

Directions for Use

S T Y L E

410

SILICONE-FILLED
BREAST IMPLANTS



ALLERGAN

The Science of Rejuvenation™

Caution: Investigational device. Limited by Federal (or United States) law to investigational use.

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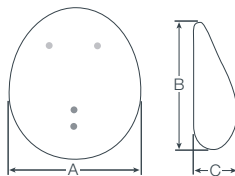
Styles Included

STYLE 410

Silicone-Filled Breast Implant
BIOCELL®

Shaped

Various height and projection
combinations are available.



Style 410

A = Width
B = Height
C = Projection

Description

The ALLERGAN™ Style 410 Silicone-Filled Breast Implant Matrix consists of implants with varying heights and projections to complement individual patient height, weight and body shape. Manufactured with our patented barrier technology silicone shell, each ALLERGAN™ Style 410 silicone filled breast implant incorporates the BIOCELL® surface texture to provide mild tissue adherence to help maintain implant positioning within the surgical pocket. The ALLERGAN™ Style 410 Silicone-Filled Breast Implant contains a more cohesive gel than previous silicone-filled breast implants and is designed to allow the implant to maintain its shape while simulating the look and feel of natural breast tissue.

Design Features

- BIOCELL® textured surface promotes mild tissue adherence which helps maintain implant position within the surgical pocket and may reduce capsular contracture.
- Patented barrier shell to minimize silicone diffusion through the implant shell.
- Implant fill weight indicated on the shell.
- Multiple shapes, each available in a variety of sizes, designed to provide lateral breast fullness with selective control over implant height/upper breast fullness, and implant projection/lower breast projection to meet a wide range of patient needs.
- A more cohesive silicone fill designed to simulate the look and feel of natural breast tissue, while maintaining its shape.
- Circular, silicone elastomer orientation marks on the anterior and posterior surfaces of the implant designed to assist in visual and tactile placement within the surgical pocket.

Inclusion Criteria

Patients will be eligible for inclusion in the study if surgery has been recommended by their physician and they meet the Patient Inclusion Criteria outlined in the Study Protocol.

Exclusion Criteria

Patients who have any of the characteristics in the Patient Exclusion Criteria outlined in the Study Protocol.

Information To Be Provided to the Patient

Patient Counseling Information

Sections of this package insert indicated by **“Patient Counseling Information”** contain points that the physician should consider when counseling the patient about this device.

Patient Counseling Information: Breast implant surgery is known to provide satisfaction to patients. Nevertheless, as with any surgical procedure, it is not without risks. Breast implantation is an elective procedure and the patient must be well-counseled on the risk/benefit relationship.

Warnings, Precautions, Adverse Reactions

Patient Counseling Information: Before the decision to proceed with surgery, the physician should inform the patient of the warnings, precautions, and adverse reactions listed in this package insert. The physician should advise the patient that medical management of serious adverse reactions may include explantation.

Informed Consent

Patient Counseling Information: Each patient must read, understand, sign and date a Patient Informed Consent form. Each form contains important information on the benefits and possible risks of silicone-filled breast implant surgery.

Device Identification Card

Also enclosed with each ALLERGAN™ Style 410 Silicone-Filled Breast Implant is a Device Identification Card. To complete the Device Identification Card, place one device identification sticker for each implant on the back of the card. Stickers are located on the internal product packaging attached to the label. If a sticker is unavailable, the lot number, catalog number and description of the device may be copied by hand from the device label. Patients should be provided with these cards for personal reference.

Warnings

1. Closed Capsulotomy

DO NOT treat capsular contracture by external compression or massage, which may result in implant damage, rupture, folds, and/or hematoma.

2. Alteration

DO NOT alter the implants. Any alteration to the original design and fabrication voids all warranties, express or implied.

3. Reuse

DO NOT reuse explanted products. Breast Implants are intended for single use only.

4. Interference with Standard Mammography

Patient Counseling Information: DO NOT rely on standard mammographic positioning and screening techniques, which have shown significant limitations when used for imaging augmented breasts. Breast implants may complicate the interpretation of mammographic images by obscuring some underlying breast tissue, and/or by compressing overlying tissue. Special mammographic guidelines are discussed in *Preoperative and Postoperative Mammography* under PRECAUTIONS.

5. Pre-existing Infection

Pre-existing infection anywhere in the body must be treated and resolved before implant surgery. Untreated pre-existing infections increase the risk of periprosthetic infections. Patients who present with wound dehiscence, tissue erosion, ischemia or necrosis run an increased risk of periprosthetic infection. Measures to protect such areas from infection should be taken.

6. Signs of Infection

Signs of acute infection reported in association with breast implants include erythema, tenderness, fluid accumulation, pain and fever. Signs of subclinical infection may be difficult to detect. Postoperative infections should be treated aggressively according to standard medical practices to avoid more serious complications. Infection that is unresponsive to treatment or necrotizing infection may require implant removal.

Toxic Shock Syndrome (TSS) has been reported as a complication of breast implant surgery and may be associated with other types of implants. Symptoms of toxic shock include, but are not limited to, sudden fever, vomiting, diarrhea, fainting, dizziness and/or a sunburn-like rash.

Warnings (continued)

7. *Explantation*

Patient Counseling Information: Patients should be advised not to consider their implants lifetime devices; explant and replacement surgery may be indicated when complications arise. Medical management of adverse reactions may include explantation. Revision surgery for explantation and replacement may also be indicated to achieve patient satisfaction, as discussed in *Dissatisfaction with Cosmetic Results*, below.

8. *Smoking*

Patient Counseling Information: Patients should be informed that smoking may interfere with the healing process.

9. *Dissatisfaction with Cosmetic Results*

Patient Counseling Information: Patients should be informed that dissatisfaction with cosmetic results related to such things as scar deformity, hypertrophic scarring, asymmetry, displacement, incorrect size, unanticipated contour, and palpability may occur. Careful surgical planning and technique can minimize, but not preclude, the risk of such results. Pre-existing asymmetry may not be entirely correctable. Physiological and behavioral differences among patients and variations in surgical techniques and medical treatments account for a wide variety of responses to silicone-filled breast implant surgery. Revision surgery may be indicated to maintain patient satisfaction, but carries additional considerations and risks.

See also *Dissatisfaction with Cosmetic Results*, under ADVERSE REACTIONS.

Precautions

1. *Preoperative and Postoperative Mammography*

Patient Counseling Information: The physician should discuss with the patient the potential risks and benefits of preoperative and postoperative mammography as baselines for future reference.

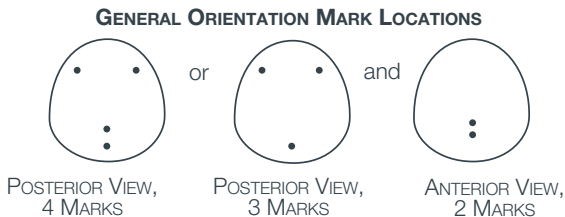
Patients should also be instructed to:

- Have mammographies and other radiologic testing performed only at centers accredited by the American College of Radiology;
- Request radiologists who are experienced with the most current radiological techniques and equipment for imaging breasts with implants;
- Request diagnostic mammography, rather than screening mammography;

Precautions (continued)

1. Preoperative and Postoperative Mammography (continued)

- Inform their radiologists of the presence, type, and placement of implants; and
- Inform their radiologists of the presence and locations of the orientation marks on their ALLERGAN™ Style 410 Silicone-Filled Breast Implants. The circular, silicone elastomer orientation marks are provided to assist the physician with visual and tactile placement of the implant within the surgical pocket. These marks may be visible on mammographic images. The posterior surface of most sizes of ALLERGAN™ Style 410 Silicone-Filled Breast Implants has (4) orientation marks; the posterior surface of some smaller and/or shorter styles may have only three (3) orientation marks, as shown below. The anterior surface of all ALLERGAN™ Style 410 implants has two (2) orientation marks, as shown below. Diligent use of displacement techniques and extra tangential images increases the proportion of breast tissue visualized. Ultrasound may be a useful adjunct to mammography because it does not require compression and allows examination from virtually any angle.



Breast tissue imaging may be improved by submuscular placement of the implant.

Biopsy must be performed in all cases of suspicious lesions.

2. Surgical Planning

The physician must carefully evaluate implant size and contour, incision placement, pocket dissection, and implant placement criteria, with respect to the patient's anatomy and desired physical outcome. Successful surgical enhancement of the breast with breast implants requires meticulous planning and execution. Planning should include clear delineation of aesthetic goals to ensure mutual understanding between physician and patient. The physician should observe current and accepted techniques to minimize the risk of adverse, and potentially disfiguring, reactions. For each implant to be used, a back-up should be readily available.

Precautions (continued)

3. *Avoiding Contamination at Surgery*

To avoid contamination, aseptic technique is essential. DO NOT expose the implant to lint, talc, sponge, towel, skin oils, and other contaminants. Contamination at the time of surgery increases the risk of periprosthetic infection, and possibly, capsular contracture.

To minimize the risk of contamination, follow the recommended procedures described in *Instructions for Use*.

Back-up implants must be readily available at the time of surgery for use in the event of contamination.

4. *Avoiding Damage During Surgery*

Extreme care should be taken to avoid damage to the implant during surgery. Possible sources of damage include sharp surgical instruments, such as scalpels and needles, used during the initial or any subsequent surgery. DO NOT use excessive force during placement of cohesive gel-filled implants. Cohesive gel may be permanently deformed due to over manipulation, resulting in deformation of the implant shape. Products must be carefully inspected for shell damage, such as nicks, prior to use. DO NOT attempt to repair damaged products.

To minimize the risk of damage, follow recommended procedures in *Instructions for Use* for implant handling, examination and placement.

In summary:

- Avoid breast implant contact with surgical instruments such as scalpels, needles, clamps, and forceps;
- Do not alter the breast implant;
- Ensure that the incision length is sufficient to allow implant insertion without excessive distortion or manipulation to avoid deformation of the implant shape;
- Do not use excessive force during breast implant placement.

Patient Counseling Information: Patients should be instructed to inform other treating physicians of the presence of implants to minimize the risk of damage.

5. *Maintaining Hemostasis/Avoiding Fluid Accumulation*

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

Precautions (continued)

5. *Maintaining Hemostasis/Avoiding Fluid Accumulation (continued)*

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

6. *Breast Examination Techniques*

Patient Counseling Information: Patients should be instructed to follow the most current medical recommendations regarding breast examination and mammography frequency appropriate for their age and medical history. To maximize the effectiveness of breast self-examinations for any palpable lesions, patients should be instructed how to distinguish the implant from breast tissue.

7. *Microwave Diathermy*

Any postoperative microwave diathermy therapy must be administered in moderation and with caution. Excessive application of heat has been associated with tissue necrosis, skin thinning, skin erosion, and extrusion of the breast implant.

Adverse Reactions

1. *Capsular Contracture*

Fibrous capsular contracture remains a common complication following breast implant surgery. While capsule formation is a normal physiological response, not all capsules contract. The etiology of capsular contracture is unknown, but is most likely multifactorial. Radiation therapy of the breast subsequent to breast implant surgery may increase the risk of capsular contracture. Contracture develops to varying degrees, unilaterally or bilaterally, and may occur within weeks to years after surgery.

Contracture of the fibrous capsular tissue surrounding the implant may cause a range of symptoms including firmness, discomfort, pain, distortion, palpability, and/or displacement. Although somewhat subjective, the Baker classification system (Grades I-IV) provides a useful standard for describing the degree of contracture. Grades III and IV are generally considered clinically significant, and may require surgical intervention. Capsular contracture may recur subsequent to corrective surgical procedures.

2. *Rupture*

Patient Counseling Information: Patients should be advised that implants may rupture, (i.e., develop a hole or tear in the shell). Shell rupture may result in release of silicone fill. Damage may result in immediate rupture or may weaken the envelope and result in rupture postoperatively.

Adverse Reactions (continued)

2. Rupture (continued)

Breast implants are not lifetime devices and cannot be expected to last forever. Some implants rupture in the first few months after being implanted and some rupture after several years, others are intact 10 or more years after the surgery.

Causes of Rupture Include:

- Damage during surgery by surgical instruments, resulting in nicks, slices, or puncture;
- Other trauma during surgery, such as improper handling or manipulation;
- Capsular contracture;
- Forcible manual external compression to relieve capsular contracture (i.e., closed capsulotomy);
- Stressors such as trauma, intense physical activity, vigorous massage and/or manipulation;
- Excessive compression during mammographic imaging;
- Age of implants: older implants which are exposed to longer wear, potentially more trauma, and may have a less resilient shell design;
- Injury to the breast;
- Unknown/unexplained reasons

When silicone gel-filled implants rupture, some women may notice decreased breast size, nodules (hard knots), uneven appearance of the breasts, pain or tenderness, tingling, swelling, numbness, burning, or changes in sensation. Other women may unknowingly experience a rupture without any symptoms (i.e., “silent rupture”). Magnetic resonance imaging (MRI) with equipment specifically designed for imaging the breast may be used for evaluating patients with suspected rupture or leakage of their silicone gel-filled implant.

Silicone gel, which escapes the fibrotic capsule surrounding the implant, may migrate away from the breast. The free silicone may cause lumps called granulomas to form in the breast or other tissues where the silicone has migrated, such as the chest wall, armpit, arm, or abdomen.

Plastic surgeons usually recommend removal of the implant if it has ruptured, even if the silicone is still enclosed within the scar tissue capsule, because the silicone gel may eventually leak into surrounding tissues. If you are considering the removal of an implant and the implantation of another one, be sure to discuss the benefits and risks with your doctor.

Adverse Reactions (continued)

2. Rupture *(continued)*

FDA completed a retrospective study on rupture of silicone gel-filled breast implants.¹ This study was performed in Birmingham, Alabama and included women who had their first breast implant before 1988. Women with silicone gel-filled breast implants had a MRI examination of their breasts to determine the status of their current breast implants. The 344 women who received a MRI examination had a total of 687 implants. Of the 687 implants in the study, at least two of the three study radiologists agreed that 378 implants were ruptured (55%). This means that 69% of the 344 women had at least one ruptured breast implant. Of the 344 women, 73 (21%) had extracapsular silicone gel in one or both breasts. Factors that were associated with rupture included increasing age of the implant, the implant manufacturer, and submuscular rather than subglandular location of the implant. A summary of the findings of this study is also available on FDA's website at <http://www.fda.gov/cdrh/breastimplants/studies/biinterview.pdf> and <http://www.fda.gov/cdrh/breastimplants/studies/birupture.pdf>.

Robinson et al. studied 300 women who had their implants for 1 to 25 years and had them removed for a variety of reasons.² Visible signs of rupture in 51% of the women studied were found. Severe silicone leakage (silicone outside the implant without visible tears or holes) was seen in another 20%. Robinson et al. also noted that the chance of rupture increases as the implant ages.

Other studies indicate that silicone may escape the capsule in 11–23% of rupture cases.^{3,4,5,6}

¹ Brown SL, Middleton MS, Berg WA, Soo MS, Pennello G. Prevalence of rupture of silicone gel breast implants in a population of women in Birmingham, Alabama. *American Journal of Roentgenology* 2000;175:1-8.

² Robinson OG, Bradley EL, Wilson DS. Analysis of explanted silicone implants: a report of 300 patients. *Ann Plast Surg.* 1995; 34:1-7.

³ Vinnik CA. Migratory silicon - clinical aspects. *Silicone in Medical Devices - Conference Proceedings.* 1991 February 1-2; Baltimore, MD: U.S. Department of Health and Human Services, FDA Publication No. 92-4249 (p.59-67).

⁴ Duffy MJ, Woods JE. Health risks of failed silicone gel breast implants: a 30-year clinical experience. *Plast Reconstr Surg* 1994;94:295-299.

⁵ Berg WA, Caskey CI, Hamper UM, Kuhlman JE, Anderson ND, Chang BW, Sheth S, Zerhouni EA. Single- and double-lumen silicone breast implant integrity: Prospective evaluation of MR and US criteria. *Radiology* 1995;197:45-52.

⁶ Gorczyca DP, Schneider E, DeBruhl ND, Foo TKF, Ahn CY, Sayre JW, Shaw WW, Bassett LW. Silicone breast implant rupture: Comparison between three-point Dixon and fast spin-echo MR imaging. *AJR* 1994;162:305-310.

Adverse Reactions (continued)

3. Infection

Pre-existing infections not resolved before implant placement increase the risk of periprosthetic infection.

Infection is an inherent risk following any type of invasive surgery. Infection around a breast implant may occur within days, weeks, or even years after surgery. Patients who present with wound dehiscence, tissue erosion, ischemia or necrosis run an increased risk of periprosthetic infection. Signs of acute infection reported in association with breast implants include erythema, tenderness, fluid accumulation, pain and fever. Signs of subclinical infection may be difficult to detect. The source of infection may be endogenous flora or bacteria introduced during surgery.

Research identifies *Staphylococcus* organisms as the most common type associated with breast implant infection. Acute infection around breast implants occurs infrequently after augmentation, with slightly higher rates associated with reconstruction. Postoperative infections should be treated aggressively according to standard medical practices to avoid more serious complications. Infection that is unresponsive to treatment may require implant removal.

Toxic Shock Syndrome (TSS) has been reported as a complication of breast implant surgery and may be associated with other types of implants. Symptoms of toxic shock include, but are not limited to, sudden fever, vomiting, diarrhea, fainting, dizziness and/or a sunburn-like rash. Capsular contracture may be related to infection in the area surrounding the implant. See also *Signs of Infection* under WARNINGS.

4. Necrosis

Necrosis may inhibit wound healing and require surgical correction and/or explantation. Infection may or may not accompany necrosis. Permanent scar deformity may occur as a result of necrosis. Other factors associated with necrosis include contamination, placement despite unsuitable skin flap, wound dehiscence, ischemia, atrophy associated with the use of steroids in the surgical pocket, smoking, and excessive heat and cold therapy.

Patient Counseling Information: Patients should be aware that smoking may interfere with the healing process.

5. Hematoma/Seroma

Postoperative hematoma and seroma may contribute to infection and/or capsular contracture. Postoperative hematoma and seroma may be minimized by meticulous attention to hemostasis during surgery, and possibly by postoperative use of a closed drainage system. Persistent, excessive bleeding must be controlled before

Adverse Reactions (continued)

5. Hematoma/Seroma (continued)

the device is implanted. Any postoperative evacuation of hematoma or seroma must be conducted with care to avoid damage to the breast implant.

6. Extrusion

Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion of the breast implant through the skin. Extrusion has been reported as an infrequent complication for both augmentation and reconstruction patients. Causes or contributing factors may include infection, wound dehiscence, necrosis with or without infection, capsular contracture, closed capsulotomy, unsuitable skin flap, improper size and placement of breast implant, and/or tissue erosion associated with implant folds.

7. Wrinkling and Folds

Thin or inadequate overlying tissue and subcutaneous placement may also contribute to the degree of palpability and visibility of wrinkling and folds. Folds may result in thinning and erosion of adjacent tissue, and possible extrusion of the breast implant. Folds may also result in crease-fold failure and rupture of the breast implant shell. Signs of skin inflammation, such as tenderness and erythema, may indicate thinning or erosion and must be promptly investigated. See also *Dissatisfaction with Cosmetic Results–Palpability*, on page 14.

8. Explantation

Medical management of adverse reactions may require surgical intervention, including revision surgery for explantation and replacement of the implant to achieve patient satisfaction, as discussed in *Dissatisfaction with Cosmetic Results*, on page 13.

9. Interference with Standard Mammography

Breast implants may complicate the interpretation of mammographic images by obscuring some underlying breast tissue, and/or by compressing overlying tissue. ALLERGAN™ Style 410 Silicone-Filled Breast Implants have orientation marks that may be visible on mammographic images, further complicating image interpretation. Standard positioning techniques have shown significant limitations when used for imaging augmented breasts.

Microcalcification of the periprosthetic capsule may simulate or obscure microcalcification associated with early breast carcinoma, and require special mammographic attention. See also *Calcification*, on page 14.

Adverse Reactions (continued)

9. Interference with Standard Mammography (continued)

Patient Counseling Information: Patients should be instructed to request radiologists who are experienced with the most current radiological techniques and equipment for imaging breasts with implants, and to inform their radiologists of the presence, type, and placement of implants.

Patients who present with capsular contracture may find the mammographic displacement and compression techniques painful, and the difficulty of mammographic imaging will increase with the grade of contracture.

10. Pain

As expected following any invasive surgical procedure, pain of varying intensity and duration may occur following implantation. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. Pain may also accompany other adverse reactions. Unexplained pain must be promptly investigated.

11. Decreased Sensation

The risk of temporary or permanent dysesthesia exists following any invasive surgical procedure. Careful surgical technique can minimize, but not preclude, this risk. Dysesthesia of the nipple/areolar complex, and less frequently, the breast area in general, has been reported following implantation, and may be temporary or permanent. The risk of neurological impairment increases with more extensive surgery.

12. Dissatisfaction with Cosmetic Results

Patient Counseling Information: Dissatisfying results such as scar deformity, hypertrophic scarring, asymmetry, displacement, incorrect size, unanticipated contour and palpability may occur. In some cases, cosmetic concerns may also lead to medical concerns. Careful surgical planning and technique can minimize, but not preclude, the risk of such results.

- **Displacement**

Displacement of a breast implant may be accompanied by discomfort and/or distortion in breast shape. Difficult placement techniques may increase the risk of displacement by reducing pocket size and placement accuracy. Displacement may require surgical intervention.

- **Asymmetry**

Asymmetry may result from improper initial placement, displacement, or failure to correct pre-existing asymmetry through variation in individual implant size. Pre-existing asymmetry may not be entirely correctable. Asymmetry may also be a

Adverse Reactions (continued)

12. Dissatisfaction with Cosmetic Results (continued)

symptom of capsular contracture, fluid accumulation, infection, postoperative breast dysplasia, unilateral discrepancy in muscle development, requiring further investigation.

- ***Palpability***

Patients may be able to feel the breast implant, wrinkling and/or folds. Palpability increases with unsuitably large or misplaced breast implants. Thin or inadequate overlying tissue and subcutaneous placement also contribute to the degree of palpability. Folds may lead to medical complications such as tissue thinning, erosion, or extrusion, as discussed above under *Wrinkling and Folds*. Palpable wrinkling and/or folds may be confused with palpable tumor, and questionable cases must be promptly investigated.

- ***Ptois***

Ptois occurs naturally in all breasts over time. Factors such as skin elasticity, muscle tone, and the size and placement of the breast implant may determine the onset and degree of this result. Periprosthetic use of steroids has been reported to cause atrophy and thinning of subcutaneous tissues, resulting in ptois.

13. Calcification

Calcification commonly occurs in mature breast tissue with or without breast implants. Calcification is also known to occur after implantation of a foreign body, although the etiology is unknown, but reported cases are rare. Microcalcification after implantation typically occurs on or around the fibrous capsule in thin plaques or accumulations. Extensive microcalcification may cause breast hardness and discomfort, and may necessitate surgical intervention.

Microcalcification of the periprosthetic capsule may simulate or obscure microcalcification associated with early breast carcinoma, and require special mammographic attention. Although the benign capsular microcalcifications are generally coarser and more extensive, they may be difficult to distinguish from malignant, or potentially malignant, microcalcifications. Submuscular placement may improve mammographic results. See also *Interference with Standard Mammography*, on page 12.

14. Breast Tissue Atrophy/Chest Wall Deformity

The pressure of the breast implant may cause breast tissue atrophy, which may be especially evident in the event of explantation without breast implant replacement. Chest wall deformity has also been reported in rare cases in association with the use of breast implants.

Adverse Reactions (continued)

15. Silicone Diffusion

Minute quantities of silicone may diffuse through the intact shell of the breast implant. The detection of small quantities of silicone in the periprosthetic capsule, axillary lymph nodes, and other distal regions in patients with apparently unruptured, conventional silicone-filled breast implants has been reported. In general, detection of minute quantities of silicone, in women with and without breast implants, remains an incidental finding of no proven significance.

Research on Silicone Implants

Patient Counseling Information: Questions have been raised regarding various potential long-term effects of silicone breast implants. This research is relevant to silicone-filled breast implants. The following information is presented to provide general safety information that may directly or indirectly apply to silicone-filled breast implant use.

- ***Tumorigenicity***

Investigators examining recent rates of tumorigenesis, or sarcomas of the breast provided by the National Cancer Institute, have seen no increased risk of sarcomas among women with breast implants, even after a ten-year latency period.

- ***Carcinogenicity***

At this time there is no scientific evidence that silicone-filled breast implants can increase the risk of cancer in women. However, this possibility cannot be completely ruled out. Average follow-up time of completed studies in women have been too short to be fully conclusive.

- ***Teratogenicity***

A review of the published literature indicates that studies in animals that have evaluated silicone materials for birth defects or other reproductive effect have shown a lack of teratogenic activity.

- ***Connective Tissue and Related Disorders***

There has been continuing concern that there may be a relationship between breast implants and connective tissue disorders. These disorders include autoimmune diseases such as lupus, scleroderma, and rheumatoid arthritis, as well as disorders such as fibromyalgia and chronic fatigue syndrome. Some women with breast implants have experienced these disorders, as well as a variety of symptoms that

Research on Silicone Implants (continued)

Connective Tissue and Related Disorders (continued)

could be related to the immune system. These symptoms include pain and swelling of the joints, tightness, redness or swelling of the skin, swollen glands or lymph nodes, unusual and unexplained fatigue, swelling of the hands and feet, excessive hair loss, memory problems, headaches, and muscle weakness or burning. However, symptoms such as these may be present in persons **without** connective tissue disease, or without breast implants. It is unclear at this time whether the signs and symptoms experienced by these women are related to their implants. Several human studies have been completed recently, which provide substantial, but not complete, information about any possible link between breast implants and immune-related disorders. These studies provide reassurance that the risk of developing a connective tissue disease due to breast implants is not high. Taken together, these studies tell us that the vast majority of women with breast implants will not develop defined immune-related disorders from their implants. None of these studies can completely resolve the question of whether silicone-filled breast implants increase the risk of connective tissue disease or related disorders. Because of limitations in study design or study size, none of them have been able to rule out the possibility that the implants could cause immune-related disorders in a small subset of women who have them. Secondly, since these studies were largely designed to find out whether women with breast implants had certain well-defined immune-related diseases, one cannot exclude the possibility that some women with breast implants might develop other signs and symptoms related to the immune system that do not conform to "classic" disease descriptions.

- ***Breast Feeding***

At this time it is not known what effect breast implants have on lactation. It is not known whether the small amount of silicone that diffuses (bleeds) from the silicone-filled breast implants can find its way into breast milk and, if this occurs, what affect it may have on the nursing infant. Further studies will provide more information about this possible risk. Any breast surgery may impair breast feeding. A woman with breast implants who has questions about risks while pregnant or breast feeding should consult her physician.

Instructions For Use

Surgical Procedure

Allergan relies on the physician to know and follow the proper surgical procedures with ALLERGAN™ Style 410 Silicone-Filled Breast Implants. The physician must carefully evaluate implant size and contour, incision placement, pocket dissection and breast implant placement criteria with respect to the patient's anatomy and desired physical outcome. Planning should include clear delineation of aesthetic goals to ensure mutual understanding between physician and patient. The physician should observe current and accepted techniques to minimize the risk of adverse, and potentially disfiguring, reactions.

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

Single Use

This product is intended for single use only.

DO NOT reuse explanted products.

Product Identification

Product labels accompany each device within the internal product packaging. The product labels provide product-specific information. Product labels may be attached to the patient's chart for identification purposes.

Sterile Product

Each sterile ALLERGAN™ Style 410 Silicone-Filled Breast Implant is supplied in a sealed, double primary package. Sterility of the implant is maintained only if the thermoform packages, including the package seals, are intact.

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

DO NOT resterilize any product.

NEVER, under any circumstances, attempt to resterilize using ethylene oxide, which is known to cause adverse tissue reaction if the residuals are not completely removed from the device.

How to Open Sterile Product Package

Remove the sterile breast implant from its package in an aseptic environment and using talc-free gloved hands.

DO NOT expose the breast implant to lint, talc, sponge, towel, and other contaminants.

Instructions For Use (continued)

How to Open Sterile Product Package (continued)

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

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

Preliminary Product Examination of Silicone-Filled Breast Implants

Prior to use, examine the breast implant for evidence of any particulate contamination, damage, or loss of shell integrity. If satisfactory, return the breast implant to the inner thermoform tray and cover it with the lid until implanted to prevent contact with airborne contaminants. **DO NOT** implant any device that may appear to have particulate contamination, damage, or loss of shell integrity. A sterile back-up breast implant must be readily available at the time of surgery.

Placement

Ensure incision is sufficiently large to facilitate insertion and to avoid damage to the device. **DO NOT** use excessive force during placement of cohesive gel-filled implants. Cohesive gel may be permanently deformed due to over manipulation, resulting in deformation of the implant shape. Inadequate pocket dissection increases the risk of rupture and implant malposition.

Orientation marks are provided on the anterior and posterior surfaces of each breast implant to assist in placement. See diagrams in *Preoperative and Postoperative Mammography* under PRECAUTIONS. Inferior marks on the posterior surface at approximately six o'clock are designed primarily for orientation through inframmary incisions. Marks on the apex of the anterior surface are designed primarily for orientation through periareolar incisions. Superior marks at ten and two o'clock are designed primarily for orientation through transaxillary incisions.

A sterile BIOCELL® Delivery Assistance Sleeve is available separately and can be used to assist with placement of the breast implant. 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.

Instructions For Use (continued)

Placement (continued)

DO NOT use lubricants to facilitate placement. Their use creates the risk of pocket contamination and may also affect the tissue-capsule interface.

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

DO NOT use excessive force during breast implant placement.

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

Method for Removing Ruptured Silicone From the Surgical Pocket

In the event of breast implant rupture with release of silicone gel, the following technique is useful for removal of the silicone gel 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 gel, blot the surgical pocket with gauze sponges. Avoid contact between surgical instruments and the silicone gel. If contact occurs, use isopropyl alcohol to remove the silicone gel from the instruments. Ruptured implants must be reported and should be returned to Allergan. In the event of implant rupture, contact the Allergan Product Support Department at 800.624.4261.

Returned Goods Policy

Product returns should be handled through an Allergan Sales Representative or through the Customer Care Department at 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. Certain products are non-returnable, including ZYDERM® dermal filler and ZYPLAST® dermal filler.

Reporting and Return of Explanted Devices

The reason for explantation should be reported and the explanted device returned to Allergan. In the event of such an explantation, please contact Product Support at 800.624.4261 for an Explant Kit and explant return instructions.

ConfidencePlus® Limited Warranties

The *ConfidencePlus*® Limited Warranties provide lifetime replacement and limited financial reimbursement in the event of loss of shell integrity resulting in implant deflation, subject to certain conditions as fully discussed in the *ConfidencePlus*® literature. For more information, please contact Product Support at 800.624.4261.

Product Ordering

To order directly in the U.S.A or for product information, please contact your Allergan Sales Representative or the Allergan Customer Care Department at 800.766.0171. The ALLERGAN™ Style 410 breast implants are available only through an Allergan clinical study.

BIOCELL® Delivery Assistance Sleeve

Sterile BIOCELL® Delivery Assistance Sleeves are available from your Allergan Sales Representative or Customer Care Department at 800.766.0171.

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