NATRELLE®
Saline-Filled Breast Implants

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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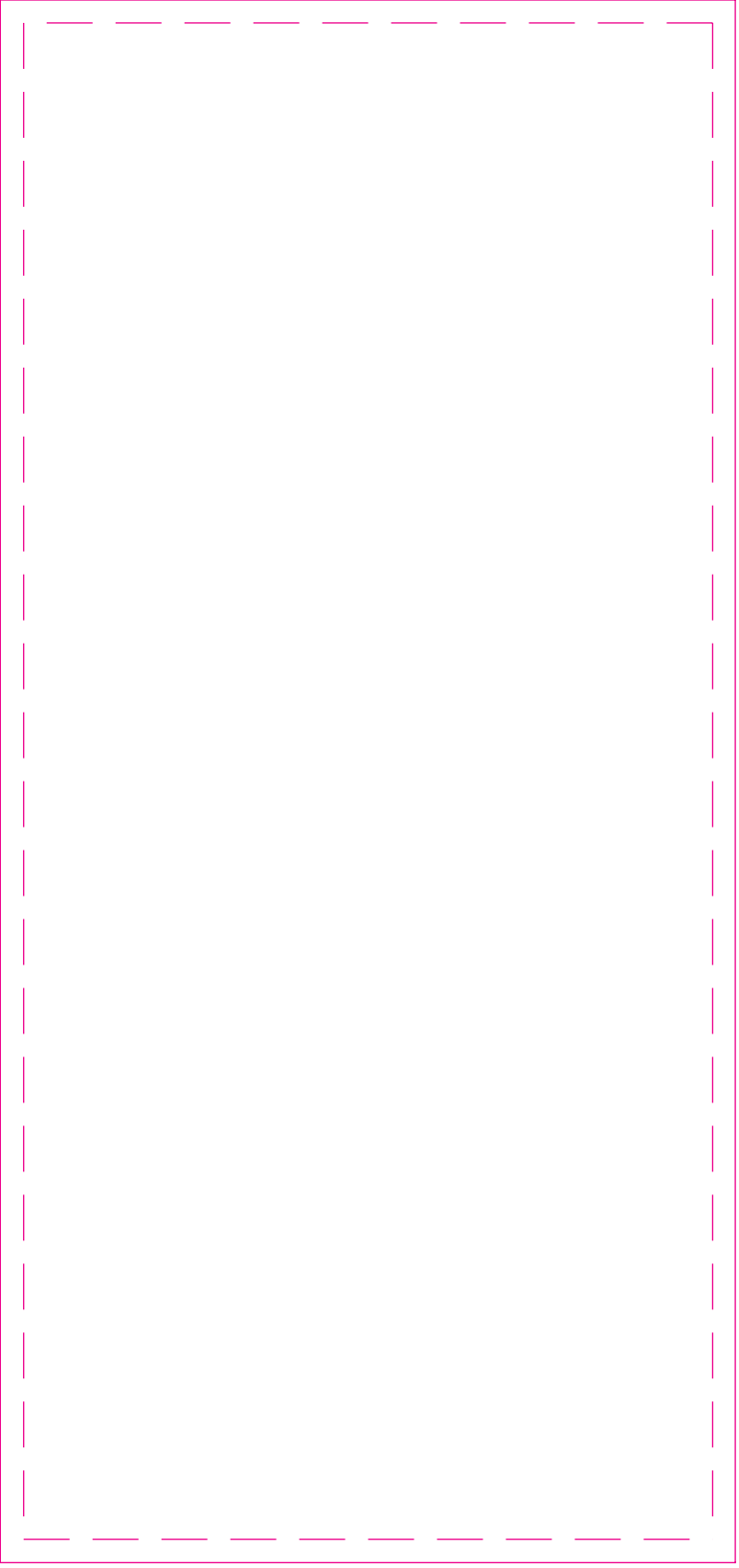

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Introduction

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***® Saline-Filled 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, **Making an Informed Decision, Breast Augmentation or Reconstruction Surgery with *NATRELLE*® Saline-Filled 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*® Saline-Filled Breast Implant**

Who is eligible to get *NATRELLE*® Saline-Filled Breast Implants

***NATRELLE*®** Saline-Filled Breast Implants have been approved for women for the following uses (procedures):

- Breast augmentation for women at least 18 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.

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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)
- Conditions that interfere with wound healing and blood clotting
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease)
- Reduced blood supply to breast tissue
- Planned chemotherapy following breast implant placement
- Planned radiation therapy 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 until resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

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What else should I consider (WARNINGS)?

The following are warnings associated with ***NATRELLE***® Saline-Filled 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.
- 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 leak 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.
- After undergoing breast implant surgery (either primary or revision), your health insurance premiums

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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*® Saline-Filled 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 studies conducted on ***NATRELLE***® Saline-Filled Breast Implants.

NATRELLE® Saline-Filled Breast Implants were evaluated in four major open label, multicenter clinical studies. The Large Simple Trial was designed to determine the 1 year rates of capsular contracture, infection, implant leakage/deflation, and implant replacement/removal. There were 2,333 patients enrolled for augmentation, 225 for reconstruction, and 317 for revision (replacement of existing implants). Of these enrolled patients, 62% returned for their 1-year follow-up visit. The A95 and R95 Studies were designed as 5-year studies to assess all complications as well as patient satisfaction, body image, body esteem, and self-concept. Patients were followed annually and data through 3 years were

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presented to FDA for marketing approval. After approval, Allergan transitioned data collection to a post-approval study. The first phase of this post-approval study consisted of completion of the A95 and R95 Studies, with collection of all risk/benefit information through 5 years. The Post Approval Survey Study (PASS) was designed to collect long-term safety data from A95/R95 patients at 6-10 years post-implant. The data were collected from surveys mailed out to the patients each year.

Results from the A95, R95 and PASS studies are discussed below. Please note that these studies assessed both smooth and BIOCELL textured breast implants. BIOCELL textured breast implants were recalled in July 2019 due to a 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.

A95 and R95 Studies

Tables 1 and 2 present complication rates reported among augmentation patients in the A95 Study and PASS through 5 and 10 years, respectively. Tables 3 and 4 present complication rates reported among reconstruction patients in the R95 and PASS through 5 and 10 years, respectively. Detailed information on complications reported in the A95 and R95 studies and PASS, including information on complications reported after implant surgery, can be found online in the patient labeling, specifically in Sections 2.2 *What are the potential risks*, 7.3 *Primary Breast Augmentation Study Results: What were the complication rates?* and 8.3 *Primary Breast Reconstruction Study Results: What were the complication rates?*

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

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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 in squeezing of the implant. 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 Sections 7.4 *Primary Breast Augmentation Study Results: What were the reasons for reoperation?* and 8.4 *Primary Breast Reconstruction Study Results: What were the 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.

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Table 1: Primary Augmentation: Complications from A95 Study

Complication*	5-Year Complication Rate N = 901 Patients
Additional Operation (Reoperation)	25.9%
Breast Pain	17.0%
Wrinkling	13.7%
Asymmetry	12.2%
Implant Palpability/Visibility	12.1%
Implant Replacement/Removal for Any Reason	11.8%
Capsular Contracture Baker Grade III/IV	11.4%
Loss of Nipple Sensation	9.9%
Intense Nipple Sensation	9.8%
Implant Malposition	9.2%
Intense Skin Sensation	7.6%
Implant Deflation	6.8%
Scarring Complications	6.5%
Irritation/Inflammation	3.2%
Seroma	2.6%
Skin Rash	1.9%
Capsule Calcification	1.8%
Hematoma	1.7%
Delayed Wound Healing, Infection	≤1% each

* Many events were assessed with severity ratings, and for these complications the rates shown in the table include only complications rated moderate, severe, or very severe (excludes mild and very mild ratings). All occurrences are included for reoperation, implant removal, leakage/deflation, scarring complications, irritation/inflammation, seroma, hematoma, skin rash, infection, implant extrusion and tissue/skin necrosis.

Table 2: Primary Augmentation: Complications from the PASS Study

Complication	10-Year Complication Rate N=901 Patients
Reoperation	36.5%
Breast Pain	29.7%
Capsular Contracture Baker Grade III/IV	20.8%
Implant Removal	20.2%
Implant Deflation	13.8%

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Table 3: Primary Reconstruction: Complications from R95 Study

Complications*	5-Year Complication Rate N = 237 Patients
Additional Operation (Reoperation)	44.5%
Asymmetry	39.0%
Capsular Contracture Baker Grade III/IV	35.7%
Implant Replacement/Removal for Any Reason	28.0%
Implant Palpability/Visibility	27.1%
Wrinkling	24.6%
Loss of Nipple Sensation	18.1%
Breast Pain	17.7%
Implant Malposition	16.9%
Implant Deflation	7.5%
Irritation/Inflammation	6.6%
Intense Skin Sensation	6.3%
Scarring Complications	6.0%
Infection	6.0%
Capsule Calcification	5.4%
Seroma	3.9%
Tissue/Skin Necrosis	3.6%
Skin Rash	3.3%
Implant Extrusion	3.2%
Delayed Wound Healing	2.7%
Hematoma	1.3%

* Many events were assessed with severity ratings, and for these complications the rates shown in the table include only complications rated moderate, severe, or very severe (excludes mild and very mild ratings). All occurrences are included for reoperation, implant removal, leakage/deflation, scarring complications, irritation/inflammation, seroma, hematoma, skin rash, infection, implant extrusion and tissue/skin necrosis.

Table 4: Primary Reconstruction: Complications from PASS Study

Complication	10-Year Complication Rate N=237 Patients
Reoperation	54.6%
Capsular Contracture Baker Grade III/IV	51.7%
Implant Removal	39.5%
Breast Pain	33.0%
Implant Deflation	22.5%

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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
- Lymphadenopathy
- 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
- 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 PASS through 10 years, the most common reason overall for implant removal in Augmentation patients was patient choice for style or size change (41.3%). For Reconstruction patients, through 10 years the most common reason for implant removal was implant deflation (32.7%). The main reasons Primary Augmentation and Primary Reconstruction patients had implants removed through 10 years are presented in Tables 5 and 6, respectively.

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Table 5: Main Reasons for Implant Removal Through 10 Years Primary Augmentation from PASS Study

Primary Reason for Implant Removal	Through 10 Years % (N = 300 Implants)
Patient Choice for Style/Size Change	41.3%
Implant Deflation	33.3%
Capsular Contracture	9.0%
Implant Malposition	5.3%
Asymmetry	2.7%
Wrinkling	2.7%
Implant Palpability/Visibility	2.0%
Breast Mass/Lump/Cyst	1.3%
Breast Pain	1.0%
Infection, Implant Extrusion, Damage to Implant During Surgery, Unknown	<1% each
Total	**100%**

Table 6: Main Reasons for Implant Removal through 10 Years Primary Reconstruction from PASS Study

Primary Reason for Implant Removal	Through 10 Years % (N = 104 Implants)
Implant Deflation*	32.7%
Patient Choice for Style/Size Change	25.0%
Capsular Contracture	21.2%
Infection	6.7%
Implant Extrusion	3.8%
Implant Malposition	2.9%
Other**	2.9%
Asymmetry	1.9%
Wrinkling	1.9%
Recurrent Breast Cancer	1.0%
Total	**100%**

* Includes removals where the reason for removal was unknown.

** Through 10 years, other reasons as reported by the physician were: abnormality on CT scan at mastectomy site (n=1), tissue expansion went poorly due to radiation (n=1), second stage breast recon (n=1).

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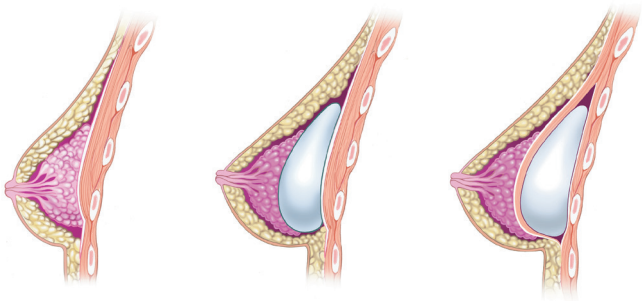
How does the breast implantation procedure work?

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 Section 4.0 *Surgical Considerations for Breast Augmentation* and Section 5.0 *Surgical Considerations for Breast Reconstruction* in the 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 2: Implant Placement



Breast before augmentation

Breast after subglandular augmentation

Breast after submuscular augmentation

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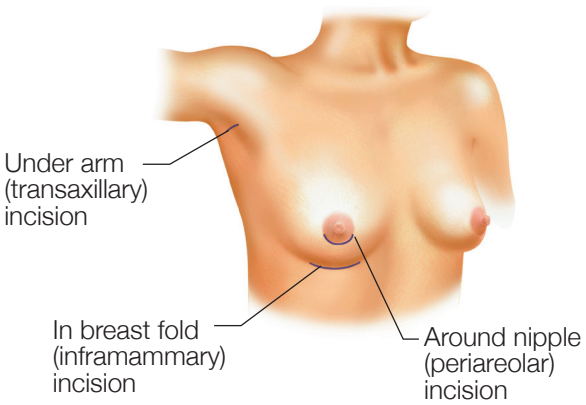
Incision Sites

To permit the smallest possible incision, the implant is typically inserted empty, and then filled with saline. You should discuss with your surgeon, the pros and cons for the incision site specifically recommended for you.

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 3: Incision Sites



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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 feeling in the breasts and nipple area also may be diminished during this time of swelling and immediate postsurgery recovery. Other possible complications are described in the Breast Implant Complications section.

Postoperative care depends on each patient's situation, may involve the use of 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, although 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 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.

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Where can I get additional information?

It is important that you read the entire patient labeling, entitled ***Breast Surgery with* NATRELLE® *Saline-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.allerganlabeling.com, or a paper copy can be obtained by calling Allergan Product Surveillance at 1.800.624.4261. Additional information is also available on the FDA website at http://www.fda.gov/breastimplants.

What is Device Tracking?

Saline-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 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.

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Allergan strongly recommends that all patients receiving *NATRELLE*® Saline-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 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.

Natrelle®

Important Factors

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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.
Deflation	Refers to loss of saline from a saline-filled breast implant due to a tear or cut in the implant shell or possibly a valve leak.
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.
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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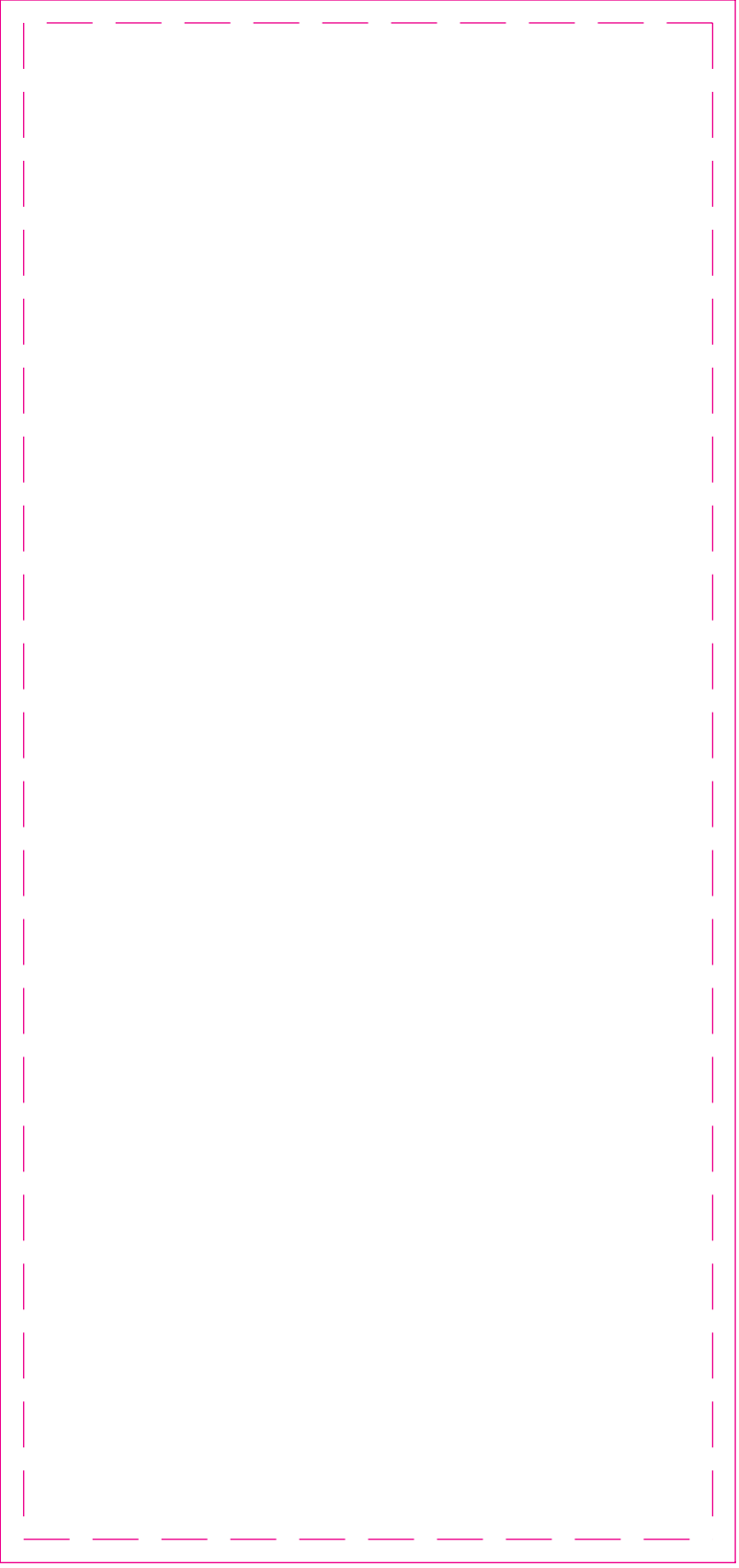

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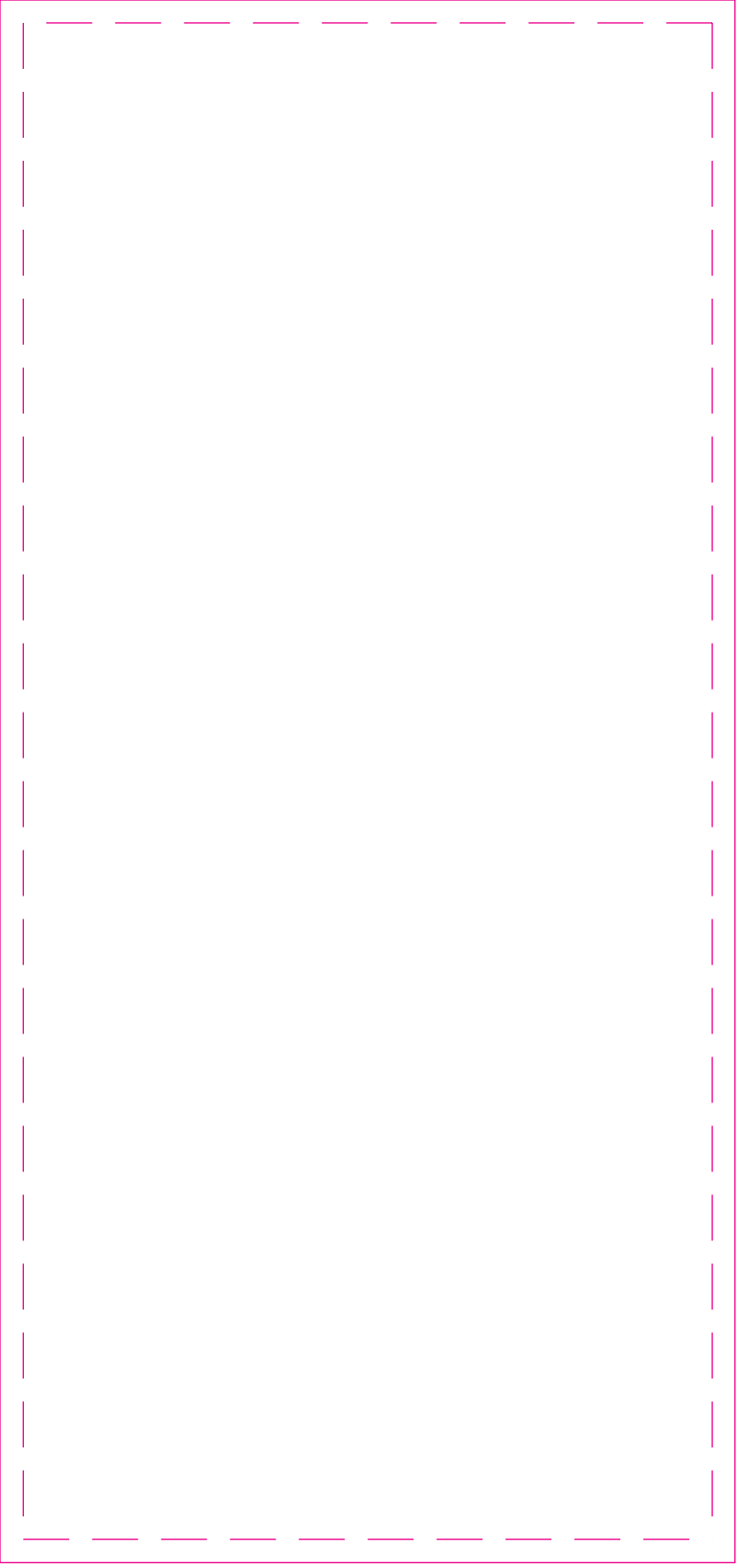

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