

Directions for Use

NATRELLE[®]
Saline-Filled
Breast Implants

Smooth &
BIOCELL[®] Texture



Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed physician.

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INTRODUCTION

• DIRECTIONS TO THE PHYSICIAN

The information supplied in this Directions for Use document is intended to provide an overview of essential information about **NATRELLE**[®] Saline-Filled Breast Implants, including the indications for use, contraindications, warnings, precautions, important factors for a patient to consider, adverse events, other reported conditions, and a summary of Allergan's clinical results.

Patient Counseling Information

You should review this document prior to counseling the patient about **NATRELLE**[®] Saline-Filled Breast Implants and breast implant surgery. Please familiarize yourself with the content of this document and resolve any questions or concerns prior to proceeding with use of the device. As with any surgical procedure, breast implantation is NOT without risks. Breast implantation is an elective procedure, and the patient must be well counseled and understand the risk/benefit relationship.

Before making the decision to proceed with surgery, the surgeon or a designated patient counselor should instruct the patient to read the patient labeling and discuss with the patient the warnings, precautions, important factors to consider, complications, and Allergan's clinical results listed in the patient labeling. The physician should advise the patient of the potential complications and that medical management of serious complications may include additional surgery and explantation.

Informed Decision

Before making the decision to proceed with surgery, each patient should receive Allergan's **Making an Informed Decision, Breast Surgery with NATRELLE[®] Saline-Filled Breast Implants** patient labeling to allow her sufficient time prior to surgery to read and adequately understand the important information on the risks, follow-up recommendations, and benefits associated with saline-filled breast implant surgery. Allow the patient at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast surgery. In the case of a revision it may be medically necessary to perform surgery sooner.

DEVICE DESCRIPTION

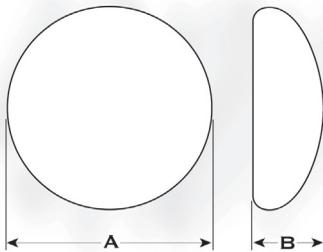
NATRELLE[®] Saline-Filled Breast Implants are constructed from Room Temperature Vulcanized (RTV) silicone elastomer, made of polydimethylsiloxane. The device is inflated to the desired size with sterile isotonic saline before implantation. Each implant is supplied sterile with a disposable fill tube and reflux valve.

Round Breast Implants:

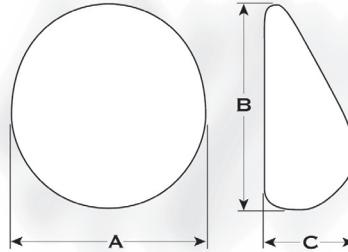
Style Number	Breast Implant Description	Size Range
Style 68LP	Smooth shell surface, anterior filling valve, low projection	125cc – 700cc
Style 68MP	Smooth shell surface, anterior filling valve, moderate projection	120cc – 850cc
Style 68HP	Smooth shell surface, anterior filling valve, high projection	160cc – 850cc
Style 168	<i>BIOCELL</i> ® Textured shell surface, anterior filling valve, moderate projection	120cc – 850cc

Shaped Breast Implants:

Style Number	Breast Implant Description	Size Range
Style 163	<i>BIOCELL</i> ® Textured shell surface, posterior filling valve, full height, full projection	360cc – 820cc
Style 363LF	<i>BIOCELL</i> ® Textured shell surface, anterior filling valve, low height, full projection. <i>Style 363 has a ptotic shape to match an existing breast in unilateral reconstruction.</i>	170cc – 720cc
Style 468	<i>BIOCELL</i> ® Textured shell surface, anterior filling valve, full height, moderate projection	195cc – 205cc



A = Width; B = Projection
Round Breast Implant



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

INDICATIONS

NATRELLE[®] Saline-Filled Breast Implants are indicated for females for the following:

- **Breast augmentation for women at least 18 years old.** Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.
- **Breast reconstruction.** Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

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.

Surgical Practices in which product use is contraindicated due to compromise of product integrity:

- **Adulterated Fill.** Do not place drugs or substances inside the implant other than sterile saline for injection.
- **Alteration.** Do not alter the implant or valve.
- **Do not inject** through the implant shell.
- **Stacking** of implants: Do not place more than one implant per breast pocket
- Do not allow the implant to come into prolonged contact with povidone iodine.

WARNINGS

- ***Closed Capsulotomy***

DO NOT treat capsular contracture by forceful external compression, which will likely result in implant damage, deflation, folds, and/or hematoma. Capsule firmness must not be treated by overexpansion of the device.

- ***Reuse***

Breast implants are intended for single use only. Do not resterilize.

- ***Avoiding Damage during Surgery***

- Care should be taken not to damage the prosthesis with surgical instruments.
- Do not insert or attempt to repair a damaged prosthesis.
- Use care in subsequent procedures such as open capsulotomy, breast pocket revision, hematoma/seroma aspiration, and biopsy/lumpectomy to avoid damage to the implant shell or valve.
- Do not contact the implant with disposable, capacitor-type cautery devices.

- ***Proper Filling***

Follow the recommended fill volume on the product data sheet; do not overfill or underfill the implant. Following recommended fill volumes may decrease the possibility of shell wrinkling and crease fold failure.

- ***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.

- ***Use of endoscopic instruments or the periumbilical approach for placement of the implant has not been studied in the Allergan clinical trial and is not recommended as damage to the device may occur.***

PRECAUTIONS

Specific Populations

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

- Autoimmune diseases (e.g., lupus and scleroderma).
- A compromised immune system (for example, currently receiving immunosuppressive therapy).
- Conditions or medications which interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue.
- Radiation to the breast following implantation.
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders 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.

Surgical Precautions

- **Surgical technique**

The implantation of breast implants involves a variety of surgical techniques. Therefore, the surgeon is advised to use the method which her/his own practice and discretion dictate to be best for the patient, consistent with this Directions for Use document. It is advisable to have more than one size breast implant in the operating room at the time of surgery to allow for flexibility in determining the appropriate size implant to be used. A backup implant should also be available.

- **Implant Selection**

Some of the important surgical and implant sizing variables that have been identified include the following:

- Textured implants, larger implants, subglandular placement, and an insufficient amount of skin/tissue available to cover the implant may cause the implant to be more palpable.
- The implant should be consistent in size with the patient's chest wall dimensions, including base width measurements, bearing in mind the laxity of the tissue and the projection of the implant.

- A thorough discussion should be conducted with the patient, employing appropriate visual aids such as imaging, sizing implants, or other options to clarify her objectives and reduce the incidence of reoperation for size change.
- Available tissue must provide adequate coverage of the implant.

- **Incision Site Selection**

- The periareolar site is typically more concealed, but it is associated with a higher likelihood of difficulties in successfully breast feeding as compared to other incision sites. A periareolar incision may result in changes in nipple sensation.
- The inframammary incision is generally less concealed than the periareolar, but it is associated with less breast feeding difficulty than the periareolar incision site.
- The axillary incision is less concealed than the periareolar site.
- The periumbilical approach has not been studied in the clinical studies and should not be used for a wide variety of reasons, including potential damage to the implant shell.

- **Implant Placement Selection**

- A well-defined, dry pocket of adequate size and symmetry must be created to allow the implant to be placed flat on a smooth surface.
- Submuscular placement may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to perform some reoperation procedures than subglandular placement. The possible benefits of this placement are that it may result in less palpable implants, less likelihood of capsular contracture, and easier imaging of the breast for mammography. Also, submuscular placement may be preferable if the patient has thin or weakened breast tissue.
- Subglandular placement may make surgery and recovery shorter, may be less painful, and may be easier to access for reoperation than the submuscular placement. However, this placement may result in more palpable implants, greater likelihood of capsular contracture, and increased difficulty in imaging the breast with mammography.

- **Explantation**

If it is necessary to perform explantation of the implant, care must be taken to minimize manipulation of the product (particularly in regards to sharp-edged openings). Evaluation of the condition of the device following explantation will be performed by Allergan.

IMPORTANT FACTORS TO BE DISCUSSED WITH THE PATIENT

Breast implantation is an elective procedure and the patient must be thoroughly counseled on the risks, as well as the benefits, of these products and procedures. You should advise your patient that she must read the patient labeling for either augmentation or reconstruction, as applicable. The patient labeling is intended as the primary means to relate uniform risk and benefit information to assist your patient in making an informed decision about primary breast augmentation and revision-augmentation, or primary reconstruction and revision-reconstruction surgery (as applicable), but is not intended to replace consultation with you. The patient should review and consider this information before deciding whether to have this surgery.

Below are some of the important factors your patients need to be aware of when using saline-filled breast implants.

- **Reoperation** – Patients should be advised that additional surgery to their breast and/or implant will be likely over the course of their life.
- **Explantation** – Patients should be advised that implants are not considered lifetime devices and they will likely undergo implant removal, with or without replacement, over the course of their life. Patients should also be advised that the changes to their breast following explantation are irreversible.
- **Mammography** – Breast implants may complicate the interpretation of mammographic images by obscuring underlying breast tissue and/or by compressing overlying tissue. Accredited mammography centers and use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast. 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. Patients should be instructed to inform their mammographers about the presence of their implants.
- **Lactation** – Patients should be advised that breast implants may interfere with the ability to successfully breastfeed, either by reducing or eliminating milk production.
- **Breast Examination Techniques** – Patients should be instructed to perform breast self-examinations monthly and be shown how to distinguish the implant from their breast tissue. The patient should be instructed not to manipulate (i.e., squeeze) the valve excessively, which may cause valve leakage.
- **Avoiding Damage During Treatment** – Patients should inform other treating physicians of the presence of implants to minimize the risk of damage to the implants.

- **Smoking** – Smoking may interfere with the healing process.
- **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 may increase the likelihood of capsular contracture, necrosis, and implant extrusion.
- **Insurance Coverage** – Patients should be advised that health insurance premiums may increase, insurance coverage may be dropped, and/or future coverage may be denied based on the presence of breast implants. Treatment of complications may not be covered as well. Patients should check with their insurance company regarding coverage issues before undergoing surgery.
- **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.
- **Long Term Effects**
Safety and effectiveness beyond 10 years has not been clinically evaluated.

ADVERSE EVENTS

Potential adverse events that may occur with saline-filled breast implant surgery include: reoperation, pain, wrinkling, asymmetry, implant palpability/visibility, implant removal, capsular contracture, changes in nipple and breast sensation, implant displacement/migration, implant deflation, scarring, infection, hematoma/seroma, breastfeeding complications, implant extrusion, necrosis, delayed wound healing, breast tissue atrophy/chest wall deformity, calcium deposits, and lymphadenopathy.

Below is a description of these adverse events. For specific adverse event rates/outcomes for **NATRELLE**® Saline-filled Breast Implants, refer to Allergan's Clinical Study section below.

- **Deflation** – *Breast implants are not lifetime devices.* Saline breast implants deflate when the shell develops a tear or hole. Deflation 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 implants to deflate: damage by surgical instruments; folding or wrinkling of the implant shell; excessive force to the chest (e.g., 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 causes of deflation for Allergan's product; however, it is not conclusively known whether these tests have identified all causes of deflation.

- **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 deflation, 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. Capsular contracture may increase the risk of deflation.

- **Reoperation** – Patients should be advised that additional surgery to their breast and/or implant will likely be necessary over the course of their life. Patients may decide to change the size or type of their implants, requiring a reoperation, or they may have a reoperation to improve or correct their outcome.
- **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 life. Patients should also be advised that the changes to their breast following explantation are irreversible.
- **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.
- **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.

- ***Unsatisfactory Results*** – Patients should be informed that dissatisfaction with cosmetic results related to such things as scar deformity, hypertrophic scarring, capsular contracture, asymmetry, wrinkling, implant displacement/migration, incorrect size, 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. Revision surgery may be indicated to maintain patient satisfaction but carries additional considerations and risks.
- ***Breastfeeding Complications*** – 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.
- ***Additional Complications*** – After breast implant surgery the following may occur and/or persist, with varying intensity and/or for a varying length of time: hematoma/seroma, 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

There have been reports in the literature of other conditions in women with breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. No cause-and-effect relationship has been established between breast implants and the conditions listed below. Furthermore, there is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants. It should also be noted that the cited references include data from augmentation and/or reconstruction patients, as well as from a variety of manufacturers and implant models.

- ***Connective Tissue Disease (CTD)***

Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature with small numbers of women with implants. A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants.

- *Cancer*

Published studies indicate that breast cancer is no more common in women with implants than those without implants. A large, long-term follow-up found no significant increases in the risk rates for a wide variety of cancers, including stomach cancer, leukemia, and lymphoma.

Based on information reported to FDA and found in medical literature, a possible association has been identified between breast implants and the rare 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 ALCL in the fluid or scar capsule adjacent to the implant.

ALCL has been reported globally in patients with an implant history that includes Allergan's and other manufacturers' breast implants.

You should consider the possibility of ALCL when you have a patient with late onset, persistent peri-implant seroma. In some cases, patients presented with capsular contracture or masses adjacent to the breast implant. When testing for ALCL, collect fresh seroma fluid and representative portions of the capsule, and send for pathology tests to rule out ALCL. If your patient is diagnosed with peri-implant ALCL, develop an individualized treatment plan in coordination with a multi-disciplinary care team. Because of the small number of cases worldwide, there is no defined consensus treatment regimen for peri-implant ALCL.

For more complete and up-to-date information on FDA's analysis and review of the ALCL in patients with breast implants please visit: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>

- *Effects on Children*

There have been concerns raised regarding potential damaging effects on children born of mothers with implants. A review of the published literature on this issue suggests that the information is insufficient to draw definitive conclusions.

ALLERGAN'S CLINICAL STUDIES

Clinical Studies Overview

Allergan's Saline-Filled Breast Implants were evaluated in four major open label, multicenter clinical studies: the Large Simple Trial (LST, which involved 2,875 patients), the 1995 Augmentation Study (A95, which involved 901 patients), the 1995 Reconstruction Study (R95, which involved 237 patients), and the Post Approval Survey Study (PASS, which was a continuation of the A95/R95 studies).

Study Design

Patients studied were those seeking implant surgery for augmentation or reconstruction of the breast. The LST Study was designed as a 1 year study to assess the 4 safety outcomes of capsular contracture, infection, implant leakage/deflation, and implant removal for a large number of patients. As the results from that study were similar to those found in the larger studies, the data are not reported here.

The A95/R95 Studies were designed as 5 year studies to assess safety and effectiveness. Patient follow-up was yearly for 5 years. Safety assessments in the A95/R95 Studies consisted of adverse event rates and rates of secondary surgical treatment. Effectiveness assessments in the A95/R95 Studies consisted of patient satisfaction, breast size change, and measures of body esteem/self esteem/body image. The PASS study utilized patient surveys for collection of specific risk/benefit information 6 through 10 years post implant.

Five-year data from the A95/R95 study and 10-year data from the PASS study are presented in this brochure.

Patient Accounting and Baseline Demographic Profile

The A95 Study enrolled 901 augmentation patients. Of those A95 patients available to be seen for their 5-year follow-up visit, 81% returned and were seen at 5 years after implant surgery. The R95 Study enrolled 237 reconstruction patients. Of those R95 patients available to be seen for their 5-year follow-up visit, 80% returned and were seen at 5 years after implant surgery. Demographic information obtained from the 1995 Studies revealed that nearly 90% of both augmentation and reconstruction patients were Caucasian and more than half of study participants were married. The median age of the augmentation patients was 32 years (range 19-66); for reconstruction patients the median age was 47 years (range 25-77). With respect to surgical baseline factors in the 1995 Studies, for augmentation patients, the most frequently used devices were textured round, the most common incision sites were periareolar and inframammary, and the most frequent placement of the implant was submuscular. For reconstruction patients, the most frequently used devices were textured shaped, the most common incision site was the mastectomy scar, and the most frequent placement of the implant was submuscular.

The post-approval study transitioned patients from data collection via physicians (0-5 years post-implantation) to data collection via mailed patient-completed surveys (6-10 years post-implantation). 85% of the augmentation patients and 86% of the reconstruction patients expected for follow-up at 10 years returned surveys to Allergan according to study protocol.

Effectiveness Outcomes

The benefits of saline-filled breast implants were assessed by a variety of outcomes, including bra cup size change (augmentation patients only), body image, body esteem, self concept, and patient satisfac-

tion. Bra cup size was measured within the first year and a half after surgery. Body image, esteem, and self concept were assessed for patients with both original and replacement saline devices before implantation and at 3 years after surgery. Satisfaction was measured at every follow-up visit through 5 years.

Augmentation

859 (95%) of the original 901 augmentation patients had a breast measurement within 18 months of surgery. Of these 859 patients, 38% increased by 1 cup size; 49% increased by 2 cup sizes; 9% increased by 3 cup sizes, and 4% had no increase.

Of the original 901 augmentation patients, 683 (76%) provided a satisfaction rating at 5 years, with 95% indicating they were satisfied with their breast implants. The patient surveys showed 88% of the augmentation patients who provided satisfaction scores were satisfied with their breast implants at 10 years post-implant.

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

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

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

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

Reconstruction

Of the original 237 reconstruction patients, 137 (58%) provided a satisfaction rating at 5 years, with 89% indicating they were satisfied with their breast implants. The patient surveys showed 86% of the reconstruction patients who provided satisfaction scores were satisfied with their breast implants at 10 years post-implant.

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

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

Safety Outcomes

The A95 Study and R95 Study safety outcomes for primary implantation are presented in Tables 2 through 7.

The cumulative Kaplan-Meier risk of first occurrence of adverse events (and 95% confidence interval) is shown in Table 1 for the A95/R95 Study and Table 2 for the PASS Study. The rates reflect the number of patients out of 100 who experienced the listed complication at least once within the first 5 or 10 years after their implantation. Some complications occurred more than once for some patients.

Table 2
Complications
A95/R95: 5-Year Cumulative First Occurrence Kaplan-Meier Risk Rates, By Patient

Complication*	Augmentation (N=901)		Reconstruction (N=237)	
	5-Year		5-Year	
	Rate (%)	(95% CI)	Rate (%)	(95% CI)
Reoperation	25.9	(23.0, 28.9)	44.5	(37.9, 51.0)
Breast Pain	17.0	(14.5, 19.5)	17.7	(12.4, 23.0)
Wrinkling	13.7	(11.3, 16.1)	24.6	(18.6, 30.6)
Asymmetry	12.2	(10.0, 14.4)	39.0	(32.1, 45.8)
Implant Palpability/Visibility	12.1	(9.8, 14.3)	27.1	(20.6, 33.5)
Implant Removal for Any Reason	11.8	(9.6, 14.0)	28.0	(22.1, 34.0)
Capsular Contracture Baker Grade III/IV	11.4	(9.2, 13.5)	35.7	(29.0, 42.4)
Loss of Nipple Sensation	9.9	(7.8, 11.9)	18.1	(12.5, 23.8)
Nipple Paresthesia	9.8	(7.8, 11.8)	<1	(0.0, 1.2)
Implant Malposition	9.2	(7.3, 11.2)	16.9	(11.7, 22.2)
Skin Paresthesia	7.6	(5.9, 9.4)	6.3	(2.9, 9.6)
Implant Deflation	6.8	(5.0, 8.5)	7.5	(3.8, 11.2)
Scarring Complications	6.5	(4.9, 8.2)	6.0	(2.7, 9.2)
Irritation/Inflammation	3.2	(2.0, 4.3)	6.6	(3.3, 9.8)
Seroma	2.6	(1.6, 3.7)	3.9	(1.4, 6.4)
Skin Rash	1.9	(1.0, 2.8)	3.3	(0.9, 5.7)
Capsular Calcification	1.8	(0.9, 2.7)	5.4	(2.3, 8.6)
Hematoma	1.7	(0.8, 2.5)	1.3	(0.0, 2.8)
Infection	1.0	(0.3, 1.6)	6.0	(2.8, 9.2)
Delayed Wound Healing	<1	<1	2.7	(0.6, 4.9)
Implant Extrusion	<1	<1	3.2	(0.9, 5.6)
Tissue/Skin Necrosis	<1	<1	3.6	(1.1, 6.0)

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

Table 3
Complications
Post Approval: 10 Year First Occurrence Kaplan-Meier Risk Rates, By Patient

Complication	10-Year Risk			
	Augmentation (N = 901)		Reconstruction (N = 237)	
	Rate (%)	(95% CI)	Rate (%)	(95% CI)
Reoperation	36.5	(33.4, 39.9)	54.6	(48.1, 61.5)
Breast Pain	29.7	(26.6, 33.0)	33.0	(26.4, 40.7)
Capsular Contracture Baker Grade III/IV	20.8	(18.1, 23.8)	51.7	(44.6, 59.2)
Implant Replacement/Removal	20.2	(17.7, 23.1)	39.5	(33.3, 46.5)
Implant Deflation	13.8	(11.5, 16.4)	22.5	(16.8, 29.7)

Reasons for Reoperations

Table 4 shows the reasons for augmentation reoperation 5 years post-implantation from the A95 Study and 10 years post-implantation from the PASS Study based on the total number of reoperations.

Of the 901 augmentation patients in the A95 Study, at least one reoperation was performed on 225 patients (25%) through 5 years. A total of 293 reoperations were performed. The primary reason for reoperation through 5 years was implant deflation at 18.1%.

In the PASS Study, at least 1 reoperation was performed on 315 patients (36.5%) through 10 years. A total of 424 reoperations were performed. The primary reason for reoperation through 10 years on augmentation patients was implant deflation at 21.7%. The percentage of reoperations due to lump/mass/cyst increased from 8.5% of 293 reoperations through 5 years to 13.9% of 424 reoperations through 10 years. The occurrence of lumps, masses, and cysts can be expected to naturally increase as patients age and could be an explanation for the increase.

Table 4
Augmentation: Main Reasons for Reoperation Through 5 and 10 Years

Reasons for Reoperation*	5 Years		10 Years	
	N = 293		N = 424	
	n	%	n	%
Implant Deflation	53	18.1	92	21.7
Capsular Contracture	52	17.7	56	13.2
Implant Malposition	27	9.2	31	7.3
Lump/Mass/Cyst	25	8.5	59	13.9
Patient Request for Style/Size Change	25	8.5	48	11.3
Hematoma/Seroma	25	8.5	29	6.8
Scarring	20	6.8	20	4.7
Ptosis	14	4.8	26	6.1
Asymmetry	12	4.1	13	3.1
Add/Remove Saline	9	3.1	13	3.1
Wrinkling	7	2.4	8	1.9
Implant Palpability	4	1.4	5	1.2
Delayed Wound Healing	4	1.4	4	0.9
Infection	4	1.4	4	0.9
Nipple Complications	4	1.4	4	0.9
Skin Lesion/Cyst	3	1.0	3	0.7
Breast Pain	2	0.7	2	0.5
Capsule Calcification	1	0.3	1	0.2
Implant Extrusion	1	0.3	1	0.2
Irritation	1	0.3	1	0.2
Cancer	0	0.0	4	0.9
Total	293	100.0	424	100.0

*The reoperation rate excludes planned secondary surgeries. If more than one reason for a given reoperation was reported, the following hierarchy was used to determine a primary reason for that reoperation: implant deflation; infection; capsular contracture; extrusion; necrosis; hematoma/seroma; delayed wound healing; skin lesion/cyst; breast pain; irritation; capsule calcification; implant malposition; wrinkling; implant palpability; asymmetry; ptosis; scarring; nipple complications; cancer; lump/mass/cyst; patient request for style/size change; and add/remove saline.

Table 5 shows the reasons for reconstruction reoperation through 5 years in the R95 Study and 10 years in the PASS Study based on the total number of reoperations.

Of the 237 patients in the R95 Study, at least 1 reoperation was performed on 99 patients (42%) for a total of 125 reoperations through 5 years. The primary reason for reoperation through 5 years was capsular contracture at 25.6%.

In the PASS Study, at least one unplanned reoperation was performed on 120 patients (50.6%) through 10 years. A total of 159 reoperations were performed. The primary reason for reoperation through 10 years on reconstruction patients was also capsular contracture at 21.4%.

Table 5
Reconstruction: Main Reasons for Reoperation Through 5 and 10 Years

Reasons for Reoperation*	5 Years		10 Years	
	N = 125		N= 159	
	n	%	n	%
Capsular Contracture	32	25.6	34	21.4
Asymmetry	17	13.6	17	10.7
Implant Deflation	11	8.8	29	18.2
Patient Request for Style/Size Change	10	8.0	14	8.8
Scarring	10	8.0	10	6.3
Lump/Mass/Cyst	9	7.2	15	9.4
Infection	9	7.2	9	5.7
Hematoma/Seroma	5	4.0	5	3.1
Implant Extrusion	5	4.0	5	3.1
Implant Malposition	4	3.2	6	3.8
Tissue/Skin Necrosis	4	3.2	4	2.5
Wrinkling	3	2.4	3	1.9
Delayed Wound Healing	2	1.6	2	1.3
Skin Lesion/Cyst	2	1.6	2	1.3
Nipple Complications	1	0.8	2	1.3
Implant Palpability	1	0.8	1	0.6
Cancer	0	0.0	1	0.6
Total	125	100.0	159	100.0

*The reoperation rate excludes planned secondary surgeries. If more than one reason for a given reoperation was reported, the following hierarchy was used to determine a primary reason for that reoperation: implant deflation; infection; capsular contracture; extrusion; necrosis; hematoma/seroma; delayed wound healing; skin lesion/cyst; breast pain; irritation; capsule calcification; implant malposition; wrinkling; implant palpability; asymmetry; ptosis; scarring; nipple complications; cancer; lump/mass/cyst; patient request for style/size change; and add/remove saline.

Reasons for Implant Removal

Of the 901 augmentation patients in A95, there were a total of 98 patients (10.9%) who had 166 implants removed through 5 years. Of the 166 augmentation implants removed through 5 years, 94% were replaced. The most common reason for implant removal was patient choice for style/size change (43.4%). Through 10 years, 300 implants were removed from 170 patients. The most common reason was also patient choice for style/size change (41.3%).

The primary reason for implant removal in augmentation patients based on the number of implants removed is shown in Table 6 below.

Table 6
Augmentation: Reasons for Implant Removal Through 5 and 10 Years

Primary Reason for Implant Removal	5 Years		10 Years	
	N = 166		N = 300	
	n	%	n	%
Patient Choice for Size/Style Change	72	43.4	124	41.3
Implant Deflation*	54	32.5	100	33.3
Capsular Contracture	17	10.2	27	9.0
Wrinkling	6	3.6	8	2.7
Implant Palpability/Visibility	6	3.6	6	2.0
Asymmetry	3	1.8	8	2.7
Breast Pain	3	1.8	3	1.0
Malposition	2	1.2	16	5.3
Iatrogenic Injury	1	0.6	1	0.3
Infection	1	0.6	2	0.7
Implant Extrusion	1	0.6	1	0.3
Breast Mass/Lump/Cyst	0	0	4	1.3
Total	166	100	300	99.9

*Includes unreported/unknown (n=1 augmentation)

Of the 237 reconstruction patients in R95, there were 62 patients (26.2%) who had 70 implants removed through 5 years. Of the 70 reconstruction implants removed through 5 years, 70% were replaced. The most common reason for implant removal was capsular contracture (31.4%). Through 10 years, there were 104 implants removed from 85 patients. The most common reason for implant removal was implant leakage/deflation (32.7%).

The main reasons for implant removal in reconstruction patients are shown in Table 7 below.

Table 7
Reconstruction: Reasons for Implant Removal Through 5 and 10 Years

Primary Reason for Implant Removal	5 Years		10 Years	
	N = 70		N = 104	
	n	percent	n	percent
Capsular Contracture	22	31.4	22	21.2
Patient Choice for Style/Size Change	15	21.4	26	25.0
Implant Deflation*	12	17.1	34	32.7
Infection	7	10.0	7	6.7
Implant Extrusion	4	5.7	4	3.8
Implant Malposition	3	4.3	3	2.9
Other**	3	4.3	3	2.9
Wrinkling	2	2.9	2	1.9
Asymmetry	1	1.4	2	1.9
Recurrent Breast Cancer	1	1.4	1	1.0
Total	70	100	104	100.0

*Includes unreported/unknown (n=2 reconstruction)

**Other reasons as reported by the physician were *Abnormality on CT Scan at Mastectomy Site (n=1)*, *Tissue Expansion Went Poorly Due to Radiation (n=1)*, *Second Stage Breast Recon (n=1)*

As additional safety information, Table 8 shows the 5-year cumulative Kaplan-Meier adverse event risk rates of first occurrence following implant replacement (i.e., revision) on a by implant basis for the A95 and R95 Studies. There were 126 augmentation implants and 40 reconstruction implants in the A95/R95 Studies that were removed and replaced with Allergan study devices.

Table 8
A95/R95: 5 Year Cumulative First Occurrence Kaplan Meier Risk Rates Following Implant Replacement, by Implant

Complication Following Replacement of Implants	Augmentation N = 126 Implants		Reconstruction N = 40 Implants	
	%	95% CI	%	95% CI
Removal/Replacement	18.3	(12.7, 25.9)	28.2	(17.2, 44.0)
Capsular Contracture Baker Grade III/IV	13.2	(8.3, 20.6)	42.4	(27.8, 60.6)
Leakage/Deflation	9.0	(5.4, 14.6)	15.4	(6.9, 32.3)

Other Clinical Data Findings

This section summarizes post-implant observations from the A95 and R95 Studies pertaining to connective tissue/autoimmune (CTD) disease and breast disease (including breast carcinoma). These data should be interpreted with caution in that there was no comparison group of similar women without implants. Confirmed reports were based on a diagnosis by a physician. Data pertaining to effects on offspring and mammographic detection of tumors/lesions were not collected in these studies.

Breast Disease

Through 5 years, there were 81 reports of breast disease for augmentation patients; eighty (80) were benign and one incident was malignant.

For the reconstruction patients, there were 99 reports of breast disease; 75 were benign and 24 were malignant.

CTD

For augmentation patients through 5 years, there were 7 confirmed reports of CTD disease (3 instances of Graves' Disease, and 2 instances each of hyperthyroiditis and chronic fatigue syndrome/fibromyalgia).

For reconstruction patients through 5 years, there was one confirmed report of Graves' disease.

CTD Signs and Symptoms

In the pivotal study, self-reported signs and symptoms were collected in the categories of General, Gastrointestinal, Neurological, Urinary, Global, Pain, Fatigue, Fibromyalgia, Joint, Muscular, Skin, and Other. For Primary Augmentation patients, no significant increases were found. Statistically significant increases were found for Primary Reconstruction patients in the symptom categories of Joint and Pain at 4 years.

The pivotal study was not designed to evaluate the cause and effect associations because there is no comparison group of women without implants, and because other contributing factors, such as medications and lifestyle/exercise, were not studied. Therefore, it cannot be determined whether this increase was due to the implants or not, based on the pivotal study. However, a patient should be aware that she may experience an increase in these symptoms after receiving breast implants.

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. The Device Identification Card should be provided to the patient for personal reference.

Surgical Planning

Allergan relies on the surgeon to know and follow the proper surgical procedures with *NATRELLE*[®] Saline-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 must carefully evaluate implant size and contour, incision placement, pocket dissection, and implant placement criteria with respect to the patient's anatomy and desired physical outcome. 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.

Sterile Product

Each sterile saline-filled breast implant is supplied in a sealed, double primary package. Style-specific sterile product accessories are also supplied within the product packaging. 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 and accessories from their packages 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 implant damaged or contaminated breast implants.

DO NOT store the breast implant with the fill tube in place, which may damage the integrity of the valve seal.

DO NOT resterilize the product.

NEVER, under any circumstances, attempt to resterilize using ethylene oxide, which is known to cause adverse tissue reaction if not completely removed from the device. Avoid unnecessary exposure of the breast implant to lint, talc, sponge, towel, skin oils, and other contaminants.

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

1. Peel open the lid of the outer thermoform package.
2. Invert the outer thermoform over the sterile field, allowing the sealed inner thermoform to gently fall into the field.
3. Peel open the lid of the inner package using the pull tab.
4. Gently retrieve the breast implant.

Surgical Procedure

Breast augmentation with saline-filled implants can be carried out through several different incisions including inframammary, periareolar, or transaxillary. The transumbilical incisional approach is not recommended. 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 implant may be filled with saline either before or after insertion. If inserted without saline, the implant may be inserted as received (i.e., filled with air), or the air may be evacuated prior to insertion. Regardless of which insertion technique is used, it is important to ultimately evacuate as much air from the implant as possible. It is also important to maintain proper orientation of any BioDIMENSIONAL® implant. 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 is available to cover the implant and that the implant be properly sized and positioned based upon careful preoperative planning. Educational materials are available through the Allergan Customer Care Department to supplement surgical knowledge of the dimensional techniques intended for use with BioDIMENSIONAL® styles.

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.

Technique for Using Breast Implants with Diaphragm Valve

The fill volume range is specified on the product package labeling and data sheet. Following recommended fill volumes can decrease the possibility of shell wrinkling and crease fold failure.

DO NOT underfill or overfill the breast implant beyond the range specified.

DO NOT use excessive force during any of the steps in the following procedure.

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

1. Fill tube insertion

Prepare the fill tube by attaching the reflux valve to the Luer adapter of the fill tube as shown in **Figure 1**. The reflux valve prevents back-flow during intra-operative filling. This two-way valve opens when a syringe is attached, and closes when the syringe is removed.

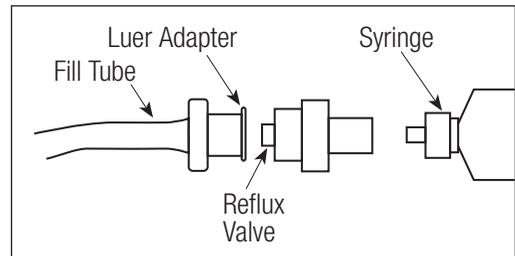


Figure 1

Figure 2 shows a cross section of the diaphragm valve with the strap closure in place and the valve closed. To insert the fill tube, wet the tip of the fill tube in sterile saline for injection and push the strap closure to one side of the valve entrance.

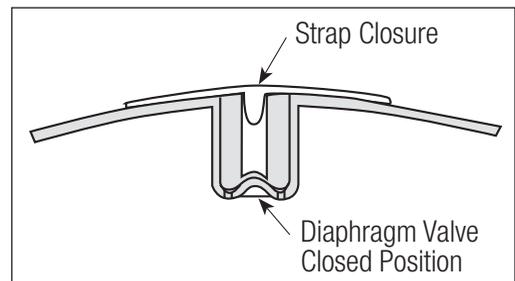


Figure 2

Insert the fill tube by gently pushing the fill tube tip into the valve entrance. Do not use excessive force while inserting the fill tube tip. When the fill tube flange nears or makes contact with the implant shell, the fill tube is in the proper position and the diaphragm valve is open (**Figure 3**).

2. Air aspiration

After the fill tube is properly inserted, remove any air from the breast implant by aspiration with an empty sterile syringe attached to the reflux valve on the fill tube.

3. Placement

To assist with placement, a sterile **BIOCELL**[®] Delivery Assistance Sleeve is available separately. Use of this sleeve for insertion of **BIOCELL**[®] textured breast implants provides a shell/tissue interface with less friction. Insert the breast implant into one end of the sleeve. Insert the proximal end of the sleeve into the surgically-prepared pocket. With the tissue retracted, the sleeve can be twisted at its distal end to gently guide the breast implant into the pocket. Once the implant is inserted, gently remove the sleeve, and verify the correct orientation of the valve and the implant.

DO NOT use lubricants to facilitate placement, which create the risk of pocket contamination.

Lubricants may also affect tissue adherence.

DO NOT use the breast implant for expansion or dissection of the pocket.

4. Filling

Use a syringe filled with sterile, pyrogen-free Sodium Chloride U.S.P. Solution for Injection to fill the prosthesis and fill to a volume within the recommended fill range specified on the product package labeling and data sheet. Only sterile pyrogen-free Sodium Chloride U.S.P. Solution for Injection drawn from its original container should be used. As it is known that bacterial infections may result from contaminated saline, it is recommended that a new sterile saline container be used with each surgery and implant-filling procedure.

NOTE: The order of filling, placement, and orientation may vary with surgeon preference and technique.

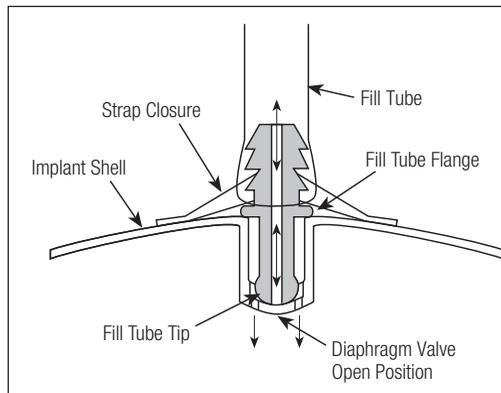


Figure 3

5. *Residual Air*

After filling is completed, aspirate any residual air bubbles. Then use gentle traction to remove the fill tube from the valve, taking care to avoid damage to shell or valve.

6. *Diaphragm Valve Closure*

Use gentle traction to remove the fill tube from the valve, taking care to avoid damage to shell or valve. Verify that the diaphragm valve is clear of particulates. Once the fill tube tip is removed the diaphragm valve is closed. To help retard tissue ingrowth or fluid accumulation in the valve entrance, engage the strap closure as follows: using the thumb and forefinger, compress the valve seat and the strap to snap the valve plug into place as shown in **Figure 2**.

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:

- *Patient Labeling*

Making an Informed Decision, Breast Surgery with NATRELLE® Saline-Filled Breast Implants should be used to facilitate patient education on the risks and benefits of saline-filled breast implant surgery. It should be given to the patient during her initial visit/consultation to allow sufficient time for review prior to making the decision to proceed with surgery. You should verify that the patient has an adequate understanding of the information in subsequent preoperative discussions. The patient should be advised to wait at least 1-2 weeks after reviewing and considering this information, before deciding whether to have this surgery, unless an earlier surgery is deemed medically necessary.

- *Device Identification Card*

Enclosed with each saline-filled breast implant is a Device Identification Card. To complete Allergan's 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.

ADDITIONAL SPECIFIC PRODUCT INFORMATION

BIOCELL® Delivery Assistance Sleeve

Sterile **BIOCELL®** Delivery Assistance Sleeves are available from your Allergan Breast Aesthetics Surgical Sales Representative or Customer Care Department at 1.800.766.0171.

Returned Goods Policy

Product returns should be handled through an Allergan Breast Aesthetics Surgical Sales Representative or through the Customer Care Department at 1.800.766.0171. 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®** Limited Warranties provide lifetime replacement and limited financial reimbursement in the event of loss of shell integrity resulting in implant deflation, subject to certain conditions as fully discussed in the **ConfidencePlus®** literature. For more information, please contact Product Support at 1.800.624.4261.

Product Ordering

To order directly in the U.S.A. or for product information, please contact your local Allergan Breast Aesthetics Surgical Sales Representative or the Allergan Customer Care Department at 1.800.766.0171.

Reporting Problems

The Food and Drug Administration (FDA) requires that serious injuries (defined as those that need medical or surgical intervention to prevent permanent damage) be reported by hospitals if they are aware of the serious injuries. In addition, injuries or complications can be voluntarily reported directly by the patient to FDA's MedWatch.

If you have a patient who has experienced one or more serious problems related to her breast implants, you are encouraged to report the serious problem(s) to the FDA through the MedWatch voluntary reporting system. Examples of serious problems include disability, hospitalization, harm to offspring, and medical or surgical intervention to prevent lasting damage.

You are also required to report any product problem or serious adverse event to Allergan. Deaths must be reported to Allergan and FDA. You can report by telephone to 1.800.FDA.1088; by FAX, use Form 3500 to 1.800.FDA.0178; electronically at <http://www.fda.gov/medwatch/index.html>; or by mail to MedWatch Food and Drug Administration, HF-2, 5600 Fishers Lane Rockville, MD 20857-9787. **Keep a copy of the completed MedWatch form for your records.**

This information reported to MedWatch is entered into databases to be used to follow safety trends (patterns) of a device and to determine whether further follow-up of any potential safety issues related to the device is needed.

These products are covered by one or more of the following U.S. Patents: 5,480,430; 5,007,929; 4,889,744 and 4,859,712 and/or foreign patents corresponding thereto.



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