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patient education brochure

BREAST AUGMENTATION
WITH SIENTRA OPUS
HIGH-STRENGTH COHESIVE
SILICONE GEL BREAST IMPLANTS

JAMIE, ACTUAL SIENTRA PATIENT

WARNING:

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

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GLOSSARY

Abdomen The part of the body between the upper chest (breasts) and the pelvis (hips); often called the stomach.

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.

Bilateral Relating to both the left and right side.

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 the 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 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).

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."

Breast Implant Any surgically implanted artificial device intended to replace missing breast tissue or to enhance a breast.

Breast Implant Associated-Anaplastic Large Cell Lymphoma (ALCL) BIA-ALCL is not breast cancer; it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system).

Breast Mass A lump in the breast.

Breast Reconstruction 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.

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 "r**evision-reconstruction**."

Calcification/ Calcium Deposits The process of a soft tissue hardening when the mineral calcium builds up in a certain place.

Capsular Contracture 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.

- Baker Grade I – Normally soft and natural appearance
- Baker Grade II – A little firm, but breast looks normal
- Baker Grade III – More firm than normal, and may look abnormal (change in shape)
- Baker Grade IV – Hard, obvious distortion, and tenderness with pain

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.

Continued Access Study A clinical study designed to obtain supplemental safety and effectiveness data for Sientra's Silicone Gel Breast Implants.

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.

Contralateral The opposite side of the body.

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 received 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.

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 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).

Lymphedema Lymphedema is a build-up of lymph fluid in the fatty tissues just under your skin. This build-up might also be called an obstruction and cause swelling and discomfort. It often happens in the arms or legs, but can also happen in the face, neck, trunk, abdomen (belly), and genitals.

Malposition When the implant is placed incorrectly during the initial surgery or when the implant has 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. There are different types of mammography including:

- Screening Mammography, conducted on women with no complaints or symptoms of breast cancer and
- Diagnostic Mammography, conducted in order to evaluate a breast complaint or suspected abnormality

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)	A radiographic technology that uses a magnetic field to create a 3-dimensional picture of a body part or organ. This imaging method currently has the best ability to detect rupture of silicone gel breast implants.
Necrosis	Death of cells or tissues.
Outpatient Surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight.
Palpability/Visibility	Palpability is when the implant can be felt with the hand 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; most silicone gel implant ruptures are silent. 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.
Unilateral	Affecting only one side of the body.
Vascular Tissue	Blood vessels (arteries and veins) that carry blood to the skin and tissues of the body and back to the heart.
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. A Patient Decision Checklist that highlights key information regarding risks of breast implant surgery is provided in Section 14 of this brochure, is located at Sientra's "Commitment to Safety" webpage (https://sientra.ca/commitment-to-safety/) and is also discussed further below. You should also be aware that there is a **Boxed Warning** for all breast implants. It is critical for you to understand these warnings. The **Boxed Warning** is located in Section 3.4 Warnings, of this brochure. Additional information regarding the risks listed in the **Boxed Warning** and other risks are discussed below in Section 4 *Risks Associated with Breast Implants*.

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 1,116 patients had primary-augmentation and 363 patients had revision-augmentation. Of the 225 patients who had primary-reconstruction, 152 patients were from the CORE study and 73 were from the Continued Access study. Of the 84 patients who had revision-reconstruction with Sientra OPUS High-Strength Cohesive Silicone Gel Breast Implants, 52 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. You can read about Sientra's CORE study and updates on the safety of it's implants that has been collected since FDA approval on Sientra's website at the "Commitment to Safety" webpage (https://sientra.ca/commitment-to-safety/).

After you receive this information, give yourself time to read and think about the information. Make sure you speak with your surgeon about your expectations of the results, as well as what you can expect regarding the length of the surgery, your recovery, and any risks and potential complications of the surgery. 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, before the surgery you will be asked to read, initial each section and sign a *Patient Decision Checklist.* that highlights key information regarding risks of breast implant surgery. The Checklist will help ensure that you have read and understood the information in this brochure and in the Boxed Warning, and that you have been informed of the benefits and risks of breast implants. Your surgeon will also sign this Checklist indicating that s/he has reviewed all of the information in this brochure with you and addressed all of your questions. There is a copy of the *Patient Decision Checklist.* at the end of this brochure in Section 14. Make sure all of your questions have been answered and you understand the information in this brochure, before you sign the *Patient Decision Checklist.*

2

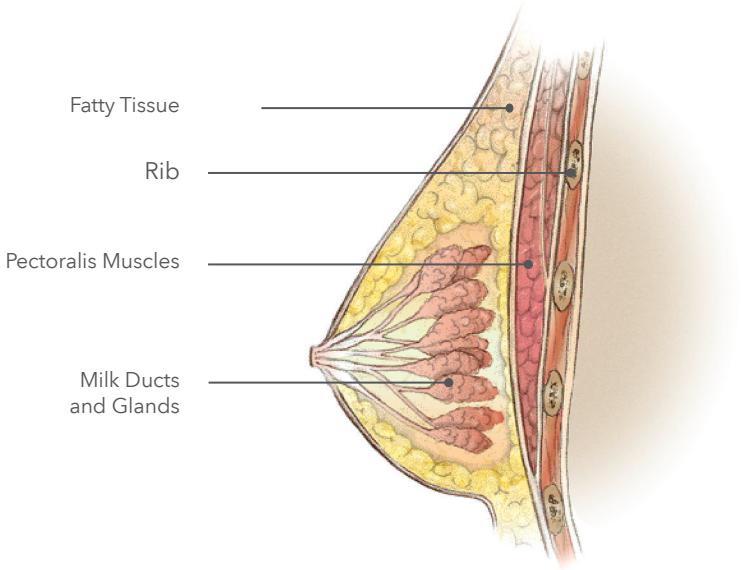
GENERAL INFORMATION ABOUT BREAST AUGMENTATION WITH BREAST IMPLANTS

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. You and your surgeon can choose the Sientra implant that best suits your individual needs. More information about the materials in Sientra's implants are presented in Table 1.

Table 1. Sientra Breast Implant Materials

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

The potential toxicity of chemicals and metals has been evaluated with both toxicity testing and risk assessments to assess the exposure levels, and were determined to be acceptable in comparison to the amount determined to likely be safe.

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), underneath part or all of the chest muscle (submuscular placement).

Factors such as pregnancy (when milk glands are temporarily enlarged), rapid weight loss, and the effects of gravity as you age combine to stretch the skin, which may cause the breast to droop or sag. However, it is important to realize that implants are used to make the breast larger. The implants alone may not adequately lift the breast, or correct the effects of pregnancy, weight loss, or skin stretching. Your surgeon may suggest additional procedures at the time of the breast augmentation, such as mastopexy, to help achieve improved breast lift.

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 OPUS High-Strength Cohesive 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

A precaution is information that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

The following are precautions; safety and effectiveness have not been established in patients with these conditions:

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

- An autoimmune disease (for example, lupus and scleroderma),
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease),
- Planned chemotherapy following breast implant placement,
- Planned radiation therapy to the breast following breast implant placement,
- History of radiation therapy to the breast
- Conditions or medications that interfere with wound healing and/or blood clotting,
- Reduced blood supply to breast tissue,
- Chemotherapy or radiation to the breast following implantation
- 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. Below is a Boxed Warning, followed by additional information regarding other warnings you should be aware of and understand before deciding to have reconstruction with breast implants.

3.5 BOXED WARNING

WARNING:

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

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. Because silent ruptures can occur and because they are difficult to detect, Health Canada and the Canadian Expert Advisory Panel on silicone gel-filled breast implants advocate the following approach to monitor patients with breast implants.

In consideration of all the available scientific information, it has been suggested that the process for determining implant integrity (e.g., rupture) should be related to clinical signs and symptoms. Thus, the following 6-step process is recommended when screening for silicone gel-filled breast implant rupture:

1. Patient self-examination
2. New Symptom or sign suspected;
3. Physician physical examination, related to a periodic review or new symptoms and signs, suggests findings that warrant further investigation;
4. Ultrasound, mammogram, or both of the implant and the breast involved should be acquired;
5. MRI if ultrasound is negative or inconclusive. The MRI should be performed at a center with a breast coil with a magnet of at least 1.5 Tesla. The MRI should be read by a radiologist who is familiar with looking for implant rupture; and
6. If signs of rupture are seen on MRI, then in consultation with the plastic surgeon, the implant(s) may be removed, with or without replacement.

- 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.

3.6 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.

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 2 presents the potential risks associated with breast implant surgery, the likelihood of the risks based on the results from Sientra's Clinical Study through 10 years, as well as the possible effects of the events for primary and revision-augmentation patients.

Table 2. Potential Risks Associated with Primary/Revision Breast Augmentation

Event	Likelihood of the Event Occurring in Primary Reconstruction Patients*	Likelihood of the Event Occurring in Revision Augmentation Patients*	Possible Resulting Effects of the Event
Key Risks			
Reoperation	24 out of 100 patients (24%)	39 out of 100 patients (39%)	• 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)	13 out of 100 patients (13%)	14 out of 100 patients (14%)	• Pain or Discomfort • Breast hardness/firmness • Reoperation • Implant removal
Implant Removal with Replacement	12 out of 100 patients (12%)	19 out of 100 patients (19%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Rupture	9 out of 100 patients (9%)	7 out of 100 patients (7%)	• Implant removal • Pain or Discomfort • Silicone Migration • Change in Breast Shape/Size
Implant Removal without Replacement	5 out of 100 patients (5%)	9 out of 100 patients 9%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Other Risks Occurring in 1% or More of Patients			
Nipple Sensation Changes	6 out of 100 patients (6%)	5 out of 100 patients 5%)	• Increased or decreased nipple sensitivity • Breast-feeding difficulties • May affect sexual response
Ptosis	5 out of 100 patients (5%)	3 out of 100 patients (3%)	• Undesirable cosmetic result • Wrinkling/rippling • Reoperation • Implant removal
Breast Mass/ Cyst/Lump	4 out of 100 patients (4%)	4 out of 100 patients (4%)	• Pain or Discomfort • Reoperation or other procedures
Implant Malposition	3 out of 100 pa-tients (3%)	5 out of 100 patients (5%)	• Implant Visibility • Asymmetry • Reoperation • Implant removal
Asymmetry	2 out of 100 patients (2%)	3 out of 100 patients (3%)	• Undesirable cosmetic result • Reoperation • Implant removal
Wrinkling/ Rippling	2 out of 100 patients (2%)	5 out of 100 patients (5%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal
Breast Pain	1 out of 100 patients (1%)	3 out of 100 patients (3%)	• Resulting effects are contingent on underlying cause(s)
Hyper-trophic/ Abnormal Scarring	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result • Pain or Discomfort
Seroma/ Fluid Accu-mulation	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Swelling • Pain or Discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Infection	Less than one out of 100 patients (0.9%)	2 out of 100 patients (2%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
Skin Sensation Changes	Less than one out of 100 patients (0.4%)	1 out of 100 patients (1%)	• Increased or decreased skin sensitivity • Discomfort

* Based on the results of Sientra's Clinical Study within the first 10 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 10 years after implant surgery was calculated. This risk is 40% for primary augmentation patients and 51% for revision-augmentation patients. This means that 40 out of 100 primary augmentation patients and 51 out of 100 revision-augmentation patients may experience a complication (of some kind) within 10 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 and creates a firm feeling, 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 13% risk of experiencing Baker Grade III or IV capsular contracture for primary augmentation patients through 10 years after receiving implants. For revision-augmentation patients, the risk is 14%. This means that 13 out of 100 primary augmentation patients and 14 out of 100 revision-augmentation patients may experience Baker Grade III or IV capsular contracture within 10 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 (2002) 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 (2001-2003,2005).[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 (2002-2003).[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 (2005).[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 (2001-2002)[2, 3] reported that women who had migrated silicone gel had a higher risk of getting a CTD. A small number of reports describe health effects in women with ruptured implants, however there was not enough information to determine if the implants were the cause (2014,2018).[7, 8] 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 (2000).[9] 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 10-year risk of reoperation is 24% for primary augmentation patients and 39% for revision-augmentation patients. This means that 24 out of 100 primary augmentation patients and 39 out of 100 revision-augmentation patients who receive Implants may have a reoperation within 10 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; breast implants are not lifetime devices. 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 10-year risk of implant removal (including removal with replacement for a size exchange) is 16% for primary augmentation patients and 26% for revision-augmentation patients. This means that 16 out of 100 primary augmentation patients and 26 out of 100 revision-augmentation patients who receive Silicone Gel Breast Implants may need to have one or both implant removed within 10 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 (2002,2006).[9, 10]

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" (2000).[9, 11]

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.

BENIGN BREAST DISEASE

Some women with breast implants have been reported to develop noncancerous breast tumors, though the frequency of this occurring may be less than with women who do not have breast implants (2015,2018).[12, 13]

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 (2009).[14] 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).

Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

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 through the end of 2020, 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 the time of the ten-year labeling, 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 (1999-2000,2005).[15-17]

BREAST CANCER

Patients with breast implants do not seem to have greater risk of developing breast cancer. (2000-2004, 2006-2007) [18-32] 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 (2000,2002,2004,2006,2019).[21, 29, 33-36]

BRAIN CANCER

Most studies, (2000,2002,2006-2007,2009,2012,2017) of brain cancer in women with silicone gel breast implants have found no increased risk.[20, 22, 24, 27-30, 32, 37] One study, (2001) reported a higher rate of brain cancer in women with breast implants, compared to the general population.[19] 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 (2000,2002,

2006-2007,2009,2012) have found no increased risk of these cancers for women with silicone gel breast implants.[20, 22, 24, 27-30, 32] Breast Implants have been associated with the development of a cancer of the immune system called breast implant- associated anaplastic large cell lymphoma (BIA-ALCL).

BREAST IMPLANT ASSOCIATED-ANAPLASTIC LARGE CELL LYMPHOMA (BIA-ALCL)

Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined (2019).[38-40] Some patients have died from BIA-ALCL(2019).[41] BIA-ALCL is not breast cancer—it is a rare type of non-Hodgkin's lymphoma (2008)[42] (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases it can spread throughout the body (2016-2018).[43-45] In the cases that have spread beyond the scar tissue and fluid near the implant, rare cases of death have been reported.

Most patients were diagnosed with BIA-ALCL when they sought medical treatment for implant-related symptoms such as swelling, pain, lumps, or asymmetry that developed after their initial surgical sites were fully healed (2008- 2009,2011-2015,2017).[12, 46-64] In the cases known to United States Food and Drug Administration (as of August 20,2020 report), BIA-ALCL was diagnosed years after the breast implant was placed. The earliest report was less than a year after implant placement and the latest was 34 years after the implant surgery. About half the cases occurred within the first 8 years after implant. BIA-ALCL was most often diagnosed in women who had textured implants. The textured implant may have been placed at the most recent surgery or at any other prior breast implant operation.

If you develop swelling or pain around your breast implants, be sure to talk to your health care provider. Your health care provider should consider the possibility of BIA-ALCL if, after you have recovered from your breast implant operation, you later notice changes in the way your breast looks or feels – including swelling or pain around the implant. If your health care provider suspects BIA-ALCL, they will refer you to an appropriate specialist for evaluation which may involve obtaining fluid and tissue samples from around your breast implant.

If a diagnosis of BIA-ALCL is confirmed, the doctor will develop an individualized treatment plan for you. Because of the small number of cases worldwide and the variety of available treatment options, there is no single defined treatment. However, if you are diagnosed with BIA-ALCL, the United States National Comprehensive Cancer Network (NCCN) recommends removing the implant and the surrounding tissue (2021).[65]

If you have breast implants, you should monitor them and follow your routine medical care. You do not need to take any additional steps. It is not necessary to remove your breast implants if you have no symptoms and you have not been diagnosed with BIA-ALCL.

You or your doctor should report all confirmed cases of BIA-ALCL to Health Canada (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/medical-device.html). In some cases, Health Canada may contact you for additional information. Health Canada will keep the identities of the reporter and the patient confidential.

You may also visit Health Canada's Breast Implants website for additional information:
https://www.canada.ca/en/health-canada/services/drugs-medical-devices/breast-implants.html

For additional information on Health Canada's analysis and review of BIA-ALCL, please visit:
https://www.canada.ca/en/health-canada/services/drugs-medical-devices/breast-implants/risks.html#rare_risk

RESPIRATORY/LUNG CANCER

Several studies (2000,2002,2006-2007,2009,2012) have found that women with silicone gel breast implants are not at greater risk for lung cancer.[20, 22, 24, 27-30, 32] One study, (2001) found an increased risk of respiratory/lung cancer in women with breast implants [19] 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, (1997,2000,2003-2004) 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;[66-68] 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 (2000,2002,2006-2007,2009,2012,2017)[20, 22, 24, 27-30, 32, 37] found that women with silicone gel breast implants have no greater risk of these cancers than women without implants. One study (2001) reported an increased incidence of cervical/vulvar cancer in women with breast implants.[19]

OTHER CANCERS

Studies have examined other types of cancer including eye, skin, 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, (2000, 2001,2003-2004,2006-2007,2009,2012) show that women with silicone gel breast implants have no greater risk of these types of cancers compared to the general population.[4, 19, 20, 22, 24, 27, 28, 30, 32, 69]

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.

Some scientific evidence supports the conclusion that there is no increased risk of CTDs or autoimmune disorders for women with silicone gel breast implants (1996-2004,2007).[2, 3, 9, 69-82] Other research has identified that there may be an increased risk of developing CTDs or autoimmune disorders, but the studies did not have enough data to reach a definitive conclusion (2016,2019).[83, 84] 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 (1998,2000-2001,2011,2016-2017,2019).[9, 37, 83-88]

Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

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 (2000) 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.[89]

In addition, questions have been raised about whether silicone gel

breast implants could harm babies whose mothers had implants while pregnant. Two studies (2001-2002) in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery.[90, 91] A third study (2004) looked at low birth weight and did not find an elevated risk.[92]

Some studies looked at lactation in women with breast implants, the risk of lactation problems was found to be similar to what was reported in women who did not have implants (2009,2016,2019).[93-96]

One study looked that the rate of reproductive problems (including miscarriage) and found that the rate of problems to be lower before breast implantation than after breast implantation (2014).[48]

Overall, there is no evidence that shows that silicone gel breast implants have any harmful effects on the children of implanted women, (2000-2002, 2004,2006).[9, 10, 90-92]

MENTAL HEALTH DISORDERS

If you have any history of a mental health issue, for example, a clinical diagnosis of depression, body dysmorphic disorder or eating disorder, you should discuss this with your surgeon during your consultation visit(s). Based on your discussion with your surgeon and/or other physicians, it may be better for you to wait to schedule surgery until after the condition resolves.

SUICIDE

Some studies (2001, 2003-2007,2010,2016), 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.[19, 33, 97-105] One researcher (2003) [106] 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 (2004) 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.[97] This may be a contributing factor to the reported higher incidence of suicide in women with breast implants. A large recent study found the rate of suicide in women with breast implants was not significantly higher than general female population (2017).[37]

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 (2000) found that there is not enough reliable evidence that neurological problems may be caused by or associated with breast implants.[9] Other researchers have found more evidence that silicone gel breast implants do not cause neurological diseases or symptoms (2000,2001).[9, 23, 107] There is one published report (2000) of an increased risk of multiple sclerosis among women with silicone gel breast implants;[73] these researchers did not find any increased risk of other neurological symptoms. A recent large study of women who had breast implants did not find an increase in the rate of multiple sclerosis diagnoses in these women compared to the national normal average (2017).[37]

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 (2000,2003).[9, 108] 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 contracture (2000)[9] and lymphadenopathy (2005,2016).[5, 109] 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

(1987,1995,1999) have demonstrated that the low concentration of platinum contained in breast implants is in the zero oxidation (most biocompatible) state.[110-113]

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 (2011), 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.[114] 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. You should also consult with your doctor on the potential benefits associated with breast implants. Your doctor may be able to provide you with before-and-after photographs and patient testimonials during your consultation.

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. If you decide to have the surgery, before the surgery you will be asked to read, initial each section and sign a *Patient Decision Checklist* that highlights key information regarding risks of breast implant surgery. The Checklist says you have read and understood the information in this brochure and in the Boxed Warning and that you have been informed of the benefits and risks of breast implants. Your surgeon will also sign this Checklist indicating that s/he has reviewed all of the information in this brochure with you and addressed all of your questions. There is a copy of the *Patient Decision Checklist* at the end of this brochure in Section 14. Make sure all of your questions have been answered and you understand the information in this brochure, before you sign the *Patient Decision Checklist*.

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 surgical suite. 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

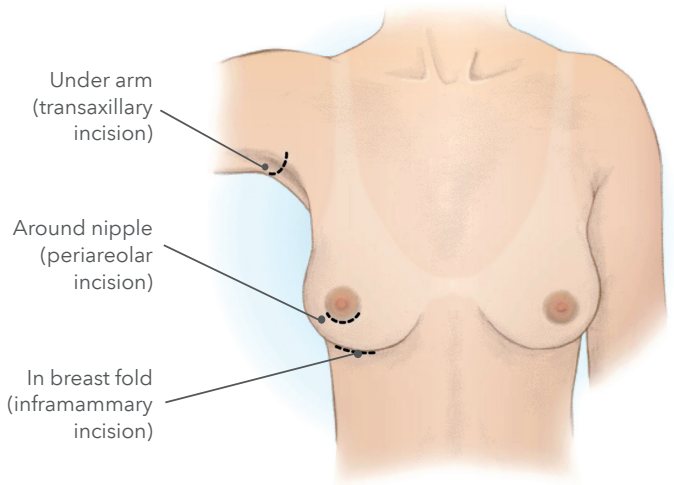
Breast implant surgery may be performed under general or local anesthesia. All anesthetics carry some risk. Discuss the risks and benefits of the anesthetic your surgeon and anesthetist recommend for you before the surgery.

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



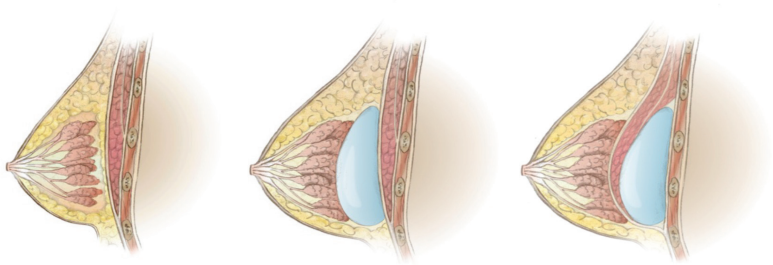
You may hear about a fourth incision site – the "periumbilical approach" (incision at your belly button). This way of placing breast implants has not been studied in the Clinical Study and should not be used. It may cause damage to the implant shell.

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) or on top of the muscle, under the skin, or under the breast gland. (Prepectoral 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
• 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 likely [9] • It may be easier to image breast with mammography • If you have thin or weakened breast tissue, submuscular positioning may work better	• 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 (2004-2005) [115, 116] • 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 OPUS High-Strength Cohesive Silicone Gel Breast Implants that are available.

Table 4. Sientra OPUS High-Strength Cohesive Silicone Gel Breast Implant Designs

Implant Shell Texture	Implant Shape	Implant Profile	Volume Range
Smooth	Round	Low	80-800 cc
		Low Plus	80-440 cc
		Moderate	80-800 cc
		Moderate Plus	95-800 cc
		High	190-800 cc
		Extra High	190-510 cc

All round styles are available in Sientra's HSC or HSC+ Gel

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 and shape options and their potential risks/benefits will be discussed with your doctor during your consultation. Additionally, further detail regarding size and shape options can be found on Sientra's website at http://sientra.ca/breast-implants.

IMPLANT SIZE AND SHAPE

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 a smooth shell

Figure 4. Photographs of smooth Sientra implant styles

Smooth Round Implant

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.

Your surgeon may choose to use a surgical mesh or acellular dermal matrix (ADM) together with the Breast Implants as part of your breast augmentation. Use of ADM was not studied as part of Sientra's Core Clinical Study; the risks and adverse events are not known. Health Canada has not approved the use of ADM with breast implants.

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?
- 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, about postoperative pain management, 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 and possibly a special postoperative bra as directed by your surgeon 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.)

Your doctor may request a "diagnostic" mammogram instead of a "screening" mammogram because more pictures are taken for a diagnostic mammogram. Make sure you are scheduled for the right kind of procedure for your situation. 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 a biopsy is performed be sure to inform the medical professional that you have 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, which may include warmth and redness in breast, heat, drainage, or swelling around the area of the stitches or scar; other symptoms may include a fever, rash, nausea, fatigue, nipple discharge, and vomiting,
- Signs of capsular contracture, which may include breast pain, hardness, or abnormal shape of breast,
- The main symptoms of BIA-ALCL are persistent swelling, presence of a mass or pain in the area of the breast implant. These symptoms may occur well after the surgical incision has healed, often years after implant placement. These symptoms may occur well after the surgical incision has healed, often years after implant placement.
- 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.

For this reason it is strongly recommended that you have periodic imaging (e.g. MRI, ultrasound) of your silicone gel-filled breast implants to screen for implant rupture regardless of whether your implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on your medical history or circumstances (i.e., screening mammography for breast cancer).

Rupture of a silicone gel breast implant may be silent/asymptomatic (i.e., there are no symptoms experienced by the patient and no physical signs of changes with the implant) rather than symptomatic. Health Canada and the Canadian Expert Advisory Panel on silicone gel-filled breast implants advocate the following approach to monitor patients with breast implants.

In consideration of all the available scientific information, it has been suggested that the process for determining implant integrity (e.g., rupture) should be related to clinical signs and symptoms. Thus, the following 6-step process is recommended when screening for silicone gel-filled breast implant rupture:

1. Patient self-examination
2. New Symptom or sign suspected;
3. Physician physical examination, related to a periodic review or new symptoms and signs, suggests findings that warrant further investigation;
4. Ultrasound, mammogram, or both of the implant and the breast involved should be acquired;
5. MRI if ultrasound is negative or inconclusive. The MRI should be performed at a center with a breast coil with a magnet of at least 1.5 Tesla. The MRI should be read by a radiologist who is familiar with looking for implant rupture; and
6. If signs of rupture are seen on MRI, then in consultation with the plastic surgeon, the implant(s) may be removed, with or without replacement.

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, 10-year prospective, multicenter clinical study conducted to examine the safety and effectiveness of the Sientra OPUS High-Strength Cohesive 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 1,116 patients had primary augmentation and 363 patients had revision-augmentation. Of the 225 patients who had primary reconstruction, 152 patients were from the CORE study and 73 were from the Continued Access study. Of the 84 patients who had revision-reconstruction with Sientra OPUS High-Strength Cohesive Silicone Gel Breast Implants, 52 were from the CORE study and 32 were from the Continued Access study. Of these patients, 398 primary augmentation patients, 115 revision-augmentation patients, 48 primary reconstruction patients and 10 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 followed patients through 10 years after their breast implant surgery. Results provided here represent the complete 10- year study data. Clinical results include data collected through the database closing date of November 15, 2017. You should also ask your surgeon if he or she has received any updated clinical information.

Study strengths include the fact that the Study is a multicenter, prospective long-term (10-year) study with a large sample size and adequate statistical power to estimate important health-related outcomes. Patient follow-up met FDA requirements for a long-term study of 10 years. Further strengths include that safety outcomes were assessed and collected by surgeons during physical examination of their patients at follow-up office visits (rather than unconfirmed or indirect patient-reported outcomes). Another potential strength is the enrollment of a mix of Sientra's various Implant styles, which provides results for a variety of styles. However, because the enrollment was not separated to enroll these equally across the study (and not equally within each cohort), this may be a weakness since particular styles were enrolled at higher rates and associated with varying outcomes.

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

8.2 WHAT ARE THE 10-YEAR FOLLOW-UP RATES?

The Study enrolled 1,116 augmentation patients. Of the women expected to be seen at the 10-year follow-up visit, 67% were seen. The Study enrolled 363 revision-augmentation patients. Of the women expected to be seen at the 10-year follow-up visits, 62% were seen. All patients were expected to obtain MRI's at regular intervals. For

augmentation patients, at 10 years, 56.7% had an MRI. For revision-augmentation patients, at 10 years, 54.2% had an MRI. Since the overall rate includes both the MRI and non-MRI, the rate of MRI rupture for the MRI cohort may be underestimated. Tables 5 and 6, below present information on rupture rates for augmentation and revision augmentation study patients who had an MRI after being implanted, and how many of those patients had a confirmed rupture.

Table 5. Suspected or Confirmed vs Confirmed Kaplan-Meier Estimated Cumulative Incidence of Rupture Based on Last MRI Exam through 10 years - *Augmentation Patients*

MRI Cohort		Non-MRI Cohort	
Enrolled: 398 patients with 795 implants MRI Follow-up compliance at 10 years: 224/327 patients (68.5%)		Enrolled: 718 patients with 1435 implants MRI Follow-up compliance at 10 years: 261/529 patients (49.3%)	
Suspected or Confirmed	***Kaplan-Meier estimated rate (95% Confidence Interval)***	***Suspected or Confirmed***	***Kaplan-Meier estimated rate (95% Confidence Interval)***
26 patients	8.5% (5.8%, 12.4%)	16 patients	6.3% (3.9%, 10.1%)
28 implants	4.7% (3.2%, 6.7%)	17 implants	3.4% (2.1%, 5.4%)
Confirmed		***Confirmed***	
14 patients	4.8% (2.8%, 8.1%)	9 patients	3.6% (1.9%, 6.9%)
15 implants	2.5% (1.5%, 4.3%)	9 implants	1.8% (1.0%, 3.5%)

Table 6. Suspected or Confirmed vs Confirmed Kaplan-Meier Estimated Cumulative Incidence of Rupture Based on Last MRI Exam through 10 years - *Revision Augmentation Patients*

MRI Cohort		Non-MRI Cohort	
Enrolled: 115 patients with 230 implants MRI Follow-up compliance at 10 years: 71/94 patients (75.5%)		Enrolled: 248 patients with 495 implants MRI Follow-up compliance at 10 years: 71/168 patients (42.3%)	
Suspected or Confirmed	***Kaplan-Meier estimated rate (95% Confidence Interval)***	***Suspected or Confirmed***	***Kaplan-Meier estimated rate (95% Confidence Interval)***
6 patients	6.8% (3.1%, 14.7%)	3 patients	3.5% (1.1%, 10.4%)
7 implants	4.0% (1.9%, 8.2%)	4 implants	2.4% (0.9%, 6.4%)
Confirmed		***Confirmed***	
2 patients	2.5% (0.6%, 9.8%)	3 patients	3.6% (1.9%, 6.9%)
2 implants	1.3% (0.3%, 5.1%)	4 implants	1.8% (1.0%, 3.5%)

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

At 10 years, 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. Eighty-two percent (82%) 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 (1%) and some had no increase (5%). 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 at 10 years 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 after 10 years on most measures. Other findings of the Study showed that most of women felt their breast implants made them feel more feminine (89%) and more attractive (86%). In addition, the majority of women indicated that their breast implants made them feel better about themselves (77%) at 10 years.

REVISION-AUGMENTATION PATIENTS

At 10 years, 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 at 10 years 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 after 10 years on most measures. Another finding of the Study showed that most women agreed that at 10 years their breast implants make them feel more feminine (87%) and more attractive (83%). In addition, the majority of women indicated that their breast implants made them feel better about themselves (78%) at 10 years.

8.4 WHAT WERE THE 10-YEAR COMPLICATION RATES?

The safety of Sientra OPUS High-Strength Cohesive 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 10 years are presented in Table 7. The most common reported complication within the 10 years after augmentation surgery was reoperation (24% or approximately 24 out of 100).

Table 7. Complication Rates[1] Reported through 10 Years Primary Augmentation Patients (N=1,116 Patients)

Key Complications	Through 3 years	Through 6 years	Through 10 years
Reoperation	12.8%	17.9%	24.0%
Capsular Contracture (Baker Grade III/IV)	5.9%	9.7%	12.9%
Implant Removal with Replacement	4.4%	7.9%	12.2%
Implant Rupture (MRI cohort)[2]	0	4.2%	8.5%
Implant Removal without Replacement	1.3%	2.7%	4.7%
Other Complications Occurring in 1% or More of Patients[3]			
Nipple Sensation Changes	2.1%	4.0%	5.9%
Ptosis	1.6%	2.8%	4.6%
Breast Mass/Cyst/Lump	0.5%	2.2%	3.5%
Implant Malposition	1.4%	2.1%	2.7%
Asymmetry	1.0%	1.2%	2.0%
Wrinkling/Rippling	0.8%	1.2%	1.9%
Breast Pain	0.8%	0.8%	1.2%
Seroma/Fluid Accumulation	0.7%	0.8%	1.2%
Hypertrophic/Abnormal Scarring	0.7%	0.9%	1.0%

1. Rates are presented using Kaplan-Meier calculation methods which are the correct way to account for Study subject drop out over time.
2. No ruptures were reported in the non-MRI cohort.
3. The following complications were reported at a risk rate of less than 1%: bruising, delayed wound healing, hematoma, implant extrusion, implant visibility, infection, redness, seroma/fluid accumulation, skin sensation changes, swelling, upper pole fullness, and other complications

REVISION-AUGMENTATION

The complications observed in women who had revision-augmentation through 10 years are presented in Table 8. The most common reported complication within the first 10 years after revision-augmentation surgery was reoperation (39% or approximately 39 out of 100).

Table 8. Complication Rates[1] Reported through 10 Years Revision - Augmentation Patients (N=363 Patients)

Key Complications	Through 3 years	Through 6 years	Through 10 years
Reoperation	20.9%	30.6%	38.8%
Implant Removal with Replacement	8.6%	12.2%	18.7%
Capsular Contracture (Baker Grade III/IV)	6.2%	11.5%	13.7%
Implant Removal without Replacement	2.7%	5.6%	9.4%
Implant Rupture (MRI cohort)[2]	0%	2.9%	6.8%
Other Complications Occurring in 1% or More of Patients[3]			
Implant Malposition	3.3%	4.8%	4.8%
Wrinkling/Rippling	3.0%	4.0%	4.8%
Nipple Sensation Changes	1.8%	2.9%	4.7%
Breast mass/cyst/lump	0%	2.3%	3.7%
Ptosis	1.2%	3.4%	3.4%
Asymmetry	2.0%	2.7%	2.7%
Breast Pain	1.2%	1.5%	2.5%
Hypertrophic/Abnormal Scarring	1.2%	1.6%	1.6%
Seroma/Fluid Accumulation	1.2%	1.6%	1.6%
Infection	1.2%	1.5%	1.5%
Skin Sensation Changes	0.6%	1.0%	1.0%

1. Rates are presented using Kaplan-Meier calculation methods which are the correct way to account for Study subject drop out over time.
2. Implant rupture was reported at a risk rate of 3.5% in the non-MRI cohort.
3. The following complications were reported at a risk rate of less than 1%: bruising, delayed wound healing, hematoma, implant extrusion, implant palpability, implant visibility, irritation, necrosis, redness, 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, 21% of the patients had at least one reoperation through 10 years (a total of 291 reoperations performed in 236 patients). Table 9 provides the main reasons for reoperation in the augmentation cohort at 3, 6, and 10 years. The two most common reasons for reoperation through 10 years in these patients were capsular contracture and the patient requesting a change in the size or style of the implant. Table 10 provides the risk of capsular contracture at 2, 4, 6, 8, and 10 years.

Table 9, Main Reasons for Reoperation At Timepoints Through 10 Years Primary Augmentation Patients

Main Reasons* for Reoperation	Through 3 Years N= 165 Patients n (%)	Through 6 Years N= 229 Patients n (%)	Through 10 Years N= 291 Patients n (%)
Suspected Rupture	0 (0%)	12 (5.2%)	19 (6.5%)
Infection	6 (3.6%)	7 (3.1%)	7 (2.4%)
Capsular Contracture	40 (24.2%)	58 (25.3%)	72 (24.7%)
Healing Related			
Extrusion	0 (0%)	1 (0.4%)	1 (0.3%)
Necrosis	0 (0%)	0 (0%)	0 (0%)
Hematoma/Seroma	20 (12.1%)	21 (9.2%)	23 (7.9%)
Delayed Wound Healing	3 (1.8%)	3 (1.3%)	3 (1%)
Irritation/Inflammation	0 (0%)	0 (0%)	0 (0%)
Pain	1 (0.6%)	1 (0.4%)	1 (0.3%)
Cosmetic			
Malposition	17 (10.3%)	20 (8.7%)	20 (6.9%)
Upper Pole Fullness	1 (0.6%)	1 (0.4%)	1 (0.3%)
Wrinkling/Rippling	4 (2.4%)	4 (1.7%)	6 (2.1%)
Palpability/Visibility	0 (0%)	0 (0%)	1 (0.3%)
Asymmetry	5 (3%)	8 (3.5%)	10 (3.4%)
Ptosis	18 (10.9%)	23 (10%)	31 (10.7%)
Scarring/Hypertrophic Scarring	10 (6.1%)	10 (4.4%)	10 (3.4%)
Nipple Related	2 (1.2%)	3 (1.3%)	3 (1%)
Breast Cancer	3 (1.8%)	3 (1.3%)	5 (1.7%)
Mass/Lump/Cyst	4 (2.4%)	8 (3.5%)	9 (3.1%)
Skin Related	0 (0%)	0 (0%)	0 (0%)
Style/Size Change	29 (17.6%)	43 (18.8%)	60 (20.6%)
Trauma	0 (0%)	0 (0%)	0 (0%)
Unknown	2 (1.2%)	3 (1.3%)	9 (3.1%)

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

Table 10. Risk of Capsular Contracture III/IV at 2, 4, 6, 8 and 10 Year Timepoints Primary Augmentation, N=1,116

2 Year	4 Year	6 Year	8 Year	10 Year
3.5%	6.1%	9.9%	12.3%	14.6%

REVISION-AUGMENTATION

In the Study, 34% of the patients had at least one reoperation through 10 years (a total of 172 reoperations performed in 123 revision-augmentation patients). Table 11 provides the main reasons for reoperation in the revision-augmentation cohort at 3, 6, and 10 years. The two most common reasons for reoperation through 10 years were the patients desiring a change in the size or style of their implants and capsular contracture. Table 12 provides the risk of capsular contracture at 2, 4, 6, 8 and 10 years.

Table 11. Main Reasons for Reoperation At Timepoints Through 10 Years For Revision Augmentation Patients

Main Reasons* for Reoperation	Through 3 Years N= 99 Patients n (%)	Through 6 Years N= 140 Patients n (%)	Through 10 Years N= 172 Patients n (%)
Suspected Rupture	0 (0%)	1 (0.7%)	4 (2.3%)
Infection	3 (3%)	4 (2.9%)	4 (2.3%)
Capsular Contracture	15 (15.2%)	20 (14.3%)	28 (16.3%)
Healing Related			

Table 11. Main Reasons for Reoperation At Timepoints Through 10 Years For Revision Augmentation Patients (cont.)

Main Reasons* for Reoperation	Through 3 Years N= 99 Patients n (%)	Through 6 Years N= 140 Patients n (%)	Through 10 Years N= 172 Patients n (%)
Extrusion	1 (1%)	1 (0.7%)	1 (0.6%)
Necrosis	0 (0%)	1 (0.7%)	1 (0.6%)
Hematoma/Seroma	4 (4%)	5 (3.6%)	5 (2.9%)
Delayed Wound Healing	5 (5.1%)	5 (3.6%)	5 (2.9%)
Irritation/Inflammation	0 (0%)	0 (0%)	0 (0%)
Pain	2 (2%)	7 (5%)	11 (6.4%)
Cosmetic			
Malposition	2 (12.1%)	14 (10%)	14 (8.1%)
Upper Pole Fullness	0 (0%)	0 (0%)	0 (0%)
Wrinkling/Rippling	9 (9.1%)	11 (7.9%)	12 (7%)
Palpability/Visibility	1 (1%)	1 (0.7%)	1 (0.6%)
Asymmetry	7 (7.1%)	10 (7.1%)	11 (6.4%)
Ptosis	6 (6.1%)	13 (9.3%)	13 (7.6%)
Scarring/Hypertrophic Scarring	9 (9.1%)	10 (7.1%)	11 (6.4%)
Nipple Related	1 (1%)	1 (0.7%)	1 (0.6%)
Breast Cancer	2 (2%)	2 (1.4%)	4 (2.3%)
Mass/Lump/Cyst	1 (1%)	5 (3.6%)	7 (4.1%)
Skin Related	0 (0%)	0 (0%)	0 (0%)
Style/Size Change	16 (16.2%)	22 (15.7%)	30 (17.4%)
Trauma	0 (0%)	0 (0%)	0 (0%)
Other**	1 (1%)	1 (0.7%)	1 (0.6%)
Unknown	4 (4%)	6 (4.3%)	8 (4.7%)

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

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

Table 12. Risk of Capsular Contracture III/IV at 2, 4, 6, 8 and 10 Year Timepoints *Revision Augmentation, N=363*

2 Year	4 Year	6 Year	8 Year	10 Year
5.3%	6.7%	10.5%	12.2%	14.7%

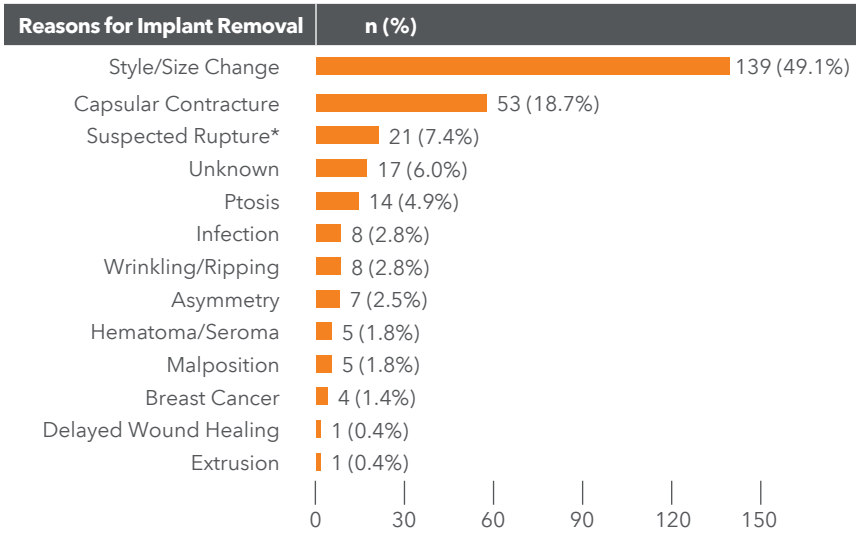
8.6 WHAT ARE THE MAIN REASONS FOR IMPLANT REMOVAL?

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, 14% of the patients had at least one removal (a total of 283 implants removed from these 151 patients). Of these 283 implants, 74% were replaced. As Figure 5 shows, the most common reason for implant removal was the patient requesting a different implant size or style.

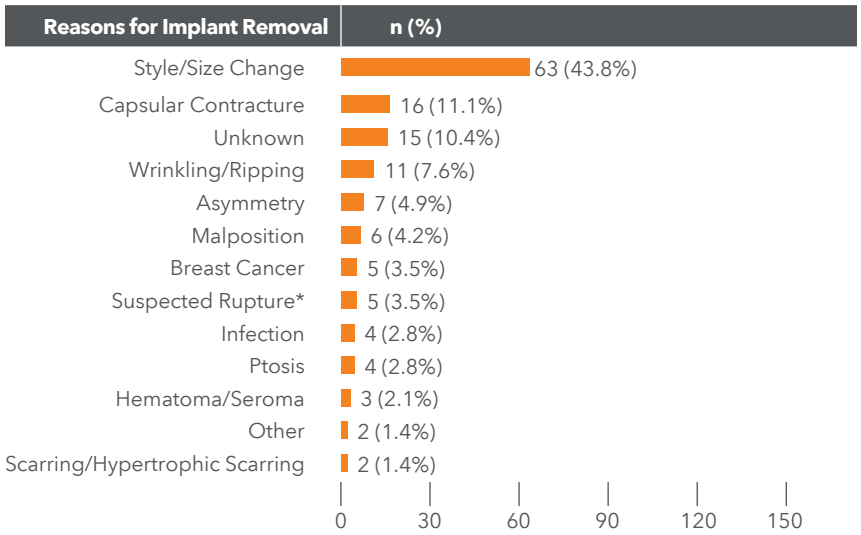
Figure 5. Main Reasons for Implant Removal through 10 Years Primary Augmentation (n= 283 implants)



REVISION-AUGMENTATION

In the Study, 22% of patients had at least one removal (a total of 144 implants removed from these 79 patients). Of these 144 implants, 69% were replaced. shows that 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 10 Years Revision-Augmentation (n= 144 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 398 primary augmentation patients enrolled in an MRI cohort study who have routine MRI screening of their implants to track rupture; Through 10 years, 93% of these patients (96% of implants) had no evidence of rupture. Through Year 10, there have been fifteen (15) confirmed implant ruptures occurring in fourteen (14) patients and thirteen (13) unconfirmed implant ruptures occurring in twelve (12) patients.

The 10-year risk of rupture was 9% per patient. This means that after receiving Silicone Gel Breast Implants, 9 out of 100 women may experience a rupture through 10 years.

There were 115 revision-augmentation patients enrolled in the MRI cohort who have routine MRI screening of their implants to track rupture. Through 10 years, 94% of these patients (96% of implants) had no evidence of rupture. Through Year 10, there have been five confirmed implant ruptures occurring in four patients and two unconfirmed implant ruptures occurring in two patients. The 10-year risk of rupture in the MRI cohort was 7% per patient. This means that 10 years after receiving Implants, 7 out of 100 women may experience a rupture through 10 years.

CANCER

Five primary augmentation patients reported breast cancer during the 10 year period following implantation (0.6%). Other types of cancers (including cervical, colon, lung, rectal, skin, and uterine cancer) occurred in 12 (1.1%) primary augmentation patients. There were 4 cases of fibrocystic disease (0.5%) in the primary augmentation cohort through 10 years. There were no reports of BIA-ALCL in any patient cohort in the Sientra Study.

Four revision-augmentation patients (1.6%) reported breast cancer. In addition, one patient (0.3%) reported lung cancer and three patients reported skin cancer (0.8%) in the revision-augmentation cohort through 10 years in the Study. There were five cases of fibrocystic disease in the revision-augmentation cohort through 10 years (1.8%).

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

CONNECTIVE TISSUE DISEASE (CTD)

Of the 1,116 primary augmentation patients in the Study, eleven primary augmentation patients were diagnosed with a CTD in the 10 years after receiving implants. The diagnoses were one patient each with chronic fatigue syndrome (diagnosed at 9 months after implantation), Grave's Disease (diagnosed at 4.1 years after implantation), lupus (diagnosed at 2.3 years after implantation) and Sjögren's Syndrome (diagnosed at 6.8 years after implantation, who also had a confirmed implant rupture); two patients each with fibromyalgia (9 months and 5.6 years after implantation) and Reynaud's phenomenon (9 months and 5.3 years after implantation) and four cases of rheumatoid arthritis (diagnosed between 2 months through 6.1 years after implantation). Based on these, the 10-year risk rate of chronic fatigue syndrome, Grave's disease, lupus and Sjögren's Syndrome are each 0.1% or less (or 1 in 1,000 patients), while the 10-year risk rate of fibromyalgia and Reynaud's

phenomenon is 0.2% (or 1 in 500 patients) and the 10-year risk rate of Rheumatoid Arthritis is 0.4% (or 4 in 1000 patients).

Of the 363 revision-augmentation patients in the Study, three revision augmentation patients were diagnosed with a CTD through 10 years, and none of these patients had a confirmed rupture. One patient was diagnosed with fibromyalgia (10 months after implantation), one patient was diagnosed with Grave's Disease (8.3 years after implantation) and one patient was diagnosed with scleroderma (9 years post implantation). Based on this, 0.3% (or 3 in 1,000 patients) of revision-augmentation patients may be diagnosed with fibromyalgia, and 0.5% (or 5 out 1000 patients) revision augmentation patients may be diagnosed with Grave's Disease or scleroderma within 10 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, compared to before having implants, no significant increases were found in any of the 13 CTD sign/symptom categories.

On the other hand, a significant decrease compared to before having implants was found for 3 of the 13 sign/symptom categories: Neurological, Endocrine/Exocrine and Vascular. For the category of Neurological, the significance is driven by the low number of post-implantation reports of migraine. In 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 Vascular the significance is driven by a decrease in Telangiectasia 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 3 decreases were due to the implants.

LACTATION COMPLICATIONS

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

There were 236 primary augmentation patients who delivered a baby after receiving their Sientra Implants. Of these patients, 85% reported no difficulties with breast feeding. Eleven percent (11%) reported difficulties related to breast feeding only after receiving implants, including difficulty producing milk, breast infection, and/or breast pain.

There were 47 revision-augmentation patients who delivered a baby after receiving their Sientra Implants; 85% of these women reported no problems with breast feeding. A total of 11% reported a lactation problem only after implantation, such as lack of milk production, breast infection, or pain, through 10 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 1,116 patients in the primary augmentation cohort, 19 (1.7%) reported postoperative pregnancy difficulties through 10 years. In addition, four women (0.4%) who had experienced preoperative pregnancy difficulties reported postoperative difficulties as well. Of the 363 patients in the revision-augmentation cohort, six (1.7%) reported postoperative pregnancy difficulties.

SUICIDE

There was one report of suicide in primary augmentation cohort and no reports of suicide in the revision-augmentation cohort in the Study through 10 years.

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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 Health Canada. Your doctor or other healthcare provider may do this, or you may report it yourself.

You can report any serious problem directly to Health Canada through the following:

- a telephone call (1-800-267-9675),
- by mandatory medical device problem reporting form (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/medeff/report-declaration/md-mm_form-eng.pdf)
- or by using the following adverse reaction form: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/medical-device.html

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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 OPUS High-Strength Cohesive 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 Sientra's website at: http://www.sientra.ca or through Sientra Customer Service (1-888-478-5782).

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

Health Canada's breast implant website (https://www.canada.ca/en/health-canada/services/drugs-medical-devices/breast-implants.html) has the latest resources for risks, reviews, evidence, list of current approved breast implants, and other resources to understand if breast implants are right for you.

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 Canadian Society for Aesthetic Plastic Surgery - https://csaps.ca/

Canadian Society of Plastic Surgeons - https://plasticsurgery.ca/

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 at: https://www.nap.edu/catalog/9602/safety-of-silicone-breast-implants.

Patient groups offer support and information to women who have had problems with their breast implants. Please find Canadian support groups at https://cbcn.ca/en/support_groups

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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.

United States 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).

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IMPORTANT CONTACT INFORMATION

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

Sientra, Inc.
3333 Michelson Drive, Suite 650, Irvine, California, 92612
United States of America

Canada Toll-Free Phone: (888) 478-5782
Phone: (805) 562-3500
Fax: (805) 562-8401
www.sientra.ca

My surgeon's name and contact information:

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WARRANTY INFORMATION

Sientra's Platinum20™ Limited Warranty and Lifetime Product Replacement Program provides limited replacement and limited financial reimbursement in the event of shell leakage or breakage resulting in implant rupture or complications of capsular contracture Baker Grade III/IV, double capsule, late forming seromas and BIA-ALCL. Sientra's Platinum20 Limited Warranty program applies to every Silicone Gel Breast Implant recipient who agrees to participate in the Device Tracking program. Further detail regarding Sientra's Platinum20 Limited Warranty may be found in The Sientra Limited Warranty and Lifetime Product Replacement Program brochure located in your Patient Information Kit. For more information, please contact Sientra's Customer Service at 1-(888) 478-5782 or visit Sientra's website at www.sientra.ca.

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PATIENT DECISION CHECKLIST

To the patient considering breast implants filled with saline or silicone gel intended for breast augmentation or breast reconstruction:

The review and understanding of this document are critical steps in making the decision whether you should choose breast implant surgery. You should learn about breast implants and then carefully consider the benefits and risks associated with breast implants and breast implant surgery before you make that decision. This form lists important risks, including those known or reported to be associated with the use of the device based on information from clinical trials, scientific literature, and reports from patients who have undergone device placement.

This patient decision checklist is intended to supplement the additional patient labeling that should be provided to you by your physician. You should receive a patient booklet/brochure that includes important information about your specific breast implant, as well as a boxed warning and patient decision checklist. After reviewing the information in the patient information booklet/brochure for the specific implant that will be used, please read and discuss the items in this checklist carefully in consultation with your physician. You should place your initials in the location provided next to each item to indicate that you have read and understood the item. Your full signature at the end of this document means that you have read the materials and that your physician has answered all questions to your satisfaction.

CONSIDERATIONS FOR A CANDIDATE FOR SUCCESSFUL BREAST IMPLANTATION

I understand that I am not a candidate for breast implants if any of the following situations applies to me:

- I have an active infection anywhere in my body;
- I have an existing cancer or pre-cancer of my breast tissue that has not been adequately treated; or
- I am pregnant or nursing.

I understand that if I have any of the following conditions, I may be at a higher risk for a poor surgical outcome:

- Medical condition that affects my body's ability to heal (e.g., diabetes, connective tissue disorder);
- Active smoker or a former smoker;
- Currently taking drugs that weaken the body's natural resistance to disease, such as steroids and chemotherapy drugs (e.g., prednisone, tacrolimus, sirolimus, mycophenolate, azathioprine, cyclosporine, methotrexate, chlorambucil, leflunomide, or cyclophosphamide);
- History of chemotherapy or planned chemotherapy following breast implant placement;
- History of radiation therapy or planned radiation following breast implant placement;
- Conditions that interfere with wound healing or blood clotting (e.g., hemophilia, von Willebrand disease, factor V Leiden, hyperhomocysteinemia, protein C deficiency, anti- thrombin III deficiency, or systemic lupus erythematosus); or
- Reduced blood supply to the breast tissue.

I understand the following conditions have not been adequately studied to determine whether the conditions put me at higher risk

- Autoimmune disease (e.g., Hashimoto's, Lupus, Rheumatoid Arthritis) or family history of autoimmune disease (breast implant premarket clinical studies have not evaluated the safety of breast implants in patients with autoimmune disease);
- Clinical diagnosis of depression or other mental health disorder (including body dysmorphic disorder or eating disorder); or
- Have other products permanently implanted in the breast.

Patient Initials: _____

RISKS OF BREAST IMPLANT SURGERY

I understand that there are risks[1] of undergoing breast implant surgery. I understand that risks of undergoing breast implant surgery may include:

- Capsular contracture Baker Grade III/IV (reported in up to 15.8% of patients)
- breast pain (reported in up to 4.5% of patients),
- skin or nipple areola sensitivity changes or loss (nipple sensation changes reported in up to 5.9% of patients; skin sensation changes reported in up to 1.0% of patients),
- asymmetry (reported in up to 16.9% of patients),
- impact of aging or weight change on size and shape of breast (ptosis reported in up to 4.6% of patients),
- infection requiring possible removal of implant (reported in up to 5.1% of patients),
- swelling (reported in up to 1.5% of patients),
- scarring (reported in up to 4.1% of patients),
- fluid collections (seroma) (reported in up to 3.6% of patients),
- hematoma (reported in up to 1.1% of patients),
- tissue death of breast skin or nipple (reported in up to 0.3% of patients),
- inability to breast feed (reported in up to 11.4% of patients),
- complications of anesthesia, (may occur but specific rates are not publicly available),
- bleeding (may occur but specific rates are not publicly available),
- chronic pain (may occur but specific rates are not publicly available),
- damage to surrounding tissue, such as muscle, nerves, and blood vessels (may occur but specific rates are not publicly available)
- impact on imaging of breast tissue (may occur but specific rates are not publicly available)

My physician has discussed these risks and has provided me with the patient information booklet/brochure (including the boxed warning) with information on the types of risks that are possible and expected rates of occurrence.

Patient Initials: _____

RISK OF CANCER - BREAST IMPLANT-ASSOCIATED ANAPLASTIC LARGE CELL LYMPHOMA (BIA-ALCL)

I understand that breast implants are associated with the development of a type of cancer of the immune system called Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Information regarding the number of medical device reports of BIA-ALCL can be found on Health Canada's website.[2]

I have received information regarding the overall incidence rates of BIA-ALCL and the rates as they pertain to my specific breast implant.[3]

I understand that the current literature reports various estimates for the incidence of BIA-ALCL. As of July 2019, these estimated rates range from a high of 1 in 3,817 patients to a low estimate of 1 in 30,000 patients.[43, 53, 117]

I understand that this cancer has been reported more frequently for textured breast implants, but that patients with smooth surfaced implants have also been diagnosed.

I understand that patients with breast implants have a risk of developing BIA-ALCL within the scar tissue and fluid surrounding the breast implant.

I understand that BIA-ALCL typically takes several years to develop after implantation, but cases have been reported as early as within one year.

1. Risk data include worst-case data for primary and revision reconstruction and augmentation patient cohorts per Sientra's CORE Study with 10 years of data

2. See " Breast Implant-associated anaplastic large cell lymphoma," available at https://www.canada.ca/en/health-canada/services/drugs-medical-devices/breast-implants/risks.html#rare_risk
3. See www.sientra.ca

Typical symptoms to be aware of include: swelling, breast tightness, pain, lumps, or swelling of the breast months or years after I receive my implants.

I understand that treatment for BIA-ALCL involves an operation to remove the implants and the surrounding scar tissue capsule. Based on the stage of the cancer at diagnosis, some patients have required chemotherapy or radiation. While BIA-ALCL typically responds well to therapy, some patients have died from BIA-ALCL. Diagnosis and treatment may be at my own expense and is not always covered by insurance.

Patient Initials: _____

SYSTEMIC SYMPTOMS

I understand that some patients who have received breast implants have reported a variety of systemic symptoms including joint pain, fatigue, rash, memory loss, and "brain fog" that some patients have called breast implant illness. While the causes of these symptoms are unclear, some patients have reported relief of these symptoms with removal of their implants and surrounding scar tissue capsule, however not all patients may experience improvement in their symptoms. Researchers are working to better understand the possible link between breast implants and these symptoms.

I also understand that some patients with breast implants have reported health problems in their children after birth or breastfeeding. While a causal link between breast implants and these reported health problems in children has not been demonstrated, more research is needed. I understand that breast implants and breast surgery may interfere with my ability to successfully breastfeed.

Patient Initials: _____

BREAST-IMPLANT SPECIFIC RISKS

I understand that a breast implant is NOT a lifetime device and the longer I have my implants, the more likely I am to experience a complication and the more likely I am to require a reoperation requiring the replacement or removal of my breast implant. As many as 39 percent of women who received Sientra Breast Implants for augmentation had their implants removed within 10 years, but my implants may last for a shorter or longer time (the percentage reported is from the 10-year Core study for Sientra breast implants. This rate specified represents the largest reported cumulative 10-year rate across all groups of augmentation patients in the study (both primary and revision).

I understand that my breast implant may rupture or leak at any time, and that the longer I have my implants, the more likely I am to experience a complication such as rupture. I understand that gel bleed (small quantities of chemicals diffusing from the implant shell) of silicone gel-filled implants may occur. I understand that if I have a saline-filled implant, my breast may deflate in appearance if there is a rupture or leakage of the saline.

I understand that if I have a silicone gel-filled breast implant, I or the physician may not be able to tell on physical exam whether my implant has ruptured or is leaking silicone gel. Because rupture or leakage of silicone gel-filled breast implants is difficult to detect, I understand that periodic imaging evaluation is recommended for screening of silicone gel-filled breast implant rupture. It is recommended that I have periodic imaging of my silicone gel-filled breast implants to screen for implant rupture regardless of whether my implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on my medical history or circumstances (i.e., screening mammography for breast cancer).

Even if I have no symptoms, I should have regular imaging evaluations as described in the "Recommended Follow-Up" section below. These imaging evaluations may not detect all ruptures or leaks, be costly, and the expense may not be covered by my medical insurance.

I understand that silicone can migrate from my implant into nearby tissues (e.g., chest wall, lymph nodes under the arm) and organs (e.g., liver, lungs) where it may not be possible to remove.

I understand that all breast implants can interfere with mammography and breast exams, which could delay the diagnosis of breast cancer. Mammography can also cause the breast implant to rupture or leak. I should tell the mammography technician if I have breast implants.

I understand that the long-term risks[4] of breast implants may include:

- painful or tightening of scar tissue (capsule) around my implant (capsular contracture) (capsular contracture III/IV reported in up to 15.8% of patients),

- rupture or leaking of the implant (reported in up to 16.5% of patients),
- wrinkling of the implant (reported in up to 4.8% of patients),
- visibility of the implant edges (reported in up to 1.0% of patients),
- shifting of the implant (implant malposition reported in up to 11.5% of patients), or
- reoperation (reported in up to 56.7% of patients).

I understand that I will receive a patient device card after my surgery that has information on each of my specific implants. I understand that it is important for me to keep each card in case I or my physician need to know what kind of implant I have many years later.

I understand that all breast implants contain chemicals and heavy metals. I understand that most of these chemicals stay inside the shell of the implant, but small quantities have been found to diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking. A list of the components, chemicals, and heavy metals is available in the patient information booklet/brochure.

Patient Initials: _____

RECOMMENDED FOLLOW-UP

Even if I have no symptoms, I understand that I should follow the 6-step process, recommended by Health Canada and the Canadian Expert Advisory Panel when screening for silicone gel-filled breast implant rupture as follows:

1. Patient self-examination
2. New Symptom or sign suspected;
3. Physician physical examination, related to a periodic review or new symptoms and signs, suggests findings that warrant further investigation;
4. Ultrasound, mammogram, or both of the implant and the breast involved should be acquired;
5. MRI if ultrasound is negative or inconclusive. The MRI should be performed at a center with a breast coil with a magnet of at least 1.5 Tesla. The MRI should be read by a radiologist who is familiar with looking for implant rupture; and
6. If signs of rupture are seen on MRI, then in consultation with the plastic surgeon, the implant(s) may be removed, with or without replacement.

I understand that I will need routine and regular follow-up with my physician as long as I have a breast implant for examination of my breast implant as well as to discuss any updates regarding breast implant issues.

Patient Initials: _____

QUESTIONS FOR MY PHYSICIAN

I have had the opportunity to ask my physician questions about his or her experience, medical degree, specialty of training, and credentials. I understand that breast implants have associated procedural risks and should only be used by physicians who are appropriately trained.

Patient Initials: _____

OPTIONS FOLLOWING MASTECTOMY

I understand that breast reconstruction is an elective procedure which I can choose to do or not.

I understand that I may choose not to have breast reconstruction ("going flat") and may choose to use an external prosthesis in my bra to look like I have a breast when wearing clothes.

I understand the surgical options for breast reconstruction, including the use of a breast implant and the use of my own tissue ("autologous reconstruction").

I understand that if my breast implants are ever removed, I may be left with dimpling, chest wall concavity, puckering, or sagging of my breasts or skin.

I understand that more surgeries may be necessary in the future due to complications or to remove or replace the breast implants.

I have discussed all of the options for breast reconstruction with my provider, including whether I am a candidate and the benefits and risks of each, and I believe that breast reconstruction with a breast implant is the best option for me.

Patient Initials: _____

BREAST AUGMENTATION OPTIONS

I understand that breast augmentation is an elective procedure to increase the size of my breasts.

I understand that breast augmentation may result in permanent changes to my breast tissue and if my implants are ever removed, I may be left with unsatisfactory appearance, changes to the size and shape of my breasts, including but not limited to dimpling, chest-wall concavity, puckering, sagging, or different incision size or location.

If I am an augmentation patient, any additional surgeries or medical procedures will likely be at my own expense.

Patient Initials: _____

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the patient information booklet/brochure for the specific implant that will be used during my surgery and that I have had time to discuss the information in it and on this document with my physician. I have had the opportunity to ask questions and understand the benefits and risks of breast implants for me, given my specific health conditions. I have considered alternatives to breast implants, including reconstruction without breast implants, no reconstruction/augmentation, and their benefits and risks.

_____

Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of breast implants as described elsewhere in the patient information booklet/brochure and in this checklist. I have also explained the benefits and risks of the alternatives. I have encouraged the patient to ask questions, and I have addressed all questions.

_____

Physician Signature and Date

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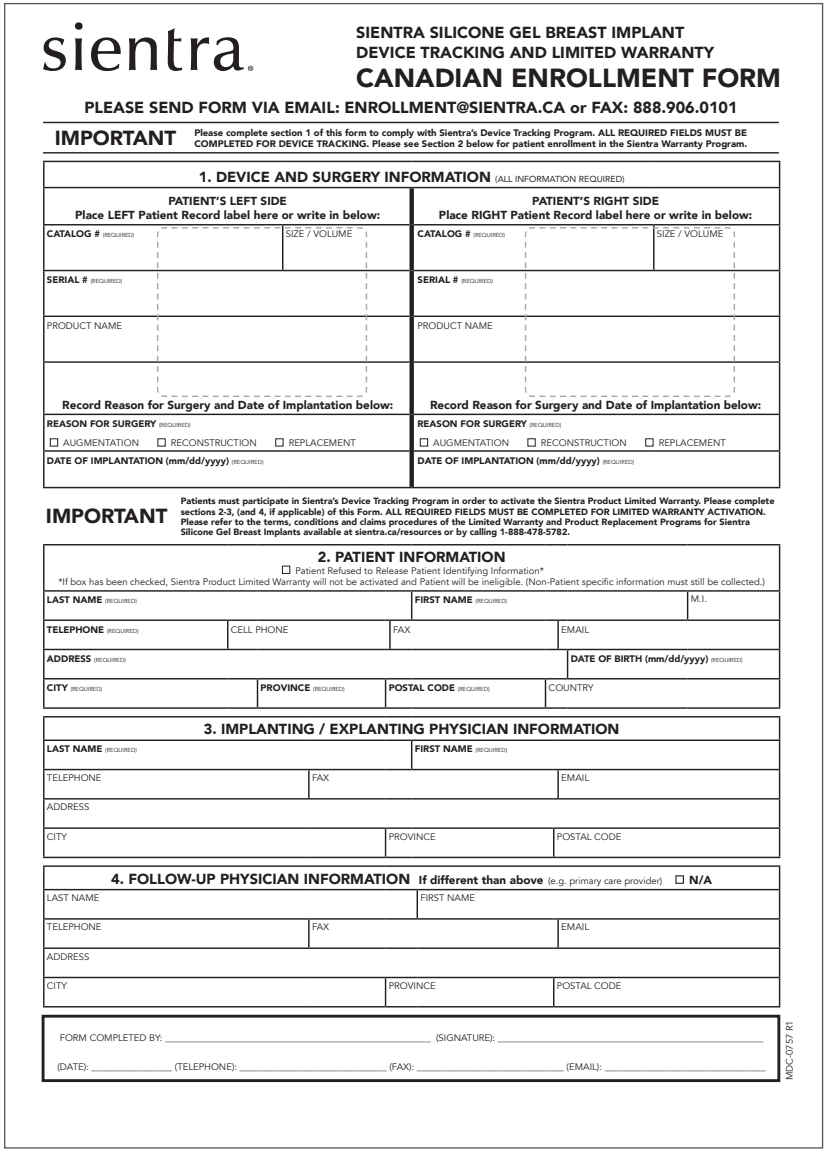
DEVICE TRACKING AND LIMITED WARRANTY ENROLLMENT FORM



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

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

IMPORTANT Please complete section 1 of this form to comply with Sientra's Device Tracking Program. ALL REQUIRED FIELDS MUST BE COMPLETED FOR DEVICE TRACKING. Please see Section 2 below for patient enrollment in the Sientra Warranty Program.

1. DEVICE AND SURGERY INFORMATION (ALL INFORMATION REQUIRED)

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:	
CATALOG # (REQUIRED)	SIZE / VOLUME	CATALOG # (REQUIRED)	SIZE / VOLUME
SERIAL # (REQUIRED)		SERIAL # (REQUIRED)	
PRODUCT NAME		PRODUCT NAME	
Record Reason for Surgery and Date of Implantation below:		Record Reason for Surgery and Date of Implantation below:	
REASON FOR SURGERY (REQUIRED) ☐ AUGMENTATION ☐ RECONSTRUCTION ☐ REPLACEMENT		REASON FOR SURGERY (REQUIRED) ☐ AUGMENTATION ☐ RECONSTRUCTION ☐ REPLACEMENT	
DATE OF IMPLANTATION (mm/dd/yyyy) (REQUIRED)		DATE OF IMPLANTATION (mm/dd/yyyy) (REQUIRED)	

IMPORTANT Patients must participate in Sientra's Device Tracking Program in order to activate the Sientra Product Limited Warranty. Please complete sections 2-3, (and 4, if applicable) of this Form. ALL REQUIRED FIELDS MUST BE COMPLETED FOR LIMITED WARRANTY ACTIVATION. Please refer to the terms, conditions and claims procedures of the Limited Warranty and Product Replacement Programs for Sientra Silicone Gel Breast Implants available at sientra.ca/resources or by calling 1-888-478-5782.

2. PATIENT INFORMATION

☐ Patient Refused to Release Patient Identifying Information*

*If box has been checked, Sientra Product Limited Warranty will not be activated and Patient will be ineligible. (Non-Patient specific information must still be collected.)

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

3. IMPLANTING / EXPLANTING PHYSICIAN INFORMATION

LAST NAME (REQUIRED)	FIRST NAME (REQUIRED)	
TELEPHONE	FAX	EMAIL
ADDRESS		
CITY	PROVINCE	POSTAL 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	PROVINCE	POSTAL CODE

FORM COMPLETED BY: _____ (SIGNATURE): _____

(DATE): _____ (TELEPHONE): _____ (FAX): _____ (EMAIL): _____

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DEVICE IDENTIFICATION CARD

DEVICE ID CARD

PATIENT DEVICE IDENTIFICATION AND LIMITED WARRANTY CARD

Plastic Surgeon and Staff: The attached Card should be provided to the patient to retain for her records. Please follow the instructions below.

Remove the attached Card and affix the applicable Patient Record Label (supplied with packaging) for each device used.

If the Patient Record Label is not available, please use a ballpoint pen to record the serial number, UDI number and catalogue number from the package label.

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

Completion and submission of the Device Tracking and Limited Warranty Enrollment 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 record of warranty enrollment activation.

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DEVICE IDENTIFICATION AND LIMITED WARRANTY CARD

PATIENT RECORD

PLEASE KEEP THIS WITH YOUR HEALTH CARE RECORDS.

When needed, present this Device ID card at your mammography centre.

☐ PATIENT LIMITED WARRANTY ENROLLMENT ACTIVATED

PATIENT NAME _____

DATE OF SURGERY _____

PHYSICIAN NAME _____

THIS CARD BELONGS TO THE PATIENT.
PLEASE GIVE IT TO THE PATIENT.

sientra. TOLL FREE: 888.478.5782
info@sientra.ca | sientra.ca

There is a boxed warning for breast implants, see web link. For more information about Sientra breast implant safety information, patient decision checklist, and labelling, including boxed warning please visit sientra.ca/commitment-to-safety

MDC-0754 R1

LEFT UDI

RIGHT UDI

LEFT SIDE

CATALOGUE NUMBER _____

SERIAL NUMBER _____

UNIQUE DEVICE IDENTIFIER (UDI) _____

DEVICE STYLE & SIZE _____

○ Smooth Round ☐ Augmentation ☐ Reconstruction ☐ Implant Replacement

PATIENT RECORD LABEL

RIGHT SIDE

CATALOGUE NUMBER _____

SERIAL NUMBER _____

UNIQUE DEVICE IDENTIFIER (UDI) _____

DEVICE STYLE & SIZE _____

○ Smooth Round ☐ Augmentation ☐ Reconstruction ☐ Implant Replacement

PATIENT RECORD LABEL

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IMPORTANT SAFETY INFORMATION

Sientra's Silicone Gel Breast Implants are indicated for breast augmentation in women at least 22 years old and for breast reconstruction. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of primary breast augmentation surgery. Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the results of a primary breast reconstruction surgery. Breast implant surgery is contraindicated in women with active infection anywhere in their bodies, with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions and, who are pregnant or nursing. Key complications include capsular contracture, implant removal, rupture and reoperation. For more detailed information about the risks and benefits of Sientra breast implants, please visit sientra.com/resources or call Sientra at 888.478.5782. Sientra breast implants with high-strength cohesive silicone gel are only available through board-certified or board-eligible plastic surgeons.

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