether to have breast implant surgery. Please refer to the following sections in this brochure for more detail on these factors: Section 4 - *RISKS ASSOCIATED WITH BREAST IMPLANTS*, Section 7 - *CARING FOR YOURSELF AFTER BREAST IMPLANT SURGERY* and Section 8 - *SIENTRA'S CLINICAL STUDY RESULTS*.

- 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. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures.

- Many of the changes to your breast that may occur as a result of breast implant surgery will be permanent and cannot be undone. If you have your implants removed, your skin may be permanently dimpled, puckered, or wrinkled.
- Breast implants may interfere with your ability to produce milk (lactate) for breast-feeding. If you are planning to breast-feed your infant, be prepared to use formula and bottle-feed your baby in the event you have difficulty breast-feeding.
- Mammography for detecting breast cancer (or cancer recurrence) may be more difficult with breast implants in place. You will need more views captured than during a routine mammogram. Therefore, the procedure will take more time and you will be exposed to more radiation than during a standard routine screening mammogram. However, the benefits of mammograms outweigh this risk. You must tell the technologist that you have silicone gel breast implants before the procedure. The technologist can then use special techniques to get the best possible views of your breast tissue.
- Your implants could rupture without you feeling the rupture or noticing any change in your breasts. In some of these instances even your doctor might not be able to tell that a rupture has occurred. A rupture that has no symptoms is called a “silent” rupture. The best way to diagnose a silent rupture is with an MRI examination. An MRI is similar to using x-ray imaging but an MRI machine uses magnetism and not x-ray radiation. 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 for as long as you have your breast implants.
- 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. Ask your surgeon to help you distinguish the implant from your breast tissue. You should perform an examination of your breasts for the presence of lumps, swelling, hardening, or change in implant shape, which may be signs of rupture of the implant. Report any of these

symptoms or persistent pain to your doctor. Your surgeon may recommend an evaluation via MRI to check for rupture.

- After undergoing breast augmentation surgery, you may experience changes in your healthcare insurance. Your health insurance premiums may increase; your coverage may be dropped or discontinued; you may not be able to get health insurance coverage in the future; and/or insurance may not cover treatment of complications associated with your breast implants. Be sure to check with your insurance company about these potential issues and understand the complete extent of your health coverage before having breast augmentation with implants.

3.5 What Are The Alternatives To Implantation With Silicone Gel-Filled Breast Implants?

If this is your first (primary) breast augmentation surgery your alternatives may include

- Electing to have no surgery,
- Wearing a padded bra or external prosthesis,
- Having a breast lift surgery (mastopexy) without implant(s), or
- Having breast augmentation with saline-filled implants.

If you are considering a revision surgery, your alternatives may include

- No revision surgery,
- Removing your implants without replacing them,
- Wearing a padded bra or external prosthesis, or
- Having revision breast augmentation with saline-filled implants.

4. 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 you have silicone gel breast implant surgery. The following addresses both general, surgery-related complications and implant-related complications.

Tables 1 and 2 present the potential risks associated with breast implant surgery, the likelihood of the risks based on the results from Sientra's Clinical Study through 3 years, as well as the possible effects of the events for primary and revision-augmentation patients.

TABLE 1
Potential Risks Associated with Primary Breast Augmentation

Event	Likelihood of the Event Occurring*	Possible Resulting Effects of the Event
Key Risks		
Reoperation	13 out of 100 patients (13%)	<ul style="list-style-type: none"> • Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal with Replacement	5 out of 100 patients (5%)	<ul style="list-style-type: none"> • Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal without Replacement	1 out of 100 patients (1%)	<ul style="list-style-type: none"> • Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Capsular Contracture (Baker Grade III/IV)	6 out of 100 patients (6%)	<ul style="list-style-type: none"> • Pain or Discomfort • Breast hardness/firmness • Reoperation • Implant removal
Implant Rupture	3 out of 100 patients (3%)	<ul style="list-style-type: none"> • Implant removal
Other Risks Occurring in 1% or more of Patients		
Nipple Sensation Changes	3 out of 100 patients (3%)	<ul style="list-style-type: none"> • Increased or decreased nipple sensitivity • Breast-feeding difficulties • May affect sexual response
Ptosis	2 out of 100 patients (2%)	<ul style="list-style-type: none"> • Undesirable cosmetic result • Wrinkling/rippling • Reoperation • Implant removal
Implant Malposition	1 out of 100 patients (1%)	<ul style="list-style-type: none"> • Implant Visibility • Asymmetry • Reoperation • Implant removal
Asymmetry	1 out of 100 patients (1%)	<ul style="list-style-type: none"> • Undesirable cosmetic result • Reoperation • Implant removal

* Based on the results of Sientra's Clinical Study within the first 3 years after implant surgery.

TABLE 2
Potential Risks Associated with Revision-Augmentation

Event	Likelihood of the Event Occurring*	Possible Resulting Effects of the Event
Key Risks		
Reoperation	20 out of 100 patients (20%)	<ul style="list-style-type: none"> • Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal with Replacement	9 out of 100 patients (9%)	<ul style="list-style-type: none"> • Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal without Replacement	3 out of 100 patients (3%)	<ul style="list-style-type: none"> • Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Capsular Contracture (Baker Grade III/IV)	5 out of 100 patients (5%)	<ul style="list-style-type: none"> • Pain or Discomfort • Breast hardness/firmness • Reoperation • Implant removal
Implant Rupture	0 out of 100 patients (0%)	<ul style="list-style-type: none"> • Implant removal

* Based on the results of Sientra's Clinical Study within the first 3 years after implant surgery.

TABLE 2 (cont.)
Potential Risks Associated with Revision-Augmentation

Event	Likelihood of the Event Occurring*	Possible Resulting Effects of the Event
Other Risks Occurring in 1% or more of Patients		
Implant Malposition	3 out of 100 patients (3%)	<ul style="list-style-type: none"> • Implant Visibility • Asymmetry • Reoperation • Implant removal
Wrinkling/Rippling	2 out of 100 patients (2%)	<ul style="list-style-type: none"> • Discomfort • Undesirable cosmetic result • Reoperation • Implant removal
Asymmetry	2 out of 100 patients (2%)	<ul style="list-style-type: none"> • Undesirable cosmetic result • Reoperation • Implant removal
Nipple Sensation Changes	1 out of 100 patients (1%)	<ul style="list-style-type: none"> • Increased or decreased nipple sensitivity • Breast-feeding difficulties • May affect sexual response
Infection	1 out of 100 patients (1%)	<ul style="list-style-type: none"> • Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
Seroma/Fluid Accumulation	1 out of 100 patients (1%)	<ul style="list-style-type: none"> • Swelling • Pain or Discomfort • Infection • Incision and drainage (reoperation) • Implant removal

* Based on the results of Sientra's Clinical Study within the first 3 years after implant surgery.

For additional information on how often Sientra has reported these events in its studies of the Implants, please read the section of this brochure on the Clinical Study (Section 8). For example, using information from Sientra's Clinical Study, the risk of a patient experiencing any complication at some point through 3 years after implant surgery was calculated. This risk is 20% for primary augmentation patients and 26% for revision-augmentation patients. This means that 20 out of 100 primary augmentation patients and 26 out of 100 revision-augmentation patients may experience a complication (of some kind) within 3 years after receiving implants.

4.1 What Are The Potential Complications?

INFECTION Infection is a possible consequence of any kind of surgery. It most often happens within days to weeks after the surgery, but you could develop an infection in your breast(s) at any time. Signs that you have an infection include: redness or rash, tenderness or pain, fluid accumulation in or around the breast(s), and fever. If you experience any of these symptoms, call your doctor right away. It is harder to treat an infection with an implant present. If antibiotics do not cure your infection, it is possible that your implant(s) may have to be removed to treat the infection.

In rare cases, Toxic Shock Syndrome (TSS) has been noted in women after surgery, including breast implant surgery. TSS is a life-threatening condition. Symptoms of TSS occur suddenly: a high fever, vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches, and/or drops in blood pressure, which may cause fainting. If you feel any of these symptoms, contact a doctor immediately.

HEMATOMA OR SEROMA You may experience a hematoma or a seroma following your surgery. A hematoma is similar to a bruise; hematomas related to breast implants are the collection of blood within the space around the implant. A seroma is a buildup of fluid around the implant.

Symptoms from a hematoma or seroma may include swelling, pain, and bruising. If a hematoma or seroma occurs, it will usually be soon after surgery. However, other injuries to the breast can cause hematomas and/or seromas in your breast. The body can absorb small hematomas and seromas on its own, but some will require surgery. When surgery is needed, it often involves draining the blood or fluid and sometimes involves placing a surgical drain in the wound temporarily for proper healing. A small scar can result from surgical draining. Implants may rupture if they are damaged by surgical instruments during the draining procedure.

CAPSULAR CONTRACTURE After your breast implant surgery, your breasts will begin to heal and to adapt to the presence of the breast implants. A regular part of this process is that the breast tissue typically forms an internal scar immediately

surrounding the implant. In many cases, this tissue forms a capsule that helps hold the implant in place. However, in some women, the scar tissue around the implant tightens and squeezes the implant. When scar tissue squeezes an implant, it is called capsular contracture.

Capsular contracture causes the breast to feel abnormally firm or hard and can cause pain. There is a scale for describing the severity of the contracture. It is called the Baker Grading Scale. The grades are:

- Grade I – contracture is observed, but the breast feels and looks normal (it is soft);
- Grade II – the breast is a little firm, but looks normal
- Grade III – the breast is firm and looks abnormal
- Grade IV – the breast is hard, painful, and looks abnormal

Capsular contracture may be more common if you have had a breast infection or hematoma/seroma. The chances of having contracture typically increase the longer you have your implants. It also seems that women who have additional surgery to replace their implants (revision surgery) are more likely to have capsular contracture than women having their first augmentation or reconstruction. However, whether or not a woman experiences capsular contracture at all and with what degree of severity varies from woman to woman.

If you feel severe pain and/or firmness (usually Grades III and IV contracture), you may need surgery to correct the problem. This could mean that the surgeon has to remove the part of your breast tissue that has contracted around the implant (the scar tissue capsule), and you could lose some breast tissue during such a surgery. During such surgery, it is possible that your implant(s) would need to be replaced. Even after having surgery to fix contracture problems once, contracture may happen again.

The Clinical Study of Silicone Gel Breast Implants reported a 6% risk of experiencing Baker Grade III or IV capsular contracture for primary augmentation patients through 3 years after receiving implants. For revision-augmentation patients, the risk is 5%. This means that 6 out of 100

primary augmentation patients and 5 out of 100 revision-augmentation patients may experience Baker Grade III or IV capsular contracture within 3 years after receiving implants. More details on capsular contracture results from the Study are found in Section 8.4.

RUPTURE Breast implants are considered to have ruptured when the implant shell develops a tear or hole. Sometimes silicone gel can minimally leak or “bleed/diffuse” through the implant shell even if there is no obvious tear in the shell. This is called “gel bleed” or “gel diffusion.”

Implants could rupture any time after your implant surgery, but the longer the Implants are in place, the higher the possibility that the Implants will rupture or the gel will leak. Breast implants may rupture or leak because of any of these reasons:

- Damage by surgical instruments at the time of implantation or during any subsequent surgical procedure,
- Stress to the implant during implant surgery that weakens it,
- Folding or wrinkling of the implant shell,
- Excessive force to the chest (for example, during closed capsulotomy, which is contraindicated),
- Trauma (like being in a car accident),
- Compression during a mammogram,
- Severe capsular contracture, or
- Normal use over time.

Sometimes there are symptoms associated with gel implant rupture that you or your doctor can notice. Sometimes your implants could rupture without you feeling the rupture or noticing any changes in your breasts. In some of these instances even your doctor might not be able to tell that a rupture has occurred. A rupture that has no symptoms is called a “silent” rupture.

Sientra has done studies to better understand what causes breast implants to rupture or leak gel. These studies might not have identified all the causes of rupture and these studies are continuing.

When silicone gel breast implants rupture, most of the silicone gel usually stays in the implant, and if any silicone does escape through a tear or hole, most of the gel stays within the scar tissue (capsule) around the implant. Sometimes, the gel does not stay there and may move to other areas around the body (gel migration). There have been rare reports of gel moving to nearby tissues such as the chest wall, armpit, or upper abdominal wall, and to more distant locations down the arm or into the groin. One group of researchers found silicone in the livers of women with ruptured silicone gel breast implants.¹

Sometimes silicone travels into the lymph nodes. When silicone gel moves into the lymph nodes, they may become enlarged. When silicone gel moves into lymph nodes or other parts of the body, small hardened lumps of silicone (called silicone granulomas) may be felt. These lumps are NOT cancer, but it can be hard to tell them from cancerous lumps just by feeling them. If you feel any lumps in your breasts, around your breasts, in your armpits or anywhere in your body, your doctor should examine them. Your doctor may have to remove a small amount of tissue from the lump(s) (called taking a biopsy) to find out if the lump is cancer. Before having a biopsy, be sure to tell your doctor that you have breast implants.

Studies have been done to find out what, if any, effects migrated silicone gel has on the body.¹⁻⁵ In most cases, no serious problems were reported. Several studies report that some women with migrated silicone gel experienced breast hardness, numbness and/or tingling in their extremities, and some seemed more sensitive to sunlight.^{1,4,6} In a few cases, migrated gel has caused nerve damage, hard silicone nodules (granulomas) in the body, and/or breakdown of the body tissues around the gel.⁵

Most doctors and researchers agree that there is NO evidence that ruptured implants or migrated gel causes any disease that affects the whole body (systemic disease) like Connective Tissue Disease (CTD) or cancer. However, one group of researchers^{2,3} reported that women who had migrated silicone gel had a higher risk of getting a CTD. This is discussed more fully in Section 4.2.

Studies on breast implants that women have had for a long time suggest that gel bleed may play a role in capsular contracture.⁷ However, complication rates for silicone gel breast implants are similar to or lower than those for saline-filled breast implants (which do not have silicone gel and, therefore, do not have gel bleed).

REOPERATION It is likely that you will need 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.

Based on the experiences of augmentation patients in the Study, the 3-year risk of reoperation is 13% for primary augmentation patients and 20% for revision-augmentation patients. This means that 13 out of 100 primary augmentation patients and 20 out of 100 revision-augmentation patients who receive Implants may have a reoperation within 3 years after their implant surgery. Reoperation information from the Study is discussed in more detail in Section 8.5.

IMPLANT REMOVAL Your Implants may be removed (with or without being replaced) at some point during the course of your life. You and your doctor may decide to remove an implant or implants because of a complication or to improve the cosmetic result.

Based on the experiences of augmentation patients in the Study, the 3-year risk of implant removal (including removal with replacement for a size exchange) is 6% for primary augmentation patients and 11% for revision-augmentation patients. This means that 6 out of 100 primary augmentation patients and 11 out of 100 revision-augmentation patients who receive Silicone Gel Breast Implants may need to have one or both implant removed within 3 years after receiving their implants. Implant removal information from the Study is discussed more fully in Section 8.6.

PAIN You will probably have some pain after your surgery. The intensity of the pain and the length of time it lasts vary from patient to patient. The pain may persist long after you have healed from surgery. In addition, improper implant size, placement, surgical technique, or capsular contracture may result in pain. Tell your surgeon if you have a lot of pain or if your pain does not go away.

CHANGES IN NIPPLE AND BREAST SENSATION Feeling in the nipple and breast can change after implant surgery. Nipples may become more or less sensitive. They may be painfully sensitive or feel nothing at all. These changes are temporary for many women, but for some, sensation may never be what it was before implant surgery. They may affect a woman's sexual response or ability to breast-feed.

COSMETIC CHANGES You may not be satisfied with the way your breasts look or feel after your surgery. Unsatisfactory results such as scarring or asymmetry (note: asymmetry that exists before breast implant surgery may not be entirely correctable), wrinkling of the skin, implant displacement/migration, incorrect size, unanticipated shape and/or implant palpability/visibility may occur.

A surgeon can minimize the chances of these things happening by planning the surgery carefully and using good surgical techniques. You should understand the possible cosmetic results and discuss them carefully with your doctor before the surgery. Your surgeon cannot promise that after implant surgery your breast(s) will look exactly as you wanted them to look. Revision surgery may be the only way to improve a result you do not like.

BREAST-FEEDING Breast implant surgery might interfere with your ability to successfully breast-feed. It is possible that you will produce less milk or not be able to produce milk at all. Some women with breast implants have also reported painful breast-feeding.^{7,8}

The Institute of Medicine (IOM) and The American College of Obstetricians and Gynecologists (ACOG) encourage women with breast implants to try breast-feeding. The IOM concluded, "Breast feeding should be encouraged in all

mothers when possible, including those with silicone breast implants. There is evidence that breast implantation may increase the risk of insufficient lactation, but no evidence that this poses a hazard to the infant beyond the loss of breast feeding itself. The evidence for the advantages of breast feeding to infant and mother is conclusive."^{7,9}

The Clinical Study collected information from patients who had babies after augmentation with Silicone Gel Breast Implants. Of those patients, 89% (of 150 patients who gave birth) in the primary augmentation group and 92% (of 39 patients who gave birth) in the revision-augmentation group reported no difficulties with lactation. Lactation experiences from the Study are discussed more fully in Section 8.7.

IMPLANT EXTRUSION Extrusion is when the breast implant comes through the skin. This can happen if your surgical wound has not healed properly or if the skin over your breast weakens. Radiation therapy has been reported to increase the chances of implant extrusion.¹⁰ Additional surgery is needed to fix implant extrusion. This can result in more scarring or loss of breast tissue. An extruding implant may have to be removed and not replaced.

NECROSIS/DELAYED WOUND HEALING Necrosis means that of most or all of the cells in a certain part of your body have died. In the case of implanted breasts, it means dead or dying breast tissue or skin. This can mean that the implant may extrude. Necrotic tissue must be surgically removed. The additional surgery may cause more scarring or loss of breast tissue. Your implant may have to be removed with or without being replaced.

Some patients may take a long time to heal after breast implant surgery. The longer it takes for your surgical wound to close and heal, the greater the risk for infection, implant extrusion, or necrosis. The normal time for wound healing is different for every patient. Infection, radiation, chemotherapy, smoking, taking steroids, and excessive heat or cold therapy can cause necrosis and delayed wound healing. Be sure to ask your surgeon how long he or she expects healing to take for you. If you do not heal in that timeframe, talk to your surgeon immediately.

BREAST ATROPHY/CHEST WALL DEFORMITY The breast implant pressing on the breast tissue may cause the tissue to become thinner. When this happens, you may be able to see and/or feel the breast implant through the skin. This tissue thinning can occur while implants are still in place or following implant removal without replacement.

The presence of breast implants can cause deformity that is noticeable, especially in very thin women.

Additional surgery may be needed to correct either of these conditions, which may mean more scarring, and removal with or without replacement of your breast implant(s).

CALCIUM DEPOSITS Calcium deposits (hard lumps of calcium) may form in your breast(s) and may be painful. Calcium deposits form in women who have not had any breast surgery and in women who have had breast surgeries. They also become more common as women get older.

Calcium deposits do not mean you are ill, but they can be mistaken for cancer. It may be difficult to tell if they are calcium deposits or cancer just by feeling them. They can show up on mammograms as possible cancer lumps. If you have hard lumps, your doctor may have to operate in order to perform a biopsy (remove a small piece of the lump for testing) or to remove the lump(s). Tell your doctor about any lumps you feel in or around the breast or anywhere on your body.

ENLARGED LYMPH NODES There are a large number of lymph glands in the body, but it is the lymph nodes in the armpit that drain the breast area of fluid. Some patients with breast implants have been found to have enlarged lymph nodes in the arm pit. This is referred to as lymphadenopathy. It has been reported to occur in women with both ruptured and intact silicone gel breast implants. If an enlarged lymph node becomes painful, it may need to be surgically removed. You should report any painful or enlarged lymph nodes to your doctor.

4.2 What Are Other Reported Conditions?

Sientra will continue its Clinical Study of its Silicone Gel Breast Implants through 10 years. Sientra will update the information it publishes about its implants (including this patient brochure) with the results of this Study. Contact your surgeon or Sientra (See Section 12 on *IMPORTANT CONTACT INFORMATION*) for updates.

Some women with breast implants have reported health problems that they believe are related to their implants, although the connection between their implants and their health problems has not been proven. Examples of such health problems include autoimmune diseases or connective tissue disease, cancer, or neurological problems (problems with the brain or nerves).

Studies have not shown that breast implants can cause these conditions. Most studies suggest that there is no connection between breast implants and these medical conditions. However, you should be aware of them. It is possible that there are risks that are not known and could be associated with breast implants in the future.

The information discussed in this section is based on studies published in the medical literature that include women with many different types, brands, and models of breast implants for augmentation and/or reconstruction.

The following potential long-term health effects of breast implants have been studied in relation to breast implants in general:

CANCER At this time, there is no scientific evidence that silicone gel breast implants increase the risk of any kind of cancer in women, but this possibility cannot be completely ruled out. Major research groups agree that silicone gel breast implants do not cause cancer.¹¹⁻¹³

BREAST CANCER Patients with breast implants do not seem to have greater risk of developing breast cancer.¹⁴⁻²⁵

The Institute of Medicine (IOM) report (a comprehensive review of studies that looked at the safety of silicone gel

breast implants since they were introduced in 1962) showed that breast cancer is no more common in women with implants than those without implants.

Some studies have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy. However, other studies reported that breast implants neither delayed breast cancer detection nor affected cancer survival.^{17,25-28}

BRAIN CANCER Most studies of brain cancer in women with silicone gel breast implants have found no increased risk.^{16,18,20,23-25} One study reported a higher rate of brain cancer in women with breast implants, compared to the general population.¹⁵ However, rates of brain cancer were not significantly higher in women with breast implants when compared to women who had other non-breast implant plastic surgeries.

LYMPHO-HEMATOPOIETIC CANCERS Lympho-hematopoietic cancers are cancers that develop in the lymph nodes or certain blood cells. Lymph nodes and the affected cells are part of the body's immune system to fight infection. These kinds of cancers include non-Hodgkin's lymphoma, Hodgkin's disease, multiple myeloma, and leukemia. Although most studies have found no increased risk of these cancers for women with silicone gel breast implants.^{16,18,20,23-25} some reports have suggested a possible association between a type of anaplastic large cell lymphoma (ALCL) and breast implants.²⁹

Anaplastic Large Cell Lymphoma Women with breast implants may have a very small, but increased risk of developing anaplastic large cell lymphoma, or ALCL, in the scar tissue and fluid adjacent to the implant. ALCL is not breast cancer—it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system).

Most patients were diagnosed when they sought medical treatment for implant-related symptoms such as pain, lumps, swelling, or asymmetry that developed after their initial surgical sites were fully healed. In the cases reported, ALCL was typically diagnosed years after the implant surgery.

Your physician should consider the possibility of ALCL if, after your surgical site is fully healed, you see changes in the way the area around the implant looks or feels—including swelling or pain around the implant. If ALCL is suspected, your physician will refer you to an appropriate specialist for evaluation which may involve obtaining fluid and tissue samples from around your breast implant. If ALCL is confirmed, your physician will develop an individualized treatment plan for you. Because of the small number of cases worldwide and variety of available treatment options, there is no single defined treatment.

If you have breast implants and have no symptoms, you do not need to do anything additional, but you should continue to routinely monitor your breast implants and follow your routine medical care. Removing the implants is not recommended in women with no symptoms without a diagnosis of ALCL.

If you do not currently have breast implants but are considering breast implant surgery, you should discuss the risks and benefits with your health care provider. You may also visit the FDA's Breast Implants website for additional information.

For additional and the most up-to-date information please visit:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>

RESPIRATORY/LUNG CANCER Several studies have found that women with silicone gel breast implants are not at greater risk for lung cancer.^{16,18,20,23-25} One study found an increased risk of respiratory/lung cancer in women with breast implants¹⁵ compared to women who had other kinds of plastic surgery (non-breast implant). However, the risk of lung cancer was not higher than national lung cancer rates for the general population. Other studies of women in Sweden and Denmark have found that women who get breast implants are more likely to be current smokers than women who get breast reduction surgery or other types of cosmetic surgery;³⁰⁻³² this may increase their risk for lung cancer.

REPRODUCTIVE SYSTEM CANCER Reproductive system cancers in women are cancers of the cervix, ovaries, uterus, vulva, vagina, and other female genital organs. Most studies^{16,18,20,23-25} found that women with silicone gel breast implants have no greater risk of these cancers than women without implants. One study reported an increased incidence of cervical/vulvar cancer in women with breast implants.¹⁵

OTHER CANCERS Studies have examined other types of cancer including eye, urinary tract (related to the bladder and urethra), connective tissue (fibrous tissues like tendons, cartilage, and bone that provide structure and support throughout the body), and endocrine system (the parts of the body that make hormones). Studies show that women with silicone gel breast implants have no greater risk of these types of cancers compared to the general population.^{4,15,16,18,20,23,24,33}

CONNECTIVE TISSUE DISEASE (CTD) AND DISORDERS OF THE IMMUNE SYSTEM The body's immune system protects the body from infection. It is a complicated system and includes a variety of different organs and cell types such as white blood cells and antibodies. Disorders of the body's immune system (also called autoimmune diseases) can cause CTDs when the patient's immune system mistakenly attacks parts of its own body, including the connective tissues of the body, like fibrous tissues (tendons,) cartilage, and bones.

Autoimmune diseases include lupus (inflammation and tissue damage in different body parts and organs), rheumatoid arthritis (inflamed and deteriorating joints), polymyositis (inflamed, weakened muscles), dermatomyositis (inflamed, weakened muscles and skin); and progressive systemic sclerosis or scleroderma (damaged skin or organs because of excess collagen, the main protein in connective tissue).

Other CTDs include

- Fibromyalgia (ongoing fatigue, widespread pain in muscles and joints, difficulty sleeping, and morning stiffness), and
- Chronic fatigue syndrome (ongoing mental and physical exhaustion, often with muscle and/or joint pain).

Some women with breast implants have experienced signs and symptoms that could be related to the immune system

but that do not fit into a definable disease, like those listed above. These signs and symptoms include: painful or swollen joints, tightness, tingling, numbness, reddened and swollen skin, swollen glands or lymph nodes, unusual or unexplained fatigue, swollen hands and feet, excessive hair loss, memory problems, headaches, and muscle weakness, pain, cramping and/or burning.

The scientific evidence strongly supports the conclusion that there is no increased risk of CTDs or autoimmune disorders for women with silicone gel breast implants.^{2,3,7,33-46} Independent scientific panels and review groups have also concluded that the weight of the evidence shows no relationship between breast implants and CTDs, or at least if a risk cannot be absolutely excluded, it is too small to be measured.^{7,47,48}

EFFECTS ON CHILDREN BORN TO MOTHERS WITH BREAST

IMPLANTS It is not known if a small amount of silicone may move through the breast implant shell and pass into breast milk. There is no test for detecting silicone in breast milk that is considered accurate. There has been a study that measured silicon levels (one component of silicone). It did not indicate higher levels of silicon in breast milk from women with silicone gel breast implants when compared to women without implants.⁴⁹

In addition, questions have been raised about whether silicone gel breast implants could harm babies whose mothers had implants while pregnant. Two studies in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery.^{50,51} A third study looked at low birth weight and did not find an elevated risk.⁵²

Overall, there is no evidence that shows that silicone gel breast implants have any harmful effects on the children of implanted women.^{7,8,50-52}

SUICIDE Some studies have reported a higher incidence of suicide in women with breast implants, but it is not clear whether these suicides were associated with having silicone gel breast implants or some other underlying condition that can lead to suicide, depression and/or anxiety.^{15,26,53-59} One researcher⁶⁰ believes that some women who want cosmetic surgery suffer from a disorder, called body dysmorphic disorder

(BDD), which may cause them to think about suicide or attempt suicide.

The strongest predictor for suicide is having been hospitalized for any psychiatric condition. One study found that women with breast implants were admitted to the hospital more often because of psychiatric problems before they even had their implant surgery, compared to women who had breast reduction or to the general population.⁵³ This may be a contributing factor to the reported higher incidence of suicide in women with breast implants.

NEUROLOGICAL DISEASE, SIGNS, AND SYMPTOMS Some women with breast implants have complained of neurological symptoms such as difficulties with vision, sensation, muscle strength, walking, balance, thinking, or remembering things. Some have been diagnosed with diseases such as multiple sclerosis (which is an autoimmune disease that affects the nerves). Some of these women believe their symptoms are related to their implants. A scientific expert panel found that there is not enough reliable evidence that neurological problems may be caused by or associated with breast implants.⁷ Other researchers have found more evidence that silicone gel breast implants do NOT cause neurological diseases or symptoms.^{7,19,61} There is one published report of an increased risk of multiple sclerosis among women with silicone gel breast implants;³⁷ these researchers did not find any increased risk of other neurological symptoms.

POTENTIAL HEALTH CONSEQUENCES OF GEL BLEED Small quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse (bleed) through an intact implant shell.^{7,62} The evidence is mixed as to whether there are any clinical consequences associated with gel bleed. For instance, studies on implants implanted for a long duration have suggested that such bleed may be a contributing factor in the development of capsular contracture⁷ and lymphadenopathy.⁵ However, evidence against gel bleed being a significant contributing factor to capsular contracture and other local complications is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast

implants than for saline-filled breast implants. Saline-filled breast implants do not contain silicone gel and, therefore, gel bleed is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in Sientra's implants does not cause toxic reactions when large amounts are administered to test animals. It should also be noted that studies reported in the literature have demonstrated that the low concentration of platinum contained in breast implants is in the zero oxidation (most biocompatible) state.⁶³⁻⁶⁶

Sientra performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact implants into the body. Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence.

5. Benefits Associated With Breast Implants

Women choose primary breast augmentation surgery to increase the size and proportion of their breast(s). In addition, women choose revision-augmentation surgery (replacement of an existing breast implant) to correct or improve the result of a primary augmentation surgery.

According to literature reports, most women who have undergone breast implant surgery have reported high levels of satisfaction with their body image and the shape, feel and size of their implants.⁶⁷ In Sientra's Clinical Study, most primary and revision-augmentation patients were pleased with the results of their implant surgery. The results showed that most women who underwent primary or revision-augmentation with the Study Implants felt their breast implants made them feel more feminine and more attractive. In addition, the majority of these women indicated that their breast implants made them feel better about themselves.

For more information on the benefits of breast augmentation with Sientra's Implants based on the results of the Clinical Study, refer to Section 8.3 of this brochure.

6. Preparing For Breast Augmentation With Silicone Gel Breast Implants

Deciding to have breast augmentation with implants is an important personal decision that has both benefits and risks. You should decide whether it is the right choice for you after discussing all the options with your plastic surgeon and any other doctors who are treating you. This section will give you the information you need to make an informed choice and help you make a number of decisions that have to be made before your surgery.

6.1 Should I Have Breast Augmentation?

Breast augmentation with Silicone Gel Breast Implants is one option that may be available to you if you wish to enhance the appearance of your breasts. A breast revision-augmentation surgery may be appropriate if you have had a breast augmentation with implants but need to complete, improve upon, or correct a part of that first surgery (called the primary augmentation).

Whether breast augmentation is right for you depends on many things; some of them are personal. You should take into account your medical condition, general health, lifestyle, how you feel emotionally, and your breast size and shape before surgery, as well as your hopes for breast size and shape after surgery. All of these things will affect the outcome of your surgery. Discuss your goals for breast augmentation with your doctors. You may also wish to consult your family and friends and breast implant support groups, to help you learn about the options and decide.

Many women who choose implants as part of their augmentation say their augmented breast(s) help them feel more self-confident, feel better about their bodies, and/or give them a greater feeling of well-being. Other women are not satisfied with their implants because of complications, like capsular contracture, rupture, or pain.

6.2 Breast Augmentation With Implants – Understanding The Procedure

The surgical procedure for breast augmentation consists of choices you and your surgical team (surgeon(s), nurses, anesthetist, etc.) will make as you plan your surgery. These choices include:

- The surgical setting (where the surgery will be performed, for example, in a hospital, surgery center, or doctor’s office),
- The type of anesthesia used,
- The location of the incisions made to insert the Implants,
- How the Implants will be placed in your breasts (subglandular or submuscular), and
- Whether your existing skin and/or breast tissue can cover implants.

Each of these is discussed in the sections that follow. The type of procedure that is available to you depends on your medical situation, breast shape and size, general health, lifestyle, and goals for the augmentation. Breast augmentation with Silicone Gel Breast Implants can usually be completed in a single surgery.

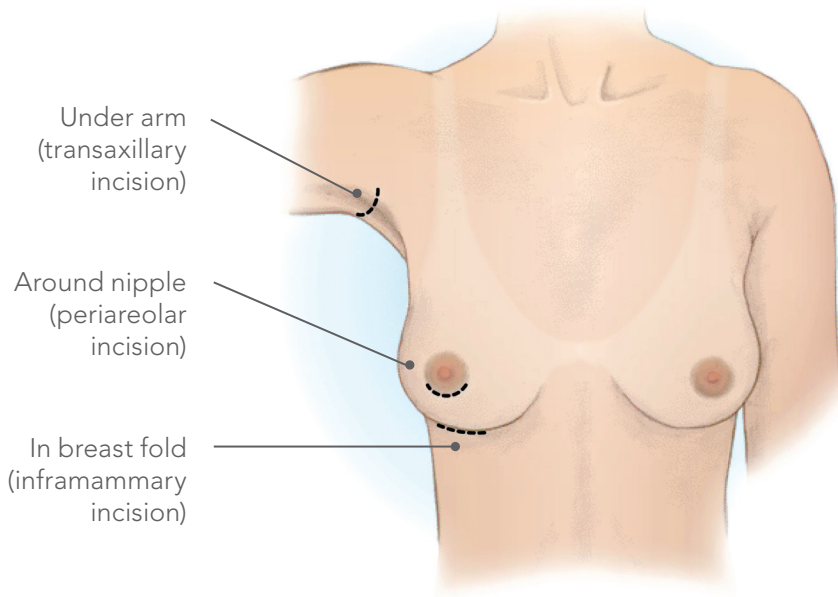
SURGICAL SETTING Breast augmentation surgery can be performed in a hospital, private surgery center, clinic, or in the surgeon’s office. Be sure you are comfortable with the location of the surgery before it happens. If you are considering having surgery in a private surgery center or office, you may want to see the area where the surgery will be performed.

ANESTHESIA Breast implant surgery may be performed under general or local anesthesia. All anesthetics carry some risk. Discuss the risks and benefits of the anesthetic your surgeon and anesthetist recommend for you before the surgery.

INCISION SITES Figure 2 shows the three incision sites (location of cut through which the breast implant is inserted in your body) usually used for breast augmentation surgery:

- Inframammary – the most common incision, made under your breast at the crease where the breast meets the body,
- Periareolar – an incision is made around the nipple, and
- Transaxillary – the incision is made in the armpit, which gives the surgeon easier access to the chest muscle.

Figure 2. Incision sites for breast augmentation surgery

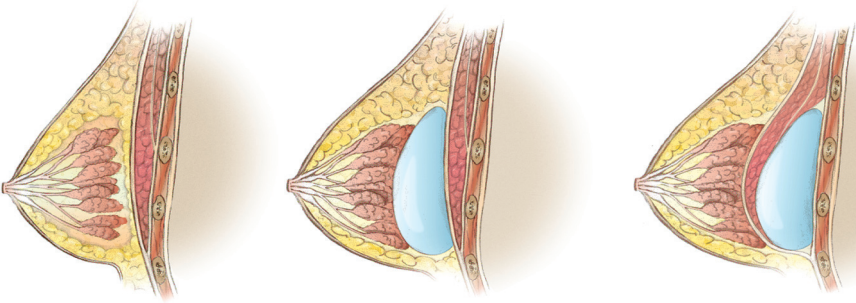


You may hear about a fourth incision site – the “periumbilical approach” (incision at your belly button). This way of placing breast implants has not been studied in the Clinical Study and should not be used. It may cause damage to the implant shell.

Your surgeon can explain which incision site he or she recommends for you and talk about the pros and cons of each with you.

IMPLANT PLACEMENT As shown in Figure 3, breast 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 3. Breast implant placement



Breast before augmentation

Breast after subglandular augmentation

Breast after submuscular augmentation

Table 3 compares positive and negative aspects (pros and cons) of each method. The “best” placement depends on you and the characteristics of your body, the types of implants you choose, and your surgeon. Talk with your surgeon about his or her reasons for choosing one placement over the other and the advantages and disadvantages of each.

TABLE 3
Comparison of Submuscular and Subglandular Placement of Breast Implants

Submuscular Placement	Subglandular Placement
<ul style="list-style-type: none"> • Surgery time may be longer • Recovery may be longer • May be more painful • Future re-operation may be more difficult • Implants may feel more like a natural part of the breast (be less “palpable”) • Capsular contracture may be less likely⁷ • It may be easier to image breast with mammography • If you have thin or weakened breast tissue, submuscular positioning may work better 	<ul style="list-style-type: none"> • Surgery time may be shorter • Recovery time may be shorter • May be less painful • Future reoperation may be easier • Implants may be more palpable (can feel the implant through breast tissue) • Capsular contracture may be more likely^{68,69} • It may be harder to image breast with mammography

6.3 Choosing The Right Implant For You

Sientra Implants are available in several different shapes, profiles (the contour the implant provides to your body), and sizes to help each woman achieve the result that is best for her body.

Table 4 lists the styles of Sientra Silicone Gel Breast Implants that are available.

TABLE 4 Sientra Silicone Gel Breast Implant Designs			
Implant Shell Texture	Implant Shape	Implant Profile	Volume Range
Smooth	Round	Moderate	80 - 700 cc
		High	95 - 695 cc
Textured	Round	Low	60 - 700 cc
		Moderate/ High	95 - 695 cc
Textured	Shaped Inferior Pole	Low	170 - 500 cc
		Moderate/ High	120 - 700 cc
Textured	Shaped Superior Pole	High	180 - 550 cc
		Moderate	115 - 690 cc

When you and your doctor decide what you want your breasts to look like after augmentation, your doctor can help you choose the right implant to get the effect you want. Your body type, height, and weight will be factors your surgeon considers to help you achieve the best result.

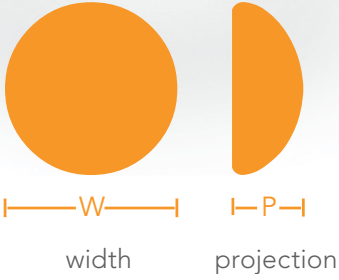
IMPLANT SIZE, SHAPE AND SURFACE Your surgeon will examine your breast tissue and skin to figure out if you will have enough to cover the implant. It is possible that you will not have enough skin and/or breast tissue to cover the implant you desire. In this case, you may be offered several choices.

Breast implants that are too big for the amount of breast tissue or skin can cause problems: they can actually speed up the effects of gravity; your breasts may droop or sag earlier with implants that are too large. Implants that are too large can also cause implant extrusion, skin wrinkling, infection, and hematoma. You may be able to feel folds on the implant created by it being squeezed too tightly by the surrounding tissue and skin. If you do not have enough skin, and it is stretched too thin over the implant, you may be able to feel or see the edges of the implant under your skin surface after surgery.

As shown in Figure 4, the Implants come with either a smooth shell or a textured shell; you should speak with your surgeon to find out whether he or she recommends smooth or textured implants for you.



Smooth Round Implant



Textured Shaped Implant

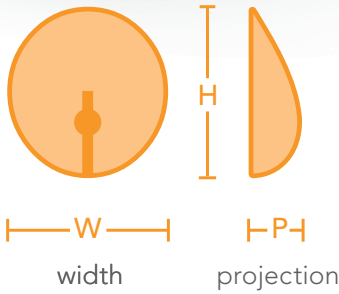


Figure 4. Photographs of smooth and textured Sientra implant styles

6.4 Other Procedures At The Time Of The Breast Augmentation

Your surgeon may recommend having other cosmetic procedures during the same surgery to get the best results from your breast implants. In some cases, breast implants alone may not give you the results you want. If, in the past, you have lost a lot of weight, been pregnant, or breast-fed, you may have sagging, stretched, or extra skin that is not completely filled out by breast tissue. In this case, your doctor may recommend doing a breast lift (mastopexy) to remove excess skin from the rest of the breast tissue in one or both breasts.

During mastopexy, your surgeon will remove a piece of skin from your breast (usually from under the breast or around the nipple). Then he or she will use stitches to close the incision where the skin was removed. This lifts the whole breast or nipple location and tightens the skin over the breast. This might cause more scarring than just having implants placed and may lengthen your recovery time. Mastopexy (to one or both breasts) may be done at the same time as the primary augmentation or may be done at a later, follow-up procedure. It is not always best to do multiple procedures during one surgery. Your doctors can discuss the risks and benefits of this procedure with you.

6.5 Choosing A Surgeon

The following are types of questions you should consider when choosing a surgeon:

- In which states is he or she licensed to practice surgery?
- Has he or she completed residency requirements in plastic surgery from a recognized and accredited academic program?
- Is he or she board certified in the United States? If so, which board?
- How many breast augmentation surgeries does he or she perform each year?
- How many years has he or she been doing breast augmentation surgeries?

- What is the most common complication he or she encounters with breast augmentation patients?
- What is his or her reoperation rate for augmentation patients? And what is the most common type of reoperation that he or she performs in his or her practice?
- Will he or she perform all of my surgery in a hospital? (Many surgeons perform breast implant surgery or components of breast augmentation in their own out-patient surgery centers. Hospitals require surgeons to prove that they are properly trained before they can operate in the hospital.)

7. Caring For Yourself After Breast Implant Surgery

How you feel after your surgery and the level of care you need in the first few days vary from patient to patient and depend on the extent of your surgery. Your wounds will take several weeks or more to heal completely. Talk with your surgeon after your surgery about how to care for yourself and how long your recovery should take.

7.1 Postoperative Care In The Hours And Days After Surgery

The first few hours after your initial augmentation surgery will be spent recovering in the hospital. You may be there for several days or you may be able to go home sooner. During these first days after your surgery, you will need to follow some simple directions to take care of yourself. Your surgeon will give you specific directions about what to do. Follow your surgeon's directions.

If you have had general anesthesia, you will remain in the hospital or surgery center until the anesthesia wears off. You may have drains in your breasts so that fluid or blood will drain out of the wound at the incision site.

You will probably leave your surgery wearing a bandage to protect the wounds and support your breasts. Your surgeon will tell you how long to keep your breasts bandaged. Eventually, you will be able to wear a bra for support instead

of the bandages. Your doctor will give you instructions about bathing or washing the area during the first few days. He or she may tell you not to take baths for a certain period of time.

Call your doctor immediately if you think you may have an infection. If your incision sites or breasts are red, swollen, hot, painful, or are weeping (draining white or yellow fluid) or if you have a fever, chills, aches, nausea, or vomiting, you may have an infection.

If you do not have any complications, you will probably be able to go back to most of your usual daily activities in 1 to 2 weeks after surgery.

7.2 Postoperative Care In The First Weeks After Surgery

In the weeks after your augmentation, 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.

7.3 Caring For Yourself In The Months And Years After Surgery

There are some things you should do to make sure your breasts stay healthy and to take care of your implants: mammograms, breast exams, and protecting your implants from certain types of damage. It will be important to monitor your breasts for breast cancer. Also monitor regularly for breast implant rupture.

MAMMOGRAMS A mammogram is a special way of x-raying the breast. Whether or not you have breast implants, having a mammogram is considered the best way to detect breast

cancer. However, there are some special considerations for women with breast implants:

- Breast implants can make it harder to see breast cancer on a mammogram.
- Breast implants can make it harder for the technologist to perform the mammogram.

The machine that does a mammogram squeezes the breast to make it as flat as possible while taking a picture. The pressure from this squeezing could make your implant rupture or cause gel bleed. You must tell the technologist that you have silicone gel breast implants before the procedure. The technologist can then use special techniques to get the best possible views of your breast tissue. He or she can also take steps to reduce the likelihood that your implants will rupture due to the mammogram.

It is a good idea to have a mammogram before your breast implant surgery. This establishes a baseline to which future mammograms can be compared. You are also encouraged to have another mammogram 6 months to 1 year after your implant surgery to establish a baseline with the implant present.

After that, the recommendations for mammograms are the same as for women without implants; have a mammogram every 1 to 2 years, starting at age 40, or as advised by your doctor. When you go for a mammogram, do the following things to get the most reliable pictures of your breast(s):

When you schedule a mammogram, tell the office that you have breast implants.

Find a mammographer who is experienced with imaging implanted breasts. (Your doctor should be able to help you find a qualified mammographer.)

You may want to request a “diagnostic” mammogram instead of a “screening” mammogram because more pictures are taken for a diagnostic mammogram. Using that language may help the mammogram site to schedule the right kind of procedure for you.

Make sure your mammographer knows what type of implants you have and how they are placed (for example, on top of the chest muscle or underneath).

Carry your Device Identification Card (that you will receive after surgery) with you and show it to the mammographer.

OTHER BREAST EXAMS Perform self-breast exams regularly. Once a month, after your period ends, is a good time to examine your breasts.

You can find brochures about how to perform breast self-exams through your doctor, a women's health clinic, or online. Your doctor can show you how to do a self-breast exam. Ask your doctor to help you learn to tell the difference between your breast implant and breast tissue. This will help you do your self-breast exams without squeezing your implant too much. If you see or feel that something has changed, talk to your doctor promptly.

It is important to have regular exams by a doctor as well. It may be hard for you to feel changes in your breast because the implant is there, especially if you have capsular contracture. The doctor will look at your breasts and palpate your breasts like in a self-exam to feel for any changes. If your doctor finds anything, he or she may refer you for a mammogram to help diagnose the change. Your doctor may also ask for an MRI if he/she suspects rupture.

PROTECTING YOUR IMPLANTS To protect your implants, you should make sure that any healthcare practitioners (doctors, emergency medical technologists, nurses, massage therapists, acupuncturists, chiropractors, physical therapists, etc.) treating you know that you have Silicone Gel Breast Implants. If they do not know about your implants, they may damage them by accident and your implants could rupture. Carry your Device Identification Card with you and show it to healthcare practitioners before receiving treatment.

You should also protect your implants by guarding against any strong or repeated pressure on your breasts.

THINGS TO CALL YOUR DOCTOR ABOUT RIGHT AWAY

Call your doctor immediately if you have

- Signs of an infection,
- A lump,
- Skin around the nipple that has become dimpled or drawn in,
- Discharge from the nipple,
- Change in the position or shape of your implant, or
- Injury to your breast(s).

If your implant becomes damaged, it may have to be removed.

PHYSICAL LIMITATIONS After you have healed from surgery, you should be able to carry on normal activities including sports. Avoid situations that put a lot of pressure on your breasts or may cause trauma to your breast. Ask your doctor if there are any activities he or she does not recommend.

7.4 Monitoring Your Implants For Rupture

Rupture is a rare occurrence with silicone gel breast implants. However, the following information will help you to monitor your implants for evidence of rupture.

DETECTING RUPTURE A variety of factors can cause your breast implants to develop a tear or hole in the shell. These tears or holes are usually called ruptures because they can allow silicone gel from inside the implant to exit your implant.

If your implant(s) ruptures, you may experience certain symptoms. Any of the following may indicate that your implant has ruptured: hard knots or lumps surrounding the implant or in the armpit, changes in breast size or shape, pain, tingling, swelling, numbness, burning, and/or hardening of the breast.

If you feel any of these symptoms, contact your doctor for an exam.

If your implant ruptures, it is more likely that you will not experience any symptoms and you will not even know your

implant had ruptured. In these situations, even your doctor may not be able to determine that a rupture has occurred. This is referred to as a “silent” rupture.

MRI examination (taking pictures of your implants similar with a device similar to an x-ray machine) is the best way to tell if a silent rupture has happened. For this reason it is strongly recommended that you have an MRI the third year after your surgery and then every 2 years after that for as long as you have your breast implants.

WHAT TO DO IF YOU SUSPECT AN IMPLANT RUPTURE

If you suspect that an implant has ruptured or if you suspect that silicone gel has moved out of your implants, call your doctor right away and schedule an exam. Your doctor may recommend an MRI or other kinds of tests to help diagnose possible rupture. MRI is currently considered the best way to diagnose rupture.

WHAT TO DO IF THE IMPLANT RUPTURE IS CONFIRMED If your doctor confirms that you have a ruptured implant or that silicone gel has bled (moved) out of your implant shell, he or she will talk with you about your options. As a precaution, Sientra recommends that ruptured implants be taken out permanently and either replaced with a new implant or not replaced, depending on your preference or medical need.

If your implant is taken out, your surgeon may also have to remove some of your breast tissue (the tissue capsule that forms around the breast implant), which will involve additional surgery, with associated risks and costs. In some cases, it may not be possible to replace your implants.

8. Sientra’s Clinical Study Results

As part of the marketing approval requirements for the Silicone Gel Breast Implant, Sientra conducted the Clinical Study with patients who received the Implants for augmentation (primary and revision) and reconstruction (primary and revision). The Study collected data from the primary augmentation and revision-augmentation cohorts of the CORE study, as well as pooled data from Sientra’s CORE and Continued Access studies for the primary reconstruction

and revision-construction cohorts. The results of the Study will provide you with useful information on the experience of other women who have received these Silicone Gel Breast Implants. The results of the Study should not be used to predict your own experience with the Implant, but the information can be used as a general guide about what you may expect. Your own benefits and complications depend on many individual factors.

8.1 Overview Of The Study

The Study is a prospective, 10-year, multicenter clinical study conducted to examine the safety and effectiveness of the Sientra Silicone Gel Breast Implants (now referred to as Sientra Implants or Implants) in patients undergoing primary augmentation, primary reconstruction, revision-augmentation, and revision-reconstruction of the breast.

There are 1,788 patients participating in the Study. A total of 1,115 patients had primary augmentation and 362 patients had revision-augmentation. Of the 229 patients who had primary reconstruction, 156 patients were from the CORE study and 73 were from the Continued Access study. Of the 82 patients who had revision-reconstruction with Sientra Silicone Gel Breast Implants, 50 were from the CORE study and 32 were from the Continued Access study. Of these patients, 230 primary augmentation patients, 74 revision-augmentation patients, 34 primary reconstruction patients and 7 revision-reconstruction patients are assessed for implant rupture for MRI at years 3, 4, 6, 8, and 10 after receiving implants.

Assessment of the safety of the Implants is based on the incidence of complications, including device failures. Effectiveness was assessed based on changes in bra size, chest circumference, and patient satisfaction in terms of quality of life, self esteem (how you feel about yourself overall), and body esteem (how you feel about your body). Several scales and questionnaires about these topics were used to collect information for analysis, including a patient-reported quality-of-life (QOL) outcomes questionnaire, the Short Form Health Survey (SF-36), the Rosenberg Self-Esteem Scale, and the Body Image Scale.

The Study will continue to follow patients through 10 years after their breast implant surgery. Results provided here represent the first 3 years of data. This brochure will be updated as more information becomes available. You should also ask your surgeon if he or she has received any updated clinical information.

The following sections provide more information about the complications and benefits you may experience following augmentation with Sientra Silicone Gel Breast Implants, based on the experiences of the augmentation patients in the Study.

8.2 What Are The 3-Year Follow-Up Rates?

The Study enrolled 1,115 augmentation patients. Of the women expected to be seen at the 3-year follow-up visit, 80% were seen. The Study enrolled 362 revision-augmentation patients. Of the women expected to be seen at the 3-year follow-up visits, 79% were seen.

8.3 What Are The Benefits?

The benefits of the Implants were examined by measuring the change in bra size (in terms of cup size and chest circumference) and assessing patient satisfaction and quality-of-life (QOL). Patient satisfaction and QOL were determined using several questionnaires that the patients responded to, including a health survey, a numeric scale that assessed body esteem, and a numeric scale that assessed body image. The information was collected before implantation and at scheduled follow-up visits (1 year and 2 years after their surgery).

PRIMARY AUGMENTATION PATIENTS Most primary augmentation patients were pleased with the results of their implant surgery. Many (91%) had increased their bra size by at least one cup size. Over 81% of patients increased by one to two cup sizes. Some increased their bra size more than two cup sizes (10%) and some increased their bra size less than one cup size (6%). Patients reported satisfaction in terms of their quality of life, self esteem (how they feel

about themselves), body esteem (how they feel about their bodies), and sexual attractiveness. According to their scores on a questionnaire about a variety of general QOL concepts (health, mental, and social well-being), these women felt better about themselves than a sample of average women in the United States. However, compared to their QOL before getting implants, most women experienced unchanged or even slightly decreased QOL on most measures. Other findings of the Study showed that over 90% of women felt their breast implants made them feel more feminine (94%) and more attractive (92%). In addition, the majority of women indicated that their breast implants made them feel better about themselves (85%).

REVISION-AUGMENTATION PATIENTS Most revision-augmentation patients were pleased with the results of their additional implant surgery. Bra size changes were not analyzed for revision-augmentation patients. According to their scores on a questionnaire about a variety of general QOL concepts (health, mental and social well-being) these women felt better about themselves than a sample of average women in the United States. However, compared to their QOL before getting implants, most women experienced unchanged or even slightly decreased QOL on most measures. Another finding of the Study showed that most women agreed that their breast implants make them feel more feminine (90%) and more attractive (89%). In addition, the majority of women indicated that their breast implants made them feel better about themselves (82%).

8.4 What Were The 3-Year Complication Rates?

The safety of Sientra Silicone Gel Breast Implants was determined by assessing the incidence of complications, including device failures.

PRIMARY AUGMENTATION The complications observed in women who had primary augmentation through 3 years are presented in Table 5. The most common reported complication within the first 3 years after augmentation surgery was reoperation (13% or approximately 13 out of 100).

TABLE 5
Complication Rates Reported through 3 Years for
Primary Augmentation Patients (N=1,115 Patients)

Key Complications	%
Reoperation	12.6%
Capsular Contracture (Baker Grade III/IV)	6.0%
Implant Removal with Replacement	4.6%
Implant Rupture (MRI cohort) ¹	2.5%
Implant Removal without Replacement	1.2%
Other Complications Occurring in 1% or more of Patients ²	%
Nipple Sensation Changes	3.2%
Ptosis	1.8%
Implant Malposition	1.2%
Asymmetry	1.1%

¹ No ruptures were reported in the non-MRI cohort.

² The following complications were reported at a risk rate of less than 1%: breast mass/cyst/lump, breast pain, bruising, delayed wound healing, hematoma, hypertrophic/abnormal scarring, implant extrusion, implant visibility, infection, redness, seroma/fluid accumulation, skin sensation changes, swelling, upper pole fullness, wrinkling/rippling, and other complications.

REVISION-AUGMENTATION The complications observed in women who had revision-augmentation through 3 years are presented in Table 6. The most common reported complication within the first 3 years after revision-augmentation surgery was reoperation (20% or approximately 20 out of 100).

TABLE 6
Complication Rates Reported through
3 Years for Revision-Augmentation Patients
(N=362 Patients)

Key Complications	%
Reoperation	20.3%
Implant Removal with Replacement	8.7%
Capsular Contracture (Baker Grade III/IV)	5.2%
Implant Removal without Replacement	2.9%
Implant Rupture (MRI cohort) ¹	–
Other Complications Occurring in 1% or more of Patients ²	%
Implant Malposition	3.2%
Wrinkling/Rippling	2.4%
Asymmetry	1.8%
Nipple Sensation Changes	1.4%
Infection	1.2%
Seroma/Fluid Accumulation	1.2%

¹ No ruptures were reported in the MRI cohort. However, implant rupture was reported at a risk rate of 0.4% in the non-MRI cohort.

² The following complications were reported at a risk rate of less than 1%: breast pain, bruising, delayed wound healing, hematoma, hypertrophic/abnormal scarring, implant extrusion, implant palpability, implant visibility, irritation, necrosis, ptosis, redness, skin sensation changes, swelling, and other complications.

8.5 What Are The Main Reasons For Reoperation?

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, etc. In addition, patients may require more than one surgical procedure.

PRIMARY AUGMENTATION In the Study, 11% of the patients had at least one reoperation through 3 years (a total of 149 reoperations performed in 127 patients). Table 7 provides the main reasons for reoperation. The two most common reasons for reoperation through 3 years in these patients were capsular contracture and the patient requesting a change in the size or style of the implant.

TABLE 7
Main Reasons for Reoperation through 3 Years for Primary Augmentation Patients (N=149 Reoperations)

Reasons for Reoperation through 3 Years ¹	%
Capsular contracture	22.1%
Patient request for size/style change	19.5%
Ptosis	12.1%
Hematoma/seroma	11.4%
Implant malposition	11.4%
Scarring/hypertrophic scarring	5.4%
Infection	4.0%
Asymmetry	3.4%
Wrinkling/rippling	2.7%
Delayed wound healing	2.0%
Mass/lump/cyst	1.3%
Nipple-related complications	1.3%
Unknown	1.3%
Breast cancer	0.7%
Upper pole fullness	0.7%
Pain	0.7%

¹ Some reoperations were performed for multiple reasons; only the primary reason is provided in the table.

REVISION-AUGMENTATION In the Study, 19% of the patients had at least one reoperation through 3 years (a total of 84 reoperations performed in 67 revision-augmentation patients). Table 8 provides the main reasons for reoperation. The two most common reasons for reoperation through 3 years were the patients desiring a change in the size or style of their implants and capsular contracture.

TABLE 8
Main Reasons for Reoperation through 3 Years for Revision-Augmentation Patients (N=84 Reoperations)

Reasons for Reoperation through 3 Years ¹	%
Patient request for size/style change	15.5%
Capsular contracture	15.5%
Implant malposition	13.1%
Wrinkling/rippling	9.5%
Unknown	8.3%
Asymmetry	6.0%
Delayed wound healing	6.0%
Ptosis	6.0%
Hematoma/seroma	4.8%
Infection	3.6%
Scarring/hypertrophic scarring	3.6%
Pain	2.4%
Breast cancer	1.2%
Implant extrusion	1.2%
Implant palpability/visibility	1.2%
Nipple-related complications	1.2%
Other ²	1.2%

¹ Some reoperations were performed for multiple reasons; only the primary reason is provided in the table.

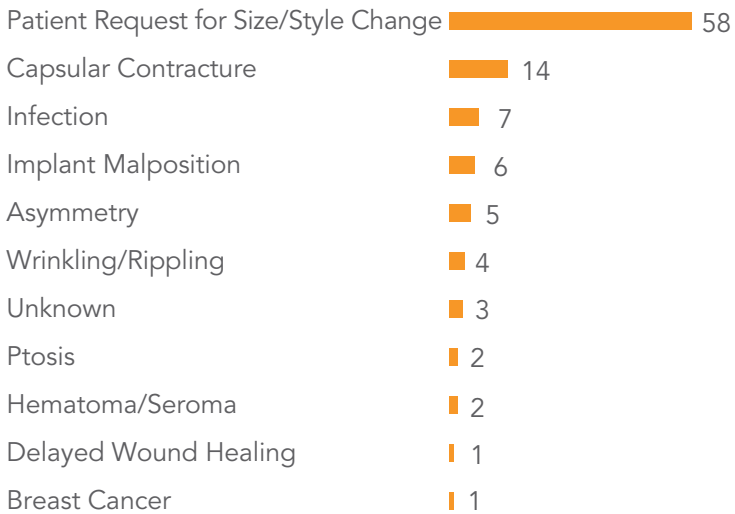
² Patient reported back pain from the weight of the Implants.

8.6 What Are The Main Reasons For Implant Removal?

Breast implants may be removed (with or without replacement) in response to a complication or to improve the cosmetic result.

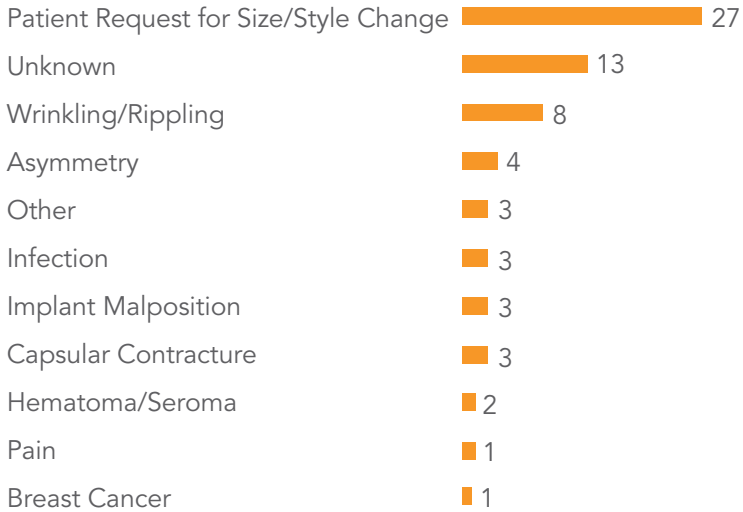
PRIMARY AUGMENTATION In the Study, 5% of the patients had at least one removal (a total of 103 implants removed from these 58 patients). Of these 103 implants, 82% were replaced. As Figure 5 shows, the most common reason for implant removal was the patient requesting a different implant size or style.

Figure 5. Main Reasons for Implant Removal through 3 Years Primary Augmentation (n=103 implants)



REVISION-AUGMENTATION In the Study, 10% of patients had at least one removal (a total of 68 implants removed from these 37 patients). Of these 68 implants, 78% were replaced. Figure 6 shows that the most common reason for implant removal was the patient requesting a different implant size or style.

Figure 6. Main Reasons for Implant Removal through 3 Years Revision-Augmentation (n=68 implants)



8.7 What Are Other Clinical Data Findings?

The Study evaluated several possible long-term health effects that have been reported in breast implant patients. These include rupture, cancer, CTD, CTD signs and symptoms, complications with lactation, reproductive complications, and suicide.

RUPTURE In the Study, there are 230 primary augmentation patients enrolled in an MRI cohort study who have routine MRI screening of their implants to track rupture; Through 3 years, 97% of these patients (99% of implants) had no evidence of rupture. Through Year 3, there have been two confirmed implant ruptures occurring in one patient and five unconfirmed implant ruptures occurring in five patients.

Overall, the 3-year risk of rupture was 3% per patient. This means that after receiving Silicone Gel Breast Implants, 3 out of 100 women may experience a rupture during the first 3 years.

There are 74 revision-augmentation patients enrolled in the MRI cohort who have routine MRI screening of their implants to track rupture. Through 3 years, all of these patients (100%) had no evidence of rupture. However, of the revision-augmentation patients in the Study who were not evaluated by MRI, there was one confirmed (silent) implant rupture occurring in one patient. Overall, the 3-year risk of rupture was 0.4% per patient. This means that 3 years after receiving Implants, 1 out of 250 women may experience a rupture.

CANCER Two primary augmentation patients reported breast cancer during the 3 year period following implantation (risk rate 0.2%). Other types of cancers (including basal cell skin cancer and uterine cancer) occurred in 6 (less than 1%) primary augmentation patients. One revision-augmentation patient (0.3%) reported breast cancer and one patient (0.3%) reported lung cancer through 3 years in the Study. No other cases of cancer were reported in revision-augmentation patients. There were no cases of fibrocystic breast disease reported through 3 years in either primary or revision-augmentation patients.

There were no reports of ALCL in any patient cohort in the Sientra Study.

CONNECTIVE TISSUE DISEASE (CTD) Of the 1,115 primary augmentation patients in the Study, two primary augmentation patients were diagnosed with a CTD in the 3 years after receiving implants; the diagnoses were one case of fibromyalgia and one case of rheumatoid arthritis. Based on these, the 3-year risk rate of fibromyalgia and rheumatoid arthritis are each 0.1% (or 1 in 1,000 patients).

Of the 362 revision-augmentation patients in the Study, one revision-augmentation patient was diagnosed with a CTD through 3 years; she was diagnosed with fibromyalgia. Based on this, 0.3% (or 3 in 1,000 patients) of revision-augmentation patients may be diagnosed with fibromyalgia within 3 years of revision-augmentation with Implants.

CTD SIGNS AND SYMPTOMS The Study collected information on CTD signs and symptoms (that did not result in a diagnosis of a CTD) in augmentation and revision augmentation patients every other year during follow up. Thirteen categories of CTD signs and symptoms were examined in the Study, including symptoms related to skin, muscles, joints, brain and/or nerves, pain, fatigue, fibromyalgia, eyes, ears, nose, and throat (EENT), blood or lymph, constitution (unexplained weight loss or fever, depression, or lupus [a disease in which there is inflammation and tissue damage in different parts of the body]); endocrine/exocrine system; and blood vessels.

In Sientra's Study, self-reported CTD signs and symptoms were collected. Compared to before having implants, significant increases were found in only 2 of the 13 CTD sign/symptom categories in the pooled primary augmentation and revision-augmentation cohorts: Pain and Fibromyalgia, for which the statistical significance is driven by the occurrence of low back pain. These increases were not found to be related to simply getting older.

On the other hand, a significant decrease compared to before having implants was found for 2 of the 13 sign/symptom categories: Endocrine/Exocrine and Constitutional. For the category of Endocrine/Exocrine the significance is driven by the low number of post-implantation reports of Hashimoto's Thyroiditis, while for the category of Constitutional the significance is driven by a decrease in Depression post-implantation.

The Sientra Study was not designed to evaluate the cause and effect associations because there is no comparison group of women without implants, and because other contributing factors, such as medications and lifestyle/exercise, were not studied. Therefore it cannot be determined whether or not these 2 increases (and 2 decreases) were due to the implants.

However, you should be aware that you may experience an increase in low back pain after receiving breast implants.

LACTATION COMPLICATIONS Lactation complications including difficulties with breast-feeding, breast infection (mastitis), and pain were examined in the Study.

There were 150 primary augmentation patients who delivered a baby after receiving their Sientra Implants. Of these patients, 89% reported no difficulties with breast-feeding. Eight percent (8%) reported difficulties related to breast-feeding only after receiving implants, including difficulty producing milk, breast infection, and/or breast pain.

There were 39 revision-augmentation patients who delivered a baby after receiving their Sientra Implants; 92% of these women reported no problems with breast-feeding. A total of 5% reported a lactation problem only after implantation, such as lack of milk production, breast infection, or pain, through 3 years.

REPRODUCTION COMPLICATIONS Reproduction complications that were examined in the Study include miscarriage, preterm labor (going into labor before a complete pregnancy), and having a stillborn baby.

Of the 1,115 patients in the primary augmentation cohort, 15 (1%) reported postoperative pregnancy difficulties through 3 years. Of the 362 patients in the revision-augmentation cohort, four (1%) reported postoperative pregnancy difficulties.

SUICIDE There were no reports of suicide in primary augmentation or revision-augmentation patients in the Study through 3 years.

9. What To Do If You Have A Problem

If you have a problem with your breast implant(s), tell your doctor about it immediately. Your doctor may need to examine you.

(Write your doctor's contact information here)

In addition to informing your doctor, you can report a problem to Sientra and/or to the U.S. Food and Drug Administration (FDA). Your doctor or other healthcare provider may do this or you may report it yourself.

You can report any serious problem directly to the FDA through its voluntary reporting program called MedWatch. (See <http://www.fda.gov/medwatch>). There is a special form you must use for voluntary reporting (FDA Form 3500). You can obtain it several ways:

- Complete Form 3500 and submit it online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>,
- Download Form 3500 from the website (<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>) and print it out, fill it in, and send it to FDA, or
- Call FDA to get a reporting package at 1-800-FDA-1088 (1-800-332-1088).

If you need to complete a Form 3500, FDA recommends that you take Form 3500 to your doctor, who can help you to complete it.

10. Where To Find More Information

Sientra has more information about its Silicone Gel Breast Implants that is available to you. You may request a copy of the package insert given to surgeons that describes how to use the Implant. It also discusses safety information and research performed on implants in general and on Sientra Silicone Gel Breast Implants in particular. Note that this document is intended only for surgeons, so it has a large amount of undefined medical and technical language.

You can find more detailed information on the studies (in animals and humans or other laboratory testing) done on these Implants in Sientra's Summary of Safety and Effectiveness Document (SSED) on the FDA's website at: <http://www.fda.gov/breastimplants>.

You can find these resources on Sientra's website at www.sientra.com or through Sientra Customer Service (888) 708-0808.

There are several other sources of information about breast implants and breast implant surgery.

The U.S. Food and Drug Administration (FDA) has published a breast implant complications booklet titled "Breast Implants: Local Complications and Adverse Outcomes." It contains descriptions of the risks of having breast implants (similar to this brochure) and links to more information. The booklet is available through the FDA website at: <http://www.fda.gov/breastimplants>.

Professional organizations for surgeons offer helpful information on their websites about making decisions about plastic/cosmetic surgery and about choosing a surgeon. You can find this information at the following websites:

The American Society for Aesthetic Plastic Surgery - <http://www.surgery.org>

American Society of Plastic Surgeons - <http://www.plasticsurgery.org>

In 2000, the Institute of Medicine (IOM) published a comprehensive review of studies that have looked at the safety of silicone gel breast implants. The report is available on the website <http://www.iom.edu/Reports/1999/Safety-of-Silicone-Breast-Implants.aspx>.

Patient groups offer support and information to women who have had problems with their breast implants. Several such websites are listed at: <http://www.fda.gov/breastimplants>.

11. Sientra's Implant Tracking Program

Each breast implant has a unique serial number that allows Sientra to identify the Implant(s) and locate important information about how and when they were manufactured. Sientra has developed an Implant tracking program to help facilitate contacting you with updated information if needed.

11.1 Breast Implant Tracking

At the time of your implant surgery, you will be asked to participate in Sientra's Implant tracking program. This will help to ensure that Sientra has a record of your contact information so that Sientra can contact you in the event there is updated information on your breast implant(s) that you need to know about.

Federal regulations require Sientra to track its Silicone Gel Breast Implants. Your surgeon will report the serial number(s) of your breast implants to Sientra, along with the date of your surgery, your personal contact information, and contact information about his or her practice. Sientra maintains this information in a confidential manner.

Participation in Sientra's Device Tracking program is mandatory in order to activate the product warranty.

Your doctor or his or her staff will fill out the Device Tracking and Limited Warranty Enrollment Form for you and return it to Sientra. A sample copy of the form is attached to this brochure. Sientra's warranty program is discussed in Section 13.

11.2 Device Identification Card

After your surgery, your surgeon will provide you a card that contains important information about your breast implants. This card will have the style, size, and serial number of your implants, along with other information. Carry the card with you and show it to doctors or other healthcare providers when you visit them. It will help them treat you appropriately and protect your implants during any medical treatment you need in the future.

If you have your implants replaced, you will get a new Device Identification Card for those implants.

Your doctor should keep a copy of the Device Identification Card with your medical records.

Please inform Sientra whenever your contact information, e.g., mailing address, email, etc., changes so that we may keep you up to date with important information about your breast implant(s).

12. Important Contact Information

Your Silicone Gel Breast Implants are manufactured for and sold by:

Sientra, Inc.

PO Box 1490, Santa Barbara, CA 93116-1490

U.S. Toll-Free Phone: (888) 708-0808

Phone: (805) 562-3500

Fax: (805) 562-8401

www.sientra.com

My surgeon's name and contact information:

13. Warranty Information

Sientra's Limited Warranty provides limited replacement and limited financial reimbursement in the event of shell leakage or breakage resulting in implant rupture. Sientra's standard Limited Warranty program applies to every Silicone Gel Breast Implant recipient who agrees to participate in the Device Tracking program. For more information, please contact Sientra's Customer Service at (888) 708-0808.

14. Acknowledgement Of Informed Decision

I understand that this patient brochure provided by Sientra is intended to provide information regarding the benefits and risks of silicone gel breast implants. I understand that some of this information is about breast implants in general and some is specific to Sientra's Implants. I understand that choosing to have augmentation breast surgery with implants involves both benefits and risks. I also understand that scientists and doctors have not been able to identify or quantify all of the risks of breast augmentation with implants and that, over time, additional information may become available.

I have had adequate time to review and understand the information in this brochure and my questions and concerns have been addressed by my doctor. I have considered alternatives to augmentation surgery, including the use of external prostheses or surgery with saline-filled breast implants, and I am choosing to proceed with silicone gel-filled breast implant surgery.

By circling my response for each statement below and signing below, I acknowledge that:

- Y N** I have had adequate time to read and fully understand the information in this brochure,
- Y N** I have had an opportunity to discuss this Information with my surgeon and to ask any questions I may have,
- Y N** I have carefully considered options other than augmentation surgery with breast implants and have decided to proceed with silicone breast implant surgery,
- Y N** I have been advised to wait an adequate amount of time after reviewing and considering this information before scheduling my silicone breast implant surgery,
- Y N** I understand that, in order to activate Sientra's Limited Warranty, I must participate in Sientra's Device Tracking program, and
- Y N** I will retain this brochure, and I am aware that I may also ask my surgeon for a copy of this signed acknowledgement.

Patient Name (Printed)

Patient Signature*

Date

* A patient must be at least 22 years old for primary and revision breast augmentation with silicone breast implants.

By my signature below, I acknowledge that:

- My patient has been given an opportunity to ask any and all questions related to this brochure, or any other issues of concern;
- All questions outlined above have been answered "Yes" by my patient;
- My patient has had an adequate amount of time before making her final decision, unless an earlier surgery was deemed medically necessary, and
- This *Acknowledgment of Informed Decision* will be retained in my patient's permanent record.

Implanting Surgeon Name (Printed)

Implanting Surgeon Signature

Date

15. Device Tracking And Limited Warranty Enrollment Form

sientra®

ENROLLMENT FORM SIENTRA SILICONE GEL BREAST IMPLANT DEVICE TRACKING AND LIMITED WARRANTY

PLEASE SEND FORM VIA EMAIL: ENROLLMENT@SIENTRA.COM or FAX: 888.906.0101

IMPORTANT

*Please Note: Patients must participate in Sientra's Device Tracking Program in order to activate the Sientra Product Warranty. Please complete section 2 of this form, all fields not marked optional must be completed for warranty activation.

1. DEVICE AND SURGERY INFORMATION

PATIENT'S LEFT SIDE Place LEFT Patient Record label here or write in below:		PATIENT'S RIGHT SIDE Place RIGHT Patient Record label here or write in below:	
REF #	SIZE / VOLUME	REF #	SIZE / VOLUME
[SN]		[SN]	
PRODUCT NAME		PRODUCT NAME	
REASON FOR SURGERY <input type="checkbox"/> AUGMENTATION <input type="checkbox"/> RECONSTRUCTION <input type="checkbox"/> REPLACEMENT		REASON FOR SURGERY <input type="checkbox"/> AUGMENTATION <input type="checkbox"/> RECONSTRUCTION <input type="checkbox"/> REPLACEMENT	
DATE OF IMPLANTATION (mm/dd/yyyy)		DATE OF IMPLANTATION (mm/dd/yyyy)	

2. PATIENT INFORMATION*

Patient Refused to Release Patient Identifying Information

(Non-Patient specific information must still be collected. All fields not marked optional must be complete.)

LAST NAME		FIRST NAME		M.I.
TELEPHONE	CELL PHONE (OPTIONAL)	FAX (OPTIONAL)	EMAIL (OPTIONAL)	
ADDRESS			DATE OF BIRTH (mm/dd/yyyy)	
CITY	STATE	ZIP CODE	COUNTRY	

3. IMPLANTING / EXPLANTING PHYSICIAN INFORMATION

LAST NAME		FIRST NAME		
TELEPHONE	FAX	EMAIL		
ADDRESS				
CITY	STATE	ZIP CODE		

4. FOLLOW-UP PHYSICIAN INFORMATION If different than above (e.g. primary care provider) N/A

LAST NAME		FIRST NAME		
TELEPHONE	FAX	EMAIL		
ADDRESS				
CITY	STATE	ZIP CODE		

FORM COMPLETED BY: _____	(SIGNATURE): _____
(DATE): _____ (TELEPHONE): _____ (FAX): _____ (EMAIL): _____	

MDC-0005 R1

16. Device Identification Card

SIENTRA DEVICE IDENTIFICATION AND LIMITED WARRANTY CARD
KEEP FOR YOUR RECORDS

PATIENT WARRANTY ENROLLMENT ACTIVATED

PATIENT NAME _____

DATE OF SURGERY _____

PHYSICIAN NAME _____

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LEFT SIDE

REFERENCE NUMBER _____ REF

SERIAL NUMBER _____ SN

IMPLANT SIZE _____

Smooth Round Augmentation
 Textured Round Reconstruction
 Textured Shaped Implant Replacement

RIGHT SIDE

REFERENCE NUMBER _____ REF

SERIAL NUMBER _____ SN

IMPLANT SIZE _____

Smooth Round Augmentation
 Textured Round Reconstruction
 Textured Shaped Implant Replacement

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 info@sientra.com
 sientra.com

DEVICE IDENTIFICATION AND LIMITED WARRANTY CARD

Plastic Surgeon and Staff: This enclosed card should be provided to the patient to retain for her records. Please follow the instructions below.

Remove the attached Device Identification Card and place the patient record labels (supplied with packaging) from each device used on the Device ID Card.

If the Patient Record Label is not available, please use a ball point pen to record the serial number and reference number from the package label.

Please complete the remaining fields prior to giving to the patient.

Completion and submission of the Device Tracking Form (supplied with packaging) is required to activate the patient's Product Warranty. Please check the box on the front of the card for the patient's records of warranty enrollment.

MDC-0008 R1

DEVICE ID CARD

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