Directions for Use

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

THE SCIENCE OF REJUVENATION™

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

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INTRODUCTION

Directions to the Physician

The information supplied in this Directions for Use document is intended to provide 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 8.

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

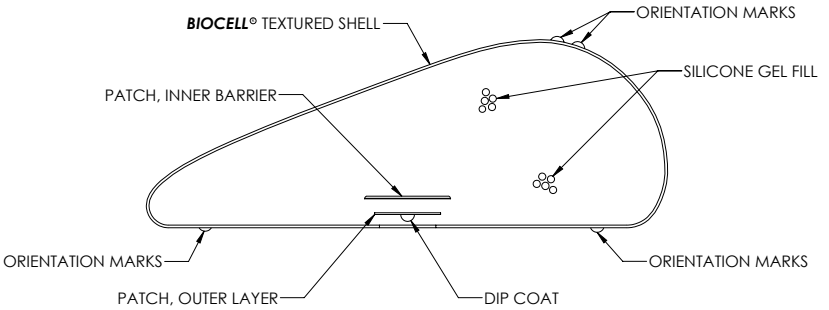
NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants are subject to Device Tracking per federal regulation. This means that the physician is required to report to Allergan the serial number of the implanted device(s), the date of surgery, information relating to the physician's 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. The use of highly cohesive gel in ***NATRELLE***® 410 Breast Implants is intended to allow the implant to maintain its shape in any position (form stable). ***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.

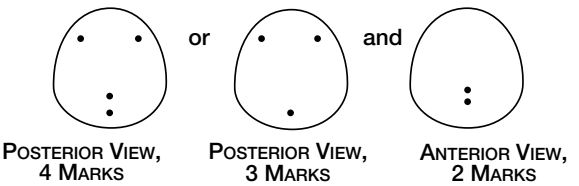
NATRELLE® 410 Highly Cohesive Anatomically Shaped



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.

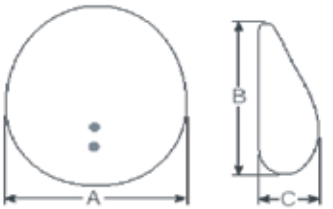
General Orientation Mark Locations



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)
FL	Full height, Low projection	320	13.5	13.0	3.8
ML	Moderate height, Low projection	285	12.1	13.0	3.8
LL	Low height, Low projection	240 – 300	10.5 – 11.4	12.5 – 13.5	3.6 – 4.0
FM	Full height, Moderate projection	205 – 670	11.0 – 16.0	10.5 – 15.5	3.8 – 5.6
MM	Moderate height, Moderate projection	160 – 450	9.1 – 12.9	10.0 – 14.0	3.6 – 5.2
LM	Low height, Moderate projection	190 – 320	9.1 – 10.9	11.0 – 13.0	4.0 – 4.8
FF	Full height, Full projection	185 – 740	10.5 – 16.0	10.0 – 15.5	4.0 – 6.2
MF	Moderate height, Full projection	140 – 640	8.6 – 13.9	9.5 – 15.5	3.7 – 6.2
LF	Low height, Full projection	175 – 595	8.6 – 13.0	10.5 – 15.5	4.2 – 6.2
FX	Full height, Extra full projection	185 - 495	10.0 – 14.0	9.5 – 13.5	4.6 – 6.2
MX	Moderate height, Extra full projection	165 - 445	8.6 – 12.5	9.5 – 13.5	4.6 – 6.2
LX	Low height, Extra full projection	195 – 405	8.6 – 11.4	10.5 – 13.5	5.1 – 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 47.
- **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

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
- Patients should have a diagnostic mammogram, rather than a screening mammogram, because more pictures are taken with a diagnostic mammogram
- 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 25.

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, 6.6)	2.7% (0.4, 17.7)	3.1% (0.8, 11.8)	0.0%
4 years	2.9% (1.1, 7.5)	2.7% (0.4, 17.7)	3.1% (0.8, 11.8)	0.0%
5 years	6.0% (3.0, 11.7)	5.7% (1.4, 20.8)	10.1% (4.7, 21.2)	14.3% (4.8, 38.0)
6 years	6.0% (3.0, 11.7)	5.7% (1.4, 20.8)	10.1% (4.7, 21.2)	14.3% (4.8, 38.0)
7 years	12.2% (7.5, 19.5)	9.0% (3.0, 25.6)	12.4% (6.0, 24.4)	19.6% (7.8, 44.4)
8 years	14.2% (9.0, 21.9)	9.0% (3.0, 25.6)	12.4% (6.0, 24.4)	19.6% (7.8, 44.4)
9 years	16.4% (10.7, 24.6)	14.7% (5.4, 36.4)	12.4% (6.0, 24.4)	19.6% (7.8, 44.4)
10 years	17.7% (11.7, 26.4)	14.7% (5.4, 36.4)	12.4% (6.0, 24.4)	19.6% (7.8, 44.4)

[a] 20 silent ruptures, none symptomatic

[b] 3 silent ruptures, 1 symptomatic

[c] 7 silent ruptures, none symptomatic

[d] 3 silent ruptures, 1 symptomatic

Cumulative Risk of First Occurrence of Implant Rupture – Non-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	0.5% (0.1, 3.3)	1.5% (0.2, 10.0)	0.0%	0.0%
3 years	1.0% (0.2, 3.7)	3.0% (0.8, 11.5)	0.0%	0.0%
4 years	3.9% (1.9, 7.6)	4.6% (1.5, 13.7)	4.9% (1.9, 12.5)	0.0%
5 years	5.8% (3.3, 10.0)	11.4% (5.6, 22.4)	6.1% (2.6, 14.0)	5.0% (0.7, 30.5)
6 years	8.8% (5.6, 13.6)	14.8% (8.0, 26.5)	6.1% (2.6, 14.0)	5.0% (0.7, 30.5)
7 years	9.3% (6.0, 14.2)	14.8% (8.0, 26.5)	6.1% (2.6, 14.0)	5.0% (0.7, 30.5)
8 years	9.3% (6.0, 14.2)	14.8% (8.0, 26.5)	6.1% (2.6, 14.0)	5.0% (0.7, 30.5)
9 years	14.8% (10.3, 20.9)	19.8% (11.3, 33.4)	7.9% (3.6, 17.1)	5.0% (0.7, 30.5)
10 years	14.8% (10.3, 20.9)	19.8% (11.3, 33.4)	10.1% (4.8, 20.6)	5.0% (0.7, 30.5)

[a] 27 silent ruptures, 2 symptomatic

[b] 9 silent ruptures, 2 symptomatic

[c] 6 silent ruptures, 1 symptomatic

[d] 1 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 was 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 were serially followed at 4 weeks, 6 months, 1 year and annually thereafter through 10 years. Final results through 10 years are reported.

Safety assessments included local complication rates, and effectiveness assessments included 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 final database lock for the study, 86.2% of eligible patients were available for analysis at the 10-year follow-up timepoint.

The 10-year follow-up rates by cohort were 65.7% (302) for Primary Augmentation, 55.3% (73) for Revision-Augmentation, 80.6% (137) for Primary Reconstruction, and 76.9% (40) for Revision-Reconstruction.

A total of 316 patients were enrolled in the MRI arm of the pivotal study to screen for breast implant rupture. Patients in the MRI cohort were screened for breast implant rupture with scheduled MRIs at years 1, 3, 5, 7, and 10.

The 10-year MRI compliance rate was 70.1% for the Primary Augmentation cohort, 64.2% for the Revision-Augmentation cohort, 72.3% for the Primary Reconstruction cohort, and 80.0% 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 – 34.4)	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=113)
Style Number					
410FM	38.3%	49.3%	31.3%	23.4%	8.8%
410FF	30.8%	21.9%	37.1%	40.1%	61.9%
410MM	19.9%	21.9%	22.9%	14.7%	10.6%
410MF	10.9%	6.9%	8.7%	21.8%	17.7%
Placement Site[a]					
Submuscular	83.2%	84.3%	71.6%	87.6%	92.1%
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, 5.7% 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, 292 (59.3%) provided a satisfaction rating at 10 years after implantation. Of these 292 patients, 89.0% indicated that they were definitely satisfied with their breast implants, 7.2% indicated they were somewhat satisfied, 0.3% indicated that they were neither satisfied nor dissatisfied, 2.1% were indicated they were somewhat dissatisfied, and 1.4% indicated they were definitely dissatisfied.

Physician satisfaction with patient results was rated in 293 cases (59.6%) at 10 years. Physicians reported being definitely satisfied with the breast implants in 86.3% of cases, somewhat satisfied in 9.2% of cases, neither satisfied nor dissatisfied in 0.7% of cases, somewhat dissatisfied in 2.7% of cases, and definitely dissatisfied in 1.0% 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 at 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 at 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, 72 (46.2%) provided a satisfaction rating at 10 years. Of these 72 patients, 70.8% indicated they were definitely satisfied with their breast implants, 16.7% indicated that they were somewhat satisfied, 1.4% indicated that they were neither

satisfied nor dissatisfied, 8.3% indicated they were somewhat dissatisfied, and 2.8% indicated that they were definitely dissatisfied.

Physician satisfaction with patient results was rated in 72 cases (46.2%) at 10 years. Physicians reported being definitely satisfied with the breast implants in 73.6% of cases, somewhat satisfied in 13.9% of cases, neither satisfied nor dissatisfied in 1.4% of cases, somewhat dissatisfied in 9.7% of cases, and definitely dissatisfied in 1.4% of cases.

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

Primary Reconstruction Patients

Of the original 225 Primary Reconstruction patients, 134 (59.6%) provided a satisfaction rating at 10 years after implantation. Of these 134 patients, 75.4% indicated that they were definitely satisfied with their breast implants, 17.9% indicated that they were somewhat satisfied, 3.0% indicated that they were neither satisfied nor dissatisfied, 2.2% indicated that they were somewhat dissatisfied, and 1.5% indicated that they were definitely dissatisfied.

Physician satisfaction with patient results was rated in 134 cases (59.6%) at 10 years. Physicians reported being definitely satisfied with the breast implants in 76.9% of cases, somewhat satisfied in 14.9% of cases, neither satisfied nor dissatisfied in 5.2% of cases, somewhat dissatisfied in 1.5% of cases, and definitely dissatisfied in 1.5% 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, 40 (58.8%) provided a satisfaction rating at 10 years after implantation. Of these 40 patients, 67.5% indicated that they were definitely satisfied with their breast implants, 22.5% indicated that they were somewhat satisfied, 2.5% indicated

that they were neither satisfied nor dissatisfied, and 7.5% indicated that they were somewhat dissatisfied.

Physician satisfaction with patient results was rated in 40 cases (58.8%) at 10 years. Physicians reported being definitely satisfied with the breast implants in 60.0% of cases, somewhat satisfied in 22.5% of cases, neither satisfied nor dissatisfied in 10.0% of cases, and somewhat dissatisfied in 7.5% of cases.

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

Safety Results

The cumulative complication rates at Years 3, 5, 7, and 10 are presented below in **Tables 7** to **10**. The reasons for reoperation at Years 3, 5, 7, and 10 and reasons for implant removal at Years 3, 5, 7, and 10 are presented in **Tables 11-14** and **Tables 15-18**, respectively.

Table 7: Kaplan-Meier Risk Rates By Patient for Augmentation Cohort (N = 492)

Complication[a,b,c]		Year 3	Year 5	Year 7	Year 10
Any complication (including reoperation)[d]		19.7% (16.4, 23.5)	24.5% (20.8, 28.6)	31.4 (27.4, 35.9)	39.2% (34.7, 43.9)
Any reoperation		12.7% (10.0, 16.0)	16.4% (13.3, 20.0)	22.6% (19.1, 26.8)	29.7% (25.6, 34.3)
Implant removal with or without replacement		5.4% (3.7, 7.8)	8.1% (5.9, 10.9)	12.7% (10.0, 16.2)	19.6% (16.1, 23.7)
Implant removal with replacement		5.0% (3.4, 7.4)	7.4% (5.4, 10.2)	11.4% (8.8, 14.7)	16.8% (13.6, 20.8)
Implant removal without replacement		0.4% (0.1, 1.8)	0.7% (0.2, 2.1)	1.4% (0.6, 3.2)	3.3% (1.9, 5.7)
Asymmetry		0.8% (0.3, 2.2)	0.8% (0.3, 2.2)	0.8% (0.3, 2.2)	1.2% (0.5, 2.9)
Breast pain		1.5% (0.7, 3.0)	2.2% (1.2, 4.0)	2.6% (1.5, 4.6)	4.5% (2.8, 7.1)
Breast/skin sensation changes		1.3% (0.6, 2.8)	1.3% (0.6, 2.8)	1.5% (0.7, 3.1)	1.5% (0.7, 3.1)
Capsular contracture III/IV		2.1% (1.1, 3.9)	4.0% (2.5, 6.2)	6.0% (4.1, 8.7)	9.2% (6.7, 12.6)
Delayed wound healing		0.8% (0.3, 2.2)	0.8% (0.3, 2.2)	1.1% (0.4, 2.5)	1.1% (0.4, 2.5)
Hematoma		0.8% (0.3, 2.2)	1.1% (0.4, 2.5)	1.1% (0.4, 2.5)	1.3% (0.6, 2.9)
Hypertrophic scarring/ scarring		0.9% (0.3, 2.3)	1.1% (0.5, 2.6)	1.4% (0.6, 3.0)	1.4% (0.6, 3.0)
Implant malposition		2.3% (1.3, 4.2)	2.8% (1.6, 4.7)	3.3% (2.0, 5.4)	4.7% (3.1, 7.3)
Implant rupture	MRI cohort	2.2% (0.7, 6.6)	6.0% (3.0, 11.7)	12.2% (7.5, 19.5)	17.7% (11.7, 26.4)
	Non-MRI cohort	1.0% (0.2, 3.7)	5.8% (3.3, 10.0)	9.3% (6.0, 14.2)	14.8% (10.3, 20.9)
Infection		1.5% (0.7, 3.0)	1.7% (0.8, 3.3)	1.7% (0.8, 3.3)	1.7% (0.8, 3.3)
Nipple complications		1.1% (0.4, 2.5)	1.3% (0.6, 2.8)	1.3% (0.6, 2.8)	1.3% (0.6, 2.8)
Ptosis		0.9% (0.3, 2.3)	0.9% (0.3, 2.3)	1.9% (0.9, 3.7)	1.9% (0.9, 3.7)
Seroma		0.8% (0.3, 2.2)	1.1% (0.4, 2.5)	1.3% (0.6, 2.9)	1.6% (0.8, 3.3)
Swelling		1.6% (0.8, 3.2)	2.1% (1.1, 3.9)	3.4% (2.1, 5.6)	4.0% (2.5, 6.3)
Other complications[e]		0.6% (0.2, 1.9)	1.3% (0.6, 2.9)	1.6% (0.8, 3.3)	1.6% (0.8, 3.3)

[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, tissue skin necrosis, upper pole fullness

[c] The following complications occurred at a rate less than 1% at all timepoints: bruising, gel fracture, implant extrusion, implant palpability/visibility, redness, skin rash, wrinkling/rippling

[d] 177 primary augmentation patients experienced at least one complication

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

Table 8: Kaplan-Meier Risk Rates By Patient for Revision-Augmentation Cohort (N = 156)

Complication[a,b,c]		Year 3	Year 5	Year 7	Year 10
Any complication (including reoperation)[d]		29.9% (23.3, 37.8)	38.4% (31.1, 46.7)	47.9% (40.1, 56.3)	57.4% (49.2, 65.8)
Any reoperation		22.2% (16.4, 29.7)	30.0% (23.3, 38.0)	38.0% (30.6, 46.4)	47.3% (39.2, 56.0)
Implant removal with or without replacement		11.1% (7.1, 17.3)	18.2% (12.8, 25.4)	24.1% (17.9, 31.9)	31.0% (23.9, 39.5)
Implant removal with replacement		9.3% (5.6, 15.2)	15.8% (10.8, 22.8)	21.8% (15.8, 29.5)	27.8% (21.0, 36.2)
Implant removal without replacement		2.0% (0.7, 6.1)	3.6% (1.5, 8.4)	3.6% (1.5, 8.4)	5.9% (2.8, 12.2)
Asymmetry		3.3% (1.4, 7.8)	5.6% (2.9, 11.0)	5.6% (2.9, 11.0)	6.9% (3.6, 13.1)
Breast pain		1.3% (0.3, 5.1)	2.1% (0.7, 6.3)	3.8% (1.6, 9.0)	5.2% (2.3, 11.5)
Capsular contracture III/IV		5.3% (2.7, 10.4)	6.9% (3.7, 12.4)	8.6% (4.9, 14.7)	11.9% (7.2, 19.3)
Delayed wound healing		1.3% (0.3, 5.1)	1.3% (0.3, 5.1)	1.3% (0.3, 5.1)	1.3% (0.3, 5.1)
Hematoma		2.0% (0.6, 6.0)	2.0% (0.6, 6.0)	2.0% (0.6, 6.0)	2.0% (0.6, 6.0)
Hypertrophic scarring		2.7% (1.0, 7.1)	2.7% (1.0, 7.1)	2.7% (1.0, 7.1)	3.7% (1.5, 8.8)
Implant extrusion		0.7% (0.1, 4.5)	1.5% (0.4, 5.8)	1.5% (0.4, 5.8)	1.5% (0.4, 5.8)
Implant malposition		4.6% (2.2, 9.4)	5.4% (2.7, 10.5)	7.2% (3.9, 13.0)	9.1% (5.2, 15.6)
Implant palpability/visibility		1.4% (0.3, 5.4)	1.4% (0.3, 5.4)	1.4% (0.3, 5.4)	1.4% (0.3, 5.4)
Implant rupture	MRI cohort	2.7% (0.4, 17.7)	5.7% (1.4, 20.8)	9.0% (3.0, 25.6)	14.7% (5.4, 36.4)
	Non-MRI cohort	3.0% (0.8, 11.5)	11.4% (5.6, 22.4)	14.8% (8.0, 26.5)	19.8% (11.3, 33.4)
Infection		1.3% (0.3, 5.1)	2.1% (0.7, 6.3)	2.1% (0.7, 6.3)	2.1% (0.7, 6.3)
Seroma		1.4% (0.4, 5.5)	1.4% (0.4, 5.5)	3.2% (1.2, 8.4)	3.2% (1.2, 8.4)
Swelling		1.9% (0.6, 5.9)	2.7% (1.0, 7.1)	2.7% (1.0, 7.1)	2.7% (1.0, 7.1)
Wrinkling/Rippling		2.7% (1.0, 7.1)	2.7% (1.0, 7.1)	3.7% (1.5, 8.6)	3.7% (1.5, 8.6)
Other complications[e]		0.7% (0.1, 4.6)	1.5% (0.4, 5.9)	1.5% (0.4, 4.9)	3.5% (1.3, 9.2)

[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: breast/skin sensation changes, capsule calcification, irritation, lymphadenopathy, lymphedema, nipple complications, palpable orientation mark, pneumothorax, ptosis, redness, skin rash, tissue/skin necrosis

[c] The following complications occurred at a rate less than 1% at all timepoints: bruising, gel fracture, upper pole fullness

[d] 82 revision-augmentation patients experienced at least one complication

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

Table 9: Kaplan-Meier Risk Rates By Patient for Reconstruction Cohort (N = 225)

Complication[a,b,c]		Year 3	Year 5	Year 7	Year 10
Any complication (including reoperation)[d]		41.7% (35.5, 48.5)	47.3% (41.0, 54.1)	53.2% (46.7, 60.0)	65.1% (58.6, 71.6)
Any reoperation		32.9% (27.1, 39.5)	39.6% (33.5, 46.4)	44.7% (38.3, 51.6)	54.6% (47.9, 61.6)
Implant removal with or without replacement		17.3% (12.9, 23.0)	22.7% (17.6, 28.9)	28.8% (23.2, 35.5)	38.3% (31.9, 45.5)
Implant removal without replacement		2.9% (1.3, 6.3)	4.6% (2.4, 8.7)	5.3% (2.8, 9.6)	6.7% (3.8, 11.7)
Implant removal with replacement		14.8% (10.7, 20.2)	18.9% (14.2, 24.8)	24.8% (19.4, 31.4)	34.3% (28.0, 41.6)
Asymmetry		8.5% (5.4, 13.2)	9.6% (6.3, 14.5)	10.2% (6.8, 15.3)	12.4% (8.4, 18.1)
Breast pain		3.0% (1.3, 6.5)	4.7% (2.4, 8.8)	5.3% (2.9, 9.6)	8.2% (4.9, 13.7)
Capsular contracture III/IV		7.8% (4.8, 12.4)	10.5% (7.0, 15.7)	11.1% (7.4, 16.4)	14.5% (10.1, 20.6)
Hematoma		1.0% (0.3, 4.0)	1.0% (0.3, 4.0)	1.0% (0.3, 4.0)	1.0% (0.3, 4.0)
Hypertrophic scarring		4.2% (2.2, 7.9)	4.8% (2.6, 8.7)	4.8% (2.6, 8.7)	4.8% (2.6, 8.7)
Implant malposition		2.9% (1.3, 6.3)	2.9% (1.3, 6.3)	3.5% (1.7, 7.3)	5.7% (3.1, 10.5)
Implant palpability/visibility		0.5% (0.1, 3.3)	0.5% (0.1, 3.3)	0.5% (0.1, 3.3)	1.2% (0.3, 4.7)
Implant rupture	MRI cohort	3.1% (0.8, 11.8)	10.1% (4.7, 21.2)	12.4% (6.0, 24.4)	12.4% (6.0, 24.4)
	Non-MRI cohort	0	6.1% (2.6, 14.0)	6.1% (2.6, 14.0)	10.1% (4.8, 20.6)
Infection		4.3% (2.2, 8.0)	5.4% (3.0, 9.5)	5.4% (3.0, 9.5)	6.1% (3.5, 10.7)
Seroma		1.4% (0.5, 4.3)	1.4% (0.5, 4.3)	2.0% (0.8, 5.4)	2.8% (1.1, 6.6)
Swelling		3.3% (1.6, 6.8)	3.8% (1.9, 7.5)	3.8% (1.9, 7.5)	5.3% (2.8, 9.7)
Upper pole fullness		4.2% (2.2, 7.8)	4.2% (2.2, 7.8)	4.2% (2.2, 7.8)	4.2% (2.2, 7.8)
Wrinkling/Rippling		2.5% (1.0, 5.8)	2.5% (1.0, 5.8)	3.7% (1.8, 7.7)	6.2% (3.3, 11.4)
Other complications[e]		3.9% (1.9, 7.6)	4.4% (2.3, 8.3)	4.4% (2.3, 8.3)	6.0% (3.3, 10.7)

[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: breast/skin sensation changes, bruising, gel fracture, irritation, lymphadenopathy, lymphedema, palpable orientation mark, pneumothorax, ptosis

[c] The following complications occurred at a rate of less than 1% at all timepoints: capsule calcification, delayed wound healing, implant extrusion, nipple complications, redness, skin rash, tissue/skin necrosis

[d] 140 primary reconstruction patients experienced at least one complication

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

Table 10: Kaplan-Meier Risk Rates By Patient for Revision-Reconstruction Cohort (N = 68)

Complication[a,b]		Year 3	Year 5	Year 7	Year 10
Any complication (including reoperation)[c]		40.3% (29.7, 53.0)	49.5% (38.2, 62.0)	60.3% (48.7, 72.0)	70.6% (59.1,81.3)
Any reoperation		21.0% (13.0, 32.9)	30.1% (20.6, 42.7)	39.9% (29.1, 52.8)	48.5% (37.0, 61.5)
Implant removal with or without replacement		15.1% (8.4, 26.2)	19.7% (12.0, 31.6)	29.8% (20.1, 42.7)	42.4% (31.0, 55.9)
Implant removal without replacement		0	1.9% (0.3, 12.6)	1.9% (0.3, 12.6)	4.9% (1.2, 18.7)
Implant removal with replacement		15.1% (8.4, 26.2)	18.2% (10.8, 29.8)	28.4% (18.9, 41.4)	39.3% (28.2, 52.9)
Asymmetry		9.4% (4.3, 19.7)	13.0% (6.7, 24.4)	14.8% (8.0, 26.7)	17.4% (9.6, 30.3)
Breast pain		3.1% (0.8, 11.9)	4.8% (1.6, 14.3)	4.8% (1.6, 14.3)	7.8% (2.9, 20.4)
Bruising		1.5% (0.2, 10.0)	1.5% (0.2, 10.0)	1.5% (0.2, 10.0)	1.5% (0.2, 10.0)
Capsular contracture III/IV		10.8% (5.3, 21.3)	16.0% (8.9, 27.7)	21.5% (13.1, 34.3)	26.8% (16.8, 41.1)
Delayed wound healing		2.9% (0.7, 11.3)	2.9% (0.7, 11.3)	2.9% (0.7, 11.3)	2.9% (0.7, 11.3)
Hypertrophic scarring/ scarring		1.5% (0.2, 10.3)	3.2% (0.8, 12.3)	3.2% (0.8, 12.3)	3.2% (0.8, 12.3)
Implant malposition		3.0% (0.8, 11.4)	3.0% (0.8, 11.4)	3.0% (0.8, 11.4)	8.0% (3.0, 20.5)
Implant palpability/visibility		1.5% (0.2, 10.3)	1.5% (0.2, 10.3)	1.5% (0.2, 10.3)	4.2% (1.0, 16.5)
Implant rupture	MRI cohort	0	14.3% (4.8, 38.0)	19.6% (7.8, 44.4)	19.6% (7.8, 44.4)
	Non-MRI cohort	0	5.0% (0.7, 30.5)	5.0% (0.7, 30.5)	5.0% (0.7, 30.5)
Infection		4.5% (1.5, 13.3)	4.5% (1.5, 13.3)	8.5% (3.6, 19.5)	8.5% (3.6, 19.5)
Nipple complications		1.7% (0.2, 11.2)	1.7% (0.2, 11.2)	1.7% (0.2, 11.2)	1.7% (0.2, 11.2)
Redness		2.9% (0.7, 11.3)	2.9% (0.7, 11.3)	4.9% (1.6, 14.7)	4.9% (1.6, 14.7)
Seroma		4.4% (1.5, 13.1)	6.2% (2.4, 15.8)	6.2% (2.4, 15.8)	6.2% (2.4, 15.8)
Swelling		1.5% (0.2, 10.0)	3.2% (0.8, 12.4)	3.2% (0.8, 12.4)	3.2% (0.8, 12.4)
Tissue/Skin Necrosis		1.5% (0.2, 10.0)	1.5% (0.2, 10.0)	1.5% (0.2, 10.0)	1.5% (0.2, 10.0)
Upper pole fullness		1.5% (0.2, 10.1)	1.5% (0.2, 10.1)	1.5% (0.2, 10.1)	1.5% (0.2, 10.1)
Wrinkling/Rippling		7.7% (3.3, 17.4)	7.7% (3.3, 17.4)	7.7% (3.3, 17.4)	12.8% (6.1, 25.6)
Other complications[d]		1.7% (0.2, 11.4)	1.7% (0.2, 11.4)	3.6% (0.9, 13.8)	3.6% (0.9, 13.8)

[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: breast/skin sensation changes, capsule calcification, gel fracture, irritation, hematoma, implant extrusion, lymphadenopathy, lymphedema, palpable orientation mark, pneumothorax, ptosis, skin rash

[c] 46 revision-reconstruction patients experienced at least one complication

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

Table 11: Main Reasons for Reoperation for Primary Augmentation Cohort

Main Reason for Reoperation[a]	Year 3	Year 5	Year 7	Year 10
	N= 72 Reoperations in 59 Patients	N= 96 Reoperations in 78 Patients	N=128 Reoperations in 102 Patients	N=167 Reoperations in 132 Patients
Asymmetry	4 (5.6%)	4 (4.2%)	4 (3.1%)	5 (3.0%)
Biopsy	0	6 (6.3%)	10 (7.8%)	14 (8.4%)
Breast cancer	1 (1.4%)	4 (4.2%)	4 (3.1%)	8 (4.8%)
Breast Mass/Cyst/Lump	4 (5.6%)	0	0	0
Breast pain	0	0	1 (0.8%)	2 (1.2%)
Breast tissue contour deformity	0	0	2 (1.6%)	2 (1.2%)
Capsular contracture	5 (6.9%)	7 (7.3%)	13 (10.2%)	19 (11.4%)
Delayed wound healing	3 (4.2%)	3 (3.1%)	4 (3.1%)	4 (2.4%)
Gel fracture	1 (1.4%)	1 (1.0%)	1 (0.8%)	1 (0.6%)
Hematoma/seroma	9 (12.5%)	9 (9.4%)	12 (9.4%)	12 (7.2%)
Implant extrusion	2 (2.8%)	1 (1.0%)	1 (0.8%)	1 (0.6%)
Implant malposition	13 (18.1%)	14 (14.6%)	15 (11.7%)	17 (10.2%)
Implant rupture (suspected)	0	3 (3.1%)	8 (6.3%)	19 (11.4%)
Infection	2 (2.8%)	4 (4.2%)	4 (3.1%)	4 (2.4%)
Nipple complications (unplanned)	1 (1.4%)	1 (1.0%)	1 (0.8%)	1 (0.6%)
Patient request for style/size change	12 (16.7%)	17 (17.7%)	21 (16.4%)	22 (13.2%)
Ptosis	6 (8.3%)	9 (9.4%)	11 (8.6%)	13 (7.8%)
Scarring/hypertrophic scarring	9 (12.5%)	12 (12.5%)	15 (11.7%)	15 (9.0%)
Wrinkling	0	1 (1.0%)	1 (0.8%)	1 (0.6%)

[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 12: Main Reasons for Reoperation for Revision-Augmentation Cohort

Main Reason for Reoperation[a]	Year 3	Year 5	Year 7	Year 10
	N=40 Reoperations in 31 Patients	N=60 Reoperations in 45 Patients	N=70 Reoperations in 55 Patients	N=83 Reoperations in 67 Patients
Asymmetry	2 (5.0%)	3 (5.0%)	4 (5.7%)	4 (4.8%)
Biopsy	4 (10.0%)	6 (10.0%)	8 (11.4%)	11 (13.3%)
Breast pain	1 (2.5%)	2 (3.3%)	3 (4.3%)	3 (3.6%)
Capsular contracture	6 (15.0%)	9 (15.0%)	9 (12.9%)	12 (14.5%)
Delayed wound healing	1 (2.5%)	1 (1.7%)	1 (1.4%)	1 (1.2%)
Hematoma/seroma	3 (7.5%)	3 (5.0%)	3 (4.3%)	3 (3.6%)
Implant extrusion	0	1 (1.7%)	1 (1.4%)	1 (1.2%)
Implant malposition	5 (12.5%)	10 (16.7%)	11 (15.7%)	12 (14.5%)
Implant palpability/visibility	1 (2.5%)	1 (1.7%)	1 (1.4%)	1 (1.2%)
Implant rupture (suspected)	1 (2.5%)	3 (5.0%)	6 (8.6%)	10 (12.0%)
Infection	3 (7.5%)	4 (6.7%)	4 (5.7%)	4 (4.8%)
Patient request for style/size change	1 (2.5%)	4 (6.7%)	6 (8.6%)	7 (8.4%)
Ptosis	5 (12.5%)	6 (10.0%)	6 (8.6%)	7 (8.4%)
Scarring/hypertrophic scarring	7 (17.5%)	7 (11.7%)	7 (10.0%)	7 (8.4%)

[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 13: Main Reasons for Reoperation for Reconstruction Cohort

Main Reason for Reoperation[a]	Year 3	Year 5	Year 7	Year 10
	N= 89 Reoperations in 69 Patients	N= 113 Reoperations in 86 Patients	N=129 Reoperations in 97 Patients	N=163 Reoperations in 115 Patients
Asymmetry	4 (4.5%)	7 (6.2%)	9 (7.0%)	13 (8.0%)
Biopsy	0	4 (3.5%)	7 (5.4%)	12 (7.4%)
Breast cancer	0	1 (0.9%)	2 (1.6%)	4 (2.5%)
Breast Mass/Cyst/Lump	1 (1.1%)	0	0	0
Breast pain	2 (2.2%)	3 (2.7%)	3 (2.3%)	4 (2.5%)
Breast tissue contour deformity	5 (5.6%)	5 (4.4%)	5 (3.9%)	5 (3.1%)
Capsular contracture	8 (9.0%)	14 (12.4%)	16 (12.4%)	20 (12.3%)
Hematoma/seroma	2 (2.2%)	2 (1.8%)	3 (2.3%)	3 (1.8%)
Implant extrusion	2 (2.2%)	2 (1.8%)	2 (1.6%)	2 (1.2%)
Implant malposition	13 (14.6%)	14 (12.4%)	16 (12.4%)	20 (12.3%)
Implant rupture (suspected)	1 (1.1%)	4 (3.5%)	7 (5.4%)	16 (9.8%)
Infection	8 (9.0%)	9 (8.0%)	9 (7.0%)	9 (5.5%)
Necrosis	1 (1.1%)	1 (0.9%)	1 (0.8%)	1 (0.6%)
Patient request for style/size change	11 (12.4%)	12 (10.6%)	12 (9.3%)	12 (7.4%)
Ptosis	5 (5.6%)	5 (4.4%)	6 (4.7%)	6 (3.7%)
Scarring/hypertrophic scarring	24 (27.0%)	27 (23.9%)	28 (21.7%)	31 (19.0%)
Wrinkling	2 (2.2%)	3 (2.7%)	3 (2.3%)	3 (1.8%)

[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 14: Main Reasons for Reoperation for Revision-Reconstruction Cohort

Main Reason for Reoperation[a]	Year 3	Year 5	Year 7	Year 10
	N= 16 Reoperations in 13 Patients	N= 24 Reoperations in 19 Patients	N=31 Reoperations in 25 Patients	N=40 Reoperations in 31 Patients
Asymmetry	1 (6.3%)	2 (8.3%)	2 (6.5%)	2 (5.0%)
Biopsy	0	1 (4.2%)	1 (3.2%)	2 (5.0%)
Breast tissue contour deformity	0	0	0	1 (2.5%)
Capsular contracture	4 (25.0%)	4 (16.7%)	7 (22.6%)	9 (22.5%)
Delayed wound healing	3 (18.8%)	3 (12.5%)	3 (9.7%)	3 (7.5%)
Gel fracture	1 (6.3%)	0	0	0
Hematoma/seroma	1 (6.3%)	1 (4.2%)	1 (3.2%)	1 (2.5%)
Implant malposition	2 (12.5%)	3 (12.5%)	3 (9.7%)	4 (10.0%)
Implant rupture (suspected)	1 (6.3%)	0	1 (3.2%)	3 (7.5%)
Infection	1 (6.3%)	1 (4.2%)	3 (9.7%)	3 (7.5%)
Nipple complications (unplanned)	0	2 (8.3%)	2 (6.5%)	2 (5.0%)
Patient request for style/size change	1 (6.3%)	4 (16.7%)	3 (9.7%)	4 (10.0%)
Scarring/hypertrophic scarring	0	1 (4.2%)	1 (3.2%)	1 (2.5%)
Wrinkling	1 (6.3%)	2 (8.3%)	2 (6.5%)	3 (7.5%)
Other	0	0	2 (6.5%)	2 (5.0%)

[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 15: Main Reasons for Implant Removal for Augmentation Cohort

Main Reason for Implant Removal[a]	Year 3	Year 5	Year 7	Year 10
	N= 44 Explants in 25 Patients	N= 68 Explants in 38 Patients	N= 99 Explants in 56 Patients	N=153 Explants in 84 Patients
Asymmetry	6 (13.6%)	6 (8.8%)	6 (6.1%)	7 (4.6%)
Biopsy	0	1 (1.5%)	1 (1.0%)	1 (0.7%)
Breast cancer	0	0	0	3 (2.0%)
Breast pain	0	0	1 (1.0%)	3 (2.0%)
Breast tissue contour deformity	0	0	4 (4.0%)	4 (2.6%)
Capsular contracture	2 (4.6%)	2 (2.9%)	8 (8.1%)	15 (9.8%)
Gel fracture	1 (2.3%)	1 (1.5%)	1 (1.0%)	1 (0.7%)
Hematoma/seroma	2 (4.6%)	2 (2.9%)	4 (4.0%)	4 (2.6%)
Implant extrusion	1 (2.3%)	1 (1.5%)	1 (1.0%)	1 (0.7%)
Implant malposition	2 (4.6%)	2 (2.9%)	4 (4.0%)	7 (4.6%)
Implant rupture (suspected)	0	4 (5.9%)	8 (8.1%)	21 (13.7%)
Infection	2 (4.6%)	3 (4.4%)	3 (3.0%)	3 (2.0%)
Patient request for style/size change	22 (50.0%)	35 (51.5%)	46 (46.5%)	52 (34.0%)
Ptosis	4 (9.1%)	10 (14.7%)	10 (10.1%)	17 (11.1%)
Wrinkling	0	1 (1.5%)	1 (1.0%)	1 (0.7%)

[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 16: Main Reasons for Implant Removal for Revision-Augmentation Cohort

Main Reason for Implant Removal[a]	Year 3	Year 5	Year 7	Year 10
	N=27 Explants in 16 Patients	N= 47 Explants in 27 Patients	N=60 Explants in 34 Patients	N=43 Explants in 38 Patients
Asymmetry	2 (7.4%)	4 (8.5%)	5 (8.3%)	5 (6.4%)
Breast pain	2 (7.4%)	2 (4.3%)	3 (5.0%)	3 (3.9%)
Capsular contracture	7 (25.9%)	11 (23.4)	12 (20.0%)	18 (23.1%)
Implant extrusion	0	1 (2.1%)	1 (1.7%)	1 (1.3%)
Implant malposition	4 (14.8%)	6 (12.8%)	6 (10.0%)	7 (9.0%)
Implant palpability/visibility	2 (7.4%)	2 (4.3%)	2 (3.3%)	2 (2.6%)
Implant rupture (suspected)	1 (3.7%)	3 (6.4%)	8 (13.3%)	13 (16.7%)
Infection	3 (11.1%)	4 (8.5%)	4 (6.7%)	4 (5.1%)
Patient request for style/size change	3 (11.1%)	11 (23.4%)	16 (26.7%)	19 (24.4%)
Ptosis	2 (7.4%)	2 (4.3%)	2 (3.3%)	4 (5.1%)
Scarring/hypertrophic scarring	1 (3.7%)	1 (2.1%)	1 (1.7%)	1 (1.3%)

[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 17: Main Reasons for Implant Removal for Reconstruction Cohort

Main Reason for Implant Removal[a]	Year 3	Year 5	Year 7	Year 10
	N= 49 Explants in 36 Patients	N= 68 Explants in 49 Patients	N=87 Explants in 61 Patients	N=115 Explants in 78 Patients
Asymmetry	in 36 Patients	N=68 Explants	10 (11.5%)	13 (11.3%)
Breast cancer	in 49 Patients	N=87 Explants	1 (1.2%)	2 (1.7%)
Breast pain	in 61 Patients	N=115 Explants	4 (4.6%)	4 (3.5%)
Breast tissue contour deformity	in 78 Patients	1 (1.5%)	1 (1.2%)	1 (0.9%)
Capsular contracture	5 (10.2%)	11 (16.2%)	13 (14.9%)	18 (15.7%)
Hematoma/seroma	1 (2.0%)	1 (1.5%)	2 (2.3%)	2 (1.7%)
Implant extrusion	2 (4.1%)	2 (2.9%)	2 (2.3%)	2 (1.7%)
Implant malposition	5 (10.2%)	5 (7.4%)	9 (10.3%)	13 (11.3%)
Implant rupture (suspected)	0	2 (2.9%)	5 (5.8%)	17 (14.8%)
Infection	5 (10.2%)	6 (8.8%)	6 (6.9%)	6 (5.2%)
Patient request for style/size change	15 (30.6%)	22 (32.4%)	26 (29.9%)	24 (20.9%)
Ptosis	1 (2.0%)	1 (1.5%)	2 (2.3%)	2 (1.7%)
Wrinkling	3 (6.1%)	5 (7.4%)	5 (5.8%)	6 (5.2%)

[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 18: Main Reasons for Implant Removal for Revision-Reconstruction Cohort

Main Reason for Implant Removal[a]	Year 3	Year 5	Year 7	Year 10
	N= 15 Explants in 10 Patients	N= 19 Explants in 12 Patients	N=28 Explants in 18 Patients	N=40 Explants in 26 Patients
Asymmetry	0	1 (5.3%)	1 (3.6%)	1 (2.5%)
Breast tissue contour deformity	0	0	0	1 (2.5%)
Capsular contracture	3 (20.0%)	3 (15.8%)	6 (21.4%)	10 (25.0%)
Delayed wound healing	1 (6.7%)	1 (5.3%)	1 (3.6%)	1 (2.5%)
Gel fracture	1 (6.7%)	0	0	0
Implant malposition	2 (13.3%)	2 (10.5%)	2 (7.1%)	3 (7.5%)
Implant rupture (suspected)	2 (13.3%)	0	1 (3.6%)	3 (7.5%)
Infection	1 (6.7%)	1 (5.3%)	3 (10.7%)	3 (7.5%)
Patient request for style/size change	3 (20.0%)	7 (36.8%)	7 (25.0%)	8 (20.0%)
Wrinkling	2 (13.3%)	4 (21.1%)	4 (14.3%)	6 (15.0%)

[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.

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 through 10 years.

CTD Diagnoses

Three Primary Augmentation patients (0.6%) were reported to have a new CTD diagnosis through 10 years. One had a diagnosis of sclerosis/scleroderma, one of Graves disease, and one of positive ANA-specific diagnosis at 1, 72, and 77 months after implantation, respectively. Through 10 years, 3 Revision-Augmentation patients (1.9%) were reported to have a new diagnosis of fibromyalgia (one patient at 46 months and the other at 84 months) and Hashimoto thyroiditis (at 30 months). There were 2 Primary Reconstruction patients (0.9%) who reported CTDs through 10 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. Through 10 years, 1 Revision-Reconstruction patient (1.5%)

reported a new diagnosis of rheumatoid arthritis at 98 months after implantation. 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. Statistically significant increases were found for Primary Reconstruction patients in the symptom category of Pain and Fatigue. For Primary Augmentation, Revision Augmentation, and 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 9 Primary Augmentation patients (1.9%) with a new diagnosis of breast cancer through 10 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 10 years and 1 patient report of bladder cancer and 1 patient report of multiple myeloma.

There were 17 Reconstruction patients (7.6%) with recurrence of breast cancer through 10 years, 1 report of Non-Hodgkin's lymphoma and 1 report of uterine cancer. There were no Revision-Reconstruction patients who reported a recurrence of breast cancer through 10 years and no reports of other cancers in Revision-Reconstruction patients.

One Reconstruction patient in the pivotal study was reported with ALCL through 10 years.

Lactation Complications

Ten (22.7%) of the 44 Primary Augmentation patients who attempted to breastfeed following breast implantation in the pivotal study through 10 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 (33.3%) 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 10 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 10 years, most commonly miscarriage. Two Revision-Augmentation patients (1.3%) experienced a reproduction problem (miscarriage and hysterectomy) through 10 years. One Primary Reconstruction patient (0.4%) and 1 revision-reconstruction patient (1.5%) reported a reproduction problem through 10 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 19** includes information by cohort through 10 years.

Table 19: 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	6	3	2	1
Reconstruction	3	1	1	1
Revision-Reconstruction	2	1	0	1

Detection of Breast Implant Rupture: MRI

Through 10 years, 153 patients had pre-explant MRIs and subsequent device explantation. Seventy-one (71) of these patients underwent MRI as part of the MRI cohort, while 82 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 20**. Sensitivity is the MRI's success in correctly identifying ruptured implants, and specificity is the success in correctly identifying non-ruptured implants.

Table 20: 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	33	8
MRI Indeterminate	0	7[a]
MRI Showed No Rupture	13[b]	208
MRI Sensitivity		
Best Case	86.8% (71.9%, 95.6%)	
Worst Case	71.7% (56.5%, 84.0%)	
MRI Specificity		
Best Case	96.3% (92.8%, 98.4%)	
Worst Case	93.3% (89.2%, 96.2%)	

[a] The 7 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 n 8 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 8 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:

- 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 Warranty

The ***ConfidencePlus***® Limited Warranty provides 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. Our standard ***ConfidencePlus***® Premier Limited Warranty program applies automatically to every Allergan ***NATRELLE***® 410 breast implant recipient 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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