# Ideal Implant Incorporated

## IDEAL IMPLANT® STRUCTURED BREAST IMPLANTS
## Instructions for Use
August 2015


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

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# INTRODUCTION

## *DIRECTIONS TO THE PHYSICIAN*

This document contains information that is essential to counseling the patient about IDEAL IMPLANT® Structured Breast Implants and breast implant surgery. Please familiarize yourself with the content of this document and resolve any questions or concerns prior to proceeding with use of the device.

The information supplied in this Instructions for Use document is intended to provide an overview of essential information about IDEAL IMPLANT Structured Breast Implants, including the indications for use, contraindications, warnings, precautions, complications and a summary of Ideal Implant's clinical results.

Sections of this Instructions for Use document indicated by "**Patient Counseling Information"** contain points that the physician should review when counseling the patient about breast implants and breast implant surgery (also see Important Factors to be Discussed with the Patient on page 7).

## *INFORMATION TO BE DISCUSSED WITH THE PATIENT*

### WARNINGS, PRECAUTIONS, ADVERSE EVENTS

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

Each patient should receive Ideal Implant's ***Making an Informed Decision IDEAL IMPLANT® Structured Breast Implant Surgery*** during her initial visit/consultation. The surgeon or a designated patient counselor should instruct the patient to read the patient information carefully and also discuss with the patient the warnings, precautions, and complications listed in this Instructions for Use document. The physician should advise the patient of the potential complications and that medical management of serious complications may include additional surgery and explantation. Patients should understand that breast implant surgery can cause irreversible changes to the breast.

### INFORMED CONSENT

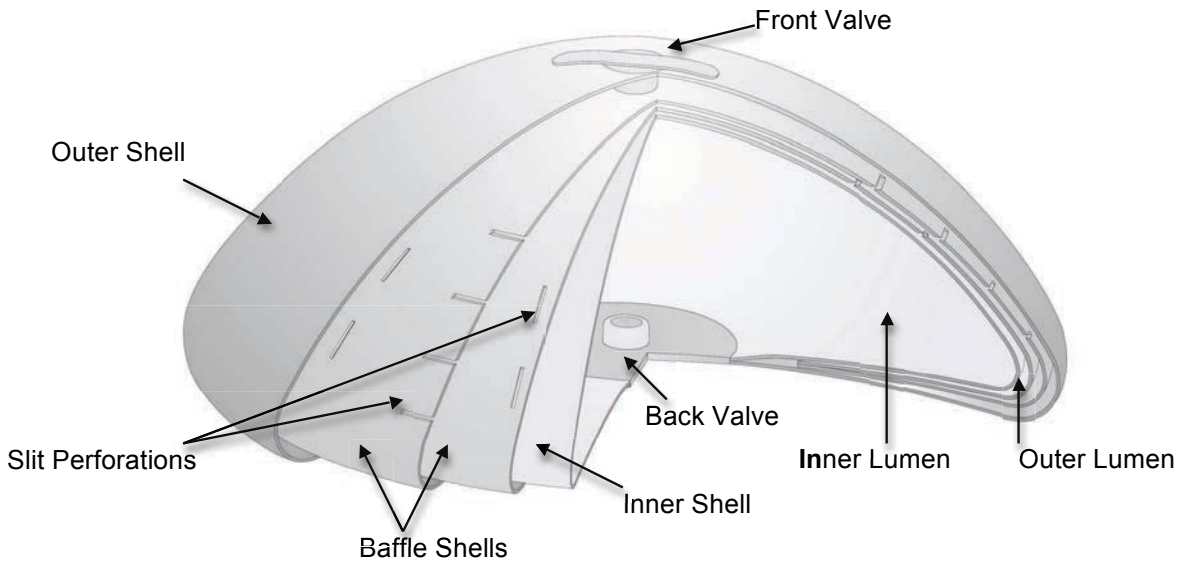
**Patient Counseling Information**
Before making the decision to proceed with surgery, the patient should be allowed at least 1-2 weeks to review and consider the information on the risks, follow-up recommendations, and benefits associated with saline-filled breast implant surgery. In the case of revision augmentation, it may be medically advisable to perform surgery sooner.

## DEVICE DESCRIPTION

The IDEAL IMPLANT is a round, smooth-surface, saline-filled breast implant that is supplied sterile in a dual tray packaging system with two disposable fill tubes and reflux valves. It was developed to provide women and surgeons with another option in addition to the original saline-filled implants or silicone gel-filled implants.

While the original saline-filled implants have a single lumen within a single shell made from cross-linked silicone elastomer, the IDEAL IMPLANT has two lumens within two nested shells that are attached at the patch on the back of the implant. The inner lumen within the inner shell is filled through a valve in the patch. The outer lumen within the outer shell and surrounding the inner shell is filled through a valve on the front. Unattached and floating within the outer lumen is a baffle structure designed to restrict movement of the saline in the outer lumen. The amount of material required for the baffle structure is proportionate to the size of the implant and the fill volume in the outer lumen (Tables 1 and 2). This baffle structure is comprised of one to three nested baffle shells that are perforated with slits so the saline is free to move through the slits, as well as around and between the shells. The inner and outer lumens are filled with saline before or after the implant has been placed in a submuscular or subglandular pocket.

A cut-away drawing of an IDEAL IMPLANT (335 cc to 555 cc size) shows the inner shell, the outer shell, the baffle structure floating in the outer lumen comprised of two baffle shells perforated with slits, the valve in the patch to fill the inner lumen and the valve on the front to fill the outer lumen.




**Cut-away of IDEAL IMPLANT (335 cc to 555 cc size) to show internal structure**

| Table 1 - Amount of Baffle Material (Shells) Relative to Implant Size and Outer Lumen Fill Volume | | |
|---|---|---|
| Implant Size | Outer Lumen Fill at "High" | Baffle Shells |
| 210 cc | 60 cc | 1 |
| 240 cc | 65 cc | 1 |
| 270 cc | 70 cc | 1 |
| 300 cc | 75 cc | 1 |
| 335 cc | 95 cc | 2 |
| 370 cc | 100 cc | 2 |
| 405 cc | 110 cc | 2 |
| 440 cc | 115 cc | 2 |
| 475 cc | 120 cc | 2 |
| 515 cc | 125 cc | 2 |
| 555 cc | 135 cc | 2 |
| 595 cc | 155 cc | 3 |
| 635 cc | 160 cc | 3 |
| 675 cc | 160 cc | 3 |

| Table 2 - Approximate Dimensions and Volumes | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Implant Size | Empty Implant Volume | Inner Lumen Volume | Outer Lumen Volume at "High" | Outer Lumen Volume at "100%" | Total Implant Volume at "High" | Total Implant Volume at "100%" | Implant Diameter at "High" | Implant Projection at "High" | Implant Diameter at "100%" | Implant Projection at "100%" |
| | cc | cc | cc | cc | cc | cc | cm | cm | cm | cm |
| **210 cc** | 30 | 120 | 60 | 85 | 210 | 235 | 9.8 | 4.0 | 9.7 | 4.4 |
| **240 cc** | 33 | 142 | 65 | 95 | 240 | 270 | 10.3 | 4.1 | 10.2 | 4.7 |
| **270 cc** | 35 | 165 | 70 | 105 | 270 | 305 | 10.7 | 4.3 | 10.6 | 4.9 |
| **300 cc** | 37 | 188 | 75 | 115 | 300 | 340 | 10.9 | 4.5 | 10.8 | 5.1 |
| **335 cc** | 52 | 188 | 95 | 135 | 335 | 375 | 11.4 | 4.6 | 11.3 | 5.1 |
| **370 cc** | 56 | 214 | 100 | 145 | 370 | 415 | 11.8 | 4.7 | 11.7 | 5.3 |
| **405 cc** | 60 | 235 | 110 | 160 | 405 | 455 | 12.0 | 4.8 | 11.9 | 5.4 |
| **440 cc** | 64 | 261 | 115 | 170 | 440 | 495 | 12.5 | 5.0 | 12.4 | 5.6 |
| **475 cc** | 68 | 287 | 120 | 180 | 475 | 535 | 12.7 | 5.2 | 12.6 | 5.8 |
| **515 cc** | 72 | 318 | 125 | 190 | 515 | 580 | 13.2 | 5.3 | 13.0 | 5.8 |
| **555 cc** | 76 | 344 | 135 | 205 | 555 | 625 | 13.4 | 5.4 | 13.3 | 6.1 |
| **595 cc** | 94 | 346 | 155 | 230 | 595 | 670 | 13.8 | 5.4 | 13.7 | 6.1 |
| **635 cc** | 102 | 373 | 160 | 235 | 635 | 710 | 14.0 | 5.6 | 13.8 | 6.4 |
| **675 cc** | 110 | 405 | 160 | 240 | 675 | 755 | 14.2 | 5.8 | 14.1 | 6.4 |
| Diameter and projection measured on a convex surface at minimum fill in the outer lumen | | | | | | | | | | |

## INDICATIONS

The IDEAL IMPLANT Structured Breast Implant is indicated for women at least 18 years old for the following:

- Primary breast augmentation to increase the breast size.
- Revision augmentation to correct or improve the result of a primary breast augmentation surgery.

## CONTRAINDICATIONS

Breast implant surgery should not be performed in:

- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions.
- Women with active infection anywhere in their body.
- Women who are currently pregnant or nursing.

## WARNINGS

The IDEAL IMPLANT has not been studied for use in breast reconstruction and therefore is not indicated for primary breast reconstruction, revision breast reconstruction or if there will be radiation of the breast.

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

- Do not place drugs or substances in the implant other than sterile 0.9% Saline for Injection.
- Do not alter the implant or valves.
- Do not inject through the implant shell.
- Do not place more than one implant per breast pocket.
- Do not immerse the implant in povidone iodine solution or place povidone iodine solution in the implant. The pocket may be irrigated with a solution of equal parts povidone iodine and normal saline.
- Do not use endoscopic placement of the implant or peri-umbilical approach in placement of the implant.

**Closed capsulotomy**

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

**Reuse**

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

**Avoiding damage during surgery**

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

**Proper filling**

Follow the recommended fill volumes shown in this Instruction for Use document; do not overfill or underfill the implant. Following recommended fill volumes may decrease the possibility of shell wrinkling and crease fold failure.

**Microwave diathermy**

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

**Surgical mesh**

The use of surgical mesh together with the breast implant has not been studied in the clinical trial.

## PRECAUTIONS

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

- Autoimmune diseases such as lupus and scleroderma.
- A compromised immune system (for example, currently receiving immunosuppressive therapy).
- Conditions or medications which compromise or complicate wound healing or blood clotting.
- Inadequate tissue cover or reduced blood supply to breast tissue.
- Absent or substantially altered breast as a result of treatment for cancer or other pathologic conditions.
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health issues with your patient prior to surgery. Patients with a diagnosis of depression, an anxiety disorder, or another mental health condition, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

Limited to use by physicians who have had training with breast implants.

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

Breast implantation is an elective procedure and the patient must be thoroughly counseled on the risks, as well as the benefits, of these products and procedures. You should advise your patient that she must read the Patient Information Booklet. The booklet 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 of existing augmentation implants, but is not intended to replace consultation with you. The patient should review and consider this information before deciding whether to have this surgery.

Below are some of the important factors your patients need to be aware of when using IDEAL IMPLANT Structured Breast Implants (also see Patient Counseling on page 3):

- **Subsequent operation** – Patients should be advised that additional surgery to their breast and/or implant will be likely over the course of their life.

- **Explantation** – Patients should be advised that implants are not considered lifetime devices, and they will likely undergo implant removal, with or without replacement,

over the course of their life. Patients should be advised that the changes to their breast following explantation are irreversible.

- **Mammography** – Breast implants may complicate the interpretation of mammographic images by obscuring underlying breast tissue and/or by compressing overlying tissue. Accredited mammography centers and use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast. Presurgical mammography with a follow-up mammogram 6 months to 1 year following surgery may be performed to establish a baseline for future routine mammography. Women should inform their mammographers about the presence of their implants.

- **Lactation** – Patients should be advised that the presence of breast implants may interfere with the ability to successfully breastfeed, either by reducing or eliminating milk production.

- **Breast Examination Techniques** – Patients should be instructed to perform breast self-examinations monthly and be shown how to distinguish the implant from their breast tissue. The patient should be instructed not to manipulate (i.e., squeeze) the valve excessively, which may cause valve leakage.

- **Avoid Damage During Treatment** – Patients should inform other treating physicians of the presence of implants to minimize the risk of damage to the implants.

- **Smoking** – Smoking may interfere with the healing process.

- **Insurance Coverage** – Patients should be advised that health insurance premiums may increase, insurance coverage may be dropped, and/or future coverage may be denied based on the presence of breast implants. Treatment of complications may not be covered as well. Patients should check with their insurance company regarding coverage issues before undergoing surgery.

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

- **Long Term Effects** – Safety and effectiveness beyond 2 years has not been clinically evaluated; however, Ideal Implant Incorporated is continuing its Core Study through ten years to further evaluate the long-term safety and effectiveness of this implant. As new information becomes available, Ideal Implant Incorporated will issue an updated version of this document.

## INSTRUCTIONS FOR USE

NOTE: A backup implant should be available in the operating room. It is advisable to have more than one size implant available to allow for flexibility in determining the appropriate size implant to be used.

DO NOT stack more than one implant per breast pocket.

**Sterilization**
Implants are sterilized by dry heat and are single use only. Do not re-sterilize.

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

- The implant should not be too small or too large in comparison to the patient's chest wall dimensions.
- Available tissue must provide adequate coverage of the implant.
- Submuscular placement of the implant may be preferable in patients with thin or poor quality tissue.
- A well-defined, dry pocket of adequate size and symmetry must be created to allow the implant to be placed flat on a smooth surface.
- An incision should be of appropriate length, about 4cm, to accommodate the implant and reduce excessive stress on the implant during insertion.

**Testing Procedure for Saline-filled Implants**
The implant should be tested for patency and shell integrity immediately prior to use. This can be accomplished by the following steps:

1. Partially inflate the implant with air through the fill tube.
2. Submerge the air-filled implant in sterile saline or water.
3. Apply mild pressure and check for possible leaks of the air inside.

**Maintaining Hemostasis/Avoiding Fluid Accumulation**
Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, the implantation should be delayed until bleeding is controlled. Postoperative evacuation of hematoma or seroma must be conducted with care to avoid breast implant contamination, or damage from sharp instruments.

**Filling Procedure**
Diaphragm valves are normally in the closed position. When the plug on the end of a fill tube is inserted into a valve, the diaphragm is held open, allowing the flow of air or saline. When the fill tube plug is removed, the diaphragm closes, sealing the valve. Overstressing the valve can cause damage such as punctures or tears and result in implant deflation. Use only the fill tube plug designed for and provided with this implant.

Since this implant has an inner lumen and an outer lumen that require different fill volumes (Table 2), the two respective fill tubes must not be confused once the implant is in the surgical pocket. For this reason, one fill tube is unmarked and is for the valve on the front of the implant while the other fill tube is marked: "**BACK---BIG---BEGIN**"

- **BACK** - for the valve on the **BACK** of the implant
- **BIG** - for the inner lumen that has a **BIG** fill volume compared to the outer lumen
- **BEGIN** - it is technically easier to **BEGIN** by filling the inner lumen and remove this fill tube from the back of the implant before filling the outer lumen from the front.

Remove and discard the protective strips between the valve straps and the valves. Wet the fill tube plugs in sterile isotonic saline for lubrication, slide the valve straps to one side and

insert the plugs into the valve openings, using thumb and forefinger to stabilize the valves. While rotating slightly, gently push the fill tube plugs into the valve openings as far as the flanges permit. Be certain that the fill tube marked "**BACK---BIG---BEGIN**" is inserted into the valve on the **BACK** of the implant and the unmarked fill tube is inserted into the valve on the front of the implant.

When the valves are open, air will freely escape from both lumens as the implant is compressed. Attach a check valve to each luer lock and use an empty, sterile syringe to completely deflate each lumen. This minimizes the size of the implant for easier passage through the incision. Any remaining air in the implant will eventually diffuse out and be absorbed by the tissue. It is not necessary to remove the small amount of entrapped air. Remove the syringe, roll the implant, moisten it with saline for lubrication and insert it into the prepared pocket.

Use only sterile, pyrogen-free 0.9% Sodium Chloride U.S.P. Solution for Injection drawn from its original container, since infection may result from contaminated saline. For this reason, a closed injection system is recommended consisting of intravenous bag, intravenous tubing, 3-way stopcock and syringe. This closed system is connected to the sterile fill tubes supplied with the implant.

Follow Table 2 of this Instructions for Use document and the implant label for the recommended fill volumes of the inner lumen and the outer lumen. For each implant, the recommended fill volumes were calculated so they are proportionate to the implant size and the capacity of the inner and outer shells. This gives the implant optimal performance. Do not overfill or underfill the implant as this may cause wrinkles, scallops and/or deflation from crease/fold failure. When filling, allow for the 3cc of saline inside each fill tube.

**BEGIN** with the fill tube marked "**BACK---BIG---BEGIN**" that is inserted into the valve on the **BACK** of the implant for the **BIG** volume inner lumen. When the inner lumen is filled, remove its fill tube before using the unmarked fill tube that is inserted into the valve on the front of the implant for the small volume outer lumen. When the outer lumen is filled, remove its fill tube.

Use care when removing the fill tube plugs from the valves to prevent damage to the valve assemblies. Support the area around each valve with fingertips and pull the fill tube plug straight out, not at an angle to the valve. Position the valve strap over each valve and insert the protective strap plug into the valve opening.

**Recording Procedure**

Each breast implant is supplied with one Patient Implant Card and six Implant Record Labels showing the size and serial number for that implant. To complete the Patient Implant Card, adhere one Implant Record Label for each implant on the back of the Patient Implant Card. Another label should be affixed to the patient's chart. The Implant Record Label shows the empty implant volume and the inner lumen volume for that size implant. The implanted position (right or left side) should be indicated on the label as well as the volume of saline placed in the outer lumen. The total implant volume (the sum of the empty implant volume, the inner lumen volume, and the outer lumen volume) should be indicated on the label.

## COMPLICATIONS

Potential adverse events that may occur with saline-filled breast implant surgery include: deflation, 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 would healing, breast tissue atrophy/chest wall deformity, calcium deposits, and lymphadenopathy. For specific adverse event rates for IDEAL IMPLANT, refer to Safety Results on page 17. Below is a description of these adverse events:

- **Deflation** – Breast implants are not lifetime devices. Saline-filled breast implants deflate when the shell develops a tear or hole, or when a valve leaks. Deflation can occur any time after implantation, but is more likely to occur the longer the implant is in place. The following may cause deflation: damage by surgical instruments, folding or wrinkling of the implant shell, excessive force to the chest, compression during mammography, and severe capsule contracture. Breast implants may also simply wear out over time. Since this implant has two lumens, deflation of only one lumen will result in only partial deflation of the implant.

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

- **Capsule Contracture** – Patients should be advised that capsule contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsule contracture occurs more commonly in revision augmentation patients than in primary augmentation patients. Capsule contracture is also a risk factor for implant deflation, and it is one of the most common reasons for reoperation.

  Patients should also be advised that additional surgery may be needed in cases where firmness is severe, ranging from removal of the implant capsule to replacement of the implant. Capsule contracture may recur following this additional surgery.

- **Implant Removal** – Patients should be advised that implants are not considered lifetime devices, and they will potentially undergo implant removal, with or without replacement, over the course of their life. Patients should also be advised that the changes to their breast following implant removal are irreversible.

- **Infection** – In rare instances, acute infection may occur in a breast with implant. Signs of acute infection include erythema, tenderness, fluid accumulation, pain, and fever. Very rarely, Toxic Shock Syndrome (TSS), a potentially life-threatening condition, has been reported in women after breast implant surgery. Symptoms occur suddenly and include high fever (102$^{o}$ F, 38.8$^{o}$ 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 contact a physician immediately for diagnosis and treatment of any of these symptoms.

- **Dissatisfaction with Cosmetic Results** – Patients should be informed that dissatisfaction with cosmetic results related to such things as scar deformity, capsule contracture, asymmetry, wrinkling, implant displacement/migration, incorrect size, and implant palpability/visibility may occur. Careful surgical planning and technique can minimize, but not preclude, the risk of such results. Pre-existing asymmetry may not be entirely correctable. Revision surgery may be indicated to maintain patient satisfaction, but carries additional risks.

- **Breastfeeding** – Difficulties have been reported following breast augmentation surgery. A periareolar approach may further increase the chance of breastfeeding difficulties.

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

## OTHER REPORTED CONDITIONS

There have been reports in the literature of other conditions in women with breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. No cause-and-effect relationship ahs been established between breast implants and the conditions listed below. There is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants.

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

- **Cancer** – Published studies indicate that breast cancer is no more common in women with implants than those without implants. One possible exception is the rare development of Anaplastic Large Cell Lymphoma (ALCL) in women with breast implants.

  - 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 a number of 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: *fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm*

- **Effects on Children** – There have been concerns raised regarding potential damaging effects on children born of mothers with implants. There is no evidence that shows breast implants have any harmful effects on the children of implanted women.

## IDEAL IMPLANT'S CLINICAL STUDY

### *CLINICAL STUDY OVERVIEW*

Ideal Implant's Structured Breast Implant Core Study is a prospective, 10-year, multi-center, open label study of the IDEAL IMPLANT in which subjects serve as their own controls for the evaluation of effectiveness. Two patient cohorts were enrolled in the study:

- At least 18 year old women undergoing bilateral primary augmentation ("Primary Augmentation Cohort"); and

- At least 18 year old women undergoing bilateral revision of existing saline-filled or silicone gel-filled augmentation implants ("Revision" Augmentation Cohort").

Within 30 days of the baseline visit, qualified subjects were to be implanted with IDEAL IMPLANTS. The protocol specifies that subjects are to return for evaluation at 2 months, 6 months, and 1 year, and then annually for 10 years post-implant. At each follow-up visit, the protocol specifies that subjects are to be examined, the implants assessed, the extent of capsule graded according to the Baker classification scheme, and patient/investigator satisfaction assessed. At 6 months and 1 year, chest measurements are to be made. At 1, 2, 4, 6, 8 and 10 years, the protocol specifies that subjects are to complete the Breast Evaluation Questionnaire and the SF-36 Questionnaire. At 1, 2, 4, 7, and 10 years, the protocol specifies that subjects are to complete the Rheumatologic and Connective Tissue Disease Screen (CTDS). Adverse events are to be documented throughout the 10-year study.

The 2-year study results are presented here. Of the patients available to be seen for their 2-year follow-up visit, 378 of the primary augmentation patients (98%) and 94 of the revision augmentation patients (98%) returned and were seen at 2 years after implant surgery.

**Table 3 - Subject Disposition and Cumulative Subject Follow-up for the Primary Augmentation Cohort and the Revision Augmentation Cohort**

| Cohort | Subject Status | Follow up Time Interval | | | |
|---|---|---|---|---|---|
| | | 2 Months | 6 Months | 1 Year | 2 Year |
| Primary Augmentation | Theoretically due* | 399 | 399 | 399 | 399 |
| | Deaths | 0 | 0 | 0 | 0 |
| | All devices removed and replaced with other manufacturer's devices | 0 | 3 | 7 | 7 |
| | Voluntary withdrawal by subject | 0 | 1 | 3 | 6 |
| | Expected** | 399 | 395 | 389 | 386 |
| | Actual (Complete follow-up) | 397 | 391 | 383 | 378 |
| | Lost to follow-up | 2 | 4 | 6 | 8 |
| | Percent follow-up (Actual/Expected) | 99.4% | 98.9% | 98.4% | 97.9% |
| Revision Augmentation | Theoretically due* | 103 | 103 | 103 | 103 |
| | Deaths | 0 | 0 | 0 | 0 |
| | All devices removed and replaced with other manufacturer's devices | 0 | 2 | 5 | 7 |
| | Voluntary withdrawal by subject | 0 | 0 | 0 | 0 |
| | Expected** | 103 | 101 | 98 | 96 |
| | Actual (Complete follow-up) | 103 | 101 | 96 | 94 |
| | Lost to follow-up | 0 | 0 | 2 | 2 |
| | Percent follow-up (Actual/Expected) | 100% | 100% | 97.9% | 97.9% |

* Subjects who would have been examined according to date of implantation and follow-up schedules.
**Subjects who are theoretically due minus the sum of the deaths, voluntary withdrawals and removals with replacement with different manufacturer's implants. Subjects with voluntary withdrawal or lost to follow-up date after a visit window in which they did not actually attend were counted as withdrawn in the relevant category at that missed visit.

### *STUDY OBJECTIVES and ENDPOINTS*

The objective of this study was to determine the safety and effectiveness of the IDEAL IMPLANT in women undergoing primary breast augmentation or revision of existing saline-filled or silicone gel-filled augmentation implants.

The safety study endpoint was that use of the IDEAL IMPLANT elicits an acceptable safety profile. In general, the safety of the IDEAL IMPLANT was assessed through the incidence and timing of all adverse events collected throughout the study.

Five effectiveness endpoints were evaluated:

- Increase in breast size for Primary Augmentation Cohort only
- Breast Evaluation Questionnaire (BEQ)
- Patient satisfaction with outcome
- Investigator satisfaction with outcome
- SF-36 Questionnaire

### *PATIENT ACCOUNTING AND BASELINE DEMOGRAPHIC PROFILE*

The study enrolled 502 patients: 399 for primary breast augmentation and 103 for revision augmentation of existing saline or silicone gel augmentation implants. Table 4 shows the subject demographics and medical history for the women in the Primary Augmentation Cohort and the Revision Augmentation Cohort. Approximately 83% of patients were

Caucasian. The median age of the primary augmentation patients was 34.0 years (range 18-68); the median age of the revision augmentation patients was 47.0 years (range 21-67).

**Table 4 – Subject Demographics and Medical History, per Subject**

| Measure | Primary Augmentation (N=399) | Revision Augmentation (N=103) |
|---|---|---|
| Age (years)[1] | 34.5±10.4 (399)<br>34.0 [18.0, 68.0] | 46.7±9.3 (103)<br>47.0 [21.0, 67.0] |
| Race[2] | | |
| American Indian Alaska Native | 1.3% (5/399) | 0% (0/103) |
| Asian | 3.0% (12/399) | 1.9% (2/103) |
| Black / African American | 5.0% (20/399) | 1.9% (2/103) |
| Native Hawaiian / Pacific Islander | 0.8% (3/399) | 0% (0/103) |
| Caucasian | 82.7% (330/399) | 83.5% (86/103) |
| Other | 9.5% (38/399) | 14.6% (15/103) |
| Ethnicity | | |
| Hispanic or Latino | 11.8% (47/399) | 14.6% (15/103) |
| Non-Hispanic or Latino | 88.2% (352/399) | 85.4% (88/103) |
| BMI (kg/m$^2$) | 22.3±3.6 (399)<br>21.6 [14.4, 53.2] | 22.4±3.9 (103)<br>21.5 [18.1, 48.7] |
| Any Pregnancy History | 73.9% (295/399) | 89.3% (92/103) |
| Number of pregnancies | 2.6±1.4 (295)<br>2.0 [1.0, 8.0] | 2.6±1.4 (92)<br>2.0 [1.0, 7.0] |
| Number of live births | 2.1±1.2 (295)<br>2.0 [0.0, 7.0] | 2.0±1.0 (92)<br>2.0 [0.0, 5.0] |

Numbers are Mean ± SD (N), Median [Min, Max] for continuous measures and Percent (Count/N) for discrete measures.
[1] Age calculated at date of implant.
[2] More than one race category may be selected for each subject.

Early in the trial, the diameter of the valve attachment component was increased from 6.3mm to 8mm to improve bond strength, which reduced the risk of spontaneous deflation, subsequent operations and implant removal, as shown in Table 5. Late in the trial, the baffle perforations were holes instead of slits.

**Table 5 - Kaplan-Meier Failure Rates for Adverse Events at 2 years for Initial Bilateral 6.3mm and Initial Bilateral 8mm Valve Attachment Component Implants, per Subject**

| Event | Primary Augmentation | | Revision Augmentation | |
|---|---|---|---|---|
| | 6.3mm (N=31) | 8mm (N=363) | 6.3mm (N=10) | 8mm (N=93) |
| All subsequent breast operations | 32.3%<br>(18.8%, 51.6%) | 14.2%<br>(11.0%, 18.3%) | 50.0%<br>(24.7%, 81.6%) | 23.7%<br>(16.3%, 33.7%) |
| Implant removal with or without replacement | 22.6%<br>(11.5%, 41.6%) | 7.5%<br>(5.2%, 10.8%) | 10.0%<br>(1.5%, 52.7%) | 15.1%<br>(9.2%, 24.2%) |
| Spontaneous deflation | 19.4%<br>(9.2%, 38.1%) | 4.8%<br>(3.0%, 7.6%) | 10.0%<br>(1.5%, 52.7%) | 3.3%<br>(1.1%, 10.0%) |

For the Primary Augmentation Cohort, 363 subjects were initially implanted with bilateral 8mm valve attachment component implants (355 had slit baffle perforations; 8 had hole baffle perforations), 31 subjects received bilateral 6.3mm component implants (all had slit baffle perforations), and 5 subjects received a 6.3mm component implant on one side and a 8mm component implant on the other side (all had slit baffle perforations). A total of 391 subjects received slit baffle perforation implants and 11 subjects received hole baffle perforations implants.

For the Revision Augmentation Cohort, 93 subjects were initially implanted with bilateral 8mm valve attachment component implants (90 had slit baffle perforations; 3 had hole baffle perforations), and 10 subjects received bilateral 6.3mm component implants (all had slit baffle perforations). A total of 100 subjects received slit baffle perforation implants.

Neither the 6.3mm diameter valve attachment component implant, nor the baffle hole perforations implant are available commercially.

Table 6 shows the operative details per implant for women in the Primary Augmentation and the Revision Augmentation Cohorts. The inframammary incision site was most common in both cohorts, and most implants were placed in the submuscular location. In the Primary Augmentation Cohort, 19.7% of the breasts had a concomitant procedure with Mastopexy being the most common. More breasts in the Revision Augmentation Cohort underwent a concomitant breast procedure (74.8%), as expected, with 81.2% of those subjects having a Capsular Procedure.

**Table 6 – Surgical Operative Data, per Implant**

| Measure | Primary Augmentation (N=798) | Revision Augmentation (N=206) |
|---|---|---|
| Diameter valve attachment | | |
| 8mm | 91.6% (731/798) | 90.3% (186/206) |
| 6.3mm | 8.4% (67/798) | 9.7% (20/206) |
| Baffle perforations | | |
| Slits | 98.0% (782/798) | 97.1% (200/206) |
| Holes | 2.0% (16/798) | 2.9% (6/206) |
| Incision site | | |
| Inframammary[1] | 70.8% (565/798) | 61.2% (126/206) |
| Periareolar | 22.2% (177/798) | 37.9% (78/206) |
| Axillary | 7.0% (56/798) | 1.0% (2/206) |
| Location | | |
| Subglandular | 8.0% (64/798) | 19.4% (40/206) |
| Submuscular | 92.0% (734/798) | 80.6% (166/206) |
| Concurrent breast procedure | 19.7% (157/798) | 74.8% (154/206) |
| Capsule procedure | 0% (0/157) | 81.2% (125/154) |
| Mastopexy | 91.7% (144/157) | 26.0% (40/154) |
| Other | 8.3% (13/157) | 18.8% (29/154) |

Numbers are Mean ± SD (N), Median [Min, Max] for continuous measures and Percent (Count/N) for discrete measures.
[1] Two subjects each had two devices implanted via abdominoplasty and are reported as inframammary due to the approach used.

***EFFECTIVENESS RESULTS***

375 (94%) of the original 399 primary augmentation patients had a breast measurement at 1-year after surgery. Of these patients, the mean increase in chest circumference was 2.5 inches.

**Table 7 - Increase in Breast Size per Subject for the Primary Augmentation Cohort**

| Chest Measurements | Primary Augmentation (N=391) |
|---|---|
| Baseline measurement (inches) | 3.6±1.4 (389)<br>3.5 [-2.0, 9.5] |
| 1-year measurement (inches) | 6.1±1.3 (375)<br>6.0 [2.0, 10.0] |
| Change from baseline at 1 year (inches) | 2.5±1.5 (374)<br>2.5 [-4.3, 6.5] |

Numbers are Mean ± SD (N), Median [Min, Max].
The measurement presented for each visit is the chest circumference at the nipples minus at the inframammary fold. The change is the difference in this measure between visits.
Eight patients were not included in the analysis because they were implanted with hole baffle perforation implants for which approval is not being sought.

The Breast Evaluation Questionnaire, a validated instrument to assess satisfaction with breast attributes, was utilized to assess subjects' satisfaction with their breasts before and after surgery. Subjects in the Primary Augmentation Cohort and the Revision Augmentation cohort experienced statistically significant increases from baseline in each domain of the BEQ at both 1 and 2 years (t-test; p-value <0.0001). At 2 years, subjects in the Primary Augmentation Cohort reported: a mean of 54.9 (60 maximum score possible) on the Comfort Fully Dressed scale, a mean increase of 14.2 compared to the baseline; a mean of 98.7 (120 maximum score possible) on the Comfort Not Fully Dressed scale, a mean increase of 43.4 compared to the baseline; and a mean of 39.8 (45 maximum score possible) on the Satisfaction with Breast Attributes scale, a mean increase of 18.4 compared to the baseline. Subjects in the Revision Augmentation Cohort reported: a mean of 54.2 on the Comfort Fully Dressed scale, a mean increase of 7.5 compared to the baseline; a mean of 93.2 on the Comfort Not Fully Dressed scale, a mean increase of 18.0 compared to the baseline; and a mean of 39.1 on the Satisfaction with Breast Attributes scale, a mean increase of 8.7 compared to the baseline.

Patient and physician satisfaction with the overall cosmetic outcome were assessed using a five-point Likert scale, which ranged from Definitely Dissatisfied to Definitely Satisfied. Satisfaction levels were very high among both investigators and subjects in both cohorts (Table 8).

| Table 8 - Physician and Patient Satisfaction with Outcome at 2 Years | | | |
|---|---|---|---|
| Cohort | Satisfaction Measure | 2-Year Follow-up Visit | |
| | | Primary Augmentation | Revision Augmentation |
| Physician Satisfaction | Physician definitely satisfied with outcome | 83.2% (615/739) | 77.9% (141/181) |
| | Physician somewhat satisfied with outcome with outcome | 12.7% (94/739) | 13.8% (25/181) |
| | Physician neither satisfied nor dissatisfied with outcome | 1.5% (11/739) | 2.8% (5/181) |
| | Physician somewhat dissatisfied with outcome | 1.9% (14/739) | 5.5% (10/181) |
| | Physician definitely dissatisfied with outcome | 0.7% (5/739) | 0% (0/181) |
| Subject Satisfaction | Subject definitely satisfied with outcome | 78.1% (577/739) | 76.2% (138/181) |
| | Subject somewhat satisfied with outcome with outcome | 16.2% (120/739) | 14.4% (26/181) |
| | Subject neither satisfied nor dissatisfied with outcome | 1.4% (10/739) | 2.8% (5/181) |
| | Subject somewhat dissatisfied with outcome | 2.8% (21/739) | 5.5% (10/181) |
| | Subject definitely dissatisfied with outcome | 1.5% (11/739) | 1.1% (2/181) |
| Numbers are Percent (Count/N).<br>The 11 subjects with hole baffle shell perforations are excluded from effectiveness analyses. | | | |

The SF-36v2® Health Survey was utilized to measure overall quality of life. For all eight scales of the survey and at all time points, the mean SF-36 scores were clinically significantly higher for subjects compared to the general female population. Comparison of baseline scores to scores at 1 and 2 years showed slight decreases in the SF-36 scores, although all scales remained higher than the general US female population and the differences were not clinically meaningful.

### *SAFETY RESULTS*

The study safety results are presented in Tables 9 through15. Additional information about complications can be found on page 10. Table 7 shows the 2-year Kaplan Meier (KM) risk rates of the first occurrence (95% confidence intervals) of adverse events for the two study cohorts per subject through 2 years. In the Primary Augmentation Cohort, complications occurring at a rate of ≥ 5% through 2 years included: all subsequent breast operations (14.2%) and implant removal with or without replacement (7.5%). In the Revision Cohort, complications occurring at a rate of ≥ 5% through 2 years included: all subsequent breast operations (23.7%), implant removal with or without replacement (15.1%), wrinkling/scalloping (12.0%), dissatisfaction with cosmetic results (8.9%), and capsular contracture – Grade III/IV (8.2%).

| Table 9 – KM Risk Rates of the First Occurrence of Adverse Events through 2 Years, per Subject | | |
|---|---|---|
| **Event (Includes all levels of severity)** | **Primary Augmentation Cohort (N=399)** | **Revision Augmentation Cohort (N=103)** |
| Any complication or reoperation* | 42.2%** (37.3%, 47.5%) | 50.5%** (40.9%, 61.0%) |
| Any breast complication or reoperation* | 34.2%** (29.5%, 39.3%) | 45.2%** (35.7%, 55.8%) |
| All subsequent breast operations* | 14.2% (11.0%, 18.3%) | 23.7% (16.3%, 33.7%) |
| Related to implant | 8.4% (6.1%, 11.7%) | 11.1% (6.3%, 19.2%) |
| Related to procedure | 4.1% (2.5%, 6.6%) | 3.0% (1.0%, 9.0%) |
| Related to dissatisfaction with implant size | 2.3% (1.2%, 4.4%) | 4.0% (1.5%, 10.2%) |
| Other reason | 6.9% (4.8%, 9.9%) | 15.7% (9.9%, 24.4%) |
| Implant removal with or without replacement* | 7.5% (5.2%, 10.8%) | 15.1% (9.2%, 24.2%) |
| Anesthesia complications | 0.0% | 1.0% (0.1%, 6.7%) |
| Neurologic complications | 0.3% (0.0%, 1.8%) | 0.0% |
| Connective Tissue Disease diagnosis | 0.5% (0.1%, 2.1%) | 0.0% |
| Reproductive problem | 0.5% (0.1%, 2.1%) | 0.0% |
| Other Adverse Event | 10.8% (8.1%, 14.3%) | 14.0% (8.6%, 22.6%) |
| Capsule contracture Grade II/III/IV | 17.1% (13.7%, 21.2%) | 24.3% (17.0%, 34.0%) |
| Capsule contracture Grade II | 14.0% (10.9%, 17.8%) | 21.3% (14.4%, 30.7%) |
| Capsule contracture Grade III | 3.6% (2.1%, 5.9%) | 8.2% (4.2%, 15.8%) |
| Capsule contracture Grade IV | 0.3% (0.0%, 1.8%) | 2.1% (0.5%, 8.1%) |
| Capsule contracture Grade III/IV | 3.8% (2.3%, 6.3%) | 8.2% (4.2%, 15.8%) |
| Wrinkling/scalloping (excludes mild severity) | 3.8% (2.3%, 6.3%) | 12.0% (7.0%, 20.2%) |
| Any complication or reoperation* | 43.3%** (38.4%, 48.7%) | 50.5%** (40.9%, 61.0%) |
| Spontaneous deflation* | 4.8% (3.0%, 7.6%) | 3.3% (1.1%, 10.0%) |
| Seroma | 0.3% (0.0%, 1.8%) | 2.9% (0.9%, 8.8%) |
| Breast tissue atrophy/chest wall deformity | 0.3% (0.0%, 1.8%) | 0.0% |
| Dissatisfaction with cosmetic results | 4.1% (2.5%, 6.6%) | 8.9% (4.7%, 16.5%) |
| Hematoma/bleeding | 1.8% (0.8%, 3.6%) | 0.0% |
| Wound healing delay/tissue necrosis/dehiscence | 1.3% (0.5%, 3.0%) | 1.0% (0.1%, 6.7%) |
| Infection | 1.3% (0.5%, 3.0%) | 1.0% (0.1%, 7.0%) |

| Table 9 – KM Risk Rates of the First Occurrence of Adverse Events through 2 Years, per Subject | | |
|---|---|---|
| **Event (Includes all levels of severity)** | **Primary Augmentation Cohort (N=399)** | **Revision Augmentation Cohort (N=103)** |
| Implant exposure/extrusion | 0.0% | 2.0% (0.5%, 7.8%) |
| Skin scar unsatisfactory | 1.5% (0.7%, 3.4%) | 3.9% (1.5%, 10.1%) |
| Mastopexy unsatisfactory | 1.5% (0.7%, 3.4%) | 0.0% |
| Implant position unsatisfactory (malposition) | 2.6% (1.4%, 4.7%) | 1.0% (0.1%, 6.7%) |
| Persistent breast pain | 0.3% (0.0%, 1.8%) | 1.1% (0.1%, 7.2%) |
| Mastitis not requiring treatment | 0.5% (0.1%, 2.1%) | 0.0% |
| Inadequate milk supply | 0.3% (0.0%, 1.8%) | 1.1% (0.2%, 7.3%) |
| Lymphadenopathy | 0.3% (0.0%, 1.8%) | 0.0% |
| Dissatisfaction with implant size selected | 3.0% (1.7%, 5.3%) | 3.9% (1.5%, 10.1%) |
| Breast ptosis - after implant procedure | 0.5% (0.1%, 2.0%) | 4.1% (1.5%, 10.4%) |
| Breast lesion – benign | 1.5% (0.7%, 3.4%) | 4.1% (1.6%, 10.5%) |
| Breast lesion – malignant | 0.5% (0.1%, 2.0%) | 0.0% |

Numbers are failure rate determined by 1 – KM event-free rate.
* KM rates for Subsequent breast operation, Implant removal and Spontaneous deflation are based upon analyses of subjects with initial bilateral 8mm valve attachment component implants, N=363 for Primary Augmentation Cohort and N=93 for Revision Augmentation Cohort.
** 151 Primary Augmentation patients and 47 Revision Augmentation patients experienced at least one complication or reoperation through 2 years. 123 Primary Augmentation patients and 42 Revision Augmentation patients experienced at least one breast complication or reoperation through 2 years.

## REASONS FOR SUBSEQUENT BREAST OPERATIONS (REOPERATIONS)

There were 63 subsequent breast operations performed in 51 Primary Augmentation Cohort patients involving 114 surgical procedures and 34 subsequent breast operations performed in 22 Revision Augmentation Cohort patients involving 62 surgical procedures. The cumulative primary reasons for subsequent breast operations (reoperations) through 2 years in the Primary Augmentation Cohort and the Revision Augmentation Cohort are summarized in Table 10. The cumulative types of subsequent surgical procedures through 2 years in the Primary Augmentation Cohort and the Revision Augmentation Cohort are summarized in Table 11.

**Table 10 - Cumulative Primary Reasons for Subsequent Breast Operation through 2 Years, Subjects with Initial Bilateral 8mm Valve Attachment Component Implants, per Operation**

| Reason Category | Reason | Primary Augmentation | Revision Augmentation |
|---|---|---|---|
| Implant-related | Capsular contracture (II) | 4.8% (3/63) | 2.9% (1/34) |
| | Capsular contracture (III-IV) | 7.9% (5/63) | 2.9% (1/34) |
| | Wrinkling/scalloping | 4.8% (3/63) | 11.8% (4/34) |
| | Spontaneous deflation (includes inner or outer lumen) | 25.4% (16/63) | 11.8% (4/34) |
| | Wide sternum anatomically | 1.6% (1/63) | 0.0% |
| Procedure-related | Hematoma/bleeding | 4.8% (3/63) | 0.0% |
| | Wound healing delay/necrosis/dehiscence (no exposure) | 3.2% (2/63) | 0.0% |
| | Infection | 0.0% | 5.9% (2/34) |
| | Implant exposure/extrusion | 0.0% | 23.5% (8/34) |
| | Skin Scar Unsatisfactory | 3.2% (2/63) | 0.0% |
| | Mastopexy unsatisfactory | 4.8% (3/63) | 0.0% |
| | Implant position unsatisfactory (malposition) | 7.9% (5/63) | 0.0% |
| | Excess tissue breast fold | 1.6% (1/63) | 0.0% |
| | Stretched skin from ruptured silicone implant capsulectomy | 0.0% | 2.9% (1/34) |
| Dissatisfaction with size | Dissatisfaction with implant size (unilateral or bilateral) | 9.5% (6/63) | 11.8% (4/34) |
| Other reasons | Breast Ptosis prior to implant placement procedure | 3.2% (2/63) | 0.0% |
| | Breast Ptosis after implant placement procedure due to pregnancy, change in weight, and/or change in breast size | 1.6% (1/63) | 0.0% |
| | Breast Lesion – benign or malignant | 3.2% (2/63) | 0.0% |
| | Inadequate saline volume | 9.5% (6/63) | 14.7% (5/34) |
| | Absence of implant | 0.0% | 2.9% (1/34) |
| | Dissatisfaction with cosmetic result | 1.6% (1/63) | 8.8% (3/34) |
| | Tubular breast | 1.6% (1/63) | 0.0% |

Numbers are Percent (Count/N)
Denominator is the number of subsequent breast operations prior to the upper end of the visit window. One primary reason is summarized per operation. Subsequent breast operations were performed in 51 primary augmentation patients and 22 revision augmentation patients.
If both implants were operated on and had differ ent reasons, the primary reason will be selected following the reasons matching the collected categories as close as possible to the FDA guideline hierarchy.

| Table 11 - Cumulative Types of Subsequent Surgical Procedures in Subjects with Initial Bilateral 8mm Valve Attachment Component Implants through 2 Years, per Procedure | |
|---|---|
| **Procedure** | **Primary Augmentation (N=114)** |
| Explant and replacement using new IDEAL IMPLANT | 23.7% (27/114) |
| Fill volume adjustments | 19.3% (22/114) |
| Mastopexy – primary or revision | 14.0% (16/114) |
| Explant and replacement using other manufacturer's implant | 14.0% (16/114) |
| Capsular procedures | 10.5% (12/114) |
| Reposition a malpositioned implant | 6.1% (7/114) |
| Other* | 3.5% (4/114) |
| Evacuate hematoma/control bleeding | 2.6% (3/114) |
| Skin scar revision and/or secondary wound closure | 2.6% (3/114) |
| Treatment of breast lesion (e.g., open biopsy, lumpectomy) | 1.8% (2/114) |
| Explant and no immediate replacement with any implant | 0.9% (1/114) |
| I&D and/or debridement | 0.9% (1/114) |
| **Procedure** | **Revision Augmentation (N=62)** |
| Fill volume adjustments | 24.2% (15/62) |
| Explant and replacement using other manufacturer's implant | 22.6% (14/62) |
| Capsular procedures | 19.4% (12/62) |
| Explant and replacement using new IDEAL IMPLANT | 11.3% (7/62) |
| Other** | 9.7% (6/62) |
| Explant and no immediate replacement with any implant | 8.1% (5/62) |
| Skin scar revision and/or secondary wound closure | 3.2% (2/62) |
| Mastopexy - primary or revision | 1.6% (1/62) |
| Numbers are Percent (Count/N)<br>Denominator is the total number of procedures prior to the upper end of the visit window.<br>* Mastectomy and fat grafting to breasts.<br>** Excise skin, fat transfer to breasts and replace implants. | |

## REASONS FOR IMPLANT REMOVAL

The cumulative primary reasons for implant removal with or without replacement through 2 years are provided in Table 12 for the Primary Augmentation Cohort and the Revision Augmentation Cohort. There were 44 implants removed from 27 patients in the Primary Augmentation Cohort and 26 implants removed from 14 patients in the Revision Augmentation Cohort.

| Table 12 - Cumulative Primary Reasons for Implant Removal through 2 Years, Subjects with Initial Bilateral 8mm Valve Attachment Component Implants, per Implant | | | |
|---|---|---|---|
| **Reason Category** | **Reason** | **Primary Augmentation** | **Revision Augmentation** |
| Implant-related | Capsular contracture (II) | 2.3% (1/44) | 3.8% (1/26) |
| | Capsular contracture (III-IV) | 6.8% (3/44) | 3.8% (1/26) |
| | Wrinkling/scalloping | 2.3% (1/44) | 7.7% (2/26) |
| | Spontaneous deflation (includes inner or outer lumen) | 36.4% (16/44) | 19.2% (5/26) |
| Procedure-related | Healing delay/Necrosis/dehiscence (no exposure) | 2.3% (1/44) | 0.0% |
| | Infection | 0.0% | 3.8% (1/26) |
| | Implant exposure/extrusion | 0.0% | 15.4% (4/26) |
| Dissatisfaction with size | Dissatisfaction with implant size (unilateral or bilateral) | 29.5% (13/44) | 23.1% (6/26) |
| Other reasons | Breast Lesion – benign or malignant | 2.3% (1/44) | 0.0% |
| | Dissatisfaction with cosmetic result | 4.5% (2/44) | 23.1% (6/26) |
| | Replaced to match other implant | 11.4% (5/44) | 0.0% |
| | Preventive mastectomy | 2.3% (1/44) | 0.0% |
| Numbers are Percent (Count/N)<br>Denominator is the number of implants removed (with or without replacement). Implants were removed from 27 primary augmentation patients and from 14 revision augmentation patients. | | | |

## ADVERSE EVENTS AFTER IMPLANT REMOVAL

Among the Primary Augmentation patients, there were 28 implants removed and replaced with IDEAL IMPLANTS. Among the Revision Augmentation patients, there were 9 implants removed and replaced with IDEAL IMPLANTS. Table 13 below reflects the number of replaced implants (not patients) associated with the listed complications within 2 years following replacement. There were no new adverse events reported among patients who had their implants removed and not replaced.

| Table 13- New Adverse Events after Removal of IDEAL IMPLANT and Replacement with IDEAL IMPLANT, per Implant | | |
|---|---|---|
| **Event** | **Primary Augmentation** | **Revision Augmentation** |
| Capsule contracture Grade II/III/IV | 0.0% (0/28) | 11.1% (1/9) |
| Wrinkling/scalloping | 0.0% (0/28) | 11.1% (1/9) |
| Dissatisfaction with cosmetic results | 0.0% (0/28) | 11.1% (1/9) |
| Wound infection | 3.6% (1/28) | 11.1% (1/9) |
| Implant exposure/extrusion | 0.0% (0/28) | 11.1% (1/9) |
| Subsequent breast operation | 7.1% (2/28) | 22.2% (2/19) |
| Based upon analyses of subjects with initial bilateral final design of the implants: N=363 for Primary Augmentation Cohort and N=93 for Revision Augmentation Cohort. | | |

## CAPSULE CONTRACTURE

Subjects undergo an evaluation for capsular contracture using the Baker classification at each follow-up visit. Table 14 shows these data.

| Table 14 - Summary of Capsule Contracture Class Assessed at Follow-up Visits, per Implant | | | | | |
|---|---|---|---|---|---|
| **Cohort** | **Class** | **2 mo** | **6 mo** | **1 yr** | **2 yrs** |
| Primary Augmentation | I | 94.3% (749/794) | 95.9% (746/778) | 96.5% (739/766) | 94.8% (713/752) |
| | II | 5.2% (41/794) | 2.8% (22/778) | 2.6% (20/766) | 3.9% (29/752) |
| | III | 0.5% (4/794) | 1.2% (9/778) | 0.9% (7/766) | 1.3% (10/752) |
| | IV | 0.0% (0/794) | 0.1% (1/778) | 0.0% (0/766) | 0.0% (0/752) |
| Revision Augmentation | I | 96.1% (197/205) | 94.0% (188/200) | 92.1% (175/190) | 90.9% (170/187) |
| | II | 3.9% (8/205) | 5.0% (10/200) | 6.3% (12/190) | 5.9% (11/187) |
| | III | 0.0% (0/205) | 1.0% (2/200) | 1.1% (2/190) | 2.7% (5/187) |
| | IV | 0.0% (0/205) | 0.0% (0/200) | 0.5% (1/190) | 0.5% (1/187) |

***OTHER CLINICAL DATA FINDINGS***

This section summarizes post-implant observations pertaining to breast disease, connective tissue disease (CTD), lactation and reproductive problems, anaplastic large cell lymphoma (ALCL), and suicide. These data should be interpreted with caution in that there was no comparison group of similar women without implants. Confirmed reports were based on a diagnosis by a physician.

**Breast Disease**
In the Primary Augmentation Cohort, there were 4 reports of abnormal mammogram findings: 1 breast cancer at 3 months post implantation, 1 breast mass at 8 months, 1 calcification at 9 months and 1 additional evaluation necessary at 2 months. In the Revision Augmentation Cohort, there were 3 reports of abnormal mammogram findings: 1 cyst at 11 months post implantation, 1 calcification at 4 months and 1 additional evaluation necessary at 7 months.

**Anaplastic Large Cell Lymphoma**
Through 2 years, there were no reports of anaplastic large cell lymphoma (ALCL) in any patient.

**Connective Tissue/Autoimmune Disease (CTD)**
Subjects underwent a screening for connective tissue disorders at each follow-up visit. Approximately 1% (N=5) of the subjects in the Primary Augmentation Cohort and 5% (N=5) of the subjects in the Revision Augmentation Cohort were referred to a board certified Rheumatologist at the 2 year visit. A diagnosis of CTD was made in 2 patients in the Primary Augmentation Cohort: one with lupus at 13 months post implantation and one with non-specific arthritis at 24 months post implantation. No patient in the Revision Augmentation Cohort was diagnosed with a CTD.

**Lactation and Reproduction Problems**
In the Primary Augmentation Cohort, 3 patients experienced lactation complications: 2 had mastitis at 19 and 24 months post implantation; 1 had inadequate milk production at 11 months. In the Revision Augmentation Cohort, 1 patient experienced inadequate milk production at 24 months post implantation. In the Primary Augmentation Cohort, 3 patients had a reproductive problem (miscarriage) at 10, 22, and 23 months post implantation. No patient in the Revision Augmentation Cohort experienced a reproductive problem.

**Suicide**
There were no reports of suicide in either cohort through 2 years.

***CUMULATIVE RISK FOR OCCURRENCE OF EACH ADVERSE EVENT***

**Table 15 - Kaplan-Meier Rates for Adverse Events by Time Point, per Subject**

| Event (Includes all levels of severity) | Primary Augmentation (N= 399) | | | | Revision Augmentation (N=103) | | | |
|---|---|---|---|---|---|---|---|---|
| | 2 mo | 6 mo | 1 yr | 2 yr | 2 mo | 6 mo | 1 yr | 2 yr |
| Any complication or reoperation* | 19.1% (15.4%, 23.6%) | 29.4% (25.0%, 34.4%) | 35.3% (30.6%, 40.5%) | 42.2% (37.3%, 47.5%) | 23.7% (16.3%, 33.7%) | 36.6% (27.7%, 47.2%) | 44.1% (34.7%, 54.8%) | 50.5% (40.9%, 61.0%) |
| Any breast complication or reoperation* | 15.4% (12.1%, 19.6%) | 24.0% (19.9% 28.7%) | 27.9% (23.6%, 32.9%) | 34.2% (29.5%, 39.3%) | 19.4% (12.7%, 28.9%) | 31.2% (22.8%, 41.7%) | 37.6% (28.7%, 48.3%) | 45.2% (35.7%, 55.8%) |
| All subsequent breast operations* | 1.7% (0.7%, 3.6%) | 5.0% (3.2%, 7.8%) | 11.1% (8.3%, 14.8%) | 14.2% (11.0%, 18.3%) | 1.1% (0.2%, 7.4%) | 15.1% (9.2%, 24.1%) | 18.3% (11.8%, 27.7%) | 23.7% (16.3%, 33.7%) |
| Related to implant | 0.5% (0.1%, 2.0%) | 2.0% (1.0%, 4.0%) | 5.1% (3.3%, 7.8%) | 8.4% (6.1%, 11.7%) | 1.0% (0.1%, 6.7%) | 2.9% (1.0%, 8.8%) | 7.0% (3.4%, 14.2%) | 11.1% (6.3%, 19.2%) |
| Related to procedure | 1.0% (0.4%, 2.6%) | 2.0% (1.0%, 4.0%) | 3.6% (2.1%, 5.9%) | 4.1% (2.5%, 6.6%) | 0.0% | 2.0% (0.5%, 7.7%) | 3.0% (1.0%, 9.0%) | 3.0% (1.0%, 9.0%) |
| Related to dissatisfaction with implant size | 0.3% (0.0%, 1.8%) | 0.8% (0.2%, 2.3%) | 2.0% (1.0%, 4.0%) | 2.3% (1.2%, 4.4%) | 0.0% | 4.0% (1.5%, 10.2%) | 4.0% (1.5%, 10.2%) | 4.0% (1.5%, 10.2%) |
| Other reason** | 0.5% (0.1%, 2.0%) | 2.8% (1.5%, 4.9%) | 4.8% (3.1%, 7.4%) | 6.9% (4.8%, 9.9%) | 1.0% (0.1%, 6.7%) | 11.7% (6.8%, 19.6%) | 13.7% (8.3%, 22.0%) | 15.7% (9.9%, 24.4%) |
| Implant removal with or without replacement* | 0.6% (0.1%, 2.2%) | 2.5% (1.3%, 4.7%) | 4.7% (3.0%, 7.5%) | 7.5% (5.2%, 10.8%) | 0.0% | 7.5% (3.7%, 15.1%) | 10.8% (5.9%, 19.1%) | 15.1% (9.2%, 24.2%) |
| Anesthesia complications | 0.0% | 0.0% | 0.0% | 0.0% | 1.0% (0.1%, 6.7%) | 1.0% (0.1%, 6.7%) | 1.0% (0.1%, 6.7%) | 1.0% (0.1%, 6.7%) |
| Neurologic complications | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.0% | 0.0% | 0.0% | 0.0% |
| Connective Tissue Disease diagnosis | 0.0% | 0.0% | 0.0% | 0.5% (0.1%, 2.1%) | 0.0% | 0.0% | 0.0% | 0.0% |
| Reproductive problem | 0.0% | 0.0% | 0.0% | 0.5% (0.1%, 2.1%) | 0.0% | 0.0% | 0.0% | 0.0% |
| Other Adverse Event*** | 3.5% (2.1%, 5.9%) | 5.3% (3.5%, 8.0%) | 7.9% (5.6%, 11.0%) | 10.8% (8.1%, 14.3%) | 6.8% (3.3%, 13.7%) | 7.8% (4.0%, 15.0%) | 10.9% (6.2%, 18.8%) | 14.0% (8.6%, 22.6%) |
| Capsule contracture Grade II/III/IV | 7.8% (5.5%, 10.9%) | 11.3% (8.6%, 14.9%) | 13.4% (10.4%, 17.1%) | 17.1% (13.7%, 21.2%) | 5.8% (2.7%, 12.5%) | 11.8% (6.9%, 19.9%) | 18.0% (11.7%, 27.0%) | 24.3% (17.0%, 34.0%) |

**Table 15 - Kaplan-Meier Rates for Adverse Events by Time Point, per Subject**

| Event (Includes all levels of severity) | Primary Augmentation (N= 399) | | | | Revision Augmentation (N=103) | | | |
|---|---|---|---|---|---|---|---|---|
| | 2 mo | 6 mo | 1 yr | 2 yr | 2 mo | 6 mo | 1 yr | 2 yr |
| Capsule contracture Grade II | 6.5% (4.5%, 9.4%) | 9.0% (6.6%, 12.3%) | 10.9% (8.2%, 14.4%) | 14.0% (10.9%, 17.8%) | 5.8% (2.7%, 12.5%) | 9.9% (5.4%, 17.5%) | 16.0% (10.1%, 24.8%) | 21.3% (14.4%, 30.7%) |
| Capsule contracture Grade III | 1.5% (0.7%, 3.3%) | 2.3% (1.2%, 4.3%) | 2.8% (1.5%, 5.0%) | 3.6% (2.1%, 5.9%) | 0.0% | 2.0% (0.5%, 7.6%) | 4.0% (1.5%, 10.3%) | 8.2% (4.2%, 15.8%) |
| Capsule contracture Grade IV | 0.0% | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.0% | 0.0% | 1.0% (0.1%, 7.0%) | 2.1% (0.5%, 8.1%) |
| Capsule contracture Grade III/IV | 1.5% (0.7%, 3.3%) | 2.5% (1.4%, 4.6%) | 3.0% (1.7%, 5.3%) | 3.8% (2.3%, 6.3%) | 0.0% | 2.0% (0.5%, 7.6%) | 4.0% (1.5%, 10.3%) | 8.2% (4.2%, 15.8%) |
| Wrinkling/scalloping (excludes mild severity) | 0.5% (0.1%, 2.0%) | 1.8% (0.8%, 3.7%) | 3.0% (1.7%, 5.3%) | 3.8% (2.3%, 6.3%) | 2.9% (0.9%, 8.8%) | 6.9% (3.3%, 13.8%) | 9.9% (5.5%, 17.7%) | 12.0% (7.0%, 20.2%) |
| Spontaneous deflation* | 0.3% (0.0%, 1.9%) | 1.4% (0.6%, 3.3%) | 2.2% (1.1%, 4.4%) | 4.8% (3.0%, 7.6%) | 1.1% (0.2%, 7.4%) | 2.2% (0.5%, 8.4%) | 2.2% (0.5%, 8.4%) | 3.3% (1.1%, 10.0%) |
| Seroma | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 2.9% (0.9%, 8.8%) | 2.9% (0.9%, 8.8%) | 2.9% (0.9%, 8.8%) | 2.9% (0.9%, 8.8%) |
| Breast tissue atrophy/chest wall deformity | 0.0% | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.0% | 0.0% | 0.0% | 0.0% |
| Dissatisfaction with cosmetic results | 1.3% (0.5%, 3.0%) | 2.0% (1.0%, 4.0%) | 2.3% (1.2%, 4.3%) | 4.1% (2.5%, 6.6%) | 2.9% (0.9%, 8.8%) | 4.9% (2.0%, 11.3%) | 6.9% (3.3%, 13.8%) | 8.9% (4.7%, 16.5%) |
| Hematoma/bleeding | 1.5% (0.7%, 3.3%) | 1.8% (0.8%, 3.6%) | 1.8% (0.8%, 3.6%) | 1.8% (0.8%, 3.6%) | 0.0% | 0.0% | 0.0% | 0.0% |
| Wound healing delay/tissue necrosis/dehiscence | 1.0% (0.4%, 2.6%) | 1.3% (0.5%, 3.0%) | 1.3% (0.5%, 3.0%) | 1.3% (0.5%, 3.0%) | 1.0% (0.1%, 6.7%) | 1.0% (0.1%, 6.7%) | 1.0% (0.1%, 6.7%) | 1.0% (0.1%, 6.7%) |
| Wound infection | 0.5% (0.1%, 2.0%) | 1.0% (0.4%, 2.7%) | 1.3% (0.5%, 3.0%) | 1.3% (0.5%, 3.0%) | 0.0% | 0.0% | 1.0% (0.1%, 7.0%) | 1.0% (0.1%, 7.0%) |
| Implant exposure/extrusion | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 1.0% (0.1%, 6.8%) | 2.0% (0.5%, 7.8%) | 2.0% (0.5%, 7.8%) |
| Skin scar unsatisfactory | 0.8% (0.2%, 2.3%) | 1.0% (0.4%, 2.7%) | 1.0% (0.4%, 2.7%) | 1.5% (0.7%, 3.4%) | 1.9% (0.5%, 7.5%) | 3.9% (1.5%, 10.1%) | 3.9% (1.5%, 10.1%) | 3.9% (1.5%, 10.1%) |
| Mastopexy unsatisfactory | 0.8% (0.2%, 2.3%) | 1.0% (0.4%, 2.7%) | 1.0% (0.4%, 2.7%) | 1.5% (0.7%, 3.4%) | 0.0% | 0.0% | 0.0% | 0.0% |
| Implant position unsatisfactory (malposition) | 0.5% (0.1%, 2.0%) | 1.3% (0.5%, 3.0%) | 1.5% (0.7%, 3.3%) | 2.6% (1.4%, 4.7%) | 1.0% (0.1%, 6.7%) | 1.0% (0.1%, 6.7%) | 1.0% (0.1%, 6.7%) | 1.0% (0.1%, 6.7%) |

**Table 15 - Kaplan-Meier Rates for Adverse Events by Time Point, per Subject**

| Event (Includes all levels of severity) | Primary Augmentation (N= 399) | | | | Revision Augmentation (N=103) | | | |
|---|---|---|---|---|---|---|---|---|
| | 2 mo | 6 mo | 1 yr | 2 yr | 2 mo | 6 mo | 1 yr | 2 yr |
| Persistent breast pain | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.0% | 0.0% | 0.0% | 1.1% (0.1%, 7.2%) |
| Mastitis not requiring treatment | 0.0% | 0.0% | 0.0% | 0.5% (0.1%, 2.1%) | 0.0% | 0.0% | 0.0% | 0.0% |
| Inadequate milk supply | 0.0% | 0.0% | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.0% | 0.0% | 0.0% | 1.1% (0.2%, 7.3%) |
| Lymphadenopathy | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.0% | 0.0% | 0.0% | 0.0% |
| Dissatisfaction with implant size selected | 1.3% (0.5%, 3.0%) | 2.8% (1.5%, 4.9%) | 3.0% (1.7%, 5.3%) | 3.0% (1.7%, 5.3%) | 1.9% (0.5%, 7.5%) | 3.9% (1.5%, 10.1%) | 3.9% (1.5%, 10.1%) | 3.9% (1.5%, 10.1%) |
| Breast ptosis - after implant procedure | 0.0% | 0.3% (0.0%, 1.8%) | 0.3% (0.0%, 1.8%) | 0.5% (0.1%, 2.0%) | 0.0% | 1.0% (0.1%, 6.8%) | 2.0% (0.5%, 7.8%) | 4.1% (1.5%, 10.4%) |
| Breast lesion - benign | 0.0% | 0.5% (0.1%, 2.0%) | 0.8% (0.2%, 2.3%) | 1.5% (0.7%, 3.4%) | 0.0% | 1.0% (0.1%, 6.8%) | 3.0% (1.0%, 9.1%) | 4.1% (1.6%, 10.5%) |
| Breast lesion - malignant | 0.0% | 0.5% (0.1%, 2.0%) | 0.5% (0.1%, 2.0%) | 0.5% (0.1%, 2.0%) | 0.0% | 0.0% | 0.0% | 0.0% |

Numbers are failure rate determined by 1 - Kaplan Meier event-free rate. Subjects who remain in the study through 2 years and are event free at their most recent follow-up are assumed to be event free at the upper end of the 2-year visit window.

* KM rates for these Subsequent breast operation, Implant removal and Spontaneous deflation are based upon analyses of subjects with initial bilateral final design of valve attachment component implants, N=363 for Primary Augmentation Cohort and N=93 for Revision Augmentation Cohort.

**Other reasons for subsequent breast operations: For the Primary Augmentation Cohort: breast ptosis, breast lesion, inadequate saline volume, dissatisfaction with cosmetic result and tubular breast; for the Revision Augmentation Cohort: inadequate saline volume, absence of implant, dissatisfaction with cosmetic result.

***Other adverse events: For the Primary Augmentation Cohort: nasal polyps, seizure disorder, bowel obstruction, hemorrhoids, hypothyroidism, emotional issue, neck rash, abdominal muscle bleed, rotator cuff problem, cholecystitis, foot fracture, contact dermatitis, back pain, tubular breast, liver cyst, herpes zoster infection, staph infection nose, anxiety, cystitis, diabetes, depression, head trauma, urinary retention, drug overdose, borderline personality disorder, anal fissure, arm cyst, abdominal incision pain, cold, herniated disc, enlarged thymus, kidney infection, rectal prolapse, abdominal wound infection, arm pain, sinus infection, nausea, eczema arms and renal stone. For the Revision Augmentation Cohort: sebaceous cysts of scalp, sinus obstruction, renal stone, seroma to abdomen, abdominal wound infection, anemia, femoral hernia, hand numbness, stasis ulcer ankle, superficial burn, intra-arterial septal communication, rash abdomen, EKG abnormality, back pain, diverticulitis, whooping cough and knee trauma.

## CONCLUSIONS FROM CLINICAL STUDY

### *EFFECTIVENESS CONCLUSIONS*

The effectiveness outcomes demonstrate that the majority of patients who underwent a chest measurement (primary augmentation cohort only) report an increase in chest circumference. The majority of patients who provided Breast Evaluation Questionnaire assessments at the 1 and 2-year assessment point had favorable results. The majority of patients who provided a satisfaction rating at 2 years indicated that they were satisfied with

their breast implants. The majority of physicians who provided a satisfaction rating at 2 years reported being satisfied with the breast implants. Comparison of baseline SF-36 scores to scores at 1 and 2 years show no clinically significant changes.

***SAFETY CONCLUSIONS***

The risks of the device are based on nonclinical laboratory and/or animal studies as well as data collected in a clinical study conducted to support PMA approval as described above.

Cumulative risk of complication through 2-year follow-up demonstrated that 42.2% of primary augmentation patients experienced complications, and 50.5% of revision augmentation patients experienced complications. In addition, 34.2% of primary augmentation patients experienced breast related complications, and 45.2% of revision augmentation patients experienced breast related complications. The most common complications through 2 years were reoperations, implant removal with or without replacement, capsular contracture and wrinkling/scalloping.

***BENEFIT-RISK CONCLUSIONS***

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above.

Additional factors to be considered in determining probable risks and benefits for the IDEAL IMPLANT device included: the active and deliberate search/documentation of adverse events in the clinical study, single arm pivotal study design, lacking individual patient success criteria, good patient follow-up through 2 years, the availability of alternative treatments, patient-centric assessments, and risk mitigation with device use by trained surgeons in patients with informed consent.

In conclusion, given the available information above, the data support that the probable benefits outweigh the probable risks for women for IDEAL IMPLANT for the following procedures:

- Primary breast augmentation to increase breast size.
- Revision breast augmentation to correct or improve the result of a primary breast augmentation surgery.

## INFORMATION A PHYSICIAN SHOULD PROVIDE TO THE PATIENT

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

- Making an Informed Decision IDEAL IMPLANT® Structured Breast Implant Surgery This booklet can be used to facilitate patient education in the risks and benefits of saline-filled breast implant surgery. The patient should be advised to wait at least a week after reviewing and considering this information before deciding whether to have augmentation surgery.

- Patient Implant Card
  Each breast implant is supplied with a Patient Implant Card and six Implant Record Labels. To complete the Patient Implant Card, place one Implant Record Label for each implant on the back of the card. If a label in unavailable, the serial number and size of the implant may be copied by hand from the implant label. The patient should be provided with the Patient Implant Card for personal reference.

## ADDITIONAL PRODUCT INFORMATION

***EXPLANT RETURN***
The reason for explantation should be reported and the explant returned to Ideal Implant Incorporated, Product Evaluation Department, 5005 LBJ Freeway, Suite 900, Dallas, Texas, 75244 for examination and analysis. Call 214-492-2500 for instructions and shipping information.

***PRODUCT EVALUATION***
Ideal Implant Incorporated requires that any serious complications resulting from use of this implant be brought to the immediate attention of Ideal Implant Incorporated, Product Evaluation Department, 5005 LBJ Freeway, Suite 900, Dallas, Texas, 75244.

***RETURNED GOODS POLICY***
Implants returned must have the shrink wrap seal intact and must be returned within 6 months from date of shipping to be eligible for credit or replacement. Please contact Ideal Implant Incorporated for details.

***LIMITED WARRANTY***
The Ideal Implant Incorporated Breast Implant Limited Warranty provides lifetime replacement and limited financial assistance in the event of implant failure, subject to certain conditions as described in the Breast Implant Limited Warranty posted on idealimplant.com. For more information, contact Ideal Implant Incorporated.

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