

Sientra  
Patient Planning  
Guide

Breast Augmentation

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This Guide is **not** intended to replace consultation with your surgeon. For a complete review of the benefits and risks of breast augmentation surgery please read the Sientra Patient Educational Brochure for *Breast Augmentation With Sientra Silicone Gel Breast Implants* included in this Patient Information Kit.

# Congratulations!

The fact that you're reading this means your surgeon has chosen or recommended Sientra implants for your breast augmentation surgery. For over 30 years, plastic surgeons worldwide have trusted the quality and safety of the Silimed® brand of breast implants. This portfolio of implants has enhanced the appearance of over 1.5 million women like you, across the globe.

The decision to have breast augmentation surgery is an important one. With this in mind, Sientra created a Patient Information Kit to help guide and support you along the way as you think through your decision to get breast implants. This Kit contains a series of four brochures, the first of which is the *Sientra Patient Planning Guide: Breast Augmentation*.

Also, enclosed in this Kit you'll find:

- *Sientra Silicone Gel Breast Implants: Quick Facts About Breast Augmentation and Reconstruction*
- Patient Educational Brochure: *Breast Augmentation With Sientra Silicone Gel Breast Implants*
- *The Sientra Limited Warranty and Lifetime Product Replacement Programs Brochure*

At Sientra, patient safety and satisfaction are paramount. We will be here with you every step of the way to provide the tools and information you need to make informed decisions about your breast augmentation surgery. Once you have thoroughly reviewed the detailed safety information in the patient brochures included in the Patient Information Kit, we encourage you to use the notes section of this Guide to write down any issues or questions you want to discuss with your plastic surgeon.

# Smart Choices, Beautiful Results

## **A THOUGHTFUL APPROACH TO BREAST AUGMENTATION**

So you're thinking about getting breast implants. Maybe you have a vision in mind of how you'd look with breast implants, and you've probably discussed the topic with a friend or family member. This is a great start. However, for the most successful experience, and to get the results you want, it's important to take the time to do some research and familiarize yourself with the entire process—from your first consultation with your plastic surgeon through post-surgery checkups—so you know exactly what to expect. Here are some tips to keep in mind.

## Consult a Plastic Surgeon

Your most important resource is your plastic surgeon. He or she can best explain the risks and benefits related to breast implant surgery and help you reach your aesthetic goals.

## Know Your Motivation

The most important consideration is your motivation for having the surgery. And regardless of your personal motivation, it's important that the decision for you to have breast augmentation is yours and no one else's. Some of the common reasons women consider breast augmentation are:

- To restore lost breast volume following breast-feeding or significant weight loss
- To make the breasts larger or more proportionate with the body
- To feel more attractive

## Have Realistic Expectations

You probably have an idea of the shape and size of the breasts you want. Your plastic surgeon will do his or her best to provide the results you desire while ensuring that your body type and your breast tissue allow for the procedure goals. Please make sure you have a detailed conversation with your plastic surgeon about your expectations and his or her recommendations.

The Safety  
of Silicone



## Part of Our Everyday Lives

The silicone in your implants is made from silicon, a natural element derived from the silica found in sand and rock. Silicone has proven to be an ideal material for use in medical devices due to its high degree of biocompatibility. Today, silicone is used in a wide array of medical devices including catheters, implants, and as the cover or sheath of probes and pacemakers.

Silicone is manufactured in various forms and has been used for over 60 years in everyday products. Some of the common uses of silicone include:



### **Baby Products**

Pacifiers and bottle nipples



### **Hair and Skin Care**

Shampoos, conditioners, hairspray, creams, and lotions



### **Makeup**

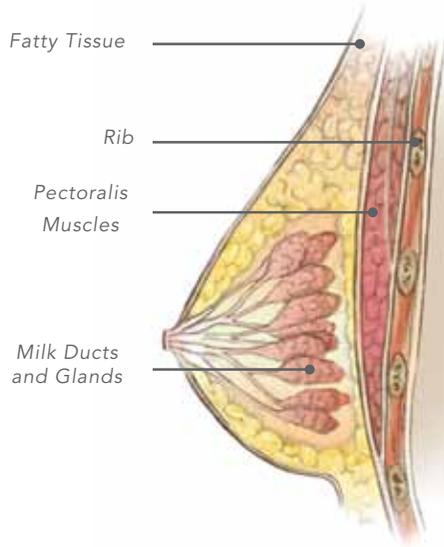
Foundation and lipstick



### **Medical Products**

Bandages and dressing, contact lenses, gastrointestinal medications, medical lubricant for needles and syringes, and various types of implants

Your breasts, located above your chest muscles (the pectoralis muscles), consist of milk ducts, glands, blood vessels, and nerves surrounded by fatty tissue.



# About Breasts

## Restoring Shape and Size

Your breasts, located above your chest muscles (the pectoralis muscles), consist of milk ducts, glands, blood vessels, and nerves surrounded by fatty tissue. The fatty tissue gives the breast its soft feel, while the glandular tissue is firmer.

For some women, breast tissue stretches over time, diminishing firmness and volume. This can result from pregnancy, nursing, or the natural aging process.

Some women experience no diminishment in firmness but simply want larger breasts.

# The Right Surgeon to Help Achieve Your Vision

## A Personal Relationship

The decision to get breast implants is a personal one; finding a plastic surgeon you feel comfortable with is important. He or she should have the expertise to help you realize your vision and to achieve the best results possible.

## Questions to Ask Your Plastic Surgeon

When it comes to choosing your plastic surgeon, you should learn as much as you can about his or her professional background and qualifications. Talking to more than

one surgeon can help you choose the one that best meets your needs. Below are some questions to help you get started.

1. Are you board certified (or board eligible) by the American Board of Plastic Surgery (ABPS)?

(You can research board membership at [www.abplsurg.org/](http://www.abplsurg.org/))

2. How many breast augmentation surgeries do you perform each year?
3. How many years have you been doing breast augmentation surgeries?



4. What is the most common complication you encounter with breast augmentation patients?
5. What is your reoperation rate for augmentation patients? And what is the most common reoperation you perform?
6. Do you have before-and-after photos of similar procedures that I can review?
7. Are you licensed to practice surgery in your state?

Your First  
Consultation



Before your plastic surgeon recommends an implant shape and size, he or she will take measurements and assess your skin and breast tissue characteristics to help determine the size, shape, and style of implants that are suitable for you.

### Your doctor will consider the following:

- The symmetry of your breasts—how they compare to each other and if there are any variations that you want to improve
- The width of your breasts in proportion to your chest wall
- The characteristics of your breast tissue—how much tissue do you have? How much stretch do you have in your breast tissue?
- Your goals and expectations for surgery
- The location of the incision and the implant placement

# A Shape for Every Silhouette

## INTRODUCING SIENTRA SILICONE GEL BREAST IMPLANTS

The hallmark of the Sientra portfolio of Silimed-brand breast implants is its worldwide heritage steeped in quality and safety. These implants have been available for nearly two decades, meeting the needs of over 1.5 million women worldwide. Known for their high-quality manufacturing according to exacting standards, Silimed has been an important partner in helping thousands of surgeons around the world address their patients' needs.

## Product Features

- Sientra's portfolio of Silicone Gel Breast Implants is FDA approved.
- Each implant is filled with medical grade, high-strength cohesive silicone gel.
- Sientra is the only company to imprint a unique serial number on each implant, indicating another level of quality and ensuring complete postoperative traceability.
- Controlled and predictable gel distribution to maintain the desired shape.



Implant serial number



Smooth surface



Textured surface

## Surface

Sientra offers implants with both smooth and textured shells. Your surgeon will discuss whether a smooth or textured implant is best suited to achieve your desired outcome.

## Volume

One of the dimensions of a breast implant is volume, which is measured in cubic centimeters (your surgeon may refer to it as cc's), not bra cup size. Determining the appropriate implant volume for your body is an important step in the process of choosing the correct implant. Sientra offers a wide range of volumes for you and your surgeon to discuss.

## Silicone Gel

All Sientra Silicone Gel Breast Implants are filled with a proprietary formulation of medical grade, high-strength silicone gel. This implant filler material is a cohesive gel that holds together uniformly.

## Shapes and Styles

Sientra offers a wide array of breast implant sizes and styles catering to women of all body types and sizes. Your surgeon will select the optimal shape and style of implant based on your individual body proportions and the look you want to achieve. Sientra offers four unique implant styles for your surgeon to choose from.

# The Sientra Choice

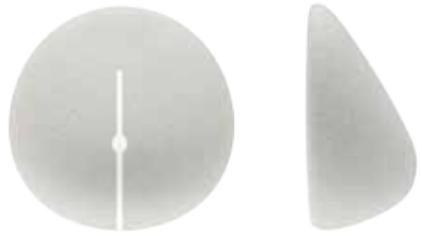
Round implants can provide fullness in the upper portion of the breast as well as across the width of the breast. They come in a variety of sizes, in both smooth and textured surfaces.

Shaped implants provide a different profile, featuring more fullness in the lower portion of the breast. Three styles of shaped implants are available depending on the proportions you and your surgeon

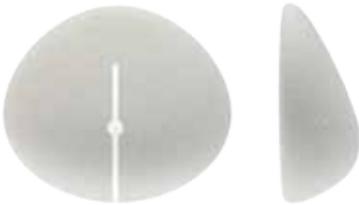
want to achieve. With the round base, height and width are equal to each other. With the oval base, width is larger than height. With the classic base, height is larger than width. All three styles of Sientra's shaped implants are available with a textured surface.



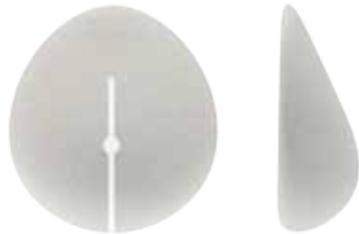
*Round, Round Base*



*Shaped, Round Base*



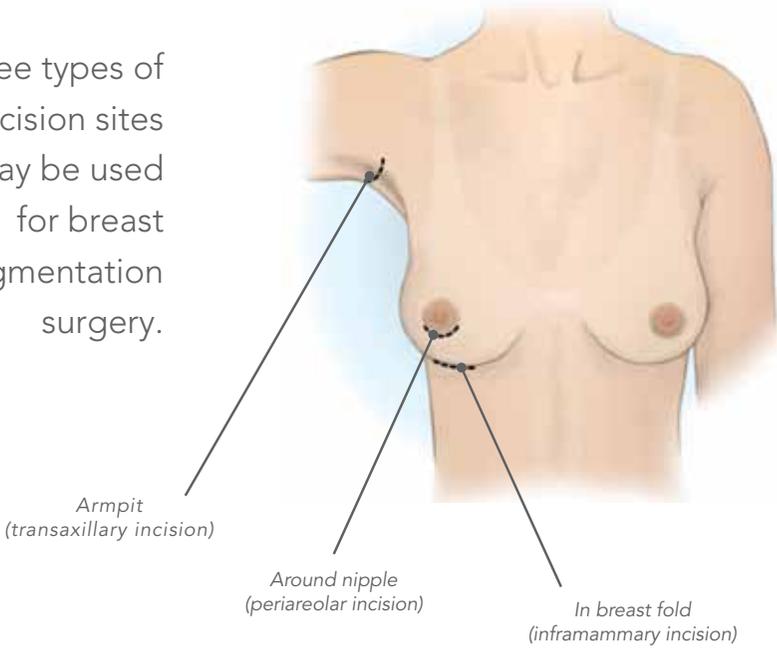
*Shaped, Oval Base*



*Shaped, Classic Base*

# Shaping Your Expectations

Three types of incision sites may be used for breast augmentation surgery.



## UNDERSTANDING THE PROCEDURE

Now that you're familiar with some of the planning that happens prior to breast augmentation surgery, it's time to find out what you can expect during the actual procedure.

### Surgical Setting

Breast augmentation surgery can be performed in a private surgery center, a clinic, a private surgical suite, or a hospital.

### Anesthesia

General or local anesthesia may be used for breast implant surgery. Discuss the risks and benefits of these choices with your surgeon before surgery.

## Incision Sites

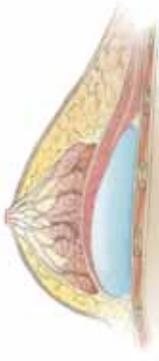
There are three types of incision sites that may be used for breast augmentation surgery. Your surgeon can explain each of the following in detail and tell you which of them he or she recommends for you:

- **Inframammary**  
An incision is made under your breast at the crease where it meets the body. Inframammary incision is the most common type of incision.
- **Periareolar**  
An incision is made around the nipple.
- **Transaxillary**  
An incision is made in the armpit.

# Placement Options



*Breast before augmentation*



*Breast after placement under the muscle (submuscular)*



*Breast after placement over the muscle (subglandular)*

## There are two options for implant placement:

- Under part or all of the chest muscle
- Above the chest muscle and below the breast glands

Your surgeon will select a placement site based on the characteristics of your breast tissue and whether there is appropriate tissue to cover the desired implant volume. If your surgeon hasn't already explained the advantages and disadvantages of each site, be sure to ask him or her.

## Comparison of Submuscular and Subglandular Placement of Breast Implants

Submuscular Placement	Subglandular Placement
Surgery time may be longer	Surgery time may be shorter
Recovery may be longer	Recovery time may be shorter
May be more painful	May be less painful
Future reoperation may be more difficult	Future reoperation may be easier
Implants may feel more like a natural part of the breast (be less "palpable")	Implants may be more palpable (can feel the implant through breast tissue)
Capsular contracture may be less likely	Capsular contracture may be more likely
It may be easier to image the breast with mammography	It may be harder to image the breast with mammography
If you have thin or weakened breast tissue, submuscular positioning may work better	

# Preoperative Checklist

The level of care needed in the first few days after surgery varies from patient to patient.

## A Few Days Prior to Surgery

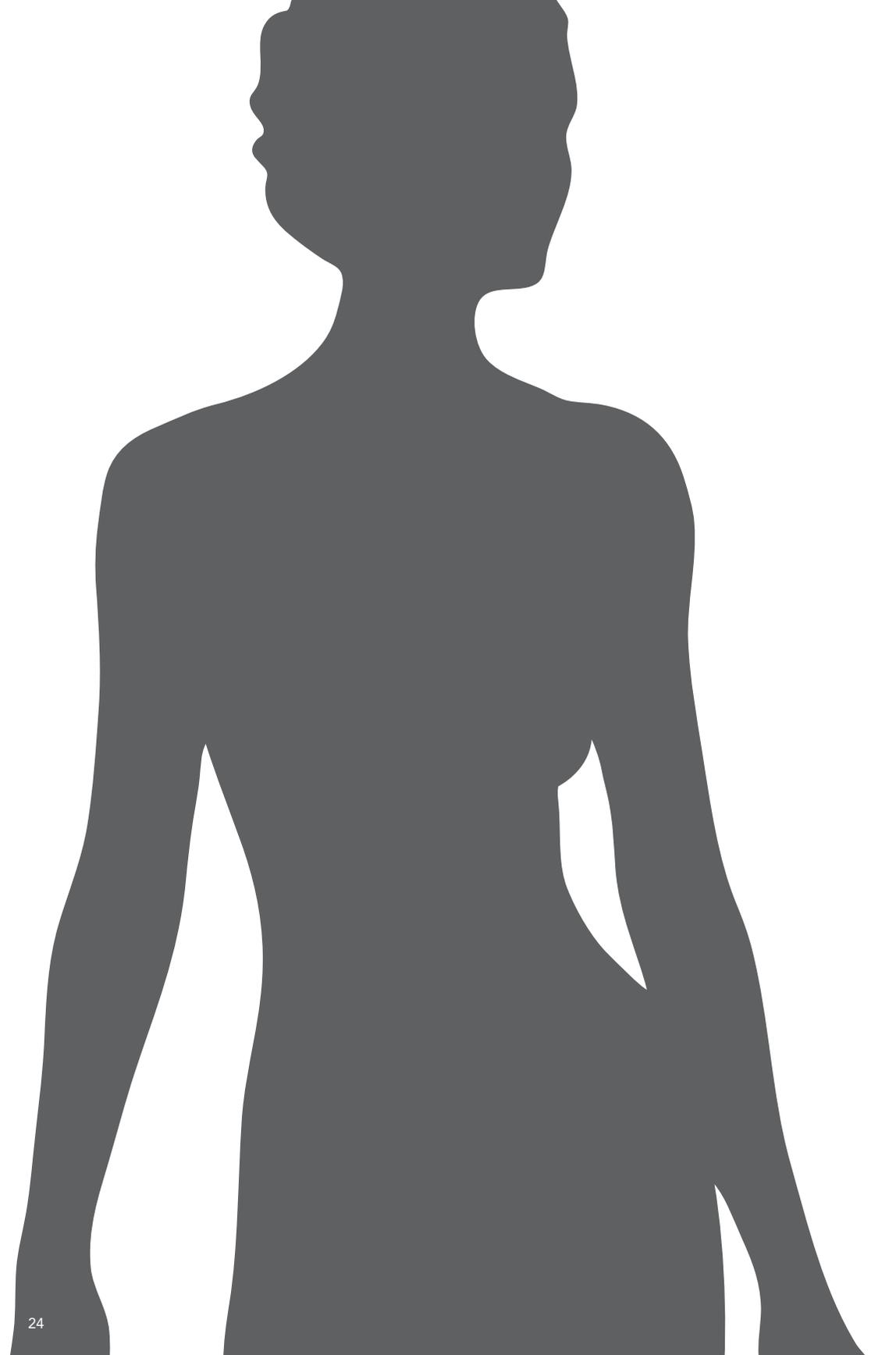
- Follow any pre-surgery instructions from your surgeon.
- Fill any prescriptions even if you won't need the medicine until after the procedure.
- Ask a friend or relative to take you to and from surgery, as well as help you for up to 48 hours following surgery. In the days following your surgery it is best to limit physical activity—particularly if it places any strain on your incision site.
- If you have young children, arrange for childcare for at least 2 days.
- Seek help with pet care, including walks and litter changes.
- Make sure you have the items that you may need for recovery as recommended by your surgeon.
- Make sure you have a supply of comfortable clothes and pajamas to wear in the days after surgery.

## The Day Before Surgery

- Remember to follow pre-surgery instructions provided by your surgeon regarding eating and drinking.
- Pick out some loose-fitting pants and a top that opens in front to wear after surgery.
- Prepare a relaxing environment for recovery by taking care of household chores like doing the dishes and taking out the trash.
- Your DVD player or DVR can be a great companion during recovery—set it up ahead of time with your favorite movies and TV shows.
- You may want to sleep on your couch or recliner for the first few nights following surgery. If so, make up your couch with sheets and a pillow before you leave home.
- Get plenty of rest before the big day!

## Before You Head Off to Surgery

- Follow your surgeon's preoperative instructions.
- Shower before your appointment.
- Do not wear makeup, hairspray, or deodorant.
- Wear comfortable clothes, including a shirt that opens in the front. You may also want to wear or bring warm socks for your comfort.
- Do not wear jewelry.
- Place your toiletries, such as your toothbrush, within easy reach.
- Bring lip balm or wax to moisturize dry lips.
- If you normally wear contact lenses, put on eyeglasses instead. Bring your contact lenses and eyeglass case with you if you feel you'll want your contact lenses after surgery.
- Confirm that someone is staying with you after the surgery if recommended by your surgeon.



# Postoperative Tips

- Have someone stay with you for the first 48 hours post-surgery.
- Drink plenty of water and other fluids. Drinking frequently will help replenish body fluids lost due to surgery.
- Wear whichever compression bra your surgeon has recommended.
- Focus on relaxing, especially your shoulders.

## Remember

At your first follow-up appointment, make sure that your surgeon has submitted your Device Tracking and Limited Warranty Enrollment Form to Sientra. You will receive a letter or email confirming your enrollment.

# Resuming Day-to-Day Activities

## CARING FOR YOURSELF AFTER SURGERY

Recovery time is different for each patient and also depends on the extent of the surgery. Your body will take several weeks or more to heal completely. Your surgeon will be able to tell you how to care for yourself and give you an idea of how long your recovery should take.

**Note:** *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.*

## The First Few Hours and Days

You'll spend your first few hours following surgery recovering in the surgery center or hospital.

Once settled at home, it is important to watch for signs of infection. These symptoms can include fever, chills, aches, nausea, vomiting, or breasts that are red, swollen, hot, painful, or draining white or yellow fluid (sometimes called "weeping"). Call your doctor immediately if you think you may have any of these symptoms or think 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.

## The First Few Weeks

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

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.

## The Months and Years After Surgery

After having breast augmentation surgery, it's important to stay aware of your body and your implants. Be sure to have regular breast exams and mammograms, and to monitor your breasts on an ongoing basis in the event that any changes occur.

## Scarring

Scars are part of any invasive surgery. Your surgeon will do his/her best to minimize scarring and to conceal any scars as much as possible. Advise your surgeon prior to surgery if, in the past, you have had a previous surgical incision or an injury that developed thick, raised, or red scars.

# Frequently Asked Questions

## How will my breasts feel after the surgery?

It is normal to feel some discomfort for a few days after surgery. Expect a softer, more comfortable result over time and continued improvement in the months to come.

## How long will my breast implants last?

Breast implants are not intended to be lifetime devices. For this reason, an annual clinical follow-up is recommended. There are a few techniques currently available for the evaluation of breast implant integrity. The FDA recommends magnetic resonance imaging (MRI).

## What warranties come with Sientra Silicone Gel Breast Implants?

Sientra has two complimentary programs:

Sientra's Limited Warranty Program provides up to \$3,600 in financial assistance for the costs of surgery necessary to replace a ruptured implant that is removed during the first 10 years following implantation.

Sientra's Lifetime Product Replacement Program provides no-charge replacement implants when needed due to rupture anytime during your life.

There are additional claim requirements and limitations in both Programs. To learn more about the Sientra Limited Warranty and Lifetime Product Replacement Programs, please refer to the Warranty Brochure in this Kit, and for a complete list of warranty terms and conditions please visit our website at [www.sientra.com](http://www.sientra.com).

## Do implants interfere with breast-feeding?

A 10-year, multicenter clinical study was conducted to examine the safety and effectiveness of the Sientra Silicone Gel Breast Implants in patients undergoing primary augmentation and revision-augmentation. Lactation complications including difficulties with breast-feeding, breast infection (mastitis), and pain were examined in the Study.

The majority of women who delivered a baby after receiving their Sientra Implants reported no difficulties with breast-feeding.

Please refer to your Patient Educational Brochure for details and results of the study.

## Will the implants interfere with mammography?

Implants may affect the quality of a mammogram. For this reason, you are advised to request the services of technologists who are familiar with mammography techniques for people with implants.

Don't forget to show your Sientra Device ID Card to the technologist.

Other methods such as ultrasound and magnetic resonance imaging (MRI) may be useful together with mammography because they do not require compression and allow examinations to be made from any angle. Please talk this through with your surgeon.

# Sientra Device Tracking

## Enrollment Is Effortless

At the time of your 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 information so that we can contact you in the event there is updated information on your breast implant(s) that you need to know about. You should know that each Sientra Silicone Gel Breast Implant has a unique serial number that allows us to identify the implant and locate important information. Sientra is the only breast implant manufacturer in the United States that offers this unique feature.



The image shows a sample of the Sientra Device Identification and Limited Warranty Card. The card is white with a grey vertical bar on the right side. The text on the card is as follows:

**SIENTRA DEVICE IDENTIFICATION AND LIMITED WARRANTY CARD**  
KEEP FOR YOUR RECORDS

PATIENT WARRANTY ENROLLMENT ACTIVATED

PATIENT NAME \_\_\_\_\_

DATE OF SURGERY \_\_\_\_\_

PHYSICIAN NAME \_\_\_\_\_

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## Device Identification Card

After your surgery, your surgeon will provide you with 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 may need in the future. If you ever 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 Note:** *Participation in Sientra's Device Tracking program is required to activate the Sientra Limited Warranty and Lifetime Product Replacement Programs. To learn more about these programs, please see the Warranty Brochure in your Patient Information Kit.*

## Sientra's Long-term Commitment to Patient Safety

In addition to our warranty and tracking programs, Sientra is conducting a 10-year post-approval study to assess the long-term safety of our Silicone Gel Breast Implants. Sientra's clinical study of safety and effectiveness of our breast implants in nearly 1,800 women is the largest pivotal breast-implant study ever done in the United States. Please refer to the Patient Educational Brochure for more information. These studies are intended to ensure that our implants continue to enjoy the worldwide reputation for quality, safety, and innovation that they have for the past two decades. Our commitment to patient safety is at the core of our guiding principles.



# Important Milestones on Your Journey With Sientra

## Pre-Surgery

- Read the information provided in this Patient Information Kit.
- Spend at least 1 to 2 weeks considering the benefits and risks of breast augmentation surgery with Sientra Silicone Gel Breast Implants.
- Sign the Acknowledgment of Informed Decision Form included in the Patient Educational Brochure (within this Kit) titled: *Breast Augmentation With Sientra Silicone Gel Breast Implants*.

## Post-Surgery

- Ensure that your plastic surgeon has given you the Device ID card. Keep this card with you as long as you have your implants.
- Make sure to verify that your plastic surgeon has completed and submitted the Device Tracking and Limited Warranty Enrollment form to Sientra. You will receive a letter or email from Sientra acknowledging that your Limited Warranty and Lifetime Product Replacement Programs are active.

# Additional Resources

Here are other resources that can provide more information about breast implants and breast implant surgery:

The American Society for Aesthetic Plastic Surgery® (ASAPS)  
<http://www.surgery.org>

American Society of Plastic Surgeons® (ASPS)  
<http://www.plasticsurgery.org>

The United States Food and Drug Administration (FDA)  
<http://www.fda.gov/breastimplants>

Institute of Medicine (IOM)  
<http://www.iom.edu/Reports/1999/Safety-of-Silicone-Breast-Implants.aspx>

### Let's Stay in Touch:

At Sientra we are committed to safety, quality and innovation—and we believe in continual improvement. If you have any feedback about our products or any aspect of your experience, please don't hesitate to call us at (888) 708-0808 or email us at [patientsvoice@sientra.com](mailto:patientsvoice@sientra.com).









