Breast Reconstruction with *NATRELLE*® Gel-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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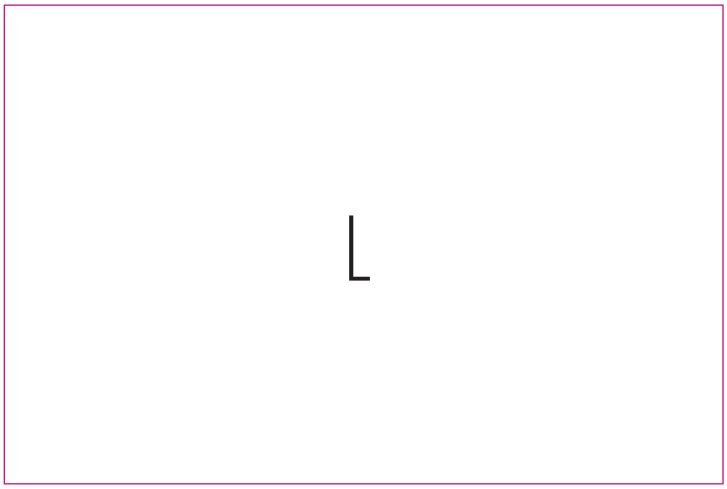

Place Your Device Identification Card(s) Here

Dear Patient,

Allergan has developed this BREAST SURGERY WITH *NATRELLE*® GEL-FILLED BREAST IMPLANTS PATIENT PLANNER to function as a resource for all aspects of your surgery. Please give yourself adequate time to consider this information before deciding to proceed with surgery.

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

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

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

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

SECTION I

- Important Information for Women About Breast Reconstruction with *NATRELLE*® Silicone-Filled Breast Implants

SECTION II — FORMS

- Preoperative and Postoperative Checklists and Instructions
- Patient Self Assessment
- Patient Surgery Record
- Optional *ConfidencePlus*® Premier Warranty Enrollment
- Mammography Information
- To the Primary Care Physician

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SECTION I

Important Information for Women About Breast Reconstruction with *NATRELLE*® Gel-Filled Breast Implants

Glossary

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

Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	Lack of proportion of shape, size, and/or position between the two breasts.
Atrophy	Thinning or diminishing of tissues or muscle.
Autoimmune disease	A disease in which the body mounts an "attack" response to its own tissues or cell types. Normally, the body's immune mechanism is able to distinguish clearly between what is a normal substance and what is foreign. In autoimmune diseases, this system becomes defective and mounts an attack against normal parts of the body, causing tissue injury. Certain diseases such as rheumatoid arthritis, lupus, and scleroderma are considered to be autoimmune diseases.
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 Dysmorphic Disorder	A psychological condition characterized by excessive worry about an imagined or minor physical flaw to the point that it can interfere with normal daily activities.
Body Esteem Scale	A questionnaire which asks about a person's body image.

Breast augmentation	A surgical procedure to increase breast size. For this document, it refers to placement of a breast implant.
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 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 pain and possibly abnormal appearance. Grade IV usually results in the need for additional surgery (reoperation) because of unacceptable appearance. Capsular contracture II may also result in the need for additional surgery. Capsular contracture is a risk for implant rupture. Below is a description of each Baker Grade. • 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.
Capsulorrhaphy	Surgical stitching of a tear in the scar tissue capsule around the implant.
Capsulotomy (closed)	An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but is a known risk for rupture of the implant and is contraindicated.

Capsulotomy (open)	Surgical incision into the scar tissue capsule around the implant.
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 anomaly	An abnormal development in part of the body, present in some form since birth.
Connective tissue disease/disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc., and/or the immune system. Connective tissue diseases ("CTDs") that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.
Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Contralateral	Opposite side.
Core Study	The primary clinical study of augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients with TruForm® 1 Gel-Filled Breast Implants that supported product approval. Safety and effectiveness data are collected yearly through 10 years, with the follow-up from years 5 through 10 being performed as part of a postapproval pivotal study.
Delayed wound healing	Delayed progress in the healing of an opened wound.
Displacement	Movement of the implant from the usual or proper place.

Epidemiological	Relating to the science of explaining the relationships of factors that determine disease frequency and distribution.
Extracapsular rupture	A type of rupture in which the silicone gel is outside of the scar tissue capsule surrounding the implant.
Extrusion	Skin breakdown with the pressing out of the implant through the surgical wound or skin.
Fibromyalgia	A disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue.
Fibrous tissues	Connective tissues composed mostly of fibers.
Flap	A portion of tissue (which may include muscle, fat, and skin) moved from one part of the body to another. The tissue flap may or may not have its blood supply attached.
Form stable	No migration of the gel; the device maintains its shape.
Gel bleed	When silicone gel leaks or "bleeds" or diffuses through the implant shell.
Gel fracture	Appearance of a fissure or fault line in highly cohesive gel in response to an applied force.
Granuloma	A lump or mass made of inflammatory cells surrounding a foreign substance due to longstanding inflammation.
Hematoma	A collection of blood within a space.
Hypertrophic scarring	An enlarged scar remaining after the healing of a wound.
Immune response	A bodily response to the presence of a foreign substance.
Incision	A cut made to the tissue during surgery.

Infection	Invasion with microorganisms (for example, bacteria, viruses). An infection usually results in fever, swelling, redness, and/or pain.
Inflammation	The response of the body to infection or injury that is characterized by redness, swelling, warmth, pain, and/or loss of function.
Inframammary	Below the breast.
Inframammary fold	The crease at the base of the breast and the chest wall.
Inframammary incision	An incision made in the fold below the breast.
Inpatient surgery	A surgical procedure in which the patient is required to stay overnight in the hospital.
Intracapsular rupture	A type of rupture in which the silicone gel remains inside the scar tissue capsule surrounding the implant.
Lactation	The production and secretion of milk by the breast glands
Latissimus dorsi	Two triangular muscles running from the spinal column to the shoulder.
Low molecular weight silicones	Components of silicone of smaller molecular weight that may bleed (leak) out of silicone gel.
Lymph nodes	Structures that play an important part in the body's defense against infection. They filter lymph, which travels throughout the body in the lymph system, as part of the immune system. Common areas where the lymph nodes can be felt with the fingers include: groin, armpit, neck, under the jaw and chin, behind the ears, and on the back of the head.
Lymphadenopathy	Enlargement of the lymph node(s).
Lymphedema	Swelling of the lymph node(s).

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

Mastectomy	The removal of breast tissue due to the presence of a cancerous or precancerous growth. • Subcutaneous mastectomy: surgical removal of the breast tissues, but sparing the skin, nipple, and areola. • Total mastectomy: surgical removal of the breast including the nipple, areola, and most of the overlying skin. • Modified radical mastectomy: surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the lymphatic-bearing tissue in the axilla. • Radical mastectomy: surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the pectoral muscles, lymphatic bearing tissue in the axilla, and various other neighboring tissue.
Mastitis	Inflammation of the breast.
Mastopexy	Plastic surgery to move sagging breasts into a more elevated position.
Metastatic Disease	Spreading of cancer cells from the original site to other parts of the body.
Migration	Movement of silicone materials outside the breast implant.
Necrosis	Death of cells or tissues.
Oncologist	A doctor who studies, identifies, and treats cancer.
Outpatient surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight.
Palpability	The ability to feel the implant.
Palpate/palpable	To feel with the hand.
Patch assembly	The patch assembly seals the implant shell
Pectoralis	Major muscle of the chest.

Periareolar	Around the darkened or pigmented area surrounding the nipple of the breast.
Plastic surgery	Surgery intended for the improvement of appearance of the body.
Pneumothorax	Pneumothorax (sometimes called "collapsed lung") occurs when air leaks into the space between the lung and chest wall
Postoperatively	After surgery.
Primary breast reconstruction	The first time a breast implant is placed for the purpose of breast reconstruction.
Ptosis	Breast sagging that is usually the result of normal aging, pregnancy, or weight loss.
Reoperation	An additional surgery after your first breast implantation.
Revision-reconstruction	Refers to the correction or improvement of a primary reconstruction. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast reconstruction.
Rheumatological disease/disorder	A variety of diseases involving connective tissue structures of the body, especially the joints and fibrous tissue. These diseases are often associated with pain, inflammation, stiffness, and/or limitation of motion of the affected parts. Can include autoimmune diseases. Fibromyalgia is a rheumatological disorder.
Rosenberg Self Esteem Scale	A questionnaire which measures overall self esteem.
Rowland Expectation Scale	A 16 item questionnaire intended to measure expectations and perceived results of implant surgery.
Rupture	A tear or hole in the implant shell. Silicone implant ruptures may be silent or symptomatic. Ruptures can be intracapsular or extracapsular.

Saline	A solution that is made up of water and a small amount of salt.
Scar revision	A surgical procedure to improve the appearance of a scar.
Seroma	A build-up of the watery portion of the blood in a tissue location.
SF-36 Scale	A questionnaire intended to measure physical, mental, and social health.
Silent rupture	A breast implant rupture without symptoms and which is not apparent except through appropriate imaging techniques such as MRI. Most silicone gel-filled breast implant ruptures are silent. (See symptomatic rupture below).
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
Subglandular placement	Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.
Submuscular placement	Placement of a breast implant wholly or partially underneath the chest muscle.
Surgical incision	A cut made to body tissue during surgery.
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Symptomatic	Any evidence or sign of disease or disorder reported by the patient.
Symptomatic rupture	A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape). Some silicone breast implant ruptures are symptomatic, but most are silent.
Systemic	Pertaining to or affecting the body as a whole.
Tennessee Self Concept Scale	A questionnaire that evaluates how the patient sees herself and what she does, likes, and feels.

Tissue expander	An 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.
Toxic shock syndrome	A rare, but life-threatening bacterial infection that may occur after surgery. It occurs most often in the vagina of menstruating women using superabsorbent tampons. Symptoms include sudden high fever, vomiting, diarrhea, decreased blood pressure, fainting, dizziness, and sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment if toxic shock syndrome is suspected.
Transaxillary	Under the arm.
Warning	Statement that alerts reader about a situation which, if not avoided, could result in serious injury or death.

1. Considering Silicone Gel-Filled Breast Implant Surgery

You may be considering breast implant surgery to restore your breast shape after a mastectomy or an injury that resulted in either partial or total loss of the breast(s) or to correct a birth defect. This is referred to as breast reconstruction. Or you may need revision of a previous breast reconstruction, which is called revision-reconstruction. Whether you decide to have breast reconstruction depends on your own individual case, medical condition, general health, lifestyle, emotional state, and breast size and shape. You may wish to speak with your family, friends, breast implant support groups, and breast cancer support groups to help you in making this decision.

If you are considering breast reconstruction and do not have a plastic surgeon, ask your general surgeon for the names of experienced, board-certified plastic surgeons in your area. Your general surgeon, plastic surgeon, and oncologist should work together to plan your mastectomy and reconstruction procedure to give you the best possible result.

Allergan has prepared this information to help you better understand the breast implant procedure and assist you in making an informed decision about breast reconstruction or revision-reconstruction surgery. It will help to answer some of the questions you may have about the surgery and about breast implants in general. It will also provide you with specific information about the risks and benefits of Allergan's *NATRELLE*® gel-filled breast implant collection

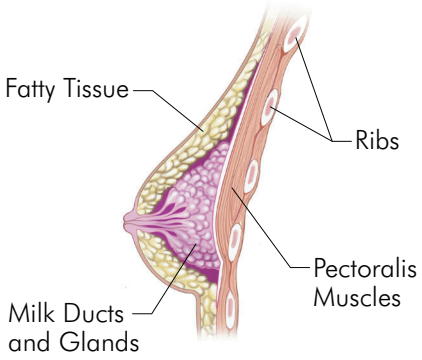
This information cannot and should not replace discussing your surgery with your plastic surgeon. Your decision whether or not to get breast implants should be based on realistic expectations of the outcome. There is no guarantee that your results will match those of other women. Your results will depend on many individual factors, such as your overall health (including age), chest structure, breast/nipple shape and position, skin texture, healing capabilities (which may be slowed by radiation and chemotherapy treatment, smoking, alcohol, and various medications), tendency to bleed, prior breast surgery, surgical team's skill and experience, type of surgical procedure, and type and size of implant. Make sure you speak with your surgeon about your expectations of the results, as well as what you can expect regarding the length of the surgery, your recovery, and any risks and potential complications of the surgery. Ask questions. You and your surgeon will work together to help achieve the body image you desire.

As part of your decision both you and your surgeon should sign Allergan's ***Acknowledgement of Informed Decision and Patient Checklist*** form that confirms your understanding of what you have read and what you have learned from your surgeon. This Allergan document will be provided to you by your surgeon.

Review and consider this information before deciding whether to have primary breast reconstruction surgery. In the case of a revision-reconstruction, however, your surgeon may find it medically necessary to perform surgery 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 or to restore/replace breast tissue. The implants alone may not adequately lift the breast, or correct the effects of pregnancy, weight loss, or skin stretching. Your surgeon may suggest additional procedures at the time of the breast reconstruction, such as mastopexy, to help achieve improved breast lift.

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

1.2 What Is a Silicone Gel-Filled Breast Implant?

A silicone gel-filled breast implant is a sac (implant shell) of silicone elastomer (rubber) filled with silicone gel. It is surgically implanted either under your breast tissue or under your chest muscle.

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

The *NATRELLE*® Collection

The *NATRELLE*® Collection includes both saline-filled and 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. 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® TruForm® 1, 2, and 3 Gel-Filled Breast Implants

NATRELLE® gel-filled breast implants are pre-filled with either a soft cohesive silicone gel or a more highly cohesive silicone gel. Silicone gel is generally considered to provide a more "natural" feeling implant. 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 and reliable, making it an appropriate choice. Allergan has approval for three types of silicone gel fillers: TruForm® 1 silicone gel, TruForm® 2 silicone gel, and TruForm® 3 silicone gel. Each gel filling varies in the amount of firmness it provides to the

implant. TruForm® 1 silicone gel is the least firm gel and TruForm® 3 is the most firm gel offered. TruForm® 2 silicone gel has a firmness level that is in between that of the TruForm® 1 silicone gel and the TruForm® 3 silicone gel. TruForm® 1 gel-filled breast implants typically require a larger incision than saline, and TruForm® 2 and 3 implants require a larger incision than both saline and softer cohesive silicone implants; however, they may look and feel more natural.

NATRELLE® TruForm® 1 Gel-Filled Breast Implants (previously referred to as Cohesive Round) have a round shape and are filled with a soft cohesive gel. These implants are available with a smooth surface shell.

NATRELLE® TruForm® 2 and 3 Gel-Filled Breast Implants (previously referred to as Highly Cohesive Soft Touch and Highly Cohesive) are round and are filled with a highly cohesive (firmer) gel. *NATRELLE*® TruForm® 2 and 3 implants are considered form stable as there is no movement of the gel, allowing the implant to retain its shape. The TruForm® 1, 2 and 3 round breast implants are available with smooth surface shells. The image shown below is an example of the *NATRELLE*® Gel-Filled Breast Implants and *NATRELLE INSPIRA*® Breast Implants you may have seen at your surgeon's office.

Example of a Round Implant

NATRELLE® Silicone-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. All detected elements were below levels that are considered unsafe. However, individual responses to chemicals may vary, and all reactions cannot be predicted. Most of these chemicals stay inside the shell of the implant but small quantities have been found to diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking.

Breast Implant Device Materials

Implant Component	Device Materials
Shell, inner/outer layers	Dimethyl Silicone Elastomer Dispersion
Shell, barrier layer	Diphenyl Silicone Elastomer Dispersion
Shell textured layer	MED-6400 Silicone Elastomer
Patch assembly	MED 2174 and MED 2-6650 Silicone Elastomer
Gel	Silicone Gel: Base and Crosslinker; platinum cure

Chemicals Released by NATRELLE® Silicone-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.

Analysis for volatiles present in the shell and patch material showed that the shell contained up to 279µg of 1, 1, 1 trichloroethane and 251µg of isopropyl alcohol. Analysis for volatiles present in the gel was not necessary because the gel materials do not contain any organic solvents.

To assess for extractables, the shell and the gel components were separated for analysis. "Virgin shells" which contained the patch assembly and had been sterilized but not yet gel-filled were also analyzed. An analysis technique called exhaustive extraction was used. The highest level of extractable material was used when hexane, a non-polar solvent, was used for the extraction, and thus results with the hexane extracts are shown below. The concentrations of smaller molecular weight extractables, as shown below, were highly comparable to those present with FDA-approved saline-filled breast implants.

Identification	Gel (ppm)	Implant Shell and Patch (ppm)	Virgin Shell and Patch (ppm)
D3	ND (<146)	ND (<17)	ND (<7)
D4	ND (<69)	ND (<8)	ND (<3)
D5	ND (<6)	ND (<1)	ND (<1)
D6	ND (<6)	ND (<1)	ND (<1)
D7	ND (<6)	ND (<1)	ND (<1)
D8	ND (<8)	ND (<1)	ND (<1)
D9	ND (<8)	6	ND (<1)
D10	ND (<8)	12	2
D11	11	21	9
D12	32	94	26
D13	64	62	65
D14	237	186	209
D15	366	278	285
D16	491	351	317
D17	593	432	328
D18	729	527	342
D19	678	601	0
D20	735	605	212
D21	668	474	129
L1	ND (<63)	ND (<7)	ND (<3)
L2	ND (<8)	ND (<1)	ND (<1)
L3	ND (<8)	ND (<1)	ND (<1)
L4	ND (<10)	ND (<1)	ND (<1)
L5	ND (<8)	ND (<1)	ND (<1)
L6	ND (<7)	ND (<1)	ND (<1)
L7	ND (<8)	2	4
L8	ND (<8)	2	ND (<1)
L9	ND (<9)	8	ND (<1)
L10	19	17	ND (<1)
L11	35	29	ND (<1)
L12	63	49	ND (<1)
L13	103	84	ND (<1)
L14	132	108	ND (<1)
L15	169	128	ND (<1)
L16	183	106	ND (<1)
L17	161	137	ND (<1)
L18	177	128	ND (<1)
Diphenyl siloxanes	242	985	2762

Heavy Metal Analysis

Analyses were conducted on breast implants to determine your potential exposure to inorganic (metallic) elements. Any metallic elements not listed in the table were non-detectable.

Metal	Virgin Shell (standard dispersion) (ppm)	Virgin Shell (barrier dispersion) (ppm)	Patch (ppm)	Gel (ppm)
Antimony	ND (<0.1)	ND (<0.1)	ND (<0.1)	ND (<0.1)
Arsenic	ND (<0.1)	ND (<0.1)	ND (<0.1)	ND (<0.1)
Barium	1	1	2	1
Beryllium	ND (<0.1)	ND (<0.1)	ND (<0.1)	ND (<0.1)
Cadmium	ND (<0.1)	ND (<0.1)	ND (<0.1)	ND (<0.1)
Calcium	ND (<10)	ND (<10)	ND (<10)	ND (<10)
Chromium	0.3	0.4	1.8	0.2
Cobalt	ND (<0.2)	ND (<0.2)	ND (<0.2)	ND (<0.2)
Copper	ND (<0.1)	ND (<0.1)	ND (<0.1)	ND (<0.1)
Iron	ND (<0.1)	0.2	8.7	1.2
Lead	ND (<0.2)	ND (<0.2)	ND (<0.2)	0.3
Magnesium	ND (<10)	ND (<10)	ND (<10)	ND (<10)
Manganese	ND (<0.05)	ND (<0.05)	0.15	ND (<0.05)
Mercury	ND (<1)	ND (<1)	ND (<1)	ND (<1)
Molybdenum	ND (<0.5)	ND (<0.5)	ND (<0.5)	ND (<0.5)
Nickel	ND (<0.2)	1	0.7	ND (<0.2)
Potassium	ND (<1)	8	1	ND (<1)
Selenium	ND (<0.1)	ND (<0.1)	ND (<0.1)	ND (<0.1)
Silver	ND (<0.1)	0.2	ND (<0.1)	ND (<0.1)
Sodium	ND (<10)	ND (<10)	ND (<10)	ND (<10)
Thallium	ND (<1)	ND (<1)	ND (<1)	ND (<1)
Vanadium	ND (<0.4)	ND (<0.4)	ND (<0.4)	ND (<0.4)
Zinc	0.12	ND (<0.05)	3.9	0.22

ND (<X) = Not detected at less than X, the concentration in parts per million

In addition, catalyst metal analyses were carried out on the shell and gel components of the device. The shell and patch were found to contain 5.9 ppm of platinum, the patch was found to contain 6.6 ppm of tin, and the gel was found to contain 4.0 ppm of platinum. Platinum is a metal used as a catalyst in the manufacture of the shell and gel components of silicone breast implants. The small amounts of platinum remaining in the product following manufacturing may enter the body, either by diffusing through the intact shell

(i.e., through gel bleed) or through an implant rupture. However, based on a review of the gel bleed testing, the published literature on the topic, as well as the biocompatibility testing and clinical data on the device, FDA concluded that the platinum contained in breast implants is in the zero oxidation state, which has the lowest toxicity and, thus, does not pose a significant risk to women with silicone breast implants.

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

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

- **Breast augmentation for women at least 22 years old.** Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery. (A separate patient brochure is available for those women considering breast augmentation surgery and should be read prior to reaching a decision to undergo breast augmentation.)
- **Breast reconstruction.** Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

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.

PRECAUTIONS

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

- Autoimmune diseases (for example, lupus and scleroderma).
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease).
- Planned chemotherapy following breast implant placement
- Planned radiation therapy to the breast following breast implant placement

- Conditions that interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue.
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders with your surgeon prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

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 the cover page.

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.

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 breasts. These additional surgeries can include implant removal or replacement, or other surgical procedures. Later surgeries to replace implants (revision-augmentation) carry higher risks of complications than the first (primary) augmentation surgery. Therefore, you should also consider the complication rates for revision-augmentation since you may experience these risks in the future.

WARNING – Your *NATRELLE*® Silicone-Filled Breast Implants or *NATRELLE INSPIRA*® Breast Implants may rupture without any symptoms (silent rupture). This means that neither you nor your surgeon will know that your implants have ruptured. It is recommended that you take a multi-step approach to monitor

the integrity of the implant throughout the lifetime of the device beginning with a patient self-examination. Obtain an ultrasound or mammogram if a new symptom or sign is suspected or as part of a periodic review with a physician. If the ultrasound is negative or inconclusive, obtain an MRI. If MRI results suggest a rupture, discuss explantation of the implant with your plastic surgeon.

1.4 Important Factors You Should Consider in Choosing Silicone Gel-Filled Implants

You should be aware that there are many factors that will affect the outcome and timing of your reconstruction with breast implants. These factors include the stage of your disease, the type and extent of cancer removal surgery you have had, the amount of skin and soft tissue available for the reconstruction, and additional treatments such as chemotherapy and radiation, which you may require. Talk to your doctor about how chemotherapy or radiation may affect your implants.

- If you undergo a mastectomy, removal of the breast tissue eliminates the ability to breastfeed with the removed breast. In addition, contralateral breast augmentation may affect your ability to breastfeed, either by reducing or eliminating milk production.
- Due to the greater cohesivity of the TruForm® 3 implants, it may be more difficult to identify an implant rupture by clinical exam for these implants.
- With breast implants, routine screening mammography for breast cancer will be more difficult. If you are of the proper age for mammography screening, you should continue to undergo routine mammography screening as recommended by your primary care physician. The implant may interfere with finding breast cancer during mammography. Because the breast and implant are squeezed during mammography, an implant may rupture during the procedure. More x-ray views are necessary for women with breast implants; therefore, you will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays. Be sure to inform the mammography technologist that you have implants.
- You should perform an examination of your breasts every month for cancer screening; however, this may be more difficult with implants. You should ask your surgeon to help you distinguish the implant from your breast tissue.

- You should perform an examination of your breasts for the presence of lumps, swelling, hardening, or change in implant shape, which may be signs of symptomatic rupture of the implant. Any of these symptoms, and/or if you notice persistent pain, should be reported to your surgeon and possibly evaluated with an MRI to screen for rupture.
- The timing for any revision following reconstruction surgery should be discussed with your surgeon so that all issues such as the potential effects of radiation, chemotherapy, and additional cancer surgery or treatments can be fully discussed.
- You should inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.
- Closed capsulotomy (use of pressure or force to "break up" the capsule) should not be used to treat capsular contracture. Closed capsulotomy can cause implant rupture.
- Smoking may interfere with the healing process after surgery.
- Allergan's clinical study of the TruForm® 1 implants (the Core Study) monitored the long-term (10 years) safety and effectiveness of these products. Refer to the clinical study section of this brochure for more details on this study. In addition, Allergan has initiated a separate, 10-year study (the Breast Implant Follow-Up Study, or BIFS) to address issues beyond the scope of the Core study, as well as to provide a real-world assessment of some endpoints. The endpoints in the BIFS study include long-term local complications, connective tissue disease (CTD), neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI results. Allergan will update its labeling on a regular basis with the results of these studies. You should also ask your surgeon for any available updated Allergan clinical information and visit the website.
- 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 Reconstruction

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

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

2.1 Should You Have Primary Breast Reconstruction?

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

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

You should also be aware that, for primary reconstruction patients, alternatives may include:

- Having reconstruction using your own tissue (flap procedure).
- Having surgery with saline implants.

For revision-reconstruction patients, alternatives may include:

- No revision.
- Removal with or without replacement.

2.2 What Are the Options in Primary Breast Reconstruction?

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

2.3 What Are the Choices in Primary Reconstructive Procedures?

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

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

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

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

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

2.5 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.

Breast reconstruction with Responsive silicone implants requires a larger incision size than saline implants, and reconstruction with Highly Cohesive silicone implants requires a larger incision size than Responsive implants.

2.6 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.

2.7 The Timing of Your Primary Breast Implant Reconstruction

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

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

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

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

2.8 What Is the Primary Breast Implant Reconstruction Procedure?

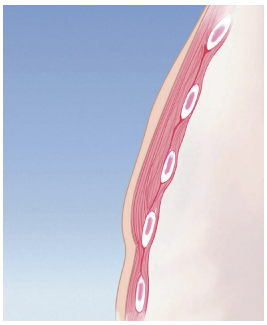
IMMEDIATE OR DELAYED BREAST IMPLANT RECONSTRUCTION

Breast reconstruction using only a breast implant may be done immediately at the time of your mastectomy or sometime thereafter. After the general

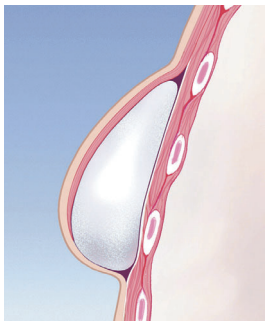
surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant that completes the reconstruction. In reconstruction following mastectomy, a breast implant is most often placed submuscularly.

EXPANDER-ASSISTED (IMMEDIATE OR DELAYED) BREAST IMPLANT RECONSTRUCTION

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



Side View, Breast Tissue Removed



Side View, Expander Inserted and Filled

TISSUE EXPANSION

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

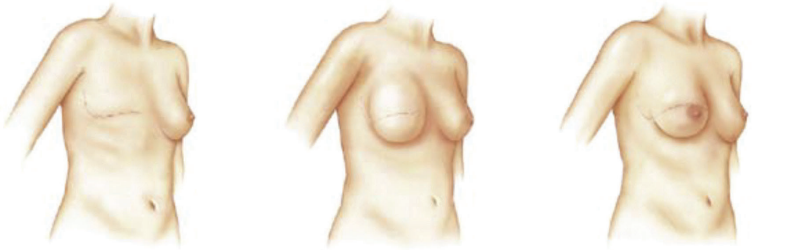
The tissue expander is a balloon-like device made from elastic silicone rubber. It is inserted unfilled, and over time, sterile saline fluid is added by inserting a small needle through the skin to the filling port of the device. As the tissue expander fills, the tissues over the expander begin to stretch,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

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

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

PLACING THE BREAST IMPLANT

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



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

2.9 What About Primary Breast Reconstruction Without Implants: Tissue Flap Procedures

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

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

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

The most common types of tissue flaps are the 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 the details, expectations, benefits and risks of each of the procedures.

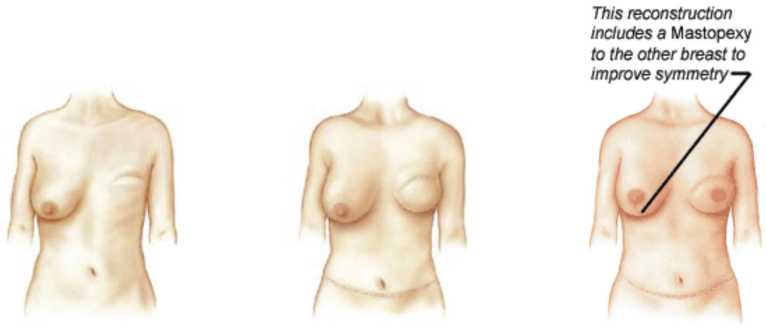
DIEP FLAP

During a DIEP flap procedure, the surgeon removes fat, skin, and blood vessels from the abdomen, and moves it to your chest to reconstruct the breast. Abdominal muscles are not removed. The surgeon will reattach blood vessels in the flap to blood vessels in your 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 procedure requires special surgical training and expertise in microsurgery. You will have a large scar on your abdomen and additional scars on your 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

2.10 General Surgical Considerations

CHOOSING A SURGEON

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

- How many breast reconstruction implantation procedures does he/she perform per year?
- How many years has he/she performed breast reconstruction procedures?
- Has he/she completed Allergan's Physician Education Program (Allergan Academy™) for the use of *NATRELLE*® gel-filled breast implants?
- Is he/she board certified, and if so, with which board?
- In which province(s) is he/she licensed to practice surgery? (Note that some 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 reconstruction?
- What is his/her reoperation rate with breast reconstruction, and what is the most common type of reoperation he/she performs?
- Can he/she perform this surgery in a hospital, as well as in the surgeon's independent surgery center? (Note that hospitals require evidence of appropriate training in specific procedures before allowing surgeons to operate in their facilities.)

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

- 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)?

2.11 What Are Choices And Options Associated With The Surgery?

IMPLANT SHAPE AND SIZE

Depending on the desired shape you wish to achieve, you and your surgeon have implants with different profiles, or styles, and sizes from which to choose. Generally, the larger you want your cup size, the larger the breast implant size or the higher the profile the surgeon will consider (measured in grams or cubic centimeters [cc's], not in cup sizes, because cup size depends on the size and shape of the individual woman's chest).

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

you that breast implant edges may be visible or palpable postoperatively. Also, excessively large breast implants may speed up the effects of gravity on the breast, and can result in droop or sag at an earlier age. A recent report indicates that larger-sized implants (greater than 350cc) may be too large for many women, increasing the risk of developing complications such as implant extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling requiring surgical intervention to correct these complications.

SURFACE

NATRELLE® Silicone-Filled Breast Implants and *NATRELLE INSPIRA*® Breast Implants come in a variety of profiles and sizes with a smooth surface shell. Surface texturing is designed to adhere to surrounding tissue. Some studies suggest that surface texturing reduces the chance of severe capsular contracture while other studies do not. Data from reconstruction and revision patients in Allergan's Core Study of TruForm® 1 did not show a difference in the likelihood of developing capsular contracture with textured implants compared to smooth implants.

IMPLANT PALPABILITY

Implants may be more palpable or noticeable if there is an insufficient amount of skin/tissue available to cover the implant and/or when the implant is placed subglandularly.

POSTOPERATIVE CARE

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

Postoperative care depends on each patient's situation, 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."

3. Follow-Up Examinations

BREAST SELF-EXAMINATIONS

Following breast reconstruction you should continue to perform a breast self-examination monthly. This may be more difficult with a breast implant in place. To continue to perform a monthly breast self-examination efficiently, you should ask your surgeon to help you identify the difference between the implant and your breast tissue. Being able to identify the implant from breast tissue will decrease the necessity of excessive squeezing of the implant during examination. Any new lumps should be evaluated with a biopsy, as appropriate. If a biopsy is performed, be sure to inform the medical professional performing the biopsy that you have breast implants so that care will be taken to avoid injuring the implant.

SCREENING FOR IMPLANT RUPTURE

Symptoms associated with rupture may include hard knots or lumps surrounding the implant or in the armpit, loss of size of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast. If you notice any of these changes, see your plastic surgeon so that he or she can examine the implants for rupture or other changes. You may need to have further testing to determine if your symptoms are due to rupture of the implant. If rupture has occurred, you should consider having your implant removed. Consult with your doctor regarding this and any other medical decisions related to your implants.

In consideration of all the available scientific information, it has been suggested that the process for determining implant integrity (e.g. rupture) should be related to clinical signs and symptoms. Thus, the following 6-step process is recommended for screening for silicone gel-filled breast implant rupture:

1. Patient self-examination;

2. New symptom or sign suspected;
3. Physician physical examination, related to a periodic review or new symptoms and signs, suggests findings that warrant further investigation;
4. Ultrasound, mammogram, or both of the implant and the breast involved should be acquired;
5. MRI if ultrasound is negative or inconclusive. The MRI should be performed at a centre with a breast coil with a magnet of at least 1.5 Tesla. The MRI should be read by a radiologist who is familiar with looking for implant rupture; and
6. If signs of rupture are seen on MRI, then in consultation with your plastic surgeon, you may decide to have your implant removed, with or without replacement.

MAMMOGRAPHY

If you have had a mastectomy, discuss with your surgeon regarding what type of 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 rupture and to get the best possible views of the breast tissue.

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 as 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?

Discussed below are some of the known risks of breast reconstruction along with possible effects of those risks. The information is based on results of Allergan's Core Study of 98 Primary Reconstruction patients and 15 Revision-Reconstruction patients. The Allergan Core Study 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.

- RUPTURE

Breast implants are not lifetime devices. Breast implants rupture when the shell develops a tear or hole. Ruptures can occur at any time after implantation, but they are more likely to occur the longer the implant is implanted. The following things may cause your implant to rupture: damage by surgical instruments; stressing the implant during implantation which may weaken it; folding or wrinkling of the implant shell; excessive force to the chest (for example, during closed capsulotomy, which is contraindicated); trauma; compression during mammographic imaging; and severe capsular contracture. Breast implants may also simply wear out over time. Laboratory studies have identified some of the types of rupture for Allergan's product; however, it is not known whether these tests have identified all causes of rupture. These laboratory studies will continue postapproval.

Silicone gel-filled breast implant ruptures are most often silent. This means that most of the time neither you nor your plastic surgeon will know if the implant has a tear or hole in the shell. However, sometimes there are symptoms associated with gel implant rupture. These symptoms include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.

If your surgeon determines you have signs or symptoms of rupture, you should discuss with him or her having the implant and any gel removed, with or without replacement of the implant. It also may be necessary to remove the

tissue capsule as well as the implant, which will involve additional surgery, with associated costs. If you have symptoms such as breast hardness, a change in breast shape or size, and/or breast pain, you should discuss with your surgeon additional tests or procedures (such as an MRI) to determine whether rupture is present.

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

Rupture Information on TruForm® 1 Implants

In Allergan's Core Study, rupture was assessed for patients who had scheduled MRIs to screen for silent rupture (i.e., part of the MRI cohort) and those who were not assessed for rupture by MRI (i.e., part of the non-MRI cohort). For primary reconstruction patients in the MRI cohort, the rupture rate was 35.4% through 10 years. For revision-reconstruction patients in the MRI cohort, the rupture rate was 0% through 10 years. This means that through 10 years, approximately 35 of every 100 primary reconstruction women had at least one ruptured breast implant. There were no revision-reconstruction patients with a ruptured breast implant. Two ruptures were reported in the non-MRI primary reconstruction cohort and 1 was reported in the revision-reconstruction cohort. The rupture rate for the whole MRI cohort in the Core Study through 10 years was 13.0% for patients and 7.7% for implants. Rupture rates are presented by patient and by implant as some patients may experience rupture in both implants. Across all patients in the Core Study, most ruptures were intracapsular with 3 cases of extracapsular gel (one rupture progressed to extracapsular gel following exploratory surgery to confirm the rupture and then implant replacement was delayed). There were no cases of migrated gel.

Further rupture information on TruForm® 1 implants is provided from a published European study known as the International MRI Study. Silent rupture data were collected via a single MRI on 77 augmentation, 11 reconstruction, and 18 revision patients implanted with smooth and textured implants by five surgeons. The average age of the implants was approximately 11 years. Silent rupture was found in approximately 15% of the combined group of augmentation,

reconstruction, and revision patients and 8% of the implants. There was one possible case of extracapsular rupture with the remainder classified as intracapsular ruptures. No cases of migrated gel were found.

Additional information on rupture will be collected through Allergan's postapproval Breast Implant Follow-Up Study (BIFS).

- CAPSULAR CONTRACTURE

The scar tissue (capsule) that normally forms around the implant may tighten and squeeze the implant, making your breast feel firmer and sometimes painful. This is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in revision-reconstruction than in primary reconstruction. Because you may have your initial implants replaced, you should be aware that your risk of capsular contracture increases with revision-reconstruction. Capsular contracture is a risk factor for implant rupture, and it is one of the most common reasons for reoperation.

Symptoms of capsular contracture range from mild firmness and mild discomfort to severe pain, distorted shape of the implant, and palpability (ability to feel the implant). Capsular contracture is graded into 4 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 may be needed in cases where pain and/or firmness are severe. This surgery ranges from removal of the implant capsule tissue to removal and possible replacement of the implant itself. This surgery may result in loss of your breast tissue. Capsular contracture may happen again after these additional surgeries. Capsular contracture may increase the risk of rupture.

Capsular Contracture Information on TruForm® 1 Implants

In Allergan's Core Study, for women receiving reconstruction implants for the first time, the risk of severe capsular contracture was 25% through 10 years. This means that 25 out of every 100 women who received TruForm® 1 implants for primary breast reconstruction had severe capsular contracture at least once during the first 10 years after receiving the implants.

For women receiving revision-reconstruction implants, the risk of severe capsular contracture was 7% through 10 years. This means that 7 out of every 100 women who received TruForm® 1 implants for revision-reconstruction had severe capsular contracture at least once during the first 10 years after receiving the implants.

- ADDITIONAL SURGERIES (REOPERATIONS)

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

Reoperation Information on TruForm® 1 Implants

In Allergan's Core Study, the reoperation rate was 72% for primary reconstruction patients and 47% for revision-reconstruction patients, which means that 72 out of every 100 women who received TruForm® 1 implants for primary reconstruction and 47 out of every 100 women who received TruForm® 1 implants for revision-reconstruction had a reoperation during the first 10 years after receiving the implants.

For women receiving primary reconstruction implants, the 3 most common reasons for reoperation were implant malposition, asymmetry, and device rupture. For women receiving revision-reconstruction implants, the most common reason reported for reoperations was nipple complications.

- IMPLANT REMOVAL

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

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

risks of future complications. For example, the risks of capsular contracture and reoperation increase for patients with implant replacement compared to first time placement. You should consider the possibility of having your implants replaced and its consequences when making your decision to have implants.

Implant Removal Information on TruForm® 1 Implants

For women receiving primary reconstruction implants in Allergan's Core Study, 54% had their implants removed at least once through 10 years. Suspected device rupture, implant malposition, and asymmetry were the most common reasons for implant removal. Three women receiving revision-reconstruction implants in Allergan's Core Study had implants removed through 10 years. The reasons for removal were asymmetry and capsular contracture.

- UNSATISFACTORY RESULTS

Unsatisfactory results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, and/or hypertrophic scarring, may occur. Some of these results may cause discomfort. Pre-existing asymmetry may not be entirely correctable by implant surgery. Revision surgery may be recommended to maintain patient satisfaction, but carries additional considerations and risks. Selecting an experienced plastic surgeon may minimize, but not necessarily prevent, unsatisfactory results.

- PAIN

Pain of varying intensity and length of time may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain. You should tell your surgeon about significant pain or if your pain persists.

- CHANGES IN NIPPLE AND BREAST SENSATION

Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. While some of these changes can be temporary, they can also be permanent, and may affect your sexual response or your ability to nurse a baby. (See the paragraph on breastfeeding below).

- INFECTION

Infection can occur with any surgery or implant. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. In addition, breast and nipple piercing procedures may increase the possibility of infection. Infections in tissue

with an implant present are harder to treat than infections in tissue without an implant. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved (cleared up). As with many other surgical procedures, in rare instances, toxic shock syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. You should contact a doctor immediately for diagnosis and treatment if you have these symptoms.

- HEMATOMA/SEROMA

Hematoma is a collection of blood within the space around the implant, and a seroma is a build-up of fluid around the implant. Having a hematoma and/or seroma following surgery may result in infection and/or capsular contracture later on. Symptoms from a hematoma or seroma may include swelling, pain, and bruising. If a hematoma or seroma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, some will require surgery, typically involving draining and potentially placing a surgical drain in the wound temporarily for proper healing. A small scar can result from surgical draining. Implant rupture also can occur from surgical draining if there is damage to the implant during the draining procedure.

- BREASTFEEDING

Breastfeeding difficulties have been reported following breast surgery, including breast reduction and breast reconstruction. If your surgeon uses a periareolar surgical approach (an incision around the colored portion surrounding the nipple), it may further increase the chance of breastfeeding difficulties. 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 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.

- DELAYED WOUND HEALING

Some patients may experience a prolonged wound healing time. Delayed wound healing may increase the risk of infection, extrusion, and necrosis. Depending on the type of surgery or the incision, wound healing times may vary. Smoking may interfere with the healing process. You should contact your surgeon immediately if your wound does not heal within the period of time he/she has discussed with you.

- BREAST TISSUE ATROPHY/CHEST WALL DEFORMITY

The pressure of the breast implant may cause breast tissue thinning (with increased implant visibility and palpability) and chest wall deformity. This can occur while implants are still in place or following implant removal without replacement. Either of these conditions may result in additional surgeries and/or unacceptable dimpling/puckering of the breast.

- LYMPHADENOPATHY

Lymphadenopathy is a chronic enlargement of the lymph nodes. A lymph node is a round mass of tissue which makes cells as part of your immune system. The lymph nodes in the armpit (axilla) drain the breast area of fluid. 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.

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

- 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 signs and 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.

There have been reports in the literature of other conditions in women with silicone gel-filled 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 silicone gel-filled 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 connective tissue diseases, without having the actual disease. Patients receiving breast implants have reported a variety of signs and 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 connective tissue disease; however, you should be aware that you may experience these signs and symptoms after undergoing breast implantation. If you notice an increase in these signs or symptoms, you should consider seeing a rheumatologist to determine whether these signs or symptoms are due to a connective tissue disorder or autoimmune disease.

- CANCER

Breast Cancer – Reports in the medical literature indicate that patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer. Some reports have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy; however, other reports in the published medical literature indicate that breast implants neither significantly delay breast cancer detection nor adversely affect cancer survival of women with breast implants. A large follow-up study reported no evidence of an association between breast implants and cancer, and even showed a decreased incidence of breast cancer compared to the general population.

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

Respiratory/lung cancer – Studies have reported an increased incidence of respiratory/lung cancer in women with breast implants. Other studies of women in Sweden and Denmark have found that women who get breast implants are more likely to be current smokers than women who get breast reduction surgery or other types of cosmetic surgery.

Cervical/vulvar cancer – Two studies have reported an increased incidence of cervical/vulvar cancer in women with breast implants, while another long-term follow-up study showed equivalent incidences of cervical cancer in women with breast implants compared to the general population.

Other cancers – One study has reported an increased incidence of stomach cancer and leukemia in women with breast implants compared to the general population. This increase was not significant when compared to women

who had other types of plastic surgeries. A study of over 6,000 women in Scandinavia with breast implants (primarily silicone implants) found no significant increases in the risk rates for a wide variety of cancers, including stomach cancer and leukemia.

- NEUROLOGICAL DISEASES, SIGNS, AND SYMPTOMS

Some women with breast implants have complained of neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking or remembering things) or diseases (such as multiple sclerosis), which they believe are related to their implants. A scientific expert panel report found that the evidence for a neurological disease or syndrome caused by or associated with breast implants is insufficient or flawed.

- SUICIDE

In several studies, a higher incidence of suicide was observed in women with breast implants. The reason for the observed increase is unknown, but it was found that women with breast implants had higher rates of hospital admission due to psychiatric causes prior to surgery, as compared with women who had breast reduction or in the general population of Danish women.

- EFFECTS ON CHILDREN

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

In addition, concerns have been raised regarding potential damaging effects on children born to mothers with implants. Two studies in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery. Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding. A recent epidemiological review found that children of women with breast implants are not at increased risk for birth defects.

- GEL DIFFUSION

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

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

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

- DELAYED-TYPE HYPERSENSITIVITY

While there is no scientific evidence that silicone can cause hypersensitivity reactions in humans, some animal testing reports in the literature suggest evidence of a delayed-type hypersensitivity to silicone. The biological mechanism and outcome for these findings in animal models remain unknown.

5. Allergan's Clinical Study Results

This section of the brochure summarizes the most recent results of the ongoing clinical studies conducted on the *NATRELLE*® gel-filled breast implants for primary reconstruction and revision-reconstruction. The Allergan Core Study was the primary clinical study for the TruForm® 1 implants. *NATRELLE*® *INSPIRA*® implants were not included in these studies. The Allergan Core Study included both smooth and BIOCELL textured breast implants. The BIOCELL textured breast implants were recalled in July 2019 for their higher risk associated with BIA-ALCL and no longer are manufactured or marketed. The results of the clinical studies give you useful information on the experience of other women with *NATRELLE*® gel-filled breast implants. While the results cannot be used to predict your individual outcome, they can be used as a general guide of what you may expect. Your own complications and benefits depend on many individual factors. You should also ask your surgeon for any available updated Allergan clinical information.

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

5.1 Allergan's Core Study (TruForm® 1 Implants)

The Core Study was a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients with TruForm® 1 implants. Patient follow-up was at 0-4 weeks, 6 months, 12 months, and annually through 10 years. Safety was assessed by complications, such as implant rupture, capsular contracture, and reoperation. Benefit (effectiveness) was assessed by breast size change, patient satisfaction and measures of quality of life.

The Allergan Core Study consisted of 715 patients. This included 455 primary augmentation patients, 147 revision-augmentation patients, 98 primary reconstruction patients, and 15 revision-reconstruction patients. Of these patients, 158 primary augmentation patients, 50 revision-augmentation patients, 51 primary reconstruction patients, and 5 revision-reconstruction patients were in the MRI cohort, which means that they were assessed for silent rupture by MRI at years 1, 3, 5, 7, and 9. The study is complete, with the results through 10 years reported in this brochure.

Allergan's results indicate that the risk of at least one occurrence of any complication (including reoperation) at some point through 10 years after implant surgery is 47% for primary reconstruction patients and 47% for revision-reconstruction patients. The information below provides more details about the complications and benefits you may experience. More detailed data tables are found in the Appendix of this brochure. Please refer to the glossary for the definition of any complication you may not understand.

5.2 Core Study: What Are The 10-Year Follow-Up Rates?

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

The Allergan Core Study enrolled 98 reconstruction patients. Of the women expected to be seen at the 10-year follow-up visit, 75% were seen.

The Allergan Core Study enrolled 15 revision-reconstruction patients. Of the women expected to be seen at the 10-year follow-up visit, 80% were seen.

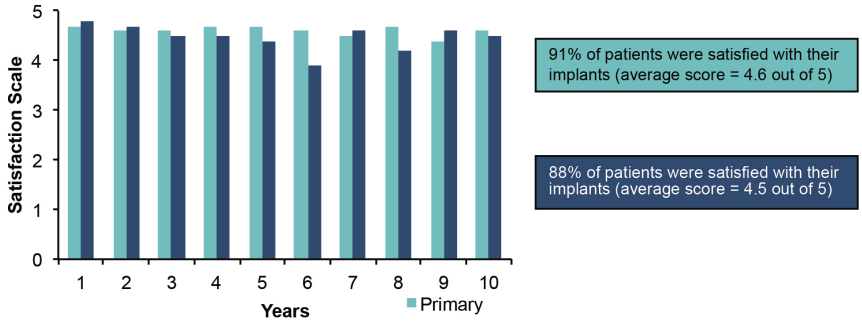
5.3 Core Study: What Are The Benefits?

The benefits of TruForm® 1 breast implants were assessed by a variety of outcomes, including assessments of patient satisfaction and quality of life. Data were collected before implantation and at scheduled follow-up visits.

Patient Satisfaction: Allergan's patient satisfaction was based on a 5-point scale assessment of satisfaction with their implants at the time of the follow-up visits. Of the original 98 primary reconstruction patients, 43 (44%) provided a satisfaction rating at 10 years after implantation, with 39 (91%) of these patients indicating that they were satisfied with their breast implants.

Of the original 15 revision-reconstruction patients, 8 (53%) provided a satisfaction rating at 10 years. Of these 8 patients, 7 (88%) indicated that they were satisfied with their breast implants. See Figure 1.

Figure 1. Primary Reconstruction and Revision-Reconstruction Patient Satisfaction Through 10 Years (responses of somewhat satisfied, satisfied, or definitely satisfied)



On a scale of 1 (definitely satisfied) to 5 (definitely dissatisfied)

Quality of Life Assessments: Quality of life assessments were obtained prior to implantation and at 1, 2, 4, 6, 8, and 10 years post-surgery. The 10-year data are provided here. For primary reconstruction patients, the SF-36, which is a collection of scales that measure mental and physical health, showed no changes after 10 years. For patient responses to questions regarding overall self-concept/self-esteem, there was no change in self-concept on the Tennessee Self Concept Scale and no change in overall self-esteem on the Rosenberg Self Esteem Scale 10 years after receiving implants. Patient responses to questions on the Body Esteem Scale regarding overall body image also did not show a change 10 years after receiving implants. On the Rowland Expectation Scale patients showed significant improvement in self-image and social relations.

For revision-reconstruction patients, responses were similar pre- and post-implantation on the SF-36, Tennessee Self Concept Scale, Rosenberg Self Esteem Scale, and Body Esteem Scale after 10 years. On the Rowland Expectation Scale patients showed improvement in self-image, social relations, and daily living.

For both primary reconstruction and revision-reconstruction patients, breast satisfaction was significantly increased after 10 years, including satisfaction with breast size, shape, feel, and how well they matched (Table 1).

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

Quality of Life Scale	Primary Reconstruction		Revision-Reconstruction	
	Year 1	Year 10	Year 1	Year 10
Satisfaction with Breasts	Improved	Improved	Improved	Improved
How Well Breasts Matched	Improved	Improved	Improved	Improved
Satisfaction with Breast Shape	Improved	Improved	Improved	Improved
Satisfaction with Breast Size	Improved	Improved	Improved	Improved
Satisfaction with Breast Feel/Touch	Improved	Improved	Improved	Improved

5.4 Core Study: What Are The 10-Year Complication Rates?

The complications observed in primary reconstruction and revision-reconstruction women through 10 years are presented in the Appendix, Table 1. The rates reflect the percentage of patients who experienced the listed complication at

least once within the first 10 years after their implantation. Some complications occurred more than once for some patients.

The most common complications experienced within the first 10 years of implantation for primary reconstruction patients were reoperation (72% or approximately 72 patients out of 100) and implant removal with replacement (48% or approximately 48 patients out of 100). The most common complications experienced within the first 10 years of implantation for revision-reconstruction patients were reoperation (47%), implant malposition (13.3%), and implant removal with replacement (13.3%).

5.5 Core Study: What Are The Main Reasons For Reoperation?

The reasons for reoperation observed in primary reconstruction and revision-reconstruction women through 10 years are presented in the Appendix, Table 3. There may be one or more reasons identified for having a reoperation (additional surgery after the primary or revision breast reconstruction). Furthermore, there may be multiple surgical procedures (for example, implant removal with or without replacement, capsule procedures, incision and drainage, implant reposition, scar revision) performed during a reoperation.

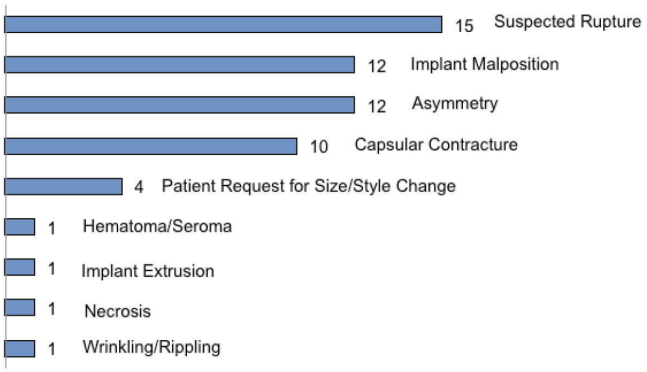
The most common reason for reoperation through 10 years in primary reconstruction patients was because of implant malposition (16 of 94 reoperations). The most common reason for reoperation through 10 years in revision-reconstruction patients was because of nipple complications (5 out of 12 reoperations).

5.6 Core Study: What Are The Main Reasons For Implant Removal?

The main reasons for implant removal among primary reconstruction patients over the 10 years are shown in Figure 2. For primary reconstruction, there were 57 implants removed in 44 patients. Of these 57 implants, 47 were replaced. The most common reason for implant removal was suspected rupture (15 of the 57 implants removed).

Among revision-reconstruction patients, there was 3 implants removed in 3 patients due to asymmetry and capsular contracture. Of these 3 implants, 2 were replaced.

Figure 2. Main Reason for Implant Removal Through 10 Years
Primary Reconstruction (n = 57)



5.7 Core Study: What Are Other Clinical Data Findings?

Below is a summary of clinical findings from the Core Study with regard to connective tissue disease (CTD), cancer, lactation complications, reproduction complications, and suicide. These issues, along with others, are being further evaluated as part of an Allergan postapproval study of a large number of patients followed through 10 years (Breast Implant Follow-Up Study, or BIFS).

CTD Diagnoses

There was 1 (1%) primary reconstruction patient who was reported to have a new diagnosis of an undifferentiated CTD according to a rheumatologist at 3 months after implantation and 1 patient (1%) with a new diagnosis of rheumatoid arthritis according to a rheumatologist at 5.5 years after implantation. No revision-reconstruction patients had new diagnoses of a CTD through 10 years. It cannot be concluded that these CTD diagnoses were caused by the implants because there was no comparison group of similar women without implants

Cancer

There were 13 primary reconstruction patients (13%) with recurrence of breast cancer through 10 years. There was a 17% benign breast disease risk rate and an 18% malignant breast disease rate through 10 years. For revision-reconstruction patients, there were no reports of new diagnoses or recurrence of breast cancer. There was a 7% benign breast disease rate

through 10 years. There was 1 report of metastatic cervical cancer in a revision-reconstruction patient and no reports of other cancers, such as brain or respiratory, in primary reconstruction or revision-reconstruction patients.

Lactation Complications

One of the 98 primary reconstruction patients attempted to breastfeed following breast implantation in the Core Study through 10 years and did not experience any difficulties. No revision-reconstruction patients attempted to breastfeed after receiving breast implants.

Reproduction Complications

Two (2%) of the primary reconstruction patients in the Core Study reported a reproduction problem through 10 years. No revision-reconstruction patients experienced a post-implantation reproduction problem.

Suicide

There were no reports of suicide in the primary reconstruction and revision-reconstruction patients in the Core Study through 10 years.

6. Additional Information

6.1 Types of *NATRELLE*® Gel-Filled Breast Implants Available from Allergan

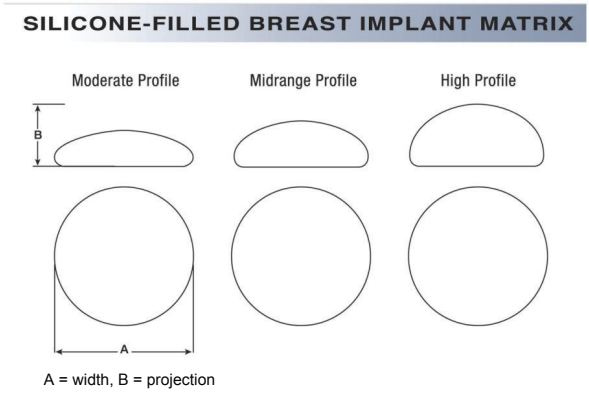
The *NATRELLE*® Collection of silicone gel-filled breast implants come in a variety of profiles and sizes with either a textured shell of smooth surface shell and are filled with TruForm® 1, 2, or 3 gel. TruForm® 1 is a soft cohesive gel that is responsive to movement with a shape that is influenced by the surrounding breast tissue. TruForm® 2 is a slightly firmer, form-stable cohesive gel that retains a natural feel while helping to create the desired shape for more predictable long-term control. TruForm® 3 is a form-stable cohesive gel developed specifically for anatomical implants with a firmer feel for the ultimate shape control providing predictable aesthetic results over time.

NATRELLE® TruForm® 1 are round implants filled with TruForm® 1 gel. The following diagram may help you to understand the projections of TruForm® 1 implants as your surgeon discusses the various options with you.

The images shown below are examples of the *NATRELLE*® Gel-Filled Breast Implants and *NATRELLE INSPIRA*® Breast Implants you may have seen at your surgeon's office.

Examples of TruForm® 1 Breast Implant Styles

Style 10 Style 15 Style 20

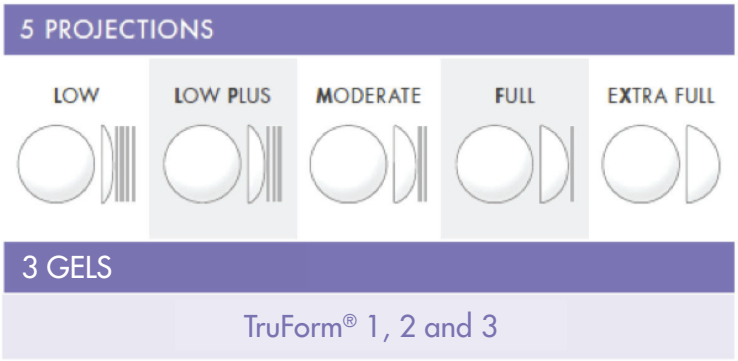


A = width, B = projection

The *NATRELLE*® INSPIRA® line of breast implants are also round implants that have a higher fill than *NATRELLE*® TruForm 1 breast implants and are available with either TruForm® 1, TruForm® 2, or TruForm® 3 gel. *NATRELLE*® INSPIRA® implants are available in multiple configurations, which provides the surgeon with another option to customize a result for each patient. Your plastic surgeon will discuss with you the implant design that will best help you achieve the result and fit that is right for you.

Examples of *NATRELLE*® INSPIRA® TruForm® 1, 2 and 3 Breast Implant Styles

Extra Full	*Full*	*Moderate*	*Low Plus*	*Low*



6.2 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.

6.3 What is Device Tracking

Health Canada has mandated that silicone gel-filled breast implants be 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 silicone-filled 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*® Silicone-Filled Breast Implants or *NATRELLE INSPIRA*® Breast Implants participate in Allergan's Device Tracking program. This will help ensure that Allergan has a record of each patient's contact information so that all patients can be contacted in the case of a recall or other problems with your implants.

6.4 If You Experience a Problem

You should immediately report any problems that you notice with your implants to your plastic surgeon. If you believe that you have experienced a serious problem(s) related to your breast implants, you should have your health professional report the problem(s) to Allergan.

6.5 *ConfidencePlus*® Limited Warranties

The *ConfidencePlus*® and *ConfidencePlus*® Premier Warranty provide lifetime replacement and limited financial reimbursement for various events not limited to shell leakage or breakage resulting in implant rupture, subject to certain conditions as fully discussed in the *ConfidencePlus*® literature. Our standard *ConfidencePlus*® Warranty program applies automatically to every *NATRELLE*® breast implant recipient subject to the conditions discussed in the *ConfidencePlus*® literature. For more information, please visit www.natrelle.ca or contact Allergan's Product Support Department at 1.800.624.4261.

6.6 How To Receive More Information

You may access the package insert (Information for Physicians/Directions for Use; *NATRELLE*® Gel-Filled Breast Implants document) online at https://www.allergan.ca/en-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 at (www.hc-sc.gc.ca).

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

TOLL-FREE NUMBER

If you are a patient or a prospective patient and wish to speak to a *NATRELLE*® 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 1.866.653.9308.

ADDITIONAL RESOURCES

Allergan
1.800.624.4261
www.natrelle.ca

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 240.276.3103

www.fda.gov/breastimplants

APPENDIX - DATA TABLES

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

Table 1. Core Study (TruForm® 1 Implants)

10-Year Complication Rates by Patient

Complication*	Primary Reconstruction N = 98 Patients	Revision-Reconstruction N = 15 Patients
Reoperation	71.5%	46.7%
Implant Removal with Replacement	48.0%	13.3%
Implant Rupture (MRI cohort)	35.4%	0%
Capsular Contracture Baker Grade III/IV	24.6%	6.7%
Asymmetry	23.2%	6.7%
Implant Removal without Replacement	13.6%	6.7%
Wrinkling/Rippling	10.2%	0%
Swelling	7.1%	0%
Breast Pain	6.8%	0%
Implant Palpability/Visibility	6.4%	6.7%
Hypertrophic/Other Abnormal Scarring	5.5%	0%
Nipple Complications	3.3%	0%
Infection	3.2%	0%
Implant Malposition	2.3%	13.3%
Seroma/Fluid Accumulation	2.3%	6.7%
Tissue/Skin Necrosis	2.3%	0%
Redness	2.1%	0%
Skin Rash	2.0%	6.7%
Hematoma	1.5%	0%
Bruising	1.0%	6.7%
Breast/Skin Sensation Changes, Delayed Wound Healing, Implant Extrusion, Other Complications	1.0% each	0%
Capsule Calcification, Gel Migration, Irritation, Lymphadenopathy, Lymphedema, Pneumothorax, Ptosis	0%	0%

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

Table 2. Core Study (TruForm® 1 Implants)

Main Reason for Reoperation through 10 Years

Reason for Reoperation	Primary Reconstruction n	Revision-Reconstruction n
Implant Malposition	16	0
Asymmetry	15	2
Suspected Rupture	14	0
Capsular Contracture	12	2
Need for Biopsy	8	1
Hematoma/Seroma	8	0
Ptosis (sagging)	4	1
Scarring	3	1
Breast Cancer Mass, Patient Request for Style/Size Change	3 each	0
Breast Tissue Contour Deformity, Implant Extrusion	2 each	0
Nipple Complications	1	5
Delayed Wound Healing, Necrosis, Wrinkling/Rippling	1 each	0
Total	94	12

For Further Reading and Information

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FORMS
SECTION II

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 Reconstruction with *NATRELLE*® Gel-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 various events, 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.
Capsular 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 for rupture and deflation, 5 years of product replacement for capsular contracture (Baker grade III.IV), double capsule, and late seroma, and up to $3,500 US (silicone) in financial assistance subject to the conditions discussed in the *ConfidencePlus*® literature.

The optional *ConfidencePlus*® Premier breast implant limited warranty provides additional coverage for deflation of *NATRELLE*® saline-filled breast implants. For the low enrollment fee of $200 US you are eligible for up to $3,500 US in financial assistance in the event of a *NATRELLE*® saline deflation subject to the conditions discussed in the *ConfidencePlus*® literature.

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*® Gel-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*® Gel-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
https://www.smartbeautyguide.com/procedures/breast/breast-reconstruction/

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*® Gel-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*® Gel-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
https://www.smartbeautyguide.com/procedures/breast/breast-reconstruction/

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 gel breast implants. I understand that some of this information is about breast implants in general and some is specific to Allergan's breast implants. I understand that choosing to have 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 labeling. 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 11.7% of patients[1]),
- skin or nipple areola sensitivity changes or loss (nipple complications reported in up to 6.3% of patients[1] and breast/skin sensation changes reported in up to 2.2% of patients[1]),
- asymmetry (reported in up to 23.2% of patients[1]),
- impact of aging or weight change on size and shape of breast (ptosis reported in up to 4.9% of patients[1]),
- infection requiring possible removal of implant (reported in up to 3.2% of patients[1]),

[1] Based on the largest complication rate reported in the Core Clinical Study through 10-years of follow-up. See the Natrelle® Gel-Filled Breast Implants patient brochures for Breast Augmentation (Section 4) or Breast Reconstruction (Section 5).

- swelling (reported in up to 9.2% of patients[1]),
- scarring (hypertrophic scarring reported in up to 6.6% of patients[1]),
- fluid collections (seroma)(reported in up to 6.7% of patients[1]),
- hematoma (reported in up to 2.1% of patients[1]),
- tissue death of breast skin or nipple (tissue/skin necrosis reported in up to 2.3% of patients[1]),
- inability to breast feed (lactation complications reported in up to 30% of patients[1]),
- complications of anesthesia (may occur but specific rates are not publicly available in the Allergan Core Study),
- bleeding (may occur but specific rates are not publicly available in the Allergan Core Study),
- chronic pain (may occur but specific rates are not publicly available in the Allergan Core Study),
- damage to surrounding tissue, such as muscle, nerves, and blood vessels (may occur but specific rates are not publicly available in the Allergan Core Study), and
- impact on imaging of breast tissue (may occur but specific rates are not publicly available in the Allergan Core Study).

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.[2] Discussion of the risk of BIA-ALCL can be found on Health Canada's website.[3]

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.

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.

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[2] 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

[3] https://www.canada.ca/en/health-canada/services/drugs-medical-devices/breast-implants/risks.html#rare_risk

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 32.4% of women who received 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 Core Clinical Study for Natrelle Silicone gel-filled breast implants. The rate specified represents the largest reported cumulative 10-year rate across all groups of augmentation patients in the study (both primary and revision)).

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 28.7% of patients[1]),
- rupture or leaking of the implant (reported in up to 35.4% of patients[1]),
- wrinkling of the implant (wrinkling/rippling reported in up to 10.2% of patients[1]),
- visibility of the implant edges (implant palpability/visibility reported in up to 6.7% of patients[1]),
- shifting of the implant (implant malposition reported in up to 13.3% of patients[1]), or
- reoperation (reported in up to 71.5% 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 the section entitled, "*NATRELLE*® Silicone-Filled/Saline-Filled Breast Implant Device 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 surgeon, 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 an 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 respective 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

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Irvine, CA 92612

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