



MINELA

Student
Natrella® Style 15

Choices in Breast Augmentation

A GUIDE TO SURGICAL OPTIONS
AND THE NATRELLE® COLLECTION



Natrella



QUYNH


Lawyer, Mother of Two
Natalle® Style 15





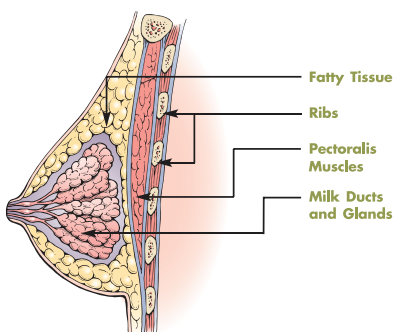
At Allergan,

we've been a leader in science and medical innovation for over 50 years — and a leader in breast aesthetics for over 25 years. Now we're pleased to introduce the *Natrelle*® Collection — a line of breast implants specially designed to enhance and complement your body's unique shape. As a global pioneer in breast aesthetics, we are committed to helping you make sense of the many implant choices, so you and your surgeon can find the right fit.



Your Breasts are Unique, and So are You

All breasts are made up of fatty tissue, glands, ducts and a thin layer of soft skin. The size and shape of your breasts reflect your individual body type. While some women are happy with their breasts, others are



dissatisfied. If you are one of these women, breast implant surgery is a consideration for you. Luckily, there have never been more breast implant

options to choose from — including the numerous options in the *Natrelle*® Collection — to help you find the fit you and your surgeon want.

Surgeons believe that to be a good candidate for breast implant surgery, you should:

Educate yourself

Many women begin by asking friends and family who have had breast implant surgery. Another excellent information source is the Internet. The most valuable resource, however, is your surgeon. Trust his or her expertise to help you understand the



risks and benefits associated with breast implants and surgery, as well as the limitations that may exist due to the characteristics of your breast tissue and body type. Respecting these limitations will help to ensure a safe and lasting result. Every woman wants to feel great about herself. And while there are many reasons to enhance the size or shape of your breasts, you must remember that no two people are exactly alike. The right fit is one that balances what you want with what your breast tissue will safely allow. This is your first step toward attaining the best possible result for you. Talk honestly with your surgeon about your expectations for surgery.

Do it for you

Your personal motivation for surgery is one of the most important considerations in your decision-making process. So spend some time evaluating why you believe surgery is right for you. Surgeons who use *Natrelle*[®] gel- or saline-filled breast implants will help you understand the process and what to expect from surgery. Once you've carefully considered all the factors and talked with your surgeon, you should be able to establish whether or not breast implantation is the right option for you to fulfill your goals.

How Can You Be Sure You'll Find the Right Fit?

Today, Allergan makes sure that women considering breast augmentation surgery have more options than ever before. While you were once limited to saline, you may now decide that teardrop shaped or round gel-filled breast implants are the best way to increase your breast size.

Everyone's body is different. Even the smallest differences are important when it comes to selecting the right kind of breast implant. Before your surgeon recommends an implant, he or she may perform a series of comprehensive measurements and evaluate your skin and breast tissue characteristics. These measurements play a key role in determining what kind of implants fit your unique shape.

Your surgeon may consider the following:

- The symmetry of your breasts
- The width of your breasts
- Your skin and breast tissue characteristics
- The location of the incision and the implant
- Your goals and desires for surgery

Careful preoperative planning is important because a breast implant that is too large for your tissue can result in excessive stretching of the skin and can contribute to the need for future corrective surgeries.



In addition, the implant edges may be apparent or visible under the skin. Also, excessively large breast implants may speed up the effects of gravity and result in earlier drooping or sagging. Once the breast tissue is damaged like this, your surgeon may not be able to reverse the damage. So, listen to your surgeon's advice and recommendations.

CASEY

Paralegal
Natrelle® Style 15





AMBER

Nurse
Natrellé® Style 68HP



The *Natrelle*[®] Collection

Find the fit that's right for you

When it comes to breast implants, you can never have too many choices. That's why the *Natrelle*[®] Collection has many variations of breast implants. With so many combinations of texture, volume and projection, the *Natrelle*[®] Collection makes it easier for your surgeon to find the right breast implant for your unique shape and body tissue.



Round gel

A round-shaped breast implant filled with a cohesive gel. Helps deliver your desired look with a soft feel.



Saline

A round-shaped breast implant filled with saline. Helps deliver your desired look with a small incision size.

A Closer Look at Silicone

What is silicone?

The gel implants in the *Natrelle*[®] Collection are filled with cohesive silicone. The saline- and gel-filled implant options also use a silicone outer shell. Silicone is made from silicon — a naturally occurring substance found in sand, quartz and rock — and it can be manufactured in a variety of forms. Silicone has been part of the consumer marketplace and has been shown to be biocompatible, reliable, flexible and easy to sterilize — making it an ideal choice for implantable and non-implantable medical devices.

Silicone can take many forms, from liquid to oil to a near-solid state. The graphic to the right shows the spectrum of silicone, and where the silicone in breast implants fits.

The safety of silicone

Over the past 25 years, silicone gel-filled breast implants have been used consistently in more than 60 countries. This includes the continuous use since 1992 for breast reconstruction surgery under clinical study protocols in the United States.



The history of silicone gel-filled breast implants

1970s — Present

Used extensively for breast augmentation and reconstruction in over 60 countries worldwide

1992

Moratorium in the U.S. on the use of silicone implants, pending further safety information



Natrelle

LIQUID	Hair spray
	Suntan lotion
	Moisturizing cream
	Cohesive breast implant filler
	Highly cohesive breast implant filler
	Shells of both saline and silicone breast implants
Catheters, baby pacifiers	
SOLID	Artificial joints

In 1992, the FDA called for a voluntary moratorium (delay) on the use of silicone gel-filled breast implants until new safety information could be thoroughly reviewed by the FDA’s advisory panel. In 1999, the FDA allowed the use of silicone gel-filled breast implants in Allergan’s Core Clinical Study to assess the safety and effectiveness of these devices, and based on new data, they were approved again in 2006. For more information, please refer to the Allergan Core Clinical Study section.

Silicone gel-filled breast implants are among the most studied medical devices. They are the subject of thousands of studies and published reports. As a leader in breast aesthetics, Allergan is committed to the long-term safety of our breast implants. For nearly 10 years, we have conducted ongoing studies of more than 50,000 women with breast implants.

1992

FDA lifts moratorium later that year and allows silicone implants to be used for reconstruction in clinical studies

1999

Breast augmentation and reconstruction clinical study by Allergan

2006

Based on new data, FDA approves silicone gel-filled breast implants for use in the U.S.

What Other Breast Implant Variables Should You Consider?

After talking to your surgeon about your preferred filler material, you'll want to discuss other variables such as implant size, shape, profile and shell type. He or she will consider your breast tissue characteristics and your desired outcome for surgery.

Implant size

Implant size should be a joint decision determined by you and your surgeon. It should be based as much as possible on your individual measurements rather than a specific cup size.

Selecting the proper implant width is critical to helping ensure your long-term satisfaction with your breast surgery. If the implant is too wide, it can place stress on your breast tissue, leading to complications. If the implant is too narrow, the cosmetic result may not meet your expectations.

It's important to recognize that bra cup sizes are not standard. Expressing your desired result in terms of cup size will help your surgeon to understand your expectations, but your implant size will ultimately be based on the measurements of your existing breasts, the characteristics of your skin and your body type.

Implant shape

The *Natrelle*[®] Collection offers a variety of implant styles of gel-filled and saline-filled breast implants. Choosing the implant shape that is right for your breast tissue will be a decision you will make with your surgeon. The right fit for you is a balance between what you want and your breast measurements and breast tissue characteristics.



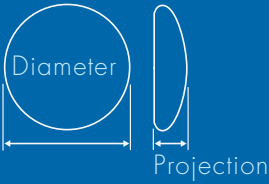
Round Implant Projection

The *Natrelle*[®] Collection of Breast Implants comes in a variety of projections:

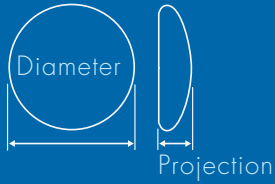
Gel

Saline

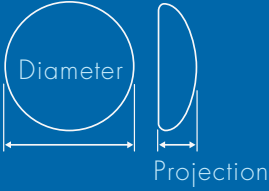
Moderate



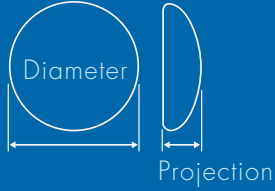
Low



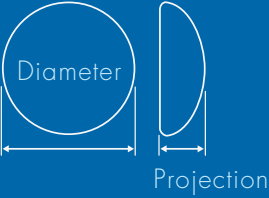
Moderate-Plus



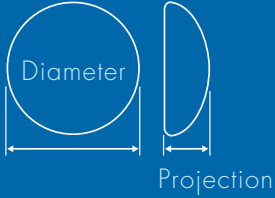
Moderate



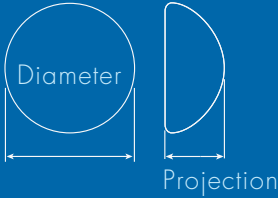
High



High



Extra-High



Implant shell surface

Implants can be either smooth or textured. Texturing is designed to help keep the implant from shifting in place. Your surgeon will determine whether this option is right for you.

How is the Placement of Your Breast Implants Determined?

Another factor to consider is where your breast implant will be placed. Implants can be placed either partially under the pectoralis major muscle (submuscular) or over the muscle and under the breast glands (subglandular). The decision depends on the thickness of your breast tissue and its ability to adequately cover the breast implant. You should discuss with your surgeon the pros and cons of the implant placement in order to obtain the result that is right for you.

How is the Incision Site for Your Breast Implants Determined?

There are three common incision sites: within the breast fold (inframammary), around the nipple (periareolar) or under the arm (transaxillary).

Inframammary

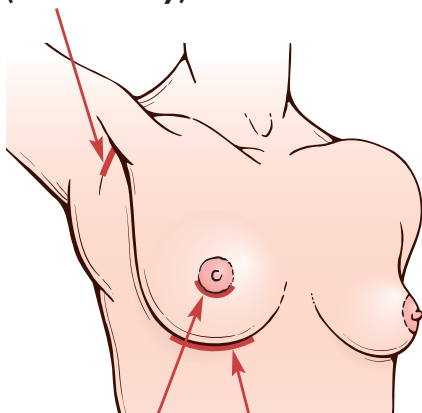
This incision is generally less concealed than the periareolar and associated with less difficulty than the periareolar incision site when breastfeeding.

Periareolar

This incision is typically more concealed than the other incisions, but is associated with a higher likelihood of an inability to successfully breastfeed.



Under arm (transaxillary) incision



Around nipple (periareolar) incision

In breast fold (inframammary) incision

Transaxillary

This incision is less concealed than the periareolar and is associated with less difficulty than the periareolar when breastfeeding.

Surgical setting and anesthesia

Surgery is usually performed on an outpatient basis, in either a hospital operating room, surgery center, or surgical suite in the surgeon's office. Surgery usually lasts one to two hours. General anesthesia is commonly used, but local anesthesia is also an option.

What About Recovery?

Learning what to expect during recovery can tell you a lot about your augmentation before you have it. Your experiences during recovery are directly affected by what happens during your surgery. Shorter recovery times are now more commonplace, thanks to advances in surgical techniques. For more information, talk with your surgeon.

The Allergan Core Clinical Study

At Allergan, we're committed to the long-term safety of our breast implants. So we've made significant investments in research and clinical studies.

Allergan's Core Clinical Study is a 10-year study of women who had breast augmentation, reconstruction or revision of a previous surgery between 1999 and 2000. Safety and effectiveness were evaluated through patient follow-up at zero to four weeks, 6 months, 12 months, 24 months, and annually through 10 years. Safety was assessed by complications, such as implant rupture, capsular contracture (tightening of the tissue capsule surrounding an implant) and reoperation. Benefit (effectiveness) was assessed by patient satisfaction and measures of body image/esteem and self-esteem.

The result: The FDA evaluated Allergan's Core Clinical Study data at four years for 715 women and determined that *Natrelle*[®] Silicone Gel-Filled Breast Implants are safe and effective for use in breast augmentation and breast reconstruction.



The Allergan Adjunct Clinical Study

Enrollment for the Allergan Adjunct Clinical Study was limited to reconstruction and revision surgery patients who met certain inclusion criteria. Between 1998 and 2006, when enrollment was closed, more than 80,000 breast implants were placed in over 50,000 women enrolled in the adjunct study. Safety data is collected at one, three and five years, and is used as supplemental data to support the safety of *Natrelle*[®] Silicone Gel-Filled Breast Implants.

While these studies collected information specific to *Natrelle*[®] Silicone Gel-Filled Breast Implants, the National Institutes of Health's Institute of Medicine (IOM) released a landmark 400-page report entitled "Safety of Silicone Breast Implants." This 1999 report on the safety of silicone concluded, "There is insufficient evidence to support an association of silicone breast implants with defined connective tissue disease." The IOM also stated, "There is no convincing evidence for atypical connective tissue disease or rheumatic disease or a novel constellation of signs and symptoms in women with silicone breast implants."



KATELYN

Mother of Four
Natrell[®] Style 20



Important Factors You Should Consider When Choosing Natrelle® Breast Implants

For many women, breast implant surgery brings great rewards, both physically and emotionally. However, it is important to consider the risks, as well as the benefits, before making your decision.

- Breast implants are not lifetime devices, and breast implantation is not necessarily a one-time surgery. You will likely need additional surgeries on your breasts due to complications or unacceptable cosmetic results.
- Many of the changes to your breasts following implantation are irreversible. If you later choose to have your implants removed and not replaced, you may experience unacceptable dimpling, puckering, wrinkling or other cosmetic changes of the breast, which may be permanent.
- Breast implants may affect your ability to breastfeed, either by reducing or eliminating milk production.
- Rupture of a silicone-filled breast implant is most often silent. This means that neither you nor your surgeon will know that your implants have a rupture. In fact, the ability of a plastic surgeon who is familiar with breast implants to detect a rupture through a physical examination is 30%, compared to the 89% ability of an MRI to detect a rupture. Therefore, you will need regular MRI screenings over your lifetime in order to determine if rupture is present. If implant rupture is noted on an MRI, you should have the implant removed, with or without replacement.

- The health consequences of a ruptured silicone gel-filled breast implant have not been fully established.
- With breast implants, routine screening mammography for breast cancer will be more difficult. The implant may interfere with breast cancer detection during mammography and because the breast and implant are squeezed during mammography, an implant may rupture during the procedure.
- You should perform self-examination of your breasts every month for cancer screening. However, this may be more difficult with implants. You should ask your surgeon to help you distinguish the implant from your breast tissue. The presence of lumps, persistent pain, swelling, hardening, or change in implant shape, may be signs of a rupture of the implant. These signs should be reported to your surgeon and possibly evaluated with an MRI.
- After undergoing breast implant surgery (either primary or revision), your health insurance premiums may increase, your insurance coverage may be dropped, and/or future coverage may be denied. Additionally, treatment of complications may not be covered.
- You should inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.
- It is important that you read the entire MAKING AN INFORMED DECISION ON SALINE-FILLED BREAST IMPLANT SURGERY or the entire IMPORTANT INFORMATION FOR WOMEN ABOUT BREAST AUGMENTATION WITH NATRELLE® SILICONE-FILLED BREAST IMPLANTS



because you need to understand the risks and benefits, and have realistic expectations for your surgery. You should wait at least 1-2 weeks after reviewing and considering the complete risk information, before deciding whether to have breast surgery, unless your surgeon finds it medically necessary to perform surgery sooner (as may be the case in a revision surgery).

Natrelle® Silicone Gel-Filled Breast Implants are Indicated for Females for the Following Uses:

- **Breast Augmentation.** Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.
- **Breast Reconstruction.** Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

NOTE: The FDA has determined that patients seeking breast augmentation with silicone-filled implants must be at least 22 years of age. Patients seeking breast augmentation with saline implants must be at least 18 years of age. There is no age restriction for reconstruction patients with either implant type.



CRYSTAL
Singer
Natrell® Style 20



Contraindications

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

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

Precautions

Safety and effectiveness have not been established in patients with the following:

- Autoimmune diseases (for example, lupus and scleroderma).
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease).
- Conditions that interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue.
- Radiation to the breast following implantation.
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders with your surgeon prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait for resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

Safety Data

Safety Outcomes of Natrelle® Silicone-Filled Breast Implants

The tables below provide a summary of the risk of occurrence of the most common complications.

PRIMARY AUGMENTATION/REVISION-AUGMENTATION Complications by Patient					
Primary Augmentation (N=455)			Revision-Augmentation (N=147)		
Complication	4 Year Rate	7 Year Rate	Complication	4 Year Rate	7 Year Rate
Reoperation	23.5%	30.1%	Reoperation	35.3%	40.5%
Capsular Contracture III/IV	13.2%	15.5%	Capsular Contracture III/IV	17.0%	20.4%
Breast Pain	8.2%	11.6%	Implant Removal with Replacement	10.5%	20.9%
Swelling	7.8%	9.2%	Swelling	6.4%	8.4%



ROSE

Actress, Mother
Natrelle® Style 363



Safety Outcomes of Natrelle® Saline-Filled Breast Implants

The tables below provide a summary of the risk of occurrence of the most common complications.

PRIMARY AUGMENTATION	
Complications by Patient (N=901)	
Complication	7 Year Rate
Reoperation	29.9%
Breast Pain	24.5%
Capsular Contracture III/IV	15.7%
Implant Removal	14.5%



Breast Augmentation with the *Natrelle*[®] Collection

Ask the right questions to find the fit that's right for you

Communicating to your surgeon your goals for breast implant surgery is one of the most important steps in getting the individualized aesthetic result that is right for you. Please consider the following important questions for discussion at your next consultation.

Is there a *Natrelle*[®] Collection option that's right for me? _____

What are my shape, size, shell surface, filler and placement options, and what are the differences between them? _____

How do I determine what's best for me? _____

What are the risks/complications associated with breast augmentation? _____





ERICA

Bookkeeper
Natalie® Style 20

What course of action can we take in the event that something unexpected does happen? _____

How will implants affect things like pregnancy, breastfeeding and mammograms? _____

Is there anything in my medical history that I should consider when contemplating surgery? _____

What can I expect on the day of my surgery? _____

What should I expect post-surgery? _____

How long before I'm back to my normal activities? _____



Allergan's Legacy of Innovation

Our commitment to science, safety and innovation is reflected in our entire portfolio of products and in the way we operate as a company. We reinvest 16% of all our sales directly into research and development. So today's products are helping support tomorrow's innovations.

Beyond dollars, we have also made significant investments in people and programs. For example, more than half of our employees hold positions that are dedicated to physicians or advancing innovation across our line of products. Our ALLERGAN ACADEMY™ is an unparalleled educational program that helps surgeons gain access to important clinical information about today's silicone gel-filled breast implants.

Allergan is committed to your safety and to helping you achieve the best possible result.

To learn more about breast augmentation surgery, or to locate a surgeon who can help you find your right fit, visit **Natrelle.com** or call **1-800-970-6967**.



We encourage you to seek out a surgeon who can best answer your questions before you make a decision.

Here are additional resources you can explore:

American Society of Plastic Surgeons

plasticsurgery.org

American Society for Aesthetic Plastic Surgery

surgery.org

Food and Drug Administration

fda.gov/cdrh/breastimplants

National Cancer Institute

[cancer.net.nci.nih.gov](https://cancer.net/nci.nih.gov)

Institute of Medicine Report on the Safety of Silicone Implants

nap.edu/catalog/9618.html

Important Information for Women about Breast Augmentation with *Natrelle*[®] Silicone Gel-Filled Breast Implants

natrelle.com/safety_information

Making an Informed Decision about Saline-Filled Breast Implant Surgery

natrelle.com/safety_information

What is silicone?

siliconesafety.com

Understanding Silicone Gel-Filled Breast Implants

breastimplantanswers.com



Natrella.com[®]

 **ALLERGAN**

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