Your Surgery Planner

ANOTHER STEP FORWARD

RECONSTRUCTION SURGERY WITH *NATRELLE*® SILICONE-FILLED BREAST IMPLANTS

Natrelle®

ALLERGAN

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PLACE YOUR IDENTIFICATION CARD(S) HERE

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Dear Patient,

Allergan has developed this RECONSTRUCTION SURGERY WITH *NATRELLE*® *SILICONE GEL-FILLED BREAST IMPLANTS PATIENT PLANNER to* function as a resource for all aspects of your surgery. Please give yourself at least 1 to 2 weeks time to consider this information before deciding to proceed with surgery unless an earlier surgery is deemed medically necessary by your surgeon.

This patient planner should serve primarily as your source of information on the risks and benefits of surgery with *NATRELLE*® Silicone-Filled Breast Implants but also as a convenient place where everything necessary for planning, follow-up and keeping can be securely stored.

The information contained in Section I is intended to provide you with an understanding of the risks and benefits of surgery with silicone gel-filled breast implants, as well as provide an overview of the experience of patients in the Allergan Core Clinical Study.

Please thoroughly review this information. Following your review, complete the Patient Self Assessment. This assessment will help determine your understanding of the information presented and help your surgeon ensure that your preoperative consultation is effective and comprehensive. Make notes about issues that you would like to further discuss with your plastic surgeon, and ask questions. Give yourself time to consider your choices and proceed with surgery only after you are satisfied you understand the risks and follow-up recommendations associated with silicone gel-filled breast implants, and that the decision to proceed is the right decision for you.

You should become familiar with and use the following components provided in this planner:

SECTION I

- Breast Reconstruction with *NATRELLE*® Silicone-Filled Breast Implants

SECTION II — FORMS

- Preoperative and Postoperative Checklists and Instructions
- Patient Self Assessment
- Acceptance of Risk and Surgery Consent
- Patient Surgery Record
- Device Tracking Enrollment
- Optional *ConfidencePlus*® Premier Warranty Enrollment Form
- Mammography Information
- To the Primary Care Physician

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Glossary

Note: A glossary word appears in **bold** the first time it occurs in the text of this brochure.

Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	Lack of proportion of shape, size, and/or position between the two breasts.
Atrophy	Thinning or diminishing of tissues or muscle.
Autoimmune disease	A disease in which the body mounts an "attack" response to its own tissues or cell types. Normally, the body's immune mechanism is able to distinguish clearly between what is a normal substance and what is foreign. In autoimmune diseases, this system becomes defective and mounts an attack against normal parts of the body, causing tissue injury. Certain diseases such as rheumatoid arthritis, lupus, and scleroderma are considered to be autoimmune diseases.
Axillary	Pertaining to the armpit area.
Biocompatible	The condition of being compatible with living tissues or systems without being toxic.
Biopsy	The removal and examination of tissues, cells, or fluid from the body.
Body Esteem Scale	A questionnaire which asks about a person's body image.
Breast augmentation	A surgical procedure to increase breast size. For this document, it refers to placement of a breast implant.
Breast implant	An internal artificial device or implant intended to replace the breast.
Breast mass	A lump in the breast.

Breast reconstruction

A surgical procedure 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. For this document, it refers to placement of a breast implant. The first time a breast implant is placed, it is called primary reconstruction. All subsequent times the implant is replaced, it is called revision-reconstruction.

Calcification

Process of hardening by calcium salts.

Capsular contracture

A tightening of the tissue capsule surrounding an implant, resulting in firmness or hardening of the breast and in squeezing of the implant if severe. Capsular contracture is classified by Baker Grades. Baker Grades III or IV are the most severe. Baker Grade III often results in the need for additional surgery (reoperation) because of pain and possible abnormal appearance. Baker Grade IV usually results in the need for additional surgery (reoperation) because of pain and unacceptable appearance. Capsular contracture Baker Grades II may also result in the need for additional surgery. Capsular contracture is a risk for implant rupture. Below is a description of each Baker Grade.

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 looks abnormal (change in shape)
Baker Grade IV: Hard, obvious distortion, and tenderness with pain

Capsule

Scar tissue which forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture.

Capsulectomy

Surgical removal of the scar tissue capsule around the implant.

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 is a known risk for rupture of 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 heed 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 postapproval Core Study.
Delayed wound healing	Delayed progress in the healing of an opened wound.
Diffusion	Movement from one location to another.

Displacement	Movement of the implant from the usual or proper place.
Dysmorphic disorder	A psychological condition characterized by an obsession with a minor or an imagined physical flaw to the point that it can interfere with normal functioning.
Epidemiological	Relating to the science of explaining the relationships of factors that determine disease frequency and distribution.
Extracapsular rupture	A type of rupture in which the silicone gel is outside of the scar tissue capsule surrounding the implant.
Extrusion	Skin breakdown with the pressing out of the implant through the surgical wound or skin.
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.
Granuloma	A lump or mass made of inflammatory cells surrounding a foreign substance due to longstanding inflammation.
Hematoma	A collection of blood within a space.
Hypertrophic scarring	An enlarged scar remaining after the healing of a wound.
Immune response	A bodily response to the presence of a foreign substance.

Infection	Invasion with microorganisms (for example, bacteria, viruses). An infection usually results in fever, swelling, redness, and/or pain.
Inflammation	The response of the body to infection or injury that is characterized by redness, swelling, warmth, pain, and/or loss of function.
Inframammary	Below the breast.
Inframammary fold	The crease at the base of the breast.
Inframammary incision	An incision made in the fold below the breast.
Inpatient surgery	A surgical procedure in which the patient is required to stay overnight in the hospital.
Intracapsular rupture	A type of rupture in which the silicone gel remains inside the scar tissue capsule surrounding the implant.
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.
Lymphadenopathy	Enlargement of the lymph node(s).
Lymphedema	Swelling of the lymph nodes.
MRI	Magnetic resonance imaging. A radiographic examination that currently has the best ability to detect rupture of silicone gel-filled breast implants.
Malposition	Implant malposition or displacement is when the implant is not in the correct spot in the breast. This could have been due to incorrect placement of the implant during the surgery or due to shifting of the implant position over time.

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 — The removal of breast tissue 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 — Plastic surgery to lift sagging breasts higher.

Metastatic Disease	Spreading of cancer cells from the original site to other parts of the body.
Migration	Movement of silicone materials outside the breast implant.
Necrosis	Death of cells or tissues.
Oncologist	A doctor who studies, identifies, and treats 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.
Palpate/palpable	To feel with the hand.
Paresthesis	The feelings of pins and needles in a particular area of your body (particularly the arms and legs).
Pectoralis	Major muscle of the chest.
Periareolar	Around the darkened or pigmented area surrounding the nipple of the breast.
Plastic surgery	Surgery intended for the improvement of appearance of the body.
Postoperatively	After surgery.
Primary breast reconstruction	The first time a breast implant is placed for the purpose of breast reconstruction.
Ptosis	Breast sagging that is usually the result of normal aging, pregnancy, or weight loss.
Reoperation	An additional surgery after your first breast implantation.
Revision-reconstruction	Refers to the correction or improvement of a primary reconstruction. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast reconstruction.

Rheumatological 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 10-item questionnaire intended to measure overall self-esteem through statements related to feelings of self-worth and self-acceptance.
Rupture	A tear or hole in the implant shell. Silicone implant ruptures may be with or without symptoms. Ruptures can be intracapsular or extracapsular.
Saline	A solution that is made up of water and a small amount of salt.
Scar revision	A surgical procedure to improve the appearance of a scar.
Seroma	A build-up of the watery portion of the blood in a tissue location.
SF-36 Scale	A 36-item questionnaire intended to measure patient health in areas such as vitality, physical functioning, bodily pain, general health, social and emotional functioning, and mental health.
Silent rupture	A breast implant rupture without symptoms and which is not apparent except 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 of a breast implant wholly or partially underneath the chest muscle.
Surgical incision	A cut made to body tissue during surgery.
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Symptomatic	Any evidence or sign of disease or disorder reported by the patient.
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 gel-filled breast implant ruptures are symptomatic, but most are silent.
Systemic	Pertaining to or affecting the body as a whole.
Tennessee Self-Concept Scale	A questionnaire intended to measure the patient's view of her body and state of health, as well as her attitude about appearance, skills, and sexuality. The questionnaire administered in the Core Study consisted of 18 items.
Toxic shock syndrome	Infection from staphylococci, occurring most often in the vagina of menstruating women using superabsorbent tampons but can also occur in other soft tissue infections. Symptoms include high fever, vomiting, diarrhea, rash, decreased blood pressure and shock, which can result in death.
Transaxillary	Through the axilla (armpit); an incision made under the arm.

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 the breast(s) or to correct a birth defect. This is referred to as **breast reconstruction**. Or you may need revision of a previous breast reconstruction, 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 *NATRELLE*® Silicone-Filled Breast Implants.

This information cannot and should not replace discussing your surgery with your plastic surgeon. Your decision 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,

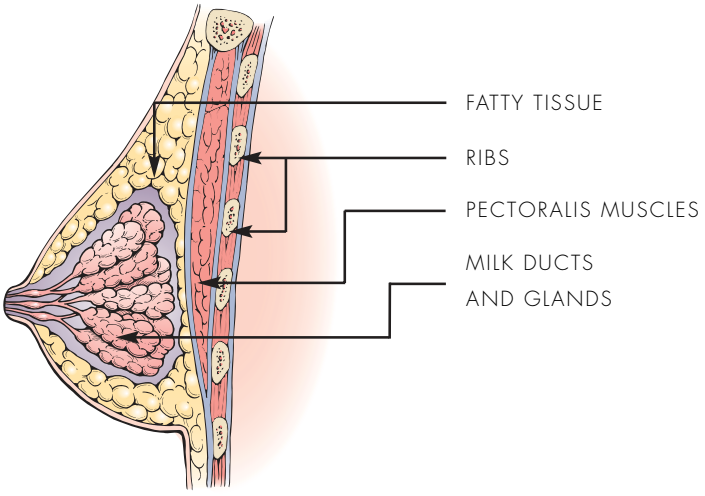
alcohol, and various medications), tendency to bleed, prior breast surgery, surgical team's skill and experience, type of surgical procedure, and type and size of implant. Make sure you speak with your surgeon about your expectations of the results, as well as what you can expect regarding the length 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 will be required to sign Allergan's consent to surgery form that confirms your understanding of what you have read. This Allergan consent document will be provided to you by your surgeon.

You should wait at least 1-2 weeks after reviewing and considering this information before deciding whether to have **primary breast reconstruction** surgery. In the case of a revision-reconstruction, however, your surgeon may find it medically necessary 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).



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. However, it is important to realize

that implants are used to make the breast larger or to restore/replace breast tissue. 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 can significantly change the shape of the breast, to a greater or lesser degree, depending on a number of factors. These factors include how much breast tissue is removed in a partial or complete mastectomy; how much skin is removed at the time of surgery; and how much tissue reaction or scarring there is in the remaining breast and skin in response to chemotherapy or radiation therapy.

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. It is surgically implanted either under your breast tissue or under your chest muscle.

1.3 Are Silicone Gel-Filled Breast Implants Right For You?

NATRELLE® Silicone-Filled Breast Implants are indicated 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. (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).
- Breast reconstruction. Breast reconstruction includes primary 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.

CONTRAINDICATIONS

Breast implant surgery should not be performed in:

- Women with active **infection** anywhere in their body.
- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions.
- Women who are currently pregnant or nursing.

PRECAUTIONS

Safety and effectiveness have not been established in patients with the following:

- **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).
- Conditions that interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue.
- Radiation to the breast following implantation.

- Clinical diagnosis of depression or other mental health disorders, including body **dysmorphic disorder** and eating disorders. Please discuss any history of mental health disorders with your surgeon prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

1.4 What Important Factors Should You Consider In Choosing Silicone Gel-Filled Implants?

- You should be aware that there are many factors that will affect the outcome and timing of your reconstruction with breast implants, such as 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.
- ***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 **contralateral** augmented breasts because of complications or unacceptable cosmetic outcomes. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures. When you have your implants replaced (revision-reconstruction), your risk of future complications increases compared to first time (primary) reconstruction surgery, so you should also review the complication rates for revision-reconstruction patients to see what future risk rates you may experience.

- Many of the changes to your breast following implantation are irreversible (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 of the breast, which can be permanent.
- If you undergo a mastectomy, removal of the breast tissue eliminates the ability to breastfeed with the removed breast. In addition, contralateral breast augmentation may affect your ability to breastfeed, by either reducing or eliminating milk production.
- **Rupture** of a silicone gel-filled breast implant is most often without symptoms (silent). This means that most of the time neither you nor your surgeon will know that your implants have a rupture. In fact, the ability of a physical examination by a plastic surgeon who is familiar with breast implants to detect silicone breast implant rupture is 30%[3] compared to 89% for **MRI**.[4] You will need regular screening MRI examinations over your lifetime in order to determine if **silent rupture** is present. You should have your first MRI at 3 years after your initial implant surgery and then every 2 years, thereafter. The cost of MRI screenings may exceed the cost of your initial surgery over your lifetime. This cost, which may not be covered by your insurance, should be considered in making your decision.
- If implant rupture is noted on MRI, you should have the implant removed, with or without replacement.
- 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. The implant may interfere with finding breast cancer during mammography. Because the breast and implant are squeezed during mammography, an implant may rupture during the procedure. 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.

- You should perform an examination of your breasts every month for cancer screening; however, this may be more difficult with implants. You should ask your surgeon to help you distinguish the implant from your breast tissue.
- You should perform an examination of your breasts for the presence of lumps, swelling, hardening, or change in implant shape, which may be signs of **symptomatic rupture** of the implant. Report any of these symptoms or persistent pain to your surgeon. Your surgeon may recommend an evaluation via MRI to screen for rupture.
- The timing for any revision following reconstruction surgery should be discussed with your surgeon so that all issues such as the potential effects of radiation, chemotherapy, and additional cancer surgery or treatments can be fully discussed.
- After undergoing cancer treatment and/or reconstructive breast surgery (either primary or revision), your health insurance premiums may increase, your insurance coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should discuss the complete extent of your insurance coverage with your insurance company before undergoing reconstructive surgery with breast implants.
- You should inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.
- Allergan will continue its ongoing clinical **Core Study** through 10 years to further evaluate the long-term

safety and effectiveness of these products. In addition, Allergan has initiated a separate, 10-year postapproval study (the Breast Implant Follow-Up Study, or BIFS) to address specific issues for which the Allergan Core Study was not designed to fully answer, as well as to provide a real-world assessment of some endpoints. The endpoints in the large postapproval study include long-term local complications, **connective tissue disease (CTD)**, CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, **lactation** issues, cancer, suicide, mammography issues, and MRI compliance and results. Allergan will update its labeling on a regular basis with the results of these two studies. You should also ask your surgeon for any available updated Allergan clinical information.

- It is important that you read this entire brochure because you need to understand the risks and benefits and to have realistic expectations of the outcome of your surgery.

2. BREAST IMPLANT COMPLICATIONS

Undergoing any type of surgical procedure involves risks (some serious) such as the effects of anesthesia, infection, swelling, redness, bleeding, pain, and even death, which need to be balanced against the benefits of the surgery itself. There are potential complications specific to breast implant surgery and breast implants, as described below. Located at the end of this brochure is a list of published studies used to gather the information discussed in the sections below. These 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 as well. It should be noted that the references include augmentation and/or reconstruction patients, as well as implants of different types and from a variety of manufacturers.

2.1 What Are the Potential Complications?

- **Rupture**

Breast implants are not lifetime devices. Breast implants rupture when the shell develops a tear or hole. Ruptures can occur at any time after implantation, but they are more likely to occur the longer the implant is implanted. 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. Laboratory studies have identified some of the types of rupture for Allergan's product; however, it is not known whether these tests have identified all causes of rupture. These laboratory studies will continue postapproval.

Silicone gel-filled breast implant ruptures are most often silent. (MRI examination is currently the best method to screen for silent rupture.) This means that most of the time neither you nor your plastic surgeon will know if the implant has a tear

or hole in the shell. This is why MRI is recommended at 3 years and then every 2 years, thereafter, to screen for rupture. However, sometimes there are symptoms associated with gel implant rupture. These symptoms include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.

When MRI signs of rupture are found, or if your surgeon determines you have signs or symptoms of rupture, you should have the implant and any gel removed, with or without replacement of the implant. It also may be necessary to remove the tissue **capsule** as well as the implant, which will involve additional surgery, with associated costs. If you have symptoms such as breast hardness, a change in breast shape or size, and/or breast pain, you should have an MRI to determine whether rupture is present. [1,5]

There are also consequences of rupture. If rupture occurs, silicone gel may either remain within the scar tissue capsule surrounding the implant (**intracapsular rupture**), move outside the capsule (**extracapsular rupture**), or gel may move beyond the breast (gel **migration**). There is also a possibility that rupture may progress from intracapsular to extracapsular and beyond. There have also been health consequences reported in the literature. See below for details.

Rupture Information on Allergan Implants

In Allergan's Core Study, rupture was assessed for patients who had scheduled MRIs to screen for silent rupture (i.e., part of the MRI cohort) and those who were not assessed for rupture by MRI (i.e., part of the non-MRI cohort). For primary reconstruction patients in the MRI cohort, the by-patient rupture rate was 11.4% and the by-implant rupture rate was 9.3% through 7 years. For revision-reconstruction patients in the MRI cohort, the rupture rate was 0% through 7 years. This means that through 7 years, approximately 11 of every 100 primary reconstruction women had at least one ruptured breast implant. There were no revision-reconstruction patients with a ruptured breast implant. No ruptures were reported in the non-MRI primary reconstruction and revision-reconstruction cohorts.

The rupture rate for the whole MRI cohort in the Core Study (including augmentation, revision-augmentation, reconstruction, and revision-reconstruction patients) through 7 years was 7.3% for patients and 4.5% for implants. Across all patients in the Allergan Core Study, all ruptures were intracapsular with 1 case 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.[2] 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 five 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 postapproval studies: the continuing Core Study and Breast Implant Follow-Up Study (BIFS).

Additional Information on Consequences of Rupture from Literature

Since silicone implants were not available in the United States for many years but were used in Europe during that time, some information on rupture rates comes from studies conducted in Europe. Studies of Danish women evaluated with MRI involving a variety of manufacturers and implant models showed that about three-fourths of implant ruptures are intracapsular and the remaining one-fourth are extracapsular.[6] Additional studies of Danish women indicate that over a 2-year period, about 10% of the implants with intracapsular rupture progressed to extracapsular rupture as detected by MRI.[5] This means that for women with silicone gel rupture within the scar tissue capsule detected via MRI after 2 years, 1 in 10 of these women had progression of the gel

outside the scar tissue capsule. In about half of these cases of progression from intracapsular to extracapsular rupture, the women had had trauma or mammography. In the other half, no cause was given. In the women with extracapsular rupture, after 2 years, the amount of silicone outside the scar tissue capsule increased for about 14% of these women. This means that for 100 women with silicone gel rupture outside the scar tissue capsule, the amount of gel outside the scar tissue capsule increased for 14 women 2 years later. This type of information pertains to a variety of silicone implants from a variety of manufacturers and implant models, and it is not specific to Allergan implants.

Below is a summary of information related to the health consequences of implant rupture, which have not been fully established. These reports were in women who had implants from a variety of manufacturers and implant models.

- Local breast complications reported in the published literature which were associated with rupture include breast hardness, a change in breast shape or size, and breast pain.[5] These symptoms are not specific to rupture, as they also are experienced by women who have capsular contracture.
- There have been rare reports of gel movement to nearby tissues such as the chest wall, armpit, or upper abdominal wall, and to more distant locations down the arm or into the groin. This has led to nerve damage, **granuloma** formation and/or breakdown of tissues in direct contact with the gel in a few cases.There have been reports of silicone presence in the liver of patients with silicone breast implants. Movement of silicone gel material to lymph nodes in the axilla also has been reported, even in women without evidence of rupture, leading to **lymphadenopathy**.[43]
- Concerns have been raised over whether ruptured implants are associated with the development of connective tissue or rheumatic diseases and/or symptoms such as fatigue and fibromyalgia.[11,12,18,19]

A number of epidemiology studies have evaluated large populations of women with breast implants. These studies do not, taken together, support a significant association of breast implants with a typical, diagnosed rheumatic disease. Other than one small study,[12] these studies do not distinguish whether the women had ruptured or intact implants.

• 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 it is one of the most common reasons 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 levels depending on its severity.* Baker Grades III and IV are considered severe, and often additional surgery is needed to correct these grades.

Baker Grade I: the breast is normally soft and looks natural
Baker Grade II: the breast is a little firm but looks normal
Baker Grade III: the breast is firm and looks abnormal
Baker Grade IV: the breast is hard, painful, and looks abnormal

In Allergan's Core Study, for women receiving reconstruction implants for the first time, the risk of severe capsular contracture was 17% through 7 years. This means that 17 out of every 100 women who received Allergan implants for primary breast reconstruction had severe capsular contracture at least once during the first 7 years after receiving the implants.

* Baker, J.L. Augmentation mammaplasty. In: Owsley, J.Q. and Peterson, R., Eds. *Symposium on aesthetic surgery of the breast*. St. Louis, MO: Mosby; 1978:256-263.

For women receiving revision-reconstruction implants, the risk of severe capsular contracture was 7% through 7 years.

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. Capsular contracture may increase the risk of rupture.[1]

• Additional Surgeries (Reoperations)

You should assume that you will need to have additional surgeries (**reoperations**). In Allergan's Core Study, the reoperation rate was 53% for primary reconstruction patients, and 40% for revision-reconstruction patients, which means that 53 out of every 100 women who received Allergan implants for primary reconstruction and 40 out of every 100 women who received Allergan implants for revision-reconstruction had a reoperation during the first 7 years after receiving the implants.

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. Tables 3 and 4, which summarize the main reasons for performing reoperations in the Core Study, are located in section 3.5. For women receiving primary reconstruction implants, the three most common reasons for reoperation were implant malposition, asymmetry, and capsular contracture. For women receiving revision-reconstruction implants, the most common reason reported for reoperation was nipple complications.

• 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. Having your implants removed and replaced increases your chances of getting future complications.

For women receiving primary reconstruction implants in

Allergan's Core Study, 30% had their implants removed at least once through 7 years. Implant malposition, asymmetry, and capsular contracture were the most common reasons for implant removal. One woman receiving revision-reconstruction implants in Allergan's Core Study had an implant removed through 7 years. The reason for removal was asymmetry.

Most women who have their implants removed have them replaced with new implants, but some women do not. If you choose not to replace your implants, you may have cosmetically unacceptable dimpling, puckering, wrinkling, and/or other potentially permanent cosmetic changes of the breast following removal of the implant. 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.

- 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.

- 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. You should tell your surgeon about significant pain or if your 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. (See paragraph on breastfeeding below).

• 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 reconstruction. If your surgeon uses a periareolar surgical approach (an incision around the colored portion surrounding the nipple), it may further increase the chance of breastfeeding difficulties.

• 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 has been reported to increase the likelihood of extrusion. Extrusion requires additional surgery and possible removal of the implant, which may result in additional scarring and/or loss of your breast tissue.

• 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. Factors associated with increased necrosis include infection, use of steroids, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

• Delayed Wound Healing

Some patients may experience a prolonged wound healing time. **Delayed wound healing** may increase the risk of infection, extrusion, and necrosis. Depending on the type of surgery or the incision, wound healing times may vary. 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. 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. 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.

Literature reports associate lymphadenopathy with both intact and ruptured silicone breast implants. One study reported that armpit lymph nodes from women with both intact and ruptured silicone gel implants had abnormal tissue reactions, granulomas, and the presence of silicone.[43] These reports were in women who had implants from a variety of manufacturers and implant models.

2.2 What Are Other Reported Conditions?

There have been reports in the literature of other conditions in women with silicone gel-filled breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. Although no cause-and-effect relationship has been established between breast implants

and the conditions listed below, you should be aware of these reports. Furthermore, there is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants.

• Connective Tissue Disease (CTD)

Connective tissue diseases include diseases such as lupus, scleroderma, and rheumatoid arthritis. **Fibromyalgia** is 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. There have been a number of published **epidemiological** studies which have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease.[1,10-18] The published studies overall show that breast implants are not significantly associated with a risk of developing a typical or defined connective tissue disease.[1,13-15] However, the study size needed to conclusively rule out a small risk of connective tissue disease among women with silicone gel-filled implants would need to be very large. These studies do not distinguish between women with intact and ruptured implants. Only one study evaluated specific connective tissue disease diagnoses and symptoms in women with silent ruptured versus intact implants, but the study was too small to rule out a small risk.[12]

• CTD Signs and Symptoms

Literature reports have also been made associating silicone breast implants with various rheumatological signs and symptoms such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. Scientific expert panels and literature reports have found no evidence of a consistent pattern of signs and symptoms in women with silicone breast implants.[1,19-22] Having these rheumatological signs and symptoms does not necessarily mean you have a connective tissue disease; 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 patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer.[23,25,27,30,35] Some reports have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy; however, other reports in the published medical literature indicate that breast implants neither significantly delay breast cancer detection nor adversely affect cancer survival of women with breast implants.[23,28,31,34,35]

Brain cancer – One recent study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population.[24] The incidence of brain cancer, however, was not significantly increased in women with breast implants when compared to women who had other plastic surgeries. Another recently published review of four large studies of women with cosmetic implants concluded that the evidence does not support an association between brain cancer and breast implants.

Respiratory/lung cancer – One study has reported an increased incidence of respiratory/lung cancer in women with breast implants.[24] 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.[26,29,32]

Cervical/vulvar cancer – One study has reported an increased incidence of cervical/vulvar cancer in women with breast implants.[24] The cause of this increase is unknown.

Other cancers – One study has reported an increased incidence of stomach cancer and leukemia in women with breast implants compared to the general population.[24] This increase was not significant when compared to women who had other types of plastic surgeries.

• 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 scientific expert panel report found that the evidence for a neurological disease or syndrome caused by or associated with breast implants is insufficient or flawed.[1]

• Suicide

In several studies, a higher incidence of suicide was observed in women with breast implants.[36-39] The reason for the observed increase is unknown, but it was 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.[37]

• Effects on Children

At this time, it is not known if a small amount of silicone may pass through from the breast implant silicone shell into breast milk during breastfeeding. Although there are no current established methods for accurately detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone gel-filled implants when compared to women without implants.

In addition, concerns have been raised regarding potential damaging effects on children born to mothers with implants. Two studies in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery.[41,42] Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding.[40] The author recommended further research on infant health.

• Potential Health Consequences of Gel Bleed

Small quantities of **low molecular weight (LMW) silicone** compounds, as well as platinum (in zero oxidation state), have been found to diffuse (bleed) through an intact implant shell.[1,45] The evidence is mixed as to whether there are any clinical consequences associated with gel bleed. For instance, studies on implants implanted for a long duration

have suggested that such bleed may be a contributing factor in the development of capsular contracture and lymphadenopathy.[43] However, evidence against gel bleed being a significant contributing factor to capsular contracture and other local complications is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast implants than for **saline**-filled breast implants. Saline-filled breast implants do not contain silicone gel and, therefore, gel bleed is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in Allergan's implants does not cause toxic reactions when large amounts are administered to test animals. It should also be noted that studies reported in the literature have demonstrated that the low concentration of platinum contained in breast implants is in the zero oxidation (most **biocompatible**) state.[44,46,47,49]

Allergan performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact implants into the body. Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence.

3. ALLERGAN'S CLINICAL STUDY RESULTS

This section of the brochure summarizes the results of the Allergan Core Study conducted on *NATRELLE*® Silicone-Filled Breast Implants for primary reconstruction and revision-reconstruction. The Allergan 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 of what you may expect. Your own complications and benefits depend on many individual factors.

As a note, supplemental safety information was also obtained from another Allergan clinical study (the Adjunct Study), the Danish Breast Implant Registry, an international clinical MRI study, and the literature to help assess long-term rupture rate and the consequences of rupture for this product. The literature, which had the most available information on the consequences of rupture, was also used to assess other potential complications associated with silicone gel-filled breast implants. The key literature information was discussed throughout the **Breast Implant Complications** section above and the references can be found at the end of this brochure.

3.1 What Are the Overview Findings of Allergan's Core Study?

The Allergan Core Study is a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients. Patient follow-up is at 0-4 weeks, 6 months, 12 months, 24 months, and annually through 10 years. Safety is assessed by complications, such as implant rupture, capsular contracture, and reoperation. Benefit (effectiveness) is assessed by patient satisfaction and measures of quality of life (QoL).

The Allergan Core Study consists of 715 patients. This includes 455 primary reconstruction patients, 147 revision-reconstruction 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 are in the MRI cohort, which means that they are assessed for silent rupture by MRI at years 1, 3, 5, 7, and 9. The study is currently ongoing, with the results through 7 years reported in this brochure. Allergan will periodically update this brochure as more information becomes available. You should also ask your surgeon for any available updated Allergan clinical information.

Allergan's Core Study results indicate that the risk of at least one occurrence of any complication (including reoperation) at some point through 7 years after implant surgery is 70% for primary reconstruction patients and 73% for revision-reconstruction patients. The information below provides more details about the complications and benefits you may experience. More detailed data tables are found in the Appendix of this brochure. Please refer to the glossary for the definition of any complication you may not understand.

3.2 What Are the 7-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 reconstruction patients. Of the women expected to be seen at the 7-year follow-up visit, 87% were seen.

The Allergan Core Study enrolled 15 revision-reconstruction patients. Of the women expected to be seen at the 7-year follow-up visit, 83% were seen.

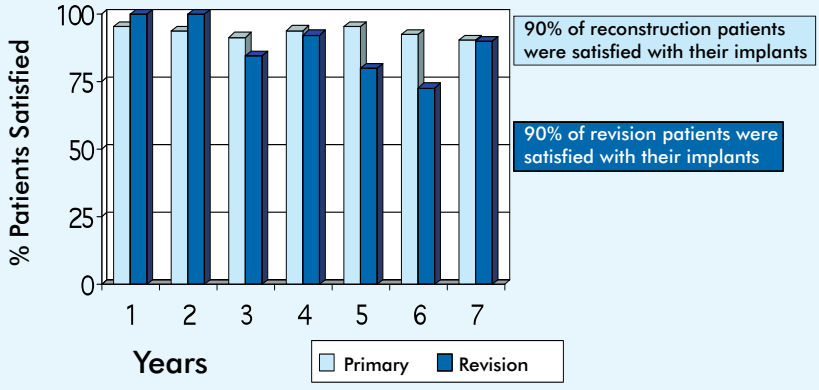
3.3 What Are the Benefits?

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 at 1, 2, 4, and 6 years post-implant for those patients who still had their original implants and who came back for these visits.

Patient Satisfaction: Allergan's patient satisfaction was based on a 5-point scale assessment of satisfaction with their implants at the time of the follow-up visits. Of the original 98 primary reconstruction patients, 63 (64%) provided a satisfaction rating at 7 years after implantation, with 57 (90%) of these patients indicating that they were satisfied with their breast implants.

Of the original 15 revision-reconstruction patients, 10 (67%) provided a satisfaction rating at 7 years. Of these 10 patients, 9 (90%) indicated that they were satisfied with their breast implants. See Figure 1 below.

Figure 1. Primary Reconstruction and Revision-Reconstruction Patient Satisfaction Through 7 Years



Quality of Life Assessments: Quality of life assessments were obtained prior to implantation and at 1, 2, 4, and 6 years post-surgery. The 6-year data is provided here. For primary reconstruction patients, the **SF-36**, which is a collection of scales that measure mental and physical health, showed no changes after 6 years. For patient responses to questions regarding overall self-concept/self-esteem, there was no change in self-concept on the **Tennessee Self Concept Scale** and no change in overall self esteem on the **Rosenberg Self Esteem Scale** 6 years after receiving implants. Patient responses to questions on the **Body Esteem Scale** regarding overall body image also did not show a change 6 years after receiving implants.

For revision-reconstruction patients, responses were similar pre- and post-implantation on the SF-36, Tennessee Self Concept Scale, Rosenberg Self Esteem Scale, and Body Esteem Scale after 6 years.

3.4 What Are the 7-year Complication Rates?

The complications observed in primary reconstruction and revision reconstruction women through 7 years are presented in Table 1 and Table 2, respectively. The rates reflect the percentage of patients who experienced the listed complication at least once within the first 7 years after their implantation. 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 experienced within the first 7 years of implantation for primary reconstruction patients were reoperation (53% or approximately 53 patients out of 100) and implant removal with replacement (24% or approximately 24 patients out of 100). The most common complications experienced within the first 7 years of implantation for revision-reconstruction patients were reoperation (40%), asymmetry (13.3%), and implant malposition (13.3%).

Table 1 7-year Complication Rates for Primary Reconstruction Patients N = 98 Patients	
Key Complications[1]	**%**
Reoperation	53.3%
Implant Removal with Replacement	23.7%
Capsular Contracture Baker Grade III/IV	17.1%
Implant Rupture (MRI cohort)[2]	11.4%
Implant Removal without Replacement	7.7%
Other Complications Occurring in ≥ 1% of patients[2,3]	**%**
Asymmetry	22.8%
Wrinkling/Rippling	9.1%
Swelling	7.1%
Breast Pain	4.8%
Scarring/Hypertrophic Scarring	4.5%
Implant Palpability/Visibility	4.1%
Implant Malposition	3.9%
Nipple Complications	3.3%
Infection	3.2%
Tissue/Skin Necrosis	2.3%
Redness	2.1%
Skin Rash	2.0%
Hematoma	1.5%
Bruising	1.0%
Delayed Wound Healing	1.0%
Implant Extrusion	1.0%
Other Complications	1.0%

[1] Most events were assessed with severity ratings, and the rates shown in the table include only complications rated moderate, severe or very severe (excludes mild and very mild ratings). All occurrences of reoperation, implant removal, implant rupture, implant extrusion and pneumothorax are included.

[2] MRI cohort sample size for Reconstruction equals 51 patients. No ruptures were reported in the non-MRI cohort, which had a sample size of 47 patients.

[3] The following complications were reported at a rate of 0%: breast/skin sensation changes, capsule calcification, gel migration, irritation, lymphadenopathy, lymphedema, pneumothorax, ptosis, and seroma/fluid accumulation.

Table 2 7-year Complication Rates for Revision-Reconstruction Patients N = 15 Patients	
Key Complications[1]	**%[2]**
Reoperation	40.0%
Implant Removal with Replacement	6.7%
Capsular Contracture Baker Grade III/IV	6.7%
Implant Removal without Replacement	0%
Implant Rupture (MRI cohort)[3]	0%
Other Complications Occurring in ≥ 1% of patients[4]	**%**
Asymmetry	13.3%
Implant Malposition	13.3%
Breast Pain	6.7%
Bruising	6.7%
Lymphedema	6.7%
Implant Palpability/Visibility	6.7%
Seroma/Fluid Accumulation	6.7%
Wrinkling/Rippling	6.7%
Skin Rash	6.7%

[1] Most events were assessed with severity ratings, and the rates shown in the table include only complications rated moderate, severe or very severe (excludes mild and very mild ratings). All occurrences of reoperation, implant removal, implant rupture, implant extrusion and pneumothorax are included.
[2] Calculated as a percentage of enrolled with binomial confidence interval.
[3] MRI cohort sample size for Revision-Reconstruction equals 5 patients. No ruptures were reported in the non-MRI cohort, which had a sample size of 10 patients.
[4] The following complications were reported at a rate of 0%: breast/skin sensation changes, capsule calcification, delayed wound healing, gel migration, hematoma, implant extrusion, infection, irritation, lymphadenopathy, nipple complications, other complications, pneumothorax, ptosis, redness, scarring/hypertrophic scarring, swelling, and tissue/skin necrosis.

3.5 What Are the Main Reasons for Reoperation?

The reasons for reoperation observed in primary reconstruction and revision-reconstruction women through 7 years are presented in Table 3 and Table 4, respectively. There may be one or more reasons identified for having a reoperation (additional surgery

after the primary or revision breast reconstruction). Furthermore, there may be multiple surgical procedures (for example, implant removal with or without replacement, capsule procedures, incision and drainage, implant reposition, **scar revision**, etc.) performed during a reoperation.

The most common reason for reoperation through 7 years in primary reconstruction patients was because of implant malposition (14 of 73 reoperations). In Allergan's Core Study, there were 155 surgical procedures performed during 73 reoperations involving 49 primary reconstruction patients.

The most common reason for reoperation through 7 years in revision-reconstruction patients was because of nipple complications (5 out of 9 reoperations). In Allergan's Core Study, there were 11 surgical procedures performed during 9 reoperations involving 6 revision-reconstruction patients.

Table 3
Main Reasons for Reoperation in Primary Reconstruction Patients Through 7 Years

Reason for Reoperation	n
Implant Malposition	14
Asymmetry	12
Capsular Contracture	10
Need for Biopsy	8
Hematoma/Seroma	6
Ptosis	4
Patient Request for Style/Size Change	3
Scarring/Hypertrophic Scarring	3
Suspected Rupture	3
Breast Cancer, Breast Tissue Contour Deformity, Implant Extrusion	2 each
Delayed Wound Healing, Necrosis, Nipple Complications, Wrinkling	1 each
TOTAL	**73**

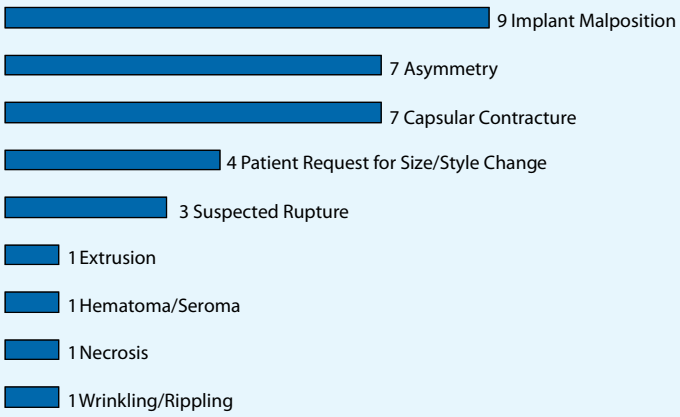
Table 4 Main Reasons for Reoperation in Revision-Reconstruction Patients Through 7 Years	
Reason for Reoperation	**n**
Nipple Complications	5
Asymmetry	1
Capsular Contracture	1
Ptosis	1
Scarring/Hypertrophic Scarring	1
TOTAL	**9**

3.6 What Are the Main Reasons For Implant Removal?

The main reasons for implant removal observed in primary reconstruction women through 7 years are presented in Figure 2. For primary reconstruction, there were 34 implants removed in 27 patients. Of these 34 implants, 27 were replaced. The most common reason for implant removal was implant malposition (9 of the 34 implants removed).

Among revision-reconstruction patients, there was 1 implant removed in 1 patient due to asymmetry. The implant was replaced.

Figure 2. Main Reasons for Implant Removal Through 7 Years Primary Reconstruction (n=34)



3.7 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 postapproval study of a large number of patients followed through 10 years (Breast Implant Follow-Up Study, or BIFS).

CTD DIAGNOSES

There was 1 primary reconstruction patient (1%) in the Allergan Core Study who was reported to have 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 7 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

In Allergan's Core Study, numerous signs and symptoms were collected at 2, 4, and 6 years post-implant. For primary reconstruction patients at 6 years after implantation, a statistically significant increase was found for the symptom category of Joint (includes joint pain, stiffness in the morning, and swelling in other joints or hands). No significant increases were found in the categories of General, Skin, Muscular, Neurological, Urinary, Fatigue, Pain, Gastrointestinal, Fibromyalgia, and Other. For revision-reconstruction patients at 6 years after implantation, no statistically significant increases were found in any of the symptom categories.

The Core Study was not designed to evaluate cause-and-effect associations because there is no comparison group of women without implants, and because other contributing factors, such as medications and lifestyle/exercise, were not studied. Therefore, it cannot be determined whether this increase 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 8 primary reconstruction patients (8%) with recurrence of breast cancer through 7 years in the Allergan Core Study. There was a 17% benign breast disease rate and a 10% malignant breast disease rate through 7 years.

For revision-reconstruction patients, there were no reports of new diagnoses or reoccurrence of breast cancer. There was a 7% benign breast disease rate through 7 years. There were no reports of other cancers, such as brain, respiratory, or cervical/vulvar, in primary reconstruction or revision-reconstruction patients.

LACTATION COMPLICATIONS

One of the 98 primary reconstruction patients attempted to breastfeed following breast implantation in the Allergan Core Study through 7 years and did not experience any difficulties. No revision-reconstruction patients attempted to breastfeed after receiving breast implants.

REPRODUCTION COMPLICATIONS

Two (2%) of the primary reconstruction patients in Allergan's Core Study reported a reproduction problem through 7 years. No revision-reconstruction patients experienced a post-implantation reproduction problem.

SUICIDE

There were no reports of suicide in the primary reconstruction and revision-reconstruction patients in the Allergan Core Study through 7 years.

4. SURGICAL CONSIDERATIONS FOR BREAST RECONSTRUCTION

This section provides a discussion of surgical considerations for primary breast reconstruction, followed by a discussion of general surgical considerations.

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 reconstruction 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 are advised to 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.

4.1 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 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.

You should also be aware that, 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 or without replacement.

4.2 What Are the Options in Primary Breast Reconstruction?

You may choose not to undergo breast reconstruction. In this case, you may or may not decide to wear an external breast form (prosthesis) inside your bra. Breast forms are available in a variety of shapes, sizes, and materials such as foam, cotton, and silicone. Custom prostheses are also available to match the size and shape of your breast.

4.3 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 prosthesis (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 from your stomach, back, or other area of your body to the chest area, and shaped into a new breast. A tissue flap also may be used to provide skin or other tissue needed to make up for what was removed at the time of surgery, or 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 several-stage reconstruction of the removed breast, or to shape the remaining breast to bring it into better balance with the reconstructed one. Most commonly, breast implants are placed after a space has been created for them using a temporary soft tissue expander that can be placed at the time of mastectomy or at a later time.

Portions of the reconstruction may be done in stages. For example, because the nipple and **areola** are usually removed with the breast tissue in mastectomy, the nipple is usually reconstructed by using a skin graft from another area of the body or the opposite breast, in addition to tattooing the area to obtain a better color match. Nipple reconstruction is usually done as a separate outpatient procedure after the initial reconstruction surgery is complete.

4.4 What is Breast Reconstruction With Breast Implants?

Your surgeon will decide whether your health and medical condition makes you an appropriate candidate for breast implant reconstruction. Women with small or medium-sized breasts are the best candidates for breast reconstruction with implants.Women with larger breasts may require reconstruction with a combination of a tissue flap and an implant. Your surgeon may recommend breast implantation of the opposite, uninvolved breast in order to make your breasts more alike (maximize symmetry), or he/she may suggest breast reduction (reduction **mammoplasty**) or a breast lift (mastopexy) to improve symmetry. 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. Reduction mammoplasty involves removal of breast tissue and skin. If it is important to you 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.

4.5 What Reconstruction Incision Sites Are Used?

In reconstructive surgery, the incision placement and length is decided by your surgeon, and largely influenced by the type of cancer surgery that is planned for you.

Most implants in breast reconstruction use the mastectomy scar either immediately (during the mastectomy procedure) or after tissue expansion.

4.6 What About the Surgical Settings and Anesthesia?

Reconstruction surgery is usually performed on an inpatient basis in an operating room when it begins at the same time as the mastectomy. Some of the stages, such as nipple reconstruction, or placement of the implant after soft tissue expansion, can be done as an outpatient. General anesthesia is most often used.

4.7 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 is made after consultation with the cancer treatment team based on your individual situation. Immediate reconstruction may involve placement of a breast implant, but typically involves placement of a tissue expander, which is used to recreate skin that was removed during the cancer surgery. The tissue expander will eventually be replaced with a breast implant. It is important to 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 and that there may be cost savings and potentially fewer days in the hospital for you in combining the mastectomy procedure with the first stage of the reconstruction. However, there may be a higher risk of capsular contracture, extrusion, and other complications associated with immediate reconstruction as a result of postoperative radiation and chemotherapy treatments. 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.

4.8 What Is the Primary Breast Implant Reconstruction Procedure?

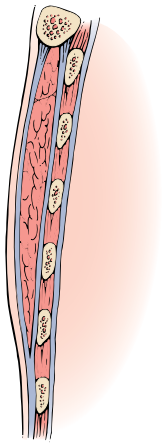
IMMEDIATE OR DELAYED BREAST IMPLANT RECONSTRUCTION

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 **submuscularly**.

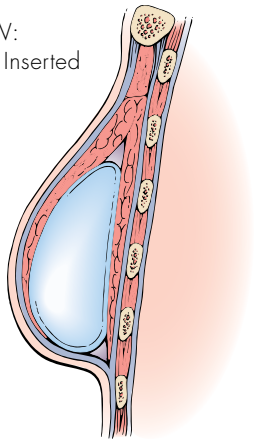
EXPANDER-ASSISTED (IMMEDIATE OR DELAYED) BREAST IMPLANT RECONSTRUCTION

Breast reconstruction usually occurs as a multistage procedure, starting with the placement of a breast tissue expander, which is replaced several months later with a breast implant. The tissue expander placement may be done 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 tissues flat and tight. To create a breast shaped space for the breast implant, a tissue expander is placed under the remaining chest tissues.

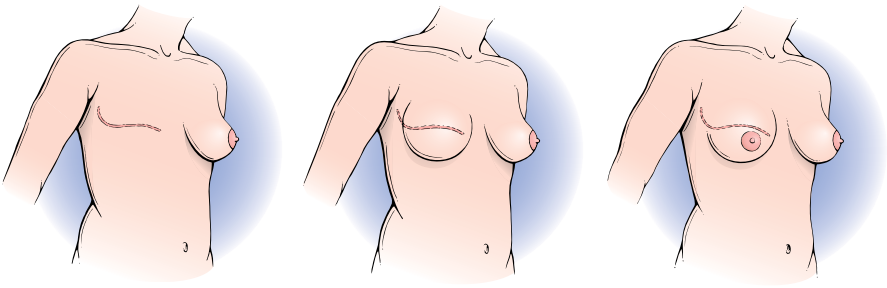
The tissue expander is a balloon-like device made from elastic silicone rubber. It is inserted unfilled, and over time, sterile saline fluid is added by inserting a small needle through the skin to the filling port of the device. As the tissue expander fills, the tissues over the expander begin to stretch,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

Tissue expander placement usually occurs under general anesthesia in an operating room. Operative time is generally 1 to 2 hours. The procedure may require a brief hospital stay or be done on an outpatient basis. Typically, you can resume normal daily activity after 2 to 3 weeks.

Because the chest skin is usually numb from the mastectomy surgery, it is possible that you may not experience pain from the placement of the tissue expander. However, you may experience feelings of pressure, tightness, or discomfort after each filling of the expander, which subsides as the tissue expands but may last for a week or more. Tissue expansion typically takes four to six months.

PLACING THE BREAST IMPLANT

After the tissue expander is removed, the breast implant is placed in the pocket. In reconstruction, following mastectomy, a breast implant is most often placed submuscularly. 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 brief hospital stay or be done on an outpatient basis.



Post Mastectomy

Stage 1:
Tissue Expander Placed
and Expansion Under Way

Stage 2:
Breast Implant and Nipple/
Areola Reconstruction

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

The breast can be reconstructed by surgically moving a section of skin, fat, and muscle 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 the 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 breast area by microsurgical techniques (a free flap). Operating time is generally longer with free flaps, because of the microsurgical requirements.

Flap surgery requires a hospital stay of several days and generally a longer recovery time than implant reconstruction. 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 tissue in the chest area. This may be useful when the chest tissues have been damaged and are not suitable for tissue expansion. Another advantage of flap procedures over implant reconstruction is that alteration of the unaffected breast is generally not needed to improve symmetry.

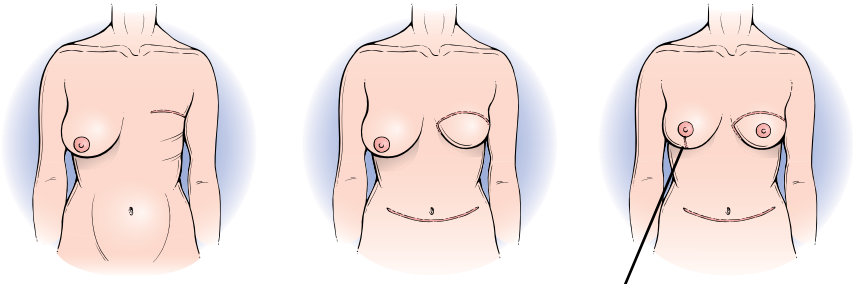
The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap, which uses tissue from the abdomen) and the Latissimus dorsi flap (which uses tissue from the upper back).

It is important for you to 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.

THE TRAM FLAP (PEDICLE OR FREE)

During a TRAM flap procedure, the surgeon removes a section of tissue from your abdomen 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 abdominal 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.



Post Mastectomy

TRAM Flap

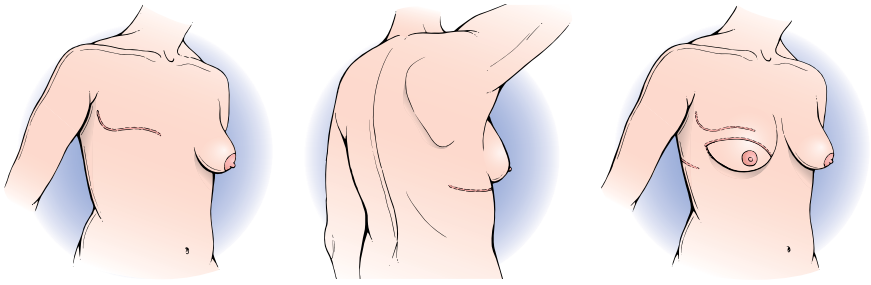
Final Result with Nipple/Areola Reconstruction

THIS RECONSTRUCTION INCLUDES A MASTOPEXY TO THE OTHER BREAST TO IMPROVE SYMMETRY

THE LATISSIMUS DORSI FLAP WITH OR WITHOUT BREAST IMPLANTS

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

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



Post Mastectomy

View Showing Back Scar

Latissimus Dorsi Flap and Nipple/Areola Reconstructon

4.10 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?
- Has he/she completed Allergan's Physician Certification Program for the use of its silicone-filled breast implants?
- Is he/she board certified, and if so, with which board?
- 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. Insurance coverage for reoperation procedures or additional surgeon's visits following reconstruction may not be covered, depending on the policy. For example, a reoperation may include temporary removal of the implant to facilitate the oncologist's ongoing surveillance for breast cancer recurrence. Because coverage policies vary and can change over time, no guidance can be given with respect

to coverage under any particular health plan. It is, therefore, recommended that you contact your health plan to obtain specific information regarding its coverage policies before deciding to proceed with reconstructive surgery.

WHAT ARE CHOICES AND OPTIONS ASSOCIATED WITH THE SURGERY?

There are two approved types of breast implant fillers, saline and silicone, which gives more options to you in terms of the 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. The focus of this brochure is silicone-filled breast implants; a separate brochure is available for saline-filled implants. Carefully review the section on complications 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 both silicone and saline breast implants.

IMPLANT SHAPE AND SIZE

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 (measured in cubic centimeters, or cc's, not in cup sizes, because cup size depends on the size and shape of the individual woman's chest).

Your surgeon will also evaluate your existing breast and skin tissue to determine if you have enough to cover the breast implant you are considering, or, in some cases such as after pregnancy, 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 the breast, and can result in droop or sag at an earlier age. A recent report indicates that larger-sized implants (greater than 350cc) may be too large for many women, increasing the risk of developing complications such as implant extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling requiring surgical intervention to correct these complications.[7]

SURFACE TEXTURING

Some studies suggest that surface texturing reduces the chance of severe capsular contracture,[9] while other studies do not.[7,8] 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 without undue stress, which 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 **subglandularly**.

POSTOPERATIVE CARE

You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size. The feeling in the breasts and nipple area also may be diminished during this time of swelling and immediate post-surgery recovery. Other possible complications are described in the Breast Implant Complications section.

Postoperative care depends on each patient's situation and may involve the use of a special postoperative bra, compression bandage, or jog bra for extra support and positioning while you heal. Some surgeons may not want you to wear a bra at all for a period of time following the surgery. At your surgeon's recommendation, you will most likely be able to return to work within a few days, although for at least a couple of weeks you should avoid any strenuous activities that could raise your pulse and blood pressure, or require strenuous use of your arms and chest. Your surgeon may also recommend breast massage exercises.

Note: If you experience fever, do not feel well, or see noticeable swelling and/or 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 removal of an intact implant (for example, **capsulotomy** and pocket adjustments), while others do not require removal of the implant. Any device that has been removed during revision surgery should not be reimplanted. Allergan breast implants are "for single use only."

5. FOLLOW-UP EXAMINATIONS

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 identify the implant from breast tissue will decrease the necessity of excessive squeezing of the implant during examination. 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 care will be taken to avoid damaging the implant.

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. Therefore, evaluation of your implants 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.

It is recommended that your first MRI evaluation take place starting at 3 years after implant surgery and then every 2 years, thereafter, even if you are experiencing no problems with your implant. If signs of rupture are seen on MRI, then you should have your implant removed, with or without replacement. Your doctor should assist you in locating a radiology/screening center, as well as a radiologist who is familiar with the technique and equipment for proper MRI screening for silent rupture of your breast implant.

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 so that he or she can examine the implants and determine whether you need to have an MRI examination to find out if your symptoms are due to rupture of the implant. If rupture has occurred, you should have your implant removed. Consult with your doctor regarding this and any other medical decisions related to your implants. More information on rupture is provided in section 4 of this brochure.

MAMMOGRAPHY

The current recommendations for getting screening/preoperative mammograms are no different for women with breast implants than for those without implants. Mammography exams should be interpreted by radiologists experienced in the evaluation of women with breast implants. It is essential that you tell your mammography technologist before the procedure that you have an implant. You 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.

6. ADDITIONAL INFORMATION

6.1 What Types of *NATRELLE*® Silicone Filled Breast Implants Are Available from Allergan?

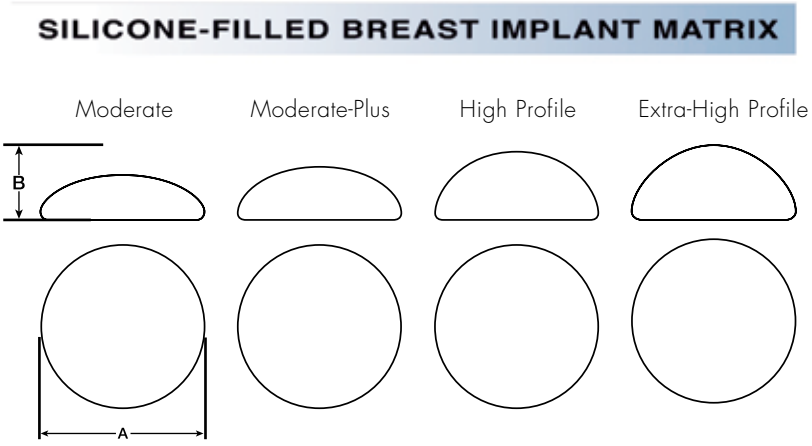
NATRELLE® Silicone-Filled Breast Implants come in a variety of profiles and sizes with either a textured shell or smooth surface shell. Your plastic surgeon will discuss with you the implant design that will best help you achieve the result that is right for you.

Examples of *NATRELLE*® Smooth and Textured Implant Styles

Smooth Implant

Textured Implant

The following diagram may help you to understand the projections of implants as your surgeon discusses the various options with you.



A=Width, B=Projection

Approved Allergan Implant Styles		
Style Number	**Breast Implant Description**	**Size Range**
Style 10	Smooth shell surface, moderate profile	120cc–800cc
Style 15	Smooth shell surface, moderate-plus profile	155cc–752cc
Style 20	Smooth shell surface, high profile	120cc–800cc
Style 40	Smooth shell surface, moderate profile	80cc–560cc
Style 45	Smooth shell surface, extra-high profile	120cc–800cc
Style 110	BIOCELL® textured shell surface, moderate profile	90cc–510cc
Style 115	BIOCELL® textured shell surface, moderate-plus profile	150cc–716cc
Style 120	BIOCELL® textured shell surface, high profile	180cc–650cc

6.2 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 1.888.463.INFO.FDA (1.888.463.6332), from 10 am-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.

6.3 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 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, including you, can be contacted in the case of a recall or other problems with your implants that you should be made aware of.

You are encouraged to complete the Device Tracking Form you received following surgery and return it to Allergan in the postage paid business reply envelope provided. Please inform Allergan whenever your contact information changes.

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* patient planner provided prior to your surgery. This question asks you to verify that you received and had adequate time to review this patient labeling information. Please check either yes or no. When the Required Information section is complete, return it to Allergan in the postage-paid business reply envelope provided.

6.4 What Are the *ConfidencePlus*® Limited Warranties?

The *ConfidencePlus*® Limited Warranties provide 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. Allergan offers two levels of coverage under its warranty program. Our standard *ConfidencePlus*® Limited Warranty program applies automatically to every Allergan breast implant recipient subject to the conditions discussed in the *ConfidencePlus*® literature. The optional *ConfidencePlus*® Premier Limited Warranty program is available for a low enrollment fee and increases the financial benefit in the event of implant rupture, subject to the conditions discussed in the *ConfidencePlus*® literature. For more information, please visit **www.cppwarranty.com** or contact Allergan's Product Support Department at 1.800.362.4426.

6.5 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 document). You can request a copy from your surgeon or from Allergan. It can also be found on **www.NATRELLE.com**. 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 **http://www.fda.gov/cdrh/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
www.breastimplantanswers.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/cdrh/breastimplants

FOR FURTHER READING AND INFORMATION

Overall Safety Assessment

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Implant Rupture

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Capsular Contracture

7. Henriksen, T.F., et al. 2005. Surgical intervention and capsular contracture after breast augmentation: a prospective study of risk factors. *Ann. Plast. Surg*. 54(4):343-51.
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Connective Tissue Disease (CTD)

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CTD Signs and Symptoms

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INDEX

FORMS

Checklists for you and
your surgeon to review

Preoperative Checklist

❑ PATIENT SELF ASSESSMENT

Completed by the patient prior to surgery for discussion with the physician

❑ ACCEPTANCE OF RISK AND SURGERY CONSENT

Reviewed and initialed by the patient and physician and retained in patient's medical file

❑ PATIENT SURGERY RECORD

Important pre- and postoperative appointments and related information recorded by the patient

Postoperative Checklist

- ❑ ALLERGAN DEVICE IDENTIFICATION CARD(S)

  Supplied following surgery and retained by patient in designated area of the Breast Reconstruction Surgery Planner

- ❑ DEVICE TRACKING ENROLLMENT FORM

  Completed and returned by the patient to Allergan in the business reply envelope provided

- ❑ OPTIONAL *CONFIDENCEPLUS*® PREMIER WARRANTY ENROLLMENT FORM

  Completed and returned by the patient to Allergan in the business reply envelope provided

- ❑ INFORMATION FOR YOUR HEALTHCARE PROVIDERS

  Completed by the patient to give to her mammography center and primary care physician

A simple questionnaire to ensure you understand the risks and benefits of surgery

Patient Self Assessment

Following your review of Section 1, Important Information for Women About Breast Reconstruction with *NATRELLE*® Silicone-Filled Breast Implants, use this Patient Self Assessment to evaluate your understanding of the information presented. Be sure to bring this breast surgery planner with the completed Patient Self Assessment to your consultation with your doctor. He or she will review the assessment and use it to help guide additional discussion about the risks and benefits of surgery. There is additional space at the end of the self assessment to make notes about the information or record specific questions that you would like to discuss with your surgeon.

Each of the following statements is clearly true or false. Indicate your answers by checking true or false. Your surgeon will review your answers with you.

If signs of rupture are seen on an MRI, you should have your implant removed.

❑ TRUE ❑ FALSE

Additional surgery to your breast and/or implant will be likely over the course of your life.

❑ TRUE ❑ FALSE

Your implants are not considered lifetime devices and you will likely undergo implant removal, with or without replacement, during your life.

❑ TRUE ❑ FALSE

You should inform your mammographers about the presence of your implants.

❑ TRUE ❑ FALSE

Your breast implants may interfere with your ability to successfully breastfeed.

❑ TRUE ❑ FALSE

You should perform breast self-examinations monthly and should make sure you know how to distinguish the implant from your breast tissue.

❑ TRUE ❑ FALSE

Silicone gel-filled breast implants have not been clinically tested in women with autoimmune diseases like lupus or scleroderma.

❑ TRUE ❑ FALSE

If you have serious health problems or conditions such as a weakened immune system or compromised blood supply to the breast, you should discuss with your surgeon whether breast reconstruction surgery is appropriate for you.

❑ TRUE ❑ FALSE

To detect possible silent rupture, an MRI is recommended 3 years following initial surgery and every 2 years thereafter.

❑ TRUE ❑ FALSE

Although rare, there have been reports in the scientific literature providing evidence that the silicone gel fill may move beyond the fibrous capsule and into the breast tissue or away from the breast (gel migration), particularly if the scar capsule is ruptured, causing local complications such as pain and neuropathy.

❑ TRUE ❑ FALSE

Capsular contracture or hardening of the tissue surrounding the breast implant may result in the need for additional surgery.

❑ TRUE ❑ FALSE

ADDITIONAL QUESTIONS OR TOPICS I WANT TO DISCUSS WITH MY SURGEON:

Initial your acceptance of the risks of surgery and provide your written consent

Acceptance of Risk and Surgery Consent

Surgeon and patient initial each

	SURGEON	PATIENT
If signs of rupture are seen on an MRI, then you should have your implant removed.	_____	_____
Additional surgery to your breast and/or implant will be likely over the course of your life.	_____	_____
Your implants are not considered lifetime devices and you will likely undergo implant removal, with or without replacement, during your life.	_____	_____
You should inform your mammography technologist about the presence of your implants.	_____	_____
Your breast implants may interfere with your ability to successfully breastfeed.	_____	_____
You should perform breast self-examinations monthly and should make sure you know how to distinguish the implant from your breast tissue.	_____	_____
To monitor your breast implants for silent rupture, an MRI is recommended three (3) years following surgery and then every two (2) years after that.	_____	_____
The scar tissue or capsule that normally forms around the implant may tighten (contracture) and squeeze the implant, making your breast feel firmer and sometimes painful.	_____	_____
Allergan maintains a breast implant device tracking database and your participation in this database is strongly recommended.	_____	_____

Consent to Surgery

My surgeon has provided me with the RECONSTRUCTION SURGERY WITH ***NATRELLE***® SILICONE-FILLED BREAST IMPLANTS PATIENT PLANNER to inform me prior to my surgery.

I have had adequate time to review and understand the information presented in the RECONSTRUCTION SURGERY WITH SILICONE GEL-FILLED BREAST IMPLANTS PATIENT PLANNER. 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.

Patient Name (Printed): _____

Patient Signature: _____

Date: _____

Surgeon Name (Printed): _____

Surgeon Signature: _____

Date: _____

All the surgery information you need
in one convenient place

PATIENT SURGERY
RECORD

Patient Surgery Record

Use this section to record important dates and contact information related to your breast surgery.

Pre-operative mammogram baseline (if necessary):_____

Pre-operative appointment date: _____

Surgery date: _____

Surgery location: _____

Contact person at surgery location: _____

Contact phone number: _____

First post-operative appointment date: _____

Subsequent post-operative appointment dates:_____

MRIs are recommended at 3 years following initial surgery and every 2 years thereafter to monitor implant integrity.

Month and year of my first scheduled MRI: _____

Post-surgery mammogram (6 months to 1 year following surgery): _____

Allergan Device Identification Card(s) Information

Record information from your Allergan device identification card(s) below and then place your card(s) in the pocket on the front cover of this planner for a permanent record.

Catalog Number: Left_____

Catalog Number: Right _____

Serial Number: Left_____

Serial Number: Right _____

Important information your surgeon is required to provide

Device Tracking Instructions

NATRELLE® Silicone-Filled Breast Implants are subject to device tracking per federal regulation. Because your implant is a tracked device, your healthcare provider is required to report certain information to Allergan following surgery, including implant-specific information like serial number and catalog number as well as the date of surgery, implanting surgeon name and contact information and patient-specific information.

The device tracking form is a 2-part document and the top portion has been forwarded to Allergan by your surgeon. Upon receipt by Allergan of the healthcare provider portion of the device tracking form, you are entered in the device tracking database. The patient portion of the form was supplied to you following surgery in order to complete enrollment in Allergan's device tracking database. Your device tracking form should have stickers with information about your implant(s). If the stickers are not already attached, use your patient/device ID card supplied following surgery to enter the serial number (SN) and catalog number (REF) of your implant(s). Allergan strongly encourages you to participate in device tracking. As information regarding the long-term safety of silicone gel-filled breast implants becomes available, your participation will allow us to provide this information to you. If you do *not* wish to participate in device tracking, check the indicated box and Allergan will remove your personal information from the database.

If you do wish to participate in the device tracking program but do *not* want Allergan to release your personal information to any third parties, such as the FDA, please check the appropriate box.

Finally, please indicate if you received this patient planner and had adequate time to review the information and consider your decision to proceed with breast surgery. Your answer here will help us evaluate the effectiveness of the communication program that Allergan has developed and make improvements if needed.

Place your completed device tracking form in the envelope provided and return it to Allergan.

ALLERGAN
The Science of Rejuvenation™

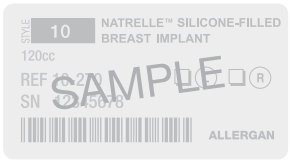
DEVICE TRACKING
NATRELLE™ Silicone-Filled Breast Implants
71 S. Los Carneros Road Goleta, CA 93117
800.972.9378 *f:* 800.432.8803

I. Complete Upon Implant

Device and Surgery Information

DATE OF IMPLANTATION mm _____ /dd _____ /yy _____

Affix Left Device Tracking Label *OR* Fill In The Device Data

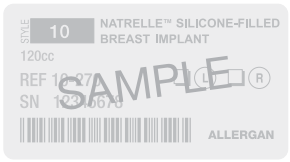


_____
(Left) REF

_____
(Left) SN

❑ Reconstruction ❑ Augmentation
❑ Revision

Affix Right Device Tracking Label *OR* Fill In The Device Data



_____
(Right) REF

_____
(Right) SN

❑ Reconstruction ❑ Augmentation
❑ Revision

IMPLANTING/EXPLANTING PHYSICIAN INFORMATION

LAST NAME	FIRST NAME	
ADDRESS	CITY, STATE/PROVINCE	ZIP/POSTAL CODE
E-MAIL	TELEPHONE	FAX

ATTENDING/FOLLOWING PHYSICIAN INFORMATION (*if different from above*)

LAST NAME	FIRST NAME	
ADDRESS	CITY, STATE/PROVINCE	ZIP/POSTAL CODE
E-MAIL	TELEPHONE	FAX

PATIENT INFORMATION

LAST NAME	FIRST NAME	
ADDRESS	CITY, STATE/PROVINCE	ZIP/POSTAL CODE
DATE OF BIRTH	SOCIAL SECURITY NUMBER	TELEPHONE

II. Complete if Device Discarded or Destroyed ❑ N/A

❑ Device(s) on this form were discarded/destroyed prior to completion of this procedure

Date: mm_____ /dd_____ /yy_____ Reason/Comments: _____

III. Complete if NATRELLE™ Silicone-Filled Breast Implants Were Removed ❑ N/A

Explanted Device Information

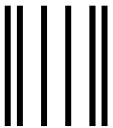
Date of explant mm _____ /dd_____ /yy_____

(Left) Serial # _____ ❑ Unknown	(Right) Serial # _____ ❑ Unknown
(Left) Ref # _____ ❑ Unknown	(Right) Ref # _____ ❑ Unknown
Reason for removal _____	Reason for removal _____
Original implant date: mm____ /dd____ /yy____ ❑ Unknown	Original implant date: mm____ /dd____ /yy____ ❑ Unknown
Original implanting physician _____ ❑ Unknown	Original implanting physician _____ ❑ Unknown

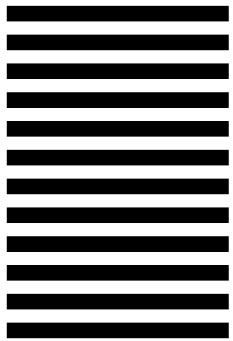
COMPLETE AND RETURN THIS PAGE TO ALLERGAN IN THE ATTACHED ENVELOPE OR FAX TO 800.432.8803

L030-06

For reference only



NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES



BUSINESS REPLY MAIL

FIRST-CLASS MAIL PERMIT NO. 1639 SANTA BARBARA, CA

POSTAGE WILL BE PAID BY ADDRESSEE

DEVICE TRACKING
ALLERGAN
71 S LOS CARNEROS RD
SANTA BARBARA CA 93117-9817

Optional additional coverage
from a trusted industry leader

Optional *ConfidencePlus*® Premier Warranty Form

Confidence…it's more than a sense of well-being.

It's the peace of mind that comes with the knowledge your breast implants are covered by an industry-leading warranty program. Allergan *ConfidencePlus*® breast implant limited warranty programs offer you coverage in the event of implant rupture, including product replacement and financial assistance to cover expenses not reimbursed by your insurance carrier.

Our standard *ConfidencePlus*® applies automatically to every ***NATRELLE***® breast implant recipient and includes lifetime product replacement and up to $1200 in financial assistance subject to the conditions discussed in the *ConfidencePlus*® literature.

The optional *ConfidencePlus*® Premier breast implant limited warranty provides all the peace of mind included with our standard *ConfidencePlus*® program, but increases the financial assistance to $2400 and offers free contralateral implant replacement. For the low enrollment fee of $100, you have access to lifetime product replacement, 10 years of coverage, the freedom to change styles or size as part of your replacement surgery, free contralateral implant replacement and up to $2400 in financial assistance.[1]

That's peace of mind…that's *ConfidencePlus*® Premier!

To enroll in our optional *ConfidencePlus*® Premier breast implant limited warranty program, use the information contained on your Allergan device identification card(s) supplied to you after surgery or complete the purchase form that follows this page. Once complete, detach the form from this breast surgery planner and return to Allergan in the envelope provided. You may also fax your completed enrollment form with credit card information to 888.647.4029.

Your purchase form and $100 must be received or postmarked within 45 days of surgery and must accompany a certified check, money order, or valid credit card number in order to process your purchase. *Do not send a personal check. ConfidencePlus*® Premier enrollment forms that accompany a personal check will *not* be processed.

[1]A charge may apply on product with a higher list price. The optional *ConfidencePlus*® Premier warranty is non-transferable and non-refundable. For complete program details see the *ConfidencePlus*® warranty program and terms at www.allergan.com or call Allergan at 1.800.624.4261.

CONFIDENCEPLUS® PREMIER LIMITED WARRANTY OPTION

Mail or fax this completed enrollment form along with your payment to:

Allergan Warranty Processing
71 S. Los Carneros Road, Goleta, CA 93117
Fax 888.647.4029

***Do not** send a personal check. Enrollment forms that include a personal check **will not** be processed.*

TO PAY BY CREDIT CARD:

Credit Card Type: ❑ Visa ❑ MasterCard ❑ American Express

Credit Card Number: _____

Expiration Date: _____

Cardholder Name (if other than Patient): _____

Cardholder Signature: _____

TO PAY BY CERTIFIED CHECK OR MONEY ORDER:

Please make payable to: Allergan *ConfidencePlus*® Premier Limited Warranty

Name: _____

Address: _____

City: _____

State/Zip: _____

Social Security Number: _____

Date of Birth: _____

Home Phone: _____

Implanting Physician Name: _____

Physician Telephone: _____

Date of Surgery: _____

Implant Serial Number(s): Left Side _____

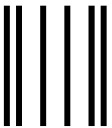
Implant Serial Number(s): Right Side _____

(The serial number follows the letters SN on your device identification card provided by your surgeon.)

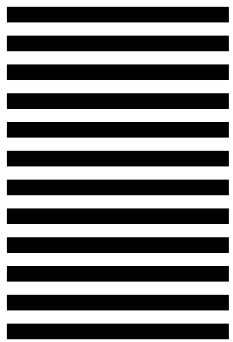
You will receive a certificate verifying your enrollment in the *ConfidencePlus*® Premier Warranty. Please allow 8–10 weeks for processing.

Note: Enrollment in the *ConfidencePlus*® Premier Warranty may be voided if the information provided is incorrect. The *ConfidencePlus*® Premier Warranty is non-refundable and non-transferable.

*For full details on the *ConfidencePlus*® Warranty and *ConfidencePlus*® Premier Warranty, refer to the *ConfidencePlus*® Warranty Program & Terms, on www.allergan.com, or available from Allergan at 1.800.624.4261.



NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES



BUSINESS REPLY MAIL

FIRST-CLASS MAIL PERMIT NO. 1639 SANTA BARBARA, CA

POSTAGE WILL BE PAID BY ADDRESSEE

WARRANTY PROCESSING
ALLERGAN
71 S LOS CARNEROS RD
SANTA BARBARA CA 93117-9817

Bring this information about your implant surgery to your Mammography Center

Information for the Mammography Center

Please update my patient file to reflect the presence of *NATRELLE*® Silicone-Filled Breast Implants. Since the examination of breasts reconstructed with breast implants requires more time, please allow additional time when scheduling my next mammogram and alert the physician and technologists performing the exam about the presence of my implants.

You may be aware that the FDA has approved Allergan's *NATRELLE*® Silicone-Filled Breast Implants for use in augmentation, reconstruction, and revision surgery. As part of a women's healthcare network, it is important that you are aware of the latest information on the safety of silicone gel-filled breast implants. For additional information, please consider the following resources:

Institute of Medicine Report on the Safety of Silicone Breast Implants
www.nap.edu/catalog/9618.html

Food and Drug Administration
www.fda.gov/cdrh/breastimplants

Breast Implant Safety
www.breastimplantsafety.org

PATIENT INSTRUCTIONS

Please record the catalog and serial numbers exactly as they appear on your Allergan device identification card(s) before giving this page to your mammography center.

Location of implants
(submuscular or subglandular): _____

Catalog Number: Left_____

Catalog Number: Right _____

Serial Number: Left_____

Serial Number: Right _____

Provide this information to your Primary Care Physician at your next scheduled appointment

Information for Your Primary Care Physician

Your patient has been implanted with *NATRELLE*® Silicone-Filled Breast Implants. It is important that you include this information in her chart because while silicone-filled breast implants have been proven safe in thousands of patients worldwide, they can present additional challenges for attending physicians. So to ensure your patient receives the care she needs, when appropriate, please alert other physicians about the presence of her implants.

You may be aware that the FDA has approved Allergan's *NATRELLE*® Silicone-Filled Breast Implants for use in augmentation, reconstruction, and revision surgery. As part of a women's healthcare network, it is important that you are aware of the latest information on the safety of silicone gel-filled breast implants. For additional information, please consider the following resources:

Institute of Medicine Report on the Safety of Silicone Breast Implants
www.nap.edu/catalog/9618.html

Food and Drug Administration
www.fda.gov/cdrh/breastimplants

Breast Implant Safety
www.breastimplantsafety.org

PATIENT INSTRUCTIONS

Please record the catalog and serial numbers exactly as they appear on your Allergan device identification card(s) before giving this page to your primary care physician. If you have multiple primary care physicians, make copies of this form before providing to your physician.

Location of implants

(submuscular or subglandular): _____

Catalog Number: Left_____

Catalog Number: Right _____

Serial Number: Left_____

Serial Number: Right _____

Natrelle®.com

ALLERGAN
71 South Los Carneros Road, Santa Barbara, CA 93117

Tel: 1.800.624.4261
www.allergan.com

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