

Reconstruction

BREAST
RECONSTRUCTION
WITH *NATRELLE*[®]
SILICONE-FILLED BREAST
IMPLANTS AND
NATRELLE INSPIRA[®]
BREAST IMPLANTS



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Glossary

Anaplastic large cell lymphoma (ALCL)	ALCL is not breast cancer; it is a rare type of non-Hodgkin's lymphoma, a cancer involving the cells of the immune system.
Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	Uneven appearance between a woman's left and right breasts in terms of size, shape, or breast level.
Atrophy	Thinning or diminishing of tissues or muscle.
Autoimmune disease	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.
Biocompatible	The ability to exist along with living tissues or systems without causing harm.
Biopsy	The removal and examination of tissues, cells, or fluid from the body.
Body Dysmorphic Disorder	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.
Body Esteem Scale	A questionnaire which asks about a person's body image.
Breast augmentation	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."
Breast implant	Any surgically implanted artificial device intended to replace missing breast tissue or to enhance a breast.
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 brochure, 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.¹⁶

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

Scar tissue which forms around the breast implant.

Capsule



Capsulotomy (closed)	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.
Capsulotomy (open)	An attempt to break the scar tissue capsule around the implant by surgical incision into the capsule.
Congenital abnormality	An abnormal development in part of the body, present in some form since birth.
Connective tissue disease/disorder (CTD)	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.
Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Contralateral	Opposite side.
Core Study	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.
Delayed wound healing	Unusually slow progress in the healing of a wound; surgical incision site fails to heal normally or takes longer to heal.
Displacement	Movement of the implant from the usual or proper place.
Extrusion	Skin breakdown with the implant pressing through the skin or surgical incision.
Fibromyalgia	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.
Fibrous tissues	Connective tissues composed mostly of fibers.

Flap	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.
Gel bleed	When silicone gel leaks or “bleeds” or diffuses through the implant shell.
Gel fracture	Appearance of a fissure or fault line in highly cohesive gel in response to an applied force.
Granuloma	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.
Hematoma	A collection of blood within a space.
Hypertrophic scarring	An enlarged scar that remains after a wound heals.
Incision	A cut made to the tissue during surgery.
Infection	The growth in the human body of microorganisms such as bacteria, viruses, or fungi. An infection usually results in fever, swelling, redness, and/or pain. It can occur as a result of any surgery.
Inflammation	The response of the body to infection or injury that is characterized by redness, swelling, warmth, and/or pain.
Inframammary	Below the breast.
Inpatient surgery	A surgical procedure in which the patient is required to stay overnight in the hospital.
Lactation	The production and secretion of milk by the breast glands.
Latissimus dorsi	Two triangular muscles running from the spinal column to the shoulder.
Low molecular weight silicones	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.

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.

Postoperative Precautions	After surgery. 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 brochure, 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.
Seroma	Similar to a bruise, a seroma occurs when the watery portion of the blood collects around a surgical incision or around a breast implant.
SF-36 Scale	The Short Form 36 Health Scale; a questionnaire intended to measure physical, mental, and social health.

Silent rupture	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).
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
Subglandular placement	Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.
Submuscular placement	Placement of a breast implant wholly or partially underneath the chest muscle.
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Symptomatic	Experiencing symptoms; any evidence or sign of disease or disorder.
Symptomatic rupture	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.
Systemic	Pertaining to or affecting the body as a whole.
Tissue expander	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. 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*[®] Silicone-Filled Breast Implants and *NATRELLE INSPIRA*[®] Breast Implants. Similar information to help you understand breast reconstruction is available from your plastic surgeon, Allergan, or at www.natrelle.com.

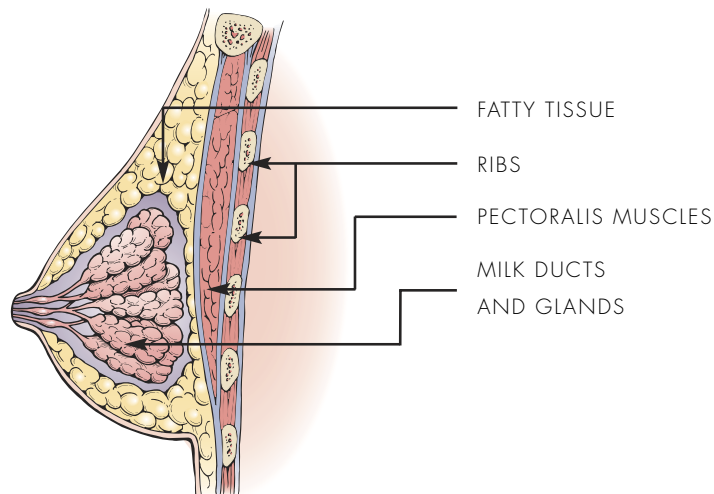
This information cannot and should not replace talking to your plastic surgeon. Your decision on whether or not to get breast implants should be based on realistic expectations of the outcome. There is no guarantee that your results will match those of other women. Your results will depend on many individual 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" 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 on page 67](#).

Because breast implants will require monitoring and care for the rest of your life, you should wait 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast reconstruction surgery. In the case of a revision-reconstruction, however, your surgeon may find it medically advisable to perform 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 3 types of silicone gel fillers: *Responsive* silicone gel, *SoftTouch* silicone gel, and *Highly Cohesive* silicone gel. This brochure focuses on round implants filled with *Responsive* silicone gel, *SoftTouch* silicone gel, and *Highly Cohesive* silicone gel. A separate brochure is available for anatomically shaped implants filled with *Highly Cohesive* silicone gel from your plastic surgeon, from Allergan, or at www.natrelle.com.

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

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

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



Example of *NATRELLE INSPIRA*[®] Breast Implant



Example of *NATRELLE INSPIRA*[®] Textured Breast Implant



1.3 Who is eligible for *NATRELLE*[®] Silicone-Filled Breast Implants and *NATRELLE INSPIRA*[®] Breast Implants, and what is the indication statement?

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 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 What are the 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. Read this entire brochure 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.

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.

WARNING – Be aware that many of the changes to your breast following implantation cannot be undone. 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. You will likely need additional unplanned surgeries on your reconstructed and/or opposite augmented breasts because of complications or unacceptable cosmetic outcomes. These additional surgeries can include implant removal or replacement, or they can include 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. In order to detect silent rupture, you will need to have regular screening MRI examinations. You should have an MRI 3 years after your breast implant surgery and then every 2 years after that for as long as you have your breast implants.



2. 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. These benefits and risks of breast implants are described below. At the end of this brochure 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.^{1,3,8} 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. 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 ^a	Likelihood of Event Occurring in Revision-Reconstruction Patients ^a	Possible Resulting Effects of the Event
Key Risks				
Additional Surgeries (Reoperations)		72 out of 100 patients (72%)	47 out of 100 patients (47%)	<ul style="list-style-type: none"> • Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal with Replacement		48 out of 100 patients (48%)	13 out of 100 patients (13%)	<ul style="list-style-type: none"> • Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal without Replacement		14 out of 100 patients (14%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> • Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Capsular Contracture (Baker Grade III/IV)		25 out of 100 patients (25%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> • Pain or Discomfort • Breast hardness/firmness • Reoperation • Implant removal
Rupture	MRI Cohort	35 out of 100 patients (35%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> • Implant Removal
	Non-MRI Cohort	18 out of 100 patients (18%)	7 out of 100 patients (7%)	
Other Risks Occurring in 1% or more of Patients				
Asymmetry		23 out of 100 patients (23%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> • Undesirable cosmetic result • Reoperation • Implant Removal
Wrinkling/Rippling		10 out of 100 patients (10%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> • Discomfort • Undesirable cosmetic result • Reoperation • Implant removal



Event	Likelihood of Event Occurring in Primary Reconstruction Patients ^a	Likelihood of Event Occurring in Revision-Reconstruction Patients ^a	Possible Resulting Effects of the Event
Breast Pain	7 out of 100 patients (7%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> Resulting effects are contingent on underlying causes
Swelling	7 out of 100 patients (7%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> Pain or discomfort Resulting effects are contingent on underlying cause(s)
Implant Palpability/Visibility	6 out of 100 patients (6%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> Undesirable cosmetic result Reoperation Implant removal
Hypertrophic/Other Abnormal Scarring	6 out of 100 patients (6%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> Scar revision procedure (reoperation) Undesirable cosmetic result
Infection	3 out of 100 patients (3%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> Redness or rash Pain or tenderness Swelling Fever Reoperation Implant removal
Nipple Complications	3 out of 100 patients (3%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> Increased or decreased nipple sensitivity Breastfeeding difficulties May affect sexual response
Implant Malposition	2 out of 100 patients (2%)	13 out of 100 patients (13%)	<ul style="list-style-type: none"> Implant visibility Asymmetry Reoperation Implant Removal
Seroma/Fluid Accumulation	2 out of 100 patients (2%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> Swelling Pain or discomfort Infection Incision and drainage (reoperation) Implant removal
Skin rash	2 out of 100 patients (2%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> Swelling Pain or discomfort Infection
Hematoma	2 out of 100 patients (2%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> Swelling Pain or discomfort Infection Incision and drainage (reoperation) Implant removal
Necrosis	2 out of 100 patients (2%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> Pain or discomfort Scarring Reoperation Implant removal
Redness	2 out of 100 patients (2%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> Resulting effects are contingent on underlying cause(s)

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

^a 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 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.²⁰ 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.

- **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, 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.

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.¹² 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.¹³ You will need regular MRI examinations over your lifetime in order to determine if your implants have a silent rupture. You should have your first MRI at 3 years after your initial implant surgery and then every 2 years, thereafter. The cost of these MRI 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.^{1,14}

If you have an MRI 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. 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.¹¹ 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.¹⁴ 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.⁸¹
- Concerns have been raised that women with ruptured implants are more likely to develop connective tissue disease, rheumatic disease, fatigue, or fibromyalgia.^{22,24,38,39} 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.²⁴ 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?

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. The scientific evidence strongly supports the conclusion that there is no increased risk of connective tissue

disease or autoimmune disorders for women with silicone gel breast implants.^{1,21-27,29-32,34,36,39,40,42} Independent scientific panels and review groups 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.^{1,8,10,22,23,28,29,33,35,37-39}

- **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. Some reports have linked silicone breast implants with some of these signs and symptoms, such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. Panels of expert scientists and literature reports have found no evidence that silicone breast implants cause a consistent pattern of CTD signs and symptoms.^{1,41-44} 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 indicate that breast implants do not increase the risk for developing breast cancer.^{45,51,57,64,65} Some reports have suggested that breast implants may make it harder to detect breast cancer by mammography or biopsy. Other reports indicate that breast implants do not delay breast cancer detection, nor do they decrease cancer survival of women with breast implants.^{45,51,57,64,65} A large follow-up study 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.⁵⁶

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 one

year after implant placement and the latest was 23 years after the implant surgery. About half the cases occurred within the first 7 years after implant. 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.theptf.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 <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064106.htm>.

For additional information on FDA's analysis and review of BIA-ALCL, please visit: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>

Brain cancer – Most studies of brain cancer in women with silicone gel breast implants have found no increased risk.^{47,52,54,62,63,65} One study reported a higher rate of brain cancer in women with breast implants compared to the general population.⁴⁶ 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 concluded that breast implants are not associated with brain cancer.⁶¹

Respiratory/lung cancer – Several studies have found that women with silicone gel breast implants are not at greater risk for lung cancer.^{47,54,62,63,65} Studies have reported an increased incidence of respiratory/lung cancer in women with breast implants.^{46,52,56} However, the risk of lung cancer was not higher than national lung cancer rates for the general population. Other studies of women in Sweden and Denmark have 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.^{49,55,58} Therefore, the increased incidence of respiratory/lung cancer could be due to smoking rather than breast implants.

Cervical/vulvar cancer – Most studies found that women with silicone gel breast implants have no greater risk of cervical/vulvar cancers than women without implants.^{47,54,62,63,65} Two studies reported an increased incidence of cervical/vulvar cancer in women with breast implants.^{46,52}

Other cancers – Studies have examined other types of cancer including eye, urinary tract, connective tissue, and endocrine system. Studies show that women with silicone gel breast implants have no greater risk of these types of cancers compared to the general population.^{28,42,46,47,52,54,62,63} A large, long-term study found that women with breast implants were not at greater risk for a wide variety of cancers, including stomach cancer and leukemia.⁴²

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 found that the evidence linking neurological diseases with breast implants is insufficient or flawed.¹ Other researchers have found more evidence that silicone gel breast implants do not cause neurological diseases or symptoms.^{1,66,67}

- **Suicide**

Some studies 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.^{46,67,69-76} 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.⁷⁰

The strongest predictor for suicide is having been hospitalized for any psychiatric condition. One study 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.⁶⁹ 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 in humans have found that children born to women with breast implants did not have an increased risk of birth defects.^{79,80} A third study looked at low birth weight and did not find an elevated risk.⁷⁸ A recent review including many women found that children of women with breast implants are not at increased risk for birth defects.¹⁰ Overall, there is no evidence that shows silicone gel breast implants have any harmful effects on the children of implanted women.^{1,77,78-80}

- **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.^{1,83} The evidence is mixed as to whether gel bleed can affect your health. For instance, studies on implants implanted for a long time have suggested that gel bleed may contribute to capsular contracture¹ and lymphadenopathy.⁸¹ 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 have shown that it is in the safest state.^{82,84,85,87}

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. 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.

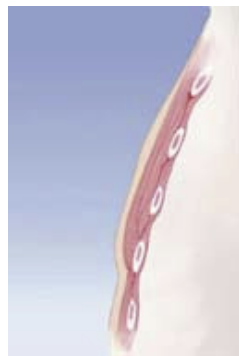
3.8 What Is the Primary Breast Implant Reconstruction Procedure?

IMMEDIATE OR DELAYED BREAST IMPLANT RECONSTRUCTION

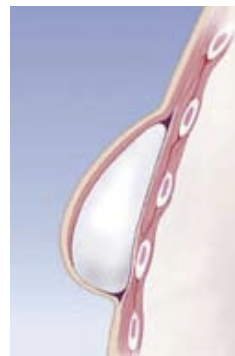
Breast reconstruction using only a breast implant may be done immediately at the time of your mastectomy or sometime thereafter. After the general surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant that completes the reconstruction. In reconstruction following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

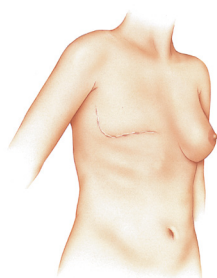
The tissue expander is a balloon-like device made from elastic silicone rubber. The surgeon inserts it unfilled, and over time, adds sterile saline fluid by inserting a small needle through the skin into a filling port. As the tissue expander fills, the tissues over the expander begin to stretch, similar 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.

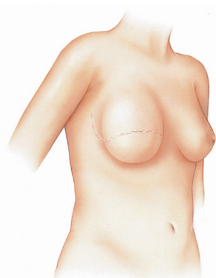
Because the chest skin is usually numb from the mastectomy surgery, you may not experience pain from the placement of the tissue expander. However, you may feel pressure, tightness, or discomfort after each time the expander is filled. These feelings subside as the tissue expands, but may last for a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

PLACING THE BREAST IMPLANT

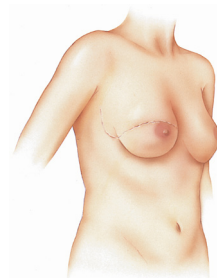
Once the tissue has expanded, your plastic surgeon will remove the tissue expander and replace it with a breast implant. In reconstruction following mastectomy, the breast implant is most often placed under the chest muscle. The surgery to replace the tissue expander with a breast implant (implant exchange) 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 the TRAM (transverse rectus abdominus musculocutaneous flap, which uses tissue from the abdomen) and the Latissimus dorsi flap (which uses tissue from the upper back).

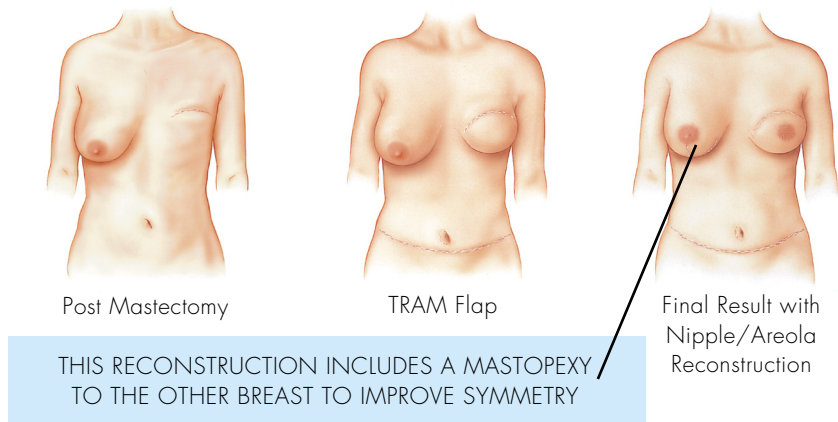
You should be aware that flap surgery, particularly the TRAM flap, is a major operation, and more extensive than your mastectomy operation. It requires good general health and strong emotional motivation. If you are very overweight, smoke cigarettes, have had previous surgery at the flap site, or have 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.

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. The TRAM flap is sometimes referred to as a "tummy tuck" reconstruction, because it may leave the stomach area flatter.

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

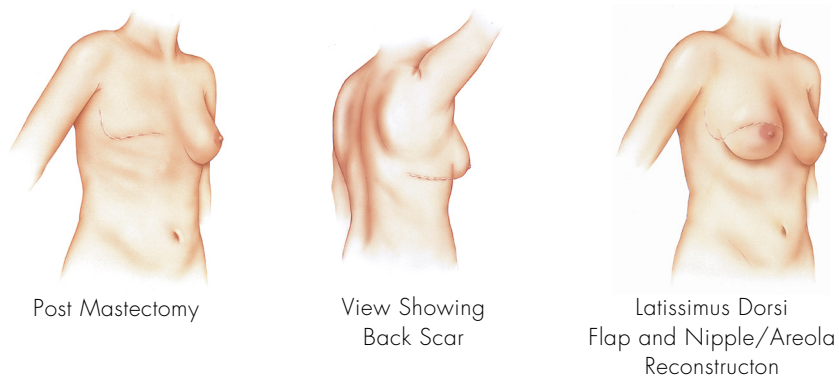
6 to 8 weeks. Some women, however, report that it takes up to 1 year to resume a normal lifestyle. You may have temporary or permanent muscle weakness in the stomach area. If you are considering pregnancy after your reconstruction, you should discuss this with your surgeon. You will have a large scar 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.



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.)

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 brochure is for *Responsive*, *SoftTouch*, and *Highly Cohesive* silicone-filled round breast implants; separate brochures are available for anatomically shaped *Highly Cohesive* silicone-filled breast implants and 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.

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. 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, from which to choose. Generally, the larger you want your cup size, the larger the breast implant 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
Style 110	BIOCELL [®] Textured shell surface, <i>Responsive</i> silicone gel, moderate profile	90cc – 510cc
Style 115	BIOCELL [®] Textured shell surface, <i>Responsive</i> silicone gel, moderate-plus profile	150cc – 716cc
Style 120	BIOCELL [®] Textured shell surface, <i>Responsive</i> silicone gel, high profile	180cc – 650cc



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
Style TRL	BIOCELL [®] Textured shell surface, <i>Responsive</i> silicone gel, low profile	110cc – 610cc
Style TRLP	BIOCELL [®] Textured shell surface, <i>Responsive</i> silicone gel, low plus profile	125cc – 640cc
Style TRM	BIOCELL [®] Textured shell surface, <i>Responsive</i> silicone gel, moderate profile	140cc – 755cc
Style TRF	BIOCELL [®] Textured shell surface, <i>Responsive</i> silicone gel, full profile	180cc – 770cc
Style TRX	BIOCELL [®] Textured shell surface, <i>Responsive</i> silicone gel, extra-full profile	205cc – 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



Approved NATRELLE INSPIRA® SoftTouch Breast Implant Styles

Style Name	Breast Implant Description	Size Range
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
Style TSL	BIOCELL® Textured shell surface, <i>SoftTouch</i> silicone gel, low profile	110cc – 610cc
Style TSLP	BIOCELL® Textured shell surface, <i>SoftTouch</i> silicone gel, low plus profile	125cc – 640cc
Style TSM	BIOCELL® Textured shell surface, <i>SoftTouch</i> silicone gel, moderate profile	140cc – 755cc
Style TSF	BIOCELL® Textured shell surface, <i>SoftTouch</i> silicone gel, full profile	180cc – 770cc
Style TSX	BIOCELL® Textured shell surface, <i>SoftTouch</i> silicone gel, extra-full profile	205cc – 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
Style TCL	BIOCELL® Textured shell surface, <i>Highly Cohesive</i> silicone gel, low profile	110cc – 610cc
Style TCLP	BIOCELL® Textured shell surface, <i>Highly Cohesive</i> silicone gel, low plus profile	125cc – 640cc
Style TCM	BIOCELL® Textured shell surface, <i>Highly Cohesive</i> silicone gel, moderate profile	140cc – 755cc
Style TCF	BIOCELL® Textured shell surface, <i>Highly Cohesive</i> silicone gel, full profile	180cc – 770cc
Style TCX	BIOCELL® Textured shell surface, <i>Highly Cohesive</i> silicone gel, extra-full profile	205cc – 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.⁷

SURFACE TEXTURING

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

A textured implant may require a larger incision because the rougher textured surface may make it harder to place into the pocket. Forcing the implant through too small of an incision might damage the implant or decrease its durability.

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. 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 limit the need to over-squeeze the implant. 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 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. The best method of screening is currently MRI at a center with a breast coil, with a magnet of at least 1.5 Tesla. The MRI should be 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.

Your first MRI evaluation should take place 3 years after your implant surgery. You should have another MRI every 2 years, thereafter, even if you are experiencing no problems with your implant. If there are signs of rupture on MRI, then you should have your implant removed or replaced. More information on rupture is provided in [Section 2.3](#) of this brochure.

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

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. Allergan's Clinical Study Results

This section summarizes the results of the Allergan Core Study conducted on *NATRELLE*[®] Breast Implants for Primary Reconstruction and Revision-Reconstruction. The Core Study is the primary clinical study for this product. The results of the Core Study give you useful information on the experience of other women with *NATRELLE*[®] 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 brochure.

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.

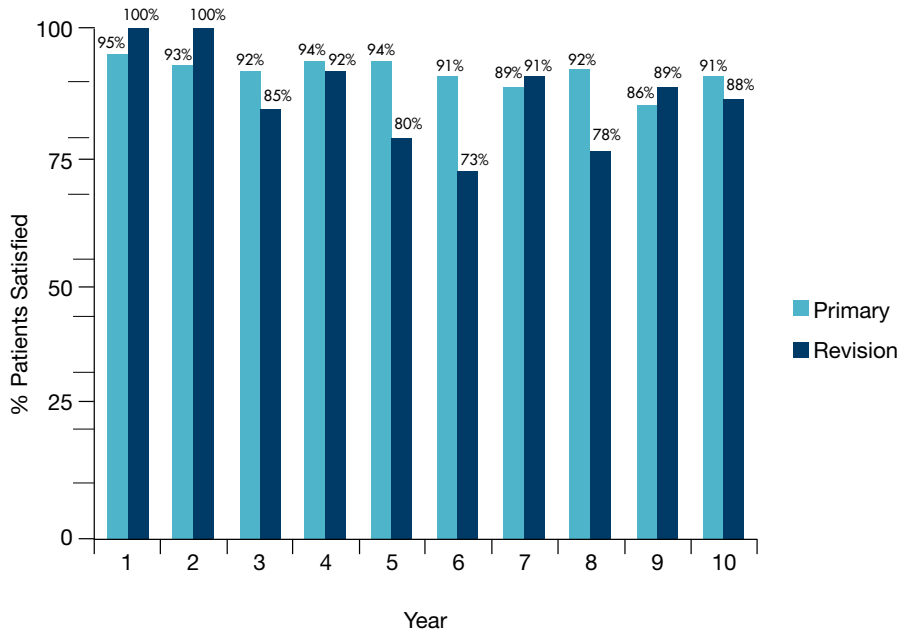
5.3 What Are the Benefits?

The benefits of *NATRELLE*[®] 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



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 brochure 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^a	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^{b,c}	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%	
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 ^c	1.0%	1.0%	1.0%	1.0%	

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

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

^c Other complications include upper pole crescent deformity



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

Key Complications^a	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^{b,c}	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%

^a 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.

^b Calculated as a percentage of enrolled with binomial confidence interval

^c 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%)
Ptoxis	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%)
Total	55 Reoperations (100%)	65 Reoperations (100%)	76 Reoperations (100%)	94 Reoperations (100%)

Table 5
Main Reasons for Reoperations for Revision-Reconstruction Cohort

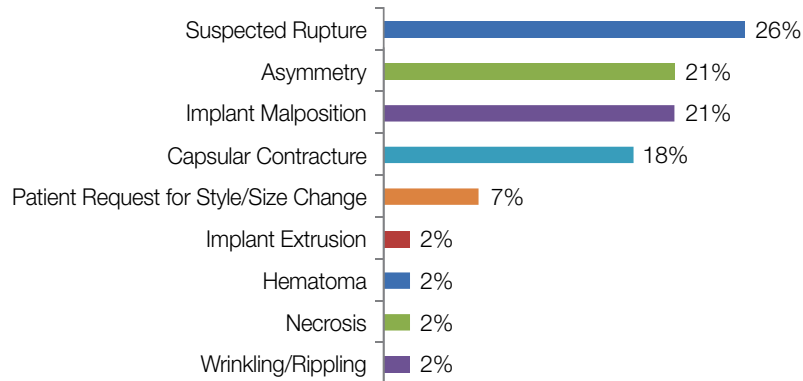
Main Reason for Reoperation	Year 3	Year 5	Year 7	Year 10
Asymmetry	0%	1 (12.5%)	1 (11.1%)	2 (16.7%)
Biopsy	0%	0%	0%	1 (8.3%)
Breast tissue contour deformity	0%	0%	0%	0%
Capsular contracture	1 (14.3%)	1 (12.5%)	1 (11.1%)	2 (16.7%)
Delayed wound healing	0%	0%	0%	0%
Gel fracture	0%	0%	0%	0%
Hematoma/seroma	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%
Ptoxis	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%
Total	7 Reoperations (100%)	8 Reoperations (100%)	9 Reoperations (100%)	12 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 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. Additional Information

6.1 What If I Experience a Problem?

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

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 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 <http://www.fda.gov/medwatch/index.html>. 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 bottom portion 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 important information. Please check either yes or no. When the Required Information section is complete, return the entire page to Allergan by fax or mail, using the information provided on the form.

Please inform Allergan whenever your contact information changes by calling 1.877.641.4844 or e-mailing SB-DeviceTracking@Allergan.com.

6.3 What Is the *ConfidencePlus*[®] Limited Warranty?

The *ConfidencePlus*[®] 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*[®] literature. Our *ConfidencePlus*[®] Premier Limited Warranty program applies automatically to every Allergan *NATRELLE*[®] Silicone-Filled Breast Implant or *NATRELLE INSPIRA*[®] Breast Implant recipient subject to the conditions discussed in the *ConfidencePlus*[®] literature. For more information, please visit www.cppwarranty.com or contact Allergan's Product Surveillance Department at 1.800.624.4261.

6.4 How Can I Receive More Information?

Upon request, you will be provided with a copy of the package insert (Directions for Use; *NATRELLE*[®] Silicone-Filled Breast Implants and *NATRELLE INSPIRA*[®] Breast Implants). You can request a copy from your surgeon or from Allergan. It can also be found on www.allergan.com/labeling/usa.htm. The package insert has many undefined medical and technical terms because it contains information directed only 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 www.fda.gov/breastimplants

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.

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 1.800.362.4426 (7 am to 5 pm Pacific Time).

ADDITIONAL RESOURCES

Allergan

1.800.624.4261

www.natrelle.com

www.allergan.com

Institute of Medicine Report on the Safety of Silicone Implants

www.nap.edu/catalog/9618.html

Food and Drug Administration

1.888.INFO.FDA or 1.240.276.3103

www.fda.gov/breastimplants



For Further Reading And Information

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Acknowledgement of Informed Decision

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 patient labeling, *Important Information for Women about 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.

I am choosing to proceed with silicone gel-filled breast implant surgery.

By circling my response for each statement below and signing below, I acknowledge that:

Yes / No I have had adequate time to read and fully understand the information in this brochure,

Yes / No I have had an opportunity to discuss this information with my surgeon and to ask any questions I may have,

Yes / No I have carefully considered options other than reconstruction surgery with breast implants and have decided to proceed with silicone gel breast implant surgery,

Yes / No I have been advised to wait an adequate amount of time after reviewing and considering this information before scheduling my silicone gel breast implant surgery,

Yes / No I am aware that this patient labeling is available online, and I am aware that I may also ask my surgeon for a copy of this signed acknowledgment

Patient Name (Printed): _____

Patient Signature: _____

Date: _____

By my signature below, I acknowledge that:

- My patient has been given an opportunity to ask any and all questions related to this brochure, or any other issues of concern;
- All questions outlined above have been answered "Yes" by my patient;
- My patient has had an adequate amount of time before making her final decision, unless an earlier surgery was deemed medically necessary,
- This *Acknowledgement of Informed Decision* will be retained in my patient's permanent record, and
- I have provided the device tracking form to my patient.

Surgeon Name (Printed): _____

Surgeon Signature: _____

Date: _____



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ALLERGAN
2525 Dupont Drive, Irvine, CA 92612

1.800.624.4261

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