NATRELLE® SILICONE-FILLED BREAST IMPLANTS AND *NATRELLE INSPIRA*® BREAST IMPLANTS WITH SMOOTH SURFACE

Important Factors Breast Augmentation and Reconstruction Patients Should Consider

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.

The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Allergan.

Natrelle®

Important Factors

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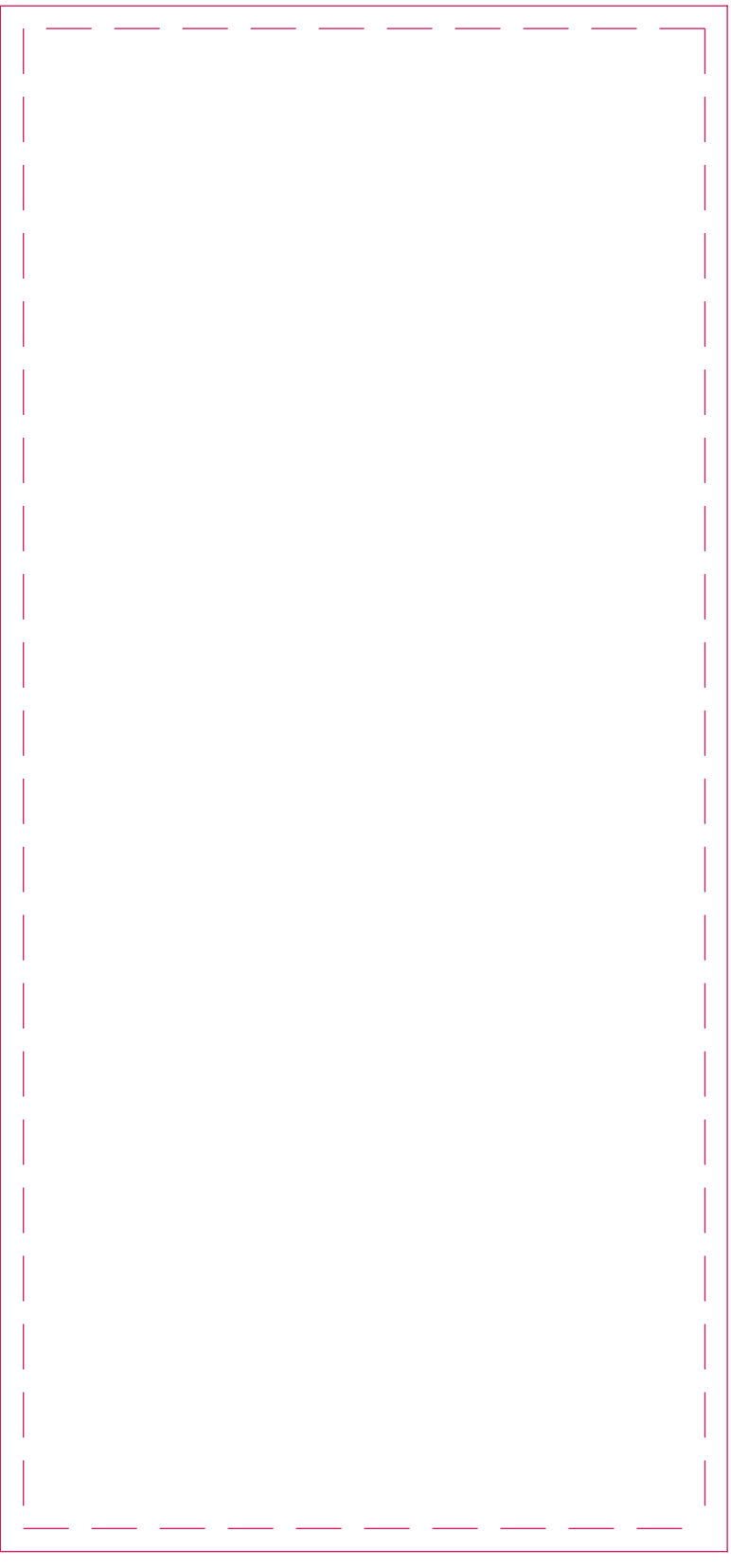

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Introduction

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®*** Silicone-Filled Breast Implants and *NATRELLE INSPIRA®* Breast Implants with smooth surface. 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, **Important Information for Women about Breast Augmentation/Reconstruction with *NATRELLE®* Silicone-Filled Breast Implants and *NATRELLE INSPIRA®* Breast Implants with Smooth Surface**, available online at www.allerganlabeling.com. To help guide you, the locations of where you can find specific additional information in the patient labeling are provided throughout this 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, please call toll free at 1.800.678.1605 (7 am to 5 pm Pacific Time).

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Figure 1:
NATRELLE® Silicone-Filled Breast Implant

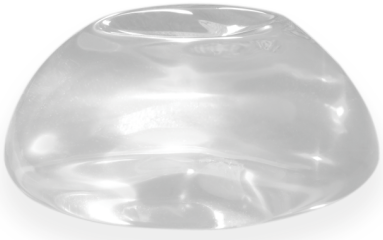

Figure 2.
NATRELLE INSPIRA® Breast Implant

Who is eligible to get *NATRELLE*® Silicone-Filled Breast Implants and *NATRELLE INSPIRA*® Breast Implants

NATRELLE® Silicone-Filled Breast Implants and *NATRELLE INSPIRA*® 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.

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- 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

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

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- 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***® Silicone-Filled Breast Implants and *NATRELLE INSPIRA*® Breast Implants. There is a boxed warning for breast implants. Please see the cover page .

- 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, even if you have no symptoms, you should have your

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first ultrasound or MRI at 5-6 years after your initial implant surgery and then every 2-3 years thereafter. If you have symptoms at any time or uncertain ultrasound results for breast implant rupture, an MRI is recommended.

- 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 imaging.
- 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

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What are some complications with *NATRELLE*® Silicone-Filled Breast Implants and *NATRELLE INSPIRA*® 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 Core clinical study conducted on ***NATRELLE***® Silicone-Filled Breast Implants. The Allergan Core Study assessed both BIOCELL textured and smooth breast implants. BIOCELL textured breast implants were recalled in July 2019 for their higher risk associated with BIA-ALCL and are no longer manufactured or marketed.

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

Allergan Core Study

Tables 1 and 2 below present complication rates reported in the Allergan Core Study through 10 years. Detailed information on complications reported in the Core 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

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2.2 What are the potential risks, 5.4 *Allergan's Clinical Study Results: What are the 10-Year Complication Rates*, and 5.7 *Allergan's Clinical Study Results: What are Other Clinical Data Findings?*

In the Allergan Core 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 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 5.5 *Allergan's Clinical Study Results: What are the Main Reasons for Reoperation?*

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Table 1: Key Complication Rates Reported through 10 Years

Complication		Primary Augmentation N = 455
Any complication (including reoperation)		32.9%
Key Complications		
Reoperation		36.1%
Implant removal with replacement		18.6%
Implant removal without replacement		2.8%
Implant rupture	MRI cohort	9.3%
	Non-MRI cohort	13.7%
Capsular contracture (Baker Grade III/IV)		18.9%

Table 2: Other Complication Rates Reported through 10 Years

Complication[a,b]	Primary Augmentation N= 455
Asymmetry	3.3%
Breast Pain	11.5%
Bruising	<1%
Breast/skin sensation changes	1.6%
Delayed Wound Healing	1.1%
Gel Migration	<1%
Hematoma	1.6%
Hypertrophic Scarring	4.2%
Implant extrusion	<1%
Implant malposition	6.9%
Implant palpability/visibility	1.6%
Infection	<1%
Irritation	0
Lymphedema	<1%
Nipple Complications	6.3%
Ptosis	2.0%
Redness	<1%
Seroma	1.8%
Skin Rash	<1%
Swelling	9.2%
Tissue/Skin Necrosis	<1%
Wrinkling/Rippling	1.8%
Other Complications[c]	0.2%

[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: capsule calcification, lymphadenopathy, pneumothorax

[c] Other complications include complications such as flexion of pectoral muscle, herniation following an auto accident, upper pole crescent deformity

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Revision-Augmentation N = 147	Primary Reconstruction N = 98	Revision-Reconstruction N = 15
38.6%	47.0%	46.7%
46.0%	71.5%	46.7%
30.1%	48.0%	13.3%
4.0%	13.6%	6.7%
5.4%	35.4%	0
10.1%	18.3%	6.7%
28.7%	24.6%	6.7%

Revision-Augmentation N = 147	Primary Reconstruction N = 98	Revision-Reconstruction N = 15
6.5%	23.2%	6.7%
11.7%	6.8%	0
3.0%	1.0%	6.7%
2.2%	1.0%	0
<1%	1.0%	0
0	0	0
2.1%	1.5%	0
6.6%	5.5%	0
0	1.0%	0
6.0%	2.3%	13.3%
6.0%	6.4%	6.7%
1.4%	3.2%	0
<1%	0	0
0	0	0
1.4%	3.3%	0
4.9%	0	0
<1%	2.1%	0
6.0%	2.3%	6.7%
<1%	2.0%	6.7%
8.2%	7.1%	0
0	2.3%	0
5.4%	10.2%	0
0.7%	1.0%	0

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 Breast Implant-Associated Anaplastic Large Cell Lymphoma or BIA-ALCL
- Suicide
- Potential Effects on Offspring

[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.

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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 Allergan Core Study through 10 years, the most common reason overall for implant removal was capsular contracture in Augmentation and Revision-Augmentation patients (32% and 36%, respectively). For Reconstruction patients, through 10 years the most common reason for implant removal was suspected implant rupture (26%). Among Revision-Reconstruction patients, 2 patients had implant removal due to asymmetry and one patient due to capsular contracture.

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 women had implants removed through 10 years are presented in Figure 4. As stated above, 3 Revision-Reconstruction patients had their implants removed through 10 years due to asymmetry and capsular contracture (not presented in a separate figure).

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Figure 2:
Main Reasons for Implant Removal Through 10 Years
Primary Augmentation (N = 156 implants)

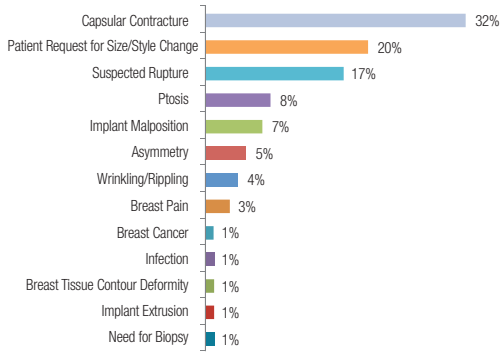


Figure 3:
Main Reasons for Implant Removal Through 10 Years
Revision-Augmentation (N = 78 implants)

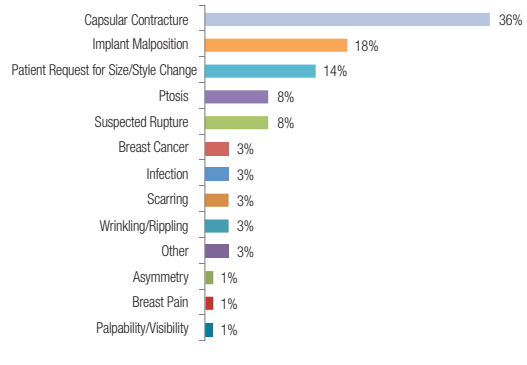
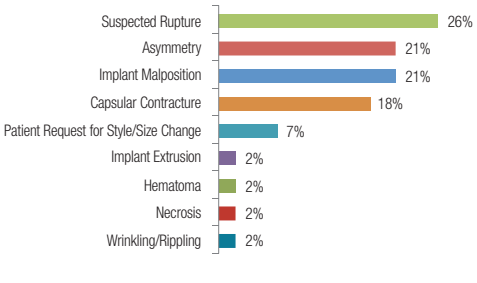


Figure 4:
Main Reasons for Implant Removal Through 10 Years
Primary Reconstruction (N = 57 implants)



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What are the Overview Findings from Allergan's Post-Approval Clinical Studies?

Additional clinical safety and effectiveness data on NATRELLE® Silicone-Filled Breast Implants are being gathered through the BIFS post-approval study through two separate study arms: the BIFS-arm and the NBIR-arm. The NBIR-arm of the study was completed in 2022, and a summary of results is provided below. Detailed information can be found online in the patient labeling in Section 6 *Allergan's Post Approval Studies*.

BIFS-001 NBIR-Arm Post-Approval Study

The purpose of the BIFS-001 NBIR-Arm was to collect reoperation data on NATRELLE® Silicone-Filled Breast Implants in the post-market environment. Subjects implanted with NATRELLE® Silicone-Filled Breast Implants or saline-filled breast implants for at least 5 years were followed for 10 years post-implantation.

Data were collected only when NBIR-arm subjects returned to their implanting physician (i.e., study investigator) for a reoperation. Information on the reasons for reoperation was collected. To maximize data collection, all study investigators were contacted at the end of the study to request entry of any reoperations that had not been previously provided. Of the 953 sites contacted, 283 were responsive.

Among subjects implanted with NATRELLE® Silicone-Filled Breast Implants, 180 (0.5%) had a reported reoperation. Among subjects implanted with saline breast implants,10 (<0.1%) had a reported reoperation.

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All reasons for reoperation by frequency and percentage among patients who underwent reoperation are presented in Table 3. Of note, subjects may have undergone reoperation for more than one reason and may have had more than one reoperation. Thus, the total number of reasons exceed the number of patients who had a reoperation.

Table 3
Reasons for Reoperation

Reasons for Reoperation[a]	Silicone N=180 patients with reoperation n (%)[b]	Saline N=10 patients with reoperation n (%)[b]
Complications		
Capsular Contracture	72(40%)	1(10%)
Extracapsular Extravasation	3(1.7%)	0
Hematoma	1(0.6%)	0
Infection	3(1.7%)	0
Ptosis	21(11.7%)	0
Scarring	2(1.1%)	0
Seroma	3(1.7%)	0
Skin Necrosis	0	0
Wound Problems	0	0
Wrinkling/Rippling	12(6.7%)	1(10%)
Device Maintenance		
Correction of Asymmetry	39(21.7%)	0
Device Migration	10(5.6%)	0
Implant Malposition	16(8.9%)	1(10%)
Suspected Rupture/Deflation[c]	33(18.3%)	6(60%)
Patient Request/Other		
Patient wish change shape/size/style	79(43.9%)	4(40%)
Need for Biopsy	2(1.1%)	0
Staged Reconstruction	0	0
Tumor	3(1.7%)	0
Other	59(32.8%)	1(10%)
Missing	0	0

a Subjects may have more than one reason for reoperation.
b Percentages are based on subjects who had a reoperation
c Rupture occurring in silicone and deflation in saline implants.

Most of the reoperations involved implant removal (175 subjects implanted with *NATRELLE*® Silicone-Filled Breast Implants and 10 subjects implanted with saline breast implants). No subjects in the NBIR-Arm reported BIA-ALCL in the capsule around breast implants.

The strength of the BIFS-001 NBIR-arm Post-Approval Clinical Study is that it followed 50,000 subjects who were originally enrolled in the large cohort BIFS-001 post-approval clinical study through 10 years of implantation to assess the occurrence of reoperations in the post-market environment. Though there were no mandatory follow-up visits, study investigators had the opportunity to provide reoperation data either when it occurred or retrospectively.

However, the weakness of the study is that the number of reoperations reported in the NBIR-arm is low compared to the reoperation rates reported in the Core Study. The difference may reflect possible missing reports of reoperation due to the lack of mandatory follow-up visits for the NBIR-arm. In contrast, the CORE study required annual in-office visits with the investigator. Furthermore, the study was limited to data obtained from study investigators only. Over the course of 10 years, subjects may have seen other medical practitioners instead of their implanting surgeon for a reoperation. Thus, the results may represent an underestimation of reoperations occurring in the post-market environment.

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.

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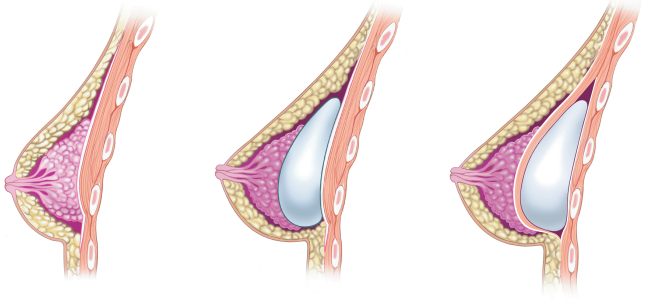
Implant Placement

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



Breast before augmentation | Breast after subglandular augmentation | Breast after submuscular augmentation

Incision Sites

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

Breast augmentation with *Responsive* silicone implants requires a larger incision than saline implants. Breast augmentation with *SoftTouch* silicone implants or *Highly Cohesive* silicone implants requires a larger incision than *Responsive* 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.

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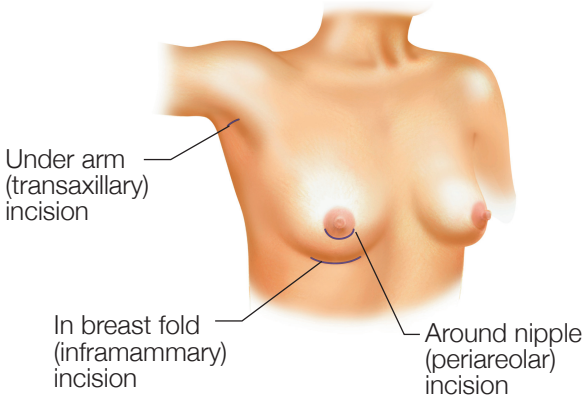
Figure 7:
Incision Sites



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.

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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 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®** ***Silicone-Filled Breast Implants and*** **NATRELLE INSPIRA®** ***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.allerganlabeling.com, or a paper copy can be obtained by calling Allergan Product Surveillance at1.800.624.4261. Additional information is also available on the FDA website at http://www.fda.gov/breastimplants.

What is Device Tracking?

Silicone-filled breast implants are subject to device tracking by federal regulation and your device specific information has been provided to Allergan for these device tracking purposes. Unless you opt-out, as part of Allergan's Device Tracking Program, your personal information (including name, address, phone number, date of birth, email and social security number) will also be provided to Allergan, any of its vendors/third parties

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providing device tracking services on its behalf, and any relevant regulatory authorities for device tracking purposes, in accordance with applicable laws and regulations. As part of Allergan's Device Tracking Program, Allergan may share your information with your surgeon and may occasionally be asked to release your information to a third party, such as the FDA. If you choose to participate in Allergan's Device Tracking Program but DO NOT want Allergan to release your patient specific information, you may opt-out of this sharing. Please note that there may be instances where Allergan is legally required to share your information as per federal regulation.

Allergan strongly recommends that all patients receiving *NATRELLE*® Silicone-Filled 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 your implants.

Acknowledgement of Informed Decision and Patient Decision Checklist

The review and understanding of the patient information documents is a critical step in deciding 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 your decision. At the end of the electronic patient labeling document (available at http://www.allerganlabeling.com), there is a form (Acknowledgement of Informed Decision and Patient Decision Checklist) that lists important risks, including those known or reported to be associated with the use of the device, based on information from clinical trials, scientific

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literature, and reports from patients who have undergone device placement.

After reviewing the information in the patient information documents, read and discuss the items in the Patient Decision Checklist carefully in consultation with your surgeon. Your surgeon can provide a copy for you to place your initials next to each item to indicate that you have read and understood the item. Your full signature at the end of the document will confirm that you have read the materials and that your surgeon has answered all questions to your satisfaction. In order to formally record a successful informed decision process, the ***Acknowledgement of Informed Decision and Patient Decision Checklist*** document (available separately and within the patient labeling document at: www.allerganlabeling.com) should be signed by both you and the surgeon. A copy should be provided to you.

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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.

Asymmetry

Uneven appearance between a woman's left and right breasts in terms of size, shape, or breast level.

Breast Implant Associated Anaplastic large cell lymphoma (BIA-ALCL)

BIA-ALCL is not breast cancer; it is a rare type of non-Hodgkin's lymphoma, a cancer involving the cells of the immune system.

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 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

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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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