

# Reconstruction

## Breast Reconstruction with *NATRELLE*<sup>®</sup> Silicone-Filled Breast Implants and *NATRELLE INSPIRA*<sup>®</sup> Breast Implants Smooth Surface Implants

**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 the information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Allergan.



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# Glossary

<b>Areola</b>	The pigmented or darker colored area of skin surrounding the nipple of the breast.
<b>Asymmetry</b>	Uneven appearance between a woman's left and right breasts in terms of size, shape, or breast level.
<b>Atrophy</b>	Thinning or diminishing of tissues or muscle.
<b>Autoimmune disease</b>	An autoimmune disease is a disease in which the body's immune system attacks its own cells or tissues by mistake, causing damage and dysfunction. Autoimmune diseases can affect connective tissue in the body (the tissue that binds together body tissues and organs). Autoimmune diseases can affect many parts of the body, like nerves, muscles, glands, and the digestive system.
<b>Axilla</b>	The junction of your arm and your body (armpit).
<b>Biocompatible</b>	The ability to exist along with living tissues or systems without causing harm.
<b>Biopsy</b>	The removal and examination of tissues, cells, or fluid from the body.
<b>Body Dysmorphic Disorder</b>	A psychological condition characterized by excessive worry about an imagined or minor physical flaw to the point that it can interfere with normal daily activities.
<b>Body Esteem Scale</b>	A questionnaire which asks about a person's body image.
<b>Breast augmentation</b>	A surgical procedure to increase breast size. For this brochure, it refers to placement of a breast implant. The first time an implant is placed for augmentation is called "primary augmentation." Any time there is another surgery to replace the implant, it is referred to as "revision-augmentation."
<b>Breast implant</b>	Any surgically implanted artificial device intended to replace missing breast tissue or to enhance a breast.
<b>Breast Implant Associated Anaplastic large cell lymphoma (BIA-ALCL)</b>	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.

Breast mass

A lump in the breast.

Breast reconstruction

A surgical procedure to replace breast tissue or reconstruct a breast after tissue was taken out because of cancer or injury. Breast reconstruction also includes the surgical correction of a breast that has failed to develop properly due to a severe abnormality or congenital defect. For this document, it refers to placement of a breast implant.

The first time a breast implant is placed to replace breast tissue is referred to as "primary reconstruction." Any time there is another surgery to replace the implant it is referred to as "revision-reconstruction."

Calcification

Process of hardening by calcium salts.

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.<sup>16</sup>

- 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

<b>Capsule</b>	Scar tissue which forms around the breast implant.
<b>Capsulotomy (closed)</b>	An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but may rupture the implant and is contraindicated.
<b>Capsulotomy (open)</b>	An attempt to break the scar tissue capsule around the implant by surgical incision into the capsule.
<b>cc</b>	Cubic centimeters. A measure of implant volume. The higher the cc value, the higher the implant volume. For example, an 800 cc implant is larger than a 200 cc implant.
<b>Congenital abnormality</b>	An abnormal development in part of the body, present in some form since birth.
<b>Connective tissue disease/disorder (CTD)</b>	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc., and/or the immune system. Connective tissue diseases (CTDs) that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.
<b>Contraindication</b>	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
<b>Contralateral</b>	Opposite side.
<b>Core Study</b>	The primary clinical study of augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients that supported the approval of the premarket approval (PMA) application. Safety and effectiveness data are collected yearly through 10 years, with the follow-up from years 5 through 10 being performed as part of a post-approval Core Study.
<b>Delayed wound healing</b>	Unusually slow progress in the healing of a wound; surgical incision site fails to heal normally or takes longer to heal.
<b>Displacement</b>	Movement of the implant from the usual or proper place.
<b>Extrusion</b>	Skin breakdown with the implant pressing through the skin or surgical incision.

<b>Fibromyalgia</b>	A disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue.
<b>Fibrous tissues</b>	Connective tissues composed mostly of fibers.
<b>Flap</b>	A portion of tissue (which may include muscle, fat, and skin) moved from one part of the body to another. The tissue flap may or may not have its blood supply attached.
<b>Gel bleed</b>	When silicone gel leaks or “bleeds” or diffuses through the implant shell.
<b>Gel fracture</b>	Appearance of a fissure or fault line in highly cohesive gel in response to an applied force.
<b>Granuloma</b>	A noncancerous lump that can form around any foreign material, such as silicone. Like any lump, it should be evaluated to distinguish it from a lump that might be cancerous.
<b>Hematoma</b>	A collection of blood within a space.
<b>Hypertrophic scarring</b>	An enlarged scar that remains after a wound heals.
<b>Incision</b>	A cut made to the tissue during surgery.
<b>Infection</b>	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.
<b>Inflammation</b>	The response of the body to infection or injury that is characterized by redness, swelling, warmth, and/or pain.
<b>Inframammary</b>	Below the breast.
<b>Inpatient surgery</b>	A surgical procedure in which the patient is required to stay overnight in the hospital.
<b>Lactation</b>	The production and secretion of milk by the breast glands.
<b>Latissimus dorsi</b>	Two triangular muscles running from the spinal column to the shoulder.
<b>Low molecular weight silicones</b>	Small silicone molecules that might leak out of the implant.



## Lymph nodes

Glands that play an important part in the body's defense against infection. They produce lymph, which travels throughout the body in the lymph system, and filters impurities from the body. Common areas where the lymph nodes can be felt with the fingers include: groin, armpit, neck, under the jaw and chin, behind the ears, and on the back of the head.

## Lymphadenopathy

Enlargement of the lymph node(s).

## Lymphedema

Swelling of the lymph node(s).

## 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, or capsular contracture.

## Mammary

Pertaining to the breast.

## Mammography

A type of x-ray examination of the breasts used for detection of cancer.

Screening mammography – x-ray examination of the breast that is performed on women with no complaints or symptoms of breast cancer; the goal is to detect breast cancer when it is still too small to be felt by a physician or the patient.

Diagnostic mammography – x-ray examination in order to evaluate a breast complaint or abnormality detected by physical exam or screening mammography; additional views of the breast are usually taken.

## Mammoplasty

Plastic surgery of the breast.

## Mastectomy

Partial or complete removal of the breast due to the presence of a cancerous or precancerous growth.

- Subcutaneous mastectomy: surgical removal of the breast tissues, but sparing the skin, nipple, and areola.
- Total mastectomy: surgical removal of the breast including the nipple, areola, and most of the overlying skin.
- Modified radical mastectomy: surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the lymphatic-bearing tissue in the axilla.
- Radical mastectomy: surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the pectoral muscles, lymphatic bearing tissue in the axilla, and various other neighboring tissue.

## Mastitis

Inflammation of the breast.

## Mastopexy

Surgical procedure to raise and reshape sagging breasts.

## Metastatic disease

A stage of cancer after it has spread from its original site to other parts of the body.

## Migration

Movement of silicone materials outside the breast implant to other parts of the body.

## MRI (Magnetic Resonance Imaging)

A radiographic examination that currently has the best ability to detect rupture of silicone gel-filled breast implants.

## Necrosis

Death of cells or tissues.

## Oncologist

A medical doctor who specializes in diagnosing and treating cancer.

## Outpatient surgery

A surgical procedure in which the patient is not required to stay in the hospital overnight.

## Palpability

The ability to feel the implant.

## Palpable

Felt with the hand.

## Patch assembly

The patch assembly seals the implant shell.

## Pectoralis

Major muscle of the chest.

## Periareolar

Around the darkened or pigmented area surrounding the nipple of the breast.

Plastic surgery	Surgery intended to enhance or improve the appearance of the body.
Pneumothorax	Pneumothorax (sometimes called "collapsed lung") occurs when air leaks into the space between the lung and chest wall.
Postoperative	After surgery.
Precautions	Information that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
Primary breast reconstruction	The first time a breast implant is placed for the purpose of breast reconstruction.
Ptosis	Sagging or drooping of the breast.
Reoperation	An additional surgery after your first breast implantation.
Revision-reconstruction	Refers to the correction or improvement of a primary reconstruction. For this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast reconstruction.
Rheumatologic disease/disorder	A variety of diseases involving connective tissue structures of the body, especially the joints and fibrous tissue. These diseases are often associated with pain, inflammation, stiffness, and/or limitation of motion of the affected parts. Can include autoimmune diseases. Fibromyalgia is a rheumatological disorder.
Rosenberg Self-Esteem Scale	A questionnaire that measures overall self-esteem.
Rowland Expectation Scale	A 16-item questionnaire intended to measure expectations and perceived results of implant surgery.
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).
Saline	A solution made of water and a small amount of salt.
Scar revision	A surgical procedure to improve the appearance of a scar.

<b>Seroma</b>	Similar to a bruise, a seroma occurs when the watery portion of the blood collects around a surgical incision or around a breast implant.
<b>SF-36 Scale</b>	The Short Form 36 Health Scale; a questionnaire intended to measure physical, mental, and social health.
<b>Silent rupture</b>	A breast implant rupture without symptoms or a visible change. Silent rupture cannot be felt by the woman or detected by a doctor through physical examination. Silent rupture can only be discovered through appropriate imaging techniques such as MRI. Most silicone gel-filled breast implant ruptures are silent (see symptomatic rupture below).
<b>Silicone elastomer</b>	A type of silicone that has elastic properties similar to rubber.
<b>Subglandular placement</b>	Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.
<b>Submuscular placement</b>	Placement of a breast implant wholly or partially underneath the chest muscle.
<b>Symptom</b>	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
<b>Symptomatic</b>	Experiencing symptoms; any evidence or sign of disease or disorder.
<b>Symptomatic rupture</b>	A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape). Some silicone breast implant ruptures are symptomatic, but most are silent.
<b>Systemic</b>	Pertaining to or affecting the body as a whole.
<b>Tissue expander</b>	An adjustable implant that can be inflated with saline to stretch the tissue at the mastectomy site. This is used to create a new tissue flap that is large enough to cover the breast implant.

## Toxic shock syndrome

A rare, but life-threatening bacterial infection that may occur after surgery. It occurs most often in the vagina of menstruating women using superabsorbent tampons. Symptoms include sudden fever, vomiting, diarrhea, decreased blood pressure, fainting, dizziness, and sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment if toxic shock syndrome is suspected.

## Transaxillary

Under the arm.

## Warning

Statement that alerts the reader about a situation which, if not avoided, could result in serious injury or death.



## 1.0 Considering Silicone Gel-Filled Breast Implant Surgery

You may be considering breast implant surgery to restore your breast shape after a mastectomy or an injury that resulted in either partial or total loss of your breast(s) or to correct a birth defect. This is referred to as breast reconstruction. Or you may need to have implants from a previous breast reconstruction corrected or improved, which is called revision-reconstruction. Whether you decide to have breast reconstruction depends on your own individual case, medical condition, general health, lifestyle, emotional state, and breast size and shape. You may wish to speak with your family, friends, breast implant support groups, and breast cancer support groups to help you in making this decision.

If you are considering breast reconstruction and do not have a plastic surgeon, ask your general surgeon for the names of experienced, board-certified plastic surgeons in your area. Your general surgeon, plastic surgeon, and oncologist should work together to plan your mastectomy and reconstruction procedure to give you the best possible result.

Allergan has prepared this information to help you better understand the breast implant procedure and assist you in making an informed decision about breast reconstruction or revision-reconstruction surgery. It will help to answer some of the questions you may have about the surgery and about breast implants in general. It will also provide you with specific information about the risks and benefits of Allergan's **NATRELLE**<sup>®</sup> Silicone-Filled Breast Implants and **NATRELLE INSPIRA**<sup>®</sup> Breast Implants. Similar information to help you understand breast reconstruction is available from your plastic surgeon, Allergan, or at [www.allerganlabeling.com](http://www.allerganlabeling.com).

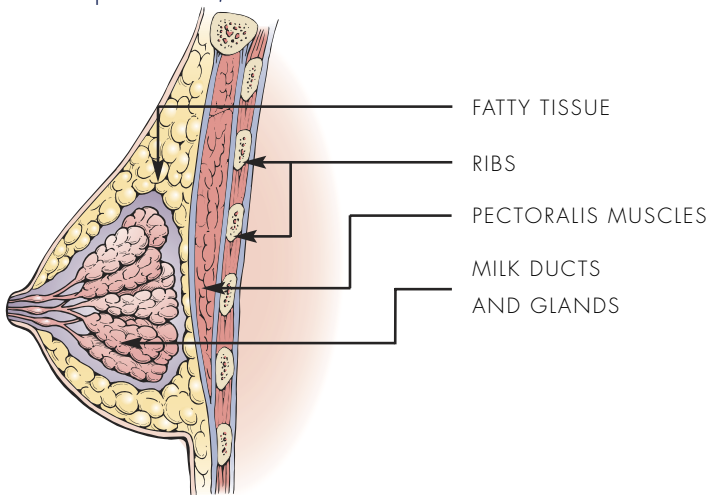
This information cannot and should not replace talking to your plastic surgeon. Your decision on whether or not to get breast implants should be based on realistic expectations of the outcome. There is no guarantee that your results will match those of other women. Your results will depend on many individual factors, such as your overall health (including age), chest structure, breast/nipple shape and position, skin texture, healing capabilities (which may be slowed by radiation and chemotherapy treatment, smoking, alcohol, and various medications), tendency to bleed, prior breast surgery, surgical team's skill and experience, type of surgical procedure, and type and size of implant. Make sure you speak with your surgeon about your expectations of the results, as well as what you can expect regarding the length of the surgery, your recovery, and any risks and potential complications of the surgery. Ask questions.

As part of your decision, both you and your surgeon should sign Allergan's "[Acknowledgement of Informed Decision and Patient Decision Checklist](#)" form that confirms your understanding of the risks and benefits of Allergan's **NATRELLE®** Silicone-Filled Breast Implants and **NATRELLE INSPIRA®** Breast Implants. This form is located at the end of this document.

Because breast implants will require monitoring and care for the rest of your life, you should wait at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast reconstruction surgery. In the case of a revision-reconstruction, however, your surgeon may find it medically advisable to perform your surgery sooner.

## 1.1 What Gives the Breast Its Shape?

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. Beneath the breast is the chest muscle (pectoralis major muscle).



Implants are used to make the breast larger or to restore/replace breast tissue. Factors such as pregnancy (when milk glands are temporarily enlarged), rapid weight loss, and the effects of gravity as you age, combine to stretch the skin, which may cause the breast to droop or sag. The implants alone may not adequately lift the breast, or correct the effects of pregnancy, weight loss, or skin stretching. Your surgeon may suggest additional procedures at the time of the breast reconstruction, such as mastopexy, to help achieve improved breast lift.

Breast cancer surgery (full or partial mastectomy or lumpectomy) can greatly change the shape and appearance of the breast. When a woman has a mastectomy some, much, or all of the breast tissue may be removed, and some skin may be removed as well. There will be scarring, and the tissue (skin and breast tissue) may be more sensitive because of the surgery, or chemotherapy, and/or radiation treatments. All of these can affect the size, shape, and overall outcome of reconstruction with breast implants.



## 1.2 What Is a Silicone-Filled Breast Implant?

A silicone gel-filled breast implant is a sac (implant shell) of silicone elastomer (rubber) filled with silicone gel. Allergan has approval for three types of silicone gel fillers: *Responsive* silicone gel, *SoftTouch* silicone gel, and *Highly Cohesive* silicone gel. Each gel filling varies in the amount of firmness it provides to the implant. *Responsive* silicone gel is the least firm gel and *Highly Cohesive* is the most firm gel offered. *SoftTouch* silicone gel has a firmness level that is in between that of the *Responsive* silicone gel and the *Highly Cohesive* silicone gel. This document focuses on round implants filled with each of the three gel types.

Allergan offers two lines of round silicone-filled breast implants: **NATRELLE**<sup>®</sup> Silicone-Filled Breast Implants and **NATRELLE INSPIRA**<sup>®</sup> Breast Implants. **NATRELLE**<sup>®</sup> Silicone-Filled Breast Implants are filled with *Responsive* silicone gel. **NATRELLE INSPIRA**<sup>®</sup> Breast Implants are filled with *Responsive* silicone gel (**NATRELLE INSPIRA**<sup>®</sup> *Responsive* Breast Implants), *SoftTouch* silicone gel (**NATRELLE INSPIRA**<sup>®</sup> *SoftTouch* Breast Implants), and *Highly Cohesive* silicone gel (**NATRELLE INSPIRA**<sup>®</sup> *Cohesive* Breast Implants). Refer to [Section 3.1.1](#) for more information on the different **NATRELLE**<sup>®</sup> Silicone-Filled Breast Implants and **NATRELLE INSPIRA**<sup>®</sup> Breast Implants available from Allergan.

Product Name	Gel Filling
<i>NATRELLE</i> <sup>®</sup> Silicone-Filled Breast Implants	<i>Responsive</i> silicone
<i>NATRELLE INSPIRA</i> <sup>®</sup> <i>Responsive</i> Breast Implants	<i>Responsive</i> silicone
<i>NATRELLE INSPIRA</i> <sup>®</sup> <i>SoftTouch</i> Breast Implants	<i>SoftTouch</i> silicone
<i>NATRELLE INSPIRA</i> <sup>®</sup> <i>Cohesive</i> Breast Implants	<i>Highly Cohesive</i> silicone

The images shown below are examples of the **NATRELLE®** Silicone-Filled Breast Implants and **NATRELLE INSPIRA®** Breast Implants you may have seen at your surgeon's office.

**Example of a NATRELLE® Silicone-Filled Breast Implant**



**Example of NATRELLE INSPIRA® Breast Implant**



**NATRELLE® Silicone-Filled Breast Implant Device Materials**

The potential toxicity of the chemicals and metals listed in the following tables have been evaluated with both toxicity testing and risk assessments to assess the exposure levels in comparison to the amount determined to likely be safe. All detected elements were below levels that are considered unsafe. However, individual responses to chemicals may vary, and all reactions cannot be predicted. Most of these chemicals stay inside the shell of the implant but small quantities have been found to diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking.

**Breast Implant Device Materials**

Implant Component	Device Materials
Shell, inner/outer layers	Dimethyl Silicone Elastomer Dispersion
Shell, barrier layer	Diphenyl Silicone Elastomer Dispersion
Shell textured layer	MED-6400 Silicone Elastomer
Patch assembly	MED 2174 and MED 2-6650 Silicone Elastomer
Gel	Silicone Gel: Base and Crosslinker; platinum cure

## Chemicals Released by NATRELLE® Silicone-Filled Breast Implants

**Volatiles:** Chemicals that are released by breast implants as a gas.

**Extractables:** Chemicals that are released by breast implants following soaking in water and/or organic solvent (liquid).

The breast implants were analyzed to understand your potential exposure to chemicals.

Analysis for volatiles present in the shell and patch material showed that the shell contained up to 279µg of 1, 1, 1 trichloroethane and 251µg of isopropyl alcohol. Analysis for volatiles present in the gel was not necessary because the gel materials do not contain any organic solvents.

To assess for extractables, the shell and the gel components were separated for analysis. "Virgin shells", which contained the patch assembly and had been sterilized, but not yet gel-filled, were also analyzed. An analysis technique called exhaustive extraction was used. The highest level of extractable material was used when hexane, a non-polar solvent, was used for the extraction, and thus results with the hexane extracts are shown below.

The concentrations of smaller molecular weight extractables, as shown below, were highly comparable to those present with FDA-approved saline-filled breast implants.

Identification	Gel (ppm)	Implant Shell and Patch (ppm)	Virgin Shell and Patch (ppm)
D3	ND (<146)	ND (<17)	ND (<7)
D4	ND (<69)	ND (<8)	ND (<3)
D5	ND (<6)	ND (<1)	ND (<1)
D6	ND (<6)	ND (<1)	ND (<1)
D7	ND (<6)	ND (<1)	ND (<1)
D8	ND (<8)	ND (<1)	ND (<1)
D9	ND (<8)	6	ND (<1)
D10	ND (<8)	12	2
D11	11	21	9
D12	32	94	26
D13	64	62	65
D14	237	186	209
D15	366	278	285
D16	491	351	317
D17	593	432	328
D18	729	527	342
D19	678	601	0
D20	735	605	212
D21	668	474	129
L1	ND (<63)	ND (<7)	ND (<3)

Identification	Gel (ppm)	Implant Shell and Patch (ppm)	Virgin Shell and Patch (ppm)
L2	ND (<8)	ND (<1)	ND (<1)
L3	ND (<8)	ND (<1)	ND (<1)
L4	ND (<10)	ND (<1)	ND (<1)
L5	ND (<8)	ND (<1)	ND (<1)
L6	ND (<7)	ND (<1)	ND (<1)
L7	ND (<8)	2	4
L8	ND (<8)	2	ND (<1)
L9	ND (<9)	8	ND (<1)
L10	19	17	ND (<1)
L11	35	29	ND (<1)
L12	63	49	ND (<1)
L13	103	84	ND (<1)
L14	132	108	ND (<1)
L15	169	128	ND (<1)
L16	183	106	ND (<1)
L17	161	137	ND (<1)
L18	177	128	ND (<1)
Diphenyl siloxanes	242	985	2762

ND (<X) = Not detected at less than X, the concentration in parts per million

## Heavy Metal Analyses

Analyses were conducted on breast implants to determine your potential exposure to inorganic (metallic) elements. Any metallic elements not listed in the table were non-detectable.

Metal	Virgin Shell (standard dispersion) (ppm)	Virgin Shell (barrier dispersion) (ppm)	Patch (ppm)	Gel (ppm)
Antimony	ND (<0.1)	ND (<0.1)	ND (<0.1)	ND (<0.1)
Arsenic	ND (<0.1)	ND (<0.1)	ND (<0.1)	ND (<0.1)
Barium	1	1	2	1
Beryllium	ND (<0.1)	ND (<0.1)	ND (<0.1)	ND (<0.1)
Cadmium	ND (<0.1)	ND (<0.1)	ND (<0.1)	ND (<0.1)
Calcium	ND (<10)	ND (<10)	ND (<10)	ND (<10)
Chromium	0.3	0.4	1.8	0.2
Cobalt	ND (<0.2)	ND (<0.2)	ND (<0.2)	ND (<0.2)
Copper	ND (<0.1)	ND (<0.1)	ND (<0.1)	ND (<0.1)
Iron	ND (<0.1)	0.2	8.7	1.2
Lead	ND (<0.2)	ND (<0.2)	ND (<0.2)	0.3
Magnesium	ND (<10)	ND (<10)	ND (<10)	ND (<10)
Manganese	ND (<0.05)	ND (<0.05)	0.15	ND (<0.05)
Mercury	ND (<1)	ND (<1)	ND (<1)	ND (<1)

Metal	Virgin Shell (standard dispersion) (ppm)	Virgin Shell (barrier dispersion) (ppm)	Patch (ppm)	Gel (ppm)
Molybdenum	ND (<0.5)	ND (<0.5)	ND (<0.5)	ND (<0.5)
Nickel	ND (<0.2)	1	0.7	ND (<0.2)
Potassium	ND (<1)	8	1	ND (<1)
Selenium	ND (<0.1)	ND (<0.1)	ND (<0.1)	ND (<0.1)
Silver	ND (<0.1)	0.2	ND (<0.1)	ND (<0.1)
Sodium	ND (<10)	ND (<10)	ND (<10)	ND (<10)
Thallium	ND (<1)	ND (<1)	ND (<1)	ND (<1)
Vanadium	ND (<0.4)	ND (<0.4)	ND (<0.4)	ND (<0.4)
Zinc	0.12	ND (<0.05)	3.9	0.22

ND (<X) = Not detected at less than X, the concentration in parts per million

In addition, catalyst metal analyses were carried out on the shell and gel components of the device. The shell and patch were found to contain 5.9 ppm of platinum, the patch was found to contain 6.6 ppm of tin, and the gel was found to contain 4.0 ppm of platinum. Platinum is a metal used as a catalyst in the manufacture of the shell and gel components of silicone breast implants. The small amounts of platinum remaining in the product following manufacturing may enter the body, either by diffusing through the intact shell (i.e., through gel bleed) or through an implant rupture. However, based on a review of the gel bleed testing, the published literature on the topic, as well as the biocompatibility testing and clinical data on the device, FDA concluded that the platinum contained in breast implants is in the zero oxidation state, which has the lowest toxicity and, thus, does not pose a significant risk to women with silicone breast implants.

### 1.3 Who is eligible for **NATRELLE®** Silicone-Filled Breast Implants and **NATRELLE INSPIRA®** Breast Implants?

**NATRELLE®** Silicone-Filled Breast Implants and **NATRELLE INSPIRA®** Breast Implants have been approved for females 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.

A separate patient brochure is available for those women considering breast augmentation surgery and should be read prior to reaching a decision to undergo breast augmentation.

## 1.4 Who Should not get Breast Implants (What are the Contraindications)?

A contraindication is a condition or circumstance that, if present, means a procedure should not be done. Contraindications for breast implant surgery are discussed in this section.

Breast implant surgery should not be performed in:

- Women with active infection anywhere in their body, because the implant will make the infection much harder to treat should the infection move into the breast.
- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions, because radiation and chemotherapy treatments may increase the risk of some complications seen with breast implants. Also, breast implants may interfere with radiation or chemotherapy treatments.
- Women who are currently pregnant or nursing, because surgery may interfere with the safety of the pregnancy/nursing. Since breast reconstruction is an elective surgery, it should be postponed until you are no longer pregnant or nursing.

## 1.5 Precautions

A precaution is information that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. The following are precautions; safety and effectiveness have not been established in patients with these conditions:

- 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 until these conditions have resolved or stabilized prior to undergoing breast implantation surgery.

## 1.6 Warnings

Warnings are statements that alert the reader about a situation which, if not avoided, could result in serious injury or death. Please take the time to read this entire document before having breast implant surgery. This is important so that you will understand the risks and benefits and have realistic expectations of the outcome of your surgery. Breast implants are associated with many short-term and long-term risks.

There is a boxed warning for breast implants. Please see the cover page.

**WARNING** – Be aware that there are many factors that will affect the outcome and timing of your reconstruction with breast implants. These factors include the stage of your disease, the type and extent of cancer removal surgery you have had, the amount of skin and soft tissue available for the reconstruction, and additional treatments such as chemotherapy and radiation, which you may require. Talk to your doctor about how chemotherapy or radiation may affect your implants.

**WARNING** – Be aware that many of the changes to your breast following implantation cannot be reversed. If you later choose to have your implant(s) removed and not replaced, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes to the breast, which can be permanent.

**WARNING** – Before you decide to have breast implant surgery, you should know that breast implants are not lifetime devices, and breast implantation is likely not a one-time surgery. The longer implants are in place, the greater the potential risk for complications. In the event of complications or unacceptable cosmetic outcomes, you will likely need additional unplanned surgeries on your reconstructed and/or opposite augmented breasts. These additional surgeries can include implant removal or replacement, or other surgical procedures. Later surgeries to replace implants (revision-reconstruction) carry higher risks of complications than the first (primary) reconstruction surgery. Therefore, you should also consider the complication rates for revision-reconstruction since you may experience these risks in the future.

**WARNING** – Your **NATRELLE®** Silicone-Filled Breast Implants or **NATRELLE INSPIRA®** Breast Implants may rupture without any symptoms (silent rupture). This means that neither you nor your surgeon will know that your implants have ruptured. It is recommended that you have periodic imaging (e.g. MRI, ultrasound) of your silicone gel filled breast implants to screen for implant rupture regardless of whether your implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on your medical history or circumstances (i.e., screening mammography

for breast cancer.) 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.

## 2.0 Breast Implant Benefits And Risks

Undergoing any type of surgical procedure involves risks such as the effects of anesthesia, infection, swelling, redness, bleeding, pain, and even death. Some of these risks are serious, and all of these risks need to be balanced against the benefits of the surgery itself. These benefits and risks of breast implants are described below. At the end of this document is a list of published studies used to gather the information discussed in the sections below. These studies may be helpful to you if you wish to learn more about a specific complication or condition. The reference list is not complete because studies are being conducted all the time. Your physician may have other resources for further reading. The information provided below focuses on women undergoing primary reconstruction or revision-reconstruction with **NATRELLE®** Silicone-Filled Breast Implants or **NATRELLE INSPIRA®** Breast Implants. The studies in the list of references also include women undergoing breast augmentation and other types of implants from a variety of manufacturers. The risks and benefits of augmentation may differ from those for breast reconstruction, and the risks of other types of implants may differ from those of **NATRELLE®** Silicone-Filled Breast Implants and **NATRELLE INSPIRA®** Breast Implants.

### 2.1 What are the Benefits?

Breast reconstruction can replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe abnormality. In addition, revision-reconstruction can correct or improve the result of a primary reconstruction surgery.

Breast reconstruction has the potential to offer both physical and psychological benefits to women, including facilitating emotional healing after cancer and regaining body symmetry.<sup>1,3-8</sup> Many studies have reported that a majority of breast implantation patients are satisfied with the results of their surgery. In Allergan's Core Study through 10 years, approximately 9 out of 10 women undergoing primary reconstruction and 7 out of 10 women undergoing revision-reconstruction with **NATRELLE®** Silicone-Filled Breast Implants were satisfied with their breast implants. [Section 5.3](#) provides more information on benefits seen in Allergan's Core Study.



## 2.2 What are the Potential Risks?

Table 1 describes some of the known risks of breast reconstruction along with possible effects of those risks. This information is based on the results of Allergan’s Core study of 98 Primary Reconstruction patients and 15 Revision-Reconstruction patients. 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 no longer are manufactured or marketed. Additional useful information related to these risks is provided following Table 1. [Sections 5.4](#) through [5.7](#) as well as [Tables 2](#) and [3](#) provide more information on risks seen in Allergan’s Core Study.

**Table 1**  
**Risks of Breast Reconstruction Through 10 Years with NATRELLE®**  
**Silicone-Filled Breast Implants**

Event	Likelihood of Event Occurring in Primary Reconstruction Patients <sup>a</sup>	Likelihood of Event Occurring in Revision-Reconstruction Patients <sup>a</sup>	Possible Resulting Effects of the Event
<b>Key Risks</b>			
Additional Surgeries (Reoperations)	72 out of 100 patients (72%)	47 out of 100 patients (47%)	<ul style="list-style-type: none"> <li>• Infection</li> <li>• Scarring</li> <li>• Hematoma or Seroma</li> <li>• Delayed wound healing</li> <li>• Necrosis</li> <li>• Pain or Discomfort</li> <li>• Anesthesia-related complications</li> <li>• Loss of breast tissue</li> <li>• Undesirable cosmetic result</li> </ul>
Implant Removal with Replacement	48 out of 100 patients (48%)	13 out of 100 patients (13%)	<ul style="list-style-type: none"> <li>• Infection</li> <li>• Scarring</li> <li>• Hematoma or Seroma</li> <li>• Delayed wound healing</li> <li>• Necrosis</li> <li>• Pain or Discomfort</li> <li>• Anesthesia-related complications</li> <li>• Loss of breast tissue</li> <li>• Undesirable cosmetic result</li> </ul>
Implant Removal without Replacement	14 out of 100 patients (14%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> <li>• Infection</li> <li>• Scarring</li> <li>• Hematoma or Seroma</li> <li>• Delayed wound healing</li> <li>• Necrosis</li> <li>• Pain or Discomfort</li> <li>• Anesthesia-related complications</li> <li>• Loss of breast tissue</li> <li>• Undesirable cosmetic result</li> </ul>

Event		Likelihood of Event Occurring in Primary Reconstruction Patients <sup>a</sup>	Likelihood of Event Occurring in Revision-Reconstruction Patients <sup>a</sup>	Possible Resulting Effects of the Event
Capsular Contracture (Baker Grade III/IV)		25 out of 100 patients (25%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> <li>• Pain or Discomfort</li> <li>• Breast hardness/firmness</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Rupture	MRI Cohort	35 out of 100 patients (35%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Implant Removal</li> </ul>
	Non-MRI Cohort	18 out of 100 patients (18%)	7 out of 100 patients (7%)	
<b>Other Risks Occurring in 1% or more of Patients</b>				
Asymmetry		23 out of 100 patients (23%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> <li>• Undesirable cosmetic result</li> <li>• Reoperation</li> <li>• Implant Removal</li> </ul>
Wrinkling/Rippling		10 out of 100 patients (10%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Discomfort</li> <li>• Undesirable cosmetic result</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Breast Pain		7 out of 100 patients (7%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Resulting effects are contingent on underlying causes</li> </ul>
Swelling		7 out of 100 patients (7%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> <li>• Resulting effects are contingent on underlying cause(s)</li> </ul>
Implant Palpability/Visibility		6 out of 100 patients (6%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> <li>• Undesirable cosmetic result</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Hypertrophic/Other Abnormal Scarring		6 out of 100 patients (6%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Scar revision procedure (reoperation)</li> <li>• Undesirable cosmetic result</li> </ul>
Infection		3 out of 100 patients (3%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Redness or rash</li> <li>• Pain or tenderness</li> <li>• Swelling</li> <li>• Fever</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Nipple Complications		3 out of 100 patients (3%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Increased or decreased nipple sensitivity</li> <li>• Breastfeeding difficulties</li> <li>• May affect sexual response</li> </ul>
Implant Malposition		2 out of 100 patients (2%)	13 out of 100 patients (13%)	<ul style="list-style-type: none"> <li>• Implant visibility</li> <li>• Asymmetry</li> <li>• Reoperation</li> <li>• Implant Removal</li> </ul>
Seroma/Fluid Accumulation		2 out of 100 patients (2%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> <li>• Swelling</li> <li>• Pain or discomfort</li> <li>• Infection</li> <li>• Incision and drainage (reoperation)</li> <li>• Implant removal</li> </ul>
Skin rash		2 out of 100 patients (2%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> <li>• Swelling</li> <li>• Pain or discomfort</li> <li>• Infection</li> </ul>

Event	Likelihood of Event Occurring in Primary Reconstruction Patients <sup>a</sup>	Likelihood of Event Occurring in Revision-Reconstruction Patients <sup>a</sup>	Possible Resulting Effects of the Event
Hematoma	2 out of 100 patients (2%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Swelling</li> <li>• Pain or discomfort</li> <li>• Infection</li> <li>• Incision and drainage (reoperation)</li> <li>• Implant removal</li> </ul>
Necrosis	2 out of 100 patients (2%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> <li>• Scarring</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Redness	2 out of 100 patients (2%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Resulting effects are contingent on underlying cause(s)</li> </ul>
Bruising	1 out of 100 patients (1%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> <li>• Swelling</li> <li>• Pain or discomfort</li> <li>• Infection</li> <li>• Incision and drainage (reoperation)</li> <li>• Implant removal</li> </ul>
Delayed wound healing	1 out of 100 patients (1%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> <li>• Scarring</li> <li>• Implant extrusion</li> <li>• Necrosis</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Implant Extrusion	1 out of 100 patients (1%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> <li>• Scarring</li> </ul>
Other Complications	1 out of 100 patients (1%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Resulting effects are contingent on underlying cause(s)</li> </ul>

<sup>a</sup> Based on the results of the Allergan Core Clinical Study for the first 10 years after implant surgery. There were 98 Primary Reconstruction patients and 15 Revision-Reconstruction patients enrolled.

### • Additional Surgeries (Reoperations)

You should assume that you will need to have additional surgeries (reoperations). In Allergan's Core Study, approximately 72 out of every 100 women (72%) undergoing primary reconstruction and 47 out of every 100 women (47%) undergoing revision-reconstruction had 1 or more reoperations. Approximately 19 out of every 100 women (19%) undergoing primary reconstruction and 20 out of every 100 women (20%) undergoing revision-reconstruction had 2 or more reoperations. The costs of additional surgeries may not be covered by insurance.

Patients may decide to change the size or type of their implants, requiring additional surgery. In addition, problems such as rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional surgery. Reoperation increases the risk of certain complications, such as rupture, capsular contracture, and infection. [Section 5.5](#) provides more information on reoperations reported in Allergan's Core Study.

- **Implant Removal**

Because these are not lifetime devices, the longer you have your implants the more likely it will be for you to have them removed for any reason, either because of dissatisfaction, an unacceptable cosmetic result, or a complication such as capsular contracture. In Allergan's Core study, approximately 54 out of every 100 women (54%) undergoing primary reconstruction and 20 out of every 100 women (20%) undergoing revision-reconstruction had their implants removed. The vast majority of patients who had their implants removed had them replaced with new implants, which can increase the risk of capsular contracture or reoperation. Removing implants without replacing them can result in dimpling, puckering, wrinkling, or other cosmetic changes in the breast. These changes may be permanent.

Even if you have your implants replaced, implant removal may result in loss of your breast tissue. Also, implant replacement increases your risks of future complications. For example, the risks of capsular contracture and reoperation increase for patients with implant replacement compared to first time placement. You should consider the possibility of having your implants replaced and its consequences when making your decision to have implants. [Section 5.6](#) provides more information on implant removals reported in Allergan's Core Study.

- **Capsular Contracture**

The scar tissue (capsule) that normally forms around the implant may tighten over time and compress the implant, making it feel firm and leading to what is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in revision-reconstruction than in primary reconstruction. Because you may have your initial implants replaced, you should be aware that your risk of capsular contracture increases with revision-reconstruction. Capsular contracture is a risk factor for implant rupture and is the most common reason for reoperation.

Symptoms of capsular contracture range from mild firmness and mild discomfort to severe pain, distorted shape of the implant, and palpability (ability to feel the implant). Capsular contracture is graded into 4 Baker Grade levels depending on its severity:

- 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

Baker Grades III and IV are considered severe, and often additional surgery is needed to correct these grades. Additional surgery may be needed in cases where pain and/or firmness are severe. This surgery ranges from removal of the implant capsule tissue to removal and possible replacement of the implant itself. This surgery may result in loss of your breast tissue. Capsular contracture may happen again after these additional surgeries.

- **Rupture**

An implant rupture is caused by 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). All women should have regular ultrasound or MRI examinations to detect silent rupture. All women who have ruptured implants should have the implants and any gel removed. With **NATRELLE®** Silicone-Filled Breast Implants and **NATRELLE INSPIRA®** Breast Implants silicone rarely migrates outside of the scar tissue capsule. Further information on rupture is provided in [Section 2.3](#) and further information on rupture reported in Allergan's Core Study is provided in [Section 5.7](#).

- **Unsatisfactory Results**

Unsatisfactory results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, and/or hypertrophic scarring, may occur. Some of these results may cause discomfort. Pre-existing asymmetry may not be entirely correctable by implant surgery. Revision surgery may be recommended to maintain patient satisfaction but carries additional considerations and risks. Selecting an experienced plastic surgeon may minimize, but not necessarily prevent, unsatisfactory results.

In Allergan's Core Study, the most common unsatisfactory result was asymmetry. Approximately 37 out of 100 women (37%) who underwent reconstruction had additional surgery to improve asymmetry.

- **Pain**

Pain of varying intensity and length of time may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain. In a European study through 5 years, approximately 1 out of every 100 women with any breast implant had breast pain lasting longer than 3 months.<sup>20</sup> Tell your surgeon about significant pain or if pain persists.

- **Changes in Nipple and Breast Sensation**

Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. While some of these changes can be temporary, they can also be permanent, and may affect your sexual response or your ability to nurse a baby.

- **Infection**

Infection can occur with any surgery or implant. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. In addition, breast and nipple piercing procedures may increase the possibility of infection. Infections in tissue with an implant present are harder to treat than infections in tissue without an implant. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved (cleared up). As with many other surgical procedures, in rare instances, toxic shock syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. You should contact a doctor immediately for diagnosis and treatment if you have these symptoms.

- **Hematoma/Seroma**

Hematoma is a collection of blood within the space around the implant, and a seroma is a build-up of fluid around the implant. Having a hematoma and/or seroma following surgery may result in infection and/or capsular contracture later on. Symptoms from a hematoma or seroma may include swelling, pain, and bruising. If a hematoma or seroma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, some will require surgery, typically involving draining and potentially placing a surgical drain in the wound temporarily for proper healing. A small scar can result from surgical draining. Implant rupture also can occur from surgical draining if there is damage to the implant during the draining procedure.

- **Breastfeeding**

Breastfeeding difficulties have been reported following breast surgery, including breast reduction and breast augmentation. A periareolar incision (an incision around the colored portion surrounding the nipple) may increase the likelihood of problems with breastfeeding. The most common breastfeeding problem is inadequate milk production. [Section 5.7](#) provides more information on breastfeeding complications reported in Allergan's Core Study.

- **Calcium Deposits in the Tissue Around the Implant**

Calcium deposits can form in the tissue capsule surrounding the implant. Symptoms may include pain and firmness. Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer. If additional surgery is necessary to examine and/or remove calcifications, this may cause damage to the implants. Calcium deposits also occur in women who undergo breast reduction procedures, in patients who have had hematoma formation, and even in the breasts of women who have not undergone any breast surgery. The occurrence of calcium deposits increases significantly with age.

- **Extrusion**

Extrusion is when the breast implant comes through your skin. This may occur, for example, when your wound has not closed or when breast tissue covering your implants weakens. Radiation therapy might increase the likelihood of implant extrusion. Most women with extrusion need to have their implant removed. Extrusion requires additional surgery and removal of the implant which may result in additional scarring and/or loss of your breast tissues.

- **Necrosis**

Necrosis is the death of cells or tissues. This may prevent or delay wound healing and require surgical correction, which may result in additional scarring and/or loss of your breast tissue. Implant removal may also be necessary. Infection, steroid use in the surgical pocket, smoking, chemotherapy, radiation, and excessive heat or cold therapy may increase the likelihood of necrosis.

- **Delayed Wound Healing**

Some patients may experience a prolonged wound healing time. Delayed wound healing may increase the risk of infection, extrusion, and necrosis. Smoking may interfere with the healing process. You should contact your surgeon immediately if your wound does not heal within the period of time he/she has discussed with you.

- **Breast Tissue Atrophy/Chest Wall Deformity**

The pressure of the breast implant may cause breast tissue thinning (with increased implant visibility and palpability) and chest wall deformity. This can occur while implants are still in place or following implant removal without replacement. The likelihood of breast tissue atrophy or chest wall deformity is unknown in women undergoing primary reconstruction or revision-reconstruction. Either of these conditions may result in additional surgeries and/or unacceptable dimpling/puckering of the breast.

- **Lymphadenopathy**

Lymphadenopathy is a chronic enlargement of the lymph nodes. A lymph node is a round mass of tissue which makes cells as part of your immune system. The lymph nodes in the armpit (axilla) drain the breast area of fluid. Some patients with breast implants report having enlarged lymph nodes in the armpit(s). Sometimes the enlarged lymph nodes are painful. If they become too large or painful, the lymph node(s) may need to be surgically removed. Painful and/or enlarged lymph nodes should be reported to your doctor. Lymphadenopathy has been associated with tissue reactions, granulomas, and silicone at the lymph nodes of women with intact and ruptured silicone breast implants.<sup>86</sup>

- **Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)**

If you have breast implants you have a very small, but increased risk of developing breast implant associated anaplastic large cell lymphoma, or BIA-ALCL. BIA-ALCL is not breast cancer – it is a rare type of non-Hodgkin’s lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases, it can spread throughout the body. In the cases that have spread beyond the scar tissue and fluid near the implant, rare cases of death have been reported.

Most patients were diagnosed with BIA-ALCL when they sought medical treatment for implant-related symptoms such as swelling, pain, lumps, or asymmetry that developed after their initial surgical sites were fully healed. In the cases known to FDA to date, BIA-ALCL was diagnosed years after the breast implant was placed. The earliest report was less than one year after implant placement and the latest was 34 years after the implant surgery. About half the cases occurred within the first 8 years after implant as of the August 20, 2020 FDA report. BIA-ALCL was most often diagnosed in women who had textured implants. The textured implant may have been placed at the most recent surgery or at any other prior breast implant operation.

If you develop swelling or pain around your breast implants, be sure to talk to your health care provider. Your health care provider should consider the possibility of BIA-ALCL if, after you recover from your breast implant operation, you later notice changes in the way your breast looks or feels – including swelling or pain around the implant. If your health care provider suspects BIA-ALCL, they will refer you to an appropriate specialist for evaluation which may involve obtaining fluid and some tissue samples from around your breast implant. If a diagnosis of BIA-ALCL is confirmed, the doctor will develop an individualized treatment plan for you. Because of the small number of cases worldwide and the variety of available treatment options, there is no single defined treatment. However, if you are diagnosed with BIA-ALCL, the National Comprehensive Cancer Network (NCCN) recommends removing the implant and the surrounding tissue. If you have breast implants you should monitor them and follow your routine medical care. You do not need to take any additional steps. It is not necessary to remove your breast implants if you have no symptoms without a diagnosis of BIA-ALCL.

If you are diagnosed with BIA-ALCL, you can help the FDA understand the disease and effectiveness of treatment.

You or your doctor should report all confirmed cases of BIA-ALCL to the FDA (<https://www.fda.gov/Safety/MedWatch/>). In some cases, the FDA may contact you for additional information. The FDA will keep the identities of the reporter and the patient confidential.



In addition, if you are diagnosed with BIA-ALCL, talk to your doctor about reporting it to the PROFILE Registry (<https://www.thepsf.org/research/clinical-impact/profile.htm>). Every case of BIA-ALCL should be reported to the PROFILE Registry because this helps provide a better understanding of the disease.

If you are considering breast implant surgery, you should discuss the risks and benefits with your health care provider. You may also visit the FDA's Breast Implants website for additional information [www.fda.gov/medical-devices/breast-implants/risks-and-complications-breast-implants](http://www.fda.gov/medical-devices/breast-implants/risks-and-complications-breast-implants).

For additional information on FDA's analysis and review of BIA-ALCL, please visit:

[www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl](http://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl)

## 2.3 What Causes Breast Implants to Rupture and How Can I Tell if My Implants Are Ruptured?

*Breast implants are not lifetime devices.* Breast implants rupture when the shell develops a tear or hole. Your breast implants can rupture any time after they are implanted, but they are more likely to rupture the longer you have them. The following things may cause your implant to rupture: damage by surgical instruments; stressing the implant during implantation which may weaken it; folding or wrinkling of the implant shell; excessive force to the chest (for example, during closed capsulotomy, which is contraindicated); trauma; compression during mammographic imaging; and severe capsular contracture. Breast implants may also simply wear out over time.

If a device rupture is found, Allergan conducts laboratory studies to determine the cause of the rupture, such as damage during surgery, or a "wear-out" of the device. These studies include a comprehensive visual and microscopic inspection of the shell, including a measurement of shell thickness, and observation of various characteristics near the rupture location as well as in the entire shell. Mechanical testing of the implant shell may also be performed to better determine the cause of an observed rupture. There may still be unidentified causes of rupture. These laboratory studies will continue to try to identify any additional causes of rupture.

When the shell of a breast implant develops a tear or hole, the silicone gel inside **NATRELLE®** Silicone-Filled Breast Implants and **NATRELLE INSPIRA®** Breast Implants tends to stay in place, making ruptures especially difficult to detect. This means that most of the time neither you nor your plastic surgeon will know if your breast implant has a tear or hole, called a silent rupture. In fact, a plastic surgeon who is familiar with breast implants is likely to detect less than 3 out of every 10 ruptured silicone breast implants by physical examination.<sup>12</sup> The best method to identify a silent rupture is currently MRI examination.

MRI examination can detect about 9 out of every 10 ruptured silicone breast implants.<sup>13</sup> It is recommended that you have periodic imaging (e.g. MRI, ultrasound) of your silicone gel filled breast implants to screen for implant rupture regardless of whether your implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on your medical history or circumstances (i.e., screening mammography for breast cancer.) 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 cost of these image screenings may exceed the cost of your initial surgery over your lifetime. This cost may not be covered by your insurance, so you should take it into account when deciding to have breast reconstruction.

Sometimes there are symptoms associated with gel implant rupture. If your implants rupture, you may notice hard knots or lumps surrounding the implant or in the armpit, your breast or the implant may change shape or get smaller, or you may notice pain, tingling, swelling, numbness, burning, or hardening in your breast. If you have any of these symptoms you should have an MRI to determine if your implants have ruptured.<sup>1,14</sup>

If you have an MRI or ultrasound that shows signs of rupture, or if your surgeon determines you have signs or symptoms of rupture, he or she will talk with you about your options. As a precaution, Allergan recommends that ruptured implants be taken out permanently and replaced with a new implant or not replaced, depending on your preference or medical need.

There are also consequences of rupture. If your implants rupture, the silicone gel may remain within the scar tissue capsule around the implant. The silicone gel may also move outside the capsule or it may move beyond the breast (gel migration). The silicone gel from a ruptured implant may begin inside the capsule and progress outside the capsule through gel migration if it is not removed. Ruptured implants might also have consequences on your health. More information on these consequences, as reported in the literature, is included below.

In Allergan's 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. They are called the non-MRI cohort. The rupture rate for the whole MRI cohort in Allergan's Core Study (including augmentation, revision-augmentation, reconstruction, and revision-reconstruction patients) through 10 years was 13.0% for patients and 7.7% for implants. For the non-MRI cohort, the rupture rate through 10 years was 9.5% for patients and 5.6% for implants. Rupture rates are presented by patient and by implant as some patients may experience

rupture in both implants. Across all patients in Allergan's Core Study, all ruptures were intracapsular, with the exception of 3 cases of extracapsular gel (one rupture progressed to extracapsular gel following exploratory surgery to confirm the rupture and then implant replacement was delayed). There were no cases of migrated gel.

Further rupture rate information on *NATRELLE*® Silicone-Filled Breast Implants is provided from a published European study known as the International MRI Study.<sup>11</sup> Silent rupture data were collected via a single MRI on 77 Augmentation, 11 Reconstruction, and 18 Revision patients implanted with smooth and textured *NATRELLE*® implants by 5 surgeons. The average age of the implants was approximately 11 years. Silent rupture was found in approximately 15% of the combined group of Augmentation, Reconstruction, and Revision patients and 8% of the implants. There was one possible case of extracapsular rupture, with the remainder classified as intracapsular ruptures. No cases of gel migration were found.

Additional information on rupture will be collected through Allergan's post-approval study called the Breast Implant Follow-Up Study (BIFS).

#### Additional Information on Consequences of Rupture from Literature

Below is a summary of information related to the health consequences of implant rupture. Keep in mind that some doctors and scientists disagree as to the validity of some of these reports. These reports were in women who had implants from a variety of manufacturers and implant models.

- Ruptured breast implants have been associated with breasts becoming hard, changing shape or size, and becoming painful.<sup>14</sup> These symptoms are not specific to rupture, as they also are experienced by women who have capsular contracture.
- There have been rare reports of the silicone gel from implants moving to nearby locations such as the chest wall, armpit, or upper abdominal wall, and even as far as the arm or the groin. This migrating gel has damaged nerves, formed granulomas and/or broken down tissues in direct contact with the gel in a few cases. There have been reports of silicone in the liver of women with silicone breast implants. Silicone gel material has moved to lymph nodes in the armpit, even in women whose implants did not appear to have ruptured, leading to lymphadenopathy.<sup>86</sup>
- Concerns have been raised that women with ruptured implants are more likely to develop connective tissue disease, rheumatic disease, fatigue, or fibromyalgia.<sup>23,25,40,41</sup> To determine if these diseases are related to ruptured implants, a number of studies have evaluated many women with breast implants. Only one small study distinguished between women with ruptured or intact implants.<sup>25</sup> Most doctors and researchers agree that there is no evidence that ruptured implants or migrated gel causes any disease that affects the whole body (systemic disease) like Connective Tissue Disease (CTD) or cancer.

## 2.4 What Are Other Reported Conditions?

Patients receiving breast implants have reported a variety of signs and 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.

There have been reports of women with silicone gel-filled breast implants developing other conditions. The relationships between many of these conditions and breast implants have been studied and are discussed below. Furthermore, there may be unknown risks associated with breast implants.

- **Connective Tissue Disease (CTD)**

Connective tissue diseases include diseases such as lupus, scleroderma, rheumatoid arthritis, and fibromyalgia. Some scientific evidence published from 1988 to 2007 supports the conclusion that there is no increased risk of connective tissue disease or autoimmune disorders for women with silicone gel breast implants.<sup>1,21-28,30-34,36,38,41,42,44</sup> Some independent scientific panels and review groups (1988-2016) have also concluded that the weight of the evidence shows no relationship between breast implants and connective tissue disease, or at least if a risk cannot be absolutely excluded, it is too small to be measured.<sup>1,8,10,21,23,24,29,30,35,33,37,39-41</sup>

- **CTD Signs and Symptoms**

Some women (even without breast implants) may have some of the signs or symptoms of CTDs, without having the actual disease. Patients receiving breast implants have reported a variety of signs and 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.

Some panels of expert scientists and literature reports published between 2000 and 2004 found no evidence that silicone breast implants cause a consistent pattern of CTD signs and symptoms.<sup>1,43-46</sup> Having these CTD signs and symptoms does not necessarily mean you have a CTD; however, you should be aware that you may experience these signs and symptoms after undergoing breast implantation. If you notice an increase in these signs or symptoms, you should consider seeing a rheumatologist to determine whether these signs or symptoms are due to a connective tissue disorder or autoimmune disease.

- **Cancer**

Breast Cancer – Reports in the medical literature (1995-2004) indicate that breast implants do not increase the risk for developing breast cancer.<sup>47,53,61,69,70</sup> Some reports have suggested that breast implants

may make it harder to detect breast cancer by mammography or biopsy. Other reports (2000-2004) indicate that breast implants do not delay breast cancer detection, nor do they decrease cancer survival of women with breast implants.<sup>47,53,61,69,70</sup> A large follow-up study published in 2001 reported no evidence that breast implants are associated with cancer and even showed that women with breast implants had less breast cancer than the general population.<sup>60</sup>

Brain cancer – Most studies of brain cancer published between 2000 and 2007 in women with silicone gel breast implants found no increased risk.<sup>49,54,58,67,68,70</sup> One study published in 2001 reported a higher rate of brain cancer in women with breast implants compared to the general population.<sup>48</sup> However, rates of brain cancer were not significantly higher in women with breast implants when compared to women who had other non-breast implant plastic surgery. The data from 4 large studies of women with breast implants and a long-term follow-up study published in 2004 concluded that breast implants are not associated with brain cancer.<sup>66</sup>

Respiratory/lung cancer – Several studies published between 2000 and 2006 found that women with silicone gel breast implants are not at greater risk for lung cancer.<sup>49,58,67,68,70</sup> Studies published between 2001 and 2007 reported an increased incidence of respiratory/lung cancer in women with breast implants.<sup>48,54,60</sup> However, the risk of lung cancer was not higher than national lung cancer rates for the general population. Other studies published between 1997 and 2003 of women in Sweden and Denmark found that women who get breast implants are more likely to be current smokers than women who get breast reduction surgery or other types of cosmetic surgery.<sup>51,59,62</sup> Therefore, the increased incidence of respiratory/lung cancer could be due to smoking rather than breast implants.

Cervical/vulvar cancer – Most studies (2000-2006) found that women with silicone gel breast implants have no greater risk of cervical/vulvar cancers than women without implants.<sup>49,58,67,68,70</sup> Two studies (2001 and 2007) reported an increased incidence of cervical/vulvar cancer in women with breast implants.<sup>48,54</sup>

Other cancers – Studies published between 2000 and 2007 examined other types of cancer including eye, urinary tract, connective tissue, and endocrine system. These studies showed that women with silicone gel breast implants have no greater risk of these types of cancers compared to the general population.<sup>29,44,48,49,54,58,67,68</sup> A large, long-term study published in 2004 found that women with breast implants were not at greater risk for a wide variety of cancers, including stomach cancer and leukemia.<sup>44</sup>

Cancer Screening – With breast implants, routine screening mammography for breast cancer will be more difficult. If you are of the proper age for mammography screening, you should continue to undergo routine mammography screening as recommended by your primary care physician. More x-ray views are necessary for women with breast implants; therefore, you will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays. Be sure to inform the mammography technologist that you have implants. The technologist can then use special techniques to get the best possible views of your breast tissue.

- **Neurological Disease, Signs, and Symptoms**

Some women with breast implants have complained of neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking or remembering things) or diseases (such as multiple sclerosis), which they believe are related to their implants. A panel of expert scientists (Institute of Medicine, 2000) found that the evidence linking neurological diseases with breast implants is insufficient or flawed.<sup>1</sup> Other researchers published more evidence that silicone gel breast implants do not cause neurological diseases or symptoms in 2001.<sup>1,71,72</sup>

- **Suicide**

Some studies published between 2001 and 2007 showed that women with breast implants were more likely to commit suicide than women without breast implants, but it is not clear whether these suicides were associated with having silicone gel breast implants or an underlying condition that can lead to suicide, depression, and/or anxiety.<sup>48,72,74-81</sup> One researcher believes that some women who want cosmetic surgery suffer from a disorder, called body dysmorphic disorder, which may cause them to think about suicide or attempt suicide.<sup>75</sup>

The strongest predictor for suicide is having been hospitalized for any psychiatric condition. One study published in 2004 found that women with breast implants had higher rates of hospital admission due to psychiatric causes prior to surgery, as compared with women who had breast reduction or in the general population of Danish women.<sup>74</sup> This may be a contributing factor to the reported higher incidence of suicide in women with breast implants.

- **Effects on Children**

At this time, doctors do not know if a small amount of silicone passes through the silicone shell of breast implants into breast milk during breastfeeding. Although doctors cannot accurately measure silicone levels in breast milk, silicon (one component in silicone) levels were not higher in breast milk from women with silicone gel-filled implants than in breast milk from women without implants.

In addition, questions have been raised about whether breast implants can have damaging effects during pregnancy. Two studies published in 2001 and 2002 in humans found that children born to women with breast implants did not have an increased risk of birth defects.<sup>84,85</sup> A third study published in 2004 looked at low birth weight and did not find an elevated risk.<sup>83</sup> A review published in 2007 including many women found that children of women with breast implants are not at increased risk for birth defects.<sup>10</sup> Overall, there is no evidence from studies published between 2000 and 2007 that shows silicone gel breast implants have any harmful effects on the children of implanted women.<sup>1, 10,82,83-85</sup>

- **Potential Health Consequences of Gel Bleed**

Small quantities of low molecular weight silicone compounds, as well as platinum, have been found to leak through an intact implant shell. This is called gel bleed.<sup>1,88</sup> The evidence is mixed as to whether gel bleed can affect your health. For instance, studies published in 2000 and 2005 on implants implanted for a long time suggested that gel bleed may contribute to capsular contracture<sup>1</sup> and lymphadenopathy.<sup>86</sup> However, saline-filled breast implants have similar or higher rates of capsular contracture and other complications. Because saline-filled breast implants do not contain silicone gel, gel bleed cannot cause these complications in women with saline-filled breast implants and might not cause these complications in women with silicone gel-filled breast implants. Furthermore, the silicone material used in Allergan's implants did not cause toxic reactions when large amounts were placed in test animals. There is little platinum contained in breast implants, and studies published between 1987 and 1999 have shown that it is in the safest state.<sup>87,89,90,92</sup>

Allergan performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may diffuse out of intact implants into the body. Over 99% of the low molecular weight silicones and platinum stayed in the implant. The overall body of evidence supports that gel bleed is minimal and has no health consequences.

## **3.0 Surgical Considerations For Breast Reconstruction**

This section provides surgical considerations for primary breast reconstruction, followed by considerations for surgery in general.

Your decision to have breast reconstruction is an important personal choice involving both risks and benefits. There are other options for breast reconstruction that do not involve breast implants. Be sure to ask your surgeon for a detailed explanation of each alternative to help you decide which option is most suitable for you and your lifestyle. This brochure is intended to provide general information about silicone breast implants and surgery but is not a

substitute for a thorough consultation with your surgeon. You should carefully review and consider all the information you have received before deciding whether to have reconstruction surgery. Prepare a list of questions after reading this brochure, and discuss them with your surgeon.

### 3.1 Should You Have Primary Breast Reconstruction?

Whether you decide to have breast reconstruction depends on your own individual case, medical condition, general health, lifestyle, emotional state, and breast size and shape. You should consult your surgeon to discuss your personal goals for breast reconstruction, and you may also consider consulting your family, friends, breast implant support groups, and breast cancer support groups to help you in making this decision.

If you are considering breast reconstruction and do not have a reconstructive surgeon, ask your general surgeon for a referral for the names of experienced, board-certified surgeons in your area. Your general surgeon, breast reconstruction surgeon, and oncologist should work together to plan your mastectomy and reconstruction procedure and to advise you based on your specific clinical needs and desired outcome.

### 3.2 What Are the Alternatives to Implantation with NATRELLE® Silicone-Filled Breast Implants or NATRELLE INSPIRA® Breast Implants?

For primary reconstruction patients, alternatives may include:

- Accepting your breasts as they are and having no surgery.
- Wearing a padded bra or external prostheses.
- Having reconstruction using your own tissue (flap procedure).
- Having surgery with saline implants.

For revision-reconstruction patients, alternatives may include:

- No revision.
- Removal with:
  - No replacement
  - A padded bra or external prostheses
  - Reconstruction using your own tissue (flap procedure)
  - Replacement using saline implants



### 3.3 What Are the Choices in Primary Reconstructive Procedures?

The type of breast reconstruction procedure available to you depends on your medical situation, breast shape and size, general health, lifestyle, and goals.

Breast reconstruction can be accomplished by the use of a breast implant (either silicone gel or saline-filled), your own tissues (a tissue flap), or a combination of the two. A tissue flap is a combination of skin, fat, and/or muscle that is moved to the chest area. This tissue can come from your stomach, back, or another area of your body. A tissue flap may be used to shape a completely new breast or provide extra skin or other tissue depending on what was removed at the time of surgery, or what changed following radiation therapy. Your surgeon can help you decide what method of breast reconstruction is most suitable for your particular situation.

Whether or not you have reconstruction with or without breast implants, you will probably undergo additional surgeries to improve symmetry and appearance. These additional surgeries may be part of a breast reconstruction that occurs in several stages. For example, the nipple and areola are usually removed with the breast tissue in mastectomy. After the initial reconstruction surgery is complete, nipple reconstruction is usually done as a separate outpatient surgery. The nipple is usually reconstructed by using a skin graft from another area of the body or the opposite breast and a tattoo to match the color. Most commonly, before breast implants can be placed, a temporary soft tissue expander must create a space for them. The tissue expander can be placed at the time of mastectomy or at a later time.

Alternatively, additional surgeries may shape the remaining breast to bring it into better balance with the reconstructed one.

### 3.4 What Is Breast Reconstruction with Breast Implants?

Your surgeon will decide whether your health and medical condition makes you an appropriate candidate for breast reconstruction with implants. If you are having reconstruction in only one breast, your surgeon may recommend placing a breast implant in the opposite, uninvolved breast in order to make your breasts more alike. Alternatively, he/she may suggest breast reduction (reduction mammoplasty) or a breast lift (mastopexy) to improve symmetry. Reduction mammoplasty involves removing breast tissue and skin. Mastopexy involves removing a strip of skin from under the breast or around the nipple and using it to lift and tighten the skin over the breast. If you choose not to alter the unaffected breast, you should discuss this with your plastic surgeon, as it may affect the breast reconstruction methods considered for your case.

### 3.5 What Reconstruction Incision Sites Are Used?

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. However, use of *Responsive* silicone implants requires a larger incision size than saline implants, and use of *SoftTouch* or *Highly Cohesive* silicone implants requires a larger incision size than *Responsive* implants.

### 3.6 What About the Surgical Setting and Anesthesia?

When reconstruction surgery begins at the same time as the mastectomy, it is usually performed as an inpatient surgery, which involves an overnight hospital stay. Most reconstruction surgeries occur under general anesthesia. Some stages of reconstruction surgery, such as nipple reconstruction, or placement of the implant after soft tissue expansion, can be done as an outpatient surgery.

### 3.7 What Is the Timing of Primary Breast Implant Reconstruction?

The following description applies to reconstruction following mastectomy, but similar considerations apply to reconstruction following breast trauma or reconstruction for congenital anomalies. The breast reconstruction process may begin at the time of your mastectomy (immediate reconstruction) or months to years afterwards (delayed reconstruction). This decision should involve your cancer treatment team and is based on your individual situation. Immediate reconstruction may involve placing a breast implant but typically involves placing a tissue expander. The tissue expander recreates skin that was removed during the cancer surgery. The tissue expander will eventually be replaced with a breast implant. You should know that any type of surgical breast reconstruction may take several steps to complete.

A potential advantage to immediate reconstruction is that your breast reconstruction starts at the time of your mastectomy. Combining the mastectomy procedure with the first stage of the reconstruction may result in cost savings and potentially fewer days in the hospital. However, immediate reconstruction can expose the implant to postoperative radiation and chemotherapy treatments, which might increase the risk of capsular contracture, extrusion, and other complications. Your initial operative time and recovery time may also be longer.

A potential advantage to delayed reconstruction is that you can delay your reconstruction decision and surgery until other treatments, such as radiation therapy and chemotherapy, are completed. Delayed reconstruction may be advisable if your surgeon anticipates healing problems with your mastectomy, or if you just need more time to consider your options.

There are medical, financial, and emotional considerations to choosing immediate versus delayed reconstruction. You should discuss with your general surgeon, reconstructive surgeon, and oncologist the pros and cons of the options available in your individual case.

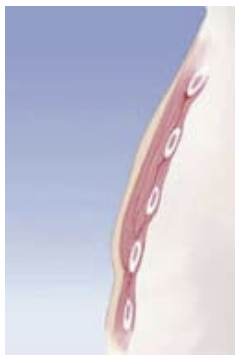
### 3.8 What Is the Primary Breast Implant Reconstruction Procedure?

#### *Immediate or Delayed Breast Implant Reconstruction*

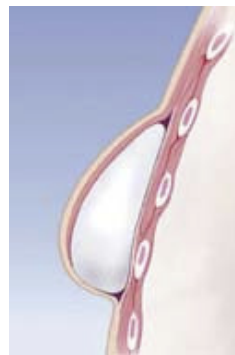
Breast reconstruction using only a breast implant may be done immediately at the time of your mastectomy or sometime thereafter. After the general surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant that completes the reconstruction. In reconstruction following mastectomy, a breast implant is most often placed beneath the chest muscle.

#### *Expander-Assisted (Immediate or Delayed) Breast Implant Reconstruction*

Breast reconstruction usually occurs in several stages. Initially, your plastic surgeon will place a breast tissue expander, which is replaced several months later with a breast implant. The tissue expander may be placed immediately, at the time of your mastectomy, or be delayed until months or years later.



Side View,  
Breast Tissue  
Removed



Side View,  
Expander  
Inserted and Filled

## *Tissue Expansion*

During a mastectomy, the general surgeon removes skin as well as breast tissue, leaving the chest tissue too flat and tight to allow a breast implant. To create a breast shaped space for the breast implant, a tissue expander is placed under the remaining chest tissues.

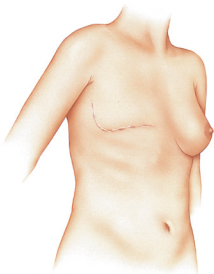
The tissue expander is a balloon-like device made from elastic silicone rubber. The surgeon inserts it unfilled, and over time, adds sterile saline fluid by inserting a small needle through the skin into a filling port. As the tissue expander fills, the tissues over the expander begin to stretch, similar to the gradual expansion of a woman's stomach during pregnancy. The tissue expander creates a new breast-shaped space for a breast implant.

Tissue expanders are usually placed when you are under general anesthesia in an operating room. The operation generally takes 1 to 2 hours. The procedure may require a brief hospital stay or be done as an outpatient surgery. Typically, you can resume normal daily activity after 2 to 3 weeks.

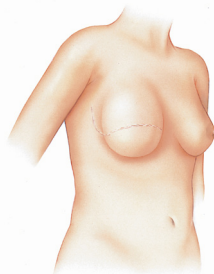
Because the chest skin is usually numb from the mastectomy surgery, you may not experience pain from the placement of the tissue expander. However, you may feel pressure, tightness, or discomfort after each time the expander is filled. These feelings subside as the tissue expands but may last for a week or more. Tissue expansion typically takes 4 to 6 months.

## *Placing the Breast Implant*

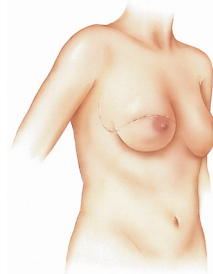
Once the tissue has expanded, your plastic surgeon will remove the tissue expander and replace it with a breast implant. In reconstruction following mastectomy, the breast implant is most often placed under the chest muscle. The surgery to replace the tissue expander with a breast implant (implant exchange) is usually done under general anesthesia in an operating room. It may require a short hospital stay or be done as an outpatient surgery.



Post Mastectomy



Stage 1:  
Tissue Expander Placed  
and Expansion Underway



Stage 2:  
Breast Implant and Nipple/  
Areola Reconstruction

## 3.9 What About Primary Breast Reconstruction Without Implants (Tissue Flap Procedures)?

The breast can be reconstructed using a section of skin, fat, and muscle (a tissue flap) that is surgically moved from one area of your body to another. The section of tissue may be taken from such areas as your abdomen, upper back, upper hip, or buttocks.

The tissue flap may be left attached to its original blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap), or it may be removed completely and reattached to the blood supply in the breast area (a free flap). A free flap generally requires a longer operation, because of the time required to reconnect the blood supply.

Breast reconstruction with a flap typically requires a hospital stay of several days and a longer recovery time than reconstruction with an implant. Flap surgery also creates scars at the site where the flap was taken and on the reconstructed breast. However, flap surgery has the advantage of being able to replace the lost tissue in your chest area. You may need to replace these tissues when your chest tissues have been damaged and are not suitable for tissue expansion. Another advantage of flap procedures over implantation is that flap procedures generally do not require additional surgery on the unaffected breast to improve symmetry.

The most common types of tissue flaps are DIEP (Deep Inferior Epigastric Perforator), TRAM (Transverse Rectus Abdominus Musculocutaneous flap, which uses tissue from the abdomen) and the Latissimus Dorsi flap (which uses tissue from the upper back).

You should be aware that flap surgery, is a major operation, and more extensive than your mastectomy operation. It requires good general health and strong emotional motivation. If you are very overweight, smoke cigarettes, have had previous surgery at the flap site, or have any circulatory problems; you may not be a good candidate for a tissue flap procedure. Also, if you are very thin, you may not have enough tissue in your abdomen or back to create a breast mound with this method. Please discuss with your surgeon the details, expectations, benefits and risks of each of the procedures.

### **DIEP flap**

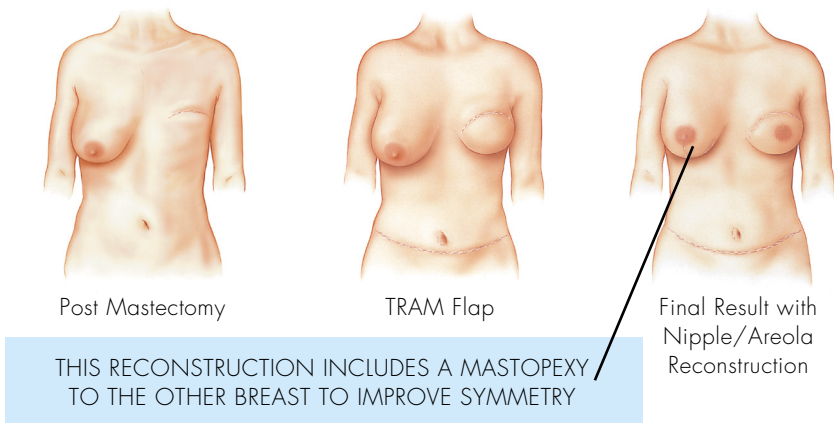
During a DIEP flap procedure, the surgeon removes fat, skin, and blood vessels from the abdomen, and moves it to your chest to reconstruct the breast. Abdominal muscles are not removed. The surgeon will reattach blood vessels in the flap to blood vessels in your chest using microsurgery. As no muscle is removed, most women have a lower risk of losing abdominal muscle strength compared to TRAM flap procedures. However, the procedure requires special surgical training and expertise in microsurgery. You will have a large scar on your abdomen and additional

scars on your reconstructed breast. You should obtain details, such as procedure details, expectations, risks and benefits, length of hospital stay and recovery time from your surgeon about the DIEP procedure you are considering.

### TRAM Flap (Pedicle or Free)

During a TRAM flap procedure, the surgeon removes a section of tissue from your stomach and moves it to your chest to reconstruct the breast.

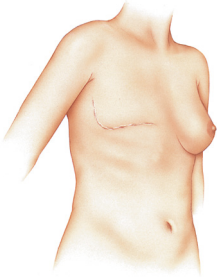
A pedicle TRAM flap procedure typically takes 3 to 6 hours of surgery under general anesthesia; a free TRAM flap procedure generally takes longer. The TRAM procedure may require a blood transfusion. Typically, the hospital stay is 2 to 5 days. You can resume normal daily activity after 6 to 8 weeks. Some women, however, report that it takes up to 1 year to resume a normal lifestyle. You may have temporary or permanent muscle weakness in the stomach area. If you are considering pregnancy after your reconstruction, you should discuss this with your surgeon. You will have a large scar on your abdomen and may also have additional scars on your reconstructed breast.



### The Latissimus Dorsi Flap With or Without Breast Implants

During a Latissimus Dorsi flap procedure, the surgeon moves a section of tissue from your back to your chest to reconstruct the breast. Because the Latissimus Dorsi flap is usually thinner and smaller than the TRAM flap, this procedure may be more appropriate for reconstructing a smaller breast.

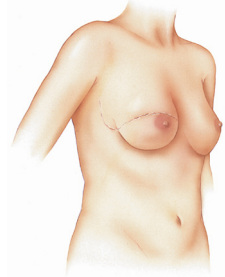
The Latissimus Dorsi flap procedure typically takes 2 to 4 hours of surgery under general anesthesia. Typically, the hospital stay is 2 to 3 days. You can resume daily activity after 2 to 3 weeks. You may have some temporary or permanent muscle weakness and difficulty with movement in your back and shoulder. You will have a scar on your back, which can usually be hidden in the bra line. You may also have additional scars on your reconstructed breast.



Post Mastectomy



View Showing  
Back Scar



Latissimus Dorsi  
Flap and Nipple/Areola  
Reconstruction

## 3.10 What Are Some General Surgical Considerations?

### Choosing a Surgeon

When choosing a surgeon who is experienced with breast reconstruction, you should find out the answers to the following questions:

- How many breast reconstruction implantation procedures does he/she perform per year?
- How many years has he/she performed breast reconstruction procedures?
- Does the surgeon only perform breast reconstruction with breast implants? What types of implants does the surgeon primarily use (saline, silicone, *Responsive* silicone, *SoftTouch* silicone, *Highly Cohesive* silicone)?
- Has he/she completed Allergan's Physician Certification Program for the use of its silicone-filled breast implants?
- Are there other breast reconstruction procedures performed routinely by the surgeon, such as autologous tissue reconstruction (operations that use tissue from the stomach or flank to reconstruct breast tissue), flap reconstruction, etc.?
- How many reconstructions does he/she perform that do not involve implants per year?
- Is he/she board certified, and if so, with which board?
- Did he/she complete a residency in plastic surgery from a recognized and accredited program?
- In which state(s) is he/she licensed to practice surgery? (Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients, either by request or on the Internet.)
- What is the most common complication he/she encounters with breast reconstruction?
- What is his/her reoperation rate with breast reconstruction, and what is the most common type of reoperation he/she performs?
- Can he/she perform this surgery in a hospital, as well as in the surgeon's independent surgery center? (Note that hospitals require evidence of appropriate training in specific procedures before allowing surgeons to operate in their facilities.)



The following list of questions may help to remind you of topics to discuss with your surgeon. You may have other questions as well.

- What are all my options for breast reconstruction?
- What are the risks and complications of each type of breast reconstruction surgery and how common are they?
- What if my cancer recurs or occurs in the other breast?
- Will reconstruction interfere with my cancer treatment?
- How many steps are there in each procedure, and what are they?
- How long will it take to complete my reconstruction?
- How much experience do you have with each procedure?
- Do you have before and after photos I can look at for each procedure and what results are reasonable for me?
- What will my scars look like?
- What kind of changes in my implanted breast can I expect over time?
- What kind of changes in my implanted breast can I expect with pregnancy?
- What are my options if I am dissatisfied with the cosmetic outcome of my implanted breast?
- Can I talk with other patients about their experiences?
- What is the estimated total cost of each procedure?
- How much will my health insurance carrier cover, especially any complication that may require surgery?
- How much pain or discomfort will I feel, and for how long?
- How long will I be in the hospital?
- Will I need blood transfusions, and can I donate my own blood?
- When will I be able to resume my normal activity (or sexual activity, or athletic activity)?

## Insurance

In general, private insurance that covers medically necessary mastectomies will also cover breast reconstructive surgery per the Women's Health and Cancer Rights Act (WHCRA). After the initial reconstruction, insurance may not cover reoperation procedures or additional surgeon's visits, depending on the policy. For example, a reoperation may include temporarily removing the implant so that your oncologist can see if your breast cancer has recurred. Because coverage policies vary and can change over time, no guidance can be given here with respect to coverage under any particular health plan. Therefore, you should contact your health plan to get specific information regarding its coverage policies before deciding to have reconstructive surgery.

## 3.11 What Are Choices and Options Associated With the Surgery?

There are 2 approved types of breast implant fillers (saline and silicone), and Allergan has 3 types of silicone fillers (*Responsive* silicone gel, *SoftTouch* silicone gel, and *Highly Cohesive* silicone gel). These options allow your surgeon to use the best type of implant to achieve the effect you desire. Your surgeon can discuss these options with you and may make recommendations to you based upon the physical contours of your body. This document is for *Responsive*, *SoftTouch*, and *Highly Cohesive* silicone-filled round breast implants; a separate document is available for saline-filled breast implants. Carefully review the [section on risks](#) and the [section on Allergan's clinical study](#) so that you may make an informed choice. Be sure to ask your surgeon to see and touch samples of *Responsive*, *SoftTouch*, and *Highly Cohesive* silicone as well as saline-filled breast implants.

### The NATRELLE® Collection

The NATRELLE® Collection includes both saline-filled and silicone gel-filled implants, allowing you and your surgeon to select the best implant for your needs.

#### NATRELLE® Saline-Filled Breast Implants

**NATRELLE®** Saline-Filled Breast Implants have a self-sealing valve that is used for filling the implant with sterile saline solution (saltwater) at the time of surgery. Saline solutions are very common and are used to clean wounds and the surface of the eye. The watery saline solution used in breast implants is isotonic (has the same salt concentration as the normal cells of the body and the blood) and presents no health risk to the patient even if the implant deflates and the saline leaks out. **NATRELLE®** Saline-Filled Breast Implants typically require a smaller incision. However, visible wrinkling or rippling of the skin over the implant may be more likely to occur.

#### NATRELLE® Silicone-Filled Breast Implants

**NATRELLE®** Silicone-Filled Breast Implants are pre-filled with a soft cohesive silicone gel, which may make the implant feel more “natural.” Other medical devices utilizing silicones are artificial joints, catheters, drainage systems, facial implants, and tissue expanders. The silicone gel used in **NATRELLE®** Silicone-Filled Breast Implants has been shown to be biocompatible, making it an appropriate choice for breast implants. Silicone-filled breast implants typically require a larger incision than used for saline implants; however, they may look and feel more natural.

## Implant GEL FILL, Shape, and Size

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

Breast Implants are round implants that come in a variety of profiles and sizes. **NATRELLE®** Silicone-Filled Breast Implants are filled with *Responsive* gel. **NATRELLE INSPIRA®** Breast Implants are filled with *Responsive* gel, *SoftTouch* gel, or *Highly Cohesive* gel. Each gel filling varies in the amount of firmness it provides to the implant. Responsive silicone gel is the least firm gel and Highly Cohesive is the most firm gel offered. SoftTouch silicone gel has a firmness level that is in between that of the Responsive silicone gel and the Highly Cohesive silicone gel. In general, **NATRELLE INSPIRA®** Breast Implants have a fuller appearance than **NATRELLE®** Silicone-Filled Breast Implants. Your plastic surgeon will discuss with you the implant options that will best help you achieve the result that is right for you.

The following figures and tables may help you to understand the various sizes and styles of implants as your surgeon discusses the various options with you. Depending on the desired shape you wish to achieve, you and your surgeon have implants with different round profiles, or styles, and sizes from which to choose. Generally, the larger you want your cup size, the larger the breast implant size or the higher the profile the surgeon will consider. Breast implant sizes are measured in volume, by cubic centimeters (cc), not in cup sizes, because cup size depends on the size and shape of the individual woman's chest. Overviews of the styles and sizes of **NATRELLE®** Silicone-Filled Breast Implants and **NATRELLE INSPIRA®** Breast Implants are provided in the tables below.

### Approved **NATRELLE®** Silicone-Filled Breast Implant Styles

Style Number	Breast Implant Description	Size Range
Style 10	Smooth shell surface, <i>Responsive</i> silicone gel, moderate profile	120cc – 800cc
Style 15	Smooth shell surface, <i>Responsive</i> silicone gel, moderate-plus profile	155cc – 752cc
Style 20	Smooth shell surface, <i>Responsive</i> silicone gel, high profile	120cc – 800cc
Style 40	Smooth shell surface, <i>Responsive</i> silicone gel, moderate profile	80cc – 560cc
Style 45	Smooth shell surface, <i>Responsive</i> silicone gel, extra-high profile	120cc – 800cc



**Natrelle® Style 10**  
Moderate Profile



**Natrelle® Style 15**  
Moderate-Plus Profile



**Natrelle® Style 20**  
High Profile



**Natrelle® Style 45**  
Extra-High Profile

## Approved NATRELLE INSPIRA® Responsive Breast Implant Styles

Style Name	Breast Implant Description	Size Range
Style SRL	Smooth shell surface, <i>Responsive</i> silicone gel, low profile	110cc – 610cc
Style SRLP	Smooth shell surface, <i>Responsive</i> silicone gel, low plus profile	125cc – 640cc
Style SRM	Smooth shell surface, <i>Responsive</i> silicone gel, moderate profile	140cc – 755cc
Style SRF	Smooth shell surface, <i>Responsive</i> silicone gel, full profile	180cc – 770cc
Style SRX	Smooth shell surface, <i>Responsive</i> silicone gel, extra-full profile	200cc – 800cc

## Approved NATRELLE INSPIRA® SoftTouch Breast Implant Styles

Style Name	Breast Implant Description	Size Range
Style SSL	Smooth shell surface, <i>SoftTouch</i> silicone gel, low profile	110cc – 610cc
Style SSLP	Smooth shell surface, <i>SoftTouch</i> silicone gel, low plus profile	125cc – 640cc
Style SSM	Smooth shell surface, <i>SoftTouch</i> silicone gel, moderate profile	140cc – 755cc
Style SSF	Smooth shell surface, <i>SoftTouch</i> silicone gel, full profile	180cc – 770cc
Style SSX	Smooth shell surface, <i>SoftTouch</i> silicone gel, extra-full profile	200cc – 800cc

## Approved NATRELLE INSPIRA® Cohesive Breast Implant Styles

Style Name	Breast Implant Description	Size Range
Style SCL	Smooth shell surface, <i>Highly Cohesive</i> silicone gel, low profile	110cc – 610cc
Style SCLP	Smooth shell surface, <i>Highly Cohesive</i> silicone gel, low plus profile	125cc – 640cc
Style SCM	Smooth shell surface, <i>Highly Cohesive</i> silicone gel, moderate profile	140cc – 755cc
Style SCF	Smooth shell surface, <i>Highly Cohesive</i> silicone gel, full profile	180cc – 770cc
Style SCX	Smooth shell surface, <i>Highly Cohesive</i> silicone gel, extra-full profile	200cc – 800cc



Your surgeon will also evaluate your existing breast and skin tissue to determine if you have enough tissue to cover the breast implant you are considering. In some cases, such as after pregnancy, you might have too much extra skin. If you desire a breast implant size that is too large for your tissue, the surgeon may warn you that breast implant edges may be visible or palpable postoperatively. Also, excessively large breast implants may speed up the effects of gravity on your breasts and can make your breasts droop or sag at an earlier age. Larger sized implants may be too large for many women, and can increase the risk of implant extrusion, hematoma, infection, palpable implant folds, or visible skin wrinkling requiring surgical intervention to correct these complications.<sup>7</sup>

## Surface

**NATRELLE®** Silicone-Filled Breast Implants and **NATRELLE INSPIRA®** Breast Implants come in a variety of profiles and sizes with a smooth surface shell. Some studies suggest that surface texturing reduces the chance of severe capsular contracture,<sup>19</sup> while other studies do not.<sup>17,18</sup> Allergan's Core Study did not show a difference in the likelihood of developing capsular contracture with textured implants compared to smooth implants.

## Implant Palpability

Implants may be more palpable or noticeable if there is an insufficient amount of skin/tissue available to cover the implant and/or when the implant is placed underneath and within the breast glands (breast tissue) but on top of the chest muscle.

## 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.

Your surgeon may place postoperative pain balls or other pain medication infusion devices alongside the breast implant to help control your pain after 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.

**Note:** *If you experience fever, do not feel well, or see noticeable swelling, redness, or drainage in your implanted breast(s), you should contact your surgeon immediately.*

## Other Factors to Consider In Revision-Reconstruction Surgery

Some revision surgeries require removing an intact implant (for example, capsulotomy and pocket adjustments), while others leave the implant in place. Any device that has been removed during revision surgery should not be re-implanted. Allergan breast implants are "for single use only."

The timing for any revision surgery following reconstruction should be discussed with your surgeon so that you can consider all issues, such as the potential effects of radiation, chemotherapy, and additional cancer surgery or treatments.

## 4.0 Follow-Up Examinations

After your breast implant surgery, you will need regular examinations to detect potential complications. You should inform any doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.

### Breast Self-Examinations

Following breast reconstruction you should continue to perform a breast self-examination monthly. This may be more difficult with a breast implant in place. To continue to perform a monthly breast self-examination efficiently, you should ask your surgeon to help you identify the difference between the implant and your breast tissue. Being able to distinguish the implant from breast tissue will decrease the necessity of excessive squeezing of the implant during examination. If you have any pain in your breasts, or you find any lumps, swelling, hardening, or change in implant shape, you should report these to your surgeon. In some cases, your surgeon may recommend an MRI or ultrasound to screen for breast implant rupture. Any new lumps should be evaluated with a biopsy, as appropriate. If a biopsy is performed, be sure to inform the medical professional performing the biopsy that you have breast implants so that he or she can take care to avoid damaging the implant.

You should also examine your breasts for the presence of lumps, swelling, hardening, or a change in implant shape. These may be signs that your implant has ruptured. Report any of these symptoms or persistent pain to your surgeon. Your surgeon may recommend an MRI or ultrasound to screen for rupture.

### Screening for Silent Rupture

Because most ruptures of silicone-filled breast implants are silent, in most cases neither you nor your surgeon will be able to find evidence of rupture by a physical examination. Therefore, a different method is needed to screen for implant rupture. 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 MRI should be performed at a center with a breast coil utilizing a magnet of at least 1.5 Tesla and read by a radiologist who is familiar with looking for implant rupture. Your doctor should assist you in locating a radiology/screening center, as well as a radiologist who is familiar with the MRI techniques and equipment used to screen breast implants for silent rupture.

If there are signs of rupture on imaging, then you should have your implant removed or replaced. More information on rupture is provided in Section 2.3 of this document.

### Symptomatic Rupture

Symptoms associated with rupture may include hard knots or lumps surrounding the implant or in the armpit, loss of size of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast. If you notice any of these changes, see your plastic surgeon. He or she will examine the implants and determine whether you need to have an MRI examination to find out if your implant has ruptured. As a precaution, Allergan recommends that ruptured implants be taken out and either replaced with a new implant or not replaced, depending on your preference or medical need. Consult with your doctor regarding this and any other medical decisions related to your implants.

### Mammography

If you have had a mastectomy, discuss with your surgeon regarding what type of imaging is recommended for you.

If you did not have mastectomy, the current recommendations for getting screening/preoperative mammograms are no different for women with breast implants than for those without implants. You need to tell your mammography technologist before the procedure that you have an implant.

Mammography exams should be interpreted by radiologists experienced in the evaluation of women with breast implants. Your surgeon should request a diagnostic mammogram, rather than a screening mammogram, because more pictures are taken with diagnostic mammography. The technologist can use special techniques to reduce the possibility of rupture and to get the best possible views of the breast tissue.

## 5.0 Allergan's Clinical Study Results

This section summarizes the results of the Allergan Core Study conducted on **NATRELLE**<sup>®</sup> Breast Implants for Primary Reconstruction and Revision-Reconstruction. The Core Study is the primary clinical study for this product. The Allergan Core Study included both smooth and BIOCELL textured breast implants. The BIOCELL textured breast implants were recalled in July 2019 for their higher risk associated with BIA-ALCL and no longer are manufactured or marketed. The results of the Core Study give you useful information on the experience of other women with **NATRELLE**<sup>®</sup> Silicone-Filled Breast Implants. While the results cannot be used to predict your individual outcome, they can be used as a general guide to what you may expect. Your own complications and benefits depend on many individual factors.

## 5.1 What are the Overview Findings of Allergan's Core Study?

The Allergan Core Study was a 10-year study to assess safety and effectiveness in Primary Augmentation, Primary Reconstruction, and Revision (Revision-Augmentation and Revision-Reconstruction) patients. Patient follow-up was at 0-4 weeks, 6 months, and annually through 10 years. Safety was assessed by complications, such as implant rupture, capsular contracture, and reoperation. Benefit (effectiveness) was assessed by patient satisfaction and measures of quality of life.

Allergan's Core Study consisted of 715 patients. This includes 455 Primary Augmentation patients, 147 Revision-Augmentation patients, 98 Primary Reconstruction patients, and 15 Revision-Reconstruction patients. Of these patients, 158 Primary Augmentation patients, 50 Revision-Augmentation patients, 51 Primary Reconstruction patients, and 5 Revision-Reconstruction patients were in the MRI cohort, which means that they were assessed for silent rupture by MRI at years 1, 3, 5, 7, and 9. Final results through 10 years are reported in this document.

Allergan's Core Study results indicate that 83.6% of Primary Reconstruction patients and 60.0% of Revision-Reconstruction patients will have at least 1 occurrence of any complication (including reoperation) at some point through 10 years after implant surgery. The information below provides more details about the complications and benefits you may experience. Please refer to the glossary for the definition of any complication you may not understand.

## 5.2 What Are the 10-Year Follow-Up Rates?

Follow-up rates from a clinical study show you how many women continue to provide information on their experience with breast implants.

The Allergan Core Study enrolled 98 Primary Reconstruction patients. Of the women expected to be seen at the 10-year follow-up visit, 75.4% were seen.

The Allergan Core Study enrolled 15 Revision-Reconstruction patients. Of the women expected to be seen at the 10-year follow-up visit, 80.0% were seen.

## 5.3 What Are the Benefits?

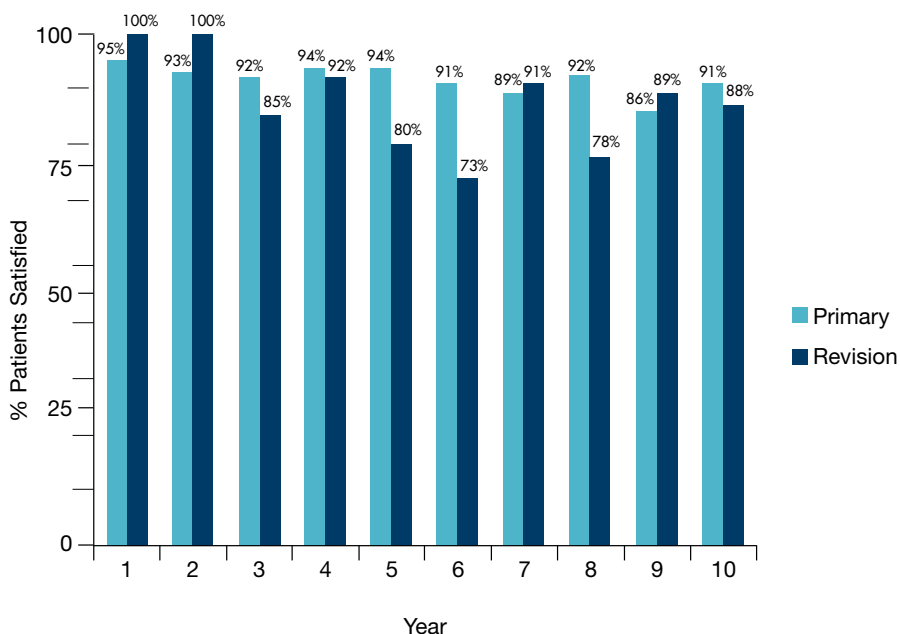
The benefits of *NATRELLE*<sup>®</sup> Silicone-Filled Breast Implants were assessed by a variety of outcomes, including assessments of patient satisfaction and quality of life. Data were collected before implantation and at scheduled follow-up visits through 10 years.



**Patient Satisfaction:** Patients used a 5-point scale to rate their level of satisfaction with their implants at the time of the follow-up visits. Of the original 98 Primary Reconstruction patients, 43 (43.8%) provided a satisfaction rating at 10 years after implantation. Of these 43 patients, 67.4% indicated that they were definitely satisfied with their breast implants, 23.3% indicated that they were somewhat satisfied, and 9.3% indicated that they were neither satisfied nor dissatisfied.

Of the original 15 Revision-Reconstruction patients, 8 (53.3%) provided a satisfaction rating at 10 years. Of these 8 patients, 87.5% were definitely satisfied with their breast implants and 12.5% were definitely dissatisfied with their breast implants. See Figure 1 below, which indicates the percentage of patients who were satisfied and very satisfied with their breast implants through 10 years.

**Figure 1. Primary Reconstruction and Revision-Reconstruction Patient Satisfaction Through 10 Years (responses of somewhat satisfied, satisfied, or definitely satisfied)**



**Quality of Life Assessments:** To assess quality of life, patients answered a series of questions collected from several quality of life scales.

For Primary Reconstruction patients, prior to implantation, scores on the SF-36, which measures mental and physical health, were significantly higher than the general female population. There were no significant changes after 10 years. Scores on the Rosenberg Self Esteem Scale and on the Body Esteem Scale also showed no significant changes at 10 years. Scores on the Rowland Expectation instrument showed significant improvement in “self image” and “social relations” at 10 years.

Primary Reconstruction patients also had significantly improved satisfaction with specific aspects of their breasts after 10 years, including satisfaction with breast size, shape, feel, and how well they matched.

For Revision-Reconstruction patients, statistical analyses were not performed on QoL results due to the small sample size though results were generally similar on the SF-36, Rosenberg Self Esteem Scale and Body Esteem Scale and higher on the Rowland Expectation instrument after 10 years.

## 5.4 What Are the 10-Year Complication Rates?

The complications observed in Primary Reconstruction and Revision-Reconstruction patients through 10 years are presented in Table 2 and Table 3, respectively. The rates reflect the percentage of patients who experienced the listed complication at least once within the first 10 years after their implant surgery. Some complications occurred more than once for some patients. Please refer to the Glossary at the front of this document for the definition of any complication you may not understand.

The most common complications for Primary Reconstruction patients within the first 10 years following implantation were reoperation (71.5% or 72 patients out of 100) and implant removal with replacement (48.0% or 48 patients out of 100). The most common complications Revision-Reconstruction patients experienced were reoperation (46.7%) and implant malposition (13.3%).

**Table 2**  
**Complication Rates for Primary Reconstruction Patients (N = 98)**

Key Complications <sup>a</sup>		Year 3	Year 5	Year 7	Year 10
Reoperation		43.0%	49.2%	54.3%	71.5%
Implant Rupture	MRI Cohort	0%	11.9%	19.4%	35.4%
	Non-MRI Cohort	0%	6.7%	6.7%	18.3%
Implant Replacement		16.8%	20.7%	24.8%	48.0%
Capsular Contracture (Baker Grade III/IV)		13.2%	16.1%	20.9%	24.6%
Implant Removal without Replacement		3.5%	7.6%	7.6%	13.6%
Other Complications Occurring in at least 1% of Patients <sup>b,c</sup>		Year 3	Year 5	Year 7	Year 10
Asymmetry		17.0%	19.9%	19.9%	23.2%
Breast Pain		3.1%	3.1%	4.8%	6.8%
Breast/Skin Sensation Changes		1.0%	1.0%	1.0%	1.0%
Bruising		1.0%	1.0%	1.0%	1.0%
Delayed Wound Healing		1.0%	1.0%	1.0%	1.0%
Hematoma		0%	1.5%	1.5%	1.5%
Hypertrophic/Other Abnormal Scarring		5.5%	5.5%	5.5%	5.5%
Implant Extrusion		1.0%	1.0%	1.0%	1.0%

Key Complications <sup>a</sup>	Year 3	Year 5	Year 7	Year 10
Implant Malposition	2.3%	2.3%	2.3%	2.3%
Implant Palpability/visibility	2.5%	4.1%	4.1%	6.4%
Infection	3.2%	3.2%	3.2%	3.2%
Nipple Complications	3.3%	3.3%	3.3%	3.3%
Redness	2.1%	2.1%	2.1%	2.1%
Seroma	0%	0%	0%	2.3%
Skin Rash	2.0%	2.0%	2.0%	2.0%
Swelling	7.1%	7.1%	7.1%	7.1%
Tissue/Skin Necrosis	2.3%	2.3%	2.3%	2.3%
Wrinkling/Rippling	5.7%	8.7%	10.2%	10.2%
Other Complications <sup>c</sup>	1.0%	1.0%	1.0%	1.0%

<sup>a</sup> 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.

<sup>b</sup> The following complications were reported at a rate of 0%: capsule calcification, gel migration, irritation, lymphadenopathy, lymphedema, pneumothorax, ptosis

<sup>c</sup> Other complications include upper pole crescent deformity (inadequate implant size)

**Table 3**  
**Cumulative Incidence Rates for Revision-Reconstruction Patients (N = 15)**

Key Complications <sup>a</sup>	Year 3	Year 5	Year 7	Year 10
Reoperation	33.3%	33.3%	40.0%	46.7%
Implant Rupture	MRI Cohort	0%	0%	0%
	Non-MRI Cohort	0%	0%	6.7%
Implant Replacement	0%	6.7%	6.7%	13.3%
Capsular Contracture (Baker Grade III/IV)	0%	6.7%	6.7%	6.7%
Implant Removal without Replacement	0%	0%	0%	6.7%
Other Complications Occurring in at least 1% of Patients <sup>b,c</sup>	Year 3	Year 5	Year 7	Year 10
Asymmetry	6.7%	6.7%	6.7%	6.7%
Bruising	6.7%	6.7%	6.7%	6.7%
Implant Malposition	6.7%	6.7%	13.3%	13.3%
Implant Palpability/visibility	6.7%	6.7%	6.7%	6.7%
Seroma	6.7%	6.7%	6.7%	6.7%
Skin Rash	6.7%	6.7%	6.7%	6.7%

<sup>a</sup> Most events 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.

<sup>b</sup> Calculated as a percentage of enrolled with binomial confidence interval

<sup>c</sup> The following complications were reported at a rate of 0%: breast pain, breast/skin sensation changes, capsule calcification, delayed wound healing, gel migration, hematoma, implant extrusion, infection, irritation, lymphedema, lymphadenopathy, nipple complications, other complications, pneumothorax, ptosis, redness, scarring/hypertrophic scarring, swelling, tissue/skin necrosis, and wrinkling/rippling.

## 5.5 What Are the Main Reasons for Reoperation?

The reasons Primary Reconstruction and Revision-Reconstruction patients underwent additional surgery for their breast implant (reoperation) at years 3, 5, 7, and 10 are presented in Table 4 and Table 5, respectively.

Women may have had a reoperation for one or more reasons.

Furthermore, a surgeon may perform multiple surgical procedures during a single reoperation. For example, during a single reoperation a surgeon may perform incision and drainage, remove the capsule, replace the implant, reposition the implant, and perform scar revision.

In Allergan's Core Study through 10 years, there were 217 surgical procedures performed during 94 reoperations involving 62 Primary Reconstruction patients. The most common reason for reoperation through 10 years in Primary Reconstruction patients was because of implant malposition (16 of 94 reoperations).

In Allergan's Core Study through 10 years, there were 15 surgical procedures performed during 12 reoperations involving 7 Revision-Reconstruction patients. The most common reason for reoperation through 10 years in Revision-Reconstruction patients was because of nipple complications (5 out of 12 reoperations).

**Table 4**  
**Main Reasons for Reoperations for Reconstruction Cohort**

Main Reason for Reoperation	Year 3	Year 5	Year 7	Year 10
Asymmetry	8 (14.5%)	11 (16.9%)	12 (15.8%)	15 (16.0%)
Biopsy	4 (7.3%)	4 (6.2%)	8 (10.5%)	8 (8.5%)
Breast cancer	0%	0%	0%	0%
Breast Mass/Cyst/Lump	2 (3.6%)	2 (3.1%)	3 (3.9%)	3 (3.2%)
Breast pain	0%	0%	0%	0%
Breast tissue contour deformity	2 (3.6%)	2 (3.1%)	2 (2.6%)	2 (2.1%)
Capsular contracture	9 (16.4%)	10 (15.4%)	10 (13.2%)	12 (12.8%)
Delayed wound healing	1 (1.8%)	1 (1.5%)	1 (1.3%)	1 (1.1%)
Hematoma/seroma	6 (10.9%)	7 (10.8%)	8 (10.5%)	8 (8.5%)
Implant extrusion	2 (3.6%)	2 (3.1%)	2 (2.6%)	2 (2.1%)
Implant malposition	13 (23.6%)	14 (21.5%)	15 (19.7%)	16 (17.0%)
Implant rupture (suspected)	0%	0%	2 (2.6%)	14 (14.9%)
Infection	0%	0%	0%	0%
Necrosis	1 (1.8%)	1 (1.5%)	1 (1.3%)	1 (1.1%)
Nipple complications (unplanned)	1 (1.8%)	1 (1.5%)	1 (1.3%)	1 (1.1%)
Patient request for style/size change	2 (3.6%)	3 (4.6%)	3 (3.9%)	3 (3.2%)
Ptoisis	2 (3.6%)	3 (4.6%)	4 (5.3%)	4 (4.3%)
Scarring/hypertrophic scarring	2 (3.6%)	3 (4.6%)	3 (3.9%)	3 (3.2%)
Wrinkling	0%	1 (1.5%)	1 (1.3%)	1 (1.1%)
<b>Total</b>	<b>55</b> Reoperations (100%)	<b>65</b> Reoperations (100%)	<b>76</b> Reoperations (100%)	<b>94</b> Reoperations (100%)

**Table 5**  
**Main Reasons for Reoperations for Revision-Reconstruction Cohort**

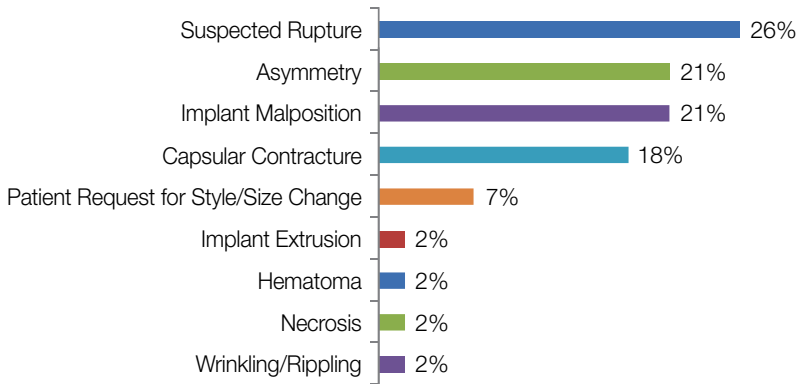
Main Reason for Reoperation	Year 3	Year 5	Year 7	Year 10
Asymmetry	0%	1 (12.5%)	1 (11.1%)	2 (16.7%)
Biopsy	0%	0%	0%	1 (8.3%)
Breast tissue contour deformity	0%	0%	0%	0%
Capsular contracture	1 (14.3%)	1 (12.5%)	1 (11.1%)	2 (16.7%)
Delayed wound healing	0%	0%	0%	0%
Gel fracture	0%	0%	0%	0%
Hematoma/seroma	0%	0%	0%	0%
Implant malposition	0%	0%	0%	0%
Implant rupture (suspected)	0%	0%	0%	0%
Infection	0%	0%	0%	0%
Nipple complications (unplanned)	5 (71.4%)	5 (62.5%)	5 (55.6%)	5 (41.7%)
Patient request for style/size change	0%	0%	0%	0%
Ptoisis	0%	0%	1 (11.1%)	1 (8.3%)
Scarring/hypertrophic scarring	1 (14.3%)	1 (12.5%)	1 (11.1%)	1 (8.3%)
Wrinkling	0%	0%	0%	0%
<b>Total</b>	<b>7</b> Reoperations (100%)	<b>8</b> Reoperations (100%)	<b>9</b> Reoperations (100%)	<b>12</b> Reoperations (100%)

## 5.6 What Are the Main Reasons for Implant Removal?

The main reasons Primary Reconstruction women had implants removed through 10 years are presented in Figure 2. For Primary Reconstruction patients, 57 implants were removed from 44 patients. Of these 57 implants, 47 were replaced. The most common reason for implant removal was suspected rupture (15 of the 57 implants removed).

For Revision-Reconstruction patients, 3 implants were removed from 3 patients through 10 years (not presented in a separate Figure). In 2 of the cases, the main reason for implant removal was due to asymmetry. The third subject underwent implant removal due to capsular contracture. Two of the implants were replaced.

Figure 2. Main Reasons for Implant Removal Through 10 Years Primary Reconstruction (n = 57 implants)



## 5.7 What Are Other Clinical Data Findings?

Below is a summary of clinical findings from the Allergan Core Study with regard to connective tissue disease (CTD), CTD signs and symptoms, cancer, lactation complications, reproduction complications, and suicide. These issues, along with others, are being further evaluated as part of an Allergan post-approval study of a large number of patients followed through 10 years (Breast Implant Follow-Up Study, or BIFS).

### Implant Rupture

The rupture rate for the whole MRI cohort in Allergan's Core Study (including Primary Augmentation, Revision-Augmentation, Primary Reconstruction, and Revision-Reconstruction patients) through 10 years was 13.0% for patients and 7.7% for implants. For the non-MRI cohort, the rupture rate through 10 years was 9.5% for patients and 5.6% for implants. For Primary Reconstruction patients in the MRI cohort, 35.4% of patients had a ruptured implant, and 28.8% of implants ruptured through 10 years. For Revision-Reconstruction patients in the MRI cohort, 0% of patients had a ruptured implant and 0% of implants ruptured through 10 years. This means that through 10 years, approximately 35 out of 100 Primary Reconstruction patients and 0 out of 100 Revision-Reconstruction patients had at least one ruptured breast implant.

Across all patients in the Core Study, all ruptures were intracapsular with 3 cases of both intracapsular and extracapsular gel (one rupture progressed to extracapsular gel following exploratory surgery to confirm the rupture and then implant replacement was delayed).

## CTD Diagnoses

There was 1 Primary Reconstruction patient (1%) in the Allergan Core Study who reported a new diagnosis of an undifferentiated CTD at 3 months after implantation and 1 patient (1%) with a new diagnosis of rheumatoid arthritis at 5.5 years after implantation. No Revision-Reconstruction patients had new diagnoses of a CTD through 10 years. It cannot be concluded that these CTD diagnoses were caused by the implants because there was no comparison group of similar women without implants.

## CTD Signs and Symptoms

Patients who are not diagnosed with a CTD may still have some of the signs or symptoms of these diseases. In Allergan's Core Study, self-reported signs and symptoms were collected at the 2, 4, 6, 8, and 10-year follow-up visits in the categories of General, Gastrointestinal, Neurological, Urinary, Global, Pain, Fatigue, Fibromyalgia, Joint, Muscular, Skin, and Other. For Primary Reconstruction patients at 10 years, statistically significant increases after accounting for age were found in the symptom category of Skin. For Revision-Reconstruction patients, no significant increases were found.

The Core Study was not designed to evaluate cause-and-effect associations because there is no comparison group of patients without implants. Further, other factors that might contribute to CTD signs and symptoms, such as medications, lifestyle, and exercise, were not studied. Therefore, it cannot be determined whether any increase in CTD signs and symptoms was due to the implants or not, based on the Core Study. However, you should be aware that you may experience an increase in these symptoms after receiving breast implants.

## Cancer

There were 13 Primary Reconstruction patients (13.3%) with a recurrence of breast cancer through 10 years.

For Revision-Reconstruction patients, there were no reports of new diagnoses or recurrence of breast cancer.

There were no reports of other cancers, such as brain, respiratory, or cervical/vulvar, in Primary Reconstruction or Revision-Reconstruction patients.

No patients in the Core Study were reported with ALCL through 10 years.

## Lactation Complications

One Primary Reconstruction patient attempted to breastfeed following implantation in the Core Study and did not experience any difficulties with breastfeeding. No Revision-Reconstruction patients attempted to breastfeed following implantation.



## Reproduction Complications

Two (2%) of the Primary Reconstruction patients in Allergan's Core Study reported a reproduction problem through 10 years.

## Suicide

There were no reports of suicide in the Primary Reconstruction and Revision-Reconstruction patients in Allergan's Core Study through 10 years.

# 6.0 Additional Information

## 6.1 What If I Experience a Problem?

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

You should immediately report any problems that you notice with your implants to your plastic surgeon. If you believe that you have experienced a serious problem(s) related to your breast implants, you should have your health professional report the problem(s) to the Food and Drug Administration (FDA) and/or to Allergan. You may also report any serious problem (sometimes referred to as an "adverse event") directly through the FDA's MedWatch voluntary reporting system. An adverse event is considered serious and should be reported when it results in a hospitalization, disability, congenital problem with your child, or other medical or surgical intervention. The information reported to MedWatch is entered into databases to be used to follow safety trends (patterns) of a device and to determine whether further follow-up of any potential safety issues related to the device is needed.

To report, use MedWatch Form 3500, which may be obtained through FDA's website at <https://www.fda.gov/Safety/MedWatch/>. You may also call 1.888.INFO.FDA (1.888.463.6332), from 10 am to 4 pm Eastern Time, Monday through Friday, to receive an additional FDA MedWatch Package. Keep a copy of the MedWatch form completed by your surgeon for your records.

## 6.2 What Is Device Tracking?

Silicone gel-filled breast implants are subject to Device Tracking by federal regulation. This means that your physician will be required to submit to Allergan the serial number of the implant(s) you receive, the date of surgery, information relating to the physician's practice and information on the patient receiving the implant(s). Your surgeon will write this information on the Device Tracking Form supplied by Allergan with each silicone-filled breast implant. Your surgeon will return the top portion of the form to

Allergan following surgery. The second page of the form will be provided to you following surgery. You have the right to remove your personal information from Allergan's Device Tracking program. If you choose NOT to participate in Device Tracking, please check the appropriate box on the Device Tracking form and return to Allergan. You also have the right to have your personal information withheld from disclosure to third parties who may request information from Allergan, such as the FDA. If you choose to participate in the Device Tracking program but do NOT want your personal information to be released to third parties, please also check the appropriate box.

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

### Assessment of Information Effectiveness

The "Required Information" section of the Device Tracking Form also has a question designed to assess the effectiveness of the *Breast Reconstruction with **NATRELLE®** Silicone-Filled Breast Implants and **NATRELLE INSPIRA®** Breast Implants* patient brochure provided prior to your surgery. This question asks you to verify that you received and had adequate time to review this patient labeling information. Please check either yes or no. When the Required Information section is complete, return the entire page to Allergan by mail, using the information provided on the form.

Please inform Allergan whenever your contact information changes by calling 1.800.972.9378 or e-mailing [AbbVie\\_Device\\_Tracking@AbbVie.com](mailto:AbbVie_Device_Tracking@AbbVie.com).

## 6.3 What Is the *ConfidencePlus*<sup>®</sup> Limited Warranty?

The *ConfidencePlus*<sup>®</sup> Limited Warranty provides lifetime replacement and limited financial reimbursement in the event of shell leakage or breakage resulting in implant rupture, subject to certain conditions as fully discussed in the *ConfidencePlus*<sup>®</sup> literature. Our *ConfidencePlus*<sup>®</sup> Premier Limited Warranty program applies automatically to every Allergan **NATRELLE**<sup>®</sup> Silicone-Filled Breast Implant or **NATRELLE INSPIRA**<sup>®</sup> Breast Implant recipient subject to the conditions discussed in the *ConfidencePlus*<sup>®</sup> literature. For more information, please visit [www.cppwarranty.com](http://www.cppwarranty.com) or contact Allergan's Product Surveillance Department at 1.800.624.4261.

## 6.4 How Can I Receive More Information?

You may request a copy of the package insert (Directions for Use; **NATRELLE**<sup>®</sup> Silicone-Filled Breast Implants and **NATRELLE INSPIRA**<sup>®</sup> Breast Implants). The package insert can also be found on [www.allerganlabeling.com](http://www.allerganlabeling.com). The package insert has many undefined medical and technical terms because it contains information primarily directed to the surgeon.

For more detailed information on the preclinical and clinical studies conducted by Allergan, you are referred to the Summary of Safety and Effectiveness Data (SSED) for this product which may be accessed at [https://www.accessdata.fda.gov/cdrh\\_docs/pdf2/P020056B.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf2/P020056B.pdf).

If, after reading this information, you have additional questions about breast implants or breast implant surgery, there are a number of resources available to you.

## 6.5 What is the National Breast Implant Registry?

The Plastic Surgery Foundation has developed the National Breast Implant Registry (NBIR) in collaboration with the FDA, patients and breast implant manufacturers to strengthen the post-market surveillance infrastructure for current and future breast implant devices in the United States. The NBIR, first launched in 2018, is a quality improvement initiative and safety surveillance registry that collects clinical, procedural and outcomes data at the time of operation and any subsequent reoperations for all US patients receiving breast implants. NBIR allows surgeons to register implants with the manufacturers for the purpose of device tracking while also submitting data to the registry.

## TOLL-FREE NUMBER

If you are a patient or a prospective patient and 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 package insert (Directions for Use), call toll free at 1.800.678.1605 (7 am to 5 pm Pacific Time).

## ADDITIONAL RESOURCES

Allergan  
1.800.624.4261  
[www.natrelle.com](http://www.natrelle.com)  
[www.allergan.com](http://www.allergan.com)

Institute of Medicine Report on the Safety of Silicone Implants  
[www.nap.edu/catalog/9618.html](http://www.nap.edu/catalog/9618.html)

Food and Drug Administration  
1.888.INFO.FDA or 1.888.463.6332  
[www.fda.gov/breastimplants](http://www.fda.gov/breastimplants)

## BREAST RECONSTRUCTION RESOURCES

The following list of resources may help you to find more information and support for your breast reconstruction decision.

National Cancer Institute  
1.800.4.CANCER  
[www.nci.nih.gov/](http://www.nci.nih.gov/)

American Cancer Society  
1.800.ACS.2345  
[www.cancer.org/](http://www.cancer.org/)

Y-ME National Breast Cancer Organization  
<https://www.y-me.org/>

# For Further Reading And Information

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## Gel Bleed

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## Acknowledgement of Informed Decision and Patient Decision Checklist

I understand that the patient labeling provided by Allergan is intended to provide information regarding the benefits and risks of silicone gel breast implants. I understand that some of this information is about breast implants in general and some is specific to Allergan's breast implants. I understand that choosing to have reconstruction breast surgery with implants involves both benefits and risks. I also understand that scientists and doctors have not been able to identify or quantify all of the risks of breast reconstruction with implants and that, over time, additional information may become available.

I have had adequate time to review and understand the information presented in the printed patient brochure, ***Important Factors Breast Augmentation and Reconstruction Patients Should Consider***, and the electronic patient labeling, ***Breast Reconstruction with NATRELLE® Silicone-Filled Breast Implants and NATRELLE INSPIRA® Breast Implants***. My concerns and questions have been addressed by my doctor. I have considered alternatives to reconstruction surgery, including use of external prostheses or surgery with saline-filled breast implants.

## Patient Decision Checklist

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<sup>1</sup>),
- skin or nipple areola sensitivity changes or loss (nipple complications reported in up to 6.3% of patients<sup>1</sup> and breast/skin sensation changes reported in up to 2.2% of patients<sup>1</sup>),
- asymmetry (reported in up to 23.2% of patients<sup>1</sup>),
- impact of aging or weight change on size and shape of breast (ptosis reported in up to 4.9% of patients<sup>1</sup>),
- infection requiring possible removal of implant (reported in up to 3.2% of patients<sup>1</sup>),
- swelling (reported in up to 9.2% of patients<sup>1</sup>),
- scarring (hypertrophic scarring reported in up to 6.6% of patients<sup>1</sup>),
- fluid collections (seroma reported in up to 6.7% of patients<sup>1</sup>),
- hematoma (reported in up to 2.1% of patients<sup>1</sup>),
- tissue death of breast skin or nipple (tissue/skin necrosis reported in up to 2.3% of patients<sup>1</sup>),
- inability to breast feed (lactation complications reported in up to 30% of patients<sup>1</sup>),
- 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).

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: \_\_\_\_\_

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<sup>1</sup> 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**<sup>®</sup> Silicone-Filled Breast Implants and **NATRELLE INSPIRA**<sup>®</sup> Breast Implants with Smooth Surface Patient Brochures.

## 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.<sup>2</sup>

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.

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: \_\_\_\_\_

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<sup>2</sup> 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>.



## 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<sup>1</sup>),
- rupture or leaking of the implant (implant rupture reported in up to 35.4% of patients<sup>1</sup>),
- wrinkling of the implant (wrinkling/rippling reported in up to 10.2% of patients<sup>1</sup>),
- visibility of the implant edges (implant palpability/visibility reported in up to 6.7% of patients<sup>1</sup>),
- shifting of the implant (implant malposition reported in up to 13.3% of patients<sup>1</sup>), or
- reoperation (reported in up to 71.5% of patients<sup>1</sup>).

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.

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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.

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Physician Signature and Date

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