# Breast Augmentation with *NATRELLE®* *Smooth Gel-Filled* *Breast Implants*

# Table of Contents

# Glossary

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

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| **Anaplastic large cell lymphoma (ALCL)** | ALCL is not breast cancer; it is a rare type of non-Hodgkin's lymphoma, a cancer involving the cells of the immune system |
| **Areola** | The pigmented or darker colored area of skin surrounding the nipple of the breast. |
| **Asymmetry** | 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. |
| **Bilateral** | Affecting the right and left sides of the body (i.e., both breasts) |
| **Biopsy** | The removal and examination of tissues, cells, or fluid from the body. |
| **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 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. |

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| **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. 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.<br><br>• Baker Grade I – Normally soft and natural appearance<br>• Baker Grade II – A little firm, but breast looks normal<br>• Baker Grade III – More firm than normal, and looks abnormal (change in shape)<br>• 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. |
| **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, present in some form since birth. |
| **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. |
| **Delayed wound healing** | Delayed progress in the healing of an opened wound. |
| **Displacement** | Movement of the implant from the usual or proper place. |

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| **Double capsule** | The implant and breast are found as 2 separated layers, or capsules, rather than as one unified capsule |
| **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. |
| **Fibrous tissues** | Connective tissues composed mostly of fibers. |
| **Form stable** | No migration of the gel; the device maintains its shape. |
| **Granuloma** | A lump or mass made of inflammatory cells surrounding a foreign substance due to longstanding inflammation. |
| **Haematoma** | 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. |
| **Incision** | A cut made to the body tissue during surgery |
| **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 characterised 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. |

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| **MRI** | Magnetic resonance imaging. A radiographic examination that currently has the best ability to detect rupture of 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. |
| **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. |
| **Palpability** | The ability to feel the implant. |
| **Palpate/palpable** | To feel with the hand. |
| **Pectoralis** | Major muscle of the chest. |
| **Peri-areolar** | 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. |
| **Preoperatively** | Before surgery |
| **Primary breast augmentation** | The first time a breast implant is placed for the purpose of breast augmentation. |
| **Prophylactic** | A treatment or procedure used to prevent disease from occurring. With prophylactic mastectomy, the breast is surgically removed to reduce the risk of breast cancer |
| **Ptosis** | Breast sagging that is usually the result of normal aging, pregnancy, or weight loss. |

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| **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. |
| **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. |
| **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** | 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. |
| **Transaxillary** | Axillary pertains to the armpit area. A transaxillary incision is an incision made in the armpit area. |

# 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 Allergan's *NATRELLE*® gel-filled breast implants.

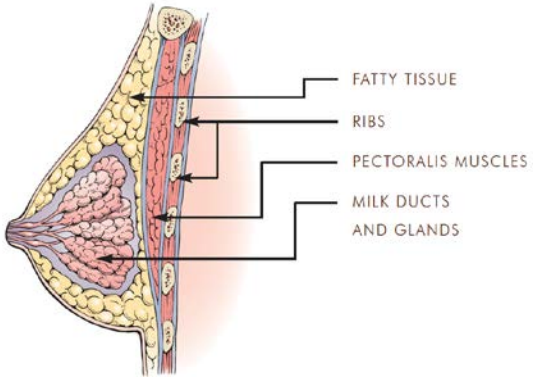
This information cannot and should not replace discussing your surgery with your plastic surgeon. Your decision whether or not to get breast implants should be based on realistic expectations of the outcome. There is no guarantee that your results will match those of other women. Your results will depend 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. You and your surgeon will work together to help you achieve the body image you desire.

As part of your decision, it is recommended that both you and your surgeon sign Allergan's Consent to Surgery form that confirms your understanding of what you have read and what you have learned from your surgeon. This Allergan consent document will be provided to you by your surgeon.

Review and consider 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 quickly.

## 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 realise 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 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 *NATRELLE*® Silicone Gel-Filled Breast Implants

*NATRELLE*® breast implants are gel-filled breast implants. Allergan offers *NATRELLE*® breast implants in a round shape with a smooth shell surface and different silicone gel fillers that are designed to simulate natural breast tissue (TruForm® 1 and TruForm® 2.). The implants are available in a variety of styles, profiles, and sizes, please see table below. A number of factors such as your augmentation goals, your body size, your desired outcome and the amount of breast skin you have will determine which style and size is most appropriate for you. Your surgeon will discuss these options with you and may make recommendations to you based upon the physical contours of your body and the look you are trying to achieve. Carefully review the section on complications so that you can make an informed choice.

| Product name | Styles | Shape | Surface | Profiles | Size (g) |
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| NATRELLE® INSPIRA® Truform 2 gel, Smooth | SSLP, SSM, SSF, SSX, SSL | Round | Smooth | Low profile Plus, Moderate, Full, Extra Full, Low | 110-800 |
| NATRELLE® INSPIRA® Truform 1 gel | SRM, SRL, SRF, SRX, SRLP | Round | Smooth | Moderate, Low, Full, Extra Full, Low profile Plus, | 110-800 |
| NATRELLE® Truform1 Gel | 45, 40 | Round | Smooth | High, Standard | 80-560 |

## 1.4 Are Silicone Gel-Filled Breast Implants Right For You?

*NATRELLE*® gel-filled breast implants are indicated for females for the following uses (procedures):

- **Breast augmentation for women at least 18 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

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

Breast implant surgery should not be performed in:

- Women with tissue covering determined to be inadequate or unsuitable by the surgeon because there may not be enough tissue to cover the breast implant
- Women with active infection anywhere in their body. The implant will make the infection much harder to treat should the infection move into the breast.
- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions. Radiation and chemotherapy treatments may increase the risk of some complications seen with breast implants. Also, breast implants may interfere with radiation or chemotherapy treatments.
- Women using drugs that may result in high surgical risk and/or significant postoperative complications, including drugs that would interfere with blood clotting.
- Women demonstrating or showing signs of psychological instability (i.e., an inappropriate attitude or motivation)
- Women who are currently pregnant or nursing. Surgery may interfere with the safety of pregnancy/nursing. Since breast augmentation is an elective surgery, it should be postponed until you are no longer pregnant or nursing.

## Precautions

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

• Ptotic breasts where nipple falls below the inframammary fold, without concurrent mastopexy.

• To varying degrees, radiation damage, ulceration, compromised vascularity or history of compromised wound healing which may affect tissue covering suitability.

• Previous repeated contour correction failures.

• Patients about to undergo radiation therapy and/or chemotherapy as this may make the use of breast implants and tissue expanders more difficult and increase the risk of complications.

• Physiological condition determined by the surgeon to pose unduly high risk of surgical and/or postoperative complications. To varying degrees, obesity, smoking, diabetes, autoimmune disease, coagulopathy, chronic lung or severe cardiovascular disease may affect patient suitability for surgical implantation.

## 1.5 Important Factors You Should Consider in Choosing Gel-Filled Implants

- ***Mammary implants have a limited lifetime.*** This implant may have to be removed or replaced which is classified as a revision surgery. You may 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. There is no guarantee that you will have a satisfactory cosmetic outcome from any reoperation. When you have your implants replaced (revision-augmentation), your risk of future complications increases compared to first time (primary) augmentation surgery. However, it is not possible to predict the lifetime of an individual device because there are many factors that can influence device lifetime including anatomy, general heath, lifestyle and unforeseen external influences.

- 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 breastfeed, either by reducing or eliminating milk production. Also, breast implants will not prevent your breast from sagging after pregnancy.

- 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. Imaging studies may be required to diagnose rupture.

- It is recommended that you take a multi-step approach to monitor the integrity of the implant throughout the lifetime of the device beginning with a patient self-examination. A radiological assessment may be required if a new symptom or sign is suspected or as part of a periodic review with a physician. If the imaging assessment is negative or inconclusive, discuss further options with your surgeon.

- 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. Any of these symptoms, and/or if you notice persistent pain, should be reported to your surgeon and possibly evaluated with additional tests to screen for rupture.

- You should inform any other doctor who treats you of the presence of your implants to minimise the risk of damage to the implants.

- Closed capsulotomy (use of pressure or force to "break up" the capsule) should not be used to treat capsular contracture. Closed capsulotomy can cause implant rupture.

- Smoking may interfere with the healing process after surgery.

- 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.

# 2.0 Breast Implant Benefits and Risks

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 in Section 2.2.

At the end of this brochure is a list of published studies used to gather the information discussed in the sections below. These studies may be helpful to you if you wish to learn more about a specific complication or condition. However, the reference list is not complete because studies are being conducted all the time. Your physician may have other resources for further reading. 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 Benefits?

Breast augmentation can change the size and proportion of the breast(s). In addition, revision-augmentation (replacement of an existing breast implant) can correct or improve the result of a primary augmentation surgery.

Breast augmentation has the potential to offer both physical and psychological benefits to women. The benefits of breast implants, therefore, relate to their ability to enhance breast volume and attain body symmetry. Many studies have reported that a majority of breast augmentation patients are satisfied with the results of their surgery.

Expected benefits include facilitating emotional healing after cancer, eliminating external prostheses, regaining body symmetry, allowing freedom in clothing and physical activities and improving sexual or interpersonal relationships.

## 2.2 What are the Potential Complications?

- **Rupture**

*Breast implants are not lifetime devices.* Breast implants can 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. Long term Allergan Post-Market Surveillance data over fourteen years on gel-filled breast implants indicate a rupture rate between 0.519% - 0.670%. Allergan's US clinical study data on gel implants indicate a rupture rate between 7.7% - 9.7% at 10 years.

Silicone gel-filled breast implant ruptures are most often silent. 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. 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.

If your surgeon determines you have signs or symptoms of rupture, you should discuss with him or her having 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 discuss with your surgeon additional tests or procedures (such as radiological assessments) to determine whether rupture is present.

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 of implant rupture reported in the literature. Keep in mind some doctors and scientists disagree as to the validity of these reports. These reports were in women who had implants from a variety of manufacturers and implant models.

- Ruptured breast implants have been associated with breasts becoming hard, changing shape or size and becoming painful. These symptoms are not specific to rupture, as they also are experienced by women who have capsular contracture.
- There have been rare reports of the silicone gel from implants moving to nearby locations such as the chest wall, armpit, or upper abdominal wall and even as far as the arm or the groin. This migrating gel has damaged nerves, formed granulomas and/ or

broken down tissues in direct contact with the gel in a few cases. There have been reports of silicone in the liver of women with silicone breast implants. Silicone gel material has moved to lymph nodes in the armpit, even in women whose implants did not appear to have ruptured, leading to lymphadenopathy.

- Concerns have been raised that women with ruptured implants are more likely to develop connective tissue disease, rheumatic disease, fatigue or fibromyalgia. To determine if these diseases are related to ruptured implants, a number of studies have evaluated many women with breast implants. Only one small study distinguished between women with ruptured or intact implants. Most doctors and researchers agree that there is no evidence that ruptured implants or migrated gel causes any disease that affects the whole body (systemic disease) like Connective Tissue Disease (CTD) or cancer.

- **Additional Surgeries (Reoperations)**

You should assume that you will need to have additional surgeries (reoperations). The reasons for reoperation include patients who 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, shifting and BIA-ALCL can require additional surgery.

- **Capsular Contracture**

The scar tissue (capsule) that normally forms around the implant may tighten and squeeze the implant making your breast feel firmer and sometimes painful. This is called capsular contracture. Capsular contracture may be more common following infection, haematoma 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 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 Baker Grade levels depending on its severity. Baker Grades III and IV are considered severe and often additional surgery is needed to correct these grades:

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| 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 |

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.

- **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.

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.

- **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, diarrhoea, fainting, dizziness and/or sunburn-like rash. You should contact a doctor immediately for diagnosis and treatment if you have these symptoms.

- **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.

- **Haematoma/Seroma**

Haematoma 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 haematoma and/or seroma following surgery may result in infection and/or capsular contracture later on. Symptoms from a haematoma or seroma may include swelling, pain and bruising. If a haematoma 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 haematomas 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.

- **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.

- **Wrinkling/Rippling and Folds**

Palpable or even visible wrinkles and folds may occur. Folds may result in thinning and erosion of nearby tissue and extrusion of the breast implant. Folds may also result in crease-fold failure and implant rupture. If wrinkling occurs, the breast implant may be replaced with an implant that has a different fill or shape.

- **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 breastfeeding below).

- **Breast-feeding**

Breast-feeding difficulties have been reported following breast surgery, including breast reduction and breast augmentation. If your surgeon uses a peri-areolar surgical approach (an incision around the coloured portion surrounding the nipple), it may further increase the chance of breast-feeding difficulties.

- **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 minimise but not necessarily prevent, unsatisfactory results.

- **Ptosis**

Ptosis or sagging of the breasts occurs naturally in all breasts over time. In the case of ptosis, a mastopexy (breast lift) may be performed and/or the breast implant may be replaced by another device.

- **Calcium Deposits in the Tissue Around the Implant (Calcification)**

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 haematoma formation, and even in the breasts of women who have not undergone any breast surgery. The occurrence of calcium deposits increases significantly with age.

- **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.

- **Gel Diffusion**

Small quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse (leak) through an intact implant shell. The evidence is mixed as to whether there are any clinical consequences associated with gel diffusion. For instance, studies on implants implanted for a long duration have suggested that such diffusion may be a contributing factor in the development of capsular contracture and lymphadenopathy. However, evidence against gel diffusion 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 diffusion is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in the 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.

Allergan performed a laboratory test to analyse the silicones and platinum (used in the manufacturing process), which may diffuse 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 diffusion is of no clinical consequence.

- **Breast Implant Associated Anaplastic Large Cell Lymphoma**

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

Most patients were diagnosed with BIA-ALCL when they sought medical treatment for implant-related symptoms such as swelling, pain, lumps or asymmetry that developed after their initial surgical sites were fully healed. In the cases known to date, BIA-ALCL was diagnosed years after the breast implant was placed. The earliest report was one year after implant placement and the latest was 23 years after the implant surgery. About half the cases occurred within the first 7 years after implant. BIA-ALCL was most often diagnosed in women who had textured implants. The textured implant may have been placed at the most recent surgery or at any other prior breast implant operation.

If you develop swelling or pain around your breast implants, be sure to talk to your health care provider. Your health care provider should consider the possibility of BIA-ALCL if, after you have recovered from your breast implant operation, you later notice changes in the way your

breast looks or feels — including swelling or pain around the implant. If your health care provider suspects, they will refer you to an appropriate specialist for evaluation which may involve obtaining fluid and some tissue samples from around your breast implant. If a diagnosis of BIA-ALCL is confirmed, the doctor will develop an individualised treatment plan for you. Because of the small number of cases worldwide and the variety of available treatment options, there is no single defined treatment. However, if you are diagnosed with BIA-ALCL, the National Comprehensive Cancer Network (NCCN) recommends removing the implant and the surrounding tissue.

If you have breast implants you should monitor them and follow your routine medical care. You do not need to take any additional steps. It is not necessary to remove your implants if you have no symptoms without a diagnosis of BIA-ALCL.

Education and information regarding the risk and benefits of breast implants should be part of the consent process. Your surgeon is responsible for providing this information to you and will often have information in addition to this leaflet for you to read. A patient implant card should also be provided to you following surgery. This card provides you with sufficient information to identify the breast implant(s) you have. It also has contact details for the manufacturer should you want more information or to report any issues.

Ask your surgeon if they contribute to a breast implant registry in your country. Registries collect details on your implant, surgery, and complications you may have. Including your details in a registry helps us to track the long-term safety and performance of breast implants. It also helps in notifying you and other patients of any safety concerns related to breast implants. Here are links to some breast implant registries that may be available to you:

Australian Breast Device Registry: https://www.abdr.org.au

Dutch Breast Implant Registry: https://dica.nl/dbir/about-dbir or https://dica.nl/dbir/home

United Kingdom Breast and Cosmetic Implant Registry https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry

Ask your surgeon about how your personal data will be protected in the registry.

You are encouraged to contact the supplier of your breast implants or your country's health authority if you have an issue. Reporting issues assists in identifying any trends so that action can be taken at the earliest opportunity.

## 2.3 What are Other Reported Conditions

Research on Silicone Implants

A report published in 1998 by a US National Science Panel, appointed by Judge Sam Pointer, evaluated the scientific data on silicone breast implants in relation to connective tissue diseases and immunologic dysfunction. No association was found between silicone gel-filled implants and

any of the definite connective tissue disorders (including Sjogren's Syndrome) or other autoimmune/rheumatic conditions. They found that women with silicone breast implants do not display a silicone-induced systemic abnormality in the types or functions of cells of the immune system.

In 1999, an independent review from a committee at the Institute of Medicine in the US reported that connective tissue disorders, cancer, neurological diseases or other systemic complaints or conditions are no more common in women with breast implants than in women without implants. They concluded that a review of the toxicology studies of silicones and other substances known to be in breast implants does not provide a basis for health concerns.

# 3.0 Surgical Considerations for Breast Augmentation

## 3.1 What are the Alternatives to Breast Augmentation with Silicone Gel-Filled Breast Implants?

For primary augmentation patients, alternatives may include:

- Having mastopexy surgery (breast lift) without an implant.
- Having surgery with saline implants.

For revision-augmentation patients, alternatives may include:

- No revision.
- Removal with or without replacement.

## 3.2 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 Education Program (Allergan Academy™) for the use of *NATRELLE*® gel-filled breast implants?
- Is he/she board certified, and if so, with which board?
- In which country is he/she licensed to practice surgery? (Note that some countries 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 centre? (Note that hospitals require evidence of appropriate training in specific procedures before allowing surgeons to operate in their facilities.)

## 3.3 What are 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 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 grams or cubic centimetres [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 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 post-operatively. 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/g) may be too large for many women, increasing the risk of developing complications such as implant extrusion, haematoma, infection, palpable implant folds and visible skin wrinkling requiring surgical intervention to correct these complications.

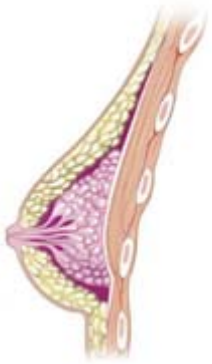
### Surface Texturing

Surface texturing is designed to adhere to surrounding tissue. Some studies suggest that surface texturing reduces the chance of severe capsular contracture while other studies do not. Data from primary augmentation patients in Allergan's study of TruForm® 1 implants did not show a difference in the likelihood of developing capsular contracture with textured implants compared to smooth implants.

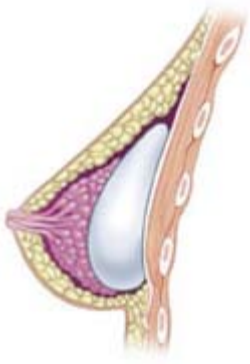
A textured implant may require a larger incision because the rougher textured surface may make it harder to place into the pocket without undue stress, which might damage the implant or decrease its durability. You should note that all *NATRELLE*® breast implants are available with a smooth shell surface.

### Implant Placement

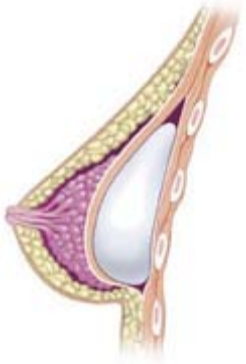
The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast glands (subglandular). You should discuss with your surgeon the advantages and disadvantages of the implant placement selected for you, as described in the table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



Breast before augmentation



Breast after subglandular augmentation



Breast after submuscular augmentation

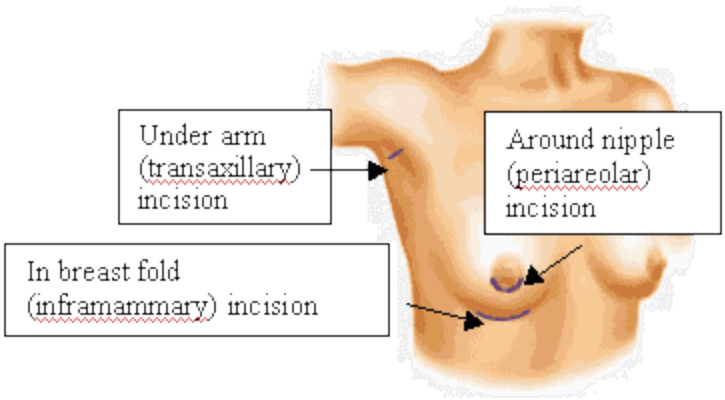
**Comparison between Submuscular versus Subglandular Placement**

| 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 | Greater likelihood of capsular contracture |
| 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: around the nipple (peri-areolar), or within the breast fold (inframammary) or under the arm (axillary).




- **Peri-areolar** - This incision is typically more concealed, but since it also involves cutting through the breast tissue, it is associated with a higher likelihood of breastfeeding difficulties, as compared to the other incision sites. Cutting through the tissue may make a change in sensation or infection more of a concern.
- **Inframammary** - This incision is generally less concealed than peri-areolar and associated with fewer breastfeeding difficulties than the peri-areolar 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.
- **Transaxillary** - This incision is less concealed than peri-areolar and associated with fewer breastfeeding difficulties than the peri-areolar 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 clinical studies 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.

**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.

**Surgical Setting and Anaesthesia**

Augmentation surgery is usually performed on an outpatient basis, in a specialised operating room which may be located in a hospital, a surgery center or surgical suite in the surgeon's office. General anaesthesia is commonly used and local anaesthesia 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 are described in the Breast Implant Complications section.

Post-operative care depends on each patient's situation may involve the use of a special post-operative 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.

You should consult your surgeon for medical follow-up after your surgery.

It is very important that you consult with your healthcare professional before using any medicine in the breast area, before any clinical examination or surgery in the breast area and if you suspect any complications.

*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 re-implanted. *NATRELLE*® breast implants are "for single use only."

# 4.0 Follow Up Examinations

## 4.1 Breast Self-Examinations and Periodic Follow-up

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 breast self-examinations 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.

Breast implants require monitoring for the life of the implant. Thus, you should also schedule regular follow-up with your surgeon to evaluate complications.

## 4.2 Screening for Implant 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 for rupture or other changes. Consult your doctor in the case of any trauma or compression to your breasts caused, for example, by some sports activity or by using a seat belt. You may need to have further testing to determine if your symptoms are due to rupture of the implant. If rupture has occurred, you should consider having your implant removed. Consult with your doctor regarding this and any other medical decisions related to your implants.

## 4.3 Mammography

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.

# 5.0 Additional Information

## 5.1 Device Identification Card

You will be given a device identification card with the style and serial number of your breast implant(s). This card is for your permanent record. It is recommended that you always carry your device identification card to facilitate medical care in case of an emergency. 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.

## 5.2 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 Allergan immediately. In Australia, you should contact Allergan by email at MedDeviceComplaintsAPAC@Allergan.com or call 1800 252 224 and contact the Therapeutic Goods Administration at https://www.tga.gov.au

## 5.3 Confidence Plus Limited Warranties

ALLERGAN is pleased to offer the *ConfidencePlus*™ and *ConfidencePlus*™ Premier Warranty Programs as part of our long-term commitment to ensuring you remain confident in the integrity of your *NATRELLE*® gel-filled breast implants. For more information, please contact Allergan's Product Support Department at +44 (0) 1628 494456 and in Australia at 1800 252 224

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