

Important Information for Women About Breast Augmentation with INAMED[®] Silicone-Filled Breast Implants



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*Formerly Inamed	

GLOSSARY

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.
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. The first time a breast implant is placed to increase breast size, it is called primary augmentation. All subsequent times the implant is replaced, it is called revision-augmentation.
Breast implant	An internal artificial device or implant intended to replace the breast.
Breast mass	A lump or body 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.

Calcification	Process of hardening by calcium salts.
Capsule	Scar tissue which forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture (below).
Capsular contracture	<p>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. Grades III or IV are the most severe. Grade III often results in the need for additional surgery (reoperation) because of pain and possibly abnormal appearance. Grade IV usually results in the need for additional surgery (reoperation) because of pain and unacceptable appearance. Capsular contracture 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.</p> <ul style="list-style-type: none"> • 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
Capsulectomy	Surgical removal of the scar tissue capsule around the implant.
Capsulorrhaphy	Surgical stitching of a tear in 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)	Surgical incision into the scar tissue capsule around the implant.
Congenital anomaly	An abnormal development in part of the body.
Connective tissue disease/disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system. Connective tissue diseases (“CTDs”) that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.
Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Contralateral	Opposite side.

Core Study	The primary clinical study of augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients that supported the approval of the premarket approval (PMA) application. Safety and effectiveness data are collected yearly through 10 years, with the follow-up from years 5 through 10 being performed as part of a postapproval Core Study.
Delayed wound healing	Delayed progress in the healing of an opened wound.
Displacement	Movement of the implant from the usual or proper place.
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.
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 and the chest wall.
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
Low molecular weight silicones	Components of silicone of smaller molecular weight that may bleed (leak) out of silicone gel.
Lymphadenopathy	Enlargement of the lymph node(s).
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.
MRI	Magnetic resonance imaging. A radiographic examination that currently has the best ability to detect rupture of silicone gel-filled breast implants.
Mammary	Pertaining to the breast.
Mammography	A type of X-ray examination of the breasts used for detection of cancer.
Mammoplasty	Plastic surgery of the breast.
Mastopexy	Plastic surgery to move sagging breasts into a more elevated position.
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.
Outpatient surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight.
Palpate	To feel with the hand.
Palpability	The ability to feel the implant.
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 augmentation	The first time a breast implant is placed for the purpose of breast augmentation.
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-Augmentation	Refers to the correction or improvement of a primary augmentation. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast augmentation.
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 questionnaire which measures overall self esteem.
Rupture	A tear or hole in the implant shell. Silicone implant ruptures may be silent or symptomatic. 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 questionnaire intended to measure physical, mental, and social health.
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
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).

Subglandular placement	Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.
Submuscular placement	Placement of a breast implant wholly or partially underneath the chest muscle.
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 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 that evaluates how the patient sees herself and what she does, likes, and feels.

1. CONSIDERING SILICONE GEL-FILLED BREAST IMPLANT SURGERY

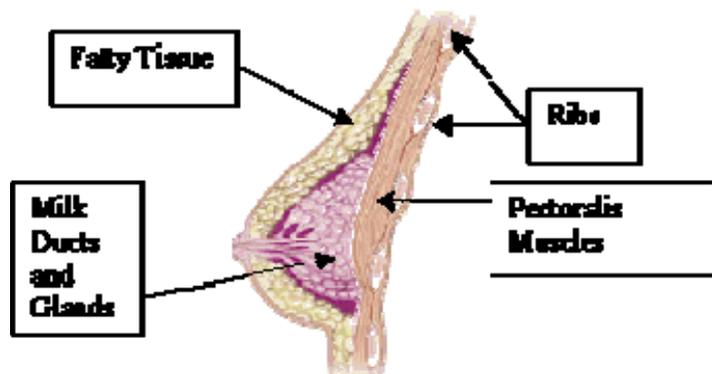
You may be considering breast implant surgery to increase the size of your breasts. This is referred to as breast augmentation. Or you may need revision of a previous breast augmentation, which is called revision-augmentation. Allergan has prepared this information to help you better understand the breast implant procedure and assist you in making an informed decision about breast augmentation or revision-augmentation 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 INAMED[®] 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 augmentation surgery. In the case of a revision-augmentation 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. 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 augmentation, such as mastopexy, to help achieve improved breast lift.

1.2 WHAT IS A SILICONE GEL-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?

INAMED® 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.
- **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. (A separate patient brochure is available for those women considering breast reconstruction surgery and should be read prior to reaching a decision to undergo breast reconstruction.)

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 IMPORTANT FACTORS YOU SHOULD CONSIDER IN CHOOSING SILICONE GEL-FILLED IMPLANTS.

- 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 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-augmentation), your risk of future complications increases compared to first time (primary) augmentation surgery, so you should also review the complication rates for revision-augmentation 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.
- Breast implants may affect your ability to breast feed, either by reducing or eliminating milk production.
- Rupture of a silicone gel-filled breast implant is most often silent. This means that neither you nor your surgeon will know that your implants have a rupture most of the time. 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%¹ compared to 89% for MRI.² 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 screening 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, persistent pain, swelling, hardening, or change in implant shape, which may be signs of symptomatic rupture of the implant. These should be reported to your surgeon and possibly evaluated with an MRI to screen for rupture.
- After undergoing breast augmentation 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 surgery.
- 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 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 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 their labeling on a regular basis with the results of these two studies. You should also ask your surgeon if he/she has 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. POTENTIAL 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 breast augmentation surgery. There are potential complications specific to breast implant surgery and breast implants, as described below. It should also be noted that the cited references include augmentation and/or reconstruction patients, as well as from a variety of manufacturers and implant models.

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 and weakening 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.^{3,4}

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 (migrated gel). 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 augmentation patients in the MRI cohort, the rupture rate was 2.7% through 4 years. For revision-augmentation patients in the MRI cohort, the rupture rate was 4.0% through 4 years. This means that through 4 years, approximately 3 of every 100 primary augmentation women and 4 out of every 100 revision-augmentation women had at least one ruptured breast implant. For the non-MRI cohort, there was 1 primary augmentation and 1 revision-augmentation patient who had reported rupture through 4 years. Across all patients in the Allergan Core Study, of the 9 implants reported as ruptured, all 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 information on Allergan implants is provided from a published European study known as the International MRI Study.⁵ Silent rupture data were collected via a single MRI on 77 augmentation, 11 reconstruction, and 18 revision patients implanted with smooth and textured Allergan 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. There was one possible case of

extracapsular rupture with the remainder classified as intracapsular ruptures. No cases of migrated gel were found.

Additional information on rupture will be collected through Allergan's postapproval Core Study and large postapproval study.

Additional Information on Consequences of Rupture from Literature

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 is 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.⁷ 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.⁸ 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 (see glossary) 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.⁹
- 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.^{10,11,12,13} 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,¹⁴ 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-augmentation than in primary augmentation. Because you may have your initial implants replaced, you should be aware that your risk of capsular contracture increases with revision-augmentation. Capsular contracture is a risk factor for implant rupture, and it is the most common reason for reoperation.

Symptoms of capsular contracture range from mild firmness and mild discomfort to severe pain, distorted shape of the implant, and palpability (ability to feel the implant). Capsular contracture is graded into 4 levels depending on its severity. Grades III or IV are considered severe and often additional surgery is needed to correct these grades:

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

In Allergan's Core Study, for women receiving augmentation implants for the first time, the risk of severe capsular contracture was 13% through 4 years. This means that 13 out of every 100 women who received Allergan implants for primary breast augmentation had severe capsular contracture at least once during the first 4 years after receiving the implants.

For women receiving revision-augmentation implants, the risk of severe capsular contracture was 17% through 4 years. This means that 17 out of every 100 women who received Allergan implants for breast revision-augmentation had severe capsular contracture at least once during the first 4 years after receiving the implants.

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.¹⁵

- **Additional Surgeries (Reoperations)**

You should assume that you will need to have additional surgeries (reoperations). In Allergan's Core Study, the reoperation rate was 24% for primary augmentation patients, which means that 24 out of every 100 women who received Allergan implants for primary augmentation had a reoperation during the first 4 years after receiving the implants. The reoperation rate was 35% for revision-augmentation patients, which means that 35 out of every 100 women who received Allergan implants for revision-augmentation had a reoperation during the first 4 years after receiving the implants.

Patients may decide to change the size or type of their implants, requiring additional surgery. Problems such as rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional surgery. Summary tables are provided on pages 24-25 that describe the main reasons for performing reoperations in the Allergan Core Study. For women receiving primary augmentation implants, the three most common reasons for reoperations were capsular contracture, implant malposition, and ptosis (sagging). For women receiving revision-augmentation implants, the three most common reasons for additional surgery were capsular contracture, hematoma/seroma, and ptosis (sagging).

- **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 severe capsular contracture. Having your implants removed and replaced increases your chances of getting future complications.

For women receiving primary augmentation implants in Allergan's Core Study, 9% had their implants removed at least once through 4 years. Severe capsular contracture and patient request were the most common reasons for implant removal. For women receiving revision-augmentation implants in Allergan's Core Study, 12% had their implants removed at least once

through 4 years. The most common reasons for implant removal were severe capsular contracture and patient request.

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 severe 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 the paragraph on breast feeding 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.

- **Breast Feeding**

Breast feeding difficulties have been reported following breast surgery, including breast reduction and breast augmentation. If your surgeon uses a periareolar surgical approach (an incision around the colored portion surrounding the nipple), it may further increase the chance of breast feeding 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.¹⁶ 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. The study size needed to conclusively rule out a smaller risk of connective tissue disease among women with silicone gel-filled implants would need to be very large.^{17,18,19,20,21,22,23,24,25,26} The published studies taken together show that breast implants are not significantly associated with a risk of developing a typical or defined connective tissue disease.^{27,28,29,30} 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.³¹

- **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.^{32,33,34,35,36} 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.^{37,38,39,40,41} 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.^{42,43,44,45,46}

Brain cancer – One recent study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population.⁴⁷ 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 in women with cosmetic implants concluded that the evidence does not support an association between brain cancer and breast implants.⁴⁸

Respiratory/lung cancer – One study has reported an increased incidence of respiratory/lung cancer in women with breast implants.⁴⁹ 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.^{50,51,52}

Cervical/vulvar cancer – One study has reported an increased incidence of cervical/vulvar cancer in women with breast implants.⁵³ 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.⁵⁴ 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.⁵⁵

- **Suicide**

In several studies, a higher incidence of suicide was observed in women with breast implants.^{56,57,58,59} 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.⁶⁰

- **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.⁶¹

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.^{62,63} Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding.⁶⁴ This 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.^{65,66} 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 contracture⁶⁷ and lymphadenopathy.⁶⁸ 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.^{69,70,71,72}

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 CORE STUDY RESULTS

This section of the brochure summarizes the results of the Allergan Core Study conducted on the INAMED[®] silicone-filled breast implants for primary augmentation and revision-augmentation. The Allergan Core Study is the primary clinical study for this product. The results of the Allergan Core Study give you useful information on the experience of other women with INAMED[®] 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 the Allergan Adjunct Study, the Danish Breast Implant Registry, an international 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 is referenced throughout the **Breast Implant Complications** section above.

3.1 OVERVIEW 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 consisted of 715 patients. This includes 455 primary augmentation patients, 147 revision-augmentation patients, 98 primary reconstruction patients, and 15 revision-reconstruction patients. Of these patients, 158 primary augmentation patients, 50 revision-augmentation patients, 51 primary reconstruction patients, and 5 revision-reconstruction patients 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 4 years reported in this brochure. Allergan will periodically update this brochure as more information becomes available. You should also ask your surgeon if he/she has 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 4 years after implant surgery is 41% for primary augmentation patients and 57% for revision-augmentation patients. The information below provides more details about the complications and benefits you may experience.

Described below are the benefits and complications reported in the Allergan Core Study for augmentation patients. The findings are described separately for primary augmentation and revision-augmentation patients.

3.2 WHAT WERE THE 4-YEAR FOLLOW-UP RATES?

The Allergan Core Study enrolled 455 augmentation patients. Of the women expected to be seen at the 4-year follow-up visit, 83% were seen.

The Allergan Core Study enrolled 147 revision-augmentation patients. Of the women expected to be seen at the 4-year follow-up visit, 82% were seen.

3.3 WHAT WERE THE BENEFITS?

The benefits of silicone gel-filled breast implants were assessed by a variety of outcomes, including bra cup size change and assessments of patient satisfaction and QoL. Data were collected before implantation and at scheduled follow-up visits for those patients who still had their original implants and who came back for these visits.

Primary Augmentation Patients: For primary augmentation patients, 396 (87%) of the original 455 patients had a breast measurement within 18 months of surgery. Of these 396 patients, 41% increased by 1 cup size; 45% increased by 2 cup sizes; 8% increased by more than 2 cup sizes; and 6% had no increase or decrease.

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 455 primary augmentation patients, 364 (80%) provided a satisfaction rating at 4 years after implantation, with 346 (95%) of these patients indicating that they were satisfied with their breast implants.

For primary augmentation patients, the SF-36, which is a collection of scales that measure mental and physical health, showed no significant changes after 4 years. For patient responses to questions regarding overall self-concept/self-esteem, there was a decrease in self-concept on the Tennessee Self Concept Scale and no change in overall self esteem on the Rosenberg Self Esteem Scale 4 years after receiving implants. Patient responses to questions on the Body Esteem Scale regarding overall body image did not show a change 4 years after receiving implants, but body esteem related to sexual attractiveness did show an increase in primary augmentation patients.

Revision-Augmentation Patients: Revision-augmentation patients did not undergo a measurement of breast cup size change because they were undergoing replacement of an existing breast implant.

Allergan's patient satisfaction was based on a 5-point scale of satisfaction with their implants at the time of the follow-up visits. Of the original 147 revision-augmentation patients, 111 (76%) provided a satisfaction rating at 4 years. Of these 111 patients, 96 (87%) indicated that they were satisfied with their breast implants.

For revision-augmentation patients, there were no significant changes in the SF-36, Tennessee Self Concept Scale, Rosenberg Self Esteem Scale, and Body Esteem Scale 4 years after receiving implants.

3.4 WHAT WERE THE 4-YEAR COMPLICATION RATES?

Complications Reported in the Allergan Core Study for Primary Augmentation

The complications observed in primary augmentation women through 4 years are presented in Table 1. The rates reflect the percentage of primary augmentation patients who experienced the listed complication at least once within the first 4 years after their implantation. Some complications occurred more than once for some patients. The most common complications experienced within the first 4 years of implantation were reoperation (24% or approximately 24 patients out of 100) and capsular contracture (13% or 13 patients out of 100). Please refer to the Glossary at the front of this brochure for the definition of any complication you may not understand.

Table 1
Primary Augmentation: Complications
N=455 Patients

Complication*	4-Year Complication Rate by Patient
Reoperation	23.5%
Capsular Contracture III/IV	13.2%
Breast Pain	8.2%
Swelling	7.8%
Implant Removal with Replacement	7.5%
Nipple Complications	4.9%
Implant Malposition	4.1%
Scarring/Hypertrophic Scarring	3.7%
Asymmetry	3.2%
Implant Rupture (MRI cohort)**	2.7%
Implant Removal without Replacement	2.3%
Hematoma	1.6%
Ptosis (sagging)	1.4%
Breast/Skin Sensation Changes	1.4%
Seroma/Fluid Accumulation	1.3%
Bruising, Delayed Wound Healing, Extrusion of Intact Implant, Implant Palpability/Visibility, Infection, Redness, Skin Rash, Tissue/Skin Necrosis, Wrinkling	<1%
Capsule Calcification, Irritation, Lymphadenopathy, Lymphedema, Other Complications, Pneumothorax	0%

*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.

**There was one patient with a suspected rupture of one of her implants. This rupture has not yet been confirmed with removal and visual inspection of the implant.

Complications Reported in the Allergan Core Study for Revision-Augmentation

The complications observed in revision-augmentation women through 4 years are presented in Table 2. The rates reflect the percentage of revision-augmentation patients who experienced the listed complication at least once within the first 4 years after their implantation. Some complications occurred more than once for some patients. The most common complications experienced within the first 4 years of implantation were reoperation (35% or approximately 35 patients out of 100) and capsular contracture (17% or 17 patients out of 100). Please refer to the Glossary at the front of this brochure for the definition of any complication you may not understand.

Table 2
Revision-Augmentation: Complications
N=147 Patients

Complication*	4-Year Complication Rate by Patient
Reoperation	35.3%
Capsular Contracture III/IV	17.0%
Implant Removal with Replacement	10.5%
Breast Pain	7.8%
Swelling	6.4%
Scarring/Hypertrophic Scarring	6.1%
Implant Palpability/Visibility	6.0%
Asymmetry	5.1%
Seroma/Fluid Accumulation	5.0%
Implant Malposition	4.6%
Implant Rupture (MRI cohort)**	4.0%
Wrinkling	3.9%
Implant Removal without Replacement	3.1%
Ptosis (sagging)	3.1%
Bruising	2.1%
Hematoma	2.1%
Infection	1.4%
Skin Sensation Changes	1.4%
Delayed Wound Healing, Irritation, Other Complications, Redness, Skin Rash	<1%
Capsule Calcification, Extrusion of Intact Implant, Lymphadenopathy, Lymphedema, Nipple Sensation Changes, Other Nipple Related Observation, Pneumothorax, Tissue/Skin Necrosis	0%

* 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.

**There were two patients with a suspected rupture in one of their implants. These two ruptures have not yet been confirmed with removal and visual inspection of the implants.

3.5 WHAT WERE THE MAIN REASONS FOR REOPERATION?

There may be one or more reasons identified for having a reoperation (additional surgery after the primary or revision breast augmentation). 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. In Allergan's Core Study, there were 345 additional surgical procedures performed during 135 reoperations involving 103 primary augmentation patients.

Table 3 below provides the main reason for each reoperation performed through 4 years in primary augmentation patients. The most common reason for reoperation through 4 years in primary augmentation patients was because of capsular contracture (39 of 135 reoperations).

Table 3
Primary Augmentation: Main Reason for Reoperation through 4 Years

Reason for Reoperation	n
Capsular Contracture	39
Implant Malposition	21
Ptosis (sagging)	19
Need for Biopsy	12
Hematoma/Seroma	9
Scarring/Hypertrophic Scarring	8
Patient Request for Style/Size Change	7
Suspected Rupture	6
Asymmetry	5
Delayed Wound Healing	3
Breast Cancer, Extrusion of Intact Implant, Infection, Necrosis, Nipple Complications, Breast Pain	1 each
Total	135

In Allergan's Core Study, there were 181 additional surgical procedures performed during 83 reoperations involving 49 revision-augmentation patients. Table 4 below provides the main reason for each reoperation performed through 4 years in revision-augmentation patients. The most common reason for reoperation through 4 years in revision-augmentation patients was because of capsular contracture (14 of 83 reoperations).

Table 4
Revision-Augmentation: Main Reason for Reoperation through 4 Years

Reason for Reoperation	n
Capsular Contracture	14
Hematoma/Seroma	11
Ptosis (sagging)	9
Need for Biopsy	8
Scarring/Hypertrophic Scarring	8
Implant Malposition	6
Suspected Rupture	4
Asymmetry	3
Delayed Wound Healing	3
Nipple Complications	3
Patient Request for Style/Size Change	3
Breast Cancer	2
Extrusion of Intact Implant	2
Infection	2
Breast Tissue Contour Deformity, Breast Pain, Implant Palpability/Visibility, Injury, Wrinkling	1 each
Total	83

3.6 WHAT WERE THE MAIN REASONS FOR IMPLANT REMOVAL?

The main reasons for implant removal among primary augmentation patients in the Allergan Core Study over the 4 years are shown in Table 5 below. There were 77 implants removed in 41 patients. Of these 77 implants, 60 were replaced. The most common reason for implant removal was capsular contracture (27 of the 77 implants removed).

Table 5
Primary Augmentation: Main Reason for Implant Removal through 4 Years

Reason for Removal	n
Capsular Contracture	27
Patient Request for Style/Size Change	18
Implant Malposition	9
Suspected Rupture*	7
Ptosis (sagging)	6
Asymmetry	5
Breast Pain	2
Breast Cancer, Hematoma/Seroma, Extrusion of Intact Implant	1 each
Total	77

*Three devices were removed and found to be intact (not ruptured); the other devices were confirmed to be ruptured.

The main reasons for implant removal among revision-augmentation patients in the Allergan Core Study over the 4 years are shown in Table 6 below. There were 32 implants removed in 18 patients. Of these 32 implants, 26 were replaced. The most common reason for implant removal was capsular contracture (9 of the 32 implants removed).

Table 6
Revision-Augmentation: Main Reason for Implant Removal through 4 Years

Reason for Removal	n
Capsular Contracture	9
Patient Request for Style/Size Change	6
Implant Malposition	5
Suspected Rupture*	4
Ptosis (sagging)	2
Scarring/Hypertrophic Scarring	2
Asymmetry, Breast Cancer, Infection, Breast Pain	1 each
Total	32

*Three devices were removed and found to be intact (not ruptured); the other device was confirmed to be ruptured.

3.7 WHAT WERE 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.

CTD Diagnoses

Two primary augmentation patients (0.4%) were reported to have a new diagnosis of rheumatoid arthritis according to a rheumatologist at 7 months and at 3 years after implantation in the Allergan Core Study. One revision-augmentation patient (0.7%) was reported to have a new diagnosis of fibromyalgia at 10 months after implantation. It cannot be concluded that these CTD diagnoses were caused by the implant 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. For primary augmentation patients at 4 years after implantation, statistically significant increases were found for the symptom category of Pain (which includes muscle pain, aches, and cramps). No significant increases were found in the categories of General, Joint, Muscular, Skin, Gastrointestinal, Neurological, Urinary, Fatigue, Fibromyalgia, and Other. For revision-augmentation patients at 4 years after implantation, no statistically significant increases were found in any of the symptom categories.

The Allergan 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 Allergan Core Study. However, you should be aware that you may experience an increase in these symptoms after receiving breast implants.

Cancer

There was 1 primary augmentation patient with a new diagnosis of breast cancer through 4 years in the Allergan Core Study. There was a 10% benign breast disease rate and 1% unknown breast disease (not yet diagnosed) rate through 4 years. For revision-augmentation patients, there were no reports of new diagnoses or reoccurrence of breast cancer or unknown breast disease and a 10% benign breast disease rate through 4 years. In primary augmentation patients there was 1 report of thyroid cancer and 1 report of brain cancer. There were no reports of other cancers, such as respiratory or cervical/vulvar, in revision-augmentation patients.

Lactation Complications

Nine (18%) of the 51 primary augmentation patients who attempted to breast feed following breast implantation in the Allergan Core Study through 4 years experienced difficulty with breast feeding. The most common difficulty was inadequate milk production. For the 13 revision-augmentation patients who attempted to breast feed after receiving breast implants, 2 (15%) had difficulty breast feeding, 1 due to inadequate milk production and 1 due to pain.

Reproduction Complications

Nineteen (4%) of the primary augmentation patients in the Allergan Core Study reported a reproduction problem through 4 years, most commonly miscarriage. For the 5 (3%) revision-augmentation patients who experienced a reproduction problem through 4 years, the most common problem was infertility.

Suicide

There were no reports of suicide in the primary augmentation patients and 2 reports of suicide in the revision-augmentation patients in the Allergan Core Study through 4 years.

4. SURGICAL CONSIDERATIONS FOR BREAST AUGMENTATION

4.1 WHAT ARE THE ALTERNATIVES TO BREAST AUGMENTATION WITH SILICONE BREAST IMPLANTS?

For primary augmentation patients, alternatives may include:

- Accept your breasts as they are and have no surgery.
- Wear a padded bra or external prostheses.
- Have mastopexy surgery (breast lift) without an implant.
- Have surgery with saline implants.

For revision-augmentation patients, alternatives may include:

- No revision.
- Removal with or without replacement.

4.2 CHOOSING A SURGEON

When choosing a surgeon who is experienced with breast augmentation, you should know the answers to the following types of questions:

- How many breast augmentation implantation procedures does he/she perform per year?
- How many years has he/she performed breast augmentation 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 augmentation?
- What is his/her reoperation rate with breast augmentation, 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.)

4.3 WHAT ARE OTHER CHOICES AND OPTIONS ASSOCIATED WITH THE SURGERY?

Implant Shape and Size

Depending on the desired shape you wish to achieve, you and your surgeon have implants with three different 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 this 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 tissue 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 350 cc) 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.⁷³

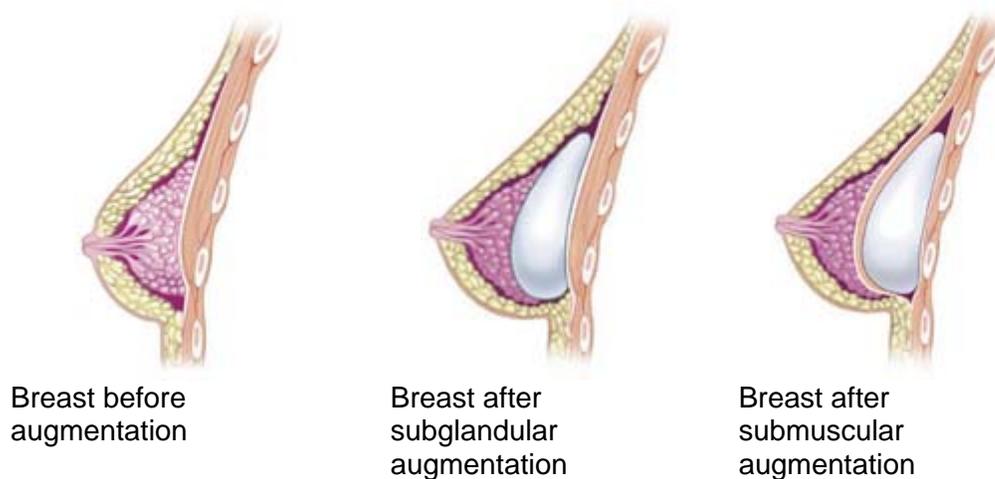
Surface Texturing

Some studies suggest that surface texturing reduces the chance of severe capsular contracture,⁷⁴ while other studies do not.^{75,76} Allergan's Core Study did not show a difference in the likelihood of developing capsular contracture with textured implants compared to smooth-surfaced 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 Placement

The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast glands (subglandular). You should discuss with your surgeon the advantages and disadvantages of the implant placement selected for you, as described in the table below.



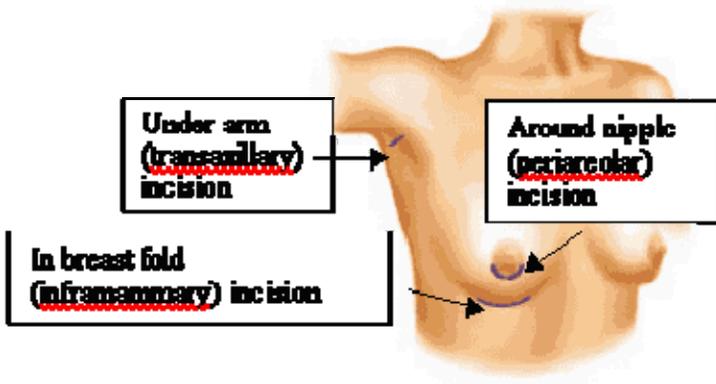
Comparison between Submuscular versus Subglandular Placement

Submuscular Placement	Subglandular Placement
Surgery may be longer	Surgery may be shorter
Recovery may be longer	Recovery may be shorter
May be more painful	May be less painful
Reoperation may be more difficult	May provide easier access for reoperation
Less visible and palpable implants	More visible and palpable implants
Less likelihood of capsular contracture ⁷⁷	Greater likelihood of capsular contracture ^{78,79}
Easier imaging during mammography exam	More difficult imaging during mammography exam
May be preferable if you have thin or weakened breast tissue	May not be recommended if you have thin or weakened breast tissue.

Incision Sites

You should discuss with your surgeon the pros and cons for the incision site specifically recommended for you.

The incision size will be larger than for a saline breast augmentation. There are 3 common incision sites: under the arm (axillary), around the nipple (periareolar), or within the breast fold (inframammary).



- **Periareolar** - This incision is typically more concealed, but since it also involves cutting through the breast tissue, it is associated with a higher likelihood of breast feeding difficulties, as compared to the other incision sites.⁸⁰ Cutting through the tissue may make a change in sensation or infection more of a concern.
- **Inframammary** - This incision is generally less concealed than periareolar and associated with less breast feeding difficulties than the periareolar incision site.

It is also the most commonly used incision site at the present time, and is felt to give the best access to and control of the breast implant pocket.

- **Axillary** - This incision is less concealed than periareolar and associated with less breast feeding difficulties than the periareolar incision site. If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive (very small) instruments, to create a “pocket” for the breast implant. This approach is more difficult, and may increase the risk of damage to, and unexpected location of, the implant.
- **Umbilical** (belly button) - This incision site has not been studied in Allergan’s Core Study and should not be used for a wide variety of reasons, including potential damage to the implant shell.

Additional Procedures at the Time of Breast Augmentation

Your surgeon will examine your breasts and help you make decisions to obtain the best result in your individual situation. In some cases, particularly after pregnancy or significant weight loss, implants alone may not address all of the issues, such as sagging or extra skin, affecting your breasts. This is particularly true when there is extra skin remaining from when the breasts were engorged with milk, or when you might have been carrying more weight.

In these situations, your surgeon may recommend a breast lift (mastopexy) to remove some of the extra skin, or to lift the breasts, at the time of implant placement. Mastopexy involves removing a strip of skin from under the breast or around the nipple to lift the nipple and breast location, and tighten the skin over the breast. Your surgeon will discuss the potential risks, and the location of the additional scars which might be required to lift your breasts or to remove the extra skin.

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.

Surgical Setting and Anesthesia

Augmentation surgery is usually performed on an outpatient basis, in a specialized operating room which may be located in a hospital, a surgery center, or surgical suite in the surgeon's office. General anesthesia is commonly used, and local anesthesia with sedation is also an option. You should be sure to check with your surgeon and with the facility where the surgery will take place, to become aware of the tests, presurgical examinations, and length of time you need to be without food or your routine medications prior to the surgical procedure.

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 have been described above.

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

4.4 FOLLOW-UP EXAMINATIONS

Breast Self-Examinations

Following breast augmentation, 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 injuring 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. More information on rupture is provided on pages 13-14 of this brochure. 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 on pages 13-14 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. More information on mammography is provided on pages 11-12.

5. ADDITIONAL INFORMATION

5.1 TYPES OF SILICONE GEL-FILLED BREAST IMPLANTS AVAILABLE FROM ALLERGAN

Allergan's silicone-gel filled breast implants come in a variety of profiles and sizes with either a textured shell or smooth surface shell. The table below shows the Allergan implants that were approved. Your plastic surgeon will discuss with you the implant design that will best help you achieve the result you desire.

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, mid-range 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, full profile	120cc – 800cc
Style 110	BIOCELL [®] Textured shell surface, moderate profile	90cc – 510cc
Style 115	BIOCELL [®] Textured shell surface, mid-range profile	150cc – 716cc
Style 120	BIOCELL [®] Textured shell surface, high profile	180cc – 650cc

5.2 IF YOU EXPERIENCE A PROBLEM

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 10:00am-4:00pm 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.

DEVICE IDENTIFICATION CARD

You will also 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.

5.3 DEVICE TRACKING

Silicone gel-filled breast implants are subject to Device Tracking by Federal regulation. This means that your physician will be required to report to Allergan the serial number of the device(s) you receive, the date of surgery, information relating to the physician's practice and information on the patient receiving the implant(s). This information will be recorded 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 Allergan silicone-gel 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 *Important Information for Women About Breast Augmentation with INAMED® Silicone-Filled Breast Implants* brochure provided prior to your surgery. This question asks you to verify that you received and had adequate time to review this patient labeling information. Please check either yes or no. When the Required Information section is complete, return it to Allergan in the postage paid business reply envelope provided.

5.4 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 contact Allergan’s Product Support Department at 800.624.4261.

5.5 HOW TO RECEIVE MORE INFORMATION

Upon request, you will be provided with a copy of the package insert (Directions for Use; INAMED® Silicone-Filled Breast Implants document). You can request a copy from your surgeon or from Allergan. 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 800.362.4426.

ADDITIONAL RESOURCES

Allergan
1-800-624-4261
www.Allergan.com

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

Food and Drug Administration
1-888-INFO-FDA or 240-276-3103
www.fda.gov/cdrh/breastimplants/

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