Directions for Use

NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants

ALLERGAN

THE SCIENCE OF REJUVENATION™

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

Table of Contents

INTRODUCTION

Directions to the Physician
The information supplied in this Directions for Use document is intended to provide physicians an overview of essential information about ***NATRELLE®*** 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants, including the indications for use, contraindications, warnings, precautions, important factors for a patient to consider, adverse events, other reported conditions, instructions for use and a summary of Allergan's pivotal clinical study results.

Patient Counseling and Informed Decision Information
You should review this document prior to counseling the patient about breast implant surgery with ***NATRELLE®*** 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants. 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.

Each patient should receive Allergan's patient brochure and also Allergan's patient labeling, ***Breast Augmentation/Reconstruction with NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants*** (both available at: www.allergan.com/labeling/usa.htm), during her initial visit/consultation. She should be advised of the potential complications and that medical management of serious complications may include additional surgery and explantation. 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.

In order to document a successful informed decision process, the ***Acceptance of Risk and Consent to Surgery*** document (available in the patient labeling document and at: www.allergan.com/labeling/usa.htm) should be signed by both the patient and the surgeon and then retained in the patient's file.

For detailed instructions regarding patient counseling and informed consent, please see the section "Patient Counseling Information: Important Factors, Possible Adverse Events and Other Reported Conditions" on page 9.

Certification
Certification via Allergan's ***Physician Certification Program*** specific to *NATRELLE®* Highly Cohesive Silicone-Filled Breast Implants is required in order to gain access to these implants. Please see the section "Preoperative Education, Planning and Preparation" in the Instructions for Use, visit **www.allerganacademy.com**, or contact your local Breast Aesthetics Business Development Manager or the Allergan Customer Care Department for detailed training information.

Device Tracking
NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants are subject to Device Tracking per federal regulation. 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

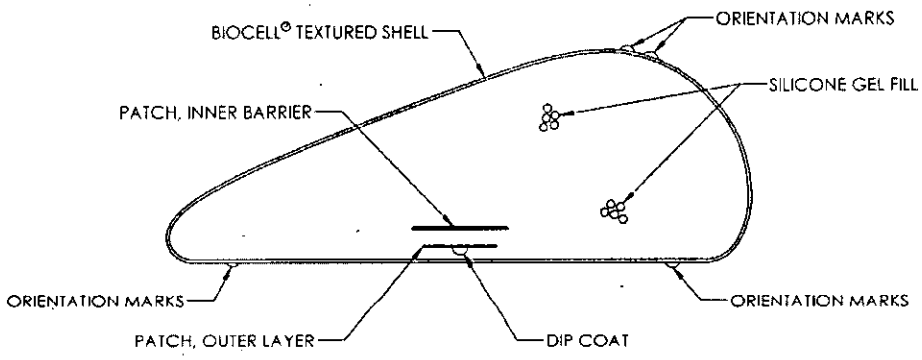
silicone gel-filled breast implant. Following surgery, return the first page of the form to Allergan by fax, using the contact information provided on the form.

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***® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants participate in Allergan's Device Tracking program. This will help ensure that Allergan has a record of each patient's contact information. Patients should be encouraged to complete the Device Tracking Form and return it to Allergan so that they can be contacted in the event of a recall or other problems with the implants.

DEVICE DESCRIPTION

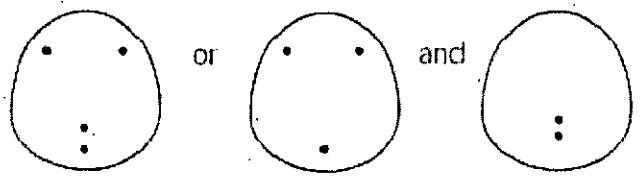
NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants are constructed with barrier shell technology and filled with a highly cohesive silicone gel. Allergan has approval for 2 types of silicone gel fillers: cohesive silicone gel and highly cohesive silicone gel. Allergan's cohesive silicone gel is a softer gel than Allergan's highly cohesive silicone gel. ***NATRELLE***® 410 Breast Implants are anatomically shaped and consist of a shell, patch, and highly cohesive silicone gel fill. ***NATRELLE***® 410 Breast Implants have the **BIOCELL**® surface texture.

NATRELLE® **410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implant**



NATRELLE® 410 Breast Implants incorporate orientation marks on the anterior and posterior sides of the shell surface to assist in aligning the implant vertically in the pocket. Two orientation marks are present on the anterior side of the implant in the lower pole. Depending on the style, there will be either 3 or 4 orientation marks on the posterior surface of the implant.

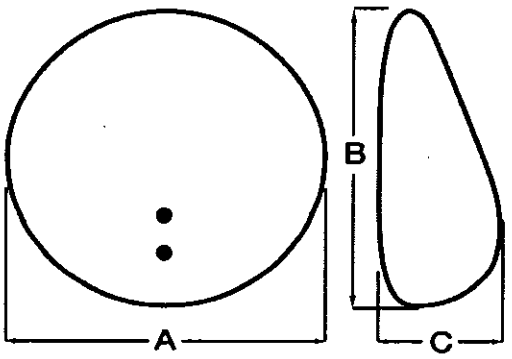
GENERAL ORIENTATION MARK LOCATIONS



To allow for selection of the appropriate implant to fit the specific needs of the patient, ***NATRELLE***® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants are offered in a range of implant heights and projections.

Table 1: Styles of *NATRELLE*® 410 Breast Implants

410 Style	Breast Implant Description	Volume (cc)	Height (cm)	Width (cm)	Projection (cm)
FM	Full height, Moderate projection	205 – 670	11.0 – 16.0	10.5 – 15.5	3.8 – 5.6
FF	Full height, Full projection	185 – 740	10.5 – 16.0	10.0 – 15.5	4.0 – 6.2
MM	Moderate height, Moderate projection	160 – 450	9.1 – 12.9	10.0 – 14.0	3.6 – 5.2
MF	Moderate height, Full projection	140 – 640	8.6 – 13.9	9.5 – 15.5	3.7 – 6.2



A = Width
B = Height
C = Projection

INDICATIONS

NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants are indicated for women for the following:

- **Breast augmentation for women at least 22 years old.** Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.

- **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

WARNINGS

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. The unique nature of the highly cohesive gel creates an implant with a precisely defined shape. Excessive force upon insertion of the implant may compromise this shape, potentially leading to an undesirable cosmetic outcome.

- 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 implants 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. Typically the incision needed for silicone-filled breast implants will be longer than the one made for a saline breast augmentation. The unique nature of the more cohesive gel in the highly cohesive breast implant requires an even larger incision to reduce excessive stress on the implant during insertion and minimize the potential for gel fracture (fissure in the gel) 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 gel-filled breast implants are prone to unintended instrument trauma during implantation or during explantation.[1,2] 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.[1] Allergan's (retrieval study) analyses of explanted devices have identified unintended surgical instrument damage as one potential cause of shell failure and thus implant rupture.

- Do not treat capsular contracture by closed capsulotomy or forceful external compression, which will likely result in implant damage, rupture, folds, and/or hematoma.

- 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.

- Do not immerse the implant in Betadine solution. If Betadine is used in the pocket, ensure that it is rinsed thoroughly so no residual solution remains in the pocket.

- Do not re-use or resterilize any product that has been previously implanted. Breast implants are intended for single use only.

- Do not place more than one implant per breast pocket.

- Do not use the periumbilical approach to place the implant.

- Do not use microwave diathermy in patients with breast implants. Microwave diathermy has been reported to cause tissue necrosis, skin erosion, and implant extrusion.

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)
- Planned chemotherapy following breast implant placement
- Planned radiation therapy to the breast following breast implant placement

- Conditions or medications that interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders 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.

Additional Precautions

- **Preoperative Planning** - 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. For detailed instructions on proper preoperative planning, please refer to section "Preoperative Education, Planning and Preparation" on page 30.
- **Back-up Implants** - 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 back-up implant should also be available.
- **Surgical Mesh** - The use of surgical mesh or acellular dermal matrix together with the breast implant has not been studied in the pivotal study.
- **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). Explanted devices should be returned to Allergan for evaluation. Contact Allergan's Product Surveillance Department at 1.800.624.4261 for an Explant Kit and explant return instructions.
- **Massage** - Breast massage exercises following implantation with ***NATRELLE®*** 410 Breast Implants are not recommended as this may lead to implant malposition.

PATIENT COUNSELING INFORMATION: IMPORTANT FACTORS, POSSIBLE ADVERSE EVENTS AND OTHER REPORTED CONDITIONS

General Patient Counseling Information

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.

Prior to making the decision to proceed with surgery, instruct the patient to read the patient labeling, ***Breast Augmentation/Reconstruction with NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants*** (available at: www.allergan.com/labeling/usa.htm).

1. The patient labeling (available at: www.allergan.com/labeling/usa.htm) 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 it is not intended to replace consultation with you.

2. Each patient should receive Allergan's patient labeling (available at: www.allergan.com/labeling/usa.htm) during her initial visit/consultation 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 highly cohesive silicone-filled breast implant surgery.

3. It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection.

4. Request that your patient openly discuss with you, prior to surgery, any history that she may have of depression or other mental health disorders.

5. Allow the patient 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.

6. Discuss with the patient the warnings, precautions, important factors to consider, possible adverse events, and Allergan's pivotal clinical study results.

7. Advise the patient of the possible adverse events and other reported conditions. Explain that medical management of serious adverse events may include additional surgery and explantation.

In order to document a successful informed decision process, the ***Acceptance of Risk* and *Consent to Surgery*** document (available in the patient labeling document and at: www.allergan.com/labeling/usa.htm) should be signed by both the patient and the surgeon and then retained in the patient's file.

Important Factors to Convey to Patients

Below are some of the important factors (Table 2), possible adverse events (Table 3), and other conditions (Table 4) your patients need to be aware of when considering ***NATRELLE***® 410 Breast Implants. The patient labeling provides additional information on important factors for patients.

Table 2: Important Factors to Convey to Patients

Insurance coverage • Patients should check with their insurance company regarding coverage issues before undergoing surgery • Insurance coverage may differ based on whether breast implants are being used for breast reconstruction or breast augmentation • 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 • Diagnostic procedures will add to the cost of having breast implants, and patients should be told that these costs may exceed the cost of their initial surgery over their lifetimes and that these costs may not be covered by their insurance carrier • Treatment of complications may not be covered
Smoking • Smoking may interfere with the healing process
Radiation to the Breast

- Allergan has not tested the 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

Breast Examination Techniques

- Patients should perform breast self-examinations monthly and be shown how to distinguish the implant from their breast tissue
- The patient should not manipulate or squeeze the implant excessively
- The patient should be told that the presence of lumps, persistent pain, swelling, hardening, or change in the implant shape may be signs of symptomatic rupture of the implant. If the patient has any of these signs, she should be told to report them and possibly have an MRI evaluation to screen for rupture

Screening Mammography

- Presurgical mammography with a follow-up mammogram after implantation may be performed to establish a baseline for routine future mammography in augmentation patients
- Patients should be instructed to undergo routine mammography exams as per their primary care physician's recommendations. The importance of having these exams should be emphasized. The current recommendations for preoperative/screening mammograms are no different for women with breast implants than for those women without implants
- Patients should be instructed to inform their mammographers about the presence, type, and placement of their implants
- Breast implants may complicate the interpretation of mammographic images by obscuring underlying breast tissue and/or by compressing overlying tissue
- Accredited mammography centers, technicians with experience in imaging patients with breast implants, and use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast
- Prior to mammography the radiologist should be alerted to the presence and location of the orientation marks on the ***NATRELLE***® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implant as these may be visible on the mammographic images. These orientation marks are circular silicone elastomer dots located on the surface of the implant and are used to assist the physician with visual and tactile placement of the implant within the surgical pocket

MRI Screening for Breast Implant Rupture

- Breast implant rupture is considered "silent" when it occurs without any other problems, signs, or symptoms. Breast implant rupture is considered "symptomatic" when it is accompanied by changes in the look or feel of the breast and/or breast implant. Advise your patient that she will need to have regular MRIs to screen for rupture even if she is having no problems.
- MRI screenings should be performed at 3 years postoperatively, then every 2 years thereafter.
- If your patient has symptoms of breast implant rupture (described in Table 4), you should recommend that she has an MRI to determine whether rupture is present.[3, 4] Provide your patient with a list of MRI facilities in her area that have:
  - at least a 1.5 Tesla magnet,
  - a dedicated breast coil, and
  - a radiologist experienced with breast implant MRI films for signs of rupture
- If rupture is noted via MRI, then you should advise your patient to have her implant removed

Avoiding Damage During Treatment

- Patients should inform other treating physicians of the presence of implants to minimize the risk of damage to the implants

POSSIBLE ADVERSE EVENTS

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

Table 3 contains a description of these adverse events. For specific adverse event rates/outcomes for ***NATRELLE***® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants, refer to the pivotal study section below on page 19.

Table 3: Possible Adverse Events

Rupture

- *Breast implants are not lifetime devices.*
- Breast implants rupture when the shell develops a tear or hole. Ruptures can occur at any time after implantation, but they are more likely to occur the longer the implant is implanted.
- The following things may cause implants to rupture: damage by surgical instruments, stressing the implant during implantation and weakening it, 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 rupture for Allergan's product. It is not conclusively known whether these tests have identified all causes of rupture. Laboratory studies to identify any additional causes of rupture are ongoing.
- Silicone gel-filled implant ruptures are most often silent. This means that most of the time neither you nor your patient will know if the implant has a tear or hole in the shell. MRI examination is currently the best method to screen for rupture. See Table 2 for additional information regarding MRI screening.
- Sometimes there are symptoms associated with gel implant rupture. These symptoms include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, and hardening of the breast.
- When MRI signs of rupture are found (such as subcapsular lines, characteristic folded wavy lines, teardrop sign, keyhole sign, noose sign), or if there are signs or symptoms of rupture, you should remove the implant and any gel you determine your patient has, with or without replacement of the implant. It also may be necessary to remove the tissue capsule.
- There are also consequences of rupture. If rupture occurs, silicone gel may either remain within the scar tissue capsule surrounding the implant (intracapsular rupture), move outside the capsule (extracapsular rupture), or move outside the breast (gel migration). There is also a possibility that rupture may progress from intracapsular to extracapsular and beyond.
- **Rupture information from the Allergan 410 Pivotal Study**
    - In Allergan's pivotal study, there was a MRI screening cohort who had regular MRIs to screen for breast implant rupture whether or not they were symptomatic (i.e., MRI cohort), and a non-MRI screening cohort who were not screened with breast implant MRIs (i.e., non-MRI cohort). On May 27, 2008, FDA approved a protocol revision so that all enrolled patients – both MRI and non-MRI cohorts – would receive MRI evaluations at the 7 and 9 year follow-up timepoints.
    - Across all patients in the pivotal study, all of the ruptures were intracapsular, with no cases of extracapsular rupture or migrated gel.

The cumulative rupture rates for the MRI and non-MRI cohorts are as follows:

Cumulative Risk of First Occurrence of Implant Rupture – MRI Cohort

	Augmentation[a]	Revision-Augmentation[b]	Reconstruction[c]	Revision-Reconstruction[d]
4 weeks	0.0%	0.0%	0.0%	0.0%
6 months	0.0%	0.0%	0.0%	0.0%
1 year	0.0%	0.0%	0.0%	0.0%
2 years	0.0%	0.0%	0.0%	0.0%
3 years	2.2% (0.7, 6.7)	2.7% (0.4, 17.7)	3.0% (0.8, 11.4)	0.0%
4 years	3.0% (1.1, 7.8)	2.7% (0.4, 17.7)	3.0% (0.8, 11.4)	0.0%
5 years	6.3% (3.2, 12.1)	5.7% (1.4, 20.8)	8.0% (3.4, 18.1)	15.0% (5.1, 39.6)
6 years	6.3% (3.2, 12.1)	5.7% (1.4, 20.8)	8.0% (3.4, 18.1)	15.0% (5.1, 39.6)
7 years	11.3% (6.7, 18.7)	8.9% (2.9, 25.2)	10.3% (4.7, 21.7)	21.1% (8.4, 47.1)

[a] 13 silent rupture, none symptomatic
[b] 2 silent rupture, 1 symptomatic
[c] 6 silent rupture, none symptomatic
[d] 3 silent rupture, 1 symptomatic

Cumulative Risk of First Occurrence of Implant Rupture – Non-MRI Cohort

	Augmentation[a]	Revision-Augmentation[b]	Reconstruction[c]	Revision-Reconstruction
4 weeks	0.0%	0.0%	0.0%	0.0%
6 months	0.0%	0.0%	0.0%	0.0%
1 year	0.0%	0.0%	0.0%	0.0%
2 years	0.7% (0.1, 4.5)	2.0% (0.3, 13.1)	0.0%	0.0%
3 years	1.3% (0.3, 5.2)	4.1% (1.0, 15.2)	0.0%	0.0%
4 years	6.2% (3.3, 11.5)	6.3% (2.1, 18.4)	8.9% (3.8, 20.1)	0.0%
5 years	6.2% (3.3, 11.5)	13.6% (6.3, 27.9)	8.9% (3.8, 20.1)	0.0%
6 years	6.2% (3.3, 11.5)	16.1% (8.0, 30.9)	8.9% (3.8, 20.1)	0.0%
7 years	6.9% (3.8, 12.4)	16.1% (8.0, 30.9)	8.9% (3.8, 20.1)	0.0%

[a] 8 silent rupture, 2 symptomatic
[b] 5 silent rupture, 2 symptomatic
[c] 5 silent rupture, none symptomatic

- **Rupture information from the 410 Swedish MRI Study[5]**
  - Rupture data were collected via a single MRI on 124 augmentation and 20 revision patients implanted with ***NATRELLE®*** 410 Breast Implants at 1 hospital. The average age of the implants was approximately 6 years. Rupture was found in approximately 2% of the combined group of augmentation and revision patients and 1% of implants. All ruptures were classified as intracapsular with no cases of extracapsular rupture or migrated gel.
- **Rupture information from the 410 European MRI Study[6]**
  - Rupture data were collected via a single MRI on 112 augmentation, 25 reconstruction, and 26 revision patients implanted with ***NATRELLE®*** 410 Breast Implants at 7 European sites. The average age of the implants was approximately 8 years. Rupture was found in approximately 3% of the patients and 2% of implants. All ruptures were classified as intracapsular with no cases of extracapsular rupture or migrated gel.
- **Additional rupture information from literature**
  - Studies of Danish women evaluated with MRI involving a variety of manufacturers and implant models *(not including the current **NATRELLE®** 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants)* showed that about three-fourths of implant ruptures are intracapsular and the remaining one-fourth are extracapsular.[7] Additional studies of Danish women indicate that over a 2-year period, about 10% of the implants with intracapsular rupture progressed to extracapsular rupture as detected

by MRI.[3] In about half of these cases of progression from intracapsular to extracapsular 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 outside the scar tissue capsule increased for about 14% of these women.
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
Reoperation • Patients should be advised that additional surgery to their breast and/or implant will likely be necessary over the course of their lives. Additional surgeries to the patients' breasts will likely be required, either because of implant rupture, other complications, or unacceptable cosmetic outcomes. 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 • Patients should be advised that their risk of future complications increases with revision surgery as compared to primary augmentation or reconstruction surgery • There is a risk that implant shell integrity could be compromised inadvertently during reoperation surgery, potentially leading to product failure
Implant Removal • Implants are not considered lifetime devices, and patients likely will undergo implant removal(s), with or without replacement, over the course of their lives • When implants are explanted without replacement, changes to the patient's breasts may be irreversible
Lactation • Breast implant surgery may interfere with the ability to successfully breastfeed, either by reducing or eliminating milk production • Breastfeeding difficulties have been reported following breast surgery, including breast reduction and breast augmentation • 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 • Sensation 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 breastfeed

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, implant malposition 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

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 silicone gel-filled 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 in Table 4. 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.

Table 4: Other Reported Conditions

Connective Tissue Disease (CTD)

Potential Conditions

- Connective tissue diseases include diseases such as lupus, scleroderma, rheumatoid arthritis and fibromyalgia
- 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 a causal association between implants and definite or atypical CTD.[8] The study size needed to conclusively rule out a small risk of connective tissue disease among women with silicone gel-filled implants would need to be very large.[4, 9-17] The published studies taken together show that breast implants are not significantly associated with a risk of developing a typical or defined connective tissue disease.[4, 12-14] These studies do not distinguish between women with intact and ruptured implants. Only one study evaluated specific connective tissue disease diagnoses and symptoms in women with silent ruptured versus intact implants, but the study was too small to rule out a small risk.[11]

Signs and Symptoms

- Literature reports have also been made associating silicone breast implants with various rheumatological signs and symptoms such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes
- Scientific expert panels and literature reports have found no evidence of a consistent pattern of signs and symptoms in women with silicone breast implants.[4, 18-21]
- 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

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.[8, 22-26]
- Reports have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy; however, other reports in the published medical literature indicate that breast implants neither significantly delay breast cancer detection nor adversely affect cancer survival of women with breast implants.[22, 25, 27-29]
- 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.[30]

Anaplastic Large Cell 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

Brain cancer

- One study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population.[31]
- The incidence of brain cancer, however, was not significantly increased in women with breast implants when compared to women who had other plastic surgeries
- A published review of 4 large studies in 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.[30, 32]
- An epidemiological review also lent support to the lack of causation between implants and any type of cancer.[8]

Respiratory/ lung cancer

- Studies have reported an increased incidence of respiratory/lung cancer in women with breast implants.[30, 31, 33]
- 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.[34-36]
- Several large studies have found no association between breast implants and respiratory/lung cancer.[22, 37-40]

Cervical/ vulvar cancer

- Two studies reported an increased incidence of cervical/vulvar cancer in women with breast implants.[31, 33]
- Another long-term follow-up study showed equivalent incidences of cervical cancer in women with breast implants compared to the general population.[30]
- Other recent large studies concluded that the evidence does not support an association between reproductive system cancers and breast implants.[22, 37-40]

Other cancers

- There have been several studies published that examined the risk of other types of cancers, e.g., thyroid cancers, urinary system cancers, sarcoma, endocrine cancer, connective tissue cancer, cancer of the eye, and unspecified cancers in women with breast implants. All of those studies found no increased risk in women with breast implants.[11, 19, 31, 33, 37-40]

Other Conditions

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.[4] Further review of the epidemiologic evidence also failed to find an association between implants and neurologic disease.[8]

Suicide

- In several studies, a higher incidence of suicide was observed in women with breast implants.[41-44]
- 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.[42]

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 currently there are no 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.[45]
- 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.[46, 47] Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding.[48] This author 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.[8]

Potential Health Consequences of Gel Bleed

- Small quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse (bleed) through an intact implant shell.[4, 49] The evidence is mixed as to whether there are any clinical consequences associated with gel bleed. For instance, studies on implants implanted for a long duration have suggested that such diffusion may be a contributing factor in the development of capsular contracture[4] and lymphadenopathy.[50] However, evidence against gel bleed being a significant contributing factor to capsular contracture and other local complications is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast implants than for saline-filled breast implants. Saline-filled breast implants do not contain silicone gel and, therefore, gel bleed is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in Allergan's implants does not cause toxic reactions when large amounts are administered to test animals. It should also be noted that studies reported in the literature have demonstrated that the low concentration of platinum contained in breast implants is in the zero oxidation (most biocompatible) state.[51-54]
- Allergan provided testing to identify the gel diffusion constituents (including the platinum species [or other catalysts]), the rate that the gel constituents diffuse out, and how that rate changes over time. Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence.

ALLERGAN'S PIVOTAL STUDY

The Allergan ***NATRELLE***® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implant pivotal study is the primary set of clinical data used to establish a reasonable assurance of safety and effectiveness of the ***NATRELLE***® 410 Breast Implants for breast augmentation, reconstruction, and revision. A summary of the clinical study is presented below. More information can also be found in the ***NATRELLE***® 410 Breast Implants Summary of Safety and Effectiveness Document (SSED) on the FDA's website at: *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm063871.htm*

Study Overview

The Allergan Style 410 pivotal study is a prospective, 10-year, multicenter, single arm observational clinical study conducted across 47 investigational sites in 941 women undergoing breast augmentation, reconstruction, and revision operations. Patients were implanted between February 5, 2001 and February 28, 2002 and are serially followed at 4 weeks, 6 months, 1 year and annually thereafter through 10 years. Patients in the MRI cohort are screened for breast implant rupture with scheduled MRIs at years 1, 3, 5, 7, and 10 years. The results through 7-year patient follow-up are currently being reported, and the study remains ongoing. Allergan will update this document with final 10-year study data once it is available.

Safety assessments include local complication rates, and effectiveness assessments include change in breast size (Augmentation patients only), patient and physician satisfaction with outcome (all patients), and quality of life (QoL) (Augmentation and Reconstruction patients).

At the time of database lock, 76.3% of eligible patients are available for analysis at the 7-year follow-up timepoint.

The 7-year follow-up rates by cohort are 74.9% (356) for Primary Augmentation, 73.8% (104) for Revision-Augmentation, 81.3% (152) for Primary Reconstruction, and 77.2% (44) for Revision-Reconstruction.

A total of 316 patients were enrolled in the MRI arm of the pivotal study to screen for breast implant rupture.

The 7-year MRI compliance rate was 69.6% for the Primary Augmentation cohort, 81.6% for the Revision-Augmentation cohort, 67.2% for the Primary Reconstruction cohort, and 83.3% for the Revision-Reconstruction cohort.

Patient Demographics and Baseline Characteristics

Demographic information for the pivotal study with regard to race is as follows: 92% of the pivotal study patients were Caucasian; 3% were Hispanic; 2% were Asian; 2% were African American; and 1% were other. The median age at surgery was 36 years for Primary Augmentation patients, 44 years for Revision-Augmentation patients, 48 years for Primary Reconstruction patients, and 52 years for Revision-Reconstruction patients. Approximately 65% of the pivotal study patients were married. Approximately 82% had some college education.

Table 5: Patient Demographics by Cohort

	All Cohorts (N = 941)	Primary Augmentation (N = 492)	Revision-Augmentation (N = 156)	Primary Reconstruction (N = 225)	Revision-Reconstruction (N = 68)	MRI (N = 316)	Non-MRI (N = 625)
Race:							
Caucasian	91.5%	90.5%	94.9%	90.7%	94.1%	92.1%	91.2%
Hispanic	3.0%	4.0%	2.6%	0.4%	4.4%	0.9%	4.0%
Asian	2.3%	3.0%	0	3.1%	0	2.8%	2.1%
African American	1.5%	0.8%	0.6%	4.0%	0	1.6%	1.4%
Other	1.3%	1.6%	0.6%	0.9%	1.5%	1.3%	1.3%
Not Provided	0.4%	0	1.3%	0.9%	0	1.3%	0
Median Age[a]	40	36	44	48	52	42	40
Median BMI[a] (Range)	21.1 (15.8 -42.8)	20.6 (15.8 - 33.3)	21.0 (16.0 - 36.4)	22.6 (17.1 - 41.6)	22.4 (18.1 - 42.8)	21.3 (16.0 - 36.4)	21.1 (15.8 - 42.8)
Married	65.1%	59.8%	69.2%	71.6%	73.5%	69.0%	63.2%
College Education[b]	81.8%	81.7%	80.8%	81.8%	85.3%	82.6%	81.4%

[a] At time of surgery
[b] Includes some college education, college graduates, post-college education

With respect to surgical characteristics in the pivotal study, for Primary Augmentation patients, the most frequently used devices were full height with moderate projection (49%), and the most common incision site was inframammary (87%). The majority of patients (79%) enrolled for augmentation only, and the remaining patients enrolled for augmentation with accompanying conditions as follows: 11% asymmetry, 7% ptosis, and 4% aplasia.

For Revision-Augmentation patients, the most frequently used devices were full height with full projection (37%), and the most common incision site was inframammary (76%).

For Primary Reconstruction patients, the most frequently used devices were full height with full projection (40%), and the most common incision site was the mastectomy scar (75%).

For Revision-Reconstruction patients, the most frequently used devices were full height with full projection (63%), and the most common incision site was mastectomy scar (54%).

Table 6: Surgical Baseline Characteristics by Cohort

	All Cohorts (N = 1759)	Primary Augmentation (N = 983)	Revision-Augmentation (N = 310)	Primary Reconstruction (N = 354)	Revision-Reconstruction (N = 112)
Style Number					
410FM	38.3%	49.3%	31.3%	23.4%	8.9%
410FF	30.8%	21.9%	37.1%	40.1%	62.5%
410MM	19.9%	21.9%	22.9%	14.7%	10.7%
410MF	10.9%	6.9%	8.7%	21.8%	17.9%
Placement Site[a]					
Submuscular	83.2%	84.3%	71.6%	87.6%	91.9%
Subglandular	14.0%	15.7%	28.4%	0.3%	2.7%

[a] Other placement sites included subcutaneous and subtissue flap

Effectiveness Results

Effectiveness assessments include change in breast size (Primary Augmentation patients only), patient and physician satisfaction with outcome (Augmentation, Reconstruction and Revision

patients), and quality of life (QoL) (Primary Augmentation and Primary Reconstruction patients). QoL is comprised of measures of self-esteem, body image, and general health outcomes assessed at baseline and Years 1 and 2. Change in breast size was assessed by cup/circumferential chest size measurements. Patient satisfaction was based on a 5-point scale assessment of satisfaction with implants at the time of follow-up visits. The QoL measures were the SF-36, the Rosenberg Self-Esteem Scale, the Body Esteem Scale, and the Rowland Expectation Scale.

Primary Augmentation Patients

For Primary Augmentation patients, 469 (95%) of the original 492 patients had a breast measurement within 18 months of surgery. Of these 469 patients, 38% increased by 1 cup size, 53.5% increased by 2 cup sizes, 5.5% increased by more than 2 cup sizes, and 2.8% had no increase or decrease due to correction of congenital asymmetry or change in shape without change in size.

Of the original 492 patients, 354 (72.0%) provided a satisfaction rating at 7 years after implantation. Of these 354 patients, 87.3% indicated that they were definitely satisfied with their breast implants, 9.0% indicated they were somewhat satisfied, 1.4% indicated that they were neither satisfied nor dissatisfied, 0.3% were indicated they were somewhat dissatisfied, and 2.0% indicated they were definitely dissatisfied.

Physician satisfaction with patient results was rated in 351 cases (71.3%) at 7 years. Physicians reported being definitely satisfied with the breast implants in 91.7% of cases, somewhat satisfied in 5.4% of cases, neither satisfied nor dissatisfied in 1.1% of cases, somewhat dissatisfied in 0.6% of cases, and definitely dissatisfied in 1.1% of cases.

For Primary Augmentation patients, prior to implantation, scores on the SF-36 Scale, which measures mental and physical health, were significantly higher than the general female population. There were no significant changes after 2 years. Scores on the Rosenberg Self-Esteem Scale and on the Body Esteem scale also generally showed no significant changes at 2 years. However, body esteem related to sexual attractiveness improved significantly after implantation, and on the Rowland Expectation instrument, patients showed significant improvement in "self image," "social relations," and "daily living."

Primary Augmentation patients also had significantly improved satisfaction with specific aspects of their breasts after 2 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 breast cup size change because they were undergoing replacement of an existing implant.

Of the original 156 Revision-Augmentation patients, 101 (64.7%) provided a satisfaction rating at 7 years. Of these 101 patients, 80.2% indicated they were definitely satisfied with their breast implants, 10.9% indicated that they were somewhat satisfied, 5.0% indicated that they were neither satisfied nor dissatisfied, 3.0% indicated they were somewhat dissatisfied, and 1.0% indicated that they were definitely dissatisfied.

Physician satisfaction with patient results was rated in 100 cases (64.1%) at 7 years. Physicians reported being definitely satisfied with the breast implants in 80.0% of cases,

somewhat satisfied in 12.0% of cases, neither satisfied nor dissatisfied in 3.0% of cases, and somewhat dissatisfied in 5.0% of cases.

Revision-Augmentation patients did not undergo a quality of life assessment.

Primary Reconstruction Patients
Of the original 225 Primary Reconstruction patients, 149 (66.2%) provided a satisfaction rating at 7 years after implantation. Of these 149 patients, 74.5% indicated that they were definitely satisfied with their breast implants, 20.8% indicated that they were somewhat satisfied, 2.7% indicated that they were neither satisfied nor dissatisfied, 1.3% indicated that they were somewhat dissatisfied, and 0.7% indicated that they were definitely dissatisfied.

Physician satisfaction with patient results was rated in 149 cases (66.2%) at 7 years. Physicians reported being definitely satisfied with the breast implants in 80.5% of cases, somewhat satisfied in 14.1% of cases, neither satisfied nor dissatisfied in 3.4% of cases, somewhat dissatisfied in 0.7% of cases, and definitely dissatisfied in 1.3% of cases.

For Primary Reconstruction patients, prior to implantation, scores on the SF-36 Scale, which measures mental and physical health, were for the most part significantly higher than the general female population. At 2 years, the only significant decrease was in the subscale "reported health transition." There were no significant changes on the Rosenberg Self-Esteem Scale and on the Body Esteem scale at 2 years. On the Rowland Expectation instrument, patients showed a significant positive change in "improve well-being."

Primary Reconstruction patients also had significantly improved satisfaction with specific aspects of their breasts after implantation, such as the size, shape, feel, and how well they matched.

Revision-Reconstruction Patients
Of the original 68 revision-reconstruction patients, 43 (63.2%) provided a satisfaction rating at 7 years after implantation. Of these 43 patients, 62.8% indicated that they were definitely satisfied with their breast implants, 30.2% indicated that they were somewhat satisfied, 4.7% indicated that they were neither satisfied nor dissatisfied, and 2.3% indicated that they were definitely dissatisfied.

Physician satisfaction with patient results was rated in 43 cases (63.2%) at 7 years. Physicians reported being definitely satisfied with the breast implants in 67.4% of cases, somewhat satisfied in 23.3% of cases, neither satisfied nor dissatisfied in 4.7% of cases, somewhat dissatisfied in 2.3% of cases, and definitely dissatisfied in 2.3% of cases.

Revision-reconstruction patients did not undergo a quality of life assessment.

Safety Results

The overall 7-year cumulative rate of complications, reasons for reoperation, and reasons for implant removal for this study are presented below in Tables 7 to 9. Tables 10 to 13 show the cumulative complication rates for key complications at Years 3, 5, and 7.

Table 7: Kaplan-Meier Risk of Other Complications by Cohort through 7 Years

KM Rates through 7 Years[a, b]		Primary Augmentation[c] N=492	Revision-Augmentation[d] N=156	Primary Reconstruction[e] N=225	Revision-Reconstruction[f] N=68
Any complication (including reoperation)		31.0% (27.0, 35.5)	47.7% (39.9,56.2)	53.0% (46.5, 59.8)	57.2% (45.7,69.2)
Any reoperation		22.4% (18.8, 26.6)	37.7% (30.3, 46.2)	45.2% (38.7, 52.1)	38.6% (27.9, 51.7)
Implant removal with or without replacement		12.6% (9.8, 16.1)	23.6% (17.4, 31.5)	29.3% (23.6, 36.0)	28.6% (19.0, 41.6)
Implant removal without replacement		1.2% (0.5, 2.9)	3.6% (1.5, 8.4)	5.3% (2.9, 9.7)	1.9% (0.3, 12.4)
Implant removal with replacement		11.5% (8.9, 14.9)	21.3% (15.4, 29.1)	25.2% (19.7, 31.8)	27.2% (17.8, 40.2)
Asymmetry		0.8% (0.3, 2.2)	5.7% (2.9, 11.0)	10.3% (6.8, 15.4)	14.8% (8.0, 26.7)
Breast pain		2.7% (1.5, 4.7)	3.0% (1.1, 7.7)	4.7% (2.5, 8.8)	4.8% (1.6, 14.3)
Breast/skin sensation changes		1.5% (0.7, 3.1)	0	0	0
Bruising		0.4% (0.1, 1.6)	0.6% (0.1, 4.5)	0	1.5% (0.2, 10.0)
Capsular contracture III/IV		6.1% (4.2, 8.9)	8.7% (5.0, 14.8)	10.7% (7.1, 15.9)	21.6% (13.1, 34.4)
Delayed wound healing		1.1% (0.4, 2.6)	1.3% (0.3, 5.1)	0.5% (0.1, 3.3)	2.9% (0.7, 11.3)
Gel Fracture		0.2% (0.0, 1.5)	0	0	0
Hematoma		1.1% (0.4, 2.5)	2.0% (0.6, 6.0)	1.0% (0.3, 4.0)	0
Hypertrophic scarring/ scarring		1.1% (0.5, 2.7)	2.7% (1.0, 7.1)	4.8% (2.6, 8.7)	3.2% (0.8, 12.3)
Implant extrusion		0.4% (0.1, 1.6)	1.5% (0.4, 5.8)	0.9% (0.2, 3.7)	0
Implant malposition		2.9% (1.7, 4.9)	7.0% (3.8, 12.6)	3.6% (1.7, 7.4)	4.8% (1.6, 14.3)
Implant palpability/visibility		0.3% (0.0, 1.9)	1.4% (0.3, 5.4)	0.5% (0.1, 3.3)	1.5% (0.2, 10.3)
Implant rupture	MRI cohort	11.3% (6.7, 18.7)	8.9% (2.9, 25.2)	10.3% (4.7, 21.7)	21.1% (8.4, 47.1)
	Non-MRI cohort	6.9% (3.8, 12.4)	16.1% (8.0, 30.9)	8.9% (3.8, 20.1)	0
Infection		1.7% (0.8, 3.4)	2.1% (0.7, 6.3)	4.8% (2.6, 8.7)	6.9% (2.6, 17.7)
Nipple complications		1.3% (0.6, 2.9)	0	0.5% (0.1, 3.3)	1.7% (0.2, 11.2)
Ptosis		1.9% (1.0, 3.8)	0	0	0
Redness		0.7% (0.2, 2.0)	0	0.9% (0.2, 3.7)	4.9% (1.6, 14.7)
Seroma		1.3% (0.6, 2.9)	3.3% (1.2, 8.6)	2.1% (0.8, 5.5)	6.2% (2.4, 15.8)
Skin Rash		0.5% (0.1, 1.9)	0	0	0
Swelling		3.5% (2.1, 5.8)	2.7% (1.0, 7.2)	3.8% (1.9, 7.5)	3.2% (0.8, 12.4)
Tissue/Skin Necrosis		0	0	0.5% (0.1, 3.2)	1.5% (0.2, 10.0)
Upper pole fullness		0	1.4% (0.4, 5.5)	4.2% (2.2, 7.8)	1.5% (0.2, 10.1)
Wrinkling/Rippling		0.7% (0.2, 2.0)	3.7% (1.5, 8.9)	3.1% (1.4, 6.8)	7.7% (3.3, 17.4)
Other complications[g]		1.3% (0.6, 2.9)	1.5% (0.4, 5.8)	4.4% (2.3, 8.3)	1.7% (0.2, 11.4)

[a] Includes reports of only ≥ moderate severity for all complications except for reoperation, implant removal, implant extrusion, implant rupture, and pneumothorax

[b] There were no reports of the following complications: capsule calcification, irritation, lymphadenopathy, lymphedema, palpable orientation mark, pneumothorax

[c] 143 primary augmentation patients experienced at least one complication

[d] 70 revision-augmentation patients experienced at least one complication

[e] 116 primary reconstruction patients experienced at least one complication

[f] 38 revision-reconstruction patients experienced at least one complication

[g] Other complications include complications such as joint swelling, implant movement, bottoming out, tear in the capsule, skin indentation, and synmastia

Table 8: Main Reasons for Reoperations through 7 Years

Reasons for Reoperation through 7 Years[a]	Primary Augmentation N=128 Reoperations in 102 Patients	Revision-Augmentation N=70 Reoperations in 55 Patients	Primary Reconstruction N=129 Reoperations in 97 Patients	Revision-Reconstruction N=31 Reoperations in 25 Patients
Asymmetry	4 (3.1%)	4 (5.7%)	9 (7.0%)	2 (6.5%)
Biopsy	10 (7.8%)	8 (11.4%)	7 (5.4%)	1 (3.2%)
Breast cancer	4 (3.1%)	0	2 (1.6%)	0
Breast pain	1 (0.8%)	3 (4.3%)	3 (2.3%)	0
Breast tissue contour deformity	2 (1.6%)	0	5 (3.9%)	0
Capsular contracture	13 (10.2%)	9 (12.9%)	16 (12.4%)	7 (22.6%)
Delayed wound healing	4 (3.1%)	1 (1.4%)	0	3 (9.7%)
Gel fracture	1 (0.8%)	0	0	0
Hematoma/seroma	12 (9.4%)	3 (4.3%)	3 (2.3%)	1 (3.2%)
Implant extrusion	1 (0.8%)	1 (1.4%)	2 (1.6%)	0
Implant malposition	15 (11.7%)	11 (15.7%)	16 (12.4%)	3 (9.7%)
Implant palpability/visibility	0	1 (1.4%)	0	0
Implant rupture (suspected)	8 (6.3%)	6 (8.6%)	7 (5.4%)	1 (3.2%)
Infection	4 (3.1%)	4 (5.7%)	9 (7.0%)	3 (9.7%)
Necrosis	0	0	1 (0.8%)	0
Nipple complications (unplanned)	1 (0.8%)	0	0	2 (6.5%)
Patient request for style/size change	21 (16.4%)	6 (8.6%)	12 (9.3%)	3 (9.7%)
Ptosis	11 (8.6%)	6 (8.6%)	6 (4.7%)	0
Scarring/hypertrophic scarring	15 (11.7%)	7 (10.0%)	28 (21.7%)	1 (3.2%)
Wrinkling	1 (0.8%)	0	3 (2.3%)	2 (6.5%)

[a] 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: rupture, gel fracture, infection, capsular contracture, extrusion, necrosis, hematoma/seroma, delayed wound healing, breast pain, implant malposition, wrinkling, palpability/visibility, asymmetry, breast tissue contour deformity, ptosis, scarring, nipple complications, device injury/iatrogenic, breast cancer mass, biopsy, and patient request for style/size change.

Table 9: Main Reasons for Implant Removal through 7 Years

Reasons for Implant Removal through 7 Years[a]	Primary Augmentation N=99 Explants in 56 Patients	Revision-Augmentation N=60 Explants in 34 Patients	Primary Reconstruction N=87 Explants in 61 Patients	Revision-Reconstruction N=28 Explants in 18 Patients
Asymmetry	6 (6.1%)	5 (8.3%)	10 (11.5%)	1 (3.6%)
Biopsy	1 (1.0%)	0	0	0
Breast cancer	0	0	1 (1.2%)	0
Breast pain	1 (1.0%)	3 (5.0%)	4 (4.6%)	0
Breast tissue contour deformity	4 (4.0%)	0	1 (1.2%)	0
Capsular contracture	8 (8.1%)	12 (20.0%)	13 (14.9%)	6 (21.4%)
Delayed wound healing	0	0	0	1 (3.6%)
Gel fracture	1 (1.0%)	0	0	0
Hematoma/seroma	4 (4.0%)	0	2 (2.3%)	0
Implant extrusion	1 (1.0%)	1 (1.7%)	2 (2.3%)	0
Implant malposition	4 (4.0%)	6 (10.0%)	9 (10.3%)	2 (7.1%)
Implant palpability/visibility	0	2 (3.3%)	0	0
Implant rupture (suspected)	8 (8.1%)	8 (13.3%)	5 (5.8%)	1 (3.6%)
Infection	3 (3.0%)	4 (6.7%)	6 (6.9%)	3 (10.7%)
Patient request for style/size change	46 (46.5%)	16 (26.7%)	26 (29.9%)	7 (25.0%)
Ptosis	10 (10.1%)	2 (3.3%)	2 (2.3%)	0
Scarring/hypertrophic scarring	0	1 (1.7%)	0	0
Wrinkling	1 (1.0%)	0	5 (5.8%)	4 (14.3%)

[a] If more than one reason for a given implant removal was reported, the following hierarchy was used to determine a primary reason for that removal: rupture, gel fracture, infection, capsular contracture, extrusion, necrosis, hematoma/seroma, delayed wound healing, breast pain, implant malposition, wrinkling, palpability/visibility, asymmetry, breast tissue contour deformity, ptosis, scarring, nipple complications, device injury/iatrogenic, breast cancer mass, biopsy, and patient request for style/size change.

Table 10: Kaplan-Meier Risk of Complications through Years 3, 5, and 7 for the Primary Augmentation Cohort (N=492)

		Kaplan Meier Rates with 95% Confidence Intervals		
		Year 3	Year 5	Year 7
Key Complications				
Reoperation		12.7% (10.0%, 16.0%)	16.5% (13.4%, 20.2%)	22.4% (18.8%, 26.6%)
Implant removal with replacement		5.0% (3.4%, 7.4%)	7.5% (5.4%, 10.3%)	11.5% (8.9%, 14.9%)
Implant removal without replacement		0.5% (0.1%, 1.8%)	0.7% (0.2%, 2.1%)	1.2% (0.5%, 2.9%)
Implant rupture	MRI cohort	2.2% (0.7%, 6.7%)	6.3% (3.2%, 12.1%)	11.3% (6.7%, 18.7%)
	Non-MRI cohort	1.3% (0.3%, 5.2%)	6.2% (3.3%, 11.5%)	6.9% (3.8%, 12.4%)
Capsular contracture (Baker Grade III/IV)[55]		2.1% (1.2%, 3.9%)	4.0% (2.5%, 6.3%)	6.1% (4.2%, 8.9%)

Table 11: Kaplan-Meier Risk of Complications through Years 3, 5, and 7 for the Revision-Augmentation Cohort (N=156)

Kaplan Meier Rates with 95% Confidence Intervals				
		Year 3	Year 5	Year 7
Key Complications				
Reoperation		22.2% (16.4%, 29.7%)	30.1% (23.4%, 38.1%)	37.7% (30.3%, 46.2%)
Implant removal with replacement		9.3% (5.6%, 15.2%)	15.8% (10.8%, 22.9%)	21.3% (15.4%, 29.1%)
Implant removal without replacement		2.0% (0.7%, 6.1%)	3.6% (1.5%, 8.4%)	3.6% (1.5%, 8.4%)
Implant rupture	MRI cohort	2.7% (0.4%, 17.7%)	5.7% (1.4%, 20.8%)	8.9% (2.9%, 25.2%)
	Non-MRI cohort	4.1% (1.0%, 15.2%)	13.6% (6.3%, 27.9%)	16.1% (8.0%, 30.9%)
Capsular contracture (Baker Grade III/IV)		5.3% (2.7%, 10.4%)	6.9% (3.7%, 12.4%)	8.7% (5.0%, 14.8%)

Table 12: Kaplan-Meier Risk of Complications through Years 3, 5, and 7 for the Primary Reconstruction Cohort (N=225)

Kaplan Meier Rates with 95% Confidence Intervals				
		Year 3	Year 5	Year 7
Key Complications				
Reoperation		33.1% (27.3%, 39.7%)	39.9% (33.7%, 46.7%)	45.2% (38.7%, 52.1%)
Implant removal with replacement		14.9% (10.7%, 20.4%)	19.0% (14.3%, 25.0%)	25.2% (19.7%, 31.8%)
Implant removal without replacement		2.9% (1.3%, 6.4%)	4.6% (2.4%, 8.8%)	5.3% (2.9%, 9.7%)
Implant rupture	MRI cohort	3.0% (0.8%, 11.4%)	8.0% (3.4%, 18.1%)	10.3% (4.7%, 21.7%)
	Non-MRI cohort	0	8.9% (3.8%, 20.1%)	8.9% (3.8%, 20.1%)
Capsular contracture (Baker Grade III/IV)		7.3% (4.5%, 11.8%)	10.1% (6.6%, 15.2%)	10.7% (7.1%, 15.9%)

Table 13: Kaplan-Meier Risk of Complications through Years 3, 5, and 7 for the Revision-Reconstruction Cohort (N=68)

Kaplan Meier Rates with 95% Confidence Intervals				
		Year 3	Year 5	Year 7
Key Complications				
Reoperation		21.0% (13.0%, 32.9%)	30.1% (20.6%, 42.7%)	38.6% (27.9%, 51.7%)
Implant removal with replacement		15.1% (8.4%, 26.2%)	18.2% (10.8%, 29.8%)	27.2% (17.8%, 40.2%)
Implant removal without replacement		0	1.9% (0.3%, 12.4%)	1.9% (0.3%,12.4%)
Implant rupture	MRI cohort	0	15.0% (5.1%, 39.6%)	21.1% (8.4%,47.1%)
	Non-MRI cohort	0	0	0
Capsular contracture (Baker Grade III/IV)		10.8% (5.3%, 21.3%)	16.0% (8.9%, 27.7%)	21.6% (13.1%, 34.4%)

Other Clinical Safety Outcomes
Below is a summary of clinical findings from the pivotal study with regard to connective tissue disease (CTD), CTD signs and symptoms, cancer, lactation complications, reproductive complications, and suicide. These issues, along with others, will be further evaluated beyond 7 years as part of an Allergan post approval study of patients followed through 10 years.

CTD Diagnoses
Three Primary Augmentation patients (0.6%) were reported to have a new diagnosis. One had a diagnosis of sclerosis/scleroderma, one of mitrochondrial myopathy, and one of positive ANA-specific diagnosis at 1, 69, and 77 months after implantation, respectively. Two Revision-Augmentation patients (1.3%) were reported to have a new diagnosis of fibromyalgia (at 46 months) and Hashimoto thyroiditis (at 30 months). There were 2 Primary Reconstruction patients (0.9%) who reported CTDs through 7 years. One patient had a new diagnosis of alopecia at 7 months after implantation and rheumatoid arthritis at 25 months after implantation, and the other patient had fibromyalgia 27 months after implantation. No revision-reconstruction patients had new diagnoses of a CTD through 7 years. It cannot be determined whether or not these CTD diagnoses were caused by the implants because there was no comparison group of similar women without implants.

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, at 6 years statistically significant increases after accounting for age were found for the symptom categories of Joint, Muscular, and Skin. Statistically significant increases were found for Primary Reconstruction patients in the symptom category of Pain and for Revision-Augmentation patients in the Gastrointestinal symptom category at 6 years after accounting for age. For Revision-Reconstruction patients, no significant increases were found.

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.

Cancer
There were 3 Primary Augmentation patients (0.7%) with a new diagnosis of breast cancer through 7 years in the Allergan pivotal study. In Primary Augmentation patients, there was 1 report of skin cancer and 1 report of renal cell cancer, and 1 Primary Augmentation patient who was pregnant at the time of implantation gave birth to a child who later developed histiocytosis. There was 1 Revision-Augmentation patient (0.8%) with a new diagnosis of breast cancer through 7 years and 1 patient report of bladder cancer and 1 patient report of multiple myeloma.

There were 11 Reconstruction patients (6.1%) with recurrence of breast cancer through 7 years and 1 report of Non-Hodgkin's lymphoma and 1 report of uterine cancer. There was 1 Revision-Reconstruction patient (1.5%) with recurrence of breast cancer through 7 years and no reports of other cancers in Revision-Reconstruction patients.

No patients in the pivotal study were reported with ALCL through 7 years.

Lactation Complications
Ten (23%) of the 44 Primary Augmentation patients who attempted to breastfeed following breast implantation in the pivotal study through 7 years reported difficulty with breastfeeding. The most common difficulty was mastitis. For the 3 Revision-Augmentation patients who attempted to breastfeed after receiving breast implants, 1 (33%) had difficulty breastfeeding due to inadequate milk production. Two of the 225 Primary Reconstruction patients attempted to breastfeed following breast implantation in the pivotal study through 7 years and did not experience any difficulties. No Revision-Reconstruction patients attempted to breastfeed after receiving breast implants.

Reproduction Complications
Seventeen (3.5%) of the Primary Augmentation patients in the Allergan pivotal study reported a reproduction problem though 7 years, most commonly miscarriage. Two Revision-Augmentation patients (1.3%) experienced a reproduction problem (miscarriage and hysterectomy) through 7 years. One Primary Reconstruction patient (0.4%) and 1 revision-reconstruction patient (1.5%) reported a reproduction problem through 7 years.

Suicide
There were no reports of suicide in the pivotal study.

Additional Analyses

Detection of Breast Implant Rupture

Implant rupture was identified from 3 sources:

- Physician Exam
- Evidence of Rupture observed by the physician upon reoperation or device explant
- Devices identified as ruptured via MRI (options included "ruptured," "indeterminate," "unreadable film," "no evidence of rupture") for those patients participating in the serial MRI portion of this study

No implant ruptures were suspected by either ultrasound or mammography.

Detection of Breast Implant Rupture: Physician Exam

In some cases, implant ruptures were suspected based on physician exam. The implants were either confirmed to be ruptured upon explant, confirmed as non-ruptured upon explant, or confirmed as non-ruptured on MRI and not explanted. Table 14 includes information by cohort.

Table 14: Resolution of Rupture Suspected Based on Physician Exam

	Suspected Rupture based on Physician Exam	Rupture Confirmed on Explant	Non-Rupture Confirmed on Explant	Non-Ruptured Assessed on MRI
Augmentation	3	2	0	1
Revision-Augmentation	4	3	1	0
Reconstruction	1	0	1	0
Revision-Reconstruction	2	1	0	1

Detection of Breast Implant Rupture: MRI

Through 7 years, 180 patients had pre-explant MRIs and subsequent device explantation. Ninety-one (91) of these patients underwent MRI as part of the MRI cohort, while 89 obtained MRI based on their symptoms. An analysis of device status upon explant was used to evaluate MRI sensitivity and specificity and is provided in Table 15. Sensitivity is the MRI's success in correctly identifying ruptured implants, and specificity is the success in correctly identifying non-ruptured implants.

Table 15: MRI Sensitivity and Specificity for Implant Rupture – Pivotal Study Patients with Both Pre-explant MRI and Device Explant

	Rupture Confirmed on Explant	Non-Rupture Confirmed on Explant
MRI Showed Rupture	15	4
MRI Indeterminate	0	6[a]
MRI Showed No Rupture	6[b]	149
MRI Sensitivity		
Best Case	94% (70%, 100%)	
Worst Case	71% (48%, 89%)	
MRI Specificity		
Best Case	97% (93%, 99%)	
Worst Case	94% (89%, 97%)	

[a] The 6 cases of indeterminate MRI results were included in the "MRI Showed Rupture"/"Non-Rupture Confirmed on Explant" cell for the calculation of worst case specificity.

[b] In 5 of these cases, more than 2 years elapsed between the time of MRI and device explants, increasing the possibility that the rupture occurred between MRI and explant These 5 cases are used in the calculation of worst case sensitivity.

ALLERGAN'S POST-APPROVAL STUDIES

Additional clinical safety and effectiveness data on ***NATRELLE***® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants will be gathered through multiple post-approval studies:

- Completion of the 10-year pivotal study;
- 5-year follow-up of patients implanted with ***NATRELLE***® 410 Breast Implants under Continued Access;
- 10-year post-approval study of newly enrolled US patients;
- Case-control studies to evaluate the association between ***NATRELLE***® 410 Breast Implants and 5 rare disease outcomes (rare connective tissue diseases, neurological diseases, brain cancer, cervical/vulvar cancer, and lymphoma).

INSTRUCTIONS FOR USE

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

Preoperative Education, Planning and Preparation

Education
ALLERGAN ACADEMY® Educational Materials are available through **www.allerganacademy.com** to supplement surgical knowledge of the dimensional techniques recommended for use with ***NATRELLE***® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants.

Please contact your local plastic surgery sales representative or the Allergan Customer Care Department for further information on the **ALLERGAN ACADEMY**® or any other Allergan physician education initiatives.

Planning & Preparation
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.

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.

Implant Size Selection

- Note that 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.

- Available tissue must provide adequate coverage of the implant.

- Carefully evaluate breast implant size and contour, incision placement, pocket dissection, and implant placement criteria with respect to the patient's anatomy and desired physical outcome.

- Select an implant 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.

Implant Placement

- Note that the possible risks of submuscular implant placement may include longer surgery, longer recovery, more postoperative pain, and greater difficulty when performing some reoperation procedures than subglandular placement. The possible benefits of submuscular implant placement may be less palpable implants, less likelihood of capsular contracture,[4] and easier imaging of the breast for mammography. Also, submuscular placement may be preferable if the patient has thin or weakened breast tissue.

- Note that 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,[56, 57] and increased difficulty in imaging the breast with mammography.

Bear in mind the importance of pocket dissection in minimizing implant rotation for the shaped ***NATRELLE***® 410 Breast Implants.

Incision Site Selection

- Note that a periareolar incision, located around the border of the areola, involves cutting through the breast tissue and may be associated with a higher likelihood of breastfeeding difficulties as compared to the other incision sites.[58] Additionally, a periareolar incision may carry an increased risk of infection and change in sensation.

- Take special care during breast reconstruction procedures carried out via the mastectomy scar to make sure that appropriate amounts of healthy tissue are available to cover the implant and that the implant is properly sized and positioned based upon careful preoperative planning.

- The periumbilical approach has not been studied in the pivotal study and should not be used for a wide variety of reasons, including potential damage to the implant shell.

Be aware that the unique nature of the highly cohesive gel may require a larger incision compared to the incision size required for other silicone-filled implants to avoid skin edge trauma, gel fracture, or implant deformation. To ensure an adequate incision length for highly cohesive implants, an incision should be a minimum of 5.0 cm. For implants larger than 300 cc, an additional 0.5 cm of incision length should be added for each 50 cc of additional volume (e.g., for a 335 cc implant use an incision length of 5.5 cm).

Intraoperative Device Examination and Handling

Examination of Silicone Gel-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 gel-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 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 resterilize the product.

Avoid unnecessary exposure of the breast implant to lint, talc, sponges, towels, 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.

How to Open Sterile Product Package
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. Stickers are also included for the Device Tracking Form and the patient's Device Identification Card.

Each sterile silicone gel-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.

Follow the steps below to remove the breast implant and accessories from their packages in an aseptic environment and using talc-free gloved hands.

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, 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.

Device Implantation and Explantation Considerations

The implantation of silicone gel-filled breast implants involves a variety of surgical techniques. Therefore, use the method which your practice and discretion dictates to be best for the patient, and is consistent with this product insert data sheet. Some of the important surgical considerations that have been identified include the following:

General

- NOTE: 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. Back-up breast implants should be available during the procedure.
- NOTE: Smoking may interfere with the healing process.
- DO NOT use more than one implant per breast.
- DO NOT damage the breast implant with sharp surgical instruments such as needles and scalpels, blunt instruments such as clamps and forceps, or by overhandling and manipulating during introduction into the surgical pocket.
- DO NOT use excessive force during breast implant placement. Excessive force upon insertion of the implant may compromise the shape of the device potentially leading to an undesirable cosmetic outcome, cause gel fracture, or cause implant rupture.
- DO NOT manipulate the implant for either radial expansion, compression, or dissection of the pocket.

Surgical 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.
- Plan out the pocket dissection preoperatively and perform pocket dissection accurately and with minimal trauma.
- Create a well-defined, dry pocket of adequate size and symmetry to allow the implant to be placed flat on a smooth surface. Careful pocket dissection is critical to prevent rotation of the shaped ***NATRELLE***® 410 Breast Implant in vivo.
- Obtain excellent hemostasis to avoid postoperative hematoma. Persistent, excessive bleeding must be controlled before implantation.
- Consider use of a sterile **BIOCELL**® textured breast implant Delivery Assistance Sleeve (available separately) to assist with placement of the breast implant. Use of this sleeve for insertion of **BIOCELL**® textured breast implants provides a shell/tissue interface with less friction. Insert the 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 breast implant is inserted, gently remove the sleeve.

- ***NATRELLE***® 410 Breast Implants have orientation marks that are circular silicone elastomer dots located on the surface of the implant. They are used to assist with visual and tactile placement of the implant within the surgical pocket. The posterior surface of most sizes of ***NATRELLE***® 410 Breast Implants has 4 orientation marks; the posterior surface of some smaller and/or shorter styles may have only 3 orientation marks. The anterior surface of all ***NATRELLE***® 410 Breast Implants has 2 orientation marks.

- Securely close the incision for the placement of the implant in several layers, whenever possible. Drains are optional.

Explantation

- NOTE: 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).

- NOTE: Explanted devices should be intraoperatively assessed by the explanting surgeon to identify the presence or absence of device deformity, gel fracture, implant rupture and gel migration and returned to Allergan for evaluation. Contact Allergan's Product Surveillance Department at 1.800.624.4261 for an Explant Kit and explant return instructions.

Method for Removing Ruptured Silicone Gel from the Surgical Pocket

- **Ruptured breast implants must be reported and should be returned to Allergan. In the event of breast implant rupture, contact Allergan Product Surveillance Department at 1.800.624.4261.**

- 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.

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 patient with the following:

- ***Device Identification Card***

  Enclosed with each silicone gel-filled breast implant is Allergan's 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® ***Textured Breast Implant Delivery Assistance Sleeve***
Sterile **BIOCELL®** Textured Breast Implant Delivery Assistance Sleeves are available from your Allergan Breast Aesthetics Business Development Manager or Customer Care Department at 1.800.766.0171.

Returned Goods Policy
Product returns should be handled through an Allergan Breast Aesthetics Business Development Manager 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 Surveillance 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 shell leakage or breakage resulting in implant rupture, subject to certain conditions as fully discussed in the **ConfidencePlus®** literature. Allergan offers two levels of coverage under its warranty program. Our standard **ConfidencePlus®** Limited Warranty program applies automatically to every Allergan breast implant recipient subject to the conditions discussed in the **ConfidencePlus®** literature. The optional **ConfidencePlus®** Premier Limited Warranty program is available for a low enrollment fee and increases the financial benefit in the event of implant rupture, subject to the conditions discussed in the **ConfidencePlus®** literature. For more information, please contact Allergan's Product Surveillance Department at 1.800.624.4261.

Product Ordering
To order directly in the U.S.A or for product information, please contact your local Allergan Plastic Surgery Sales Representative or the Allergan Customer Care Department at 1.800.766.0171.

Reporting Problems

The U.S. Food and Drug Administration (FDA) requires healthcare providers to report serious injuries involving medical devices (defined as those that need medical or surgical intervention to prevent permanent damage) to the manufacturer and/or to FDA. 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 for her. 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 (1.800.332.1088); 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, HFZ-2 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 and to determine whether further follow-up of any potential safety issues related to the device is needed.

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Patented. See: www.Allergan.com/Products/Patent_Notices

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THE SCIENCE OF REJUVENATION™

Breast Augmentation

NATRELLE® 410
Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants

Important Factors Breast Augmentation Patients Should Consider

THE SCIENCE OF REJUVENATION™

TABLE OF CONTENTS **Page**

GLOSSARY

Anaplastic large cell lymphoma (ALCL)	ALCL is not breast cancer; it is a rare type of non-Hodgkin's lymphoma, a cancer involving the cells of the immune system.
Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	Uneven appearance between a woman's left and right breasts in terms of size, shape, or breast level.
Atrophy	Thinning or diminishing of tissues or muscle.
Autoimmune disease	An autoimmune disease is a disease in which the body's immune system attacks its own cells or tissues by mistake, causing damage and dysfunction. Autoimmune diseases can affect connective tissue in the body (the tissue that binds together body tissues and organs). Autoimmune diseases can affect many parts of the body, like nerves, muscles, glands and the digestive system.
Biocompatible	The ability to exist along with living tissues or systems without causing harm.
Biopsy	The removal and examination of tissues, cells, or fluid from the body.
Body Dysmorphic Disorder	A psychological condition characterized by excessive worry about an imagined or minor physical flaw to the point that it can interfere with normal daily activities.
Body Esteem Scale	A questionnaire which asks about a person's body image.
Breast augmentation	A surgical procedure to increase breast size. For this brochure, it refers to placement of a breast implant. The first time an implant is placed for augmentation is called "primary augmentation." Any time there is another surgery to replace the implant, it is referred to as "revision-augmentation."
Breast implant	Any surgically implanted artificial device intended to replace missing breast tissue or to enhance a breast.
Breast mass	A lump in the breast.

Breast reconstruction	A surgical procedure to replace breast tissue or reconstruct a breast after tissue was taken out because of cancer or injury. Breast reconstruction also includes the surgical correction of a breast that has failed to develop properly due to a severe abnormality or congenital defect. For this brochure, it refers to placement of a breast implant.
Calcification	Process of hardening by calcium salts.
Capsular contracture	A tightening of the scar tissue (also called a capsule) that normally forms around the breast implant during the healing process after surgery. In some women, the scar tissue (capsule) squeezes the implant. When this occurs, it is called capsular contracture. This results in firmness or hardening of the breast, and is a risk for implant rupture. Capsular contracture is classified by Baker Grades. Capsular Contracture Baker Grades III and IV are the most severe. Baker Grade III often results in the need for additional surgery (reoperation) because of pain and possibly abnormal appearance. Baker Grade IV usually results in the need for additional surgery (reoperation) because of pain and unacceptable appearance. Capsular Contracture Baker Grade II may also result in the need for surgery. Each grade is described below.[12] • Baker Grade I – Normally soft and natural appearance • Baker Grade II – A little firm, but breast looks normal • Baker Grade III – More firm than normal, and may look abnormal (change in shape) • Baker Grade IV – Hard, obvious distortion, and tenderness with pain
Capsule	Scar tissue which forms around the breast implant.
Capsulotomy (closed)	An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but may rupture the implant and is contraindicated.
Capsulotomy (open)	An attempt to break the scar tissue capsule around the implant by surgical incision into the capsule.
Congenital abnormality	An abnormal development in part of the body, present in some form since birth.

Connective tissue disease/disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system. Connective tissue diseases (CTDs) that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.
Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Contralateral	Opposite side.
Delayed wound healing	Unusually slow progress in the healing of a wound; surgical incision site fails to heal normally or takes longer to heal.
Displacement	Movement of the implant from the usual or proper place.
Extrusion	Skin breakdown with the implant pressing through the skin or surgical incision.
Fibromyalgia	A disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue.
Fibrous tissues	Connective tissues composed mostly of fibers.
Gel bleed	When silicone gel leaks or "bleeds" or diffuses through the implant shell.
Gel fracture	Appearance of a fissure or fault line in the gel in response to an applied force.
Granuloma	A noncancerous lump that can form around any foreign material, such as silicone. Like any lump, it should be evaluated to distinguish it from a lump that might be cancerous.
Hematoma	A collection of blood within a space.
Hypertrophic scarring	An enlarged scar that remains after a wound heals.
Incision	A cut made to the tissue during surgery.
Infection	The growth in the human body of microorganisms such as bacteria, viruses, or fungi. An infection usually results in fever, swelling, redness, and/or pain. It can occur as a result of any surgery.
Inflammation	The response of the body to infection or injury that is characterized by redness, swelling, warmth, and/or pain.
Inframammary	Below the breast.

Inpatient surgery	A surgical procedure in which the patient is required to stay overnight in the hospital.
Lactation	The production and secretion of milk by the breast glands.
Low molecular weight silicones	Small silicone molecules that might leak out of the implant.
Lymph nodes	Glands that play an important part in the body's defense against infection. They produce lymph, which travels throughout the body in the lymph system, and filters impurities from the body. Common areas where the lymph nodes can be felt with the fingers include: groin, armpit, neck, under the jaw and chin, behind the ears, and on the back of the head.
Lymphadenopathy	Enlargement of the lymph node(s).
Lymphedema	Swelling of the lymph node(s).
Malposition	When the implant is placed incorrectly during the initial surgery or when the implant has shifted from its original position. Shifting can be caused by many factors, such as gravity, trauma, poor initial placement, and capsular contracture.
Mammary	Pertaining to the breast.
Mammography	A type of x-ray examination of the breasts used for detection of cancer. Screening mammography – x-ray examination of the breast that is performed on women with no complaints or symptoms of breast cancer; the goal is to detect breast cancer when it is still too small to be felt by a physician or the patient. Diagnostic mammography – x-ray examination in order to evaluate a breast complaint or abnormality detected by physical exam or screening mammography; additional views of the breast are usually taken.
Mammoplasty	Plastic surgery of the breast.
Mastitis	Inflammation of the breast.
Mastopexy	Surgical procedure to raise and reshape sagging breasts.
Metastatic disease	A stage of cancer after it has spread from its original site to other parts of the body.
Migration	Movement of silicone materials outside the breast implant to other parts of the body.

MRI (Magnetic Resonance Imaging)	A radiographic examination that currently has the best ability to detect rupture of silicone gel-filled breast implants.
Necrosis	Death of cells or tissues.
Outpatient surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight.
Palpability	The ability to feel the implant.
Palpable	Felt with the hand.
Pectoralis	Major muscle of the chest.
Periareolar	Around the darkened or pigmented area surrounding the nipple of the breast.
Pivotal Study	The primary clinical study of Primary Augmentation, Primary Reconstruction, and revision (Revision-Augmentation and Revision-Reconstruction) patients that supported the approval of the premarket approval (PMA) application. Safety and effectiveness data are collected yearly through 10 years.
Plastic surgery	Surgery intended to enhance or improve the appearance of the body.
Postoperative	After surgery.
Precautions	Information that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
Primary breast augmentation	The first time a breast implant is placed for the purpose of breast augmentation.
Ptosis	Sagging or drooping of the breast.
Reoperation	An additional surgery after your first breast implantation.
Revision-augmentation	Refers to the correction or improvement of a primary augmentation. For this brochure, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast augmentation.
Revision-reconstruction	Refers to the correction or improvement of a primary reconstruction. For this brochure, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast reconstruction.

Rheumatologic disease/disorder	A variety of diseases involving connective tissue structures of the body, especially the joints and fibrous tissue. These diseases are often associated with pain, inflammation, stiffness, and/or limitation of motion of the affected parts. Can include autoimmune diseases. Fibromyalgia is a rheumatological disorder.
Rosenberg Self-Esteem Scale	A questionnaire that measures overall self-esteem.
Rowland Expectation Scale	A 16 item questionnaire intended to measure expectations and perceived results of implant surgery.
Rupture	A hole or tear in the shell of the implant that allows silicone gel filler material to leak from the shell. Ruptures can be intracapsular (inside the scar tissue capsule surrounding the implant) or extracapsular (outside the scar tissue surrounding the implant).
Saline	A solution made of water and a small amount of salt.
Scar revision	A surgical procedure to improve the appearance of a scar.
Seroma	Similar to a bruise, a seroma occurs when the watery portion of the blood collects around a surgical incision or around a breast implant.
SF-36 Scale	The Short Form 36 Health Scale; a questionnaire intended to measure physical, mental, and social health.
Silent rupture	A breast implant rupture without symptoms or a visible change. Silent rupture cannot be felt by the woman or detected by a doctor through physical examination. Silent rupture can only be discovered through appropriate imaging techniques such as MRI. Most silicone gel-filled breast implant ruptures are silent (see symptomatic rupture below).
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
Subglandular placement	Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.
Submuscular placement	Placement of a breast implant wholly or partially underneath the chest muscle.
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.

Symptomatic	Experiencing symptoms; any evidence or sign of disease or disorder.
Symptomatic rupture	A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape). Some silicone breast implant ruptures are symptomatic, but most are silent.
Systemic	Pertaining to or affecting the body as a whole.
Toxic shock syndrome	A rare, but life-threatening bacterial infection that may occur after surgery. It occurs most often in the vagina of menstruating women using superabsorbent tampons. Symptoms include sudden, high fever, vomiting, diarrhea, decreased blood pressure, fainting, dizziness, and sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment if toxic shock syndrome is suspected.
Transaxillary	Under the arm.
Warning	Statement that alerts the reader about a situation which, if not avoided, could result in serious injury or death.

1.0 CONSIDERING SILICONE GEL-FILLED BREAST IMPLANT SURGERY

You may be considering breast implant surgery to increase the size of your breasts. This is referred to as breast augmentation. Or you may need to have a previous breast augmentation corrected or improved, which is called revision-augmentation. Allergan has prepared this information to help you better understand the breast implant procedure and assist you in making an informed decision about breast augmentation or revision-augmentation surgery. It will help to answer some of the questions you may have about the surgery and about breast implants in general. It will also provide you with specific information about the risks and benefits of Allergan's ***NATRELLE***® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants. Similar information to help you understand breast reconstruction is available from your plastic surgeon, Allergan, or at www.natrelle.com.

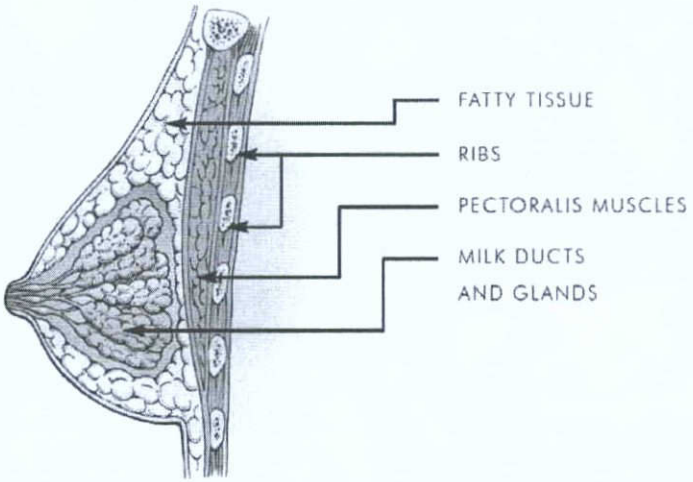
This information cannot and should not replace talking to your plastic surgeon. Your decision whether or not to get breast implants should be based on realistic expectations of the outcome. There is no guarantee that your results will match those of other women. Your results will depend on many individual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

As part of your decision, both you and your surgeon will be required to sign Allergan's "Acceptance of Risk and Consent to Surgery" form that confirms your understanding of the risks and benefits of Allergan's ***NATRELLE***® 410 Breast Implants. This form is located on page 54.

Because breast implants will require monitoring and care for the rest of your life, you should wait at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast augmentation surgery. In the case of a revision-augmentation, however, your surgeon may find it medically necessary to perform surgery sooner.

1.1 What Gives the Breast Its Shape?

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. Beneath the breast is the chest muscle (pectoralis major muscle).



Implants are used to make the breast larger or to restore/replace breast tissue. Factors such as pregnancy (when milk glands are temporarily enlarged), rapid weight loss, and the effects of gravity as you age combine to stretch the skin, which may cause the breast to droop or sag. However, it is important to realize that implants are used to make the breast larger. The implants alone may not adequately lift the breast, or correct the effects of pregnancy, weight loss, or skin stretching. Your surgeon may suggest additional procedures at the time of the breast augmentation, such as mastopexy, to help achieve improved breast lift.

1.2 What is a Highly Cohesive Silicone-Filled Breast Implant?

A silicone gel-filled breast implant is a sac (implant shell) of silicone elastomer (rubber) filled with silicone gel. Allergan has approval for 2 types of silicone gel fillers: cohesive silicone gel and highly cohesive silicone gel. The focus of this brochure is highly cohesive silicone-filled breast implants. A separate brochure is available for cohesive silicone-filled implants from your plastic surgeon, from Allergan, or at www.natrelle.com.

Allergan's ***NATRELLE***® 410 Breast Implants have a teardrop shape and are filled with a highly cohesive silicone gel that helps the implant maintain its shape over time. The highly cohesive breast implant has a textured surface.

NATRELLE® 410 Breast Implants come in a variety of heights (measured from top to bottom) and projections (extending out from the chest), and a wide range of sizes. A number of factors will determine which style and size of breast implant is most appropriate. These factors include your breast augmentation goals, your body size, your desired breast size, and the amount of breast skin you have. Your plastic surgeon will discuss with you the implant options that will best help you achieve the result that is right for you.

Example of a ***NATRELLE***® 410 Breast Implant

Refer to Section 3.3 for more information on the different ***NATRELLE***® 410 Breast Implants available from Allergan.

1.3 Who is eligible for *NATRELLE*® 410 Breast Implants and what is the indication statement?

NATRELLE® 410 Breast Implants have been approved for women for the following uses (procedures):

- Breast augmentation for women at least 22 years old. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.

- Breast reconstruction. Breast reconstruction includes primary breast reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

A separate patient brochure is available for those women considering breast reconstruction surgery and should be read prior to reaching a decision to undergo breast reconstruction.

1.4 What Are the Contraindications?

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

Breast implant surgery should not be performed in:

- Women with active infection anywhere in their body, because the implant will make the infection much harder to treat should the infection move into the breast.

- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions, because radiation and chemotherapy treatments may increase the risk of some complications seen with breast implants. Also, breast implants may interfere with radiation or chemotherapy treatments.
- Women who are currently pregnant or nursing, because surgery may interfere with the safety of the pregnancy/nursing. Since breast augmentation is an elective surgery, it should be postponed until you are no longer pregnant or nursing.

1.5 What are the Precautions?

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

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

1.6 Warnings

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

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

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

WARNING – Your ***NATRELLE***® 410 Breast Implant may rupture without any symptoms (silent rupture). This means that neither you nor your surgeon will know that your implants have ruptured. In order to detect silent rupture, you will need to have regular screening MRI examinations. You should have an MRI 3 years after your breast implant surgery and then every 2 years after that for as long as you have your breast implants.

2.0 BREAST IMPLANT BENEFITS AND RISKS

Undergoing any type of surgical procedure involves risks such as the effects of anesthesia, infection, swelling, redness, bleeding, pain, and even death. Some of these risks are serious, and all of these risks need to be balanced against the benefits of the surgery. These benefits and risks of breast implants are described below. At the end of this brochure is a list of published studies used to gather the information discussed in the sections below. These studies may be helpful to you if you wish to learn more about a specific complication or condition. The reference list is not complete because studies are being conducted all the time. Your physician may have other resources for further reading. The information provided below focuses on women undergoing primary augmentation and revision-augmentation with ***NATRELLE***® 410 Breast Implants. The studies in the list of references also include women undergoing breast reconstruction and other types of implants from a variety of manufacturers. The risks and benefits of breast reconstruction may differ from those of augmentation, and the risks of other types of implants may differ from those of ***NATRELLE***® 410 Breast Implants.

2.1 What are the Benefits?

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

Breast augmentation has the potential to offer both physical and psychological benefits to women.[1] The benefits of breast implants, therefore, relate to their ability to enhance breast volume and attain body symmetry.[1,3,5] Many studies have reported that a majority of breast augmentation patients are satisfied with the results of their surgery. In Allergan's Pivotal Study through 7 years, approximately 9 out of 10 women undergoing primary augmentation or revision-augmentation with ***NATRELLE***® 410 Breast Implants who responded to the question were definitely or somewhat satisfied with their breast implants. Section 5.3 provides more information on benefits seen in Allergan's Pivotal Study.

2.2 What Are the Potential Risks?

Table 1 describes some of the known risks of breast augmentation along with possible effects of those risks. Additional useful information related to these risks is provided following Table 1. Sections 5.4 through 5.7 as well as Tables 2 and 3 provide more information on risks seen in Allergan's Pivotal Study.

Table 1
Risks of Breast Augmentation Through 7 Years with *NATRELLE*® 410 Breast Implants

Event	Likelihood of Event Occurring in Primary Augmentation Patients[a]	Likelihood of Event Occurring in Revision-Augmentation Patients[a]	Possible Resulting Effects of the Event
Key Risks			
Additional Surgeries (Reoperations)	22 out of 100 patients (22%)	38 out of 100 patients (38%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal with Replacement	12 out of 100 patients (12%)	21 out of 100 patients (21%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal without Replacement	1 out of 100 patients (1%)	4 out of 100 patients (4%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result

Event	Likelihood of Event Occurring in Primary Augmentation Patients[a]	Likelihood of Event Occurring in Revision-Augmentation Patients[a]	Possible Resulting Effects of the Event
Capsular Contracture (Baker Grade III/IV)	6 out of 100 patients (6%)	9 out of 100 patients (9%)	• Pain or Discomfort • Breast hardness/firmness • Reoperation • Implant removal
Rupture MRI Cohort	11 out of 100 patients (11%)	9 out of 100 patients (9%)	• Implant Removal
Non-MRI Cohort	7 out of 100 patients (7%)	16 out of 100 patients (16%)	
Other Risks Occurring in 1% or more of Patients[b]			
Swelling	4 out of 100 patients (4%)	3 out of 100 patients (3%)	• Pain or discomfort • Resulting effects are contingent on underlying cause(s)
Implant Malposition	3 out of 100 patients (3%)	7 out of 100 patients (7%)	• Implant visibility • Asymmetry • Reoperation • Implant removal
Breast Pain	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Resulting effects are contingent on underlying cause(s)
Ptosis	2 out of 100 patients (2%)	0 out of 100 patients (0%)	• Undesirable cosmetic result • Wrinkling/rippling • Reoperation • Implant removal
Infection	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
Changes in Breast Sensation	2 out of 100 patients (2%)	0 out of 100 patients (0%)	• Increased or decreased breast sensitivity • Breastfeeding difficulties • May affect sexual response
Nipple Complications	1 out of 100 patients (1%)	0 out of 100 patients (0%)	• Increased or decreased nipple sensitivity • Breastfeeding difficulties • May affect sexual response
Other Complications	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Resulting effects are contingent on underlying cause(s)
Seroma/Fluid Accumulation	1 out of 100 patients (1%)	3 out of 100 patients (3%)	• Swelling • Pain or Discomfort • Infection • Incision and drainage (reoperation) • Implant removal

Event	Likelihood of Event Occurring in Primary Augmentation Patients[a]	Likelihood of Event Occurring in Revision-Augmentation Patients[a]	Possible Resulting Effects of the Event
Delayed Wound Healing	1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Pain or discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal
Hematoma	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Swelling • Pain or Discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Hypertrophic/Other Abnormal Scarring	1 out of 100 patients (1%)	3 out of 100 patients (3%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Asymmetry	Less than 1 out of 100 patients (0.8%)	6 out of 100 patients (6%)	• Undesirable cosmetic result • Reoperation • Implant removal
Wrinkling/Rippling	Less than 1 out of 100 patients (0.7%)	4 out of 100 patients (4%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal
Extrusion	Less than 1 out of 100 patients (0.4%)	2 out of 100 patients (2%)	• Pain or Discomfort • Scarring • Reoperation • Implant removal
Implant Palpability/Visibility	Less than 1 out of 100 patients (0.3%)	1 out of 100 patients (1%)	• Undesirable cosmetic result • Reoperation • Implant removal
Upper Pole Fullness	0 out of 100 patients (0%)	1 out of 100 patients (1%)	• Undesirable cosmetic result • Reoperation • Implant removal

[a] Based on the results of the Allergan 410 Clinical Study for the first 7 years after implant surgery
[b] Complications that occurred at a rate less than 1% included bruising, gel fracture, redness, and skin rash

- **Additional Surgeries (Reoperations)**

You should assume that you will need to have additional surgeries (reoperations). In Allergan's Pivotal Study, approximately 22 out of every 100 women (22%) undergoing Primary Augmentation and 38 out of every 100 women (38%) undergoing Revision-Augmentation had 1 or more reoperations. Approximately 3 out of every 100 women (3%) undergoing Primary Augmentation and 4 out of every 100 women (4%) undergoing Revision-Augmentation had 2 or more reoperations. The costs of additional surgeries may not be covered by insurance.

Patients may decide to change the size or type of their implants, requiring additional surgery. In addition, problems such as rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional

surgery. Reoperation increases the risk of certain complications, such as rupture, capsular contracture, and infection. Section 5.5 provides more information on reoperations reported in Allergan's Pivotal Study.

- **Implant Removal**

Because these are not lifetime devices, the longer you have your implants the more likely it will be for you to have them removed for any reason, either because of dissatisfaction, an unacceptable cosmetic result, or a complication such as capsular contracture. In Allergan's Pivotal Study, approximately 13 out of every 100 women (13%) undergoing Primary Augmentation and 24 out of every 100 women (24%) undergoing Revision-Augmentation had their implants removed. In approximately 8 out of 100 women (8%) undergoing Primary Augmentation and 13 out of 100 women (13%) undergoing Revision-Augmentation implants were removed because the patient requested a different size or style of implant. The vast majority of patients who had their implants removed had them replaced with new implants, which can increase the risk of capsular contracture or reoperation. Removing implants without replacing them can result in dimpling, puckering, wrinkling, or other cosmetic changes in the breast. These changes may be permanent.

Even if you have your implants replaced, implant removal may result in loss of your breast tissue. Also, implant replacement increases your risks of future complications. For example, the risks of capsular contracture and reoperation increase for patients with implant replacement compared to first time placement. You should consider the possibility of having your implants replaced and its consequences when making your decision to have implants. Section 5.6 provides more information on implant removals reported in Allergan's Pivotal Study.

- **Capsular Contracture**

The scar tissue (capsule) that normally forms around the implant may tighten over time and compress the implant, making it feel firm and leading to what is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in revision-augmentation than in primary augmentation. Because you may have your initial implants replaced, you should be aware that your risk of capsular contracture increases with revision-augmentation. Capsular contracture is a risk factor for implant rupture, and it is a common reason for reoperation.

Symptoms of capsular contracture range from mild firmness and mild discomfort to severe pain, distorted shape of the implant, and palpability (ability to feel the implant). Capsular contracture is graded into 4 Baker Grade levels depending on its severity:

  - Baker Grade I – Normally soft and natural appearance
  - Baker Grade II – A little firm, but breast looks normal
  - Baker Grade III – More firm than normal, and may look abnormal (change in shape)
  - Baker Grade IV – Hard, obvious distortion, and tenderness with pain

Baker Grades III and IV are considered severe, and often additional surgery is needed to correct these grades. Additional surgery may be needed in cases where pain and/or

firmness are severe. This surgery ranges from removal of the implant capsule tissue to removal and possible replacement of the implant itself. This surgery may result in loss of your breast tissue. Capsular contracture may happen again after these additional surgeries.

- **Rupture**

An implant rupture is caused by a hole or tear in the shell of the implant that allows silicone gel filler material to leak from the shell. Ruptures can be intracapsular (inside the scar tissue capsule surrounding the implant) or extracapsular (outside the scar tissue surrounding the implant). All women should have regular MRI examinations to detect silent rupture. All women who have ruptured implants should have the implants and any gel removed. With ***NATRELLE***® 410 Breast Implants silicone rarely migrates outside of the scar tissue capsule. Further information on rupture is provided in Section 2.3, and information on rupture reported in Allergan's Pivotal Study is provided in Section 5.7.

- **Unsatisfactory Results**

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

In Allergan's Pivotal Study the most common unsatisfactory result was implant malposition. Approximately 2 out of 100 women (2%) who underwent Primary Augmentation and 4 out of every 100 women (4%) who underwent Revision-Augmentation had additional surgery to improve asymmetry. Approximately 4 out of every 10 reoperations for women who underwent augmentation were to improve unsatisfactory cosmetic results.

- **Pain**

Pain of varying intensity and length of time may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain. In a European study through 5 years, approximately 1 out of every 100 women with any breast implant had breast pain lasting longer than 3 months.[16] Tell your surgeon about 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. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. While some of these changes can be temporary, they can also be permanent, and may affect your sexual response or your ability to nurse a baby.

- **Infection**

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

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

- **Hematoma/Seroma**

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

- **Breastfeeding**

In long-term studies, approximately 3 out of every 100 women with ***NATRELLE***® 410 Breast Implants had difficulty breastfeeding.[6,7] A periareolar incision (an incision around the colored portion surrounding the nipple) may increase the likelihood of problems with breastfeeding. The most common breastfeeding problem is inadequate milk production.[6,7] Section 5.7 provides more information on breastfeeding complications reported in Allergan's Pivotal Study.

- **Calcium Deposits in the Tissue Around the Implant**

Calcium deposits can form in the tissue capsule surrounding the implant. Symptoms may include pain and firmness. Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer. If additional surgery is necessary to examine and/or remove calcifications, this may cause damage to the implants. Calcium deposits also occur in women who undergo breast reduction procedures, in patients who have had hematoma formation, and even in the breasts of women who have not undergone any breast surgery. The occurrence of calcium deposits increases significantly with age.

- **Extrusion**

Extrusion is when the breast implant comes through your skin. This may occur, for example, when your wound has not closed or when breast tissue covering your implants weakens. Radiation therapy might increase the likelihood of implant extrusion. Most women with extrusion need to have their implant removed.

- **Necrosis**

Necrosis is the death of cells or tissues. This may prevent or delay wound healing and require surgical correction, which may result in additional scarring and/or loss of your breast tissue. Implant removal may also be necessary. Infection, steroid use, smoking,

chemotherapy, radiation, and excessive heat or cold therapy may increase the likelihood of necrosis.

- **Delayed Wound Healing**

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

- **Breast Tissue Atrophy/Chest Wall Deformity**

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

- **Lymphadenopathy**

Lymphadenopathy is a chronic enlargement of the lymph nodes. A lymph node is a round mass of tissue which makes cells as part of your immune system. The lymph nodes in the armpit (axilla) drain the breast area of fluid. Some patients with breast implants report having enlarged lymph nodes in the armpit(s). Sometimes the enlarged lymph nodes are painful. If they become too large or painful, the lymph node(s) may need to be surgically removed. Painful and/or enlarged lymph nodes should be reported to your doctor. Lymphadenopathy has been associated with tissue reactions, granulomas, and silicone at the lymph nodes of women with intact and ruptured silicone breast implants.[77]

2.3 What Causes Breast Implants to Rupture and How Can I Tell if My Implants Are Ruptured?

Breast implants are not lifetime devices. Breast implants rupture when the shell develops a tear or hole. Your breast implants can rupture any time after they are implanted, but they are more likely to rupture the longer you have them. The following things may cause your implant to rupture: damage by surgical instruments, stressing the implant during implantation which may weaken it, folding or wrinkling of the implant shell, excessive force to the chest (for example, during closed capsulotomy, which is contraindicated), trauma, compression during mammographic imaging, and severe capsular contracture. Breast implants may also simply wear out over time.

If a device rupture is found, Allergan conducts laboratory studies to determine the cause of the rupture, such as damage during surgery, or a "wear-out" of the device. These studies include a comprehensive visual and microscopic inspection of the shell, including a measurement of shell thickness, and observation of various characteristics near the rupture location as well as in the entire shell. Mechanical testing of the implant shell may also be performed to better determine the cause of an observed rupture. There may still be unidentified causes of rupture. These laboratory studies will continue to try to identify any additional causes of rupture.

When the shell of a breast implant develops a tear or hole, the silicone gel inside ***NATRELLE®*** 410 Breast Implants tends to stay in place, making ruptures especially difficult to detect. This means that most of the time neither you nor your plastic surgeon will know if your breast implant has a tear or hole, called a silent rupture. In fact, a plastic surgeon who is familiar with breast implants is likely to detect less than 3 out of every 10 ruptured silicone-filled breast implants by physical examination.[8] The best method to identify a silent rupture is currently MRI examination. MRI examination can detect about 9 out of every 10 ruptured silicone breast implants.[9] You will need regular MRI examinations over your lifetime in order to determine if your implants have a silent rupture. You should have your first MRI at 3 years after your initial implant surgery and then every 2 years, thereafter. The cost of these MRI screenings may exceed the cost of your initial surgery over your lifetime. This cost may not be covered by your insurance, so you should take it into account when deciding to have breast augmentation.

Sometimes there are symptoms associated with gel implant rupture. If your implants rupture, you may notice hard knots or lumps surrounding the implant or in the armpit, your breast or the implant may change shape or get smaller, or you may notice pain, tingling, swelling, numbness, burning, or hardening in your breast. If you have any of these symptoms you should have an MRI to determine if your implants have ruptured.[1,10]

If you have an MRI that shows signs of rupture, or if your surgeon determines you have signs or symptoms of rupture, he or she will talk with you about your options. As a precaution, Allergan recommends that ruptured implants be taken out permanently and either replaced with a new implant or not replaced, depending on your preference or medical need.

There are also consequences of rupture. If your implants rupture, the silicone gel may remain within the scar tissue capsule around the implant. The silicone gel may also move outside the capsule or it may move beyond the breast (gel migration). The silicone gel from a ruptured implant may begin inside the capsule and progress outside the capsule through gel migration if it is not removed. Ruptured implants might also have consequences on your health. More information on these consequences, as reported in the literature, is included below.

In Allergan's Pivotal Study, a group of patients had scheduled MRIs to look for rupture independent of whether or not they had any symptoms. These patients are called the MRI cohort. The remaining patients did not have scheduled MRIs to look for rupture. They are called the non-MRI cohort. The rupture rate for the whole MRI cohort in Allergan's Pivotal Study (including Primary Augmentation, Revision-Augmentation, Primary Reconstruction, and Revision-Reconstruction patients) through 7 years was 11.5% for patients and 6.7% for implants. For the non-MRI cohort the rupture rate through 7 years was 8.7% for patients and 5.3% for implants. In all of the women with ruptured implants, the silicone gel remained within the scar tissue capsule. Allergan will continue to collect information on rupture through the ongoing Pivotal Study.

Additional information on the likelihood that your ***NATRELLE®*** 410 Breast Implants will rupture comes from a published study known as the 410 Swedish MRI Study.[6] Women who had previously been implanted with ***NATRELLE®*** 410 Breast Implants for breast

augmentation or breast revision at a single hospital had an MRI to screen for silent rupture. On average the implants were about 6 years old. Approximately 2 out of every 100 women had silent rupture. In all of the women with ruptured implants, the silicone gel remained within the scar tissue capsule.

Additional information on the likelihood that your ***NATRELLE®*** 410 Breast Implants will rupture comes from a published study known as the 410 European MRI Study.[7] Women who had previously been implanted with ***NATRELLE®*** 410 Breast Implants for breast augmentation, breast reconstruction, or revision at 1 of 7 hospitals in Europe had an MRI to screen for silent rupture. On average the implants were about 8 years old. Approximately 3 in 100 women had silent rupture. In all of the women with ruptured implants, the silicone gel remained within the scar tissue capsule.

Additional Information on Consequences of Rupture from Literature
Below is a summary of information related to the health consequences of implant rupture. These reports were in women who had implants from a variety of manufacturers and implant models. Because of the nature of the reports, some doctors and scientists do not know for sure if the findings are truly associated with breast implants or not.

- Ruptured breast implants have been associated with breasts becoming hard, changing shape or size, and becoming painful.[10] These symptoms are not specific to rupture, as they also are experienced by women who have capsular contracture.

- There have been rare reports of the silicone gel from implants moving to nearby locations such as the chest wall, armpit, or upper abdominal wall, and even as far as the arm or the groin. This migrating gel has damaged nerves, formed granulomas and/or broken down tissues in direct contact with the gel in a few cases. There have been reports of silicone in the liver of women with silicone breast implants. Silicone gel material has moved to lymph nodes in the armpit, even in women whose implants did not appear to have ruptured, leading to lymphadenopathy.[77]

- Concerns have been raised that women with ruptured implants are more likely to develop connective tissue disease, rheumatic disease, fatigue, or fibromyalgia.[17,19,34,35] To determine if these diseases are related to ruptured implants, a number of studies have evaluated many women with breast implants. Only one small study distinguished between women with ruptured or intact implants.[19] Most doctors and researchers agree that there is no evidence that ruptured implants or migrated gel causes any disease that affects the whole body (systemic disease) like Connective Tissue Disease (CTD) or cancer.

2.4 What Are Other Reported Conditions?

There have been reports of women with silicone gel-filled breast implants developing other conditions. The relationships between many of these conditions and breast implants have been studied. Although no one has shown that breast implants cause the

conditions listed below, you should be aware of these reports. Furthermore, there may be unknown risks associated with breast implants.

- **Connective Tissue Disease (CTD)**

Connective tissue diseases include diseases such as lupus, scleroderma, rheumatoid arthritis, and fibromyalgia. The scientific evidence strongly supports the conclusion that there is no increased risk of connective tissue disease or autoimmune disorders for women with silicone gel breast implants.[1,17-23,25-28,30,32,35,36,38] Independent scientific panels and review groups have also concluded that the weight of the evidence shows no relationship between breast implants and connective tissue disease, or at least if a risk cannot be absolutely excluded, it is too small to be measured.[1,2,4,18,20,24,25,29,31,33-35]

- **CTD Signs and Symptoms**

Some women (even without breast implants) may have some of the signs or symptoms of connective tissue diseases, without having the actual disease. Some reports have linked silicone breast implants with some of these signs and symptoms, such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. Panels of expert scientists and literature reports have found no evidence that silicone breast implants cause a consistent pattern of CTD signs and symptoms.[1,37-40] Having these CTD signs and symptoms does not necessarily mean you have a connective tissue disease; however, you should be aware that you may experience these signs and symptoms after undergoing breast implantation. If you notice an increase in these signs or symptoms, you should consider seeing a rheumatologist to determine whether these signs or symptoms are due to a connective tissue disorder or autoimmune disease.

- **Cancer**

Breast Cancer – Reports in the medical literature indicate that breast implants do not increase the risk for developing breast cancer.[41,44,46,52,61] Some reports have suggested that breast implants may make it harder to detect breast cancer by mammography or biopsy. Other reports indicate that breast implants do not delay breast cancer detection, nor do they decrease cancer survival of women with breast implants.[41,47,53,60,61] A large follow-up study reported no evidence that breast implants are associated with cancer, and even showed that women with breast implants had less breast cancer than the general population.[52]

Anaplastic Large Cell Lymphoma (ALCL) – Women with breast implants may have a very small, but increased risk of developing anaplastic large cell lymphoma, or ALCL, in the scar tissue and fluid adjacent to the implant. ALCL is not breast cancer—it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system).

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

Most patients were diagnosed when they sought medical treatment for implant-related symptoms such as pain, lumps, swelling, or asymmetry that developed after their initial surgical sites were fully healed. In the cases reported, ALCL was typically diagnosed years after the implant surgery.

Your physician should consider the possibility of ALCL if, after your surgical site is fully healed, you see changes in the way the area around the implant looks or feels—including swelling or pain around the implant. If ALCL is suspected, your physician will refer you to an appropriate specialist for evaluation which may involve obtaining fluid and tissue samples from around your breast implant. If ALCL is confirmed, your physician will develop an individualized treatment plan for you. Because of the small number of cases worldwide and variety of available treatment options, there is no single defined treatment.

If you have breast implants and have no symptoms, you do not need to do anything additional, but you should continue to routinely monitor your breast implants and follow your routine medical care. Removing the implants is not recommended in women with no symptoms without a diagnosis of ALCL.

If you do not currently have breast implants but are considering breast implant surgery, you should discuss the risks and benefits with your health care provider. You may also visit the FDA's Breast Implants website for additional information.

For additional and the most up-to-date information please visit:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm

Brain cancer – Most studies of brain cancer in women with silicone gel breast implants have found no increased risk.[43,48,50,58,59,61] One study reported a higher rate of brain cancer in women with breast implants as compared to the general population.[42] However, rates of brain cancer were not significantly higher in women with breast implants when compared to women who had other non-breast implant plastic surgery. The data from 4 large studies of women with breast implants and a long-term follow-up study concluded that breast implants are not associated with brain cancer.[57]

Respiratory/lung cancer – Several studies have found that women with silicone gel breast implants are not at greater risk for lung cancer.[43,50,58,59,61] Studies have reported an increased incidence of respiratory/lung cancer in women with breast implants.[42,48,52] However, the risk of lung cancer was not higher than national lung cancer rates for the general population. 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.[45,51,54] Therefore, the increased incidence of respiratory/lung cancer could be due to smoking rather than breast implants.

Cervical/vulvar cancer – Most studies found that women with silicone gel breast implants have no greater risk of cervical/vulvar cancers than women without implants.[43,50,58,59,61] Two studies reported an increased incidence of cervical/vulvar cancer in women with breast implants.[42,48]

Other cancers – Studies have examined other types of cancer including eye, urinary tract, connective tissue, and endocrine system. Studies show that women with silicone gel breast implants have no greater risk of these types of cancers compared to the general population.[24,38,42,43,48,50,58,59] In Allergan's Pivotal Study there were patients who

developed cancer after implantation, and an augmentation patient who was pregnant at the time of implantation gave birth to a child who later developed histiocytosis.

Cancer Screening – With breast implants, routine screening mammography for breast cancer will be more difficult. If you are of the proper age for mammography screening, you should continue to undergo routine mammography screening as recommended by your primary care physician. More x-ray views are necessary for women with breast implants; therefore, you will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays. Be sure to inform the mammography technologist that you have implants. The technologist can then use special techniques to get the best possible views of your breast tissue.

- **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 panel of expert scientists found that the evidence linking neurological diseases with breast implants is insufficient or flawed.[1] Other researchers have found more evidence that silicone gel breast implants do not cause neurological diseases or symptoms.[1,62,63]

- **Suicide**

Some studies showed that women with breast implants were more likely to commit suicide than women without breast implants, but it is not clear whether these suicides were associated with having silicone gel breast implants or an underlying condition that can lead to suicide, depression, and/or anxiety.[42,64,65,67-72] One researcher believes that some women who want cosmetic surgery suffer from a disorder, called body dysmorphic disorder, which may cause them to think about suicide or attempt suicide.[66]

The strongest predictor for suicide is having been hospitalized for any psychiatric condition. One study 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 the general population of Danish women.[70] This may be a contributing factor to the reported higher incidence of suicide in women with breast implants.

- **Effects on Children**

At this time, doctors do not know if a small amount of silicone passes through the silicone shell of breast implants into breast milk during breastfeeding. Although doctors cannot accurately measure silicone levels in breast milk, silicon (one component in silicone) levels were not higher in breast milk from women with silicone gel-filled implants than in breast milk from women without implants.

In addition, questions have been raised about whether breast implants can have damaging effects during pregnancy. Two studies in humans have found that children born to women with breast implants did not have an increased risk of birth defects.[75,76] A third study looked at low birth weight and did not find an elevated risk.[74] A recent review including many women found that children of women with breast implants are not at increased risk for birth defects.[2] Overall, there is no evidence that shows silicone gel breast implants have any harmful effects on the children of implanted women.[1,73-76]

- **Potential Health Consequences of Gel Bleed**

Small quantities of low molecular weight silicone compounds, as well as platinum, have been found to leak through an intact implant shell. This is called gel bleed.[1,79] The evidence is mixed as to whether gel bleed can affect your health. For instance, studies on implants implanted for a long time have suggested that gel bleed may contribute to capsular contracture[1] and lymphadenopathy.[77] However, saline-filled breast implants have similar or higher rates of capsular contracture and other complications. Because saline-filled breast implants do not contain silicone gel, gel bleed cannot cause these complications in women with saline-filled breast implants, and might not cause these complications in women with silicone gel-filled breast implants. Furthermore, the silicone material used in Allergan's implants did not cause toxic reactions when large amounts were placed in test animals. There is little platinum contained in breast implants, and studies have shown that it is in the safest state.[78,80,81,83]

Allergan performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may diffuse out of intact implants into the body. Over 99% of the low molecular weight silicones and platinum stayed in the implant. The overall body of evidence supports that gel bleed is minimal and has no health consequences.

3.0 SURGICAL CONSIDERATIONS FOR BREAST AUGMENTATION

3.1 What Are the Alternatives to Breast Augmentation with *NATRELLE*® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants?

For primary augmentation patients, alternatives may include:
- Accepting your breasts as they are and having no surgery
- Wearing a padded bra or external prostheses
- Having mastopexy surgery (breast lift) without an implant
- Having surgery with saline implants

For revision-augmentation patients, alternatives may include:
- No revision
- Removal with:
  - No replacement
  - A padded bra or external prostheses
  - Replacement using saline implants

3.2 What Are Questions to Consider When Choosing a Surgeon?

When choosing a surgeon who is experienced with breast augmentation, you should find out the answers to the following questions:
- How many breast augmentation implantation procedures does he/she perform per year?
- How many years has he/she performed breast augmentation procedures?
- What types of implants does the surgeon primarily use (saline, silicone, highly cohesive silicone)?
- Is he/she board certified, and if so, with which board?

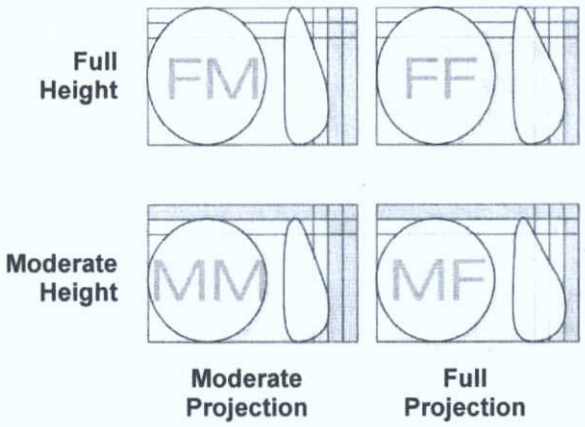
- Did he/she complete a residency in plastic surgery from a recognized and accredited program?
- In which state(s) is he/she licensed to practice surgery? (Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients, either by request or on the Internet.)
- What is the most common complication he/she encounters with breast augmentation?
- What is his/her reoperation rate with breast augmentation, and what is the most common type of reoperation he/she performs?
- Can he/she perform this surgery in a hospital as well as in the surgeon's independent surgery center? (Note that hospitals require evidence of appropriate training in specific procedures before allowing surgeons to operate in their facilities.)

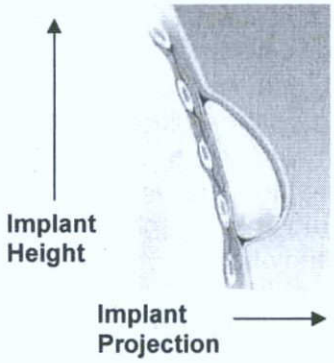
3.3 What Are Choices and Options Associated with the Surgery?

There are 2 approved types of breast implant fillers (saline and silicone), and Allergan has 2 types of silicone fillers (cohesive silicone gel and highly cohesive silicone gel). These options allow your surgeon to use the best type of implant to achieve the effect you desire. Your surgeon can discuss these options with you and may make recommendations to you based upon the physical contours of your body. This brochure is for highly cohesive silicone-filled breast implants; separate brochures are available for cohesive silicone-filled and for saline-filled implants. Carefully review the section on risks and the section on Allergan's clinical study so that you may make an informed choice. Be sure to ask your surgeon to see and touch samples of both highly cohesive silicone and cohesive silicone as well as saline-filled breast implants. As you hold a ***NATRELLE***® 410 Breast Implant in your hand and move it around, you can observe that the highly cohesive gel helps the implant maintain its shape in any position. Allergan's cohesive silicone implant has more movement as you hold it in different positions.

Implant Shape and Size

The ***NATRELLE***® 410 Breast Implant comes in a variety of height and projection combinations and a wide range of sizes. Your plastic surgeon will discuss with you the implant options that will best help you achieve the result that is right for you. The following diagram may help you to understand the various sizes and styles of implants as your surgeon discusses the various options with you. Depending on the desired shape you wish to achieve, you and your surgeon have implants with 4 different height and projection combinations, or styles, from which to choose. Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider. Breast implant sizes are measured in volume, by cubic centimeters (cc), not in cup sizes, because cup size depends on the size and shape of the individual woman's chest.





Approved *NATRELLE*® 410 Breast Implant Styles

410 Style	Breast Implant Description	Size Range
FM	full height, moderate projection	205cc – 670cc
FF	full height, full projection	185cc – 740cc
MM	moderate height, moderate projection	160cc – 450cc
MF	moderate height, full projection	140cc – 640cc

Your surgeon will also evaluate your existing breast and skin tissue to determine if you have enough tissue to cover the breast implant you are considering. In some cases, such as after pregnancy, you might have too much extra skin. If you desire a breast implant size that is too large for your tissue, the surgeon may warn you that breast implant edges may be visible or palpable postoperatively. Also, excessively large breast implants may speed up the effects of gravity on your breasts, and can make your breasts droop or sag at an earlier age. Larger sized implants may be too large for many women, and can increase the risk of implant extrusion, hematoma, infection, palpable implant folds, or visible skin wrinkling. In Allergan's Pivotal Study, a risk factor analysis showed a trend in one cohort towards an increased risk of capsular contracture with larger size implants. However, this relationship was not consistent across cohorts and timepoints, and the capsular contracture rate remained low for all cohorts.

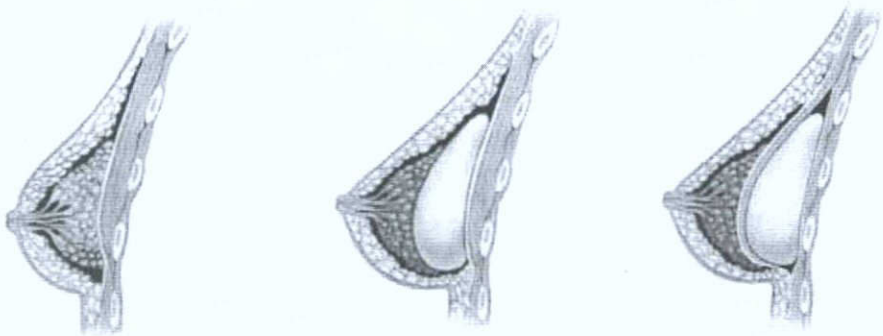
Surface Texturing

The ***NATRELLE***® 410 Breast Implant is provided with a **BIOCELL**® textured shell surface. Some studies suggest that surface texturing reduces the chance of severe capsular contracture,[15] while other studies do not.[13,14]

A textured implant may require a larger incision because the rougher textured surface may make it harder to place into the pocket. Forcing the implant through too small of an incision might damage the implant or decrease its durability.

Implant Placement

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



Breast before augmentation

Breast after subglandular augmentation

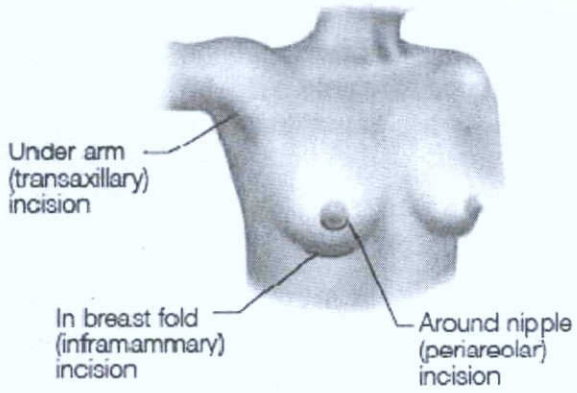
Breast after submuscular augmentation

Comparison between Submuscular versus Subglandular Placement

Submuscular Placement	Subglandular Placement
Surgery may be longer	Surgery may be shorter
Recovery may be longer	Recovery may be shorter
May be more painful	May be less painful
Reoperation may be more difficult	May provide easier access for reoperation
Less visible and palpable implants	More visible and palpable implants
Less likelihood of capsular contracture[15]	Greater likelihood of capsular contracture[13,14]
Easier imaging during mammography exam	More difficult imaging during mammography exam
May be preferable if you have thin or weakened breast tissue	May not be recommended if you have thin or weakened breast tissue

Incision Sites
You should discuss with your surgeon the pros and cons for the incision site specifically recommended for you.

Breast augmentation with highly cohesive silicone implants requires a larger incision than saline or less cohesive silicone implants. There are 3 common incision sites: around the nipple (periareolar), within the breast fold (inframammary), or under the arm (axillary or transaxillary).



- **Periareolar** – This incision is typically more concealed, but since it also involves cutting through the breast tissue, it is associated with a higher likelihood of breastfeeding difficulties, as compared to the other incision sites. Cutting through the breast tissue may make a change in sensation or infection more of a concern.
- **Inframammary** – This incision is generally less concealed than periareolar but it is associated with fewer breastfeeding difficulties than the periareolar incision site. It is also the most commonly used incision site at the present time because many surgeons feel it gives the best access to and control of the breast implant pocket.
- **Transaxillary** – This incision is less concealed than periareolar and associated with fewer breastfeeding difficulties than the periareolar incision site. If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with very small instruments, to create a "pocket" for the breast implant. This approach is more difficult, and may increase the risk of damage to, and unexpected location of, the implant.
- **Umbilical** (belly button) - This incision site has not been studied in Allergan's Pivotal Study and should not be used for a wide variety of reasons, including potential damage to the implant.

Additional Procedures at the Time of Breast Augmentation

Your surgeon will examine your breasts and help you make decisions to obtain the best result in your individual situation. In some cases, implants alone may not address all of the issues, such as sagging or extra skin, affecting your breasts. This is particularly true if there is extra skin remaining from when your breasts were engorged with milk, or if you have lost a significant amount of weight.

In these situations, your surgeon may recommend a breast lift (mastopexy) to remove some of the extra skin, or to lift the breasts, at the time of implant placement. Mastopexy involves removing a strip of skin from under the breast or around the nipple to lift the nipple and breast location, and tighten the skin over the breast. Your surgeon will discuss the potential risks, and the location of the additional scars which might be required to lift your breasts or to remove extra skin.

Implant Palpability

Implants may be more palpable or noticeable if there is an insufficient amount of skin/tissue available to cover the implant and/or when the implant is placed underneath and within the breast glands (breast tissue) but on top of the chest muscle.

444

Surgical Setting and Anesthesia
Augmentation surgery is usually performed on an outpatient basis, in a specialized operating room which may be located in a hospital, a surgery center, or surgical suite in the surgeon's office. General anesthesia is commonly used, and local anesthesia with sedation is also an option. You should be sure to check with your surgeon and with the facility where the surgery will take place, to become aware of the tests, presurgical examinations, and length of time you need to be without food or your routine medications prior to the surgical procedure.

Postoperative Care

You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size. The breasts and nipple area also may have less feeling during this time of swelling and immediately after surgery. Other possible complications have been described above.

Postoperative care depends on each patient's situation and may involve using a special postoperative bra, compression bandage, or jog bra for extra support and positioning while you heal. Some surgeons may not want you to wear a bra at all for a period of time following the surgery.

Your surgeon may place postoperative pain balls or other pain medication infusion devices alongside the breast implant to help control your pain after surgery. Breast massage exercises are not recommended after implantation as they may cause the breast implant to rotate.

At your surgeon's recommendation, you will most likely be able to return to work within a few days. However, for at least a couple of weeks you should avoid any strenuous activities that could raise your pulse and blood pressure, or require strenuous use of your arms and chest.

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

Other Factors to Consider in Revision-Augmentation Surgery
Some revision surgeries require removing an intact implant (for example, capsulotomy and pocket adjustments), while others leave the implant in place. Any device that has been removed during revision surgery should not be re-implanted. Allergan breast implants are "for single use only."

4.0 FOLLOW-UP EXAMINATIONS

After your breast implant surgery you will need regular examinations to detect potential complications. You should inform any doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.

Breast Self-Examinations

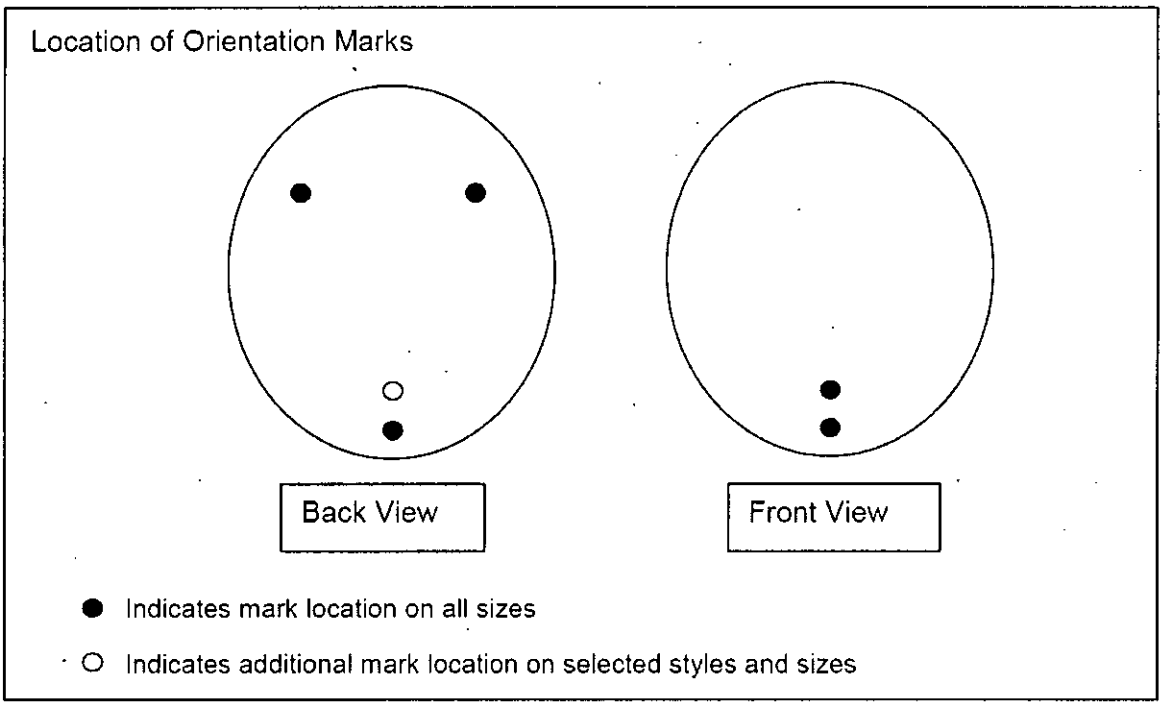
Following breast augmentation you should continue to monitor your breasts and breast implants. If you have pain in your breasts, or you find any lumps, swelling, hardening, or change in implant shape, you should report these to your surgeon. In some cases, your surgeon may recommend an MRI to screen for breast implant rupture. Any new lumps should be evaluated with a biopsy, as appropriate. If a biopsy is performed, be sure to inform the medical professional performing the biopsy that you have breast implants so that he or she can take care to avoid damaging the implant.

Screening for Silent Rupture
Because most ruptures of silicone-filled breast implants are silent, in most cases neither you nor your surgeon will be able to find evidence of rupture by a physical examination. Therefore, a different method is needed to screen for implant rupture. The best method of screening is currently MRI at a center 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. Your doctor should assist you in locating a radiology/screening center, as well as a radiologist who is familiar with the MRI techniques and equipment used to screen breast implants for silent rupture.

Your first MRI evaluation should take place 3 years after your implant surgery. You should have another MRI every 2 years, thereafter, even if you are experiencing no problems with your implant. If there are signs of rupture on MRI, then you should have your implant removed or replaced. More information on rupture is provided in Section 2 of this brochure.

Symptomatic Rupture
Symptoms associated with rupture may include hard knots or lumps surrounding the implant or in the armpit, loss of size of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast. If you notice any of these changes, see your plastic surgeon. He or she will examine the implants and determine whether you need to have an MRI examination to find out if your implant has ruptured. As a precaution, Allergan recommends that ruptured implants be taken out and either replaced with a new implant or not replaced, depending on your preference or medical need. Consult with your doctor regarding this and any other medical decisions related to your implants.

Mammography
The current recommendations for getting screening/preoperative mammograms are no different for women with breast implants than for those without implants. You need to tell your mammography technologist before the procedure that you have an implant. You should also inform your mammography technologist of the presence and location of the orientation marks on the ***NATRELLE***® 410 Breast Implant as these may be visible on the mammographic images. These orientation marks are circular silicone dots located on the surface of the implant and are used to assist the physician with placing the implant in the proper orientation. The back surface of most sizes of ***NATRELLE***® 410 Breast Implants has 4 orientation marks; the back surface of some smaller and/or shorter styles may have only 3 orientation marks, as shown below. The front surface of all ***NATRELLE***® 410 Breast Implants has 2 orientation marks, as shown below.



Mammography exams should be interpreted by radiologists experienced in the evaluation of women with breast implants. Your surgeon should request a diagnostic mammogram, rather than a screening mammogram, because more pictures are taken with diagnostic mammography. The technologist can use special techniques to reduce the possibility of rupture and to get the best possible views of the breast tissue.

5.0 ALLERGAN'S CLINICAL STUDY RESULTS

This section of the brochure summarizes the results of the Allergan Pivotal Study conducted on the ***NATRELLE***® 410 Breast Implants for Primary Augmentation and Revision-Augmentation. The Pivotal Study is the clinical study for this product. The results of the Pivotal Study give you useful information on the experience of other women with ***NATRELLE***® 410 Breast Implants. While the results cannot be used to predict your individual outcome, they can be used as a general guide to what you may expect. Your own complications and benefits depend on many individual factors.

5.1 What Are the Overview Findings of Allergan's Pivotal Study?

Allergan's Pivotal Study is a 10-year study to assess safety and effectiveness in Primary Augmentation, Primary Reconstruction, and Revision (Revision-Augmentation and Revision-Reconstruction) patients. Patient follow-up is at 0-4 weeks, 6 months, 12 months, and annually through 10 years. Safety is assessed by complications, such as implant rupture, capsular contracture, and reoperation. Benefit (effectiveness) is assessed by breast size change, patient satisfaction, and measures of quality of life.

Allergan's Pivotal Study consists of 941 patients. This includes 492 Primary Augmentation patients and 156 Revision-Augmentation patients (the remainder are Reconstruction patients). Of these patients, 150 Primary Augmentation patients and 45 Revision-Augmentation patients are in the MRI cohort, which means that they are assessed for silent rupture by MRI at years 1, 3, 5, 7, and 10. Remaining patients in the

non-MRI cohort who are MRI-eligible and consented to undergo MRIs are also being assessed for silent rupture by MRI at years 7 and 10. The study is currently ongoing, with the results through 7 years reported in this brochure. Allergan will periodically update this brochure as more information becomes available. You should also ask your surgeon for any available updated Allergan clinical information.

Allergan's Pivotal Study results indicate that 31% of Primary Augmentation patients and 48% of Revision-Augmentation patients will have at least 1 occurrence of any complication (including reoperation) at some point through 7 years after implant surgery. The information below provides more details about the complications and benefits you may experience. Please refer to the glossary for the definition of any complication you may not understand.

5.2 What Are the 7-Year Follow-Up Rates?

Follow-up rates from a clinical study show you how many women continue to provide information on their experience with breast implants.

The Pivotal Study enrolled 492 Primary Augmentation patients. Of the women expected to be seen at the 7-year follow-up visit, 75% were seen.

The Pivotal Study enrolled 156 Revision-Augmentation patients. Of the women expected to be seen at the 7-year follow-up visit, 74% were seen.

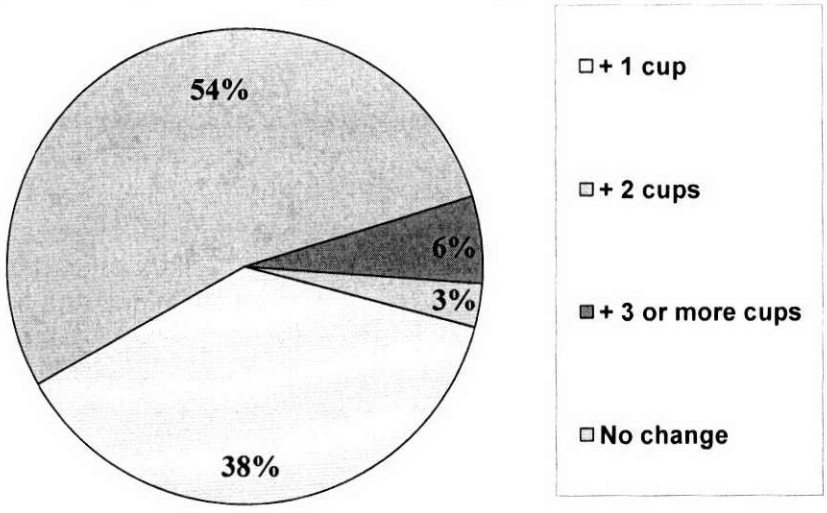
5.3 What Are the Benefits?

The benefits of ***NATRELLE***® 410 Breast Implants were assessed by a variety of outcomes, including bra cup size change and assessments of patient satisfaction and quality of life. Data were collected before implantation and at scheduled follow-up visits. Quality of life was assessed through the first 2 years after implantation.

Breast Measurement: For Primary Augmentation patients, 469 (95%) of the original 492 patients had a breast measurement within 18 months after surgery. Of these 469 patients, 38% increased by 1 cup size, 54% increased by 2 cup sizes, 6% increased by more than 2 cup sizes, and 3% had no increase. See Figure 1 below.

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

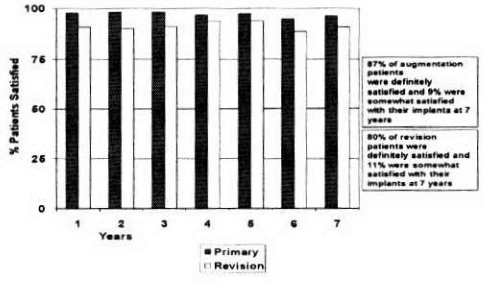
Figure 1. Cup Size Changes in Primary Augmentation Patients



Patient Satisfaction: Patients used a 5-point scale to rate their level of satisfaction with their implants at the time of the follow-up visits. Of the original 492 Primary Augmentation patients, 354 (72%) provided a satisfaction rating at 7 years after implantation. Of these 354 patients, 87% indicated that they were definitely satisfied with their breast implants, 9% indicated they were somewhat satisfied, 1% indicated that they were neither satisfied nor dissatisfied, <1% were indicated they were somewhat dissatisfied, and 2% indicated they were definitely dissatisfied.

Of the original 156 Revision-Augmentation patients, 101 (65%) provided a satisfaction rating at 7 years. Of these 101 patients, 80% indicated they were definitely satisfied with their breast implants, 11% indicated that they were somewhat satisfied, 5% indicated that they were neither satisfied nor dissatisfied, 3% indicated they were somewhat dissatisfied, and 1% indicated that they were definitely dissatisfied. See Figure 2 below.

Figure 2. Primary Augmentation and Revision-Augmentation Patient Satisfaction



Quality of Life Assessments: To assess quality of life, Primary Augmentation patients answered a series of questions collected from several quality of life scales.

For Primary Augmentation patients, prior to implantation, scores on the SF-36 Scale, which measures mental and physical health, were significantly higher than the general female population. There were no significant changes after 2 years. Scores on the Rosenberg Self-Esteem Scale and on the Body Esteem scale also generally showed no significant changes at 2 years. However, body esteem related to sexual attractiveness

improved significantly after implantation, and on the Rowland Expectation instrument, patients showed significant improvement in "self image," "social relations," and "daily living."

Primary Augmentation patients also had significantly improved satisfaction with specific aspects of their breasts after 2 years, including satisfaction with breast shape, size, feel, and how well they matched.

Revision-Augmentation patients did not undergo a quality of life assessment.

5.4 What Are the 7-Year Complication Rates?

The complications observed in Primary Augmentation and Revision-Augmentation women through 7 years are presented in Table 2 and Table 3, respectively. The rates reflect the percentage of patients who experienced the listed complication at least once within the first 7 years after their implant surgery. Some complications occurred more than once for some patients. Please refer to the Glossary at the front of this brochure for the definition of any complication you may not understand.

The most common complication for Primary Augmentation patients within the first 7 years following implantation was reoperation (22% or approximately 22 patients out of 100). The most common complication Revision-Augmentation patients experienced was also reoperation (38%).

Table 2
7-Year Complication Rates for
Primary Augmentation Patients (N = 492)

Key Complications[a]		%
Reoperation		22.4%
Implant Replacement		11.5%
Implant Rupture	MRI Cohort	11.3%
	Non-MRI Cohort	6.9%
Capsular Contracture (Baker Grade III/IV)		6.1%
Implant Removal without Replacement		1.2%

Other Complications Occurring in at least 1% of Patients[b,c]	%
Swelling	3.5%
Implant Malposition	2.9%
Breast Pain	2.7%
Ptosis	1.9%
Infection	1.7%
Breast/Skin Sensation Changes	1.5%
Nipple Complications	1.3%
Other Complications	1.3%
Seroma/Fluid Accumulation	1.3%
Delayed Wound Healing	1.1%
Hematoma	1.1%
Hypertrophic/Other Abnormal Scarring	1.1%

[a] Most complications were assessed with severity ratings. This table only includes complications rated moderate, severe, or very severe (excludes mild and very mild ratings). For reoperation, implant removal or replacement, implant rupture, implant extrusion, and pneumothorax all occurrences are included.

[b] The following complications were reported at a rate less than 1%: asymmetry, bruising, extrusion of intact implant, redness, skin rash, wrinkling/rippling, and implant palpability/visibility

[c] The following complications were reported at a rate of 0%: capsule calcification, irritation, lymphadenopathy, lymphedema, palpable orientation mark, pneumothorax, tissue/skin necrosis, and upper pole fullness

Table 3
7-Year Complication Rates for Revision-Augmentation Patients (N = 156)

Key Complications[a]		%
Reoperation		37.7%
Implant Replacement		21.3%
Capsular Contracture (Baker Grade III/IV)		8.7%
Implant Rupture	MRI Cohort	8.9%
	Non-MRI Cohort	16.1%
Implant Removal without Replacement		3.6%

Other Complications Occurring in at least 1% of Patients[b,c]	%
Implant Malposition	7.0%
Asymmetry	5.7%
Wrinkling/Rippling	3.7%
Seroma/Fluid Accumulation	3.3%
Breast Pain	3.0%
Hypertrophic/Other Abnormal Scarring	2.7%
Swelling	2.7%
Infection	2.1%
Hematoma	2.0%
Extrusion of Intact Implant	1.5%
Other Complications	1.5%
Implant Palpability/Visibility	1.4%
Upper Pole Fullness	1.4%
Delayed Wound Healing	1.3%

[a] Most events were assessed with severity ratings. This table only includes complications rated moderate, severe or very severe (excludes mild and very mild ratings). For reoperation, implant removal or replacement, implant rupture, implant extrusion, and pneumothorax all occurrences are included.
[b] The following complication was reported at a rate less than 1%: bruising
[c] The following complications were reported at a rate of 0%: breast/skin sensation changes, capsule calcification, irritation, lymphadenopathy, lymphedema, nipple complications, palpable orientation mark, ptosis, pneumothorax, redness, skin rash, and tissue/skin necrosis

5.5 What Are the Main Reasons for Reoperation?

The reasons Primary Augmentation and Revision-Augmentation patients underwent additional surgery for their breast implant (reoperation) through 7 years are presented in Table 4 and Table 5, respectively. Women may have had a reoperation for one or more reasons. Furthermore, a surgeon may perform multiple surgical procedures during a single reoperation. For example, during a single reoperation a surgeon may perform incision and drainage, remove the capsule, replace the implant, reposition the implant, and perform scar revision.

The most common reason for reoperation through 7 years in Primary Augmentation patients was because of patient request for style/size change (21 of 128 reoperations, or 16.4%). In Allergan's Pivotal Study, there were 256 surgical procedures performed during 128 reoperations involving 102 Primary Augmentation patients.

The most common reason for reoperation through 7 years in Revision-Augmentation patients was because of implant malposition (11 of 70 reoperations, or 15.7%). In Allergan's Pivotal Study, there were 151 surgical procedures performed during 70 reoperations involving 55 Revision-Augmentation patients.

Table 4
Main Reasons for Reoperation in
Primary Augmentation Patients through 7 Years

Reason for Reoperation	n (%)
Patient Request for Style/Size Change	21 (16.4%)
Implant Malposition	15 (11.7%)
Scarring/Hypertrophic Scarring	15 (11.7%)
Capsular Contracture	13 (10.2%)
Hematoma/Seroma	12 (9.4%)
Ptosis (sagging)	11 (8.6%)
Need for Biopsy	10 (7.8%)
Suspected Rupture	8 (6.3%)
Asymmetry	4 (3.1%)
Breast Cancer Mass	4 (3.1%)
Delayed Wound Healing	4 (3.1%)
Infection	4 (3.1%)
Breast Tissue Contour Deformity	2 (1.6%)
Breast Pain	1 (0.8%)
Extrusion of Intact Implant	1 (0.8%)
Gel Fracture	1 (0.8%)
Nipple Complications	1 (0.8%)
Wrinkling	1 (0.8%)
Total	**128 Reoperations (100%)**

Table 5
Main Reasons for Reoperation in
Revision-Augmentation Patients through 7 Years

Reason for Reoperation	n (%)
Implant Malposition	11 (15.7%)
Capsular Contracture	9 (12.9%)
Need for Biopsy	8 (11.4%)
Scarring/Hypertrophic Scarring	7 (10.0%)
Patient Request for Style/Size Change	6 (8.6%)
Ptosis (sagging)	6 (8.6%)
Suspected Rupture	6 (8.6%)
Asymmetry	4 (5.7%)
Infection	4 (5.7%)
Breast Pain	3 (4.3%)
Hematoma/Seroma	3 (4.3%)
Delayed Wound Healing	1 (1.4%)
Extrusion of Intact Implant	1 (1.4%)
Implant Palpability/Visibility	1 (1.4%)
Total	**70 Reoperations (100%)**

5.6 What Are the Main Reasons for Implant Removal?

The main reasons Primary Augmentation and Revision-Augmentation patients had implants removed through 7 years are presented in Figure 3 and Figure 4, respectively. For Primary Augmentation patients, 99 implants were removed from 56 patients. Of these 99 implants, 89 were replaced. The most common reason for implant removal was the patient requested a different implant style or size (46 of the 99 implants removed, or 46%).

For Revision-Augmentation patients, 60 implants were removed from 34 patients. Of these 60 implants, 53 were replaced. The most common reason for implant removal was the patient requested a different implant style or size (16 of the 60 implants removed, or 27%).

Figure 3. Main Reasons for Implant Removal Through 7 Years
Primary Augmentation (N = 99 implants)

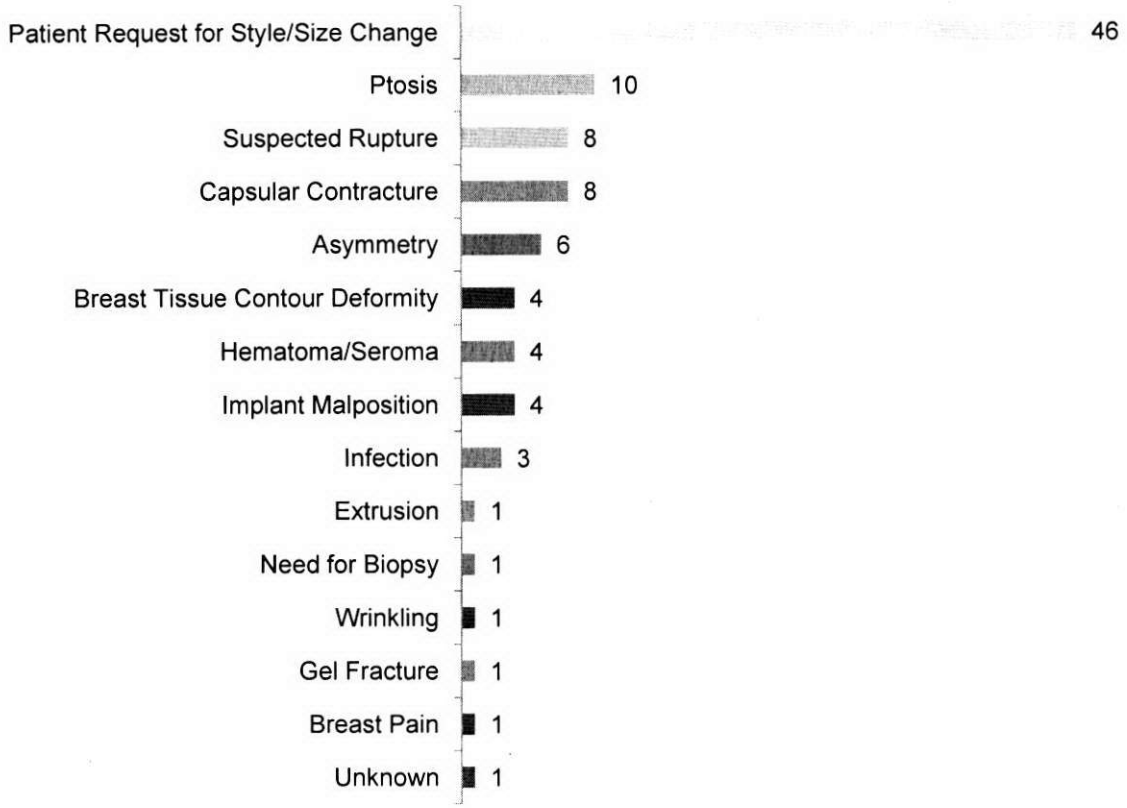
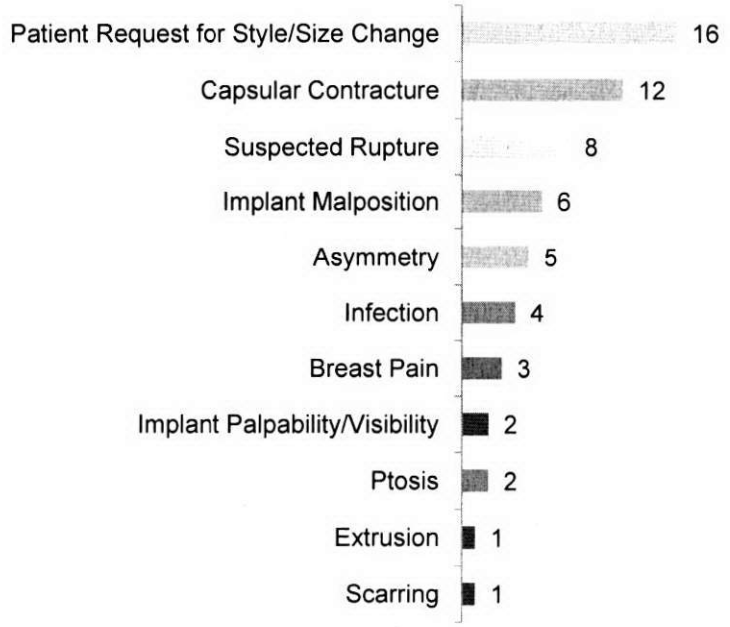


Figure 4. Main Reasons for Implant Removal Through 7 Years
Revision-Augmentation (N = 60 implants)



5.7 What Are Other Clinical Data Findings?

Below is a summary of clinical findings from the Pivotal Study with regard to connective tissue disease (CTD), CTD signs and symptoms, cancer, lactation complications, reproduction complications, and suicide. These issues, along with others, are being further evaluated as part of an Allergan post-approval study of patients followed through 10 years.

Implant Rupture

The rupture rate for the whole MRI cohort in Allergan's Pivotal Study (including Primary Augmentation, Revision-Augmentation, Primary Reconstruction, and Revision-Reconstruction patients) through 7 years was 11.5% for patients and 6.7% for implants. For the non-MRI cohort the rupture rate through 7 years was 8.7% for patients and 5.3% for implants. For Primary Augmentation patients in the MRI cohort, 11.3% of patients had a ruptured implant, and 6.6% of implants ruptured through 7 years. For Revision-Augmentation patients in the MRI cohort, 8.9% of patients had a ruptured implant, and 4.6% of implants ruptured through 7 years. This means that through 7 years, 12 of every 100 Primary Augmentation patients and 9 out of every 100 Revision-Augmentation patients had at least one ruptured breast implant.

For all ruptured implants in the Pivotal Study, the silicone gel remained within the capsule surrounding the implant.

CTD Diagnoses

Three Primary Augmentation patients (0.6%) reported new diagnoses of CTD: 1 patient reported systemic sclerosis/scleroderma at 1 month after implantation, 1 patient reported mitochondrial myopathy at 69 months after implantation, and 1 patient reported a positive ANA-specific diagnosis at 77 months after implantation in the Pivotal Study. Two Revision-Augmentation patients (1.3%) reported a new diagnosis of fibromyalgia and Hashimoto thyroiditis, respectively. It cannot be concluded that these CTD diagnoses were caused by the implant because there was no comparison group of similar women without implants.

CTD Signs and Symptoms

Patients that are not diagnosed with a CTD may still have some of the signs or symptoms of these diseases. In Allergan's Pivotal Study, self-reported signs and symptoms were collected at the 2, 4, and 6 year follow-up visits in the categories of General, Gastrointestinal, Neurological, Urinary, Global, Pain, Fatigue, Fibromyalgia, Joint, Muscular, Skin, and Other. For Primary Augmentation patients, at 6 years statistically significant increases after accounting for age were found for the symptom categories of Joint, Muscular, and Skin. Statistically significant increases were found for Revision-Augmentation patients in the Gastrointestinal symptom category at 6 years after accounting for age.

The Pivotal Study was not designed to evaluate cause-and-effect associations because there is no comparison group of women without implants. Further, other factors that might contribute to CTD signs and symptoms, such as medications, lifestyle, and exercise, were not studied. Therefore, it cannot be determined whether any increase in CTD signs and symptoms was due to the implants or not, based on the Pivotal Study.

However, you should be aware that you may experience an increase in these symptoms after receiving breast implants.

Cancer
There were 3 Primary Augmentation patients (0.6%) with a new diagnosis of breast cancer through 7 years in the Allergan Pivotal Study. In Primary Augmentation patients there was 1 report of skin cancer and 1 report of renal cell cancer, and 1 Primary Augmentation patient who was pregnant at the time of implantation gave birth to a child who later developed histiocytosis.

For Revision-Augmentation patients, there was 1 patient (0.8%) with a new diagnosis of breast cancer through 7 years. In Revision-Augmentation patients there was 1 report of bladder cancer and 1 report of multiple myeloma.

No patients in the Pivotal Study were reported with ALCL through 7 years.

Lactation Complications
Ten (23%) of the 44 Primary Augmentation patients who attempted to breastfeed following breast implantation in the Pivotal Study through 7 years reported difficulty with breastfeeding. The most common difficulty was mastitis. For the 3 Revision-Augmentation patients who attempted to breastfeed after receiving breast implants, 1 (33%) had difficulty breastfeeding due to inadequate milk production.

Reproduction Complications
Seventeen (3.5%) of the Primary Augmentation patients in the Pivotal Study reported a reproduction problem through 7 years, most commonly miscarriage. Two (1.3%) Revision-Augmentation patients experienced a reproduction problem through 7 years.

Suicide
There were no reports of suicide in the Primary Augmentation patients and the Revision-Augmentation patients in the Pivotal Study through 7 years.

6.0 ADDITIONAL INFORMATION

6.1 What If I Experience a Problem?

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

You should immediately report any problems that you notice with your implants to your plastic surgeon. If you believe that you have experienced a serious problem(s) related to your breast implants, you should have your health professional report the problem(s) to the Food and Drug Administration (FDA and/or to Allergan). You may also report any serious problem directly through the FDA's MedWatch voluntary reporting system. An adverse event is considered serious and should be reported when it results in a hospitalization, disability, congenital problem with your child, or other medical or surgical intervention. The 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.

To report, use MedWatch Form 3500, which may be obtained through FDA's website at http://www.fda.gov/medwatch/index.html. You may also call 1.888.INFO.FDA (1.888.463.6332), 10 am to 4 pm Eastern Time, Monday through Friday, to receive an additional FDA MedWatch Package. Keep a copy of the MedWatch form completed by your surgeon for your records.

6.2 What Is Device Tracking?

Silicone gel-filled breast implants are subject to Device Tracking by federal regulation. This means that your physician will be required to submit to Allergan the serial number of the implant(s) you receive, the date of surgery, information relating to the physician's practice and information on the patient receiving the implant(s). Your surgeon will write this information on the Device Tracking Form supplied by Allergan with each silicone-filled breast implant. Your surgeon will return the first page of the form to Allergan following surgery. The second page of the form will be provided to you following surgery. You have the right to remove your personal information from Allergan's Device Tracking program. If you choose NOT to participate in Device Tracking, please check the appropriate box on the Device Tracking form and return to Allergan. You also have the right to have your personal information withheld from disclosure to third parties who may request information from Allergan, such as the FDA. If you choose to participate in the Device Tracking program but do NOT want your personal information to be released to third parties, please also check the appropriate box.

Allergan strongly recommends that all patients receiving ***NATRELLE®*** 410 Breast Implants participate in Allergan's Device Tracking program. This will help ensure that Allergan has a record of each patient's contact information so that all patients can be contacted in the case of a recall or other problems with the implants.

Assessment of Information Effectiveness

The "Required Information" section of the Device Tracking Form also has a question designed to assess the effectiveness of this *Breast Augmentation with* ***NATRELLE®*** *410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants* patient brochure provided prior to your surgery. This question asks you to verify that you received and had adequate time to review this important information. Please check either yes or no. When the Required Information section is complete, return the entire page to Allergan by fax or mail, using the information provided on the form.

Please inform Allergan whenever your contact information changes by calling 1.877.641.4844 or e-mailing SB-DeviceTracking@allergan.com.

6.3 What Are the *ConfidencePlus®* Limited Warranties?

The *ConfidencePlus®* Limited Warranties provide lifetime replacement and limited financial reimbursement in the event of shell leakage or breakage resulting in implant rupture, subject to certain conditions as fully discussed in the *ConfidencePlus®* literature. Allergan offers two levels of coverage under its warranty program. Our standard *ConfidencePlus®* Limited Warranty program applies automatically to every Allergan breast implant recipient subject to the conditions discussed in the

ConfidencePlus® literature. The optional *ConfidencePlus*® Premier Limited Warranty program is available for a low enrollment fee and increases the financial benefit in the event of implant rupture, subject to the conditions discussed in the *ConfidencePlus*® literature. For more information, please visit www.cppwarranty.com or contact Allergan's Product Surveillance Department at 1.800.362.4426.

6.4 How Can I Receive More Information?

Upon request, you will be provided with a copy of the package insert (Directions for Use; ***NATRELLE***® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants). You can request a copy from your surgeon or from Allergan. It can also be found on www.allergan.com/labeling/usa.htm. The package insert has many undefined medical and technical terms because it contains information directed only to the surgeon.

For more detailed information on the preclinical and clinical studies conducted by Allergan, you are referred to the Summary of Safety and Effectiveness Data (SSED) for this product which may be accessed at www.fda.gov/breastimplants.

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

TOLL-FREE NUMBER

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

ADDITIONAL RESOURCES

Allergan
1.800.624.4261
www.natrelle.com
www.allergan.com
www.breastimplantanswers.com

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

Food and Drug Administration
1.888.INFO.FDA or 1.240.276.3103
www.fda.gov/cdrh/breastimplants/

FOR FURTHER READING AND INFORMATION

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INDEX

ACCEPTANCE OF RISK AND SURGERY CONSENT

Surgeon and patient review and initial to indicate understanding and acceptance of the following:

	SURGEON	PATIENT
If signs of rupture are seen on an MRI, then you should have your implant removed.	_____	_____
Additional surgery to your breast and/or implant will be likely over the course of your life.	_____	_____
Your implants are not considered lifetime devices and you will likely undergo implant removal, with or without replacement, during your life.	_____	_____
You should inform your mammography technologist about the presence of your implants.	_____	_____
Your breast implants may interfere with your ability to successfully breastfeed.	_____	_____
You should perform breast self-examinations monthly and should make sure you know how to distinguish the implant from your breast tissue.	_____	_____
To monitor your breast implants for silent rupture, an MRI is recommended 3 years following surgery and then every 2 years after that.	_____	_____
The scar tissue or capsule that normally forms around the implant may tighten (contracture) and squeeze the implant. This may be painful and make your breast feel firmer.	_____	_____
Allergan maintains a breast implant device tracking database and your participation in this database is strongly recommended.	_____	_____

Consent to Surgery

My surgeon has provided me with the patient labeling, ***Breast Augmentation with NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants***, to inform me prior to my surgery.

I have had adequate time to review and understand the information presented in the patient labeling, ***Breast Augmentation with NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants***. My concerns and questions have been addressed by my doctor. I have considered alternatives to augmentation surgery, including use of external prostheses or surgery with saline-filled breast implants.

I am choosing to proceed with silicone gel-filled breast implant surgery.

Patient Name (Printed): _____

Patient Signature: _____

Date: _____

Surgeon Name (Printed): _____

Surgeon Signature: _____

Date: _____

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Important Factors Breast Reconstruction Patients Should Consider

THE SCIENCE OF REJUVENATION™

TABLE OF CONTENTS **Page**

GLOSSARY

Anaplastic large cell lymphoma (ALCL)	ALCL is not breast cancer; it is a rare type of non-Hodgkin's lymphoma, a cancer involving the cells of the immune system.
Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	Uneven appearance between a woman's left and right breasts in terms of size, shape, or breast level.
Atrophy	Thinning or diminishing of tissues or muscle.
Autoimmune disease	An autoimmune disease is a disease in which the body's immune system attacks its own cells or tissues by mistake, causing damage and dysfunction. Autoimmune diseases can affect connective tissue in the body (the tissue that binds together body tissues and organs). Autoimmune diseases can affect many parts of the body, like nerves, muscles, glands and the digestive system.
Biocompatible	The ability to exist along with living tissues or systems without causing harm.
Biopsy	The removal and examination of tissues, cells, or fluid from the body.
Body Dysmorphic Disorder	A psychological condition characterized by excessive worry about an imagined or minor physical flaw to the point that it can interfere with normal daily activities.
Body Esteem Scale	A questionnaire which asks about a person's body image.
Breast augmentation	A surgical procedure to increase breast size. For this brochure, it refers to placement of a breast implant. The first time an implant is placed for augmentation is called "primary augmentation." Any time there is another surgery to replace the implant, it is referred to as "revision-augmentation."
Breast implant	Any surgically implanted artificial device intended to replace missing breast tissue or to enhance a breast.
Breast mass	A lump in the breast.

Breast reconstruction	A surgical procedure to replace breast tissue or reconstruct a breast after tissue was taken out because of cancer or injury. Breast reconstruction also includes the surgical correction of a breast that has failed to develop properly due to a severe abnormality or congenital defect. For this brochure, it refers to placement of a breast implant. The first time a breast implant is placed to replace breast tissue is referred to as "primary reconstruction." Any time there is another surgery to replace the implant it is referred to as "revision-reconstruction."
Calcification	Process of hardening by calcium salts.
Capsular contracture	A tightening of the scar tissue (also called a capsule) that normally forms around the breast implant during the healing process after surgery. In some women, the scar tissue (capsule) squeezes the implant. When this occurs, it is called capsular contracture. This results in firmness or hardening of the breast, and is a risk for implant rupture. Capsular contracture is classified by Baker Grades. Capsular Contracture Baker Grades III and IV are the most severe. Baker Grade III often results in the need for additional surgery (reoperation) because of pain and possibly abnormal appearance. Baker Grade IV usually results in the need for additional surgery (reoperation) because of pain and unacceptable appearance. Capsular Contracture Baker Grade II may also result in the need for surgery. Each grade is described below.[17] • Baker Grade I – Normally soft and natural appearance • Baker Grade II – A little firm, but breast looks normal • Baker Grade III – More firm than normal, and may look abnormal (change in shape) • Baker Grade IV – Hard, obvious distortion, and tenderness with pain
Capsule	Scar tissue which forms around the breast implant.
Capsulotomy (closed)	An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but may rupture the implant and is contraindicated.
Capsulotomy (open)	An attempt to break the scar tissue capsule around the implant by surgical incision into the capsule.
Congenital abnormality	An abnormal development in part of the body, present in some form since birth.

Connective tissue disease/disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc., and/or the immune system. Connective tissue diseases (CTDs) that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.
Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Contralateral	Opposite side.
Delayed wound healing	Unusually slow progress in the healing of a wound; surgical incision site fails to heal normally or takes longer to heal.
Displacement	Movement of the implant from the usual or proper place.
Extrusion	Skin breakdown with the implant pressing through the skin or surgical incision.
Fibromyalgia	A disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue.
Fibrous tissues	Connective tissues composed mostly of fibers.
Flap	A portion of tissue (which may include muscle, fat, and skin) moved from one part of the body to another. The tissue flap may or may not have its blood supply attached.
Gel bleed	When silicone gel leaks or "bleeds" or diffuses through the implant shell.
Gel fracture	Appearance of a fissure or fault line in the gel in response to an applied force.
Granuloma	A noncancerous lump that can form around any foreign material, such as silicone. Like any lump, it should be evaluated to distinguish it from a lump that might be cancerous.
Hematoma	A collection of blood within a space.
Hypertrophic scarring	An enlarged scar that remains after a wound heals.
Incision	A cut made to the tissue during surgery.
Infection	The growth in the human body of microorganisms such as bacteria, viruses, or fungi. An infection usually results in fever, swelling, redness, and/or pain. It can occur as a result of any surgery.
Inflammation	The response of the body to infection or injury that is characterized by redness, swelling, warmth, and/or pain.
Inframammary	Below the breast.

Inpatient surgery	A surgical procedure in which the patient is required to stay overnight in the hospital.
Lactation	The production and secretion of milk by the breast glands.
Latissimus dorsi	Two triangular muscles running from the spinal column to the shoulder.
Low molecular weight silicones	Small silicone molecules that might leak out of the implant.
Lymph nodes	Glands that play an important part in the body's defense against infection. They produce lymph, which travels throughout the body in the lymph system, and filters impurities from the body. Common areas where the lymph nodes can be felt with the fingers include: groin, armpit, neck, under the jaw and chin, behind the ears, and on the back of the head.
Lymphadenopathy	Enlargement of the lymph node(s).
Lymphedema	Swelling of the lymph node(s).
Malposition	When the implant is placed incorrectly during the initial surgery or when the implant has shifted from its original position. Shifting can be caused by many factors, such as gravity, trauma, poor initial placement, or capsular contracture.
Mammary	Pertaining to the breast.
Mammography	A type of x-ray examination of the breasts used for detection of cancer. Screening mammography – x-ray examination of the breast that is performed on women with no complaints or symptoms of breast cancer; the goal is to detect breast cancer when it is still too small to be felt by a physician or the patient. Diagnostic mammography – x-ray examination in order to evaluate a breast complaint or abnormality detected by physical exam or screening mammography; additional views of the breast are usually taken.
Mammoplasty	Plastic surgery of the breast.

Mastectomy	Partial or complete removal of the breast due to the presence of a cancerous or precancerous growth. • Subcutaneous mastectomy: surgical removal of the breast tissues, but sparing the skin, nipple, and areola. • Total mastectomy: surgical removal of the breast including the nipple, areola, and most of the overlying skin. • Modified radical mastectomy: surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the lymphatic-bearing tissue in the axilla. • Radical mastectomy: surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the pectoral muscles, lymphatic bearing tissue in the axilla, and various other neighboring tissue.
Mastitis	Inflammation of the breast.
Mastopexy	Surgical procedure to raise and reshape sagging breasts.
Metastatic disease	A stage of cancer after it has spread from its original site to other parts of the body.
Migration	Movement of silicone materials outside the breast implant to other parts of the body.
MRI (Magnetic Resonance Imaging)	A radiographic examination that currently has the best ability to detect rupture of silicone gel-filled breast implants.
Necrosis	Death of cells or tissues.
Oncologist	A medical doctor who specializes in diagnosing and treating cancer.
Outpatient surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight.
Palpability	The ability to feel the implant.
Palpable	Felt with the hand.
Pectoralis	Major muscle of the chest.
Periareolar	Around the darkened or pigmented area surrounding the nipple of the breast.

Pivotal Study	The primary clinical study of Primary Augmentation, Primary Reconstruction, and revision (Revision-Augmentation and Revision-Reconstruction) patients that supported the approval of the premarket approval (PMA) application. Safety and effectiveness data are collected yearly through 10 years.
Plastic surgery	Surgery intended to enhance or improve the appearance of the body.
Postoperative	After surgery.
Precautions	Information that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
Primary breast reconstruction	The first time a breast implant is placed for the purpose of breast reconstruction.
Ptosis	Sagging or drooping of the breast.
Reoperation	An additional surgery after your first breast implantation.
Revision-reconstruction	Refers to the correction or improvement of a primary reconstruction. For this brochure, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast reconstruction.
Rheumatologic disease/disorder	A variety of diseases involving connective tissue structures of the body, especially the joints and fibrous tissue. These diseases are often associated with pain, inflammation, stiffness, and/or limitation of motion of the affected parts. Can include autoimmune diseases. Fibromyalgia is a rheumatological disorder.
Rosenberg Self-Esteem Scale	A questionnaire that measures overall self-esteem.
Rowland Expectation Scale	A 16 item questionnaire intended to measure expectations and perceived results of implant surgery.
Rupture	A hole or tear in the shell of the implant that allows silicone gel filler material to leak from the shell. Ruptures can be intracapsular (inside the scar tissue capsule surrounding the implant) or extracapsular (outside the scar tissue surrounding the implant).
Saline	A solution made of water and a small amount of salt.
Scar revision	A surgical procedure to improve the appearance of a scar.
Seroma	Similar to a bruise, a seroma occurs when the watery portion of the blood collects around a surgical incision or around a breast implant.
SF-36 Scale	The Short Form 36 Health Scale; a questionnaire intended to measure physical, mental, and social health.

Silent rupture	A breast implant rupture without symptoms or a visible change. Silent rupture cannot be felt by the woman or detected by a doctor through physical examination. Silent rupture can only be discovered through appropriate imaging techniques such as MRI. Most silicone gel-filled breast implant ruptures are silent (see symptomatic rupture below).
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
Subglandular placement	Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.
Submuscular placement	Placement of a breast implant wholly or partially underneath the chest muscle.
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Symptomatic	Experiencing symptoms; any evidence or sign of disease or disorder.
Symptomatic rupture	A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape). Some silicone breast implant ruptures are symptomatic, but most are silent.
Systemic	Pertaining to or affecting the body as a whole.
Tissue expander	An adjustable implant that can be inflated with saline to stretch the tissue at the mastectomy site. This is used to create a new tissue flap that is large enough to cover the breast implant.
Toxic shock syndrome	A rare, but life-threatening bacterial infection that may occur after surgery. It occurs most often in the vagina of menstruating women using superabsorbent tampons. Symptoms include sudden fever, vomiting, diarrhea, decreased blood pressure, fainting, dizziness, and sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment if toxic shock syndrome is suspected.
Transaxillary	Under the arm.
Warning	Statement that alerts the reader about a situation which, if not avoided, could result in serious injury or death.

1.0 CONSIDERING SILICONE GEL-FILLED BREAST IMPLANT SURGERY

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

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

Allergan has prepared this information to help you better understand the breast implant procedure and assist you in making an informed decision about breast reconstruction or revision-reconstruction surgery. It will help to answer some of the questions you may have about the surgery and about breast implants in general. It will also provide you with specific information about the risks and benefits of Allergan's ***NATRELLE***® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants. Similar information to help you understand breast augmentation is available from your plastic surgeon, Allergan, or at www.natrelle.com.

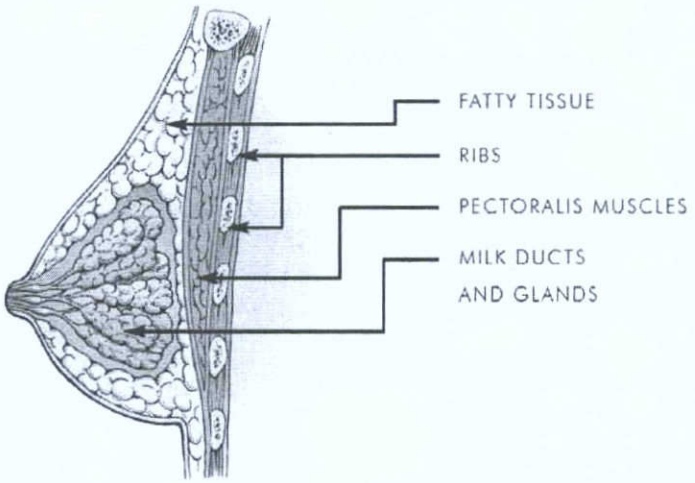
This information cannot and should not replace talking to your plastic surgeon. Your decision on whether or not to get breast implants should be based on realistic expectations of the outcome. There is no guarantee that your results will match those of other women. Your results will depend on many individual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

As part of your decision, both you and your surgeon will be required to sign Allergan's "Acceptance of Risk and Consent to Surgery" form that confirms your understanding of the risks and benefits of Allergan's ***NATRELLE***® 410 Breast Implants. This form is located on page 57.

Because breast implants will require monitoring and care for the rest of your life, you should wait 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast reconstruction surgery. In the case of a revision-reconstruction, however, your surgeon may find it medically necessary to perform surgery sooner.

1.1 What Gives the Breast Its Shape?

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. Beneath the breast is the chest muscle (pectoralis major muscle).



Implants are used to make the breast larger or to restore/replace breast tissue. Factors such as pregnancy (when milk glands are temporarily enlarged), rapid weight loss, and the effects of gravity as you age, combine to stretch the skin, which may cause the breast to droop or sag. The implants alone may not adequately lift the breast, or correct the effects of pregnancy, weight loss, or skin stretching. Your surgeon may suggest additional procedures at the time of the breast reconstruction, such as mastopexy, to help achieve improved breast lift.

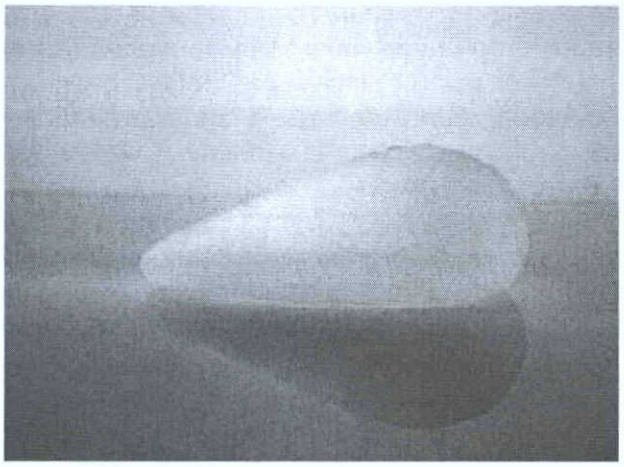
Breast cancer surgery (full or partial mastectomy or lumpectomy) can greatly change the shape and appearance of the breast. When a woman has a mastectomy some, much, or all of the breast tissue may be removed, and some skin may be removed as well. There will be scarring, and the tissue (skin and breast tissue) may be more sensitive because of the surgery, or chemotherapy, and/or radiation treatments. All of these can affect the size, shape, and overall outcome of reconstruction with breast implants.

1.2 What is a Highly Cohesive Silicone-Filled Breast Implant?

A silicone gel-filled breast implant is a sac (implant shell) of silicone elastomer (rubber) filled with silicone gel. Allergan has approval for 2 types of silicone gel fillers: cohesive silicone gel and highly cohesive silicone gel. The focus of this brochure is highly cohesive silicone-filled breast implants. A separate brochure is available for cohesive silicone-filled implants from your plastic surgeon, from Allergan, or at www.natrelle.com.

Allergan's ***NATRELLE***® 410 Breast Implants have a teardrop shape and are filled with a highly cohesive silicone gel that helps the implant maintain its shape over time. The highly cohesive breast implant has a textured surface.

Example of a ***NATRELLE***® 410 Breast Implant



Refer to Section 3.3 for more information on the different ***NATRELLE***® 410 Breast Implants available from Allergan.

1.3 Who is eligible for *NATRELLE*® 410 Breast Implants and what is the indication statement?

NATRELLE® 410 Breast Implants have been approved for women for the following uses (procedures):

- Breast augmentation for women at least 22 years old. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.

- Breast reconstruction. Breast reconstruction includes primary breast reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

A separate patient brochure is available for those women considering breast augmentation surgery and should be read prior to reaching a decision to undergo breast augmentation.

1.4 What Are the Contraindications?

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

Breast implant surgery should not be performed in:

- Women with active infection anywhere in their body, because the implant will make the infection much harder to treat should the infection move into the breast.

- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions, because radiation and chemotherapy treatments may increase the risk of some complications seen with breast implants. Also, breast implants may interfere with radiation or chemotherapy treatments.
- Women who are currently pregnant or nursing, because surgery may interfere with the safety of the pregnancy/nursing. Since breast reconstruction is an elective surgery, it should be postponed until you are no longer pregnant or nursing.

1.5 What are the Precautions?

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

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

1.6 Warnings

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

WARNING – Be aware that there are many factors that will affect the outcome and timing of your reconstruction with breast implants. These factors include the stage of your disease, the type and extent of cancer removal surgery you have had, the amount of skin and soft tissue available for the reconstruction, and additional treatments such as chemotherapy and radiation, which you may require.

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

WARNING – Before you decide to have breast implant surgery, you should know that breast implants are not lifetime devices, and breast implantation is likely not a one-time surgery. You will likely need additional unplanned surgeries on your reconstructed

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

WARNING – Your ***NATRELLE***® 410 Breast Implant may rupture without any symptoms (silent rupture). This means that neither you nor your surgeon will know that your implants have ruptured. In order to detect silent rupture, you will need to have regular screening MRI examinations. You should have an MRI 3 years after your breast implant surgery and then every 2 years after that for as long as you have your breast implants.

2.0 BREAST IMPLANT BENEFITS AND RISKS

Undergoing any type of surgical procedure involves risks such as the effects of anesthesia, infection, swelling, redness, bleeding, pain, and even death. Some of these risks are serious, and all of these risks need to be balanced against the benefits of the surgery. These benefits and risks of breast implants are described below. At the end of this brochure is a list of published studies used to gather the information discussed in the sections below. These studies may be helpful to you if you wish to learn more about a specific complication or condition. The reference list is not complete because studies are being conducted all the time. Your physician may have other resources for further reading. The information provided below focuses on women undergoing primary reconstruction or revision-reconstruction with ***NATRELLE***® 410 Breast Implants. The studies in the list of references also include women undergoing breast augmentation and other types of implants from a variety of manufacturers. The risks and benefits of augmentation may differ from those for breast reconstruction, and the risks of other types of implants may differ from those of ***NATRELLE***® 410 Breast Implants.

2.1 What are the Benefits?

Breast reconstruction can replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe abnormality. In addition, revision-reconstruction can correct or improve the result of a primary reconstruction surgery.

Breast reconstruction has the potential to offer both physical and psychological benefits to women, including facilitating emotional healing after cancer and regaining body symmetry.[1,3-8] Many studies have reported that a majority of breast implantation patients are satisfied with the results of their surgery. In Allergan's Pivotal Study through 7 years, approximately 9 out of 10 women undergoing primary reconstruction or revision-reconstruction with ***NATRELLE***® 410 Breast Implants who responded to the question were definitely or somewhat satisfied with their breast implants. Section 5.3 provides more information on benefits seen in Allergan's Pivotal Study.

2.2 What Are the Potential Risks?

Table 1 describes some of the known risks of breast reconstruction along with possible effects of those risks. Additional useful information related to these risks is provided following Table 1. Sections 5.4 through 5.7 as well as Tables 2 and 3 provide more information on risks seen in Allergan's Pivotal Study.

Table 1

Risks of Breast Reconstruction Through 7 Years with *NATRELLE*® 410 Breast Implants

Event	Likelihood of Event Occurring in Primary Reconstruction Patients[a]	Likelihood of Event Occurring in Revision-Reconstruction Patients[a]	Possible Resulting Effects of the Event
Key Risks			
Additional Surgeries (Reoperations)	45 out of 100 patients (45%)	39 out of 100 patients (39%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal with Replacement	25 out of 100 patients (25%)	27 out of 100 patients (27%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal without Replacement	5 out of 100 patients (5%)	2 out of 100 patients (2%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Capsular Contracture (Baker Grade III/IV)	11 out of 100 patients (11%)	22 out of 100 patients (22%)	• Pain or Discomfort • Breast hardness/firmness • Reoperation • Implant removal
Rupture **MRI Cohort** **Non-MRI Cohort**	10 out of 100 patients (10%) 9 out of 100 patients (9%)	21 out of 100 patients (21%) 0 out of 100 patients (0%)	• Implant Removal

Event	Likelihood of Event Occurring in Primary Reconstruction Patients[a]	Likelihood of Event Occurring in Revision-Reconstruction Patients[a]	Possible Resulting Effects of the Event
Other Risks Occurring in 1% or more of Patients[b]			
Asymmetry	10 out of 100 patients (10%)	15 out of 100 patients (15%)	• Undesirable cosmetic result • Reoperation • Implant removal
Hypertrophic/Other Abnormal Scarring	5 out of 100 patients (5%)	3 out of 100 patients (3%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Infection	5 out of 100 patients (5%)	7 out of 100 patients (7%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
Breast Pain	5 out of 100 patients (5%)	5 out of 100 patients (5%)	• Resulting effects are contingent on underlying cause(s)
Other Complications	4 out of 100 patients (4%)	2 out of 100 patients (2%)	• Resulting effects are contingent on underlying cause(s)
Upper Pole Fullness	4 out of 100 patients (4%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Reoperation • Implant removal
Swelling	4 out of 100 patients (4%)	3 out of 100 patients (3%)	• Pain or discomfort • Resulting effects are contingent on underlying cause(s)
Implant Malposition	4 out of 100 patients (4%)	5 out of 100 patients (5%)	• Implant visibility • Asymmetry • Reoperation • Implant removal
Wrinkling/Rippling	3 out of 100 patients (3%)	8 out of 100 patients (8%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal
Seroma/Fluid Accumulation	2 out of 100 patients (2%)	6 out of 100 patients (6%)	• Swelling • Pain or Discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Hematoma	1 out of 100 patients (1%)	0 out of 100 patients (0%)	• Swelling • Pain or Discomfort • Infection • Incision and drainage (reoperation) • Implant removal

Event	Likelihood of Event Occurring in Primary Reconstruction Patients[a]	Likelihood of Event Occurring in Revision-Reconstruction Patients[a]	Possible Resulting Effects of the Event
Redness	Less than 1 out of 100 patients (0.9%)	5 out of 100 patients (5%)	• Resulting effects are contingent on underlying cause(s)
Delayed Wound Healing	Less than 1 out of 100 patients (0.5%)	3 out of 100 patients (3%)	• Pain or Discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal
Nipple Complications	Less than 1 out of 100 patients (0.5%)	2 out of 100 patients (2%)	• Increased or decreased nipple sensitivity • Breastfeeding difficulties • May affect sexual response
Bruising	0 out of 100 patients (0%)	2 out of 100 patients (2%)	• Swelling • Pain or Discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Implant Palpability/Visibility	Less than 1 out of 100 patients (0.5%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Reoperation • Implant removal
Necrosis	Less than 1 out of 100 patients (0.5%)	2 out of 100 patients (2%)	• Pain or Discomfort • Scarring • Reoperation • Implant removal

[a] Based on the results of the Allergan 410 Clinical Study for the first 7 years after implant surgery
[b] Implant extrusion occurred at a rate less than 1%

- **Additional Surgeries (Reoperations)**

You should assume that you will need to have additional surgeries (reoperations). In Allergan's Pivotal Study, approximately 45 out of every 100 women (45%) undergoing Primary Reconstruction and 39 out of every 100 women (39%) undergoing Revision-Reconstruction had 1 or more reoperations. Approximately 9 out of every 100 women (9%) undergoing Primary Reconstruction and 9 out of every 100 women (9%) undergoing Revision-Reconstruction had 2 or more reoperations. The costs of additional surgeries may not be covered by insurance.

Patients may decide to change the size or type of their implants, requiring additional surgery. In addition, problems such as rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional surgery. Reoperation increases the risk of certain complications, such as rupture, capsular contracture, and infection. Section 5.5 provides more information on reoperations reported in Allergan's Pivotal Study.

- **Implant Removal**

Because these are not lifetime devices, the longer you have your implants the more likely it will be for you to have them removed for any reason, either because of dissatisfaction, an unacceptable cosmetic result, or a complication such as capsular contracture. In Allergan's Pivotal Study, approximately 29 out of every 100 women (29%) undergoing Primary Reconstruction and 29 out of every 100 women (29%) undergoing Revision-Reconstruction had their implants removed. In approximately 15 out of 100 women (15%) undergoing Primary Reconstruction and 11 out of 100 women (11%) undergoing Revision-Reconstruction implants were removed because the patient requested a different size or style of implant. The vast majority of patients who had their implants removed had them replaced with new implants, which can increase the risk of capsular contracture or reoperation. Removing implants without replacing them can result in dimpling, puckering, wrinkling, or other cosmetic changes in the breast. These changes may be permanent.

Even if you have your implants replaced, implant removal may result in loss of your breast tissue. Also, implant replacement increases your risks of future complications. For example, the risks of capsular contracture and reoperation increase for patients with implant replacement compared to first time placement. You should consider the possibility of having your implants replaced and its consequences when making your decision to have implants. Section 5.6 provides more information on implant removals reported in Allergan's Pivotal Study.

- **Capsular Contracture**

The scar tissue (capsule) that normally forms around the implant may tighten over time and compress the implant, making it feel firm and leading to what is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in revision-augmentation than in primary augmentation. Because you may have your initial implants replaced, you should be aware that your risk of capsular contracture increases with revision-augmentation. Capsular contracture is a risk factor for implant rupture, and it is a common reason for reoperation.

Symptoms of capsular contracture range from mild firmness and mild discomfort to severe pain, distorted shape of the implant, and palpability (ability to feel the implant). Capsular contracture is graded into 4 Baker Grade levels depending on its severity:

  - Baker Grade I – Normally soft and natural appearance
  - Baker Grade II – A little firm, but breast looks normal
  - Baker Grade III – More firm than normal, and may look abnormal (change in shape)
  - Baker Grade IV – Hard, obvious distortion, and tenderness with pain

Baker Grades III and IV are considered severe, and often additional surgery is needed to correct these grades. Additional surgery may be needed in cases where pain and/or firmness are severe. This surgery ranges from removal of the implant capsule tissue to removal and possible replacement of the implant itself. This surgery may result in loss

of your breast tissue. Capsular contracture may happen again after these additional surgeries.

- **Rupture**

An implant rupture is caused by a hole or tear in the shell of the implant that allows silicone gel filler material to leak from the shell. Ruptures can be intracapsular (inside the scar tissue capsule surrounding the implant) or extracapsular (outside the scar tissue surrounding the implant). All women should have regular MRI examinations to detect silent rupture. All women who have ruptured implants should have the implants and any gel removed. With ***NATRELLE***® 410 Breast Implants silicone rarely migrates outside of the scar tissue capsule. Further information on rupture is provided in Section 2.3 and further information on rupture reported in Allergan's Pivotal Study is provided in Section 5.7.

- **Unsatisfactory Results**

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

In Allergan's Pivotal Study the most common unsatisfactory result was asymmetry. Approximately 9 out of 100 women (9%) who underwent Reconstruction had additional surgery to improve asymmetry.

- **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. In a European study through 5 years, approximately 1 out of every 100 women with any breast implant had breast pain lasting longer than 3 months.[21] Tell your surgeon about 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. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. While some of these changes can be temporary, they can also be permanent, and may affect your sexual response or your ability to nurse a baby.

- **Infection**

Infection can occur with any surgery or implant. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. In addition, breast and nipple piercing procedures may increase the possibility of infection. Infections in tissue with an implant present are harder to treat than infections in tissue without an implant. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved (cleared up). As with many other surgical procedures, in rare instances, toxic shock syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting,

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

- **Hematoma/Seroma**

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

- **Breastfeeding**

In long-term studies, approximately 3 out of every 100 women with ***NATRELLE®*** 410 Breast Implants had difficulty breastfeeding.[11,12] A periareolar incision (an incision around the colored portion surrounding the nipple) may increase the likelihood of problems with breastfeeding. The most common breastfeeding problem is inadequate milk production.[11,12] Section 5.7 provides more information on breastfeeding complications reported in Allergan's Pivotal Study.

- **Calcium Deposits in the Tissue Around the Implant**

Calcium deposits can form in the tissue capsule surrounding the implant. Symptoms may include pain and firmness. Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer. If additional surgery is necessary to examine and/or remove calcifications, this may cause damage to the implants. Calcium deposits also occur in women who undergo breast reduction procedures, in patients who have had hematoma formation, and even in the breasts of women who have not undergone any breast surgery. The occurrence of calcium deposits increases significantly with age.

- **Extrusion**

Extrusion is when the breast implant comes through your skin. This may occur, for example, when your wound has not closed or when breast tissue covering your implants weakens. Radiation therapy might increase the likelihood of implant extrusion. Most women with extrusion need to have their implant removed.

- **Necrosis**

Necrosis is the death of cells or tissues. This may prevent or delay wound healing and require surgical correction, which may result in additional scarring and/or loss of your breast tissue. Implant removal may also be necessary. Infection, steroid use, smoking, chemotherapy, radiation, and excessive heat or cold therapy may increase the likelihood of necrosis.

- **Delayed Wound Healing**

Some patients may experience a prolonged wound healing time. Delayed wound healing may increase the risk of infection, extrusion, and necrosis. Smoking may

interfere with the healing process. You should contact your surgeon immediately if your wound does not heal within the period of time he/she has discussed with you.

- **Breast Tissue Atrophy/Chest Wall Deformity**

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

- **Lymphadenopathy**

Lymphadenopathy is a chronic enlargement of the lymph nodes. A lymph node is a round mass of tissue which makes cells as part of your immune system. The lymph nodes in the armpit (axilla) drain the breast area of fluid. Some patients with breast implants report having enlarged lymph nodes in the armpit(s). Sometimes the enlarged lymph nodes are painful. If they become too large or painful, the lymph node(s) may need to be surgically removed. Painful and/or enlarged lymph nodes should be reported to your doctor. Lymphadenopathy has been associated with tissue reactions, granulomas, and silicone at the lymph nodes of women with intact and ruptured silicone breast implants.

2.3 What Causes Breast Implants to Rupture and How Can I Tell if My Implants Are Ruptured?

Breast implants are not lifetime devices. Breast implants rupture when the shell develops a tear or hole. Your breast implants can rupture any time after they are implanted, but they are more likely to rupture the longer you have them. The following things may cause your implant to rupture: damage by surgical instruments, stressing the implant during implantation which may weaken it, folding or wrinkling of the implant shell, excessive force to the chest (for example, during closed capsulotomy, which is contraindicated), trauma, compression during mammographic imaging, and severe capsular contracture. Breast implants may also simply wear out over time.

If a device rupture is found, Allergan conducts laboratory studies to determine the cause of the rupture, such as damage during surgery, or a "wear-out" of the device. These studies include a comprehensive visual and microscopic inspection of the shell, including a measurement of shell thickness, and observation of various characteristics near the rupture location as well as in the entire shell. Mechanical testing of the implant shell may also be performed to better determine the cause of an observed rupture. There may still be unidentified causes of rupture. These laboratory studies will continue to try to identify any additional causes of rupture.

When the shell of a breast implant develops a tear or hole, the silicone gel inside ***NATRELLE***® 410 Breast Implants tends to stay in place, making ruptures especially difficult to detect. This means that most of the time neither you nor your plastic surgeon will know if your breast implant has a tear or hole, called a silent rupture. In fact, a plastic surgeon who is familiar with breast implants is likely to detect less than 3 out of every 10 ruptured silicone breast implants by physical examination.[13] The best method to identify a silent rupture is currently MRI examination. MRI examination can detect

about 9 out of every 10 ruptured silicone breast implants.[14] You will need regular MRI examinations over your lifetime in order to determine if your implants have a silent rupture. You should have your first MRI at 3 years after your initial implant surgery and then every 2 years, thereafter. The cost of these MRI screenings may exceed the cost of your initial surgery over your lifetime. This cost may not be covered by your insurance, so you should take it into account when deciding to have breast reconstruction.

Sometimes there are symptoms associated with gel implant rupture. If your implants rupture, you may notice hard knots or lumps surrounding the implant or in the armpit, your breast or the implant may change shape or get smaller, or you may notice pain, tingling, swelling, numbness, burning, or hardening in your breast. If you have any of these symptoms you should have an MRI to determine if your implants have ruptured.[1,15]

If you have an MRI that shows signs of rupture, or if your surgeon determines you have signs or symptoms of rupture, he or she will talk with you about your options. As a precaution, Allergan recommends that ruptured implants be taken out permanently and replaced with a new implant or not replaced, depending on your preference or medical need.

There are also consequences of rupture. If your implants rupture, the silicone gel may remain within the scar tissue capsule around the implant. The silicone gel may also move outside the capsule or it may move beyond the breast (gel migration). The silicone gel from a ruptured implant may begin inside the capsule and progress outside the capsule through gel migration if it is not removed. Ruptured implants might also have consequences on your health. More information on these consequences, as reported in the literature, is included below.

In Allergan's Pivotal Study, a group of patients had scheduled MRIs to look for rupture independent of whether or not they had any symptoms. These patients are called the MRI cohort. The remaining patients did not have scheduled MRIs to look for rupture. They are called the non-MRI cohort. The rupture rate for the whole MRI cohort in Allergan's Pivotal Study (including Primary Augmentation, Revision-Augmentation, Primary Reconstruction, and Revision-Reconstruction patients) through 7 years was 11.5% for patients and 6.7% for implants. For the non-MRI cohort the rupture rate through 7 years was 8.7% for patients and 5.3% for implants. In all of the women with ruptured implants, the silicone gel remained within the scar tissue capsule. Allergan will continue to collect information on rupture through the ongoing Pivotal Study.

Additional information on the likelihood that your ***NATRELLE***® 410 Breast Implants will rupture comes from a published study known as the 410 Swedish MRI Study.[11] Women who had previously been implanted with ***NATRELLE***® 410 Breast Implants for breast augmentation or breast revision at a single hospital had an MRI to screen for silent rupture. On average the implants were about 6 years old. Approximately 2 out of every 100 women had silent rupture. In all of the women with ruptured implants, the silicone gel remained within the scar tissue capsule.

Additional information on the likelihood that your ***NATRELLE***® 410 Breast Implants will rupture comes from a published study known as the 410 European MRI Study.[12]

Women who had previously been implanted with ***NATRELLE***® 410 Breast Implants for breast augmentation, breast reconstruction, or revision at 1 of 7 hospitals in Europe had an MRI to screen for silent rupture. On average the implants were about 8 years old. Approximately 3 in 100 women had silent rupture. In all of the women with ruptured implants, the silicone gel remained within the scar tissue capsule.

Additional Information on Consequences of Rupture from Literature
Below is a summary of information related to the health consequences of implant rupture. These reports were in women who had implants from a variety of manufacturers and implant models. Because of the nature of the reports, some doctors and scientists do not know for sure if the findings are truly associated with breast implants or not.

- Ruptured breast implants have been associated with breasts becoming hard, changing shape or size, and becoming painful.[15] These symptoms are not specific to rupture, as they also are experienced by women who have capsular contracture.

- There have been rare reports of the silicone gel from implants moving to nearby locations such as the chest wall, armpit, or upper abdominal wall, and even as far as the arm or the groin. This migrating gel has damaged nerves, formed granulomas and/or broken down tissues in direct contact with the gel in a few cases. There have been reports of silicone in the liver of women with silicone breast implants. Silicone gel material has moved to lymph nodes in the armpit, even in women whose implants did not appear to have ruptured, leading to lymphadenopathy.[82]

- Concerns have been raised that women with ruptured implants are more likely to develop connective tissue disease, rheumatic disease, fatigue, or fibromyalgia.[23,25,39,40] To determine if these diseases are related to ruptured implants, a number of studies have evaluated many women with breast implants. Only one small study distinguished between women with ruptured or intact implants.[25] Most doctors and researchers agree that there is no evidence that ruptured implants or migrated gel causes any disease that affects the whole body (systemic disease) like Connective Tissue Disease (CTD) or cancer.

2.4 What Are Other Reported Conditions?

There have been reports of women with silicone gel-filled breast implants developing other conditions. The relationships between many of these conditions and breast implants have been studied. Although no one has shown that breast implants cause the conditions listed below, you should be aware of these reports. Furthermore, there may be unknown risks associated with breast implants.

- **Connective Tissue Disease (CTD)**

Connective tissue diseases include diseases such as lupus, scleroderma, rheumatoid arthritis, and fibromyalgia. The scientific evidence strongly supports the conclusion that there is no increased risk of connective tissue disease or autoimmune disorders for women with silicone gel breast implants.[1,22-28,30-33,35,37,40,41,43] Independent scientific panels and review groups have also concluded that the weight of the evidence shows no relationship between breast implants and connective tissue disease, or at least if a risk cannot be absolutely excluded, it is too small to be measured.[1,8,10,23,25,29,30,34,36,38-40]

- **CTD Signs and Symptoms**

Some women (even without breast implants) may have some of the signs or symptoms of connective tissue diseases, without having the actual disease. Some reports have linked silicone breast implants with some of these signs and symptoms, such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. Panels of expert scientists and literature reports have found no evidence that silicone breast implants cause a consistent pattern of CTD signs and symptoms.[1,42-45] Having these CTD signs and symptoms does not necessarily mean you have a connective tissue disease; however, you should be aware that you may experience these signs and symptoms after undergoing breast implantation. If you notice an increase in these signs or symptoms, you should consider seeing a rheumatologist to determine whether these signs or symptoms are due to a connective tissue disorder or autoimmune disease.

- **Cancer**

Breast Cancer – Reports in the medical literature indicate that breast implants do not increase the risk for developing breast cancer.[46,49,51,57,66] Some reports have suggested that breast implants may make it harder to detect breast cancer by mammography or biopsy. Other reports indicate that breast implants do not delay breast cancer detection, nor do they decrease cancer survival of women with breast implants.[46,52,58,65,66] A large follow-up study reported no evidence that breast implants are associated with cancer and even showed that women with breast implants had less breast cancer than the general population.[57]

Anaplastic Large Cell Lymphoma (ALCL) – Women with breast implants may have a very small, but increased risk of developing anaplastic large cell lymphoma, or ALCL, in the scar tissue and fluid adjacent to the implant. ALCL is not breast cancer—it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system).

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

Most patients were diagnosed when they sought medical treatment for implant-related symptoms such as pain, lumps, swelling, or asymmetry that developed after their initial surgical sites were fully healed. In the cases reported, ALCL was typically diagnosed years after the implant surgery.

Your physician should consider the possibility of ALCL if, after your surgical site is fully healed, you see changes in the way the area around the implant looks or feels—including swelling or pain around the implant. If ALCL is suspected, your physician will refer you to an appropriate specialist for evaluation which may involve obtaining fluid

and tissue samples from around your breast implant. If ALCL is confirmed, your physician will develop an individualized treatment plan for you. Because of the small number of cases worldwide and variety of available treatment options, there is no single defined treatment.

If you have breast implants and have no symptoms, you do not need to do anything additional, but you should continue to routinely monitor your breast implants and follow your routine medical care. Removing the implants is not recommended in women with no symptoms without a diagnosis of ALCL.

If you do not currently have breast implants but are considering breast implant surgery, you should discuss the risks and benefits with your health care provider. You may also visit the FDA's Breast Implants website for additional information.

For additional and the most up-to-date information please visit:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm

Brain cancer – Most studies of brain cancer in women with silicone gel breast implants have found no increased risk.[48,53,55,63,64,66] One study reported a higher rate of brain cancer in women with breast implants compared to the general population.[47] However, rates of brain cancer were not significantly higher in women with breast implants when compared to women who had other non-breast implant plastic surgery. The data from 4 large studies of women with breast implants and a long-term follow-up study concluded that breast implants are not associated with brain cancer.[62]

Respiratory/lung cancer – Several studies have found that women with silicone gel breast implants are not at greater risk for lung cancer.[48,55,63,64,66] Studies have reported an increased incidence of respiratory/lung cancer in women with breast implants.[47,53,57] However, the risk of lung cancer was not higher than national lung cancer rates for the general population. 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.[50,56,59] Therefore, the increased incidence of respiratory/lung cancer could be due to smoking rather than breast implants.

Cervical/vulvar cancer – Most studies found that women with silicone gel breast implants have no greater risk of cervical/vulvar cancers than women without implants.[48,55,63,64,66] Two studies reported an increased incidence of cervical/vulvar cancer in women with breast implants.[47,53]

Other cancers – Studies have examined other types of cancer including eye, urinary tract, connective tissue, and endocrine system. Studies show that women with silicone gel breast implants have no greater risk of these types of cancers compared to the general population.[29,43,47,48,53,55,63,64] A large, long-term study found that women with breast implants were not at greater risk for a wide variety of cancers, including stomach cancer, leukemia, and lymphoma.[43]

Cancer Screening – With breast implants, routine screening mammography for breast cancer will be more difficult. If you are of the proper age for mammography screening,

you should continue to undergo routine mammography screening as recommended by your primary care physician. More x-ray views are necessary for women with breast implants; therefore, you will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays. Be sure to inform the mammography technologist that you have implants. The technologist can then use special techniques to get the best possible views of your breast tissue.

- **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 panel of expert scientists found that the evidence linking neurological diseases with breast implants is insufficient or flawed.[1] Other researchers have found more evidence that silicone gel breast implants do not cause neurological diseases or symptoms.[1,67,68]

- **Suicide**

Some studies showed that women with breast implants were more likely to commit suicide than women without breast implants, but it is not clear whether these suicides were associated with having silicone gel breast implants or an underlying condition that can lead to suicide, depression, and/or anxiety.[47,69,70,72-77] One researcher believes that some women who want cosmetic surgery suffer from a disorder, called body dysmorphic disorder, which may cause them to think about suicide or attempt suicide.[71]

The strongest predictor for suicide is having been hospitalized for any psychiatric condition. One study 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 the general population of Danish women.[70] This may be a contributing factor to the reported higher incidence of suicide in women with breast implants.

- **Effects on Children**

At this time, doctors do not know if a small amount of silicone passes through the silicone shell of breast implants into breast milk during breastfeeding. Although doctors cannot accurately measure silicone levels in breast milk, silicon (one component in silicone) levels were not higher in breast milk from women with silicone gel-filled implants than in breast milk from women without implants.

In addition, questions have been raised about whether breast implants can have damaging effects during pregnancy. Two studies in humans have found that children born to women with breast implants did not have an increased risk of birth defects.[80,81] A third study looked at low birth weight and did not find an elevated risk.[79] A recent review including many women found that children of women with breast implants are not at increased risk for birth defects.[10] Overall, there is no evidence that shows silicone gel breast implants have any harmful effects on the children of implanted women.[1,78-81]

- **Potential Health Consequences of Gel Bleed**

Small quantities of low molecular weight silicone compounds, as well as platinum, have been found to leak through an intact implant shell. This is called gel bleed.[1,84] The evidence is mixed as to whether gel bleed can affect your health. For instance, studies

on implants implanted for a long time have suggested that gel bleed may contribute to capsular contracture[1] and lymphadenopathy.[82] However, saline-filled breast implants have similar or higher rates of capsular contracture and other complications. Because saline-filled breast implants do not contain silicone gel, gel bleed cannot cause these complications in women with saline-filled breast implants, and might not cause these complications in women with silicone gel-filled breast implants. Furthermore, the silicone material used in Allergan's implants did not cause toxic reactions when large amounts were placed in test animals. There is little platinum contained in breast implants, and studies have shown that it is in the safest state.[83,85,86,88]

Allergan performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may diffuse out of intact implants into the body. Over 99% of the low molecular weight silicones and platinum stayed in the implant. The overall body of evidence supports that gel bleed is minimal and has no health consequences.

3.0 SURGICAL CONSIDERATIONS FOR BREAST RECONSTRUCTION

This section provides surgical considerations for primary breast reconstruction, followed by considerations for surgery in general.

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

3.1 Should You Have Primary Breast Reconstruction?

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

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

3.2 What Are the Alternatives to Implantation with NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants?

For primary reconstruction patients, alternatives may include:

- Accepting your breasts as they are and having no surgery

- Wearing a padded bra or external prostheses
- Having reconstruction using your own tissue (flap procedure)
- Having surgery with saline implants

For revision-reconstruction patients, alternatives may include:
- No revision
- Removal with:
  - No replacement
  - A padded bra or external prostheses
  - Reconstruction using your own tissue (flap procedure)
  - Replacement using saline implants

3.3 What Are the Choices in Primary Reconstructive Procedures?

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

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

Whether or not you have reconstruction with or without breast implants, you will probably undergo additional surgeries to improve symmetry and appearance. These additional surgeries may be part of a breast reconstruction that occurs in several stages. For example, the nipple and areola are usually removed with the breast tissue in mastectomy. After the initial reconstruction surgery is complete, nipple reconstruction is usually done as a separate outpatient surgery. The nipple is usually reconstructed by using a skin graft from another area of the body or the opposite breast and a tattoo to match the color. Most commonly, before breast implants can be placed, a temporary soft tissue expander must create a space for them. The tissue expander can be placed at the time of mastectomy or at a later time.

Alternatively, additional surgeries may shape the remaining breast to bring it into better balance with the reconstructed one.

3.4 What Is Breast Reconstruction with Breast Implants?

Your surgeon will decide whether your health and medical condition makes you an appropriate candidate for breast reconstruction with implants. If you are having reconstruction in only one breast, your surgeon may recommend placing a breast implant in the opposite, uninvolved breast in order to make your breasts more alike. Alternatively, he/she may suggest breast reduction (reduction mammoplasty) or a breast lift (mastopexy) to improve symmetry. Reduction mammoplasty involves removing breast tissue and skin. Mastopexy involves removing a strip of skin from under the breast or around the nipple and using it to lift and tighten the skin over the

breast. If you choose not to alter the unaffected breast, you should discuss this with your plastic surgeon, as it may affect the breast reconstruction methods considered for your case.

3.5 What Reconstruction Incision Sites Are Used?

In reconstructive surgery, your surgeon will decide on the incision placement and length, largely based on the type of cancer surgery you will receive.

Most implants used for breast reconstruction are placed through an incision at the mastectomy scar, either during the mastectomy procedure or after tissue expansion.

3.6 What About the Surgical Settings and Anesthesia?

When reconstruction surgery begins at the same time as the mastectomy, it is usually performed as an inpatient surgery, which involves an overnight hospital stay. Most reconstruction surgeries occur under general anesthesia. Some stages of reconstruction surgery, such as nipple reconstruction, or placement of the implant after soft tissue expansion, can be done as outpatient surgery.

3.7 What Is the Timing of Primary Breast Implant Reconstruction?

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

A potential advantage to immediate reconstruction is that your breast reconstruction starts at the time of your mastectomy. Combining the mastectomy procedure with the first stage of the reconstruction may result in cost savings and potentially fewer days in the hospital. However, immediate reconstruction can expose the implant to postoperative radiation and chemotherapy treatments, which might increase the risk of capsular contracture, extrusion, and other complications. Your initial operative time and recovery time may also be longer.

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

There are medical, financial, and emotional considerations to choosing immediate versus delayed reconstruction. You should discuss with your general surgeon,

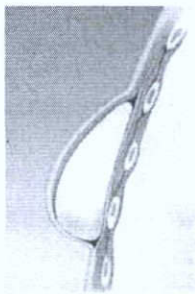
reconstructive surgeon, and oncologist, the pros and cons of the options available in your individual case.

3.8 What Is the Primary Breast Implant Reconstruction Procedure?

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

Expander-Assisted (Immediate or Delayed) Breast Implant Reconstruction
Breast reconstruction usually occurs in several stages. Initially your plastic surgeon will place a breast tissue expander, which is replaced several months later with a breast implant. The tissue expander may be placed immediately, at the time of your mastectomy, or be delayed until months or years later.

Side View, Breast Tissue Removed



Side View, Expander Inserted and Filled

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

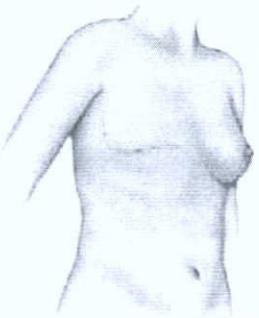
The tissue expander is a balloon-like device made from elastic silicone rubber. The surgeon inserts it unfilled, and over time, adds sterile saline fluid by inserting a small needle through the skin into a filling port. As the tissue expander fills, the tissues over the expander begin to stretch, similar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

Tissue expanders are usually placed when you are under general anesthesia in an operating room. The operation generally takes 1 to 2 hours. The procedure may require a brief hospital stay or be done as an outpatient surgery. Typically, you can resume normal daily activity after 2 to 3 weeks.

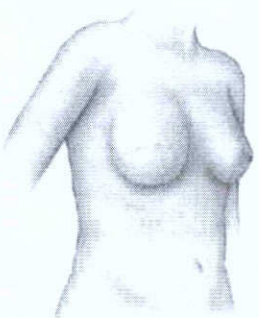
Because the chest skin is usually numb from the mastectomy surgery, you may not experience pain from the placement of the tissue expander. However, you may feel pressure, tightness, or discomfort after each time the expander is filled. These feelings subside as the tissue expands, but may last for a week or more. Tissue expansion typically takes 4 to 6 months.

Placing the Breast Implant

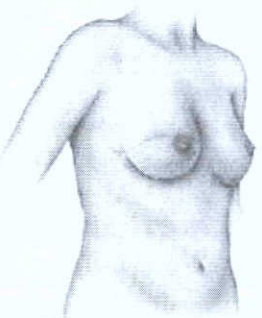
Once the tissue has expanded, your plastic surgeon will remove the tissue expander and replace it with a breast implant. In reconstruction following mastectomy, the breast implant is most often placed under the chest muscle. The surgery to replace the tissue expander with a breast implant (implant exchange) is usually done under general anesthesia in an operating room. It may require a short hospital stay or be done as an outpatient surgery.



Post Mastectomy



Stage 1: Tissue Expander Placed and Expansion Underway



Stage 2: Breast Implant and Nipple/Areola Reconstruction

3.9 What About Primary Breast Reconstruction Without Implants (Tissue Flap Procedures)?

The breast can be reconstructed using a section of skin, fat, and muscle (a tissue flap) that is surgically moved from one area of your body to another. The section of tissue may be taken from such areas as your abdomen, upper back, upper hip, or buttocks.

The tissue flap may be left attached to its original blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap), or it may be removed completely and reattached to the blood supply in the breast area (a free flap). A free flap generally requires a longer operation, because of the time required to reconnect the blood supply.

Breast reconstruction with a flap typically requires a hospital stay of several days and a longer recovery time than reconstruction with an implant. Flap surgery also creates scars at the site where the flap was taken and on the reconstructed breast. However, flap surgery has the advantage of being able to replace the lost tissue in your chest area. You may need to replace these tissues when your chest tissues have been damaged and are not suitable for tissue expansion. Another advantage of flap procedures over implantation is that flap procedures generally do not require additional surgery on the unaffected breast to improve symmetry.

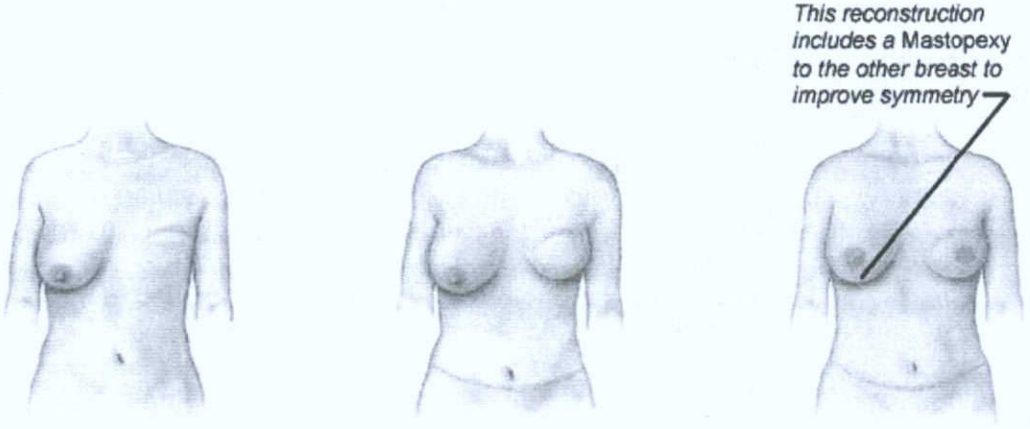
The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap) (which uses tissue from the abdomen) and the Latissimus dorsi flap (which uses tissue from the upper back).

You should be aware that flap surgery, particularly the TRAM flap, is a major operation, and more extensive than your mastectomy operation. It requires good general health and strong emotional motivation. If you are very overweight, smoke cigarettes, have had previous surgery at the flap site, or have any circulatory problems; you may not be a good candidate for a tissue flap procedure. Also, if you are very thin, you may not have enough tissue in your abdomen or back to create a breast mound with this method.

TRAM Flap (Pedicle or Free)

During a TRAM flap procedure, the surgeon removes a section of tissue from your stomach and moves it to your chest to reconstruct the breast. The TRAM flap is sometimes referred to as a "tummy tuck" reconstruction, because it may leave the stomach area flatter.

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



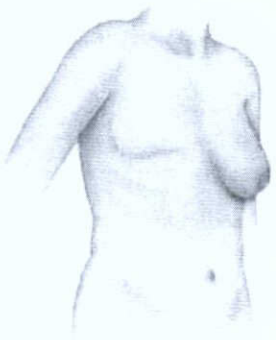
Post Mastectomy **TRAM Flap** **Final Result with Nipple/Areola Reconstruction**

The Latissimus Dorsi Flap With or Without Breast Implants

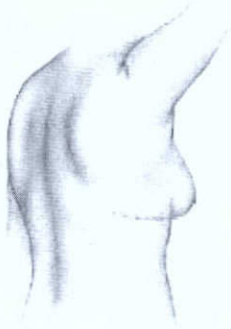
During a Latissimus Dorsi flap procedure, the surgeon moves a section of tissue from your back to your chest to reconstruct the breast. Because the Latissimus Dorsi flap is

usually thinner and smaller than the TRAM flap, this procedure may be more appropriate for reconstructing a smaller breast.

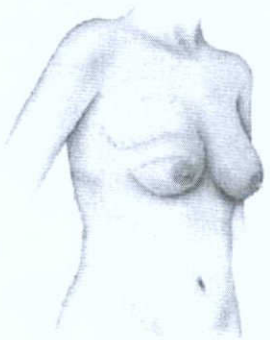
The Latissimus Dorsi flap procedure typically takes 2 to 4 hours of surgery under general anesthesia. Typically, the hospital stay is 2 to 3 days. You can resume daily activity after 2 to 3 weeks. You may have some temporary or permanent muscle weakness and difficulty with movement in your back and shoulder.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



Post Mastectomy



View Showing Back Scar



Latisimus Dorsi Flap and Nipple/Areola Reconstruction

3.10 What Are Some General Surgical Considerations?

Choosing a Surgeon

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

- How many breast reconstruction implantation procedures does he/she perform per year?
- How many years has he/she performed breast reconstruction procedures?
- Does the surgeon only perform breast reconstruction with breast implants? What types of implants does the surgeon primarily use (saline, silicone, highly cohesive silicone)?
- Are there other breast reconstruction procedures performed routinely by the surgeon, such as autologous tissue reconstruction (operations that use tissue from the stomach or flank to reconstruct breast tissue), flap reconstruction, etc.?
- How many reconstructions does he/she perform that do not involve implants per year?
- Is he/she board certified, and if so, with which board?
- Did he/she complete a residency in plastic surgery from a recognized and accredited program?
- In which state(s) is he/she licensed to practice surgery? (Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients, either by request or on the Internet.)

- What is the most common complication he/she encounters with breast reconstruction?
- What is his/her reoperation rate with breast reconstruction, and what is the most common type of reoperation he/she performs?
- Can he/she perform this surgery in a hospital as well as in the surgeon's independent surgery center? (Note that hospitals require evidence of appropriate training in specific procedures before allowing surgeons to operate in their facilities.)

Insurance

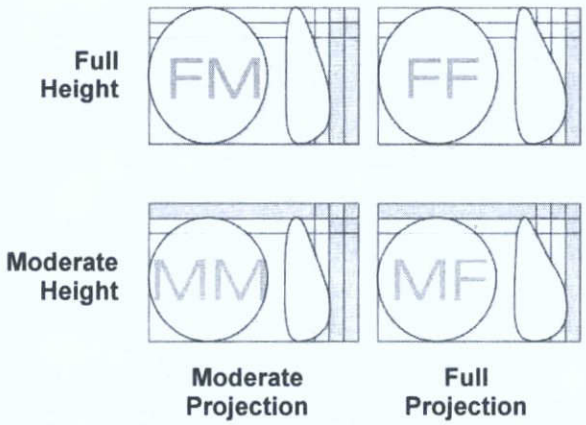
In general, private insurance that covers medically necessary mastectomies will also cover breast reconstructive surgery per the Women's Health and Cancer Rights Act (WHCRA). After the initial reconstruction, insurance may not cover reoperation procedures or additional surgeon's visits, depending on the policy. For example, a reoperation may include temporarily removing the implant so that your oncologist can see if your breast cancer has recurred. Because coverage policies vary and can change over time, no guidance can be given here with respect to coverage under any particular health plan. Therefore, you should contact your health plan to get specific information regarding its coverage policies before deciding to have reconstructive surgery.

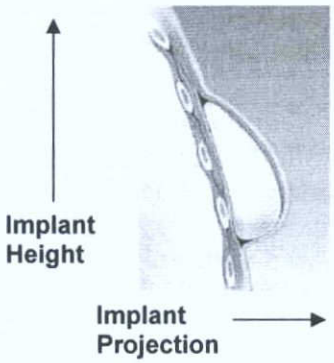
3.11 What Are Choices And Options Associated With the Surgery?

There are 2 approved types of breast implant fillers (saline and silicone), and Allergan has 2 types of silicone fillers (cohesive silicone gel and highly cohesive silicone gel). These options allow your surgeon to use the best type of implant to achieve the effect you desire. Your surgeon can discuss these options with you and may make recommendations to you based upon the physical contours of your body. This brochure is for highly cohesive silicone-filled breast implants; separate brochures are available for cohesive silicone-filled and for saline-filled implants. Carefully review the section on risks and the section on Allergan's clinical study so that you may make an informed choice. Be sure to ask your surgeon to see and touch samples of both highly cohesive silicone and cohesive silicone as well as saline-filled breast implants. As you hold a ***NATRELLE***® 410 Breast Implant in your hand and move it around you can observe that the highly cohesive gel helps the implant maintain its shape in any position. Allergan's cohesive silicone implant has more movement as you hold it in different positions.

Implant Shape and Size

The ***NATRELLE***® 410 Breast Implant comes in a variety of height and projection combinations and a wide range of sizes. Your plastic surgeon will discuss with you the implant options that will best help you achieve the result that is right for you. The following diagram may help you to understand the various sizes and styles of implants as your surgeon discusses the various options with you. Depending on the desired shape you wish to achieve, you and your surgeon have implants with 4 different height and projection combinations, or styles, from which to choose. Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider. Breast implant sizes are measured in volume, by cubic centimeters (cc), not in cup sizes, because cup size depends on the size and shape of the individual woman's chest.





Approved *NATRELLE*® 410 Breast Implant Styles

410 Style	Breast Implant Description	Size Range
FM	full height, moderate projection	205cc – 670cc
FF	full height, full projection	185cc – 740cc
MM	moderate height, moderate projection	160cc – 450cc
MF	moderate height, full projection	140cc – 640cc

Your surgeon will also evaluate your existing breast and skin tissue to determine if you have enough tissue to cover the breast implant you are considering. In some cases, such as after pregnancy, you might have too much extra skin. If you desire a breast implant size that is too large for your tissue, the surgeon may warn you that breast implant edges may be visible or palpable postoperatively. Also, excessively large breast implants may speed up the effects of gravity on your breasts, and can make your breasts droop or sag at an earlier age. Larger sized implants may be too large for many women, and can increase the risk of implant extrusion, hematoma, infection, palpable implant folds, or visible skin wrinkling. In Allergan's Pivotal Study, a risk factor analysis showed a trend in one cohort towards an increased risk of capsular contracture with larger size implants. However, this relationship was not consistent across cohorts and timepoints, and the capsular contracture rate remained low for all cohorts.

Surface Texturing

The ***NATRELLE***® 410 Breast Implant is provided with a **BIOCELL**® textured shell surface. Some studies suggest that surface texturing reduces the chance of severe capsular contracture,[20] while other studies do not.[18,19]

A textured implant may require a larger incision because the rougher textured surface may make it harder to place into the pocket. Forcing the implant through too small of an incision might damage the implant or decrease its durability.

Implant Palpability

Implants may be more palpable or noticeable if there is an insufficient amount of skin/tissue available to cover the implant and/or when the implant is placed underneath and within the breast glands (breast tissue) but on top of the chest muscle.

Postoperative Care

You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size. The breasts and nipple area also may have less feeling during this time of swelling and immediately after surgery. Other possible complications have been described above.

Postoperative care depends on each patient's situation and may involve using a special postoperative bra, compression bandage, or jog bra for extra support and positioning while you heal. Some surgeons may not want you to wear a bra at all for a period of time following the surgery.

Your surgeon may place postoperative pain balls or other pain medication infusion devices alongside the breast implant to help control your pain after surgery. Breast massage exercises are not recommended after implantation as they may cause the breast implant to rotate.

At your surgeon's recommendation, you will most likely be able to return to work within a few days. However, for at least a couple of weeks you should avoid any strenuous activities that could raise your pulse and blood pressure, or require strenuous use of your arms and chest.

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

Other Factors to Consider In Revision-Reconstruction Surgery
Some revision surgeries require removing an intact implant (for example, capsulotomy and pocket adjustments), while others leave the implant in place. Any device that has been removed during revision surgery should not be re-implanted. Allergan breast implants are "for single use only."

The timing for any revision surgery following reconstruction should be discussed with your surgeon so that you can consider all issues, such as the potential effects of radiation, chemotherapy, and additional cancer surgery or treatments.

4.0 FOLLOW-UP EXAMINATIONS

After your breast implant surgery you will need regular examinations to detect potential complications. You should inform any doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.

Breast Self-Examinations

Following breast reconstruction you should continue to perform a breast self-examination monthly. This may be more difficult with a breast implant in place. To continue to perform a monthly breast self examination efficiently, you should ask your surgeon to help you identify the difference between the implant and your breast tissue. Being able to distinguish the implant from breast tissue will limit the need to over-squeeze the implant. Any new lumps should be evaluated with a biopsy, as appropriate. If a biopsy is performed, be sure to inform the medical professional performing the biopsy that you have breast implants so that he or she can take care to avoid damaging the implant.

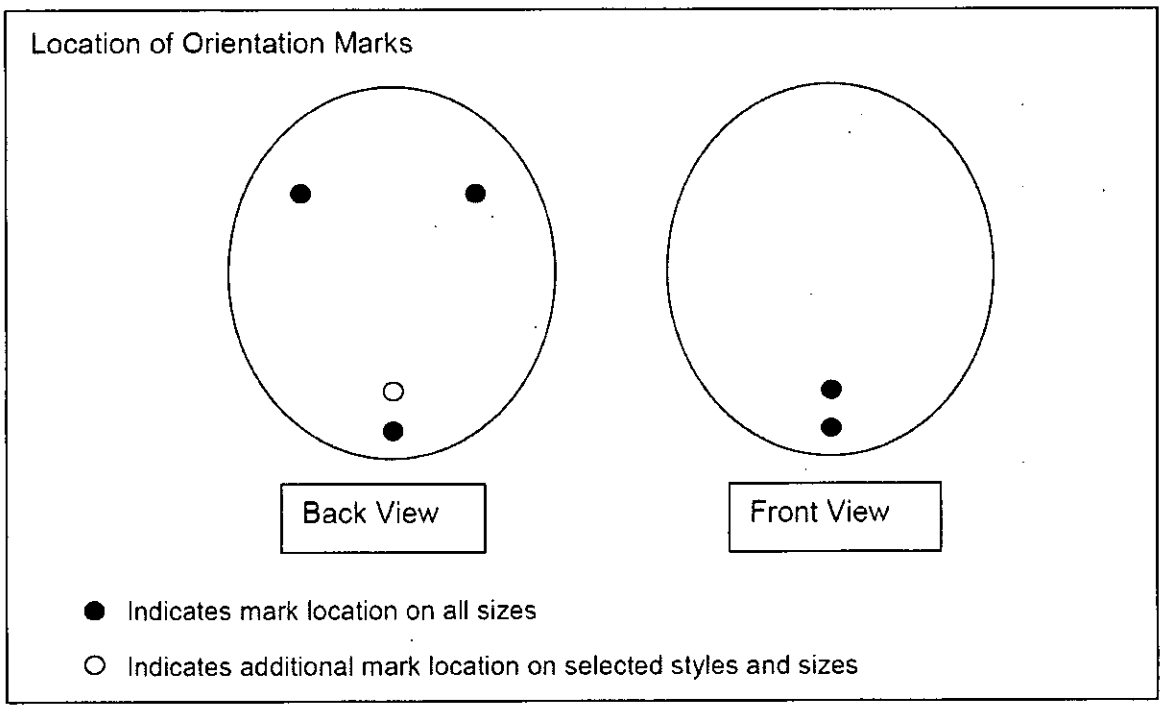
You should also examine your breasts for the presence of lumps, swelling, hardening, or a change in implant shape. These may be signs that your implant has ruptured. Report any of these symptoms or persistent pain to your surgeon. Your surgeon may recommend an MRI to screen for rupture.

Screening for Silent Rupture
Because most ruptures of silicone-filled breast implants are silent, in most cases neither you nor your surgeon will be able to find evidence of rupture by a physical examination. Therefore, a different method is needed to screen for implant rupture. The best method of screening is currently MRI at a center 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. Your doctor should assist you in locating a radiology/screening center, as well as a radiologist who is familiar with the MRI techniques and equipment used to screen breast implants for silent rupture.

Your first MRI evaluation should take place 3 years after your implant surgery. You should have another MRI every 2 years, thereafter, even if you are experiencing no problems with your implant. If there are signs of rupture on MRI, then you should have your implant removed or replaced. More information on rupture is provided in Section 2.3 of this brochure.

Symptomatic Rupture
Symptoms associated with rupture may include hard knots or lumps surrounding the implant or in the armpit, loss of size of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast. If you notice any of these changes, see your plastic surgeon. He or she will examine the implants and determine whether you need to have an MRI examination to find out if your implant has ruptured. As a precaution, Allergan recommends that ruptured implants be taken out and either replaced with a new implant or not replaced, depending on your preference or medical need. Consult with your doctor regarding this and any other medical decisions related to your implants.

Mammography
The current recommendations for getting screening/preoperative mammograms are no different for women with breast implants than for those without implants. You need to tell your mammography technologist before the procedure that you have an implant. You should also inform your mammography technologist of the presence and location of the orientation marks on the ***NATRELLE***® 410 Breast Implant as these may be visible on the mammographic images. These orientation marks are circular silicone dots located on the surface of the implant and are used to assist the physician with placing the implant in the proper orientation. The back surface of most sizes of ***NATRELLE***® 410 Breast Implants has 4 orientation marks; the back surface of some smaller and/or shorter styles may have only 3 orientation marks, as shown below. The front surface of all ***NATRELLE***® 410 Breast Implants has 2 orientation marks, as shown below.



Mammography exams should be interpreted by radiologists experienced in the evaluation of women with breast implants. Your surgeon should request a diagnostic mammogram, rather than a screening mammogram, because more pictures are taken with diagnostic mammography. The technologist can use special techniques to reduce the possibility of rupture and to get the best possible views of the breast tissue.

5.0 ALLERGAN'S CLINICAL STUDY RESULTS

This section summarizes the results of the Allergan Pivotal Study conducted on the ***NATRELLE***® Breast Implants for Primary Reconstruction and Revision-Reconstruction. The Pivotal Study is the primary clinical study for this product. The results of the Pivotal Study give you useful information on the experience of other women with ***NATRELLE***® 410 Breast Implants. While the results cannot be used to predict your individual outcome, they can be used as a general guide to what you may expect. Your own complications and benefits depend on many individual factors.

5.1 What Are the Overview Findings of Allergan's Pivotal Study?

Allergan's Pivotal Study is a 10-year study to assess safety and effectiveness in Primary Augmentation, Primary Reconstruction, and Revision (Revision-Augmentation and Revision-Reconstruction) patients. Patient follow-up is at 0-4 weeks, 6 months, 12 months, and annually through 10 years. Safety is assessed by complications, such as implant rupture, capsular contracture, and reoperation. Benefit (effectiveness) is assessed by patient satisfaction and measures of quality of life.

Allergan's Pivotal Study consists of 941 patients. This includes 225 Primary Reconstruction patients and 68 Revision-Reconstruction patients (the remainder are Augmentation patients). Of these patients, 96 Primary Reconstruction patients and 25 Revision-Reconstruction patients are in the MRI cohort, which means that they are assessed for silent rupture by MRI at years 1, 3, 5, 7, and 10. Remaining patients in the

non-MRI cohort who are MRI-eligible and consented to undergo MRI are also being assessed for silent rupture by MRI at years 7 and 10. The study is currently ongoing, with the results through 7 years reported in this brochure. Allergan will periodically update this brochure as more information becomes available. You should also ask your surgeon for any available updated Allergan clinical information.

Allergan's Pivotal Study results indicate that 53% of Primary Reconstruction patients and 57% of Revision-Reconstruction patients will have at least 1 occurrence of any complication (including reoperation) at some point through 7 years after implant surgery. The information below provides more details about the complications and benefits you may experience. Please refer to the glossary for the definition of any complication you may not understand.

5.2 What Are the 7-Year Follow-Up Rates?

Follow-up rates from a clinical study show you how many women continue to provide information on their experience with breast implants.

The Pivotal Study enrolled 225 Primary Reconstruction patients. Of the women expected to be seen at the 7-year follow-up visit, 81% were seen.

The Pivotal Study enrolled 68 Revision-Reconstruction patients. Of the women expected to be seen at the 7-year follow-up visit, 77% were seen.

5.3 What Are the Benefits?

The benefits of ***NATRELLE***® 410 Breast Implants were assessed by a variety of outcomes, including assessments of patient satisfaction and quality of life. Data were collected before implantation and at scheduled follow-up visits. Quality of life was assessed through the first 2 years after implantation.

Patient Satisfaction: Patients used a 5-point scale to rate their level of satisfaction with their implants at the time of the follow-up visits. Of the original 225 Primary Reconstruction patients, 149 (66%) provided a satisfaction rating at 7 years after implantation. Of these 149 patients, 75% indicated that they were definitely satisfied with their breast implants, 21% indicated that they were somewhat satisfied, 3% indicated that they were neither satisfied nor dissatisfied, 1% indicated that they were somewhat dissatisfied, and 1% indicated that they were definitely dissatisfied.

Of the original 68 Revision-Reconstruction patients, 43 (63%) provided a satisfaction rating at 7 years. Of these 43 patients, 63% indicated that they were definitely satisfied with their breast implants, 30% indicated that they were somewhat satisfied, 5% indicated that they were neither satisfied nor dissatisfied, and 2% indicated that they were definitely dissatisfied. See Figure 1 below.

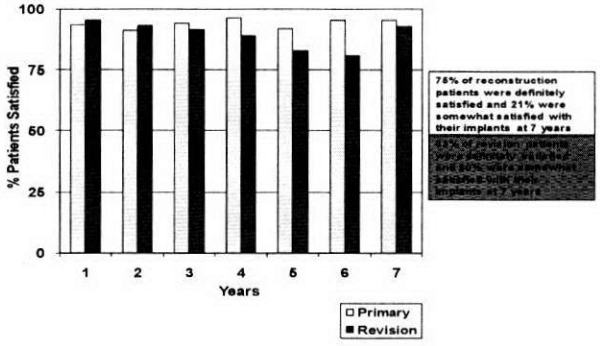
Table 2
7-Year Complication Rates for
Primary Reconstruction Patients (N = 225)

Key Complications[a]		%
Reoperation		45.2%
Implant Replacement		25.2%
Capsular Contracture (Baker Grade III/IV)		10.7%
Implant Rupture	MRI Cohort	10.3%
	Non-MRI Cohort	8.9%
Implant Removal without Replacement		5.3%

Other Complications Occurring in at least 1% of Patients[b,c]	%
Asymmetry	10.3%
Hypertrophic/Other Abnormal Scarring	4.8%
Infection	4.8%
Breast Pain	4.7%
Other Complications	4.4%
Upper Pole Fullness	4.2%
Swelling	3.8%
Implant Malposition	3.6%
Wrinkling/Rippling	3.1%
Seroma/Fluid Accumulation	2.1%
Hematoma	1.0%

[a] Most complications were assessed with severity ratings. This table only includes complications rated moderate, severe, or very severe (excludes mild and very mild ratings). For reoperation, implant removal or replacement, implant rupture, implant extrusion, and pneumothorax all occurrences are included.
[b] The following complications were reported at a rate less than 1%: delayed wound healing, implant extrusion, implant palpability/visibility, nipple complications, redness, and tissue/skin necrosis
[c] The following complications were reported at a rate of 0%: breast/skin sensation changes, bruising, capsule calcification, irritation, lymphadenopathy, lymphedema, palpable orientation mark, pneumothorax, ptosis, and skin rash

Figure 1. Primary Reconstruction and Revision-Reconstruction Patient Satisfaction Through 7 Years



Quality of Life Assessments: To assess quality of life, patients answered a series of questions collected from several quality of life scales.

For Primary Reconstruction patients, prior to implantation, scores on the SF-36 Scale, which measures mental and physical health, were for the most part significantly higher than the general female population. At 2 years, the only significant decrease was in the subscale "reported health transition." There were no significant changes on the Rosenberg Self-Esteem Scale and on the Body Esteem scale at 2 years. On the Rowland Expectation instrument, patients showed a significant positive change in "improve well-being."

Primary Reconstruction patients also had significantly improved satisfaction with specific aspects of their breasts after implantation, such as the size, shape, feel, and how well they matched.

Revision-Reconstruction patients did not undergo a quality of life assessment.

5.4 What Are the 7-Year Complication Rates?

The complications observed in Primary Reconstruction and Revision-Reconstruction patients through 7 years are presented in Table 2 and Table 3, respectively. The rates reflect the percentage of patients who experienced the listed complication at least once within the first 7 years after their implant surgery. Some complications occurred more than once for some patients. Please refer to the Glossary at the front of this brochure for the definition of any complication you may not understand.

The most common complication for Primary Reconstruction patients within the first 7 years following implantation was reoperation (45%, or 45 patients out of 100). The most common complication Revision-Reconstruction patients experienced was also reoperation (39%, or 39 patients out of 100).

Table 3
7-Year Complication Rates for
Revision-Reconstruction Patients (N = 68)

Key Complications[a]		%
Reoperation		38.6%
Implant Replacement		27.2%
Capsular Contracture (Baker Grade III/IV)		21.6%
Implant Rupture	MRI Cohort	21.1%
	Non-MRI Cohort	0
Implant Removal without Replacement		1.9%

Other Complications Occurring in at least 1% of Patients[b]	%
Asymmetry	14.8%
Wrinkling/Rippling	7.7%
Infection	6.9%
Seroma/Fluid Accumulation	6.2%
Redness	4.9%
Breast Pain	4.8%
Implant Malposition	4.8%
Swelling	3.2%
Hypertrophic/Other Abnormal Scarring	3.2%
Delayed Wound Healing	2.9%
Nipple Complications	1.7%
Other Complications	1.7%
Bruising	1.5%
Implant Palpability/Visibility	1.5%
Tissue/Skin Necrosis	1.5%
Upper Pole Fullness	1.5%

[a] Most events were assessed with severity ratings. This table only includes complications rated moderate, severe, or very severe (excludes mild and very mild ratings). For reoperation, implant removal or replacement, implant rupture, implant extrusion, and pneumothorax all occurrences are included.
[b] The following complications were reported at a rate of 0%: breast/skin sensation changes, capsule calcification, extrusion of intact implant, hematoma, irritation, lymphadenopathy, lymphedema, palpable orientation mark, pneumothorax, ptosis, skin rash

5.5 What Are the Main Reasons for Reoperation?

The reasons Primary Reconstruction and Revision-Reconstruction patients underwent additional surgery for their breast implant (reoperation) through 7 years are presented in Table 4 and Table 5, respectively. Women may have had a reoperation for one or more reasons. Furthermore, a surgeon may perform multiple surgical procedures during a single reoperation. For example, during a single reoperation a surgeon may perform incision and drainage, remove the capsule, replace the implant, reposition the implant, and perform scar revision.

The most common reason for reoperation through 7 years in Primary Reconstruction patients was because of scarring/hypertrophic scarring (28 of 129 reoperations, or 21.7%). In Allergan's Pivotal Study, there were 234 surgical procedures performed during 129 reoperations involving 97 Primary Reconstruction patients.

The most common reason for reoperation through 7 years in Revision-Reconstruction patients was because of capsular contracture (7 of 31 reoperations, or 22.6%). In Allergan's Pivotal Study, there were 65 surgical procedures performed during 31 reoperations involving 25 Revision-Reconstruction patients.

Table 4
Main Reasons for Reoperation in Primary Reconstruction Patients through 7 Years

Reason for Reoperation	n (%)
Scarring/Hypertrophic Scarring	28 (21.7%)
Capsular Contracture	16 (12.4%)
Implant Malposition	16 (12.4%)
Patient Request for Style/Size Change	12 (9.3%)
Asymmetry	9 (7.0%)
Infection	9 (7.0%)
Need for Biopsy	7 (5.4%)
Suspected Rupture	7 (5.4%)
Ptosis (sagging)	6 (4.7%)
Breast Tissue Contour Deformity	5 (3.9%)
Breast Pain	3 (2.3%)
Hematoma/Seroma	3 (2.3%)
Wrinkling	3 (2.3%)
Breast Cancer Mass	2 (1.6%)
Extrusion of Intact Implant	2 (1.6%)
Necrosis	1 (0.8%)
Total	**129 Reoperations (100%)**

Table 5
Main Reasons for Reoperation in Revision-Reconstruction Patients through 7 Years

Reason for Reoperation	n (%)
Capsular Contracture	7 (22.6%)
Delayed Wound Healing	3 (9.7%)
Implant Malposition	3 (9.7%)
Infection	3 (9.7%)
Patient Request for Style/Size Change	3 (9.7%)
Asymmetry	2 (6.5%)
Nipple Complications	2 (6.5%)
Unknown[a]	2 (6.5%)
Wrinkling	2 (6.5%)
Hematoma/Seroma	1 (3.2%)
Need for Biopsy	1 (3.2%)
Scarring/Hypertrophic Scarring	1 (3.2%)
Suspected Rupture	1 (3.2%)
Total	**31 Reoperations (100%)**

[a]Two reoperations were performed for reasons not provided

5.6 What Are the Main Reasons for Implant Removal?

The main reasons Primary Reconstruction and Revision-Reconstruction women had implants removed through 7 years are presented in Figure 2 and Figure 3, respectively. For Primary Reconstruction patients, 87 implants were removed from 61 patients. Of these 87 implants, 72 were replaced. The most common reason for implant removal was the patient requested a different implant style or size (26 of the 87 implants removed, or 30%).

For Revision-Reconstruction patients, 28 implants were removed from 18 patients. Of these 28 implants, 26 were replaced. The most common reason for implant removal was the patient requested a different implant style or size (7 of the 28 implants removed, or 25%).

Figure 2. Main Reasons for Implant Removal Through 7 Years Primary Reconstruction (N = 87 implants)

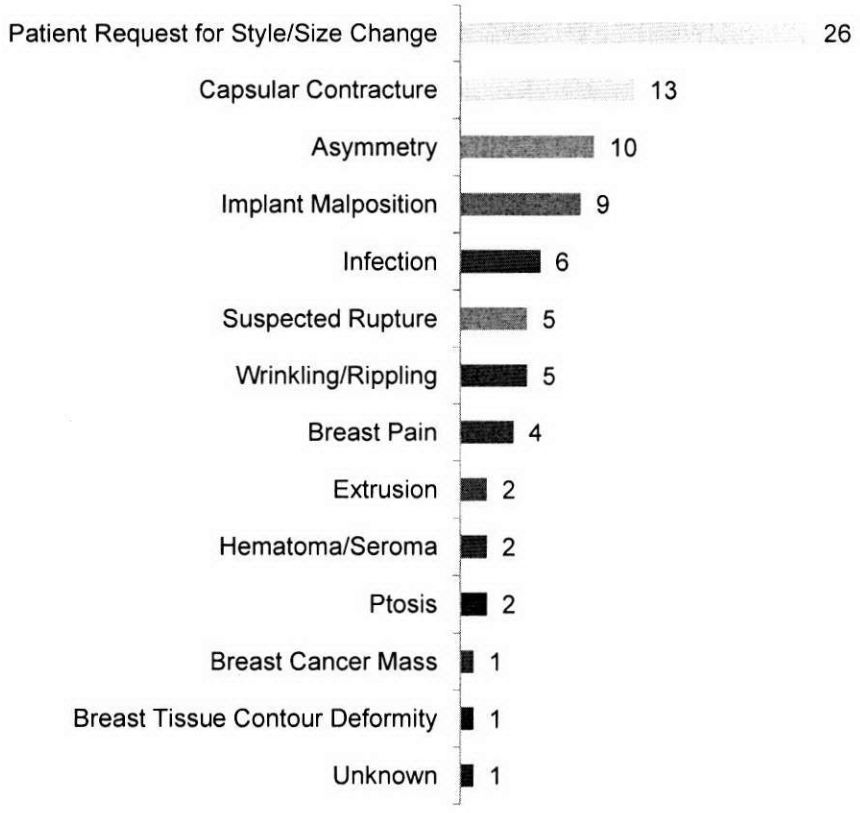
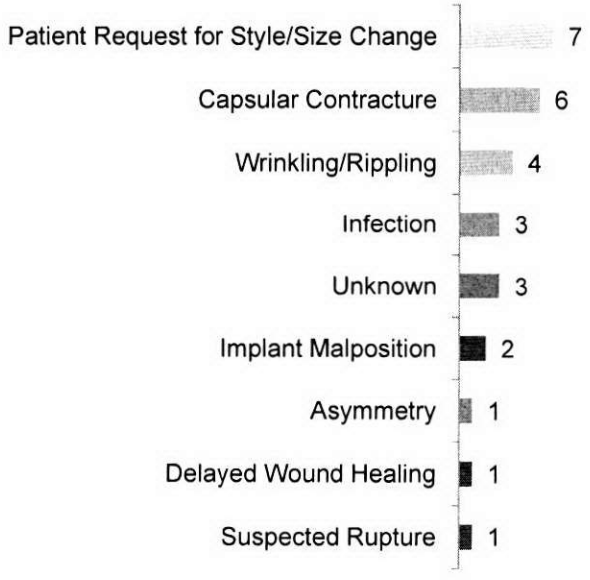


Figure 3. Main Reasons for Implant Removal Through 7 Years Revision-Reconstruction (N = 28 implants)



5.7 What Are Other Clinical Data Findings?

Below is a summary of clinical findings from the Pivotal Study with regard to connective tissue disease (CTD), CTD signs and symptoms, cancer, lactation complications, reproduction complications, and suicide. These issues, along with others, are being further evaluated as part of an Allergan post-approval study of patients followed through 10 years.

Implant Rupture

The rupture rate for the whole MRI cohort in Allergan's Pivotal Study (including Primary Augmentation, Revision-Augmentation, Primary Reconstruction, and Revision-Reconstruction patients) through 7 years was 11.5% for patients and 6.7% for implants. For the non-MRI cohort the rupture rate through 7 years was 8.7% for patients and 5.3% for implants. For Primary Reconstruction patients in the MRI cohort, 10.3% of patients had a ruptured implant, and 6.4% of implants ruptured through 7 years. For Revision-Reconstruction patients in the MRI cohort, 21.1% of patients had a ruptured implant, and 13.0% of implants ruptured through 7 years. This means that through 7 years, approximately 10 of every 100 Primary Reconstruction patients and 21 out of 100 Revision-Reconstruction had at least one ruptured breast implant.

For all ruptured implants in the Pivotal Study, the silicone gel remained within the capsule surrounding the implant.

CTD Diagnoses

There were 2 Primary Reconstruction patients (0.9%) in the Pivotal Study who reported CTDs through 7 years. One patient had a new diagnosis of alopecia at 7 months after implantation and rheumatoid arthritis at 25 months after implantation and another patient had fibromyalgia 27 months after implantation. No Revision-Reconstruction patients had new diagnoses of a CTD through 7 years. It cannot be concluded that these CTD diagnoses were caused by the implants because there was no comparison group of similar patients without implants.

CTD Signs and Symptoms

Patients who are not diagnosed with a CTD may still have some of the signs or symptoms of these diseases. In Allergan's Pivotal Study, self-reported signs and symptoms were collected at the 2, 4, and 6 year follow-up visits in the categories of General, Gastrointestinal, Neurological, Urinary, Global, Pain, Fatigue, Fibromyalgia, Joint, Muscular, Skin, and Other. Statistically significant increases were found for Primary Reconstruction patients in the symptom category of Pain. For Revision-Reconstruction patients, no significant increases were found.

The Pivotal Study was not designed to evaluate cause-and-effect associations because there is no comparison group of patients without implants. Further, other factors that might contribute to CTD signs and symptoms, such as medications, lifestyle, and exercise, were not studied. Therefore, it cannot be determined whether any increase in CTD signs and symptoms was due to the implants or not, based on the Pivotal Study. However, you should be aware that you may experience an increase in these symptoms after receiving breast implants.

Cancer
There were 11 Primary Reconstruction patients (6.1%) with a recurrence of breast cancer through 7 years, and 1 report of Non-Hodgkin's lymphoma and 1 report of uterine cancer.

There was 1 Revision-Reconstruction patient (1.5%) with recurrence of breast cancer through 7 years, and no reports of other cancers in Revision-Reconstruction patients.

No patients in the Pivotal Study were reported with ALCL through 7 years.

Lactation Complications
Two Primary Reconstruction patients attempted to breastfeed following implantation in the Pivotal Study and did not experience any difficulties with breastfeeding. No Revision-Reconstruction patients attempted to breastfeed following implantation.

Reproduction Complications
One (0.4%) of the Primary Reconstruction patients in the Pivotal Study reported a reproduction problem through 7 years. One (1.5%) Revision-Reconstruction patient experienced a reproduction problem through 7 years.

Suicide
There were no reports of suicide in the Primary Reconstruction and Revision-Reconstruction patients in the Pivotal Study through 7 years.

6.0 ADDITIONAL INFORMATION

6.1 What If I Experience a Problem?

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

You should immediately report any problems that you notice with your implants to your plastic surgeon. If you believe that you have experienced a serious problem(s) related to your breast implants, you should have your health professional report the problem(s) to the Food and Drug Administration (FDA and/or to Allergan). You may also report any serious problem directly through the FDA's MedWatch voluntary reporting system. An adverse event is considered serious and should be reported when it results in a hospitalization, disability, congenital problem with your child, or other medical or surgical intervention. The 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.

To report, use MedWatch Form 3500, which may be obtained through FDA's website at http://www.fda.gov/medwatch/index.html. You may also call 1.888.INFO.FDA (1.888.463.6332), 10 am to 4 pm Eastern Time, Monday through Friday, to receive an additional FDA MedWatch Package. Keep a copy of the MedWatch form completed by your surgeon for your records.

6.2 What Is Device Tracking?

Silicone gel-filled breast implants are subject to Device Tracking by federal regulation. This means that your physician will be required to submit to Allergan the serial number of the implant(s) you receive, the date of surgery, information relating to the physician's practice and information on the patient receiving the implant(s). Your surgeon will write this information on the Device Tracking Form supplied by Allergan with each silicone-filled breast implant. Your surgeon will return the first page of the form to Allergan following surgery. The second page of the form will be provided to you following surgery. You have the right to remove your personal information from Allergan's Device Tracking program. If you choose NOT to participate in Device Tracking, please check the appropriate box on the Device Tracking form and return to Allergan. You also have the right to have your personal information withheld from disclosure to third parties who may request information from Allergan, such as the FDA. If you choose to participate in the Device Tracking program but do NOT want your personal information to be released to third parties, please also check the appropriate box.

Allergan strongly recommends that all patients receiving ***NATRELLE***® 410 Breast Implants participate in Allergan's Device Tracking program. This will help ensure that Allergan has a record of each patient's contact information so that all patients can be contacted in the case of a recall or other problems with the implants.

Assessment of Information Effectiveness

The "Required Information" section of the Device Tracking Form also has a question designed to assess the effectiveness of this *Breast Reconstruction with* ***NATRELLE***® *410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants* patient brochure provided prior to your surgery. This question asks you to verify that you received and had adequate time to review this important information. Please check either yes or no. When the Required Information section is complete, return the entire page to Allergan by fax or mail, using the information provided on the form.

Please inform Allergan whenever your contact information changes by calling 1.877.641.4844 or e-mailing SB-DeviceTracking@allergan.com.

6.3 What Are the *ConfidencePlus*® Limited Warranties?

The *ConfidencePlus*® Limited Warranties provide lifetime replacement and limited financial reimbursement in the event of shell leakage or breakage resulting in implant rupture, subject to certain conditions as fully set forth in the *ConfidencePlus*® literature. Allergan offers two levels of coverage under its warranty program. Our standard *ConfidencePlus*® Limited Warranty program applies automatically to every Allergan breast implant recipient subject to the conditions set forth in the *ConfidencePlus*® literature. The optional *ConfidencePlus*® Premier Limited Warranty program is available for a low enrollment fee and increases the financial benefit in the event of implant rupture, subject to the conditions set forth in the *ConfidencePlus*® literature. For more information, please visit www.cppwarranty.com or contact Allergan's Product Surveillance Department at 1.800.362.4426.

6.4 How Can I Receive More Information?

Upon request, you will be provided with a copy of the package insert (Directions for Use; ***NATRELLE***® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants). You can request a copy from your surgeon or from Allergan. It can also be found on www.allergan.com/labeling/usa.htm. The package insert has many undefined medical and technical terms because it contains information directed only to the surgeon.

For more detailed information on the preclinical and clinical studies conducted by Allergan, you are referred to the Summary of Safety and Effectiveness Data (SSED) for this product which may be accessed at www.fda.gov/breastimplants.

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

TOLL-FREE NUMBER

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

ADDITIONAL RESOURCES

Allergan
1.800.624.4261
www.natrelle.com
www.allergan.com
www.breastimplantanswers.com

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

Food and Drug Administration
1.888.INFO.FDA or 1.240.276.3103
www.fda.gov/cdrh/breastimplants/

FOR FURTHER READING AND INFORMATION

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INDEX

ACCEPTANCE OF RISK AND SURGERY CONSENT

Surgeon and patient review and initial to indicate understanding and acceptance of the following:

	SURGEON	PATIENT
If signs of rupture are seen on an MRI, then you should have your implant removed.	_____	_____
Additional surgery to your breast and/or implant will be likely over the course of your life.	_____	_____
Your implants are not considered lifetime devices and you will likely undergo implant removal, with or without replacement, during your life.	_____	_____
You should inform your mammography technologist about the presence of your implants.	_____	_____
Your breast implants may interfere with your ability to successfully breastfeed.	_____	_____
You should perform breast self-examinations monthly and should make sure you know how to distinguish the implant from your breast tissue.	_____	_____
To monitor your breast implants for silent rupture, an MRI is recommended 3 years following surgery and then every 2 years after that.	_____	_____
The scar tissue or capsule that normally forms around the implant may tighten (contracture) and squeeze the implant. This may be painful and make your breast feel firmer.	_____	_____
Allergan maintains a breast implant device tracking database and your participation in this database is strongly recommended.	_____	_____

Consent to Surgery

My surgeon has provided me with the patient labeling, ***Breast Reconstruction with NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants***, to inform me prior to my surgery.

I have had adequate time to review and understand the information presented in the patient labeling, ***Breast Reconstruction with NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants***. My concerns and questions have been addressed by my doctor. I have considered alternatives to reconstruction surgery, including use of external prostheses or surgery with saline-filled breast implants.

I am choosing to proceed with silicone gel-filled breast implant surgery.

Patient Name (Printed): _____

Patient Signature: _____

Date: _____

Surgeon Name (Printed): _____

Surgeon Signature: _____

Date: _____

Allergan

71 South Los Carneros
Goleta, CA 93117
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[COVER PAGE]

NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants

Important Factors Breast Augmentation and Reconstruction Patients Should Consider

[INSIDE BROCHURE]

Introduction

Allergan has prepared this brochure to provide you with a high level overview of the facts about breast implant surgery with Allergan's FDA-Approved ***NATRELLE®*** 410 Breast Implants. This brochure is ***not*** intended to replace consultation with your surgeon. For a complete review of the benefits and risks of breast implant surgery, please read the appropriate patient labeling piece, ***Breast Augmentation/Reconstruction with NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants***, available from your surgeon or at www.allergan.com/labeling/usa.htm.

Because breast implants will require monitoring and care for the rest of your life, you should wait 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast augmentation or reconstruction surgery. In the case of a revision surgery, however, your surgeon may find it medically necessary to perform surgery sooner.

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

Figure 1: *NATRELLE®* 410 Breast Implant

Who may get *NATRELLE®* 410 Breast Implants (INDICATIONS)?

NATRELLE® 410 Breast Implants have been approved for women for the following uses (procedures):

- Breast augmentation for women at least 22 years old. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.

- Breast reconstruction. Breast reconstruction includes primary breast reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

Who should NOT get Breast Implants (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

What types of conditions require more study (PRECAUTIONS)?

Caution: Notify your doctor if you have any of the following conditions, as the risks of breast implant surgery may be higher:

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

What else should I consider (WARNINGS)?

The following are warnings associated with ***NATRELLE®*** 410 Breast Implants:

- Breast implants are not lifetime devices, and breast implantation is not necessarily a one-time surgery. You will likely need additional surgeries on your breasts due to complications or unacceptable cosmetic results.

- Many of the changes to your breasts following implantation are irreversible. If you later choose to have your implants removed and not replaced, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast, which may be permanent.

- Breast implants may affect your ability to breastfeed, either by reducing or eliminating milk production.

- Rupture of a silicone-filled breast implant is most often silent. This means that neither you nor your surgeon will know that your implants have a rupture. Therefore you will need regular MRI screenings over your lifetime in order to determine if rupture is present. You should have an MRI 3 years after your breast implant surgery and then every 2 years after that for as long as you have your breast implants. If implant rupture is noted on an MRI, you should have the implant removed, with or without replacement.

- The health consequences of a ruptured silicone gel-filled breast implant have not been fully established.

- With breast implants, a routine screening mammography for breast cancer will be more difficult. The implant may interfere with breast cancer detection during mammography and, because the breast and implant are squeezed during mammography, an implant may rupture during the procedure.

- You should perform self-examination of your breasts every month for cancer screening. However, this may be more difficult with implants. You should ask your surgeon to help you distinguish the implant from your breast tissue. The presence of lumps, persistent pain, swelling, hardening, or changes in implant shape, may be signs of a rupture of the implant. These signs should be reported to your surgeon and possibly evaluated with an MRI.

- After undergoing breast implant surgery (either primary or revision), your health insurance premiums may increase, your insurance coverage may be dropped, and/or future coverage may be denied. Additionally, treatment of complications may not be covered.

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

What are some complications with *NATRELLE®* 410 Breast Implants (COMPLICATIONS)?

Undergoing any type of surgery involves risks. There are a number of local complications (problems at or near the breast/surgical incision site) that may occur after your breast implant surgery.

Tables 1 and 2 present complication rates reported in the ***NATRELLE®*** 410 Clinical Study through 7 years. In the Clinical Study, a group of patients had scheduled MRIs to look for rupture independent of whether or not they had any symptoms. These patients are called the MRI cohort. The remaining patients did not have scheduled MRIs to look for rupture. These patients are called the non-MRI cohort. (An MRI is a radiographic examination that currently has the best ability to detect rupture of silicone gel-filled breast implants).

One of the key complications reported is called "capsular contracture." Capsular contracture is a tightening of the scar tissue (also called a capsule) that normally forms around the breast implant during the healing process after surgery. In some women, the scar tissue (capsule) squeezes the implant. This results in firmness or hardening of the breast, and it is a risk for implant rupture. Degrees of capsular contracture are classified by the Baker Grading Scale.[1] Capsular Contracture Baker Grades III and IV are the most severe. Baker Grade III often results in the need for additional surgery (reoperation) because of pain and possibly abnormal appearance. Baker Grade IV usually results in the need for reoperation because of pain and unacceptable appearance.

[1] Baker, J.L. Augmentation mammoplasty. In: Owsley, J.Q. and Peterson, R., Eds. *Symposium on aesthetic surgery of the breast*. St. Louis, MO: Mosby, 1978:256-263.

Table 1: Key Complication Rates Reported through 7 Years

Complication		Primary Augmentation N=492	Revision-Augmentation N=156	Primary Reconstruction N=225	Revision-Reconstruction N=68
Any complication (including reoperation)		31.0%	47.7%	53.0%	57.2%
Reoperation		22.4%	37.7%	45.2%	38.6%
Implant removal with replacement		11.5%	21.3%	25.2%	27.2%
Implant removal without replacement		1.2%	3.6%	5.3%	1.9%
Implant rupture	MRI cohort	11.3%	8.9%	10.3%	21.1%
	Non-MRI cohort	6.9%	16.1%	8.9%	0%
Capsular contracture (Baker Grade III/IV)		6.1%	8.7%	10.7%	21.6%

Table 2: Other Complication Rates Reported through 7 Years

Complication[a,b,c]	Primary Augmentation N=492	Revision-Augmentation N=156	Primary Reconstruction N=225	Revision-Reconstruction N=68
Asymmetry	0.8%	5.7%	10.3%	14.8%
Breast pain	2.7%	3.0%	4.7%	4.8%
Breast/skin sensation changes	1.5%	0	0	0
Bruising	0.4%	0.6%	0	1.5%
Delayed wound healing	1.1%	1.3%	0.5%	2.9%
Hematoma	1.1%	2.0%	1.0%	0
Implant extrusion	0.4%	1.5%	0.9%	0
Implant malposition	2.9%	7.0%	3.6%	4.8%
Implant palpability/visibility	0.3%	1.4%	0.5%	1.5%
Infection	1.7%	2.1%	4.8%	6.9%
Necrosis	0	0	0.5%	1.5%
Nipple complications	1.3%	0	0.5%	1.7%
Ptosis	1.9%	0	0	0
Redness	0.7%	0	0.9%	4.9%
Scarring/hypertrophic scarring	1.1%	2.7%	4.8%	3.2%
Seroma	1.3%	3.3%	2.1%	6.2%
Swelling	3.5%	2.7%	3.8%	3.2%
Upper pole fullness	0	1.4%	4.2%	1.5%
Wrinkling/Rippling	0.7%	3.7%	3.1%	7.7%
Other complications[d]	1.3%	1.5%	4.4%	1.7%

[a]Includes reports of only ≥ moderate severity for all complications except for implant extrusion and pneumothorax

[b]The following complications were reported at a risk rate of less than 1% in each cohort: skin rash, gel fracture, and tissue/skin necrosis

[c]There were no reports of the following complications: capsule calcification, irritation, lymphadenopathy, lymphedema, palpable orientation mark, pneumothorax

[d]Other complications include complications such as joint swelling, implant movement, bottoming out, tear in the capsule, skin indentation, and synmastia

Other complications not listed above have also been reported in patients with breast implants. These include:

- Breastfeeding difficulties
- Calcium deposits
- Breast tissue atrophy/chest wall deformity
- Connective Tissue Disease (CTD)
- CTD signs and symptoms
- Neurological Disease
- Neurological Signs and Symptoms
- Cancer
- Lymphoma, including Anaplastic Large Cell Lymphoma or ALCL
- Suicide
- Potential Effects on Offspring

Why are implants sometimes removed (IMPLANT REMOVAL)?

Breast implants may be removed with or without replacement in response to a complication, or to improve a cosmetic result. In the ***NATRELLE®*** 410 Clinical Study through 7 years the most common reason for implant removal was patient request for a size or style change (ranging from 25% to 46% of all implant removals).

The main reasons Primary Augmentation and Revision-Augmentation patients had implants removed through 7 years are presented in Figure 2 and Figure 3, respectively.

The main reasons Primary Reconstruction and Revision-Reconstruction women had implants removed through 7 years are presented in Figure 4 and Figure 5, respectively.

Figure 2: Main Reasons for Implant Removal Through 7 Years
Primary Augmentation (N = 99 implants)

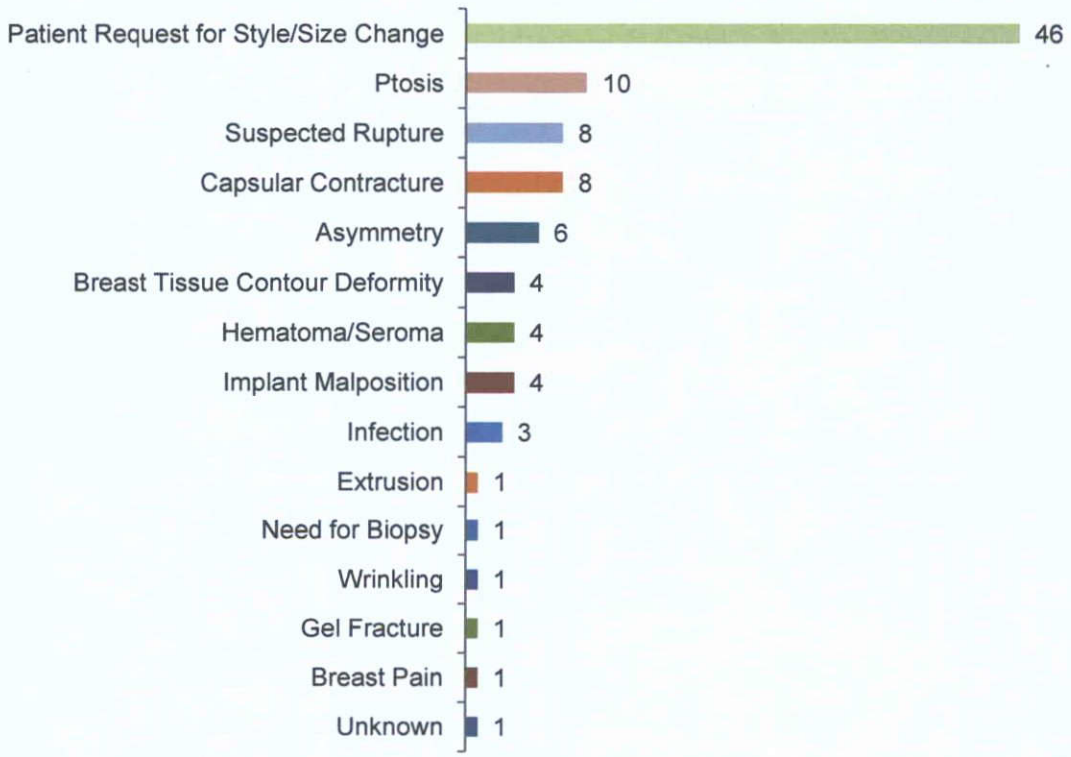


Figure 3: Main Reasons for Implant Removal Through 7 Years
Revision-Augmentation (N = 60 implants)

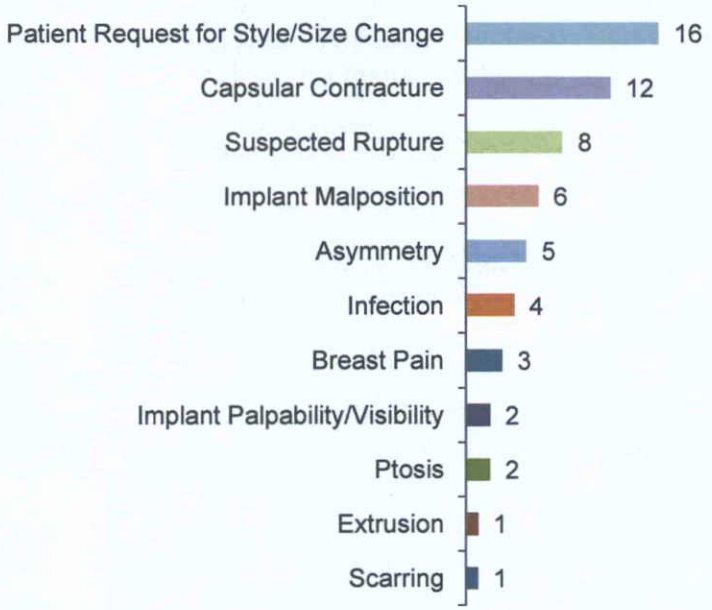


Figure 4: Main Reasons for Implant Removal Through 7 Years
Primary Reconstruction (N = 87 implants)

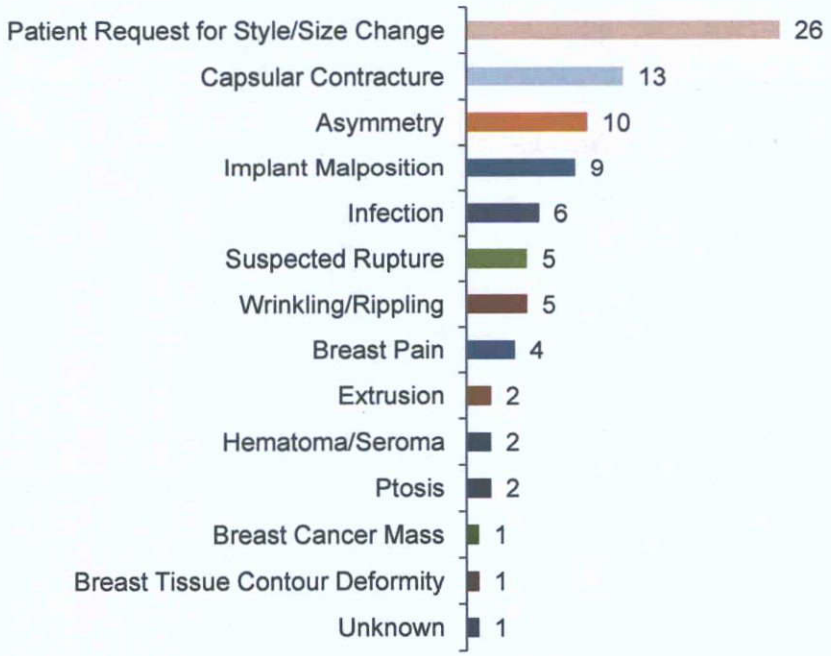
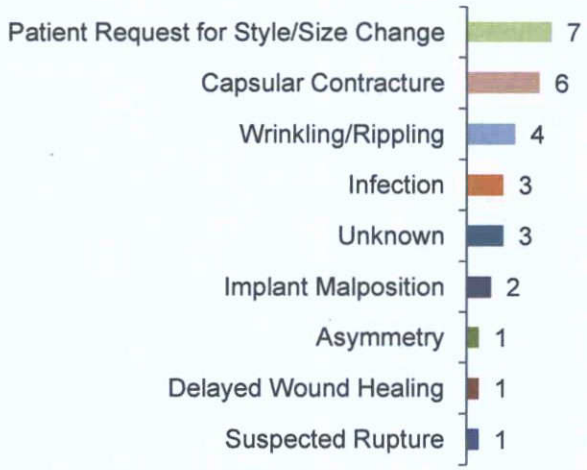


Figure 5: Main Reasons for Implant Removal Through 7 Years Revision-Reconstruction (N = 28 implants)



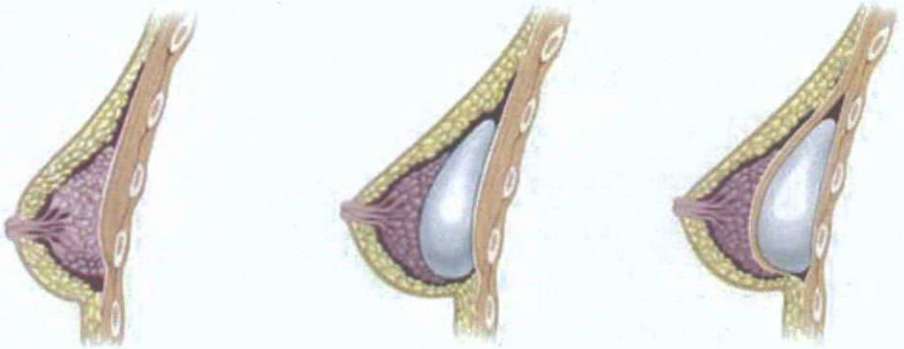
For a more detailed review of potential complications, please refer to the appropriate patient labeling piece, ***Breast Augmentation/Reconstruction with NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants***, available from your surgeon or at www.allergan.com/labeling/usa.htm.

How does the breast implantation procedure work?

Implant Placement

The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast glands (subglandular). You should discuss with your surgeon the advantages and disadvantages of each implant placement.

Figure 6: Implant Placement



Breast before augmentation

Breast after subglandular augmentation

Breast after submuscular augmentation

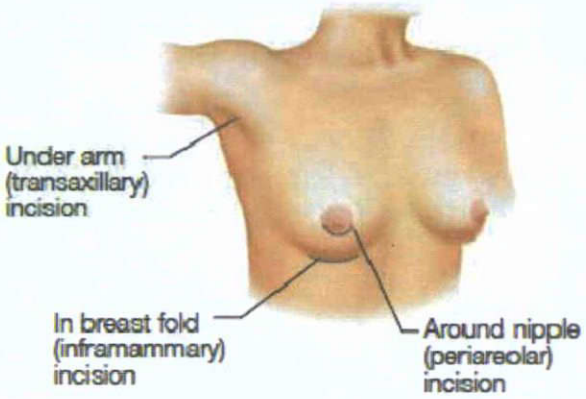
Incision Sites

You should discuss with your surgeon the pros and cons for the incision site specifically recommended for you.

Breast augmentation with highly cohesive silicone implants requires a larger incision than saline or less cohesive silicone implants. There are 3 common incision sites: around the nipple (periareolar), within the breast fold (inframammary), or under the arm (axillary or transaxillary).

In reconstructive surgery, your surgeon will decide on the incision placement and length, largely based on the type of cancer surgery you will receive. Most implants used for breast reconstruction are placed through an incision at the mastectomy scar, either during the mastectomy procedure or after tissue expansion.

Figure 7: Incision Sites



Postoperative Care

You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size. The breasts and nipple area also may have less feeling during this time of swelling and immediately after surgery. Other possible complications have been described above.

Postoperative care depends on each patient's situation and may involve using a special postoperative bra, compression bandage, or jog bra for extra support and positioning while you heal. Some surgeons may not want you to wear a bra at all for a period of time following the surgery.

At your surgeon's recommendation, you will most likely be able to return to work within a few days. However, for at least a couple of weeks you should avoid any strenuous activities that could raise your pulse and blood pressure, or require strenuous use of your arms and chest.

Where can I get additional information?

It is important that you read the entire patient labeling, entitled ***Breast Augmentation/Reconstruction with NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants***, because you need to understand the risks and benefits and have realistic expectations for your surgery. Copies of the patient labeling can be obtained from your surgeon, www.allergan.com/labeling/usa.htm, or by calling

Allergan Product Support at 1-800-433-8871. Additional information is also available on the FDA website at http://www.fda.gov/breastimplants.

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