Breast Augmentation or Reconstruction with *NATRELLE*® Saline-Filled Breast Implants Smooth surface implants

WARNING:

- Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery.
- Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.
- Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases, and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

Natrelle®

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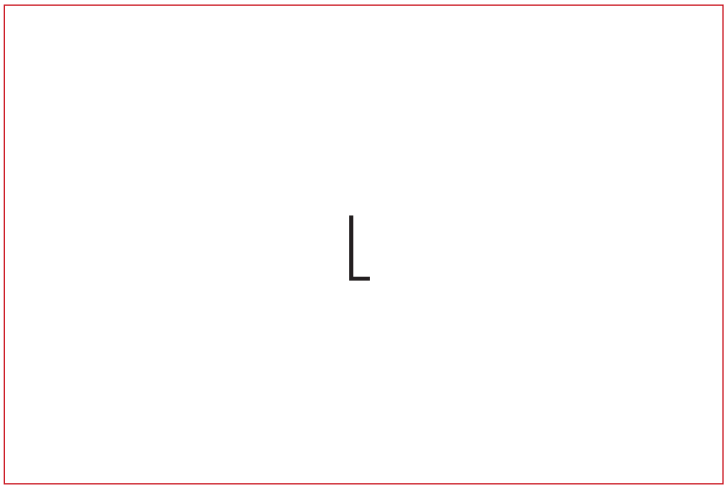

Place Your Device Identification Card(s) Here

To the Patient

The information contained in this booklet, *Breast Augmentation or Reconstruction with NATRELLE® Saline-Filled Breast Implants*, is designed to provide you with an understanding of the risks and benefits of surgery with *NATRELLE®* saline-filled breast implants, as well as provide an overview of the experience of patients in Allergan clinical studies.

Please review this information to ensure your preoperative consultation is effective and comprehensive. Make notes about issues that you would like to further discuss with your plastic surgeon and ask questions. Give yourself time to consider your choices and proceed with surgery only after you are satisfied that the decision is right for you.

To the Healthcare Professional

Discussion of the content of this document is an important part of the informed decision-making process for the patient. Please take time to familiarize yourself with the information presented here and incorporate it into your pre-operative discussion.

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SECTION I

Important Information for Women About Breast Augmentation with *NATRELLE*® Saline-Filled Breast Implants

Glossary

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

Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	Lack of proportion of shape, size and/or position between the two breasts.
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.
Axilla	The junction of your arm and your body (armpit).
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 Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)	BIA-ALCL is not breast cancer; it is a rare type of non-Hodgkin's lymphoma, a cancer involving the cells of the immune system
Breast Mass	A lump 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. For this document, it refers to placement of a breast implant. The first time a breast implant is placed, it is called primary reconstruction. All subsequent times the implant is replaced it is called revision-reconstruction.
Calcification	Process of hardening by calcium salts.
Capsular Contracture	A tightening of the tissue capsule surrounding an implant, resulting in firmness or hardening of the breast and in squeezing of the implant if severe. Capsular contracture is classified by Baker Grades. Grades III or IV are the most severe. Grade III often results in the need for additional surgery (reoperation) because of possibly abnormal appearance. Grade IV usually results in the need for additional surgery (reoperation) because of pain and unacceptable appearance. Grade II may also result in the need for additional surgery. Capsular contracture is a risk for implant breakage. Below is a description of each Baker Grade. • Baker Grade I – Normally soft and natural appearance • Baker Grade II – A little firm, but breast looks normal • Baker Grade III – More firm than normal, and looks abnormal (change in shape) • Baker Grade IV – Hard, obvious distortion, and tenderness with pain

Capsule	Scar tissue which forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture.
Capsulectomy	Surgical removal of the scar tissue capsule around the implant.
Capsulotomy (Closed)	An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but is a known risk for breakage of the implant and is contraindicated.
Capsulotomy (Open)	An attempt to break the scar tissue capsule around the implant by surgical incision into the scar tissue capsule around the implant.
cc	Cubic centimeters. A measure of implant volume. The higher the cc value, the higher the implant volume. For example, an 800 cc implant is larger than a 200 cc implant.
Congenital Abnormality	An abnormal development in part of the body, present in some form since birth.
Connective Tissue Disease/Disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc., and/or the immune system. Connective tissue diseases (CTDs) that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.
Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Deflation	Refers to loss of saline from a saline-filled breast implant due to a tear or cut in the implant shell or possibly a valve leak.
Delayed wound healing	Delayed progress in the healing of an opened wound.

Displacement	Movement of the implant from the usual or proper place.
Dysmorphic Disorder	A psychological condition characterized by an obsession with a minor or an imagined physical flaw to the point that it can interfere with normal functioning.
Epidemiological	Relating to the science of explaining the relationships of factors that determine disease frequency and distribution.
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.
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.
Latissimus dorsi	Two triangular muscles running from the spinal column to the shoulder.

Malposition	Implant malposition or displacement is when the implant is not in the correct spot in the breast. This could have been due to incorrect placement of the implant during the surgery or due to shifting of the implant position over time.
Mammary	Pertaining to the breast.
Mammography	A type of X-ray examination of the breasts used for detection of cancer.
	Screening mammography – x-ray examination of the breast that is performed on women with no complaints or symptoms of breast cancer; the goal is to detect breast cancer when it is still too small to be felt by a physician or the patient.
	Diagnostic mammography – x-ray examination in order to evaluate a breast complaint or abnormality detected by physical exam or screening mammography; additional views of the breast are usually taken.
Mammoplasty	Plastic surgery of the breast.

Mastectomy	The removal of breast tissue due to the presence of a cancerous or precancerous growth. Subcutaneous mastectomy: Surgical removal of the breast tissues, but sparing the skin, nipple, and areola. Total mastectomy: Surgical removal of the breast including the nipple, areola, and most of the overlying skin. Modified Radical Mastectomy: Surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the lymphatic-bearing tissue in the axilla. Radical Mastectomy: Surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the pectoral muscles, lymphatic-bearing tissue in the axilla, and various other neighboring tissue.
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.
Necrosis	Death of cells or tissues.
Oncologist	A doctor who studies, identifies, and treats cancer.
Outpatient surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight.
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.
Pneumothorax	Pneumothorax (sometimes called "collapsed lung") occurs when air leaks into the space between lung and chest wall.

Plastic surgery	Surgery intended for the improvement of the appearance of the body.
Pneumothorax	Pneumothorax (sometimes called "collapsed lung") occurs when air leaks into the space between lung and chest wall.
Postoperatively	After surgery
Primary Breast Augmentation or Reconstruction	The first time a breast implant is placed.
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 or reconstruction	Refers to the correction or improvement of a primary augmentation or reconstruction. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast augmentation or reconstruction.
Rosenberg Self-Esteem Scale	A questionnaire which measures overall self-esteem.
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.
Subglandular placement	Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.
Submuscular placement	Placement of a breast implant wholly or partially underneath the chest muscle.

Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Tennessee Self-Concept Scale	A questionnaire that evaluates how the patient sees herself and what she does, likes, and feels.
Tissue Expander	A temporary adjustable implant that can be inflated with saline to stretch the tissue at the mastectomy site to create a new tissue flap for implantation of the breast implant.
Transaxillary	Across the long axis of the armpit (axilla).
Umbilical	Relating to the navel.
Warning	Statement that alerts reader about a situation which, if not avoided, could result in serious injury or death.

1. Considering Saline-Filled Breast Implant Surgery

You may be considering **breast implant** surgery to increase the size of your breasts or to reconstruct a breast. 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 and breast reconstruction surgery. This educational brochure is set up to help you talk with your surgeon, as well as provide you with general information on breast implant surgery and give you specific details about *NATRELLE*® Saline-Filled Breast Implants.

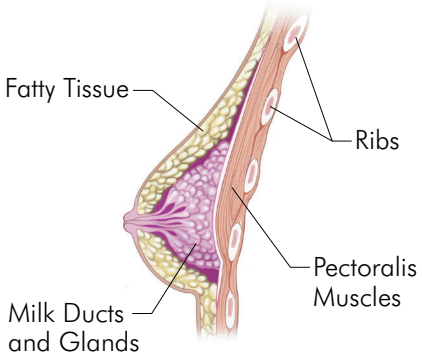
This information cannot and should not replace discussing your surgery with your plastic surgeon. Your decision whether or not to get breast implants should be based on realistic expectations of the outcome. There is no guarantee that your results will match those of other women. Your results will depend 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, 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. This Allergan consent document is located at the beginning of this brochure.

Review and consider this information before deciding whether to have primary breast surgery. In the case of a revision, 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 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, such as **mastopexy**, to help achieve improved breast lift.

1.2 What Is a Saline-Filled Breast Implant?

A saline-filled breast implant is a sac (implant shell) of **silicone elastomer** (rubber), which is surgically implanted under your breast tissue or chest muscle and then filled with sterile **saline** (a salt water solution) through a valve. *NATRELLE*® Saline-Filled Breast Implants have a round shape and come in many different sizes and styles. The image shown below is an example of a NATRELLE® Saline-Filled Breast Implant that you may have seen at your surgeon's office.

Round Saline Implant

There are two approved types of breast implant fillers, saline and silicone, which gives more options to you in terms of the type of implant to achieve the effect you desire. Your surgeon can discuss these options with you and may make recommendations to you based upon the physical contours of your body. The focus of this brochure is saline-filled breast implants; a separate brochure is available for silicone-filled implants. Carefully review the section on complications and the section on Allergan's clinical study so that you may make an informed choice. Be sure to ask your surgeon to see and touch samples of both saline and silicone breast implants.

The *NATRELLE*® Collection

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

NATRELLE® Saline-Filled Breast Implants

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

NATRELLE® Gel-Filled Breast Implants

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

NATRELLE® Saline-Filled Breast Implant Device Materials

The potential toxicity of the chemicals and metals listed in the following tables have been evaluated with both toxicity testing and risk assessments to assess the exposure levels in comparison to the amount determined to likely be safe. However, individual responses to chemicals may vary, and all reactions cannot be predicted.

Implant Component	Device Materials
Shell	Polydimethylsiloxane Silicone Elastomer Dispersion
Shell Patch/ valve component	Polydimethylsiloxane Silicone Elastomer

Chemicals Released by *NATRELLE*® Saline-Filled Breast Implants

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

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

The breast implants were analyzed to understand your potential exposure to chemicals. To detect low molecular weight components, techniques called gas chromatography-mass spectrometry and gel permeable chromatography were used. Complete metal analyses were also performed. The table below shows the amount of low molecular weight components and inorganic (metallic elements).

Concentrations of Low Molecular Weight Components and Heavy Metals Detected from Extractables Testing

(in ppm by component weight)

Identification	Molecular Weight (amu)	Finished Device (ppm)
D3	222	0.6*
D4	296	0.9*
D5	370	2.1*
D6	444	5*
D7	518	3.1*
D8	592	3.4*
D9	666	11.3
D10	740	36.7
D11	814	70
D12	888	135
D13	962	206.7
Mesiloxane	unknown	0.9*
D14	1,036	309.1
D15	1,110	407.2
D16	1,184	475.2
D17	1, 258	521
D18	1, 332	524.1
D19	1, 406	513.9
D20	1, 480	478
Isopropanol	60.09	0.71*
D25	1, 850	358.5
D30	2, 220	285.3
D35	2, 590	241.2
D40	2, 960	200.5
D45	3, 330	160.5
D48	3, 552	159.1
Acetic Acid	60.50	Not reported
Toluene	92.13	Not reported
Xylenes	106.2	5.69*
1,1,1 Trichlorethane	133.4	Not reported

Identification	Molecular Weight (amu)	Finished Device (ppm)
Hexamethyl Disilazane	161	Not reported
Methyl Triacetoxy Silane	222	Not reported
Polybiphenyls	mixture	ND*
Tin	118.7	50-100
Platinum	195.09	ND (<3)
Arsenic	74.9	ND (< 100)
Lead	207.2	ND (<10)
Manganese	54.93	ND (<1)
Zinc	65.37	ND (<30)
Phosphorous	30.97	ND (<300)
Total Extractables (hexane extract)	Mixture	2.5%

D3- D48 represent cyclic polydimethyl siloxanes (PDMS)
amu = atomic mass units (Daltons)
ND (<X) = Not detected at less than X concentration in parts per million
*analysis provided on shell only

1.3 Who is eligible for *NATRELLE®* Saline-Filled Breast Implants?

NATRELLE® Saline-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.

Who should not get breast implants (What are the 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

Warnings

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

There is a boxed warning for breast implants. Please see page Cover Page.

Surgical practices that are contraindicated in breast implantation because they may damage the shell and cause **deflation**:

- Placement of drugs/substances inside the implant other than sterile saline
- Injection through the implant shell
- Alteration of the implant
- Stacking of implants (more than one implant per breast)
- You should be aware that closed capsulotomy, the practice of forcible squeezing or pressing on the fibrous capsule around the implant to break the scar capsule, is not recommended as this may result in breakage of the implant.

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

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

Precautions

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

- **Autoimmune diseases** (for example, lupus and scleroderma)
- Conditions that interfere with wound healing and blood clotting
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease)
- Planned chemotherapy following breast implant placement
- Planned radiation therapy to the breast following breast implant placement
- Reduced blood supply to breast tissue
- Clinical diagnosis of depression or other mental health disorders, including **body dysmorphic disorder** and eating disorders. Please discuss any history of mental health disorders with your surgeon prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery

1.4 Important Factors You Should Consider in Choosing Saline-Filled Implants?

- 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.

- 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 break 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 may wish to undergo a preoperative mammogram and another one 6 months to one year after implantation to establish a baseline.

- 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.
- For patients who have undergone breast implantation either as a cosmetic procedure or a reconstructive procedure, 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.
- For breast reconstruction surgery, most insurance covers the first breast reconstruction operation. Insurance coverage for reoperation procedures or additional surgeon's visits following reconstruction may not be covered, depending on the policy.
- You should inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.
- The long-term (10-year) results from Allergan's clinical studies are included in this brochure and should be carefully reviewed.
- 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. Surgical Considerations for Breast Augmentation

2.1 What Are the Alternatives to Breast Augmentation with Saline-Filled Breast Implants?

For primary augmentation patients, alternatives may include:

- Accepting your breasts as they are and having no surgery.
- Wearing a padded bra or external prostheses.
- Having mastopexy surgery (breast lift) without an implant.
- Having surgery with silicone-filled implants.

For revision-augmentation patients, alternatives may include:

- No revision.
- Removal with or without replacement.

2.2 What are questions to consider when choosing a surgeon?

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

- How many breast augmentation/reconstruction procedures does he/she perform per year?
- How many years has he/she performed breast implantation procedures?
- Is he/she board certified, and if so, with which board?
- Did he/she complete a residency in plastic surgery from a recognized and accredited program?
- In which state/province(s) is he/she licensed to practice surgery? (Note that some states/provinces 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 implantation?
- What is his/her reoperation rate with breast augmentation, and what is the most common type of reoperation he/she performs?

- Does the surgeon only perform breast reconstruction with breast implants? What types of implants does the surgeon primarily use (saline, silicone, TruForm 1® silicone, TruForm 2® silicone, TruForm 3® silicone)
- Are there other breast reconstruction procedures performed routinely by the surgeon, such as autologous tissue reconstruction (operations that use tissue from the stomach or flank to reconstruct breast tissue), flap reconstruction, etc.?
- How many reconstructions does he/she perform that do not involve implants per year?
- Can he/she perform this surgery in a hospital, as well as in the surgeon's independent surgery center? (Note that hospitals require evidence of appropriate training in specific procedures before allowing surgeons to operate in their facilities).

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

AUGMENTATION

- What are the risks and complications associated with having breast implants?
- How many additional operations on my implanted breast(s) can I expect over my lifetime?
- How will my breasts look if I decide to have the implants removed without replacement?
- What shape, size, surface texturing, incision site, and placement site is recommended for me?
- How will my ability to breastfeed be affected?
- How can I expect my implanted breasts to look over time?
- How can I expect my implanted breasts to look after pregnancy? After breastfeeding?
- What are my options if I am dissatisfied with the cosmetic outcome of my implanted breasts?
- What alternate procedures or products are available if I choose not to have breast implants?
- Do you have before and after photos I can look at for each procedure and what results are reasonable for me?

RECONSTRUCTION

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

2.3 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 may choose a round or contoured implant shape. Generally, the larger you want your cup size or the higher the profile, the larger the breast implant your surgeon will consider (measured in cubic centimeters, or **cc**'s).

Your surgeon will also evaluate your existing tissue to determine if you have enough to cover the breast implant you are considering, or, in some cases such as after pregnancy, too much extra skin. If you desire a breast implant

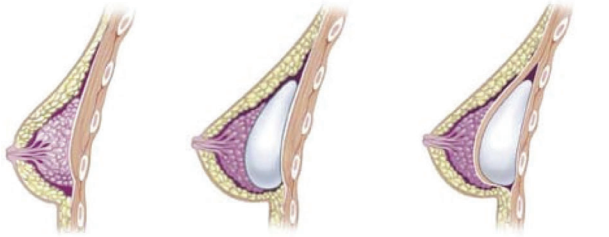
size that is too large for your tissue, the surgeon may warn you that breast implant edges may be visible or palpable **postoperatively**. Also, excessively large breast implants may speed up the effects of gravity on the breast, and can result in droop or sag at an earlier age.

SURFACE

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.

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

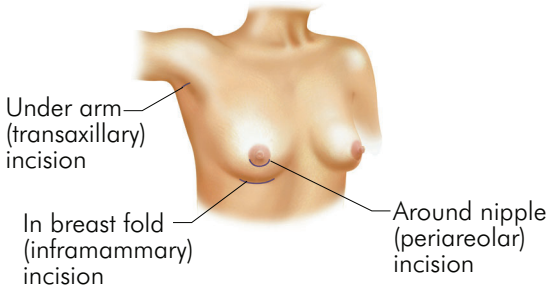
Comparison between Subglandular versus Submuscular Placement

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

INCISION SITES

To permit the smallest possible incision, the implant is typically inserted empty, and then filled with saline. You should discuss with your surgeon, the pros and cons for the incision site specifically recommended for you.

There are three common incision sites: around the nipple (**periareolar**), within the breast fold (**inframammary**), and under the arm (**axillary**).



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 breastfeeding difficulties, as compared to the other incision sites. Cutting through the tissue may make change in sensation or infection more of a concern.

Inframammary - This incision is generally less concealed than periareolar and associated with fewer breastfeeding difficulties than the periareolar incision site. It is also the most commonly used incision 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 periareolar and associated with fewer breastfeeding 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 clinical studies and should not be used for a 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 ANESTHESIA

Augmentation surgery is usually performed on an outpatient basis, in a specialized operating room which may be located in a hospital, 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.

The surgery usually lasts one to two hours. Your surgeon will make an incision and create a pocket for the breast implant. Then, the breast implant will be placed in the pocket, filled, and positioned. Finally, the incision will be closed, usually with stitches, and possibly taped.

POSTOPERATIVE CARE

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

Postoperative care depends on each patient's situation, 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, or noticeable swelling and/or redness in your implanted breast(s), you should contact your surgeon immediately.

OTHER FACTORS TO CONSIDER IN REVISION 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. Allergan breast implants are "for single use only."

2.4 Follow-up Examinations

BREAST SELF-EXAMINATIONS

Following breast implant surgery, 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.

If you have had a mastectomy, discuss with your surgeon regarding what imaging is recommended for you. If you did not have mastectomy, the current recommendations for getting screening/preoperative mammograms are no different for women with breast implants than for those without implants. 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 deflation and to get the best possible views of the breast tissue.

3. Surgical Considerations for Breast Reconstruction

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

Your decision to have breast reconstruction is an important personal choice involving both risks and benefits. There are other options for breast reconstruction that do not involve breast implants. Be sure to ask your surgeon for a detailed explanation of each alternative to help you decide which reconstruction option is most suitable for you and your lifestyle. This brochure is intended to provide general information about silicone breast implants and surgery but is not a substitute for a thorough consultation with your surgeon. You are advised to carefully review and consider all the information you have received before deciding whether to have reconstruction surgery. Prepare a list of questions after reading this brochure (section 2.2 lists some questions), and discuss them with your surgeon.

3.1 Should You Have Primary Breast Reconstruction?

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

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

3.2 What Are the Alternatives to Breast Reconstruction?

For primary reconstruction patients, alternatives may include:

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

For revision-reconstruction patients, alternatives may include:

- No revision.
- Removal with or without replacement.

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

3.3 What are the Choices in Reconstructive Procedures?

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

Breast reconstruction can be accomplished with the use of a prosthesis (a breast implant, either silicone gel- or saline-filled), your own tissues (a tissue flap), or a combination of the two. A tissue flap is a section of skin, fat and/or muscle which is moved from your stomach, back or other area of your body to the chest area, and shaped into a new breast. A tissue flap also may be used to provide skin or other tissue needed to make up for what was removed at the time of surgery, or changed following radiation therapy. Your surgeon can help you decide what method of breast reconstruction is most suitable for your particular situation.

Whether or not you have reconstruction with or without breast implants, you will probably undergo additional surgeries to improve symmetry and appearance. These additional surgeries may be part of a several-stage reconstruction of the removed breast, or to shape the remaining breast to bring it into better balance with the reconstructed one. Most commonly, breast implants are placed after a space has been created for them using a temporary soft tissue expander that can be placed at the time of mastectomy or at a later time.

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

3.4 Breast Reconstruction with Breast Implants

Women with small or medium-sized breasts are the best candidates for breast reconstruction. Reconstruction patients commonly undergo additional surgeries to improve breast symmetry and appearance. For example, because the nipple and areola are usually removed with the breast tissue in mastectomy, the nipple is usually reconstructed by using a skin graft from another area of the body or the opposite breast, in addition to tattooing the area. Nipple reconstruction is usually done as a separate outpatient procedure after the initial reconstruction surgery is complete.

Your surgeon will decide whether your health and medical condition makes you an appropriate candidate for breast implant reconstruction. Women with small or medium sized breasts are the best candidates for breast reconstruction with implants. Women with larger breasts may require reconstruction with a combination of a tissue flap and an implant. Your surgeon may recommend breast implantation of the opposite, uninvolved breast in order to make them more alike (maximize symmetry), or he/she may suggest breast reduction (reduction mammoplasty) or a breast lift (mastopexy) to improve symmetry. Mastopexy involves removing a strip of skin from under the breast or around the nipple and using it to lift and tighten the skin over the breast. Reduction mammoplasty involves removal of breast tissue and skin. If it is important to you not to alter the unaffected breast, you should discuss this with your plastic surgeon, as it may affect the breast reconstruction methods considered for your case.

3.5 Reconstruction Incision Sites

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

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

3.6 Surgical Settings and Anesthesia?

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

3.7 The Timing of Your Breast Implant Reconstruction

The following description applies to reconstruction following mastectomy, but similar considerations apply to reconstruction following breast trauma or for reconstruction for congenital defects. The breast reconstruction process may begin at the time of your mastectomy (immediate reconstruction) or weeks to years afterwards (delayed reconstruction). This decision is made after consultation with the cancer treatment team based on your individual situation. Immediate reconstruction may involve placement of a breast implant, but typically involves placement of a tissue expander, which is used to recreate skin that was removed during the cancer surgery. The tissue expander will eventually be replaced with a breast implant. It is important to know that any type of surgical breast reconstruction may take several steps to complete.

Two potential advantages to immediate reconstruction are that your breast reconstruction starts at the time of your mastectomy and that there may be cost savings and potentially fewer days in the hospital for you in combining the mastectomy procedure with the first stage of the reconstruction. However, there may be a higher risk of capsular contracture, extrusion, and other complications associated with immediate reconstruction as a result of postoperative radiation and chemotherapy treatments. Your initial operative time and recuperative time may be longer.

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

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

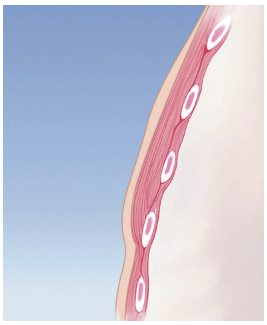
3.8 What is the Breast Implant Reconstruction Procedure?

IMMEDIATE OR DELAYED BREAST IMPLANT RECONSTRUCTION

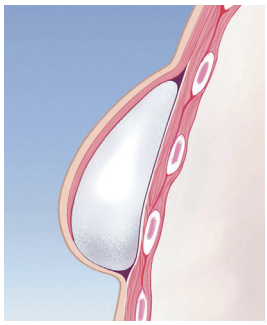
Breast reconstruction using only a breast implant may be done immediately at the time of your mastectomy or sometime thereafter. After the general surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant that completes the reconstruction. In reconstruction following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

EXPANDER-ASSISTED (IMMEDIATE OR DELAYED) BREAST IMPLANT RECONSTRUCTION

Breast reconstruction usually occurs as a staged procedure, starting with the placement of a breast tissue expander, which is replaced several months later with a breast implant. The tissue expander placement may be done immediately, at the time of your mastectomy, or be delayed until months or years later.



Side View, Breast Tissue Removed



Side View, Expander Inserted and Filled

TISSUE EXPANSION

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

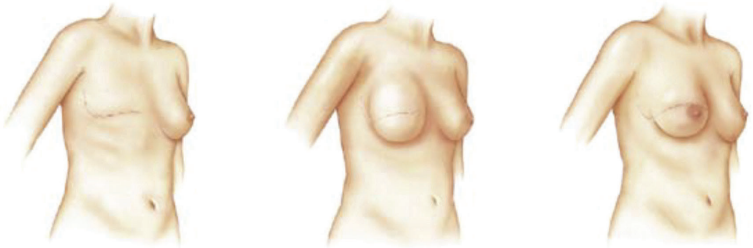
The tissue expander is a balloon-like device made from elastic silicone rubber. It is inserted unfilled, and over time, sterile saline fluid is added by inserting a small needle through the skin to the filling port of the device. As the tissue expander fills, the tissues over the expander begin to stretch,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

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

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

PLACING THE BREAST IMPLANT

After the tissue expander is removed, the unfilled breast implant is placed in the pocket, and then filled with sterile saline fluid. In reconstruction following mastectomy, a breast implant is most often placed submuscularly. The surgery to replace the tissue expander with a breast implant (implant exchange) is usually done under general anesthesia in an operating room. It may require a brief hospital stay or be done on an outpatient basis.



Post Mastectomy | **Stage 1: Tissue Expander Placed and Expansion Underway** | **Stage 2: Breast Implant and Nipple/Areola Reconstruction**

3.9 What About Breast Reconstruction Without Implants: Tissue Flap Procedures

The breast can be reconstructed by surgically moving a section of skin, fat and muscle from one area of your body to another. The section of tissue may be taken from such areas as your abdomen, upper back, upper hip, or buttocks.

The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap), or it may be removed completely and reattached to the breast area by microsurgical techniques (a free flap). Operating time is generally longer with free flaps, because of the microsurgical requirements.

Flap surgery requires a hospital stay of several days and generally a longer recovery time than implant reconstruction. Flap surgery also creates scars at the site where the flap was taken and on the reconstructed breast. However, flap surgery has the advantage of being able to replace tissue in the chest area. This may be useful when the chest tissues have been damaged and are not suitable for tissue expansion. Another advantage of flap procedures over implantation is that alteration of the unaffected breast is generally not needed to improve symmetry.

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

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

DIEP FLAP

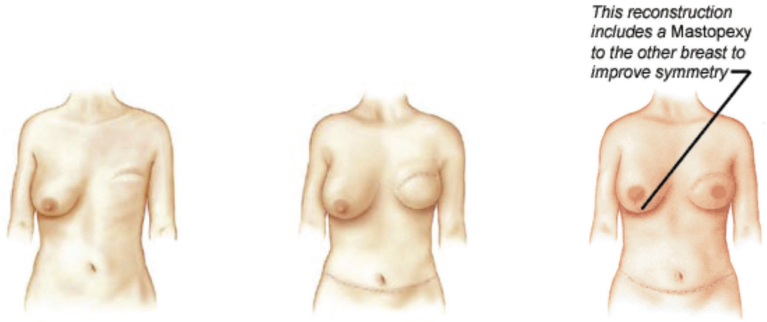
During a DIEP flap procedure, the surgeon removes fat, skin, and blood vessels from the abdomen and moves it to the chest to reconstruct the breast. Abdominal muscles are not removed. The surgeon will reattach blood vessels in the flap to blood vessels in the chest using microsurgery. As no

muscle is removed, most women have a lower risk of losing abdominal muscle strength compared to TRAM flap procedures. However, the flap procedures require special surgical training and expertise in microsurgery. Patients will have a scar on their abdomen and have additional scars on their reconstructed breast. You should obtain details, such as procedure details, expectations, risks and benefits, length of hospital stay and recovery time from your surgeon about the DIEP procedure you are considering.

THE TRAM FLAP (PEDICLE OR FREE)

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

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



Post Mastectomy **TRAM Flap** **Final Result with Nipple/Areola Reconstruction**

THE LATISSIMUS DORSI FLAP WITH OR WITHOUT BREAST IMPLANTS

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

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

Post Mastectomy

View Showing Back Scar

Latisimus Dorsi Flap and Nipple/Areola Reconstruction

POSTOPERATIVE CARE

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

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

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

OTHER FACTORS TO CONSIDER IN REVISION-RECONSTRUCTION SURGERY

Some revision surgeries require removal of an intact implant (for example, capsulotomy and pocket adjustments), while others do not require removal of the implant. Any device that has been removed during revision surgery should not be reimplanted. *NATRELLE*® breast implants are "for single use only."

4. Breast Implant Complications

Undergoing any type of surgical procedure involves risks (some serious) such as the effects of anesthesia, infection, swelling, redness, bleeding, pain, and even death, which need to be balanced against the benefits of the surgery itself. There are potential complications specific to breast implant surgery and breast implants, as described below.

Located at the end of this brochure is a list of published studies used to gather the information discussed in the sections below. These may be helpful to you if you wish to learn more about a specific complication or condition. The reference list is not complete because studies are being conducted all the time; your physician may have other resources for further reading as well. It should be noted that the references include augmentation and/or reconstruction patients, as well as implants of different types and from a variety of manufacturers.

4.1 What Are the Potential Complications?

- **Additional Surgeries (Reoperations)**

You should assume that you will need to have additional surgeries (reoperations). The reasons for reoperation include patients who decide to change the size or type of their implants, as well as problems such as deflation, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, and infection.

- **Implant Removal**

Because these are not lifetime devices, the longer you have your implants the more likely it will be for you to have them removed for any reason, either because of dissatisfaction, an unacceptable cosmetic result, or a complication such as capsular contracture. Having your implants removed and replaced increases your chances of getting future complications.

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.

- 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 than in primary breast implant surgery. Because you may have your initial implants replaced, you should be aware that your risk of capsular contracture increases with revision surgery. Capsular contracture can be a risk factor for deflation, 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 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.

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 is needed in cases where pain and/or firmness are severe. This surgery ranges from removal of the implant capsule tissue to removal and possibly replacement of the implant itself. This surgery may result in loss of your breast tissue. Capsular contracture may happen again after these additional surgeries.

- Deflation

Breast implants are not lifetime devices. Breast implants deflate when the saline solution leaks either through an unsealed or damaged valve or through a break in the implant shell. Implant deflation can occur immediately or

slowly over a period of days and is noticed by loss of size or shape of your breast. Some saline implants deflate (or rupture) in the first few months after being implanted and some deflate after several years. Causes of deflation include damage by surgical instruments during surgery, overfilling or underfilling of the implant with saline solution, capsular contracture, closed capsulotomy, stresses such as trauma or intense physical manipulation, excessive compression during mammographic imaging, umbilical incision placement, and unknown/unexplained reasons. You should also be aware that the breast implant may wear out over time and deflate.

Deflated implants require additional surgery to remove.

- Unsatisfactory Results

Unsatisfactory results such as wrinkling, asymmetry, implant **displacement** (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, hypertrophic scarring, and/or sloshing 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 always prevent, unsatisfactory results.

- Pain

Pain of varying intensity and length of time may occur and continue 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.)

- 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 an infection. Infections in tissue with an implant present are harder to treat than infections in tissues 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.

- 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.

- 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 deflation can occur from surgical draining if damage to the implant occurs during the draining procedure.

- Breastfeeding

Breastfeeding 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 increase the chance of breastfeeding difficulties. The most common breastfeeding problem is inadequate milk production.

- 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 the 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 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 in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

- 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. Some patients with breast implants report having enlarged lymph nodes in the armpit(s). Sometimes the enlarged lymph nodes are painful. If they become too large or painful, the lymph node(s) may need to be surgically removed. Painful and/or enlarged lymph nodes should be reported to your doctor. Lymphadenopathy has been associated with tissue reactions, granulomas, and silicone at the lymph nodes of women with intact and ruptured silicone breast implants.

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

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

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

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

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

Discussion of the risk of BIA-ALCL can be found on Health Canada's website. https://www.canada.ca/en/health-canada/services/drugs-medical-devices/breast-implants/risks.html#rare_risk

4.2 What Are Other Reported Conditions?

Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed.

There have been reports in the literature of other conditions in women with breast implants. Many of these conditions, which are listed below, have been studied to evaluate their potential association with breast implants. 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 the risk of connective tissue disease among women with implants would need to be very large. The published studies overall show that breast implants are not significantly associated with a risk of developing a typical or defined connective tissue disease. 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.

- CTD Signs and Symptoms

Some women (even without breast implants) may have some of the signs or symptoms of CTDs, without having the actual disease.

Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

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

- Cancer

Published studies indicate that breast cancer is no more common in women with implants than those without implants.

- Effects on Children

There have been concerns 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. Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding. The author recommended further research on infant health.

5. Overview of Allergan's Clinical Studies

Although you will experience your own risks (complications) and benefits following breast implant surgery, this section describes the specific complications and benefits of *NATRELLE*® Saline-Filled Breast Implants. Allergan's studies indicate, for example, that most women can expect to experience at least one complication at some point through 5 years after implant surgery. The studies also indicate that the chance of additional surgery through 10 years is 3 in 10 for augmentation patients. The information below provides more details about the complications and benefits you may experience.

Allergan conducted clinical studies testing of its saline-filled breast implants to determine the short-term and most common complications as well as benefits of their implants. The studies included both smooth and BIOCELL

textured breast implants. The BIOCELL textured breast implants were recalled in July 2019 for their higher risk of developing BIA-ALCL and no longer are manufactured or marketed. These were assessed in the following studies:

- The Large Simple Trial (LST)
- The 1995 Augmentation Study (A95)
- The 1995 Reconstruction Study (R95)
- The Post Approval Survey Study (PASS)

The Large Simple Trial was designed to determine the 1-year rates of capsular contracture, infection, implant leakage/deflation, and implant replacement/removal. There were 2,333 patients enrolled for augmentation, 225 for reconstruction, and 317 for revision (replacement of existing implants). Of these enrolled patients, 62% returned for their 1-year follow-up visit. The results of this study were consistent with the A95/R95 and PASS studies.

The A95 and R95 Studies were designed as 5-year studies to assess all complications as well as patient satisfaction, body image, body esteem, and self concept. Patients were followed annually and data through 3 years were presented to FDA for marketing approval. After approval, Allergan transitioned data collection to a post-approval study. The first phase of this post-approval study consisted of completion of the A95 and R95 Studies, with collection of all risk/benefit information through 5 years.

The Post Approval Survey Study (PASS) was designed to collect long-term safety data from A95/R95 patients at 6-10 years post-implant. The data were collected from surveys mailed out to the patients each year. The 10-year PASS Study data are shown within both the Augmentation and Reconstruction Sections.

6. Primary Breast Augmentation Study Results

This section summarizes the results of the clinical studies conducted on *NATRELLE*® saline-filled breast implants for primary augmentation.

6.1 What Were the Follow-Up Rates?

Follow-up rates from a clinical study show you how many women provided information on their experience with breast implants. High participation of patients demonstrates that the data you review in the sections below are based upon a satisfactory number of participants.

The A95 Study enrolled 901 augmentation patients, with 81% returning for their 5-year follow-up visit. Of the women expected to return completed surveys for the 10-year post-implantation study interval in the PASS study, data were collected for 91% of the augmentation patients.

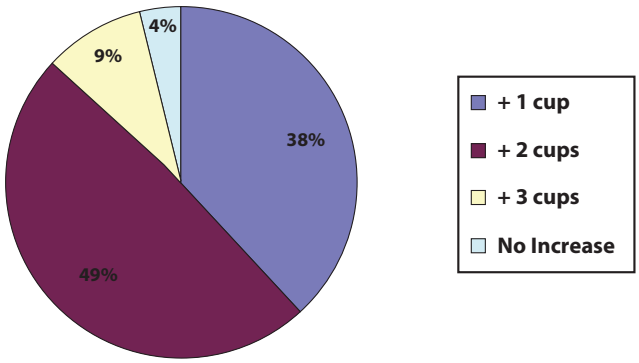
6.2 What Were the Benefits?

The benefits of saline-filled breast implants in the A95 Study were assessed by a variety of outcomes, including bra cup size change and assessments of patient satisfaction and quality of life. Data was collected before implantation and at scheduled follow-up visits.

Breast Measurement: For primary augmentation patients, 859 (95%) of the original 901 patients had a breast measurement within 18 months of surgery. Of these 859 patients, 38% increased by 1 cup size; 49% increased by 2 cup sizes; 9% increased by 3 cup sizes; and 4% had no increase or decrease. See Figure 1 below.

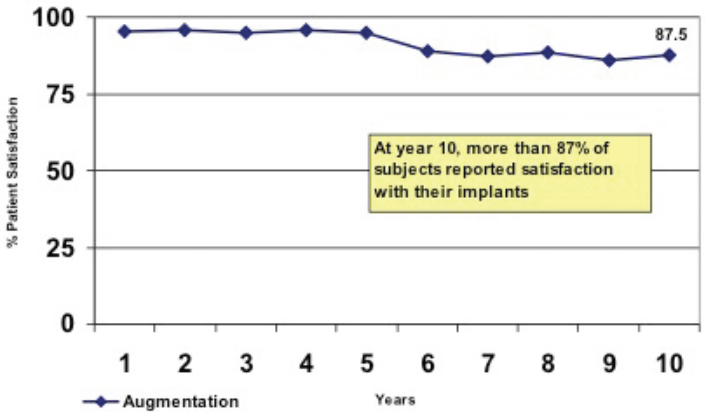
Figure 1. Cup Size Changes in Primary Augmentation Patients

Patient Satisfaction: Allergan's patient satisfaction was based on a 5-point scale assessment of satisfaction with their implants at the time of the follow-up visits. Of the original 901 primary augmentation patients,



683 (76%) provided a satisfaction rating at 5 years, with 649 (95%) of these patients indicating that they were satisfied with their breast implants. At 10 years post-implant, 88% of the patients who provided satisfaction scores on a 6-point scale indicated being satisfied with their breast implants (Figure 2).

Figure 2. Primary Augmentation Patient Satisfaction
(responses of somewhat satisfied, satisfied, or definitely satisfied)



Quality of Life Assessments: Quality of life assessments were obtained prior to implantation and at 6 months, 1 year, and 3 years after surgery. Before implantation, augmentation patients scored higher (better) than the general U.S. female population on the SF-36 scales, which measure general health-related quality of life. After 3 years, augmentation patients showed a slight worsening in their SF-36 scores, although all scales remained higher than the general U.S. female population. The Rosenberg Self Esteem Scale (which measures overall self esteem) and the Tennessee Self Concept Scale (which measures overall self concept) showed slight improvements over the 3 years. The Body Esteem Scale (which measures overall body image) showed a slight worsening overall but a large improvement in body esteem related to sexual attractiveness at 3 years.

Breast satisfaction was significantly increased after 3 years, including satisfaction with breast shape, size, feel or touch, and how well they matched (Table 1).

Table 1.
Change from Pre-Surgery in Breast Satisfaction Scale

Quality of Life Scale	Primary Augmentation	
	Year 1	Year 3
Satisfaction with Breasts	Improved	Improved
How Well Breasts Matched	Improved	Improved
Satisfaction with Breast Shape	Improved	Improved
Satisfaction with Breast Size	Improved	Improved
Satisfaction with Breast Feel/Touch	Improved	Improved

6.3 What Were the Complication Rates?

The 5-year complication rates from the A95 Study are presented in the Appendix, Table 1. The rates reflect the number of augmentation patients out of 100 who experienced the listed complication at least once within the first 5 years after implantation. Some complications occurred more than once for some patients. The two most common complications experienced within the first 5 years of implantation were reoperation (25.9% or almost 26 patients out of 100) and breast pain (17.0% or 17 patients out of 100).

The 10-year complication rates from the PASS Study are presented in the Appendix, Table 2. These results are from patient surveys rather than physician visits. The survey contained questions on only the five complications listed in Table 2. The rates reflect the number of augmentation patients out of 100 who experienced the listed complication at least once within the first 10 years after implantation. The most common complication experienced through 10 years was reoperation (36.5%, about 37 out of every 100 patients).

6.4 What Were the Reasons for Reoperation?

There may be one or more reasons identified for having a reoperation (additional surgery after the primary 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.

The reasons for reoperation in the A95 Study through 5 years and the PASS Study through 10 years are shown in the Appendix, Table 3. The totals may be greater than 100% because some reoperations were performed for multiple reasons.

There were 293 reoperations performed on 225 patients through 5 years. The most common reason for reoperation through 5 years was implant deflation (18.1% of the 293 reoperations).

Through 10 years, there were 424 reoperations performed in 315 patients. The most common reason for reoperation through 10 years was also implant deflation (21.7% of the 424 reoperations).

6.5 What Were the Reasons for Implant Removal?

Table 4 in the Appendix details the primary reasons for implant removal.

In the A95 Study through 5 years, there were 166 devices removed in 98 patients. Of these 166 devices, 156 were replaced and 10 were not. The most common reason for implant removal was patient request for a size or style change (43.4% of the implants removed).

For the PASS Study, there were 300 devices removed in 170 patients through 10 years. The most common reason for implant removal was also patient request for a size or style change (41.3% of the implants removed).

6.6 What Were the Complication Rates After Implant Replacement?

There were 78 patients in the A95 Study who had 126 implants removed and replaced with *NATRELLE*® Saline-Filled Breast Implants. Table 5 in the Appendix reflects the number of replaced implants (not patients) out of 100 implants associated with the listed complications within 3 years following replacement. For example there was capsular contracture in 13.2% or 13 out of 100 implants at some time within 3 years after replacement. The complications reported following implant replacement were restricted to the same ones collected in the Large Simple Trial and the information was collected only through 3 years.

6.7 What Were the Breast Disease and CTD Events?

Below is a summary of clinical findings from the A95 Study with regard to breast disease and connective tissue disease (CTD).

Breast Disease

There were 81 reports of breast disease through 5 years; 80 of which were benign. One malignancy was reported.

Connective Tissue Disease

There were 7 confirmed reports of connective tissue disease (CTD) through 5 years. Confirmed reports were based on a diagnosis by a doctor. These included three instances of Graves' disease and two each of hyperthyroiditis and chronic fatigue syndrome or fibromyalgia. It cannot be concluded that these CTD diagnoses were caused by the implants because there was no comparison group of similar women without implants.

7. Primary Breast Reconstruction Study Results

This section summarizes the results of the clinical studies conducted on *NATRELLE*® saline-filled breast implants for primary reconstruction.

7.1 What Were the Follow-Up Rates?

Follow-up rates from a clinical study show you how many women provided information on their experience with breast implants. High participation of patients demonstrates that the data you review in the sections below are based upon a satisfactory number of participants.

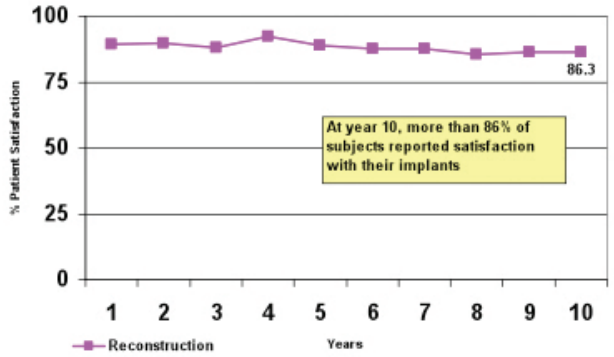
The R95 Study enrolled 237 reconstruction patients, with 80% returning for their 5-year follow-up visit. Of the women expected to return completed surveys for the 10-year post-implantation study interval, data were collected for 86% of the reconstruction patients.

7.2 What Were the Benefits?

The benefits of saline-filled breast implants in the R95 Study were assessed by patient satisfaction and quality of life. These outcomes were assessed for patients with both original and replacement saline devices before implantation and at 3 years after surgery for quality of life measurements and at every follow-up visit for patient satisfaction.

Patient Satisfaction: Allergan's patient satisfaction was based on a 5-point scale assessment of satisfaction with their implants at the time of the follow-up visits. 137 of the original 237 patients (58%) were included in an analysis of satisfaction at 5 years. Of these 137 patients, 89% indicated being satisfied with their breast implants at 5 years. At 10 years post-implant 86% of the patients who provided satisfaction scores on a 6-point scale indicated being satisfied with their breast implants (Figure 3).

Figure 3. Primary Reconstruction Patient Satisfaction
(responses of somewhat satisfied, satisfied, or definitely satisfied)



Quality of Life: Before implantation, reconstruction patients scored higher (better) than the general U.S. female population before implantation on all but one of the SF-36 scales, which measure general health-related quality of life. After 3 years, reconstruction patients showed an improvement in that SF-36 score to above the rate for the general U.S. female population. The following three overall scales showed no change over the 3 years: Tennessee Self Concept Scale (which measures overall self concept), Rosenberg Self Esteem Scale (which measures overall self-esteem), and the Body Esteem Scale (which measures overall body image).

Breast satisfaction was significantly increased after 3 years, including overall satisfaction and how well they matched.

7.3 What Were the Complication Rates?

The 5-year complication rates from the R95 Study are presented in the Appendix, Table 6. The rates reflect the number of reconstruction patients out of 100 who experienced the listed complication at least once within the first 5 years after implantation. Some complications occurred more than once for some patients. The two most common complications experienced within the first 5 years of implantation were reoperation (44.5% or about 45 patients out of 100) and asymmetry (39.0% or 39 patients out of 100).

The 10-year complication rates from the PASS Study are presented in the Appendix, Table 7. These results are from patient surveys. The surveys contained only the complications listed in Table 7. The rates reflect the number of reconstruction patients out of 100 who experienced the listed complication at least once within the first 10 years after implantation. The most common complication experienced through 10 years was reoperation (54.6%, almost 55 out of every 100 patients).

7.4 What Were the Reasons for Reoperation?

There may be one or more reasons identified for having a reoperation (additional surgery after the primary 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.

The reasons for reoperation through 5 years in the R95 Study and through 10 years in the PASS Study are presented in the Appendix, Table 8. The totals may be greater than 100% because some reoperations were performed for multiple reasons.

There were 125 reoperations performed in 99 patients through 5 years. The most common reason for reoperation through 5 years was capsular contracture (27.2% of the 125 reoperations). This does not include planned reoperations like nipple procedures.

There were 159 reoperations performed in 120 patients through 10 years in the PASS Study. The most common reason for reoperation through 10 years was also capsular contracture (23.3% of the 159 reoperations).

7.5 What Were the Reasons for Implant Removal?

Table 9 in the Appendix details the primary reasons for implant removal.

In the R95 Study through 5 years, there were 70 devices removed in 62 patients. Of these 70 devices, 49 were replaced and 21 were not. The most common reason for implant removal was capsular contracture (31.4% of the 70 implants removed).

Through 10 years in the PASS Study, there were 104 implants removed from 85 patients. The most common reason for implant removal was implant deflation (32.7% of the implants removed).

7.6 What Were the Complication Rates After Implant Replacement?

There were 37 patients in the R95 Study who had 40 implants removed and replaced with *NATRELLE*® saline implants. Table 10 in the Appendix reflects the number of replaced implants (not patients) out of 100 implants associated with the listed complications within 3 years following replacement. For example there was capsular contracture in 33.8% or about 34 out of 100 implants at some time within 5 years after replacement. The complications reported following implant replacement were restricted to the same ones collected in the Large Simple Trial.

7.7 What Were the Breast Disease and CTD Events?

Below is a summary of clinical findings from the R95 Study with regard to breast disease and connective tissue disease (CTD).

BREAST DISEASE

There were 99 reports of breast disease through 5 years; 75 of which were benign and 24 were malignant.

CONNECTIVE TISSUE DISEASE

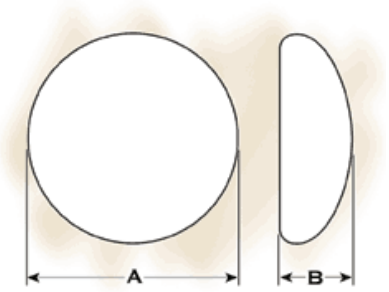
There was one confirmed report of Graves' disease through 5 years. It cannot be concluded that these CTD diagnoses were caused by the implants because there was no comparison group of similar women without implants.

8. Additional Information

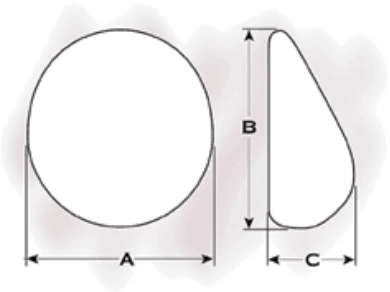
8.1 Types of *NATRELLE*® Saline-Filled Breast Implants Available from Allergan

NATRELLE® saline-filled breast implants come in a variety of shapes and sizes. All implants have a self-sealing (diaphragm) valve that is used for filling the device. Depending on the style, the filling valve may be located on the front (anterior) or the back (posterior) of the implant. Your surgeon will discuss with you the implant design that will best help you achieve the result that is right for you.

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



A = Width; B = Projection
Round Breast Implant



A = Width; B = Height; C= Projection
Shaped Breast Implant

8.2 Device Identification Card

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

8.3 What is Device Tracking

Natrelle Saline Filled Breast Implants are subject to Device Tracking. This means that your physician will be required to submit to Allergan the serial number of the implant(s) you receive, the date of surgery, information relating to the physician's practice and information on the patient receiving the implant(s). Your surgeon will write this information on the Device Tracking

Form supplied by Allergan with each breast implant. Your surgeon will return the first page to Allergan following surgery. The second page of the form will be provided to you following surgery. You have the right to remove your personal information from Allergan's Device Tracking program. If you choose NOT to participate in Device Tracking, please check the appropriate box on the Device Tracking form and return to Allergan. You also have the right to have your personal information withheld from disclosure to third parties who may request information from Allergan, such as the Health Canada. 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. Please note that there may be instances where Allergan is legally required to share your patient specific information as per applicable regulation.

Allergan strongly recommends that all patients receiving *NATRELLE®* Breast Implants participate in Allergan's Device Tracking program. This will help ensure that Allergan has a record of each patient's contact information so that all patients can be contacted in the case of a recall or other problems with your implants.

8.4 If You Experience a Problem

If you believe that you have experienced a serious problem(s) related to your breast implants, you should contact your health professional.

8.5 How To Receive More Information

You may access the package insert (Information for Physicians/Directions for Use; *NATRELLE®* Saline-Filled Breast Implants document) online at
English: www.allergan.ca/en-ca/products/medical-devices
French: www.allergan.ca/fr-ca/products/medical-devices
or 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 Basis for Decision (SBD) for this product which may be accessed on Health Canada's website (www.hc-sc.gc.ca).

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

TOLL-FREE NUMBER

If you are a patient or a prospective patient and wish to speak to an Allergan Breast Implant Support Specialist to inquire about breast implants, discuss any concerns, or request a copy of the patient labeling or package insert (Directions for Use), call toll free at 1.800.362.4426 (7 am to 5 pm Pacific Time).

ADDITIONAL RESOURCES

Allergan
1.800.624.4261
www.natrelle.ca
www.natrelle.com
www.allergan.ca
www.allergan.com

Health Canada
www.hc-sc.gc.ca

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

Food and Drug Administration
1.888.INFO.FDA or 1.301.827.3990
www.fda.gov/breastimplants

BREAST RECONSTRUCTION RESOURCES

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

National Cancer Institute
1.800.422.6234
www.nci.nih.gov/

American Cancer Society
1.800.ACS.2345
www.cancer.org/

Y-ME National Breast Cancer Organization
1.800.221.2141
www.y-me.org/

APPENDIX – DATA TABLES

The data tables from Allergan's A95, R95, and PASS clinical studies are located in this section. These tables are a supplement to the text found in sections 5 and 8. For any terms you do not understand, please refer to the glossary at the front of this brochure.

Table 1

Primary Augmentation: Complications from A95 Study

Complication*	5-Year Complication Rate N = 901 Patients
Additional Operation (Reoperation)	25.9%
Breast Pain	17.0%
Wrinkling	13.7%
Asymmetry	12.2%
Implant Palpability/Visibility	12.1%
Implant Replacement/Removal for Any Reason	11.8%
Capsular Contracture Baker Grade III/IV	11.4%
Loss of Nipple Sensation	9.9%
Intense Nipple Sensation	9.8%
Implant Malposition	9.2%
Intense Skin Sensation	7.6%
Implant Deflation	6.8%
Scarring Complications	6.5%
Irritation/Inflammation	3.2%
Seroma	2.6%
Skin Rash	1.9%
Capsule Calcification	1.8%
Hematoma	1.7%
Delayed Wound Healing, Infection	≤1% each

* Many events were assessed with severity ratings, and for these complications the rates shown in the table include only complications rated moderate, severe, or very severe (excludes mild and very mild ratings). All occurrences are included for reoperation, implant removal, leakage/deflation, scarring complications, irritation/inflammation, seroma, hematoma, skin rash, infection, implant extrusion, and tissue/skin necrosis.

Table 2

Primary Augmentation: Complications from the PASS Study

Complication	10-Year Complication Rate N = 901 Patients
Reoperation	36.5%
Breast Pain	29.7%
Capsular Contracture Baker Grade III/IV	20.8%
Implant Removal	20.2%
Implant Deflation	13.8%

Table 3
Primary Augmentation: Reason for Reoperation
in the A95 and PASS Studies

Reasons for Reoperation	5-Years	10-Years
	% (N = 293 Reoperations)	% (N = 424 Reoperations)
Implant Deflation	18.1%	21.7%
Capsular Contracture	17.7%	13.9%
Patient Choice for Style/Size Change	15.3%	20.7%
Implant Malposition	9.6%	8.5%
Hematoma/Seroma	8.9%	7.3%
Lump/Mass/Cyst	8.5%	15.6%
Scarring	7.2%	5.2%
Ptosis	5.8%	7.3%
Asymmetry	4.8%	3.3%
Add/Remove Saline	4.8%	5.0%
Wrinkling	2.7%	1.9%
Unsatisfactory Nipple Result	1.7%	1.2%
Implant Palpability	1.4%	1.2%
Delayed Wound Healing, Infection, Skin Lesion/Cyst, Infection	1.4%	<1%
Skin Lesion/Cyst	1.0%	<1%
Capsule Calcification, Breast Pain, Implant Extrusion, Irritation, Cancer	<1% each	<1% each

Table 4
Primary Augmentation: Main Reason for Implant Removal
in the A95 and PASS Studies

Primary Reason for Implant Removal	Through 5 Years	Through 10 Years
	% (N = 166 Implants)	% (N = 300 Implants)
Patient Choice for Style/Size Change	43.4%	41.3%
Implant Deflation	31.9%	33.3%
Capsular Contracture	10.2%	9.0%
Wrinkling	3.6%	2.7%
Implant Palpability/Visibility	3.6%	2.0%
Asymmetry	1.8%	2.7%
Breast Pain	1.8%	1.0%
Implant Malposition	1.2%	5.3%
Infection, Implant Extrusion, Damage to Implant During Surgery, Unknown	<1% each	<1% each
Breast Mass/Lump/Cyst	0	1.3
Total	**100%**	**100%**

Table 5

Primary Augmentation: Complication Rates after Implant Replacement

Complication Following Replacement of Augmentation Implant(s)	5-Year Complication Rate % (N = 126 Implants)
Removal/Replacement	18.3%
Capsular Contracture Baker Grade III/IV	13.2%
Implant Deflation	9.0%
Infection	2.5%

Table 6

Reconstruction: Complications from R95 Study

Complications*	5-Year Complication Rate N = 237 Patients
Additional Operation (Reoperation)	44.5%
Asymmetry	39.0%
Capsular Contracture Baker Grade III/IV	35.7%
Implant Replacement/Removal for Any Reason	28.0%
Implant Palpability/Visibility	27.1%
Wrinkling	24.6%
Loss of Nipple Sensation	18.1%
Breast Pain	17.7%
Implant Malposition	16.9%
Implant Deflation	7.5%
Irritation/Inflammation	6.6%
Intense Skin Sensation	6.3%
Scarring Complications	6.0%
Infection	6.0%
Capsule Calcification	5.4%
Seroma	3.9%
Tissue/Skin Necrosis	3.6%
Skin Rash	3.3%
Implant Extrusion	3.2%
Delayed Wound Healing	2.7%
Hematoma	1.3%

* Many events were assessed with severity ratings, and for these complications the rates shown in the table include only complications rated moderate, severe, or very severe (excludes mild and very mild ratings). All occurrences are included for reoperation, implant removal, leakage/deflation, scarring complications, irritation/inflammation, seroma, hematoma, skin rash, infection, implant extrusion, and tissue/skin necrosis.

Table 7
Reconstruction: Complications from PASS Study

Complication	10-Year Complication Rate N = 237 Patients
Reoperation	54.6%
Capsular Contracture Baker Grade III/IV	51.7%
Implant Removal	39.5%
Breast Pain	33.0%
Implant Deflation	22.5%

Table 8
Reconstruction: Reason for Reoperation in the R95 and PASS Studies

Reasons for Reoperation	5 Years	10 Years
	% (N = 125 Reoperations)	% (N = 159 Reoperations)
Capsular Contracture	27.2%	23.3%
Asymmetry	20.0%	15.7%
Patient Choice for Style/Size Change	10.4%	13.8%
Implant Deflation	8.8%	18.2%
Implant Malposition	8.8%	8.8%
Lump/Mass/Cyst	8.0%	10.1%
Scarring	8.0%	6.9%
Infection	7.2%	5.7%
Tissue/Skin Necrosis	4.8%	3.8%
Hematoma/Seroma	4.8%	3.8%
Breast Pain	4.8%	3.8%
Implant Extrusion	4.0%	3.1%
Wrinkling	4.0%	3.1%
Add/Remove Saline	3.2%	3.1%
Implant Palpability	2.4%	1.9%
Delayed Wound Healing	1.6%	1.3%
Skin Lesion/Cyst	1.6%	1.3%
Unsatisfactory Nipple Result	<1%	1.3%
Cancer	N/A	<1%

Table 9

Reconstruction: Main Reason for Implant Removal in the R95 and PASS Studies

Primary Reason for Implant Removal	Through 5 Years	Through 10 Years
	% (N = 70 Implants)	% (N = 104 Implants)
Capsular Contracture	31.4%	21.2%
Patient Choice for Style/Size Change	21.4%	25.0%
Implant Deflation*	14.3%	32.7%
Infection	10.0%	6.7%
Implant Extrusion	5.7%	3.8%
Implant Malposition	4.3%	2.9%
Other**	4.3%	2.9%
Wrinkling	2.9%	1.9%
Asymmetry	1.4%	1.9%
Recurrent Breast Cancer	1.4%	1.0%
Total	**100%**	**100%**

* Includes removals where the reason for removal was unknown.

** Through 5 years, other reasons were *abnormality of CT scan at mastectomy site, poor tissue expansion due to radiation, second stage breast reconstruction*. Through 10 years, other reasons as reported by the physician were: *abnormality on CT scan at mastectomy site* (n=1), *tissue expansion went poorly due to radiation* (n=1), *second stage breast recon* (n=1).

Table 10

Reconstruction: Complication Rates after Implant Replacement, By Implant

Complication Following Replacement of Reconstruction Implant(s)	5-Year Complication Rate % (N = 40 Implants)
Capsular Contracture Baker Grade III/IV	33.8%
Removal/Replacement	26.9%
Implant Deflation	9.5%
Infection	2.9%

Checklist for you and your surgeon to review

Preoperative Checklist

☐ PATIENT SELF ASSESSMENT

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

☐ PATIENT SURGERY RECORD

Important pre- and post-operative appointments and related information recorded by the patient

Checklist for you and your surgeon to review.

Postoperative Checklist

☐ *NATRELLE*® DEVICE IDENTIFICATION CARD(S)

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

☐ DEVICE TRACKING FORM

Completed and returned by the patient to Allergan if applicable

☐ OPTIONAL *CONFIDENCEPLUS*® WARRANTY ENROLLMENT FORM

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

☐ INFORMATION FOR YOUR HEALTHCARE PROVIDERS

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

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

Patient Self-Assessment

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

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

If signs of rupture are seen on an MRI, you should consider implant removal. Ultimately, implant removal is a medical decision to be made in consultation with your doctor.

☐ TRUE ☐ FALSE

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

☐ TRUE ☐ FALSE

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

☐ TRUE ☐ FALSE

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

☐ TRUE ☐ FALSE

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

☐ TRUE ☐ FALSE

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

☐ TRUE ☐ FALSE

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

☐ TRUE ☐ FALSE

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

☐ TRUE ☐ FALSE

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

☐ TRUE ☐ FALSE

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

Patient Surgery Record

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

Preoperative mammogram
baseline (if necessary):_____

Preoperative appointment date:_____

Surgery date: _____

Surgery location: _____

Contact person at
surgery location: _____

Contact phone number: _____

First postoperative
appointment date: _____

Subsequent postoperative
appointment dates:_____

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

NATRELLE® Device Identification Card(s) Information

Record information from your *NATRELLE*® Device Identification Card(s) below and then place your card(s) in the pockets on the front cover of this planner to keep as a record.

Catalog Number: Left_____

Catalog Number: Right _____

Serial Number: Left_____

Serial Number: Right _____

Optional additional coverage from a trusted industry leader.

Optional *ConfidencePlus*® Premier Warranty Enrollment

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

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

Adverse Event	Warranty program
BIA-ALCL confirmed	Complimentary product replacement plus financial assistance up to $7,500USD. Allergan will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of $7,500USD.
Rupture (Silicone-Filled only)	Complimentary product replacement plus financial assistance up to $3,500USD. Allergan will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of $3,500USD. Allergan will pay up to this amount for all silicone implants implanted within the last 10 years.
Deflation (Saline-Filled only)	Complimentary product replacement plus financial assistance up to $1,200USD. Allergan will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of $1,200USD. Allergan will pay up to this amount for all saline implants implanted within the last 10 years. * For *ConfidencePlus*® Premier Warranty, Allergan will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of $3,500USD. Allergan will pay up to this amount for all saline implants implanted within the last 10 years.
Capsule Contracture	Complimentary product replacement up to 10 years following the date of implantation surgery.
Late Seroma	Complimentary product replacement up to 10 years following the date of implantation surgery.

** subject to review and approval by Allergan after submission of all required documentation including: PFN complaint form, photo and/or operative note & explant*

Our standard *ConfidencePlus*® warranty applies automatically to every *NATRELLE*® breast implant recipient and includes lifetime product replacement, and up to $1,200 US in financial assistance subject to the conditions discussed in the *ConfidencePlus*® literature.

The optional *ConfidencePlus*® Premier breast implant limited warranty provides all the peace of mind included with our standard *ConfidencePlus*® warranty program, but increases the financial assistance to $3,500 US. for the low enrollment fee of $200 US.[1]

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

To enroll in our optional *ConfidencePlus*® Premier breast implant limited warranty program use the information contained on your *NATRELLE*® Device Identification Card(s) supplied to you after surgery or complete the enrollment form that follows this page. Once complete, detach the form from this breast implant surgery planner and mail it to Allergan in the envelope provided. You may also fax your completed enrollment form with credit card information to 1.888.647.4029.

Your enrollment form and $200 US must be received or postmarked within 45 days of surgery and must accompany a certified check, money order, or valid credit card number in order to process your purchase. DO NOT SEND A PERSONAL CHECK. *ConfidencePlus*® Premier enrollment forms that accompany a personal check will NOT be processed.

For complete NATRELLE ConfidencePlus warranty program details and restrictions, or to purchase the Premier warranty option, please visit www.cppwarranty.ca

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

CONFIDENCEPLUS® PREMIER LIMITED WARRANTY OPTION

Use the information contained on your Patient/Device ID Card(s) supplied to you after surgery to complete the optional *ConfidencePlus*® Premier warranty purchase form. Once complete, detach this form from the breast implant surgery planner and mail it to Allergan in the envelope provided.

Your purchase form and $200 US must be postmarked within 45 days of surgery and must accompany a certified check, money order or valid credit card number in order to process your purchase. Do not send a personal check.

If paying by certified check or money order, make check payable to Allergan *ConfidencePlus*® Premier Limited Warranty.

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

Allergan
301 W. Howard Lane, Suite 100
Austin, TX 78753
United States of America
Fax 1.888.647.4029

PAYING BY CREDIT CARD

Credit Card Type: ☐ Visa ☐ MasterCard ☐ American Express

Card Number: _____ Expiration Date: _____

Cardholder Name if other than patient: _____

PERSONAL INFORMATION

Name: _____

Address: _____

City: _____

Province: _____

Postal Code: _____

Country: _____

ONLY ONE OPTION BELOW IS REQUIRED FOR VERIFICATION

Driver's License # and Province of Issue: _____

Mother's Maiden Name: _____

SURGERY AND IMPLANT INFORMATION

Implanting Surgeon Name: _____

Address: _____

City: _____

Province: _____

Postal Code: _____

Phone Number: _____

Date of Surgery: _____

Implant Serial Number(s): _____

Take this information about your implant surgery to your Mammography Center.

Information for the Mammography Center

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

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

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

Health Canada
www.hc-sc.gc.ca

Food and Drug Administration
www.fda.gov/breastimplants

Breast Implant Safety
www.breastimplantsafety.org

NATRELLE® Collection of Breast Implants
www.natrelle.ca

PATIENT INSTRUCTIONS

Please record the catalog and serial number(s) exactly as they appear on your *NATRELLE*® Device Identification Card(s) before giving this page to your **Mammography Center**.

Location of implants
(submuscular or subglandular): _____

Catalog Number: Left_____

Catalog Number: Right _____

Serial Number: Left_____

Serial Number: Right _____

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

Information for Your Primary Care Physician

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

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

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

Health Canada
www.hc-sc.gc.ca

Food and Drug Administration
www.fda.gov/breastimplants

Breast Implant Safety
www.breastimplantsafety.org

NATRELLE® Collection of Breast Implants
www.natrelle.ca

PATIENT INSTRUCTIONS

Please record the catalog and serial numbers exactly as they appear on your *NATRELLE*® Device Identification Card(s) before giving this page to your **Primary Care Physician**. If you have multiple primary care physicians make copies of this form before providing it to your physician.

Location of implants
(submuscular or subglandular): _____

Catalog Number: Left_____

Catalog Number: Right _____

Serial Number: Left_____

Serial Number: Right _____

Acknowledgement of Informed Decision and Patient Decision Checklist

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

I have had adequate time to review and understand the information presented in the patient information documents. My concerns and questions have been addressed by my doctor. I have considered alternatives to augmentation surgery, including use of external prostheses or surgery with saline-filled breast implants

Patient Decision Checklist

To the patient considering breast implants filled with saline or silicone gel intended for breast augmentation or breast reconstruction:

The review and understanding of this document is a critical step in making the decision whether you should choose breast implant surgery. You should learn about breast implants and then carefully consider the benefits and risks associated with breast implants and breast implant surgery before you make that decision. This form lists important risks, including those known or reported to be associated with the use of the device based on information from clinical trials, scientific literature, and reports from patients who have undergone device placement.

This Patient Decision Checklist is intended to supplement the additional patient information documents that should be provided to you by your physician. You should receive patient information documents that include important information about your specific breast implant, as well as a boxed warning and Patient Decision Checklist. After reviewing the information in the patient information documents for the specific implant that will be used, please read and discuss the items in this checklist carefully in consultation with your physician. You should place your initials in the location provided next to each item to indicate that you have read and understood the item. Your full signature at the end of this document confirms that you have read the materials and that your physician has answered all questions to your satisfaction.

Health Canada has launched a new way for patients, healthcare professionals, and others to register to receive direct alerts about breast implant recalls and safety issues. This includes the following:

- the subscription service for breast implants offered by Health Canada (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/subscribe.html)
- the Health Canada website on breast implants (https://www.canada.ca/en/health-canada/services/drugs-medical-devices/breast-implants.html) and
- the new subscription service to receive information about breast implant recalls (https://recalls-rappels.canada.ca/en/subscribe)

Considerations for a Candidate for Successful Breast Implantation

I understand that I am not a candidate for breast implants if any of the following situations applies to me:

- I have an active infection anywhere in my body;
- I have an existing cancer or pre-cancer of my breast tissue that has not been adequately treated; or
- I am pregnant or nursing.

I understand that if I have any of the following conditions, I may be at a higher risk for a poor surgical outcome:

- Medical condition that affects my body's ability to heal (e.g., diabetes, connective tissue disorder);
- Active smoker or a former smoker;
- Currently taking drugs that weaken the body's natural resistance to disease, such as steroids and chemotherapy drugs (e.g., prednisone, tacrolimus, sirolimus, mycophenolate, azathioprine, cyclosporine, methotrexate, chlorambucil, leflunomide, or cyclophosphamide);
- History of chemotherapy or planned chemotherapy following breast implant placement;
- History of radiation therapy or planned radiation following breast implant placement;
- Conditions that interfere with wound healing or blood clotting (e.g., hemophilia, von Willebrand disease, factor V Leiden, hyperhomocysteinemia, protein C deficiency, antithrombin III deficiency, or systemic lupus erythematosus); or
- Reduced blood supply to the breast tissue.

I understand the following conditions have not been adequately studied to determine whether the conditions put me at higher risk:

- Autoimmune disease (e.g., Hashimoto's, Lupus, Rheumatoid Arthritis) or family history of autoimmune disease (breast implant premarket clinical studies have not evaluated the safety of breast implants in patients with autoimmune disease);
- Clinical diagnosis of depression or other mental health disorder (including body dysmorphic disorder or eating disorder); or
- Have other products permanently implanted in the breast.

Patient Initials: _____

Risks of Breast Implant Surgery

I understand that there are risks of undergoing breast implant surgery. I understand that risks of undergoing breast implant surgery may include:

- breast pain (reported in up to 33% of patients[1]),
- skin or nipple areola sensitivity changes or loss (loss of nipple sensation reported in up to 18.1% of patients[2], intense nipple sensation reported in up to 9.8% of patients[2] and intense skin sensation reported in up to 7.6% of patients[2]),
- asymmetry (reported in up to 39.0% of patients[2]),

[1] Based on the largest complication rate reported in the A95/R95 Clinical Study through 10 years of follow-up. See Sections 6 and 7 of the Natrelle Saline Filled Breast Implants Patient Document

[2] Based on the largest complication rate reported in the A95/R95 Clinical Study through 5 years of follow-up. See Sections 6 and 7 of the Natrelle Saline Filled Breast Implants Patient Document

- impact of aging or weight change on size and shape of breast (may occur in saline procedures but specific rates are not publicly available in the Allergan clinical studies),
- infection requiring possible removal of implant (reported in up to 6.0% of patients[2]),
- swelling (may occur in saline procedures but specific rates are not publicly available in the Allergan saline clinical studies)
- scarring (scarring complications reported in up to 6.5% of patients[2]),
- fluid collections (seroma) (reported in up to 3.9% of patients[2]),
- hematoma (reported in up to1.7% of patients[2]),
- tissue death of breast skin or nipple (tissue/skin necrosis reported in up to 3.6% of patients[2]),
- inability to breast feed (may occur but specific rates are not publicly available in the Allergan clinical studies),
- complications of anesthesia (may occur but specific rates are not publicly available in the Allergan clinical studies),
- bleeding (may occur but specific rates are not publicly available in the Allergan clinical studies)
- chronic pain (may occur but specific rates are not publicly available in the Allergan clinical studies)
- damage to surrounding tissue, such as muscle, nerves, and blood vessels (may occur but specific rates are not publicly available in the Allergan clinical studies)
- impact on imaging of breast tissue (may occur but specific rates are not publicly available in the Allergan clinical studies).

My physician has discussed these risks and has provided me with the patient information documents (including the boxed warning) with information on the types of risks that are possible and expected rates of occurrence.

My physician has discussed the potential use of other implanted products during my breast implant surgery. My physician has also discussed the risks and benefits of using these implanted products and their planned surgical approach.

Patient Initials: _____

Risk of Cancer - Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA- ALCL)

I understand that breast implants are associated with the development of a type of cancer of the immune system called Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Information regarding the number of medical device reports of BIA-ALCL can be found on FDA's website.[3] Discussion of the risk of BIA-ALCL can be found on Health Canada's website.[4]

As of July 2019, literature reports various estimates for the incidence of BIA-ALCL. These estimated incidence rates range from a high of 1 per 3, 817 patients to 1 in 30,000. (Clemens et al, 2017, Loch-Wilkinson et al, 2017, De Boer et al, 2018).

I have received information regarding the overall incidence rates of BIA-ALCL and the rates as they pertain to my specific breast implant.

[3] See "Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma," available at https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma
[4] https://www.canada.ca/en/health-canada/services/drugs-medical-devices/breast-implants/risks.html#rare_risk

I understand that this cancer has been reported more frequently for textured breast implants but patients with smooth surfaced implants have also been diagnosed.

I understand that patients with breast implants have a risk of developing BIA-ALCL within the scar tissue and fluid surrounding the breast implant.

I understand that BIA-ALCL typically takes several years to develop after implantation, but cases have been reported as early as within one year. Typical symptoms to be aware of may include: breast tightness, pain, lumps, or swelling of the breast months or years after I receive my implants.

I understand that treatment for BIA-ALCL involves an operation to remove the implants and the surrounding scar tissue capsule. Based on the stage of the cancer at diagnosis, some patients have required chemotherapy or radiation. While BIA- ALCL typically responds well to therapy, some patients have died from BIA-ALCL. Diagnosis and treatment may be at my own expense and is not always covered by insurance.

Patient Initials: _____

Systemic Symptoms

I understand that some patients who have received breast implants have reported a variety of systemic symptoms including joint pain, fatigue, rash, memory loss and "brain fog" that some patients have called breast implant illness. While the causes of these symptoms are unclear, some patients have reported relief of these symptoms with removal of their implants and surrounding scar capsule, however not all patients may experience improvement in their symptoms. Researchers are working to better understand the possible link between breast implants and these symptoms.

I also understand that some patients with breast implants have reported health problems in their children after birth or breastfeeding. A causal link has not been established between breast implants and these reported health problems in children and more research is needed. I understand that breast implants and breast surgery may interfere with my ability to successfully breastfeed.

Patient Initials: _____

Breast-Implant Specific Risks

I understand that a breast implant is NOT a lifetime device and the longer I have my implants, the more likely I am to experience a complication and the more likely I am to need a reoperation requiring the replacement or removal of my breast implant. As many as 20.2% of women who received Allergan saline breast implants for augmentation had their implants removed within 10 years, but my implants may last for a shorter or longer period of time. (The percentage reported is from the 10-year A95/R95 Clinical Study for Natrelle Saline-filled breast implants.)

I understand that my breast implant may rupture or leak at any time, and that the longer I have my implants, the more likely I am to experience a complication such as rupture. I understand that gel bleed (small quantities of gel diffusing from the implant shell) of silicone gel-filled implants may occur. I understand that if I have a saline-filled implant, my breast may deflate in appearance if there is a rupture or leakage of the saline.

I understand that if I have a silicone gel-filled breast implant, I or the physician may not be able to tell on physical exam whether my implant has ruptured or is leaking silicone gel. Because rupture or leakage of silicone gel-filled breast implants is difficult to detect, I understand that periodic imaging evaluation is recommended for screening of silicone gel-filled breast implant rupture. It is recommended that I have periodic imaging of my silicone gel-filled breast implants to screen for implant rupture regardless of whether my implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on my medical history or circumstances (i.e., screening mammography for breast cancer).

Even if I have no symptoms, I should have regular imaging evaluations as described in the "Recommended Follow-Up" section below. These imaging evaluations may not detect all ruptures or leaks, and the expense may not be covered by my medical insurance.

I understand that there are rare case reports of silicone migrating from breast implants into tissues (e.g., chest wall, lymph nodes under the arm) and organs (e.g., liver, lungs). It may not be possible to remove migrated silicone.

I understand that all breast implants can affect mammography and breast exams, which could potentially delay the diagnosis of breast cancer. Mammography can also cause the breast implant to rupture or leak. I should tell the mammography technician if I have breast implants.

I understand that the long-term risks of breast implants may include:

- painful or tightening of scar tissue (capsule) around my implant (capsular contracture III/IV) (reported in up to 51.7% of patients[1]),
- rupture or leaking of the implant (implant deflation reported in up to 22.5% of patients[1]),
- wrinkling of the implant (wrinkling/rippling reported in up to 24.6% of patients[2]),
- visibility of the implant edges (implant palpability/visibility reported in up to 27.1% of patients[1]),
- shifting of the implant (implant malposition reported in up to 16.9% of patients[2]), or
- reoperation (reported in up to 54.6% of patients[1]).

I understand that I will receive a Device Identification Card after my surgery that has information on each of my specific implants. I understand that it is important for me to keep each card in case, at some time in the future, I or my physician need to know what kind of implant I received many years later.

I understand that breast implant manufacturing requires the use of chemicals and heavy metals. I understand that most of these chemicals stay inside the shell of the implant. Small quantities may diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking.

A list of the components, chemicals, and heavy metals is available in section entitled, "NATRELLE Silicone-Filled/Saline-Filled Breast Implant Materials" of the patient information document.

Patient Initials: _____

Recommended Follow-up

Even if I have no symptoms, I understand that I should screen for implant rupture, which involves a multi-step process that starts with self-examination and physician examination and may include additional imaging assessments.

I understand that for as long as I have my breast implant(s), I will need routine and regular follow-up with my physician for examination of my breast implant(s) as well as to discuss any updates regarding breast implant issues.

Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma (ALCL) etiology and Epidemiology (PROFILE): I understand and have discussed with my physician that there is a registry (PROFILE) where information is collected to better understand BIA-ALCL in patients with breast implants.

Patient Initials: _____

Questions for My Physician

I have had the opportunity to ask my physician questions about his or her experience, medical degree, specialty of training, and credentials. I understand that breast implants have associated procedural risks and should only be used by physicians who are appropriately trained.

Patient Initials: _____

Options Following Mastectomy

I understand that breast reconstruction is an elective procedure, which I can choose to do or not.

I understand that I may choose not to have breast reconstruction ("going flat") and may choose to use an external prosthesis in my bra to look like I have a breast when wearing clothes.

I understand the surgical options for breast reconstruction, including the use of a breast implant and the use of my own tissue ("autologous reconstruction").

I understand that if my breast implants are ever removed, I may be left with dimpling, chest wall concavity, puckering, or sagging of my breasts or skin.

I understand that more surgeries may be necessary in the future due to complications or to remove or replace the breast implants.

I have discussed all of the options for breast reconstruction with my provider, including whether I am a candidate and the benefits and risks of each, and I believe that breast reconstruction with a breast implant is the best option for me.

Patient Initials: _____

Breast Augmentation Options

I understand that breast augmentation is an elective procedure to increase the size of my breasts.

I understand that breast augmentation may result in permanent changes to my breast tissue and if my implants are ever removed, I may be left with unsatisfactory appearance, changes to the size and shape of my breasts, including but not limited to dimpling, chest-wall concavity, puckering, sagging, or different incision size or location.

If I am an augmentation patient, any additional surgeries or medical procedures will likely be at my own expense.

Patient Initials: _____

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the patient information documents for the specific implant that will be used during my surgery and that I have had time to discuss the information in it and on this document with my physician. I have had the opportunity to ask questions and understand the benefits and risks of breast implants for me, given my specific health conditions. I have considered alternatives to breast implants, including reconstruction without breast implants, no reconstruction/ augmentation, and their benefits and risks.

_____

Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of breast implants as described elsewhere in the patient information documents and in this checklist. I have also explained the benefits and risks of the alternatives. I have encouraged the patient to ask questions, and I have addressed all questions.

_____

Physician Signature and Date

Allergan
85 Enterprise Blvd., Suite 500
Markham, ON L6G 0B5

Allergan Sales, LLC
2525 Dupont Drive
Irvine, CA 92612

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