

# Directions for Use (DFU)

## NATRELLE® Silicone-Filled Breast Implants Smooth surface implants

Physician Labeling



**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.



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# INTRODUCTION

## DIRECTIONS TO THE SURGEON

***This document contains information that is essential to the patient consultation process. Please familiarize yourself with the content of this document and resolve any questions or concerns prior to proceeding with the use of this device.***

The information supplied in this *Directions for Use* document is intended to provide an overview of essential information about NATRELLE® Gel-Filled Breast Implants, including the indications for use, contraindications, warnings, precautions, complications and summaries of clinical study results.

Sections of this *Directions for Use* document indicated by “**Patient Counseling Information**” contain points that the physician should review when counseling the patient about gel-filled breast implants and breast implant surgery.

### ***Physician Education***

Allergan offers a physician education program via the Allergan Academy™ to educate physicians on issues relevant to Allergan’s breast implants. The primary goals of the Allergan Academy™ are to convey important information to physicians from Allergan’s multicenter clinical studies and implant retrieval analyses, and to ensure that physicians are equipped with the most current clinical outcome and risk information to provide to their patients. Please contact your local Allergan Plastic Surgery Sales Representative or the Allergan Customer Care Department for further information on the Allergan Academy™ and other Allergan physician education initiatives.

## INFORMATION TO BE DISCUSSED WITH THE PATIENT

### ***WARNINGS, PRECAUTIONS, ADVERSE EVENTS***

#### ***Patient Counseling and Informed Decision Information***

Breast implant surgery is known to provide satisfaction to patients, *HOWEVER*, as with any surgical procedure, it is *NOT* without risks. Breast implantation is an elective procedure, and the patient must be well counseled and understand the risk-benefit relationship.

At the initial visit/consultation, each patient should be informed of Allergan’s **Patient Planner for Breast Augmentation or Reconstruction with NATRELLE® Gel-Filled Breast Implants**. The planner is available online:

English: [www.allergan.ca/en-ca/products/medical-devices](http://www.allergan.ca/en-ca/products/medical-devices)

French: [www.allergan.ca/fr-ca/products/medical-devices](http://www.allergan.ca/fr-ca/products/medical-devices)

The surgeon or a designated patient counselor should instruct the patient to read the patient information carefully and also discuss with the patient the warnings, precautions, and complications listed in this *Directions for Use* document. The physician should advise the patient of the potential complications and that medical management of serious complications may include additional surgery and explantation. Patients should understand that breast implant surgery can cause irreversible changes to the breast.

## **INFORMED CONSENT**

### ***Patient Counseling Information***

Before making the decision to proceed with surgery the patient should be allowed sufficient time to read and adequately understand the important patient information in Allergan's **Patient Planner** (patient decision-making aid) on the risks, follow-up recommendations, and benefits associated with silicone gel-filled breast implant surgery.

In order to document a successful informed decision process, the ***Acknowledgement of Informed Decision and Patient Decision Checklist*** document (available separately and within the Patient Planner) should be signed by both the patient and the surgeon. A copy should be provided to the patient and another retained in the patient's file.

## **DEVICE TRACKING**

Health Canada has mandated that silicone gel-filled breast implants be subject to Device Tracking. This means that the physician is required to report to Allergan the serial number of the implanted device(s), the date of surgery, information relating to the physician's practice, and information on the patient receiving the implant(s). This information should be recorded on the **Device Tracking Form** supplied by Allergan with each silicone gel-filled breast implant. Following surgery, return the first page of the form to Allergan, using the contact information provided on the form.

The second page of the form should be provided to the patient following surgery. The patient has the right to have her personal information removed from Allergan's Device Tracking program. However, 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.

**Device tracking information can also be provided electronically via the AbbVie Device Management Portal. To use the AbbVie Device Management Portal, go to [www.devicemanagement.abbvie.com](http://www.devicemanagement.abbvie.com) to register and start data entry.**

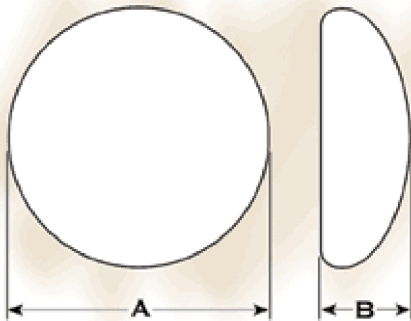
## DEVICE DESCRIPTIONS

The gel-filled breast implants in the *NATRELLE*® Collection are constructed with barrier shell technology resulting in a low diffusion silicone elastomer shell and are filled with TruForm® gel. TruForm® is the specially formulated, premium quality gel used in the *NATRELLE*® Collection. 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, and 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.

The Collection includes TruForm® 1 (formerly known as Cohesive) Gel-Filled Breast Implants, TruForm® 2 (formerly known as Soft Touch™) Gel-Filled Breast Implants, TruForm® 3 (formerly known as Highly Cohesive) Gel-Filled Breast Implants, and *INSPIRA*® (implants that are filled to about 95% of volume with TruForm® 1 or TruForm® 2 gel). All styles consist of a shell, a patch, and silicone gel fill and are dry- heat sterilized.

*NATRELLE*® TruForm® Gel-Filled Breast Implants are available with a smooth surface.

*NATRELLE*® TruForm® 1 Breast Implants are round implants filled with TruForm® 1 gel.



A = Width; B = Projection

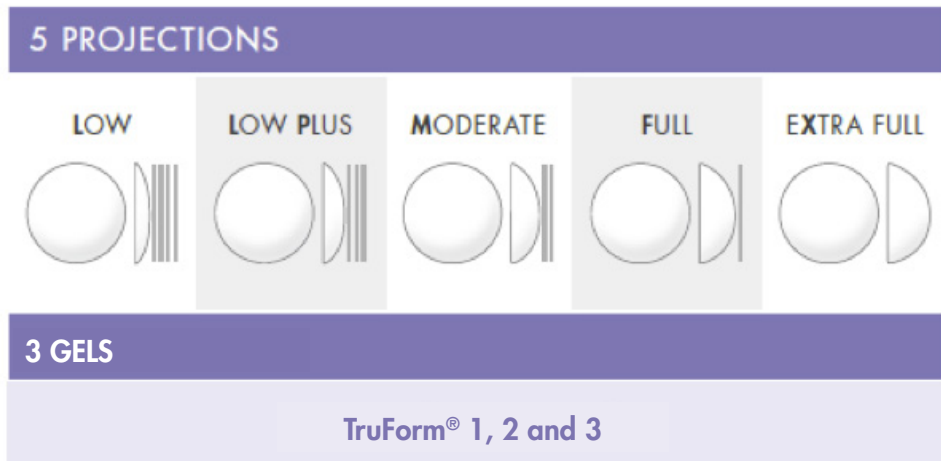


*NATRELLE* TruForm® 1 Breast Implant

<b>NATRELLE® Round TruForm® 1 Style Number</b>	<b>Breast Implant Description</b>	<b>Size Range</b>
Style 10	Smooth shell surface, moderate projection	120cc – 800cc
Style 15	Smooth shell surface, mid-range projection	155cc – 752cc
Style 20	Smooth shell surface, high projection	120cc – 800cc

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 in TruForm® 1, TruForm® 2 or TruForm® 3 gel in multiple configurations.

### **NATRELLE® INSPIRA® TruForm® 1, 2 and 3 Breast Implant Matrix**



***NATRELLE INSPIRA Breast Implant***



### **NATRELLE® INSPIRA® TruForm 1**

<b>NATRELLE® INSPIRA® TruForm® 1 Style Number</b>	<b>Breast Implant Description</b>	<b>Size Range</b>
SRL N-SRL	Smooth shell surface, responsive (TruForm® 1 gel), low profile	110 – 610g
SRLP N-SRLP	Smooth shell surface, responsive (TruForm® 1 gel), low profile plus	125 – 640g
SRM N-SRM	Smooth shell surface, responsive (TruForm® 1 gel), moderate profile	140 – 755g
SRF N-SRF	Smooth shell surface, responsive (TruForm® 1 gel), full profile	180 – 770g
SRX N-SRX	Smooth shell surface, responsive (TruForm® 1 gel), extra full profile	200 – 800g

### **NATRELLE® INSPIRA® TruForm 2**

<b>NATRELLE® INSPIRA® TruForm® 2 Style Number</b>	<b>Breast Implant Description</b>	<b>Size Range</b>
SSL N-SSL	Smooth shell surface, Soft Touch (TruForm® 2 gel), low profile	110 – 610g
SSLP N-SSLP	Smooth shell surface, Soft Touch (TruForm® 2 gel), low profile plus	125 – 640g
SSM N-SSM	Smooth shell surface, Soft Touch (TruForm® 2 gel), moderate profile	140 – 755g
SSF N-SSF	Smooth shell surface, Soft Touch (TruForm® 2 gel), full profile	180 – 770g
SSX N-SSX	Smooth shell surface, Soft Touch (TruForm® 2 gel), extra full profile	200 – 800g

## **NATRELLE® INSPIRA® Cohesive (TruForm® 3 gel)**

<b>NATRELLE® INSPIRA® Cohesive Style Number</b>	<b>Breast Implant Description</b>	<b>Size Range</b>
SCL	Smooth shell surface, Highly Cohesive (TruForm® 3 gel), low profile	110 – 610g
SCLP	Smooth shell surface, Highly Cohesive (TruForm® 3 gel), low profile plus	125 – 640g
SCM	Smooth shell surface, Highly Cohesive (TruForm® 3 gel), moderate profile	140 – 755g
SCF	Smooth shell surface, Highly Cohesive (TruForm® 3 gel), full profile	180 – 770g
SCX	Smooth shell surface, Highly Cohesive (TruForm® 3 gel), extra full profile	200 – 800g

## **INDICATIONS**

- **Breast Augmentation** - A woman must be at least 22 years old for breast augmentation.
- **Breast Reconstruction**
- **Revision of previous breast augmentation or reconstruction** to correct or improve the result of the previous surgery

## **CONTRAINDICATIONS**

### **Patient Groups in which the product is contraindicated:**

- Women with existing malignant or pre-malignant tumors of the breast without adequate treatment
- Women with an active infection anywhere in the body
- Women who are currently pregnant or nursing

## **WARNINGS**

**There is a boxed warning on all breast implants. (Please see cover page.)**

**Surgical practices in which product use is contraindicated due to potential for compromise of product integrity:**

- **Alteration:** Do not alter the implant.

- **Stacking of implants:** Do not place more than one implant per breast.
- **Reuse:** Single use only. Do not resterilize or reuse explanted implants.
- **Closed Capsulotomy:** Do not treat capsular contracture by forceful external compression, which will likely result in implant damage, rupture, folds and/or hematoma.
- **Periumbilical approach:** Do not use the periumbilical approach for placement of the implant.

### **AVOID DAMAGE DURING SURGERY**

- ***Care should be taken to avoid the use of excessive force and to minimize handling of the implant during surgical insertion.***

Data accumulated from Allergan's retrieval study analyses of explanted ruptured silicone gel-filled breast implants, observations of surgeries, and a review of the published literature, indicate that forcing an implant through too small an opening or applying concentrated, localized pressure on the implants may result in localized weakening of the breast implant shell potentially leading to shell damage and possible implant rupture.

An incision should be of appropriate length to accommodate the style, size, and profile of the implant. The incision needed for silicone-filled breast implants will be longer than the one typically made for a saline breast augmentation. The unique nature of the more cohesive gel in the TruForm® 3 breast implant requires an even larger incision to reduce excessive stress on the implant during insertion and minimize the potential for implant damage or deformation (change in shape).

- ***Care should be taken when using surgical instruments in proximity with the breast implant, including scalpel, sutures, and dissection instrumentation.***

Silicone-filled breast implants are prone to unintended instrument trauma during implantation or during explantation (Brandon et al. 2001, Young and Watson 2001). Shell failure can result from damage by scalpels, suture needles, hypodermic needles, hemostats, and Adson forceps, and has been observed in explanted device shells using scanning electron microscopy (Brandon et al. 2001). Allergan's analyses (retrieval study) of explanted devices have identified unintended surgical instrument damage as one potential cause of shell failure and thus implant rupture.

- ***Use care in subsequent procedures such as open capsulotomy, breast pocket revision, hematoma/seroma aspiration, and biopsy/lumpectomy to avoid damage to the implant.***

Re-positioning of the implant during subsequent procedures should be carefully evaluated by the medical team and care taken to avoid contamination of the implant. Use of excessive

force during any subsequent procedure can contribute to localized weakening of the breast implant shell potentially leading to decreased device performance.

- ***Do not contact the implant with disposable, capacitor-type cautery devices.***
- ***Do not alter the implants or attempt to repair or insert a damaged prosthesis.***

### **MICROWAVE DIATHERMY**

The use of microwave diathermy in patients with breast implants is not recommended, as it has been reported to cause tissue necrosis, skin erosion, and extrusion of the implant.

## **PRECAUTIONS**

### **SPECIFIC POPULATIONS**

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

- Autoimmune diseases (for example, lupus and scleroderma).
- A compromised immune system (for example, currently receiving immunosuppressive therapy).
- Conditions or medications that interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue.
- Planned chemotherapy following breast implant placement.
- Planned radiation to the breast following implantation.
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Patients should be assessed for any history of mental health disorders and should be referred to a mental health professional for further follow up and treatment if necessary. Patients with a diagnosis of depression or other mental health disorder should not undergo surgery until these conditions resolve.

### **MAMMOGRAPHY**

#### ***Patient Counseling Information***

With breast implants, routine screening mammography will be more difficult. The patient should continue to perform monthly breast examinations for cancer screening; however, this may be more difficult. The implant may interfere with finding breast cancer during mammography. Because the breast and implant is squeezed during mammography, an implant may rupture during the procedure. More x-ray views are necessary for women with breast implants; therefore, a patient will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays.

Patients should be instructed to inform their mammographers about the presence, type and placement of their implants. Patients should be advised to request **diagnostic mammography** rather than **screening mammography**.

Presurgical mammography with a follow-up mammogram 6 months to 1 year following surgery may be performed to establish a baseline for future routine mammography.

## **RADIATION TO THE BREAST**

Allergan has not tested the *in-vivo* effects of radiation therapy in patients who have breast implants. The literature suggests that radiation therapy does not compromise implant integrity, but may increase the likelihood of capsular contracture, necrosis, and extrusion.

## **LONG-TERM EFFECTS**

### ***Patient Counseling Information***

Allergan's clinical study of the TruForm® 1 implants (the Core Study) monitored the long-term (10 years) safety and effectiveness of these products. In addition, Allergan has initiated a separate large 10-year post approval study (the Breast Implant Follow-up Study, or BIFS) to address specific issues which the other studies were not designed to fully answer, as well as to provide a real-world assessment of some endpoints. Allergan will update its labeling on a regular basis with the results of these studies.

## **IMPORTANT FACTORS TO BE DISCUSSED WITH THE PATIENT**

### ***Patient Counseling Information***

The following information should be discussed with patients prior to their decision to proceed with surgery:

- ***Professional Care*** – Patients should be advised that follow-up exams as prescribed by their plastic surgeon are recommended to monitor the status of their breast implants.
- ***Avoiding Damage during Treatment*** – Patients should be instructed to inform other treating physicians of the presence of implants to minimize the risk of damage to the implants.
- ***Smoking*** – Patients should be informed that smoking may interfere with the healing process.
- ***Breast Examination Techniques*** – Patients should be instructed to follow the most current medical recommendations regarding breast examination and mammography frequency appropriate for their age and medical history. To maximize the effectiveness of breast self-examinations for any palpable lesions, patients should be instructed how to distinguish the implant from breast tissue.

- **Mental Health and Elective Surgery** – It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Request that your patient openly discuss with you, prior to surgery any history that she may have of depression or other mental health disorders.

## COMPLICATIONS

- **Rupture** – Patients should be informed that gel-filled breast implants are not lifetime devices and that there is a potential for implant rupture. The decision to remove a ruptured or suspected ruptured implant should be undertaken following review of all available clinical information and after careful consideration between you and your patient. However, if implant rupture is diagnosed, it is recommended that the implant be removed.
- **Clinical Management of Suspected and Confirmed Rupture** – Patients should be informed that following a diagnosis of suspected or confirmed rupture that implant removal might be recommended by their surgeon, particularly in those instances where there may be evidence that silicone gel has moved beyond the confines of the fibrous capsule that typically forms around the device. Most surgeons in Allergan’s clinical studies have chosen to remove implants suspected of rupture.

Patients should be aware that, rarely, an intracapsular rupture may progress to an extracapsular rupture. Studies of Danish women indicate that over a 2-year period, about 10% of the implants with intra-capsular rupture progressed to extracapsular rupture as detected by MRI, i.e. for women with silicone gel rupture within the scar tissue capsule detected via MRI after 2 years, 1 in 10 of these women will have progression of the gel outside the scar tissue capsule. In about half of these cases of progression from intra- to extra-capsular rupture, the women had experienced trauma or mammography. In the other half, no cause was given.

In the women with extracapsular rupture, after 2 years, the amount of silicone seepage outside the scar tissue capsule increased for about 14% of these women, i.e. for 100 women with silicone gel rupture outside the scar tissue capsule, the amount of gel outside the scar tissue capsule increased for 14 women 2 years later. This type of information is not available for Allergan-specific implants and it pertains to a variety of silicone implants from a variety of manufacturers and implant models. Given the greater cohesivity of TruForm® 3 implants, it is likely that they have less risk of extracapsular rupture than other silicone implants.

- **Monitoring for Implant Rupture** – Patients should be informed that periodic evaluation of the integrity of their breast implants is required to determine whether the implant has ruptured in the absence of any clinical symptoms. While there are various diagnostic methods available to evaluate for possible implant rupture including physical examination, mammogram, and ultrasound, Magnetic Resonance Imaging (MRI) has been proposed as

a means to detect breast implant rupture. In most cases, an MRI diagnosis of rupture or possible rupture is consistent with a ruptured implant at explantation (Brown et al. 2000, Holmich et al. 2004). However, the scientific value of MRI is still developing. Allergan's clinical study results and other published reports have found that in some cases MRI may falsely show a breast implant rupture when there is none (false positive). In some cases MRI may also show no breast implant rupture when there is one (false negative). Scaranelo et al. (2004) found that the sensitivity and specificity of MRI to detect rupture in asymptomatic patients was 64% and 77%, respectively. Thus, MRI findings of rupture should not be considered definitive (Scaranelo et al. 2004).

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. Health Canada and the Canadian Expert Advisory Panel on silicone gel-filled breast implants advocate the following approach to monitor patients with breast 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 the plastic surgeon, the implant(s) may be removed, with or without replacement.**

### **Rupture Rate Information on Allergan Implants**

#### ***TruForm® 1 Breast 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). The rupture rates in the MRI cohorts were 9.3% for primary augmentation, 5.4% for revision-augmentation, 35.4% for primary reconstruction, and 0% for revision-reconstruction. The rupture rate for the combined overall MRI cohort in the Core Study through 10 years was 13.0% for patients and 7.7% for implants. Across all

patients in the Core Study, all ruptures were intracapsular gel, but one rupture progressed to extracapsular gel following exploratory surgery to confirm the rupture and then implant replacement was delayed. There were no cases of migrated gel.

Further rupture rate information on TruForm® 1 implants is provided from a published European study known as the International MRI Study.<sup>29</sup> Silent rupture data were collected via a single MRI on 77 augmentation, 11 reconstruction, and 18 revision patients implanted with smooth and textured *NATRELLE*® implants by surgeons in 5 countries. 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 were three possible case of extracapsular rupture with the remainder classified as intracapsular ruptures. No cases of migrated gel were found.

- **Reoperation (Additional Surgeries)** – Patients should be advised that additional surgery to their breast and/or implant may be necessary over the course of their lives.
- **Capsular Contracture** – Patients should be advised that 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 patients than in primary augmentation or reconstruction patients. Capsular contracture is also a risk factor for implant rupture, and it is one of the most common reasons for reoperation. Patients should also be advised that 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 breast tissue. Capsular contracture may happen again after these additional surgeries.
- **Explantation (Implant Removal)** – Patients should be advised that implants are not considered lifetime devices, and they will potentially undergo implant removal, with or without replacement, over the course of their lives. Patients should also be advised that the changes to their breast following explantation are irreversible.
- **Infection** – In rare instances, acute infection may occur in a breast with implants. The signs of acute infection include erythema, tenderness, fluid accumulation, pain and fever. Very rarely, Toxic Shock Syndrome, a potentially life-threatening condition, has been reported in women after breast implant surgery. It is characterized by symptoms that occur suddenly and include high fever (102°F, 38.8°C or higher), vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches, and drops in blood pressure, which may cause fainting. Patients should be advised to contact a physician immediately for diagnosis and treatment for any of these symptoms.



- **Cosmetic Dissatisfaction (Unsatisfactory Results)** – Patients should be informed that dissatisfaction with cosmetic results related to such things as scar deformity, hypertrophic scarring, capsular contracture, asymmetry, displacement, incorrect size, unanticipated contour, and implant palpability/visibility may occur. Careful surgical planning and technique can minimize, but not preclude, the risk of such results. Pre-existing asymmetry may not be entirely correctable. Physiological and behavioral differences among patients and variations in surgical techniques and medical treatments account for a wide variety of responses to silicone gel-filled breast implant surgery. Revision surgery may be indicated to maintain patient satisfaction but carries additional considerations and risks.
- **Breastfeeding** - Difficulties have been reported following breast surgery, including breast reduction and breast augmentation surgery. A periareolar surgical approach may further increase the chance of breastfeeding difficulties.
- **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. Patients should be advised to contact their surgeon if there is significant pain or if pain persists.
- **Changes in Nipple and Breast Sensation** – Feeling in the nipple and breast can increase or decrease after implant surgery, is typically lost after complete mastectomy where the nipple itself is removed, and can be severely lessened by partial mastectomy. Radiation therapy also can significantly reduce sensation in the remaining portions of the breast or chest wall. The placement of breast implants for reconstruction may further lessen the sensation in the remaining skin or breast tissue. 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 the patient's sexual response or ability to nurse.
- **Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)**  
Based on information reported to global regulatory agencies and found in medical literature, an association has been identified between breast implants and the development of anaplastic large cell lymphoma (ALCL), a type of non-Hodgkin's lymphoma. Women with breast implants may have a very small but increased risk of developing Breast Implant Associated ALCL (BIA-ALCL) in the fluid or scar capsule adjacent to the implant, with documented potential for local, regional, and distant spread of the cancer with mortality reported in rare cases.

BIA-ALCL has been reported globally in patients with an implant history that includes Allergan's and other manufacturers' breast implants with various surface properties, styles, and shapes. Most of the cases in the literature reports describe a history of the use of textured implants.

You should consider the possibility of BIA-ALCL when a patient presents with late onset persistent peri-implant seroma, mass or ulceration typically more than one year post implantation. Rarely, BIA-ALCL can present with a mass, regional lymphadenopathy, overlying skin rash and/or capsular contracture. When testing for BIA-ALCL, collect fresh seroma fluid and representative portions of the breast implant capsule. If a mass is present, excision or core biopsy may be necessary for diagnosis. Samples should be sent to a laboratory with appropriate expertise for pathology tests to rule out BIA-ALCL, including cytology with cell block preparation, immunohistochemistry and/or flow cytometry testing for CD2, CD3, CD4, CD5, CD7, CD8, CD30 and ALK (anaplastic lymphoma kinase). If your patient is diagnosed with BIA-ALCL lymphoma staging and workup will be needed for treatment planning; develop an individualized treatment plan in coordination with a multi-disciplinary care team. Because of the small number of cases worldwide, there is no worldwide consensus on the treatment regimen for peri-implant BIA-ALCL. However, the National Comprehensive Cancer Network (NCCN) provides recommendations for treatment based on disease staging that may include chemotherapy and/or radiotherapy in addition to complete surgical excision of disease and removal of affected implants. Patients should be followed for a minimum of two years and then as clinically indicated. (Ref. NCCN Clinical Practice Guidelines in Oncology, T-cell Lymphomas. Current version).

All pertinent findings respecting cases associated with Allergan devices should be reported to Allergan (e.g., time to clinical presentation, signs or symptoms, immunohistological analysis, type of implant, texture, patient history with implants). Physicians should keep informed of BIA-ALCL in the literature and provide appropriate therapy to patients as needed.

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

- **Additional Complications** – After breast implant surgery the following may occur and/or persist, with varying intensity and/or for a varying length of time: pain, hematoma/seroma, changes in nipple and breast sensation, implant extrusion, necrosis, delayed wound healing, and breast tissue atrophy/chest wall deformity. Calcium deposits can form in the tissue capsule surrounding the implant with symptoms that may include pain and firmness. Lymphadenopathy has also been reported in some women with implants.

### **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 of other conditions in women with breast implants. Many of these conditions, which are listed below, have been studied to evaluate their potential association with breast implants. 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. 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 most recent of these concluded that the weight of the evidence did not support causal association between implants and definite or atypical CTD. The study size needed to conclusively rule out a smaller risk of connective tissue disease ( $\leq 2$ ) would need to be very large. Published studies taken together show that breast implants are not significantly associated with a risk of developing a specific CTD. These studies do not distinguish between women with intact and ruptured implants. Only one study evaluated specific CTD diagnoses and symptoms in women with silent ruptured versus intact implants, but the study was too small to rule out a small risk.

*Signs and Symptoms*

Scientific expert panels and literature reports published between 2000 and 2004 have found no evidence of a consistent pattern of signs and symptoms in women with silicone breast implants. Having these rheumatological signs and symptoms does not necessarily mean that a patient has a connective tissue disease; however, you should advise your patient that she may experience these signs and symptoms after undergoing breast implantation. If a patient has an increase in these signs or symptoms, you should refer your patient to a rheumatologist to determine whether these signs or symptoms are due to a connective tissue disorder or autoimmune disease. Please see systemic symptoms information in the Boxed Warning on the cover page.

- **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 survival of women with breast cancer. 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 recently 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 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.

- **Neurological Disease, Signs, and Symptoms**

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

- **Mental Health Disorders**

Patients should be encouraged to discuss any history of mental health disorders, including a clinical diagnosis of depression, body dysmorphic disorder or eating disorder with you during their consultation visit(s). Patients with a diagnosis of depression or other mental health disorder should be encouraged to wait to schedule surgery until these conditions resolve.

- **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. One of the authors of these human studies recommended further research on infant health. A review of the evidence did not find that offspring of women with implants were at an increased risk for esophageal disorders, rheumatic diseases, or congenital malformations.

- **Gel Diffusion and Potential Health Consequences**

Small quantities of low molecular weight (LMW) siloxane compounds and platinum (in a zero valence/biocompatible state), have been found to diffuse (leak) through an intact implant shell. 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. Other studies have shown evidence of silicone in scar tissue capsules surrounding the implant, in axillary lymph nodes, and in distant organs, which may be due to gel diffusion. The clinical significance of the presence of silicone in these tissues is unknown. Other studies have reported that certain silicones (for example, D4 and D5) and platinum leak from intact breast implants and are present in surrounding tissue. The clinical significance to humans of the presence of silicone in the body tissues is unknown. However, there has been no evidence in the medical literature or from Allergan's own testing associating gel diffusion with local complications in breast implant patients. Studies have demonstrated that the low concentration of platinum contained in breast implants is in the zero valence or most biocompatible state.

- **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.

## **PRECLINICAL STUDY INFORMATION**

Preclinical study of the silicone-filled breast implants revealed that the materials of which the devices are made are biocompatible, the silicone elastomer shell is durable, and there is a low potential for gel diffusion (bleed). A summary of the preclinical studies conducted by Allergan, including chemistry, toxicology, and physical/mechanical testing can be found in the Summary Basis for Decision (SBD) document on Health Canada's website at [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca).

## **ALLERGAN'S CLINICAL STUDIES**

### **Overview of Allergan's Core Clinical 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 implanted with TruForm® 1 breast implants. *NATRELLE*® *INSPIRA*® implants were not included in the study. Patient follow-up was at 0-4 weeks, 6 months, 12 months, 24 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 body image/esteem and self-esteem.

The Core Study consisted of 715 patients. This included 455 augmentation patients, 147 revision-augmentation patients, 98 reconstruction patients, and 15 revision-reconstruction patients. The study is complete, and the final results through 10 years are reported in this brochure. Please note that Core Study assessed both BIOCELL textured and smooth breast implants. BIOCELL textured breast implants were recalled in July 2019 due to a higher risk associated with BIA-ALCL and are no longer manufactured or marketed.

### **Augmentation and Revision-Augmentation Patients**

Described below are the benefits and complications reported in the Allergan Core Study for augmentation and revision-augmentation patients.

Allergan's results indicate that the risk of any complication at some point through 10 years after implant surgery was 32.9% for primary augmentation patients and 38.6% for revision-augmentation patients. However, the majority of women were satisfied with their implants. The results also indicate that the chance of additional surgery (reoperation) through the first 10 years was more than 1 in 3 for primary augmentation patients (with implant removal with replacement as the most common type of additional surgery), and about 1 in 2 for revision-augmentation patients (with the most common type of additional surgery being implant removal with replacement). The information below provides more details about the complications and benefits of TruForm® 1 breast implants.

#### *Patient Accounting (Follow-Up Rates)*

The Core Study enrolled 455 augmentation patients. Of the women expected to be seen at the 10-year follow-up visit, 67% were seen.

The Core Study enrolled 147 revision-augmentation patients. Of the women expected to be seen at the 10-year follow-up visit, 64% were seen.

#### **Effectiveness Outcomes**

The benefits of TruForm® 1 breast implants were assessed by a variety of outcomes, including bra cup size change and assessments of patient satisfaction, body image, body esteem, and self concept. Data were collected before implantation and at scheduled follow-up visits.

#### **Primary Augmentation Patients:**

For primary augmentation patients, 396 of the original 455 patients had a breast measurement within 18 months of surgery. Of these 396 patients, 41% increased by 1 cup size; 45% increased by 2 cup sizes; 8% increased by more than 2 cup sizes; and 5% had no increase or decrease.

Allergan patient satisfaction was based on a 5-point scale assessment of satisfaction with their implants at the time of the follow-up visits. Of the original 455 patients, 279 (61%) provided a satisfaction rating at 10 years after implantation, with 94% of these patients indicating that they were satisfied with their breast implants.

Quality of life assessments were made at 1, 2, 4, 6, 8, and 10 years post-implantation. For primary augmentation patients, the SF-36, which measures mental and physical health, showed a slight improvement in one scale and a slight worsening in some of the other scales after 10 years compared to before breast implantation, although all scales remained higher than the general U.S. female population. For patient responses to questions regarding overall self-concept/self-esteem, there was a decrease in self-concept on the Tennessee Self Concept Scale and no change in overall self-esteem on the Rosenberg Self Esteem Scale 10 years after receiving implants. Patient responses to questions on the Body Esteem Scale showed decreases regarding

overall body image, weight concern, and physical condition, and an increase with regard to sexual attractiveness. On the Rowland Expectation Scale, patients showed significant improvement in self-image, social relations, and daily living. Breast satisfaction was significantly increased after 10 years, including satisfaction with breast size, shape, feel, and how well they matched.

### **Revision-Augmentation Patients:**

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

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 147 revision-augmentation patients, 74 (50%) provided a satisfaction rating at 10 years. Of these 74 patients, 73% indicated that they were satisfied with their breast implants.

For revision-augmentation patients, the SF-36, which measures mental and physical health, showed no significant changes in all but one of these scales after 10 years. Patient responses to questions on the Tennessee Self Concept Scale and Rosenberg Self Esteem Scale regarding overall self-concept/self-esteem showed no changes 10 years after receiving implants. Patient responses to questions on the Body Esteem Scale regarding overall body image showed no changes, but a decrease with regard to physical condition was shown. On the Rowland Expectation Scale, patients showed significant improvement in self-image, social relations, and daily living. Breast satisfaction was significantly increased after 10 years, including satisfaction with breast size, shape, feel, and how well they matched.

### **Safety Outcomes**

Table 1 describes the complications experienced by primary augmentation and revision-augmentation patients in the Core Study.



**Table 1**  
**Core Study: Complications**  
**10-Year Cumulative First Occurrence Kaplan-Meier Risk Rates, By Patient**

Complication*	Primary Augmentation N = 455 Rate (%) (95% CI)	Revision-Augmentation N = 147 Rate (%) (95% CI)
Reoperation	36.1% (31.6%, 40.9%)	46.0% (38.0%, 54.9%)
Capsular Contracture Baker Grade III/IV	18.9% (15.4%, 23.1%)	28.7% (21.3%, 37.9%)
Implant Removal with Replacement	18.6% (15.0%, 22.8%)	30.1% (22.8%, 39.0%)
Breast Pain	11.5% (8.7%, 15.0%)	11.7% (7.1%, 18.8%)
Swelling	9.2% (6.8%, 12.4%)	8.2% (4.6%, 14.5%)
Implant Rupture (MRI cohort)	9.3% (5.3%, 15.8%)	5.4% (1.4%, 20.0%)
Implant Malposition	6.9% (4.8%, 9.7%)	6.0% (3.1%, 11.7%)
Nipple Complications	6.3% (4.3%, 9.1%)	1.4% (0.3%, 5.4%)
Scarring/Hypertrophic Scarring	4.2% (2.6%, 6.5%)	6.6% (3.5%, 12.3%)
Asymmetry	3.3% (2.0%, 5.6%)	6.5% (3.2%, 12.8%)
Implant Removal without Replacement	2.8% (1.6%, 5.0%)	4.0% (1.7%, 9.4%)
Ptosis	2.0% (1.0%, 3.9%)	4.9% (2.2%, 10.5%)
Seroma/Fluid Accumulation	1.8% (0.9%, 3.5%)	6.0% (3.0%, 11.7%)
Wrinkling/Rippling	1.8% (0.8%, 3.7%)	5.4% (2.6%, 11.0%)
Breast/Skin Sensation Changes	1.6% (0.8%, 3.3%)	2.2% (0.7%, 6.6%)
Hematoma	1.6% (0.7%, 3.2%)	2.1% (0.7%, 6.3%)
Implant Palpability/Visibility	1.6% (0.8%, 3.4%)	6.0% (3.0%, 11.6%)
Delayed Wound Healing	1.1% (0.5%, 2.7%)	<1%
Bruising	<1%	3.0% (1.1%, 7.8%)
Infection	<1%	1.4% (0.3%, 5.4%)
Capsule Calcification, Gel Migration, Implant Extrusion, Irritation, Lymphadenopathy, Lymphedema, Other Complications, Pneumothorax, Redness, Skin Rash, Tissue/Skin Necrosis	0% - <1%	0% - <1%

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

## Reasons for Reoperation

Table 2 provides the main reason for each reoperation performed through 10 years in primary augmentation and revision-augmentation patients.

**Table 2**  
**Core Study: Main Reason for Reoperation through 10 Years**

Reason for Reoperation	Primary Augmentation n (% of 221 reoperations)	Revision-Augmentation n (% of 108 reoperations)
Capsular Contracture	55 (24.9%)	26 (24.1%)
Suspected Rupture	29 (13.1%)	7 (6.5%)
Need for Biopsy	28 (12.7%)	9 (8.3%)
Implant Malposition	27 (12.2%)	12 (11.1%)
Ptosis	25 (11.3%)	9 (8.3%)
Hematoma/Seroma	13 (5.9%)	13 (12.0%)
Patient Request for Style/Size Change	12 (5.4%)	3 (2.8%)
Scarring/Hypertrophic Scarring	8 (3.6%)	7 (6.5%)
Asymmetry	5 (2.3%)	3 (2.8%)
Breast Cancer Mass	4 (1.8%)	3 (2.8%)
Breast Pain	3 (1.4%)	1 (0.9%)
Delayed Wound Healing	3 (1.4%)	2 (1.9%)
Wrinkling/Rippling	3 (1.4%)	2 (1.9%)
Infection	2 (0.9%)	3 (2.8%)
Implant Palpability/Visibility	1 (0.5%)	1 (0.9%)
Implant Extrusion	1 (0.5%)	1 (0.9%)
Necrosis	1 (0.5%)	0
Nipple Complications	1 (0.5%)	3 (2.8%)
Breast Tissue Contour Deformity, Device Injury, Other	0	1 each (0.9%)
<b>Total</b>	<b>221 (100%)</b>	<b>108 (100%)</b>

## Reasons for Implant Removal

The main reasons for implant removal among primary augmentation and revision-augmentation patients over the 10 years are shown in Table 3.

**Table 3**  
**Core Study: Main Reason for Implant Removal through 10 Years**

Reason for Removal	Primary Augmentation n (% of 156 Explants)	Revision-Augmentation n (% of 78 Explants)
Capsular Contracture	50 (32.1%)	28 (35.9%)
Patient Request for Style/Size Change	31 (19.9%)	11 (14.1%)
Suspected Rupture	27 (17.3%)	6 (7.7%)
Ptosis	12 (7.7%)	6 (7.7%)
Implant Malposition	11 (7.1%)	14 (18.0%)
Asymmetry	7 (4.5%)	1 (1.3%)
Wrinkling/Rippling	6 (3.9%)	2 (2.6%)
Breast Pain	5 (3.2%)	1 (1.3%)
Breast Cancer Mass	2 (1.3%)	2 (2.6%)
Infection	2 (1.3%)	2 (2.6%)
Breast Tissue Contour Deformity, Implant Extrusion, Need for Biopsy	1 each (0.6%)	0
Scarring/Hypertrophic Scarring, Other	0	2 each (2.6%)
Implant Palpability/Visibility	0	1 (1.3%)
<b>Total</b>	<b>156 (100%)</b>	<b>78 (100%)</b>

## Other Events

Through 10 years, events other than the complications described in the previous tables were collected in the Core Study for augmentation and revision-augmentation patients. Some of these events, such as breast cancer and CTD, can occur in non-implanted patients. Therefore, without a comparison group of women with similar characteristics (such as age, race, etc.) and without breast implants, no conclusions can be made about the relationship between breast implants and some of these other events.

Benign breast disease occurred in 18% of primary augmentation and in 20% of revision-augmentation patients. Malignant breast disease occurred in 1% of primary and 1% of revision-augmentation patients. CTD events occurred in 1% of primary and 1% of revision-augmentation patients.

### **Reconstruction and Revision-Reconstruction Patients**

Described below are the benefits and complications reported in the Core Study for reconstruction and revision-reconstruction patients.

Allergan's results indicate that the risk of any complication at some point through 10 years after implant surgery is 47% for primary reconstruction patients and 47% for revision-reconstruction patients. However, the majority of women were satisfied with their implants. The results also indicate that the chance of additional surgery (reoperation) through the first 10 years is about 3 in 4 for primary reconstruction patients (with implant removal and replacement as the most common type of additional surgery), and 1 in 2 for revision-reconstruction patients (with nipple reconstruction/tattoo as the most common type of additional surgery). The information below provides more details about the complications and benefits of TruForm® 1 breast implants.

#### *Patient Accounting (Follow-Up Rates)*

The Core Study enrolled 98 reconstruction patients. Of the women expected to be seen at the 10-year follow-up visit, 73% were seen.

The Core Study enrolled 15 revision-reconstruction patients. Of the women expected to be seen at the 10-year follow-up visit, 73% were seen.

### **Effectiveness Outcomes**

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

#### **Primary Reconstruction Patients:**

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 patients, 43 (44%) provided a satisfaction rating at 10 years after implantation, with 90% of these patients indicating that they were satisfied with their breast implants.

Quality of life assessments were made at 1, 2, 4, 6, 8, and 10 years post-implantation. For primary reconstruction patients, the SF-36, which measures mental and physical health, showed no changes after 10 years compared to before breast implantation. 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 self-esteem related specifically to one's body also did not show a change 10 years after receiving implants. On the Rowland Expectation Scale, patients showed significant improvement in self-image, social relations, and well-being. Breast satisfaction was significantly increased after 10 years, including satisfaction with breast size, shape, feel, and how well they matched.

### **Revision-Reconstruction Patients:**

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

For revision-reconstruction patients, responses were similar pre- and post-implantation on the SF-36, Tennessee Self Concept Scale, Rosenberg Self Esteem Scale and Body Esteem Scale. On the Rowland Expectation Scale, patients showed significant improvement in self-image, social relations, and daily living. Breast satisfaction was significantly increased after 10 years, including satisfaction with breast size, shape, feel, and how well they matched.

### **Safety Outcomes**

Table 4 describes the complications experienced by primary reconstruction and revision-reconstruction patients in the Core Study.

**Table 4**  
**Core Study: Complications**  
**10-Year Cumulative First Occurrence Kaplan-Meier Risk Rates, By Patient**

Complication*	Primary Reconstruction N = 98 Rate (%) (95% CI)	Revision-Reconstruction N = 15 Rate (%)** (95% CI)
Reoperation	71.5% (61.2%, 81.0%)	46.7% (21.3%, 73.4%)
Implant Removal with Replacement	48.0% (37.1%, 60.1%)	13.3% (1.7%, 40.5%)
Implant Rupture (MRI cohort)	35.4% (22.1%, 53.6%)	0% ***
Capsular Contracture Baker Grade III/IV	24.6% (16.2%, 36.2%)	6.7% (0.2%, 31.9%)
Asymmetry	23.2% (15.4%, 33.9%)	6.7% (0.2%, 31.9%)
Implant Removal without Replacement	13.6% (7.1%, 24.9%)	6.7% (0.2%, 31.9%)
Wrinkling/Rippling	10.2% (5.2%, 19.6%)	0%
Swelling	7.1% (3.5%, 14.4%)	0%
Breast Pain	6.8% (2.8%, 16.1%)	0%
Implant Palpability/Visibility	6.4% (2.3%, 16.8%)	6.7% (0.2%, 31.9%)
Scarring/Hypertrophic Scarring	5.5% (2.3%, 12.7%)	0%
Nipple Complications	3.3% (1.1%, 9.8%)	0%
Infection	3.2% (1.0%, 9.5%)	0%
Implant Malposition	2.3% (0.6%, 8.9%)	13.3% (1.7%, 40.5%)
Seroma/Fluid Accumulation	2.3% (0.3%, 15.4%)	6.7% (0.2%, 31.9%)
Tissue/Skin Necrosis	2.3% (0.6%, 8.8%)	0%
Redness	2.1% (0.5%, 8.3%)	0%
Skin Rash	2.0% (0.5%, 7.9%)	6.7% (0.2%, 31.9%)
Hematoma	1.5% (0.2%, 10.4%)	0%
Bruising	1.0% (0.1%, 7.1%)	6.7% (0.2%, 31.9%)
Breast/Skin Sensation Changes, Delayed Wound Healing, Implant Extrusion, Other Complications	1.0% each (0.1%, 7.2%)	0%
Capsule Calcification, Gel Migration, Irritation, Lymphadenopathy, Lymphedema, Pneumothorax, Ptosis	0% N/A	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.

\*\* Calculated as a percentage of enrolled with binomial confidence interval.

\*\*\* No ruptures were reported in the MRI cohort (n=5); 1 rupture was reported in the non-MRI cohort (n=10).

## Reasons for Reoperation

Table 5 provides the main reason for each reoperation performed through 10 years in primary reconstruction and revision-reconstruction patients.

**Table 5**  
**Core Study: Main Reason for Reoperation through 10 Years**

Reason for Reoperation	Primary Reconstruction n (% of 94 reoperations)	Revision-Reconstruction n (% of 12 reoperations)
Implant Malposition	16 (17.0%)	0
Asymmetry	15 (16.0%)	2 (16.7%)
Suspected Rupture	14 (14.9%)	0
Capsular Contracture	12 (12.8%)	2 (16.7%)
Hematoma/Seroma	8 (8.5%)	0
Need for Biopsy	8 (8.5%)	1 (8.3%)
Ptosis	4 (4.3%)	1 (8.3%)
Breast Cancer Mass	3 (3.2%)	0
Patient Request for Style/Size Change	3 (3.2%)	0
Scarring/Hypertrophic Scarring	3 (3.2%)	1 (8.3%)
Breast Tissue Contour Deformity, Implant Extrusion	2 each (2.1%)	0
Nipple Complications	1 (1.1%)	5 (41.7%)
Delayed Wound Healing, Necrosis, Wrinkling/Rippling	1 each (1.1%)	0
<b>Total</b>	<b>94 (100%)</b>	<b>12 (100%)</b>

## Reasons for Implant Removal

The main reasons for implant removal among primary reconstruction and revision-reconstruction patients over the 10 years are shown in Table 6.

**Table 6**  
**Core Study: Main Reason for Implant Removal through 10 Years**

Reason for Removal	Primary Reconstruction n (% of 57 explants)	Revision-Reconstruction n (% of 3 explants)
Suspected Rupture	15 (26.3%)	0
Implant Malposition	12 (21.1%)	0
Asymmetry	12 (21.1%)	2 (66.7%)
Capsular Contracture	10 (17.5%)	1 (33.3%)
Patient Request for Style/Size Change	4 (7.0%)	0
Hematoma/Seroma, Implant Extrusion, Necrosis, Wrinkling/Rippling	1 each (1.8%)	0
<b>Total</b>	<b>57 (100%)</b>	<b>3 (100%)</b>

## Other Events

Through 10 years, events other than the complications described in the previous tables were collected in the Core Study for reconstruction and revision-reconstruction patients. Some of these events, such as breast cancer and CTD, can occur in non-implanted patients. Therefore, without a comparison group of women with similar characteristics (such as age, race, etc.) and without breast implants, no conclusions can be made about the relationship between breast implants and some of these other events.

Benign breast disease occurred in 17% of primary reconstruction patients and in 7% of revision-reconstruction patients. Malignant breast cancer was detected in 18% of primary reconstruction patients, with none detected in revision-reconstruction patients. A 2% CTD rate (rheumatoid arthritis and undifferentiated CTD) occurred in primary reconstruction patients, with no CTDs detected in revision-reconstruction patients.



# INSTRUCTIONS FOR USE

**NOTE:** Back-up breast implants should be available during the procedure.

**DO NOT** use more than one implant per breast.

## ***Single Use***

This product is intended for **single use only**. Do not reuse explanted implants.

## ***Product Identification***

Product identification stickers accompanying each device are provided within the internal product packaging. The stickers provide product-specific information and are designed to be attached to the patient's chart for identification purposes.

## ***Surgical Planning***

Allergan relies on the surgeon to know and follow the proper surgical procedures with **NATRELLE**<sup>®</sup> Gel-Filled Breast Implants. Proper surgical planning such as allowance for adequate tissue coverage, implant placement (i.e., submuscular vs. subglandular), incision site, implant type, etc., should be made preoperatively. The surgeon should be aware that the unique nature of the highly cohesive TruForm<sup>®</sup> 3 gel may require a larger incision compared to the incision size required for other silicone-filled implants to avoid skin edge trauma or implant deformation. Excessive force upon insertion of the implant may compromise the precisely defined shape of the device, potentially leading to an undesirable cosmetic outcome. The surgeon must carefully evaluate breast implant size and profile, incision placement, pocket dissection, and implant placement criteria with respect to the patient's anatomy and desired physical outcome.

The surgeon should be aware that more upper pole fullness may be maintained by the TruForm<sup>®</sup> 3 implant than with other breast implants. Planning should include clear delineation of aesthetic goals to ensure mutual understanding between surgeon and patient. The surgeon should observe current and accepted techniques to minimize the risk of adverse, and potentially disfiguring, reactions, bearing in mind the importance of pocket dissection in minimizing implant rotation for the shaped TruForm<sup>®</sup> 2 and TruForm<sup>®</sup> 3 implants.

## ***Preliminary Product Examination***

### ***How to Open Sterile Product Package***

Remove the sterile breast implant from its package in an aseptic environment and using talc-free gloved hands. DO NOT expose the breast implant to lint, talc, sponges, towels, skin oils, or other contaminants.

1. Peel open the lid of the outer thermoform package.
2. Invert the outer thermoform package over the sterile field, allowing the sealed inner thermoform package to gently fall into the field.
3. Peel open the lid of the inner thermoform package using the pull-tab.
4. Gently retrieve the breast implant. Prior to use, keep the breast implant in the inner thermoform package to prevent contact with airborne and surgical field particulate contaminants.

### ***Examination of Silicone-Filled Breast Implants***

Prior to use, examine the breast implant for evidence of any particulate contamination, damage, or loss of shell integrity. If satisfactory, return the breast implant to the inner thermoform tray and cover it with the lid until implanted to prevent contact with airborne contaminants.

**DO NOT** implant any device that may appear to have particulate contamination, damage, or loss of shell integrity. A sterile back-up implant must be readily available at the time of surgery.

**DO NOT** implant any device that may appear to have leaks or nicks.

**DO NOT** implant damaged or contaminated breast implants.

### ***Sterile Product***

Each sterile silicone-filled breast implant is supplied in a sealed, double primary package. Sterility of the implant is maintained only if the thermoform packages, including the package seals, are intact. Use standard procedures to maintain sterility during transfer of the breast implant to the sterile field. Remove the breast implant from its package in an aseptic environment and using talc-free gloved hands.

**DO NOT** use the product if the thermoform packages or seals have been damaged.

**DO NOT** resterilize the product.

Prior to use, keep the breast implant in the inner thermoform and covered to prevent contact with airborne and surgical field particulate contaminants.

### ***Method for Removing Ruptured Silicone Gel from the Surgical Pocket***

In the event of breast implant rupture, the following technique is useful for removal of the silicone mass. Wearing double talc-free surgical gloves on one hand, use the index finger to penetrate the silicone mass. With the other hand, exert pressure on the breast to facilitate manipulation of the silicone mass into the double-gloved hand. Once the silicone is in hand, pull the outer glove over the silicone mass and remove. To remove any residual silicone, blot the surgical pocket with gauze sponges. Avoid contact between surgical instruments and the silicone. If contact occurs, use isopropyl alcohol to remove the silicone from the instruments. Ruptured breast implants must be reported and should be returned to Allergan. In the event of breast implant rupture, contact Allergan's Product Support Department at 1.800.624.4261.

### ***Surgical Procedure Placement***

Ensure incision is sufficiently large to facilitate insertion without excessive manipulation and handling of the device and to avoid damage to the device. Inadequate pocket dissection increases the risk of rupture and implant malposition.

**DO NOT** damage the breast implant with sharp surgical instruments such as needles and scalpels, blunt instruments such as clamps and forceps, or by over handling and manipulation during introduction into the surgical pocket.

**DO NOT** use excessive force during breast implant placement.

**DO NOT** manipulate the implant for either radial expansion, compression or dissection of the pocket.

**Breast augmentation** with silicone-filled implants can be carried out through several different incisions including inframammary, periareolar, or transaxillary. Some surgeons advocate a "no-touch" technique, which requires significant attention to minimizing contact between the patient's skin and the implant. Pocket dissection should be planned out preoperatively and be performed accurately and with minimal trauma. Excellent hemostasis is important to avoid postoperative hematoma. The implant may be placed subglandularly or subpectorally depending upon the balance of cosmetic and medical considerations in any given patient. The size and shape of the device may be determined preoperatively by means of dimensional planning or intraoperatively with the help of temporary sizer devices. The incision for the placement of the implant should be securely closed and in several layers, whenever possible. Drains are optional.

**Breast Reconstruction** is generally carried out in the mastectomy scar. Special care must be used in breast reconstruction to make sure that appropriate amounts of healthy tissue are available to cover the implant and that the implant be properly sized and positioned based upon careful preoperative planning.

**Allergan Academy™ Educational Materials** are available through [www.allerganacademy.com](http://www.allerganacademy.com) or [www.allerganacademy.ca](http://www.allerganacademy.ca) to supplement surgical knowledge of the dimensional techniques intended for use with **NATRELLE®** breast implants.

***Maintaining Hemostasis/Avoiding Fluid Accumulation***

Postoperative hematoma and seroma may be minimized by meticulous attention to hemostasis during surgery, and possibly also by postoperative use of a closed drainage system. Persistent, excessive bleeding must be controlled before implantation.

Any postoperative evacuation of hematoma or seroma must be conducted with care to avoid breast implant contamination or damage from sharp instruments.

## **DOCUMENTATION THE PHYSICIAN SHOULD PROVIDE TO THE PATIENT**

Breast implantation is an elective procedure and the patient must be well counseled on the risk-benefit relationship. The surgeon should provide each prospective patient with the following:

- **Bilingual *Patient Planner for Breast Augmentation or Reconstruction with NATRELLE® Gel-Filled Breast Implants***

This planner should be used to facilitate patient education on the risks and benefits of silicone gel-filled breast implant surgery. The patient should be referred to Allergan's website to obtain the patient planner (English: [www.allergan.ca/en-ca/products/medical-devices](http://www.allergan.ca/en-ca/products/medical-devices) or French: [www.allergan.ca/fr-ca/products/medical-devices](http://www.allergan.ca/fr-ca/products/medical-devices)) during her initial visit/consultation to allow sufficient time for review. You should verify that the patient has an adequate understanding of the information.

- ***Device Identification Card***

Enclosed with each silicone-filled breast implant is Allergan's Device Identification Card. To complete the Device Identification Card, place one device identification sticker for each implant on the back of the card. Stickers are located on the internal product packaging attached to the label. If a sticker is unavailable, the lot number, catalog number and description of the device may be copied by hand from the device label. Patients should be provided with these cards for personal reference.

- ***Acknowledgement of Informed Decision and Patient Decision Checklist***

In order to document a successful informed decision process, the **Acknowledgement of Informed Decision and Patient Decision Checklist** document (available separately at: [www.allergan.ca/en-ca/products/medical-devices](http://www.allergan.ca/en-ca/products/medical-devices) or [www.allergan.ca/fr-ca/products/medical-devices](http://www.allergan.ca/fr-ca/products/medical-devices)) should be signed by both the patient and the surgeon. A copy should be provided to the patient and a copy should be retained in the patient's file.

## **ADDITIONAL SPECIFIC PRODUCT INFORMATION**

### ***Returned Goods Policy***

Product returns should be handled through an Allergan Plastic Surgery Sales Representative or through the Customer Care Department at 1.866.653.9308. Return value is based on time limitations. All package seals must be intact to be eligible for return. Returned products may be subject to a restocking charge.

### ***Reporting and Return of Explanted Devices***

The reason for explantation should be reported and the explanted device returned to Allergan. In the event of an explantation, please contact Allergan's Product Support Department at 1.800.624.4261 for an Explant Kit and explant return instructions.

### ***ConfidencePlus® Limited Warranties***

The *ConfidencePlus®* and *ConfidencePlus®* Premier Warranty provides 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 and described in the table below. Our standard *ConfidencePlus®* Warranty program applies automatically to every *NATRELLE®* breast implant recipient subject to the conditions discussed in the *ConfidencePlus®* literature.

Adverse Event	Warranty program
<b>BIA-ALCL confirmed</b>	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.
<b>Rupture (Silicone-Filled only)</b>	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.
<b>Deflation (Saline-Filled only)</b>	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 <i>ConfidencePlus</i> <sup>®</sup> 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.
<b>Capsule Contracture</b>	Complimentary product replacement up to 10 years following the date of implantation surgery.
<b>Late Seroma</b>	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 and explant.*

For more information, please visit [www.natrelle.ca](http://www.natrelle.ca) or contact Allergan's Product Support Department at 1.800.624.4261.

### ***Product Ordering***

To order directly in Canada or for product information, please contact your local Allergan Plastic Surgery Sales Representative or the Allergan Customer Care Department at 1.866.653.9308.

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