

NATRELLE® 410
HIGHLY COHESIVE
ANATOMICALLY SHAPED
SILICONE-FILLED
BREAST IMPLANTS

Important Factors Breast Augmentation and
Reconstruction Patients Should Consider

Natrelle® **410**
SHAPED GEL

Natrelle®

Important Factors

Introduction

Allergan has prepared this brochure to provide you with a high level overview of the facts about breast implant surgery with Allergan's FDA-Approved *NATRELLE*[®] 410 Breast Implants. This brochure is **not** intended to replace consultation with your surgeon. For a complete review of the benefits and risks of breast implant surgery, please read the appropriate patient labeling piece, ***Breast Augmentation/Reconstruction with NATRELLE*[®] 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants**, available online at www.allergan.com/labeling/usa.htm. To help guide you, the locations of where you can find specific additional information in the patient labeling are provided throughout the brochure. A glossary of terms that you may be unfamiliar with is located at the end.

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 primary breast augmentation or reconstruction surgery. In the case of a revision surgery, however, your surgeon may find it medically necessary to perform surgery sooner.

If you wish to speak to an Allergan Breast Implant Support Specialist to inquire about breast implants, discuss any concerns, or request a copy of the patient labeling or physician Directions for Use, call toll free at 1.800.362.4426 (7 am to 5 pm Pacific Time).

Figure 1:

NATRELLE® 410 Breast Implant



Who may get NATRELLE® 410 Breast Implants (INDICATIONS)?

NATRELLE® 410 Breast Implants have been approved for women for the following uses (procedures):

- Breast augmentation for women at least 22 years old. 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 breast 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.

Who should NOT get Breast Implants (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

What types of conditions require more study (PRECAUTIONS)?

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

- 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)
- Planned chemotherapy following breast implant placement
- Planned radiation therapy to the breast following breast implant placement
- Conditions that interfere with wound healing and blood clotting
- Reduced blood supply to breast tissue



- 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.

What else should I consider (WARNINGS)?

The following are warnings associated with *NATRELLE*® 410 Breast Implants:

- 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. Therefore you will need regular MRI screenings over your lifetime in order to determine if rupture is present. You should have an MRI 3 years after your breast implant surgery and then every 2 years after that for as long as you have your breast implants. 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, a 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 changes 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.

What are some complications with NATRELLE® 410 Breast Implants (COMPLICATIONS)?

Undergoing any type of surgery involves risks. There are a number of local complications (problems at or near the breast/surgical incision site) that may occur after your breast implant surgery. The following sections present results from Allergan's two clinical studies on NATRELLE® 410 Breast Implants. The Pivotal Study is the clinical study for this product and included Styles FF, FM, MF, and MM. Allergan conducted an additional study, called 410XL-001, on Styles FX, MX, LX, LF, LM, LL, ML, and FL.

Please refer to the Glossary at the end of this brochure for the definition of terms and complications that you may not understand.

NATRELLE® 410 Pivotal Study

Tables 1 and 2 below present complication rates reported in the NATRELLE® 410 Pivotal Study through 10 years. Detailed information on complications reported in the Pivotal Study, including information on complications reported within the first 3, 5, 7, and 10 years after implant surgery, can be found online in the patient labeling, specifically in Sections 2.2 *What are the potential risks*, 5.1.4 *Allergan's Pivotal Study: What are the 10-Year Complication Rates*, and 5.1.7 *Allergan's Pivotal Study: What are Other Clinical Data Findings?*.

In the Pivotal Study, a group of patients had scheduled MRIs to look for rupture independent of whether or not they had any symptoms. These patients are called the MRI cohort. The remaining patients did not have scheduled MRIs to look for rupture. These patients are called the non-MRI cohort. (An MRI is a radiographic examination that currently has the best ability to detect rupture of silicone gel-filled breast implants).

One of the key complications reported is called "capsular contracture." Capsular contracture is a 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. This results in firmness or hardening of the breast, and it is a risk for implant rupture. Degrees of capsular contracture are classified by the Baker Grading Scale.¹ Capsular Contracture Baker Grades III and IV are the most severe. Baker Grade III often results in the need for additional surgery (reoperation) because of pain and possibly abnormal appearance. Baker Grade IV usually results in the need for reoperation because of pain and unacceptable appearance. Other reasons for reoperations are discussed in the online patient labeling in Section 5.1.5 *What are the main reasons for reoperation?*.

¹ Baker, J.L. Augmentation mammoplasty. In: Owsley, J.Q. and Peterson, R., Eds. *Symposium on aesthetic surgery of the breast*. St. Louis, MO: Mosby, 1978:256-263

Table 1: Key Complication Rates Reported through 10 Years

Complication		Primary Augmentation N=492	Revision-Augmentation N=156	Primary Reconstruction N=225	Revision-Reconstruction N=68
Any complication (including reoperation)		39.2%	57.4%	65.1%	70.6%
Key Complications					
Reoperation		29.7%	47.3%	54.6%	48.5%
Implant removal with replacement		16.8%	27.8%	34.3%	39.3%
Implant removal without replacement		3.3%	5.9%	6.7%	4.9%
Implant rupture	MRI cohort	17.7%	14.7%	12.4%	19.6%
	Non-MRI cohort	14.8%	19.8%	10.1%	5.0%
Capsular contracture (Baker Grade III/IV)		9.2%	11.9%	14.5%	26.8%

Table 2: Other Complication Rates Reported through 10 Years

Complication ^{a,b,c}	Primary Augmentation N=492	Revision-Augmentation N=156	Primary Reconstruction N=225	Revision-Reconstruction N=68
Asymmetry	1.2%	6.9%	12.4%	17.4%
Breast Pain	4.5%	5.2%	8.2%	7.8%
Bruising	<1%	<1%	0%	1.5%
Breast/skin sensation changes	1.5%	0%	0%	0%
Delayed Wound Healing	1.1%	1.3%	<1%	2.9%
Hematoma	1.3%	2.0%	1.0%	0%
Hypertrophic Scarring	1.4%	3.7%	4.8%	3.2%
Implant extrusion	<1%	1.5%	<1%	0%
Implant malposition	4.7%	9.1%	5.7%	8.0%
Implant palpability/visibility	<1%	1.4%	1.2%	4.2%
Infection	1.7%	2.1%	6.1%	8.5%
Nipple Complications	1.3%	0%	<1%	1.7%
Ptosis	1.9%	0%	0%	0%
Redness	<1%	0%	<1%	4.9%
Seroma	1.6%	3.2%	2.8%	6.2%
Swelling	4.0%	2.7%	5.3%	3.2%
Tissue/Skin Necrosis	0%	0%	<1%	1.5%
Upper pole fullness	0%	<1%	4.2%	1.5%
Wrinkling/Rippling	<1%	3.7%	6.2%	12.8%
Other Complications ^d	1.6%	3.5%	6.0%	3.6%

^a Most complications were assessed with severity ratings. This table only includes complications rated moderate, severe, or very severe (excludes mild and very mild ratings). For reoperation, implant removal or replacement, implant rupture, implant extrusion, and pneumothorax all occurrences are included, regardless of severity.

^b The following complications occurred at a rate less than 1% at all timepoints in each cohort: gel fracture

^c There were no reports of the following complications: irritation, lymphadenopathy, lymphedema, palpable orientation mark, pneumothorax

^d Other complications include complications such as joint swelling, implant movement, bottoming out, tear in the capsule, skin indentation, and synmastia

Other complications not listed above have also been reported in patients with breast implants. These include:

- Breastfeeding difficulties
- Calcium deposits

- Breast tissue atrophy/chest wall deformity
- Connective Tissue Disease (CTD)
- CTD signs and symptoms
- Neurological Disease
- Neurological Signs and Symptoms
- Cancer
- Lymphoma, including Anaplastic Large Cell Lymphoma or ALCL
- Suicide
- Potential Effects on Offspring



Why are implants sometimes removed (IMPLANT REMOVAL)?

Breast implants may be removed with or without replacement in response to a complication, or to improve a cosmetic result. In the *NATRELLE*® 410 Pivotal Study through 10 years the most common reason overall for implant removal was patient request for a size or style change (ranging from 20% to 34% of all implant removals).

The main reasons Primary Augmentation and Revision-Augmentation patients had implants removed through 10 years are presented in Figure 2 and Figure 3, respectively.

The main reasons Primary Reconstruction and Revision-Reconstruction women had implants removed through 10 years are presented in Figure 4 and Figure 5, respectively.

Figure 2:

Main Reasons for Implant Removal Through 10 Years Primary Augmentation (N = 153 implants)

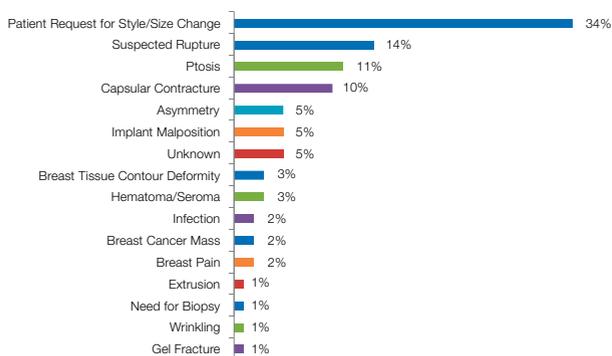


Figure 3:

Main Reasons for Implant Removal Through 10 Years Revision-Augmentation (N = 78 implants)

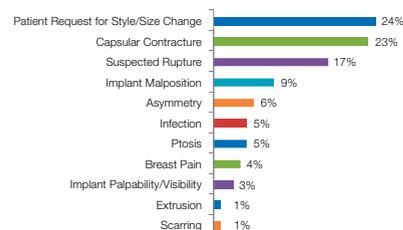


Figure 4:

Main Reasons for Implant Removal Through 10 Years Primary Reconstruction (N = 115 implants)

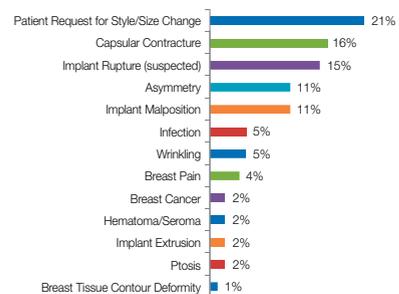
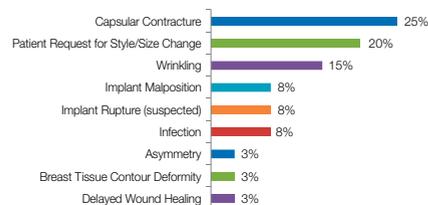


Figure 5:

Main Reasons for Implant Removal Through 10 Years Revision-Reconstruction (N = 40 implants)



NATRELLE® 410XL-001 Study

Detailed information on the 410XL-001 Study can be found in Section 5.2, *Allergan's XL-001 Study*, of the online patient labeling. Tables 3 and 4 below present complication rates reported in the NATRELLE® 410XL-001 Study through 3 years. In the 410XL-001 Study, all patients had scheduled MRIs to look for rupture independent of whether or not they had any symptoms.

Table 3: Key Complication Rates Reported through 3 Years

Complication	Primary Augmentation N=100	Revision-Augmentation N = 72	Primary Reconstruction N = 99	Revision-Reconstruction N=60
Any complication (including reoperation)	12.0%	26.4%	44.4%	35.0%
Key Complications				
Reoperation	8.0%	18.1%	37.4%	35.0%
Implant removal with replacement	0.0%	0.0%	0.0%	1.7%
Implant removal without replacement	0.0%	0.0%	0.0%	0.0%
Implant rupture	1.1%	5.6%	1.3%	7.1%
Capsular contracture (Baker Grade III/IV)	2.2%	1.4%	2.0%	1.7%

Table 4: Other Complication Rates Reported through 3 Years

Complication ^{a,b}	Primary Augmentation N=100	Revision-Augmentation N = 72	Primary Reconstruction N = 99	Revision-Reconstruction N=60
Asymmetry	1.0%	0.0%	3.0%	0.0%
Breast Pain	2.0%	0.0%	1.0%	0.0%
Delayed Wound Healing	0.0%	1.4%	0.0%	0.0%
Implant malposition	3.0%	4.2%	4.0%	1.7%
Implant palpability/visibility	0.0%	1.4%	0.0%	0.0%
Infection	0.0%	1.4%	2.0%	0.0%
Ptosis	0.0%	1.4%	0.0%	0.0%
Redness	1.0%	0.0%	2.0%	0.0%
Seroma	0.0%	1.4%	0.0%	0.0%
Wrinkling/Rippling	0.0%	2.8%	0.0%	1.7%
Other Complications ^c	1.0%	1.4%	2.5%	0.0%

^a Most complications were assessed with severity ratings. This table only includes complications rated moderate, severe, or very severe (excludes mild and very mild ratings). For reoperation, implant removal or replacement, implant rupture, implant extrusion, and pneumothorax all occurrences are included, regardless of severity.

^b There were no reports of the following complications: bruising, capsule calcification, hematoma, hypertrophic scarring/other abnormal scarring, implant extrusion, irritation, loss of nipple sensation, loss of skin sensation, lymphadenopathy, lymphedema, nipple complications, palpable orientation mark, pneumothorax, skin hypersensitivity/skin paresthesia, skin rash, swelling, tissue/skin necrosis, upper pole fullness

^c Other complications include complications such as calcifications on mammogram, thinning of mastectomy flap, deformity, ptosis, and nipple stretching

Reasons for reoperations are discussed in the online patient labeling in Section 5.2.5 *Allergan's 410XL-001 Study: What are the main reasons for reoperation?*

In the NATRELLE® 410XL-001 Study through 3 years, there was 1 revision-reconstruction patient who underwent implant removal, which was due to breast cancer mass.

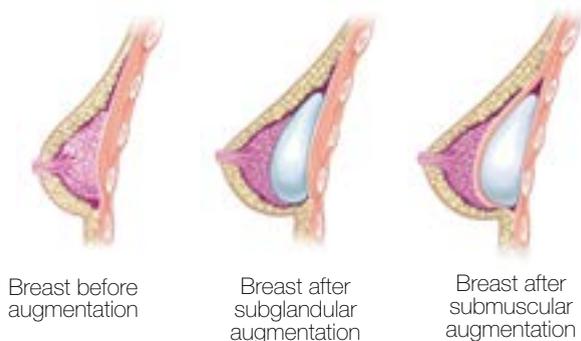
How does the breast implantation procedure work?

The sections below briefly describe some details of surgery including where breast implants can be placed and incision sites as well as what to expect after a breast implant surgery. However, there are many factors to consider with breast augmentation and breast reconstruction. Please read the Section 3.0 *Surgical Considerations for Breast Augmentation/Reconstruction* in the appropriate patient labeling piece available online.

IMPLANT PLACEMENT

The breast implant can be placed either on top of the muscle and under the breast glands (subglandular) or partially under the pectoralis major muscle (submuscular). You should discuss with your surgeon the advantages and disadvantages of each implant placement.

Figure 6:
Implant Placement



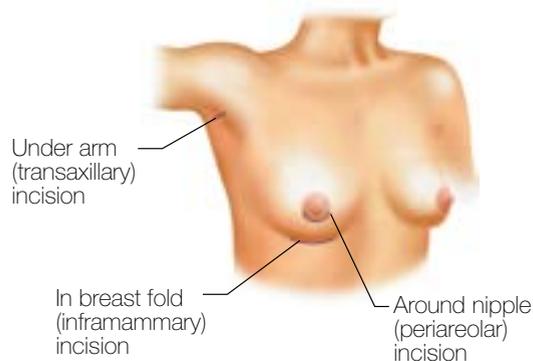
INCISION SITES

You should discuss with your surgeon the pros and cons for the incision site specifically recommended for you.

Breast augmentation with highly cohesive silicone implants requires a larger incision than saline or less cohesive silicone implants. There are 3 common incision sites: around the nipple (periareolar), within the breast fold (inframammary), or under the arm (axillary or transaxillary).

In reconstructive surgery, your surgeon will decide on the incision placement and length, largely based on the type of cancer surgery you will receive. Most implants used for breast reconstruction are placed through an incision at the mastectomy scar, either during the mastectomy procedure or after tissue expansion.

Figure 7:
Incision Sites



POSTOPERATIVE CARE

You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size. The breasts and nipple area also may have less feeling during this time of swelling and immediately after surgery. Other possible complications have been described above.

Postoperative care depends on each patient's situation and may involve using a special postoperative bra, compression bandage, or jog bra for extra support and positioning while you heal. Some surgeons may not want you to wear a bra at all for a period of time following the surgery.

At your surgeon's recommendation, you will most likely be able to return to work within a few days. However, for at least a couple of weeks you should avoid any strenuous activities that could raise your pulse and blood pressure, or require strenuous use of your arms and chest.

What if I experience a problem?

You will be given a device identification card with the style and serial number of your breast implant(s). This card is for your permanent record and should be kept in a safe place. In the event you have a concern or problem with your implant you can use this card to describe the implant to your health care provider or to Allergan.

Where can I get additional information?

It is important that you read the entire patient labeling, entitled ***Breast Augmentation/Reconstruction with NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants***, because you need to understand the risks and benefits and have realistic expectations for your surgery. The patient labeling is available online at www.allergan.com/labeling/usa.htm, or a paper copy can be obtained by calling Allergan Product Surveillance at 1.800.433.8871. Additional information is also available on the FDA website at <http://www.fda.gov/breastimplants>.

What is Device Tracking?

Silicone gel-filled breast implants are subject to Device Tracking by federal regulation. This means that your physician will be required to submit to Allergan the serial number of the implant(s) you receive, the date of surgery, information relating to the physician's practice and information on the patient receiving the implant(s). You have the right to remove your personal information from Allergan's Device Tracking program. You also have the right to have your personal information withheld from disclosure to third parties who may request information from Allergan, such as FDA. However, Allergan strongly recommends that all patients receiving *NATRELLE®* 410 Breast Implants participate in Allergan's Device Tracking Program. This will help ensure that Allergan has a record of each patient's contact information so that all patients can be contacted in the case of a recall or other problems with the implants. Please see Section 6.2 *Device Tracking* of the online patient labeling for more information on Device Tracking.

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The logo for Natrellé, featuring the brand name in a stylized, cursive font inside a light blue oval shape.

Glossary

Listed below is an abbreviated glossary of terms that you may be unfamiliar with. A full glossary can be found online in the patient labeling.text of this brochure.

Anaplastic large cell lymphoma (ALCL)	ALCL is not breast cancer; it is a rare type of non Hodgkin's lymphoma, a cancer involving the cells of the immune system.
Asymmetry	Uneven appearance between a woman's left and right breasts in terms of size, shape, or breast level.
Capsular contracture	A 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, and is a risk for implant rupture. Capsular contracture is classified by Baker Grades. Capsular Contracture Baker Grades III and IV are the most severe. Baker Grade III often results in the need for additional surgery (reoperation) because of pain and possibly abnormal appearance. Baker Grade IV usually results in the need for additional surgery (reoperation) because of pain and unacceptable appearance. .

Capsular Contracture Baker Grade II may also result in the need for surgery. Each grade is described below.

- 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 which forms around the breast implant.
Delayed wound healing	Unusually slow progress in the healing of a wound; surgical incision site fails to heal normally or takes longer to heal.
Extrusion	Skin breakdown with the implant pressing through the skin or surgical incision.
Hematoma	A collection of blood within a space.
Infection	The growth in the human body of microorganisms such as bacteria, viruses, or fungi. An infection usually results in fever, swelling, redness, and/or pain. It can occur as a result of any surgery.

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.
Necrosis	Death of cells or tissues.
Ptosis	Sagging or drooping of the breast.
Rupture	A hole or tear in the shell of the implant that allows silicone gel filler material to leak from the shell. Ruptures can be intracapsular (inside the scar tissue capsule surrounding the implant) or extracapsular (outside the scar tissue surrounding the implant).
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.



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