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.

abbvie GLOBAL LABEL MANAGEMENT

Part number	3889-01rev03	- Scale: 100%	Cyan	PMS 285
Drawing number	3889	- Drop dieline and notes before processing	Magenta	PMS 540
			Yellow	PMS 3125
			Black	Dieline

abbvie GLOBAL LABEL MANAGEMENT

Part number	3889-01rev03	- Scale: 100%	Cyan	PMS 285
Drawing number	3889	- Drop dieline and notes before processing	Magenta	PMS 540
			Yellow	PMS 3125
			Black	Dieline

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).

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.

- 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

- 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

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.

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 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 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 5.5 *Allergan's Clinical Study Results: 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 = 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,c]	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

	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

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).

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

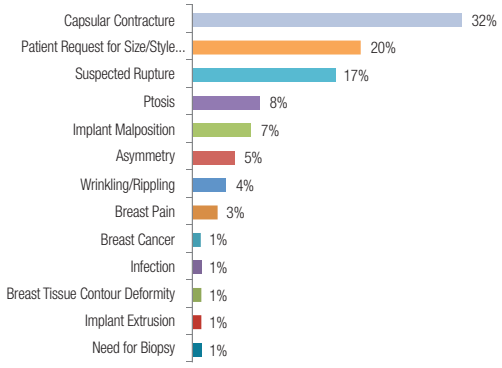


Figure 3:
Main Reasons for Implant Removal Through 10 Years
Revision-Augmentation (N = 78 implants)

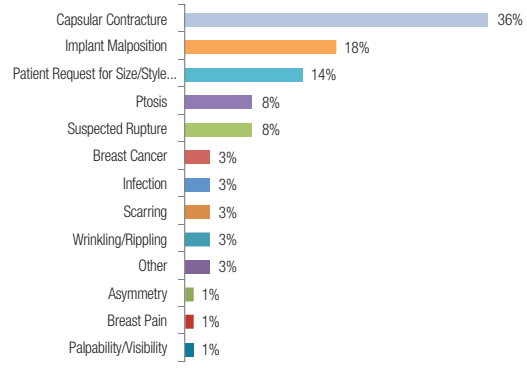
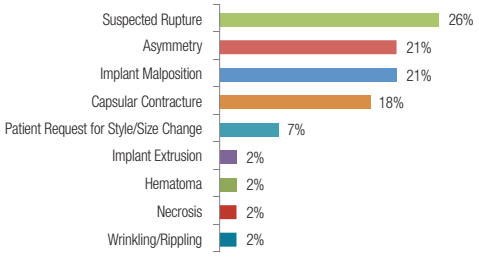


Figure 4:
Main Reasons for Implant Removal Through 10 Years
Primary Reconstruction (N = 57 implants)



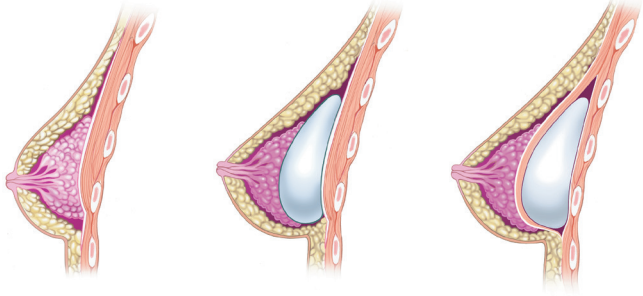
How does the breast implantation procedure work?

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



Breast before augmentation

Breast after subglandular augmentation

Breast after submuscular augmentation

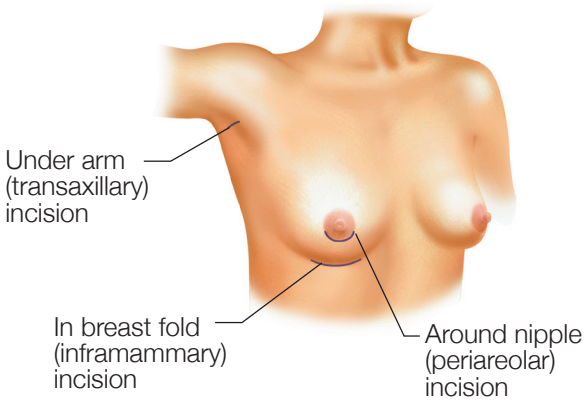
Incision Sites

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.

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 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 at 1.800.624.4261. Additional information is also available on the FDA website at http://www.fda.gov/breastimplants.

What is Device Tracking?

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

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. 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.

abbvie GLOBAL LABEL MANAGEMENT

Part number	3889-01rev03	- Scale: 100%	Cyan	PMS 285
Drawing number	3889	- Drop dieline and notes before processing	Magenta	PMS 540
			Yellow	PMS 3125
			Black	Dieline

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 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.

abbvie GLOBAL LABEL MANAGEMENT

Part number	3889-01rev03	- Scale: 100%	Cyan	PMS 285
Drawing number	3889	- Drop dieline and notes before processing	Magenta	PMS 540
			Yellow	PMS 3125
			Black	Dieline

abbvie GLOBAL LABEL MANAGEMENT

Part number	3889-01rev03	- Scale: 100%	Cyan	PMS 285
Drawing number	3889	- Drop dieline and notes before processing	Magenta	PMS 540
			Yellow	PMS 3125
			Black	Dieline

Natrelle®

Allergan™

3889-01rev03 11/2021

abbvie GLOBAL LABEL MANAGEMENT

Part number	3889-01rev03	- Scale: 100%	Cyan	PMS 285
Drawing number	3889	- Drop dieline and notes before processing	Magenta	PMS 540
			Yellow	PMS 3125
			Black	Dieline

NATRELLE® Silicone-Filled Breast Implants and *NATRELLE INSPIRA*® Breast Implants Smooth surface implants Patient Decision Checklist

Natrelle®

Allergan™

To the patient considering breast implants filled with saline or silicone gel intended for breast augmentation or breast reconstruction:

The review and understanding of this document is a critical step in making the decision 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 that decision. This form 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.

This Patient Decision Checklist is intended to supplement the additional patient information documents that should be provided to you by your physician. You should receive patient information documents that include important information about your specific breast implant, as well as a boxed warning and Patient Decision Checklist. After reviewing the information in the patient information documents for the specific implant that will be used, please read and discuss the items in this checklist carefully in consultation with your physician. You should place your initials in the location provided next to each item to indicate that you have read and understood the item. Your full signature at the end of this document confirms that you have read the materials and that your physician has answered all questions to your satisfaction.

Considerations for a Candidate for Successful Breast Implantation

I understand that I am not a candidate for breast implants if any of the following situations applies to me:

- I have an active infection anywhere in my body;
- I have an existing cancer or pre-cancer of my breast tissue that has not been adequately treated; or
- I am pregnant or nursing.

I understand that if I have any of the following conditions, I may be at a higher risk for a poor surgical outcome:

- Medical condition that affects my body's ability to heal (e.g., diabetes, connective tissue disorder);
- Active smoker or a former smoker;
- Currently taking drugs that weaken the body's natural resistance to disease, such as steroids and chemotherapy drugs (e.g., prednisone, tacrolimus, sirolimus, mycophenolate, azathioprine, cyclosporine, methotrexate, chlorambucil, leflunomide, or cyclophosphamide);
- History of chemotherapy or planned chemotherapy following breast implant placement;
- History of radiation therapy or planned radiation following breast implant placement;
- Conditions that interfere with wound healing or blood clotting (e.g., hemophilia, von Willebrand disease, factor V Leiden, hyperhomocysteinemia, protein C deficiency, antithrombin III deficiency, or systemic lupus erythematosus); or
- Reduced blood supply to the breast tissue.

I understand the following conditions have not been adequately studied to determine whether the conditions put me at higher risk:

- Autoimmune disease (e.g., Hashimoto's, Lupus, Rheumatoid Arthritis) or family history of autoimmune disease (breast implant premarket clinical studies have not evaluated the safety of breast implants in patients with autoimmune disease);
- Clinical diagnosis of depression or other mental health disorder (including body dysmorphic disorder or eating disorder); or
- Have other products permanently implanted in the breast.

Patient Initials: _____

Risks of Breast Implant Surgery

I understand that there are risks of undergoing breast implant surgery. I understand that risks of undergoing breast implant surgery may include:

- breast pain (reported in up to 11.7% of patients[1]),
- skin or nipple areola sensitivity changes or loss (nipple complications reported in up to 6.3% of patients[1] and breast/skin sensation changes reported in up to 2.2% of patients[1]),
- asymmetry (reported in up to 23.2% of patients[1]),
- impact of aging or weight change on size and shape of breast (ptosis reported in up to 4.9% of patients[1]),
- infection requiring possible removal of implant (reported in up to 3.2% of patients[1]),
- swelling (reported in up to 9.2% of patients[1]),
- scarring (hypertrophic scarring reported in up to 6.6% of patients[1]),
- fluid collections (seroma) (reported in up to 6.7% of patients[1]),
- hematoma (reported in up to 2.1% of patients[1]),
- tissue death of breast skin or nipple (tissue/skin necrosis reported in up to 2.3% of patients[1]),
- inability to breast feed (lactation complications reported in up to 30% of patients[1]),
- complications of anesthesia (may occur but specific rates are not publicly available in the Allergan Core Study),
- bleeding (may occur but specific rates are not publicly available in the Allergan Core Study),
- chronic pain (may occur but specific rates are not publicly available in the Allergan Core Study),
- damage to surrounding tissue, such as muscle, nerves, and blood vessels (may occur but specific rates are not publicly available in the Allergan Core Study), and
- impact on imaging of breast tissue (may occur but specific rates are not publicly available in the Allergan Core Study).

[1] Based on the largest complication rate reported in the Core Clinical Study through 10-years of follow-up. See Section 5.0 of either the Breast Augmentation *or* Reconstruction with Natrelle Silicone-Filled Breast Implants and Natrelle INSPIRA Breast Implants with Smooth Surface Patient Brochures.

My physician has discussed these risks and has provided me with the patient information documents (including the boxed warning) with information on the types of risks that are possible and expected rates of occurrence.

My physician has discussed the potential use of other implanted products during my breast implant surgery. My physician has also discussed the risks and benefits of using these implanted products and their planned surgical approach.

Patient Initials: _____

Risk of Cancer - Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

I understand that breast implants are associated with the development of a type of cancer of the immune system called Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Information regarding the number of medical device reports of BIA-ALCL can be found on FDA's website.[2]

As of July 2019, literature reports various estimates for the incidence of BIA-ALCL. These estimated incidence rates range from a high of 1 per 3, 817 patients to 1 in 30,000. (Clemens et al, 2017, Loch-Wilkinson et al, 2017, De Boer et al, 2018).

I have received information regarding the overall incidence rates of BIA-ALCL and the rates as they pertain to my specific breast implant.

I understand that this cancer has been reported more frequently for textured breast implants, but patients with smooth surfaced implants have also been diagnosed.

I understand that patients with breast implants have a risk of developing BIA-ALCL within the scar tissue and fluid surrounding the breast implant.

[2] See "Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma," available at https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma.

I understand that BIA-ALCL typically takes several years to develop after implantation, but cases have been reported as early as within one year. Typical symptoms to be aware of may include: breast tightness, pain, lumps, or swelling of the breast months or years after I receive my implants.

I understand that treatment for BIA-ALCL involves an operation to remove the implants and the surrounding scar tissue capsule. Based on the stage of the cancer at diagnosis, some patients have required chemotherapy or radiation. While BIA-ALCL typically responds well to therapy, some patients have died from BIA-ALCL. Diagnosis and treatment may be at my own expense and is not always covered by insurance.

Patient Initials: _____

Systemic Symptoms

I understand that some patients who have received breast implants have reported a variety of systemic symptoms including joint pain, fatigue, rash, memory loss, and “brain fog” that some patients have called breast implant illness. While the causes of these symptoms are unclear, some patients have reported relief of these symptoms with removal of their implants and surrounding scar capsule; however, not all patients may experience improvement in their symptoms. Researchers are working to better understand the possible link between breast implants and these symptoms.

I also understand that some patients with breast implants have reported health problems in their children after birth or breastfeeding. A causal link has not been established between breast implants and these reported health problems in children and more research is needed. I understand that breast implants and breast surgery may interfere with my ability to successfully breastfeed.

Patient Initials: _____

Breast-Implant Specific Risks

I understand that a breast implant is NOT a lifetime device and the longer I have my implants, the more likely I am to experience a complication and the more likely I am to need a reoperation requiring the replacement or removal of my breast implant. As many as 32.4% of women who received breast implants for augmentation had their implants removed within 10 years, but my implants may last for a shorter or longer period of time. (The percentage reported is from the 10-year Core Clinical Study for Natrelle Silicone gel-filled breast implants. The rate specified represents the largest reported cumulative 10-year rate across all groups of augmentation patients in the study (both primary and revision)).

I understand that my breast implant may rupture or leak at any time, and that the longer I have my implants, the more likely I am to experience a complication such as rupture. I understand that gel bleed (small quantities of gel diffusing from the implant shell) of silicone gel-filled implants may occur. I understand that if I have a saline-filled implant, my breast may deflate in appearance if there is a rupture or leakage of the saline.

I understand that if I have a silicone gel-filled breast implant, I or the physician may not be able to tell on physical exam whether my implant has ruptured or is leaking silicone gel. Because rupture or leakage of silicone gel-filled breast implants is difficult to detect, I understand that periodic imaging evaluation is recommended for screening of silicone gel-filled breast implant rupture. It is recommended that I have periodic imaging of my silicone gel-filled breast implants to screen for implant rupture regardless of whether my implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on my medical history or circumstances (i.e., screening mammography for breast cancer).

Even if I have no symptoms, I should have regular imaging evaluations as described in the “Recommended Follow-Up” section below. These imaging evaluations may not detect all ruptures or leaks, and the expense may not be covered by my medical insurance.

I understand that there are rare case reports of silicone migrating from breast implants into tissues (e.g., chest wall, lymph nodes under the arm) and organs (e.g., liver, lungs). It may not be possible to remove migrated silicone.

I understand that all breast implants can affect mammography and breast exams, which could potentially delay the diagnosis of breast cancer. Mammography can also cause the breast implant to rupture or leak. I should tell the mammography technician if I have breast implants.

I understand that the long-term risks of breast implants may include:

- painful or tightening of scar tissue (capsule) around my implant (capsular contracture III/IV) (reported in up to 28.7% of patients[1]),
- rupture or leaking of the implant (reported in up to 35.4% of patients[1]),
- wrinkling of the implant (wrinkling/rippling reported in up to 10.2% of patients[1]),
- visibility of the implant edges (implant palpability/visibility reported in up to 6.7% of patients[1]),
- shifting of the implant (implant malposition reported in up to 13.3% of patients[1]), or
- reoperation (reported in up to 71.5% of patients[1]).

I understand that I will receive a Device Identification Card after my surgery that has information on each of my specific implants. I understand that it is important for me to keep each card in case, at some time in the future, I or my physician need to know what kind of implant I received many years later.

I understand that breast implant manufacturing requires the use of chemicals and heavy metals. I understand that most of these chemicals stay inside the shell of the implant. Small quantities may diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking.

A list of the components, chemicals, and heavy metals is available in the section entitled, **"*NATRELLE*® Silicone-Filled/Saline-Filled Breast Implant Device Materials"** of the patient information document.

Patient Initials: _____

Recommended Follow-up

Even if I have no symptoms, I should have my first ultrasound or MRI at 5-6 years after my initial implant surgery and then every 2-3 years thereafter. If I have symptoms or uncertain ultrasound results for breast implant rupture, an MRI is recommended.

I understand that for as long as I have my breast implant(s), I will need routine and regular follow-up with my physician, for examination of my breast implant(s) as well as to discuss any updates regarding breast implant issues.

National Breast Implant Registry (NBIR): I understand and have discussed with my physician that there is a National Breast Implant Registry where information regarding my health and breast implant information can be entered. The NBIR may help understand the long-term safety and performance of breast implants.

Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma (ALCL) etiology and Epidemiology (PROFILE): I understand and have discussed with my physician that there is a registry (PROFILE) where information is collected to better understand BIA-ALCL in patients with breast implants.

Patient Initials: _____

Questions for My Physician

I have had the opportunity to ask my physician questions about his or her experience, medical degree, specialty of training, and credentials. I understand that breast implants have associated procedural risks and should only be used by physicians who are appropriately trained.

Patient Initials: _____

Options Following Mastectomy

I understand that breast reconstruction is an elective procedure, which I can choose to do or not.

I understand that I may choose not to have breast reconstruction ("going flat") and may choose to use an external prosthesis in my bra to look like I have a breast when wearing clothes.

I understand the surgical options for breast reconstruction, including the use of a breast implant and the use of my own tissue ("autologous reconstruction").

I understand that if my breast implants are ever removed, I may be left with dimpling, chest wall concavity, puckering, or sagging of my breasts or skin.

I understand that more surgeries may be necessary in the future due to complications or to remove or replace the breast implants.

I have discussed all of the options for breast reconstruction with my surgeon, including whether I am a candidate and the benefits and risks of each, and I believe that breast reconstruction with a breast implant is the best option for me.

Patient Initials: _____

Breast Augmentation Options

I understand that breast augmentation is an elective procedure to increase the size of my breasts.

I understand that breast augmentation may result in permanent changes to my breast tissue and if my implants are ever removed, I may be left with an unsatisfactory appearance, changes to the size and shape of my breasts, including but not limited to dimpling, chest-wall concavity, puckering, sagging, or different incision size or location.

If I am an augmentation patient, any additional surgeries or medical procedures will likely be at my own expense.

Patient Initials: _____

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the patient information documents for the specific implant that will be used during my surgery and that I have had time to discuss the information in it and on this document with my physician. I have had the opportunity to ask questions and understand the benefits and risks of breast implants for me, given my specific health conditions. I have considered alternatives to breast implants, including reconstruction without breast implants, no reconstruction/augmentation, and their respective benefits and risks.

_____

Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of breast implants as described elsewhere in the patient information documents and in this checklist. I have also explained the benefits and risks of the alternatives. I have encouraged the patient to ask questions, and I have addressed all questions.

_____

Physician Signature and Date

Natrelle®

Allergan Sales, LLC
2525 Dupont Drive
Irvine, CA 92612
1.800.624.4261

www.allergan.com

74009US10 11/2021

Allergan™