Making an Informed Decision

IDEAL IMPLANT® Structured Breast Implant for Breast Augmentation Surgery

August 2015

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

Table of Contents

Glossary

Anaplastic Large Cell Lymphoma (ALCL)	ALCL is not breast cancer; it is a rare type of non-Hodgkin's lymphoma, a cancer of the immune system cells.
Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	Lack of proportion of shape, size and position between the two breasts.
Autoimmune disease	A disease in which the body mounts an "attack" response to its own tissues or cell types. Normally, the body's immune mechanism is able to distinguish clearly between what is a normal substance and what is foreign. In autoimmune diseases, this system becomes defective and mounts an attack against normal parts of the body, causing tissue injury. Certain diseases such as rheumatoid arthritis, lupus and scleroderma are considered to be autoimmune diseases.
Axillary	Pertaining to the armpit area.
Baffle shell	Perforated shell inside the outer lumen of the implant that restricts saline movement.
Bilateral	Pertaining to both the left and right breast.
Biopsy	Removal and examination of sample tissue for diagnosis.
Body dysmorphic disorder	A psychological condition characterized by excessive worry about an imagined or minor physical flaw to the point that it can interfere with normal daily activities.
Breast augmentation	Enlargement of the breast by surgical implantation of a breast implant. The first time a breast implant is placed to increase breast size, it is called Primary Augmentation. All subsequent times the implant is replaced, it is called Revision Augmentation.
Breast reconstruction	A surgery to reconstruct a breast after tissue was removed because of cancer or injury.
Capsule	Scar tissue that forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture.
Capsule contracture	Tightening of the tissue surrounding a breast implant which results in a firmer breast. Capsule contracture may result in the need for additional surgery because of pain or unacceptable appearance. Capsule contracture is a risk for implant rupture. Capsule contracture is classified by Baker Grades:

Grade I - Normally soft and natural appearance
Grade II - A little firm, but breast looks normal
Grade III - More firm than normal, and looks abnormal
Grade IV - Hard, obvious distortion, tenderness with pain

Capsulectomy	Surgical removal of the scar capsule surrounding a breast implant.
Capsulotomy, closed	Compression on the outside of the breast to break the capsule and relieve contracture.
Capsulotomy, open	Surgically cutting or removing part of the capsule through an incision.
Carcinoma	Invasive malignant tumor.
Congenital anomaly	Abnormality existing at birth.
Connective tissue diseases (CTD)	A disease or group of diseases affecting connective tissue. The cause of these diseases is unknown. The diseases are grouped together on the basis of clinical signs, symptoms, and laboratory abnormalities.
Core Study	The primary clinical study of Primary Breast Augmentation and Revision Augmentation patients that supported the approval of the premarket approval (PMA) application. Safety and effectiveness date are collected yearly through 10 years.
Deflation/Rupture	Refers to loss of saline from a saline-filled breast implant due to a tear or cut in the implant shell or possibly a valve leak, resulting in a partial or complete collapse of the implant.
Delayed Wound Healing	Unusually slow progress in the healing of a wound; surgical incision takes longer to heal or fails to heal normally.
Extrusion	A breast implant being pressed out of the body through the surgical wound or skin.
Fibrous tissues	Connective tissues composed mostly of fibers.
Hematoma	A swelling or mass of blood (usually clotted) confined to a space and caused by a break in a blood vessel.
Hypertrophic scarring	Enlarged scar that remains after a wound heals.
Inflammation	The response of the body to infection or injury characterized by redness, swelling, warmth, and/or pain.
Inframammary	Below the breast.
Inframammary fold	The crease at the base of the breast and the chest wall.

Inframammary incision	A surgical incision at the inframammary fold.
Inner lumen	A space inside the inner shell of the implant that holds saline.
Inner shell	The innermost shell of the implant.
Inpatient surgery	Surgery performed in a hospital requiring an overnight stay.
Lactation	The production and secretion of milk by the breast glands.
Malposition	The implant is not in the usual or proper position.
Mammary	Pertaining to the breast.
Mammography	Use of radiography (X-rays) of the breast to detect breast cancer. Recommended as a screening technique for early detection of breast cancer.
Mastitis	Inflammation of the breast.
Mastopexy	Plastic surgery to raise and reshape sagging (ptotic) breasts into a more elevated position.
Necrosis	Death of tissue may be caused by insufficient blood supply, trauma, radiation, chemical agents or infectious disease.
Outer lumen	A space between the inner shell and outer shell of the implant that holds saline. The baffle shell(s) is within in this space.
Outer shell	The outermost shell of the implant.
Outpatient surgery	Surgery performed in a hospital or surgery center not requiring an overnight stay.
Palpability	The ability to feel the implant with the hand.
Pectoralis	The major muscle of the chest.
Periareolar Incision	A surgical incision at the edge of the areola, the pigmented area surrounding the nipple.
Plastic surgery	Surgery intended to improve, restore, repair, or reconstruct portions of the body following trauma, injury or illness.
Postoperative	After surgery.
Ptosis	Sagging of the breast usually due to normal aging, pregnancy or weight loss.
Saline	A solution of sodium chloride (salt) and water.

Seroma	Localized collection of serum, the watery portion of blood.
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
Subglandular placement	Placement of the breast implant behind the skin and mammary gland, but on top of the chest (pectoralis) muscle. Also called retromammary placement.
Submuscular placement	Placement of the breast implant under the chest (pectoralis) muscle. Also called retropectoral or subpectoral placement.
Subsequent Operation	Any surgical procedure following the initial procedure for placement of a breast implant.
Surgical incision	Cut made in tissue for surgical purposes.
Toxic shock syndrome	A rare, but life-threatening infection that may occur after surgery. Symptoms include sudden, high fever, vomiting, diarrhea, decreased blood pressure, fainting, dizziness, and sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment if toxic shock syndrome is suspected.
Transaxillary incision	Incision across the long axis of the armpit (axilla).
Umbilical	Relating to the navel.
Unilateral	Affecting only left or right breast.

1.0 Considering Breast Implant Surgery

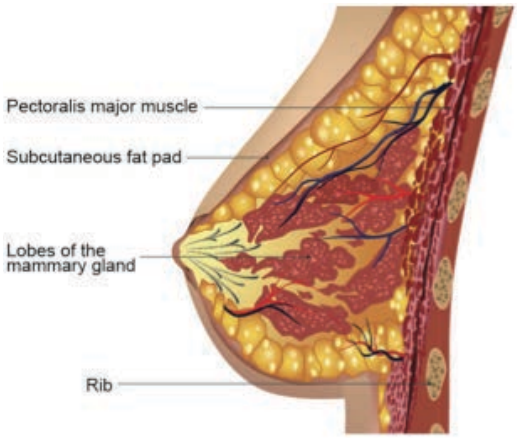
The purpose of this booklet is to assist you in making an informed decision about having breast augmentation surgery to increase the size of your breasts or revision augmentation surgery to correct or improve a previous breast augmentation. This educational booklet is not intended to replace consultation with your surgeon. This educational booklet has been prepared to help you talk with your surgeon, as well as provide you with general information on breast augmentation surgery and give you specific details about IDEAL IMPLANT Structured Breast Implants.

Please read this entire brochure carefully, and if you have any questions or there are things you do not understand, please discuss them with your surgeon before making any decisions. Your decision whether or not to get breast implants should be based on realistic expectations of the outcome. Your results will depend on many individual factors, such as your overall health, chest and breast shape, tissue thickness, and implant size. Make sure you speak with your surgeon about your expectations of the results, as well as what you can expect about the length of surgery, recovery, risks and potential complications.

You should wait at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast augmentation surgery. In the case of a revision-augmentation; however, your surgeon may find it medically advisable to perform surgery sooner.

1.1 What Gives the Breast Its Shape?

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. Situated beneath the breast is the pectoralis major muscle of the chest wall. Factors such as pregnancy (when milk glands are temporarily enlarged), rapid weight loss, and the effects of gravity as you age combine to stretch the skin, which may cause the breast to droop or sag. Your surgeon may suggest an additional procedure at the time of breast augmentation, such as mastopexy, to lift and reshape the breasts.



1.2 What is the IDEAL IMPLANT?

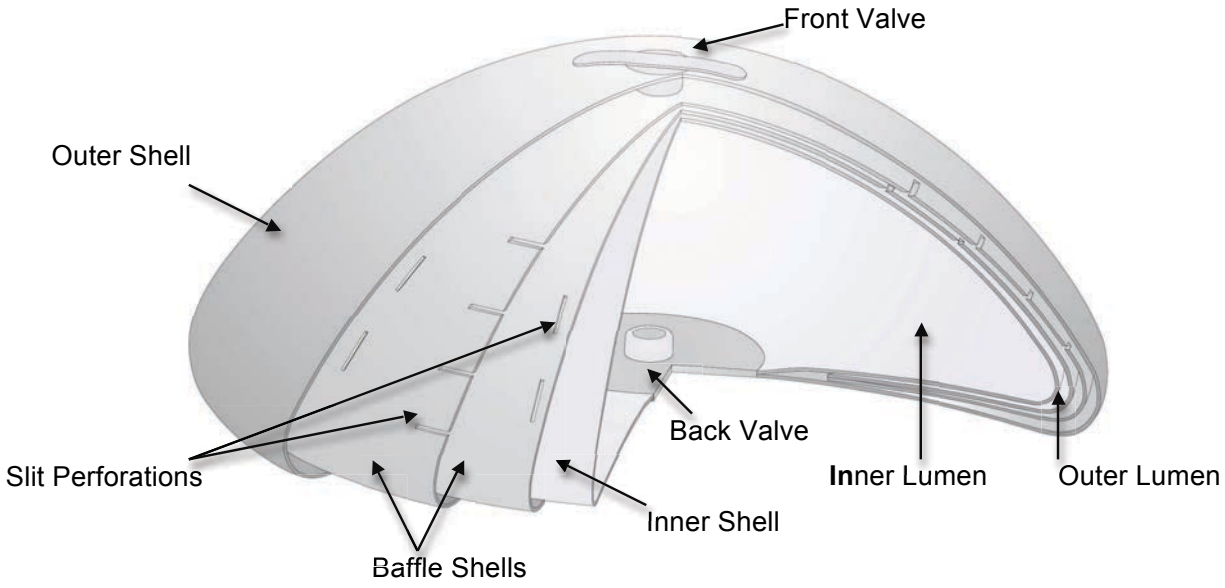
IDEAL IMPLANT on a curved surface simulating the curve of the chest wall

The IDEAL IMPLANT is a round, smooth-surface, saline-filled breast implant. 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 (Table 1). 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. See Section 4.4 for more information about the IDEAL IMPLANT.



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

Table 1 - Number of Shells Relative to Implant Size

Implant Size	Inner Shell	Baffle Shells	Outer Shell	Total Shells
210 cc	1	1	1	3
240 cc	1	1	1	3
270 cc	1	1	1	3
300 cc	1	1	1	3
335 cc	1	2	1	4
370 cc	1	2	1	4
405 cc	1	2	1	4
440 cc	1	2	1	4
475 cc	1	2	1	4
515 cc	1	2	1	4
555 cc	1	2	1	4
595 cc	1	3	1	5
635 cc	1	3	1	5
675 cc	1	3	1	5

1.3 Are You Eligible for IDEAL IMPLANT Structured Breast Implants?

These implants are indicated for women at least 18 years old for the following:

- Primary Breast Augmentation - This procedure is done to increase the size and proportion of a woman's breasts.
- Revision Augmentation - This procedure is done to correct or modify existing saline-filled or silicone gel-filled augmentation implants.

1.4 Who is Not Eligible for IDEAL IMPLANT Structured Breast Implants?

These implants are contraindicated for:

- Women with existing malignant or pre-malignant cancer of the breast without adequate treatment
- Women with an active infection anywhere in her body
- Women who are currently pregnant or nursing

1.5 What are the Precautions?

Before you have surgery, you should have a detailed conversation with all of your doctors (primary care doctor, surgeon, and any specialists you see) about breast implant surgery in light of your medical history. Your medical history will impact the complications and outcomes you encounter.

CAUTION: Tell your doctor if any of the following conditions apply to you, as the safety and effectiveness of the IDEAL IMPLANT has not been established in patients with the following conditions:

- Autoimmune diseases such as lupus and scleroderma.
- A compromised immune system (for example, currently taking drugs that weaken the body's natural resistance to disease).
- Conditions or medications that interfere with 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. If you have been diagnosed with or treated for depression, an anxiety disorder, or another mental health condition, you should wait until your condition has resolved or stabilized before having breast implant surgery. Discuss any history of mental health disorders with your doctor(s) prior to surgery

1.6 What are the Warnings?

- There is no guarantee that your results will match those of other women. Results will depend on many factors, such as your general health, chest shape, breast shape and position, skin quality, healing capability that may be slowed by smoking or various medications, tendency to bleed, previous breast surgery, surgeon's skill, type of procedure, and size of implant.
- Be aware that many of the changes to your breast following implantation cannot be undone. If you later choose to have your implants removed and not replaced, you may experience unacceptable skin dimpling, puckering, wrinkling or other changes in appearance that may be permanent.

- Breast implants are not lifetime devices, and breast implantation is likely not a one-time surgery. You likely will need additional unplanned surgery on your breasts because of complications or unacceptable cosmetic outcomes. These additional surgeries can include implant removal or replacement, or other breast procedures. Surgery to replace implants, revision augmentation, carries higher risks of complications than the initial implant procedure. Therefore, consider the complication rates for revision augmentation, since you may experience these risks in the future.
- Breast implants may affect your ability to produce milk for breast-feeding. Also, breast implants will not prevent your breasts from sagging after pregnancy.
- With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.
- Insurance does not cover breast augmentation and may not cover subsequent breast operations and additional surgeon visits following augmentation. For patients who have undergone breast implantation, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complication may not be covered as well. You should check with your insurance company regarding these coverage issues.
- 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.

1.7 What are the Other Important Factors for You to Consider?

Pre-implantation Mammography

You may wish to undergo a preoperative mammogram and another one 6 months to one year after implantation to establish a baseline.

Interference with Mammography

With breast implants, routine screening mammography for breast cancer will be more difficult. Therefore, it is essential that you tell your mammography technologist that you have an implant before the procedure. The technologist can use special techniques to minimize the possibility of rupture and to get the best possible views of the breast tissue. Because the breast is squeezed during mammography, it is possible for an implant to rupture during the procedure. More x-ray views are necessary with these special techniques; therefore, women with breast implants will receive more radiation. However, the benefit of the mammogram in finding cancer outweighs the risk of additional x-rays.

Distinguishing the Implant From Breast Tissue During Breast Self-Examination

You should perform a breast self-examination monthly on your implanted breast. In order to do this effectively, you should ask your surgeon to help you distinguish the implant from your breast tissue. Any new lumps or an abnormal finding on the mammogram should be evaluated with a biopsy. If a biopsy is performed, care must be taken to avoid puncturing the implant.

Long Term Effects

The long-term safety and effectiveness of breast implants have not been studied; 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 booklet.

Capsulotomy

You should be aware that closed capsulotomy, the practice of forcible squeezing or pressing on the fibrous capsule around the implant to break the scar capsule is not recommended as this may result in breakage of the implant.

2.0 Breast Implant Benefits and Risks

Any type of surgical procedure involves risks such as infection, swelling, redness, bleeding, pain, effects of anesthesia and even death. While some risks are more serious than others, all risks need to be balanced against the benefits of the procedure.

2.1 What are the Benefits?

Breast augmentation can increase the size and improve the proportion of the breasts. Revision augmentation replaces existing breast implants and can correct or improve the result of the initial procedure. Breast augmentation has the potential to offer psychological benefits as well as the physical benefits. Section 3.8 provides more information on benefits seen in the Ideal Implant study.

2.2 What are the Potential Risks?

Potential risks specific to breast implants are described below. The likelihood of an event occurring in primary augmentation patients and revision augmentation patients is shown below in Table 2. Sections 3.2-3.7 provide more information on risks seen in the Ideal Implant study.

Table 2 - Risks of Breast Augmentation through 2 Years with IDEAL IMPLANT

Event (Includes all levels of severity)	Likelihood of Event Occurring in Primary Augmentation Patients (N=399)	Likelihood of Event Occurring in Revision-Augmentation Patients (N=103)	Possible Resulting Effects of the Event
Key Risks			
Any complication or reoperation*	42 out of 100 patients (42%)**	50 out of 100 patients (50%)**	• Any effect listed below in any category
Any breast complication or reoperation*	34 out of 100 patients (34%)**	45 out of 100 patients (45%)**	• Any effect listed below in any breast-related category
Additional Surgeries* (Reoperations)	14 out of 100 patients (14%)	24 out of 100 patients (24%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal with or without Replacement*	8 out of 100 patients (8%)	15 out of 100 patients (15%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis

Table 2 - Risks of Breast Augmentation through 2 Years with IDEAL IMPLANT			
Event (Includes all levels of severity)	**Likelihood of Event Occurring in Primary Augmentation Patients (N=399)**	**Likelihood of Event Occurring in Revision-Augmentation Patients (N=103)**	**Possible Resulting Effects of the Event**
			• Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Capsule Contracture (Baker Grade III/IV)	4 out of 100 patients (4%)	8 out of 100 patients (8%)	• Pain or Discomfort • Breast hardness/firmness • Reoperation • Implant Removal
Deflation (Rupture)*	5 out of 100 patients (5%)	3 out of 100 patients (3%)	• Implant removal • Reoperation
Other Risks Occurring in 1% or more of Patients			
Implant Malposition	3 out of 100 patients (3%)	1 out of 100 patients (1%)	• Implant visibility • Asymmetry • Reoperation • Implant removal
Breast Pain	Less than 1 out of 100 patients (0.3%)	1 out of 100 patients (1%)	• Resulting effects are contingent on underlying cause(s)
Ptosis	Less than 1 out of 100 patients (0.5%)	4 out of 100 patients (4%)	• Undesirable cosmetic result • Wrinkling/rippling • Reoperation • Implant removal
Infection	1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
Dissatisfaction with Cosmetic Results	4 out of 100 patients (4%)	9 out of 100 patients (9%)	• Resulting effects are contingent on underlying cause(s) • Reoperation • Implant removal • Undesirable cosmetic result • Asymmetry
Seroma/Fluid Accumulation	Less than 1 out of 100 patients (0.3%)	3 out of 100 patients (3%)	• Swelling • Pain or discomfort • Infection • Incision / drainage (reoperation) • Implant removal
Delayed Wound Healing	1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Pain or discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal
Hematoma	2 out of 100 patients (2%)	0 out of 100 patients (0%)	• Swelling • Pain or Discomfort • Infection • Incision / drainage (reoperation)

Table 2 - Risks of Breast Augmentation through 2 Years with IDEAL IMPLANT

Event (Includes all levels of severity)	Likelihood of Event Occurring in Primary Augmentation Patients (N=399)	Likelihood of Event Occurring in Revision-Augmentation Patients (N=103)	Possible Resulting Effects of the Event
			• Implant removal
Dissatisfaction with Implant Size Selected	3 out of 100 patients (3%)	4 out of 100 patients (4%)	• Undesirable cosmetic result • Reoperation • Implant removal
Hypertrophic/Other Abnormal Scarring	2 out of 100 patients (2%)	4 out of 100 patients (4%)	• Scar revision procedure (reoperation)
Wrinkling/Rippling (excludes mild severity)	4 out of 100 patients (4%)	12 out of 100 patients (12%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal
Extrusion	0 out of 100 patients (0%)	2 out of 100 patients (2%)	• Pain or Discomfort • Scarring • Reoperation • Implant removal
Lesion - Benign	2 out of 100 patients (2%)	4 out of 100 patients (4%)	• Reoperation • Pain or Discomfort
Mastopexy Unsatisfactory	2 out of 100 patients (2%)	0 out of 100 patients (0%)	• Reoperation • Pain or Discomfort • Undesirable cosmetic result
Inadequate Milk Supply	Less than 1 out of 100 patients (0.3%)	1 out of 100 patients (1%)	• Breast feed difficulties • Pain or Discomfort

*Rates for Reoperation, Implant removal and Spontaneous deflation are 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. The other 36 primary augmentation subjects and 10 revision augmentation subjects received an early design of the implant which is not being manufactured, and therefore were excluded from the complication rates for these 3 events.

** 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.

Deflation (Rupture)

Breast implants deflate when the saline solution leaks either through an unsealed or damaged valve or through a break in the implant shell. Implant deflation can occur immediately or slowly over a period of days and is noticed by loss of size or shape of your breast. Some implants deflate (or rupture) in the first few months after being implanted and some deflate after several years. Causes of deflation include damage by surgical instruments during surgery, overfilling or underfilling of the implant with saline solution, capsular contracture, closed capsulotomy, stresses such as trauma or intense physical manipulation, excessive compression during mammographic imaging, umbilical incision placement, and unknown/unexplained reasons. You should also be aware that the breast implant may wear out over time and deflate. Deflated implants require additional surgery to remove and to possibly replace the implant.

In the Ideal Implant study, for women receiving augmentation implants for the first time, the risk of deflation was 4.8% through 2 years. For women receiving revision augmentation implants, the risk of deflation was 3.3% through 2 years. This means that 5 out of 100 primary augmentation patients and 3 out of every 100 revision augmentation patients may experience spontaneous deflation within 2 years after receiving implants.

Capsule Contracture

The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant making it feel firm. This is called capsule contracture. Capsule contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. It is also more common in revision augmentation than in primary augmentation. Symptoms range from mild firmness and mild discomfort to severe pain, distorted shape, palpability of the implant, and/or movement of the implant. There is a scale for describing the severity of the contracture. It is called the Baker Grading Scale. The Grades are:

- Grade I - contracture is observed, but the breast feels and looks normal and soft
- Grade II - the breast is a little firm, but looks normal
- Grade III - the breast is firm and looks abnormal
- Grade IV - the breast is hard, painful, and looks abnormal

Additional surgery is often needed in cases where pain and /or firmness is severe, such as Grades III and IV. This surgery ranges from removal of the implant capsule tissue to removal and possibly replacement of the implant itself. Capsule contracture may happen again after these additional surgeries. In the Ideal Implant study, for women receiving augmentation implants for the first time, the risk of severe capsule contracture was 3.8% through 2 years. For women receiving revision augmentation implants, the risk of severe capsule contracture was 8.2% through 2 years. This means that 4 out of 100 primary augmentation patients and 8 out of 100 revision augmentation patients may experience Baker Class III or IV capsule contracture within 2 years after receiving implants.

Pain

Pain of varying intensity and duration may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should tell your surgeon about severe pain or pain that does not go away.

Additional Surgeries (Reoperations)

You should know that there is a high chance that you will need to have additional surgery at some point to replace or remove the implant. A common reason for subsequent surgery is a desire by the patient to change the size or style of her implants. Also, problems such as deflation, capsule contracture, infection, shifting, and calcium deposits can require removal of the implants. See Section 3.5 for more information on implant removal. The costs of additional surgeries may not be covered by insurance. Many women decide to have the implants replaced, but some women do not. If you choose not to, you may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.

In the Ideal Implant study, for women receiving augmentation implants for the first time, the risk of additional breast surgery was 14.2% through 2 years. For women receiving revision augmentation implants, the risk of additional breast surgery was 23.7% through 2 years. This means that 14 out of 100 primary augmentation patients and 24 out of 100 revision augmentation patients may have additional breast surgery within 2 years after receiving implants. Sections 3.3 and 3.4 provide more information on reoperations reported in the clinical study.

Dissatisfaction with cosmetic results

Unsatisfactory results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, and/or hypertrophic (irregular, raised scar) scarring may occur. Careful surgical planning and technique can minimize but not always prevent such results. Pre-existing asymmetry may not be entirely correctable by implant surgery. You should understand the possible cosmetic results and discuss them carefully with your doctor before surgery. Revision surgery may be necessary to improve an unsatisfactory result, but carries additional considerations and risks.

Infection

Infection can occur with any surgery. Most infections resulting from surgery appear in a few days to weeks after the operation. However, infection is possible at any time after surgery. Signs that you have an infection include: redness or rash, tenderness or pain, swelling, and fever. Infections with an implant present are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved.

In rare instances, Toxic Shock Syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. A surgeon should be seen immediately for diagnosis and treatment of this condition.

Hematoma or Seroma

Hematoma is a collection of blood within the space around the implant, and a seroma is a collection of the watery portion of the blood within the space around the implant. Postoperative hematoma and seroma may contribute to infection and/or capsule contracture. Swelling, pain, and bruising may result. If a hematoma occurs, it will usually be soon after surgery, however this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, large ones will potentially require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation can occur from surgical draining if damage to the implant occurs during the draining procedure.

Changes in Nipple and Breast Sensation

Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. Changes in feeling can be temporary or permanent and may affect your sexual response or your ability to nurse a baby. (See the paragraph on breast feeding below.)

Breast Feeding

Breast implant surgery can interfere with your ability to successfully breast feed. It is possible that you will produce less milk or not be able to produce milk at all. The periareolar incision site may significantly reduce the ability to successfully breast feed. Section 3.7 provides additional information on lactation problems.

Calcium Deposits in the Tissue Around the Implant

Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish the calcium deposits from cancer.

Delayed Wound Healing

In some cases, the incision site takes longer to heal than normally. Delayed healing may increase the risk of infection, implant extrusion, and necrosis. Smoking may interfere with the healing process. You should contact your surgeon immediately if your wound does not heal in the period of time your surgeon described.

Extrusion

Unstable or compromised tissue covering the breast implant and/or delayed wound healing may result in extrusion, which is when the breast implant comes through the skin. Additional surgery is needed to fix implant extrusion, which can result in more scarring or loss of breast tissue. An extruding implant may need to be removed, and cannot be replaced until the wound has healed.

Necrosis

Necrosis is the formation of dead or dying breast tissue or skin around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

Breast Tissue Atrophy/Chest Wall Deformity

The pressure of the breast implant may cause the breast tissue to thin and shrink. When this happens, you may be able to see and/or feel the implant through the skin. This can occur while implants are still in place or following implant removal without replacement. Additional surgery may be needed to correct either of these conditions, which may mean more scarring, and removal of your breast implants, with or without replacement.

2.3 What are the Other Reported Conditions?

Some women with breast implants have developed other conditions. The relationship between many of these conditions and breast implants has been studied. Although breast implants have not been shown to cause these conditions, you should be aware that they have been reported.

Connective Tissue Disease (CTD)

Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, fibromyalgia, 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.

CTD Signs and Symptoms

Some women, even without breast implants, may have some of the signs or symptoms of connective tissue diseases, without having the actual disease. Breast implants have been linked with some of these signs and symptoms, such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. Expert scientists and literature reports have found no evidence that breast implants cause CTD signs and symptoms. If you have these CTD signs and symptoms, it does not mean you have a CTD, but you should consider seeing a rheumatologist for evaluation.

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.

> Anaplastic Large Cell Lymphoma (ALCL) – Women with breast implants may have a very small, but increased risk of developing anaplastic large cell lymphoma, or ALCL, in the scar tissue and fluid adjacent to the implant. ALCL is not breast cancer—it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system).
>
> ALCL has been reported globally in patients with an implant history that includes various manufacturers' breast implants.
>
> Most patients were diagnosed when they sought medical treatment for implant related symptoms such as pain, lumps, swelling, or asymmetry that developed after their initial surgical sites were fully healed. In the cases reported, ALCL was typically diagnosed years after the implant surgery.
>
> Your physician should consider the possibility of ALCL if, after your surgical site is fully healed, you see changes in the way the area around the implant looks or feels—including swelling or pain around the implant. If ALCL is suspected, your physician will refer you to an appropriate specialist for evaluation, which may involve obtaining fluid and tissue samples from around your breast implant. If ALCL is confirmed, your physician will develop an individualized treatment plan for you. Because of the small number of cases worldwide and variety of available treatment options, there is no single defined treatment.
>
> If you have breast implants and have no symptoms, you do not need to do anything additional, but you should continue to routinely monitor your breast implants and follow your routine medical care. Removing the implants is not recommended in women with no symptoms without a diagnosis of ALCL.
>
> If you do not currently have breast implants but are considering breast implant surgery, you should discuss the risks and benefits with your health care provider.
>
> For additional and the most up-to-date information please visit the FDA's Breast Implants website: 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.

Suicide

Some studies have reported a higher incidence of suicide in women with breast implants, but it is not clear whether these suicides were associated with having breast implants or some other underlying condition that can lead to suicide, depression and/or anxiety. The strongest predictor for suicide is having been hospitalized for any psychiatric condition.

3.0 Ideal Implant Incorporated's Clinical Study

This section describes complications and outcomes associated with the IDEAL IMPLANT Structured Breast Implants, as reported in the Core clinical study. Ideal Implant Incorporated's study indicates that the chance of additional surgery through 2 years is 14 in 100 for Primary Augmentation patients and 24 in 100 for Revision Augmentation patients. The information below provides more details about the complications and benefits you may experience.

3.1 Description of Study

Ideal Implant Incorporated conducted clinical testing of its structured breast implants to determine the 2-year rates of adverse events, patient's satisfaction with how their breasts appear, and patient and surgeon satisfaction with the outcome of the surgery. This Core Study enrolled 399 Primary Augmentation patients and 103 Revision Augmentation patients. Of these enrolled patients, 378 of the Primary Augmentation patients (98%) and 94 of the Revision Augmentation patients (98%) returned for their 2-year visit. The outcomes of patients lost to follow-up are not known. The Core Study is a 10-year study to assess safety and effectiveness; results in this booklet represent data through 2 years.

3.2 What were the Complication Rates from the Core Study?

The 2-year complication rates are shown in Table 3 below. The rates reflect the number of Primary Augmentation and Revision Augmentation patients out of 100 who experienced the listed complication at least once within the first 2 years after implantation. Some complications occurred more than once for some patients. The two most common complications experienced within the first 2 years of implantation for the Primary Augmentation patients were Subsequent Breast Operations (14.2% or 14 patients out of 100) and Capsule Contracture Grades II/III/IV (17.1% or 17 patients out of 100). The two most common complications experienced within the first 2 years of implantation for the Revision Augmentation patients were Subsequent Breast Operations (23.7% or 24 patients out of 100) and Capsule Contracture Grades II/III/IV (24.3% or 24 patients out of 100).

Table 3 - Risk of Complications within the First 2 Years, per Subject

Complication (Includes all levels of severity)	Primary Augmentation (N=399)	Revision Augmentation (N=103)
Any complication or reoperation*	43.3%**	50.5%**
All subsequent breast operations*	14.2%	23.7%
Related to implant	8.4%	11.1%
Related to procedure	4.1%	3.0%
Related to dissatisfaction with implant size	2.3%	4.0%
Other reason	6.9%	15.7%
Implant removal with or without replacement*	7.5%	15.1%
Anesthesia complications	0.0%	1.0%
Neurologic complications	0.3%	0.0%
Connective Tissue Disease diagnosis	0.5%	0.0%
Reproductive problem	0.5%	0.0%
Other Adverse Event	10.8%	14.0%
Capsule contracture Grade II/III/IV	17.1%	24.3%
Capsule contracture Grade II	14.0%	21.3%
Capsule contracture Grade III	3.6%	8.2%

Table 3 - Risk of Complications within the First 2 Years, per Subject		
Complication (Includes all levels of severity)	**Primary Augmentation (N=399)**	**Revision Augmentation (N=103)**
Capsule contracture Grade IV	0.3%	2.1%
Capsule contracture Grade III/IV	3.8%	8.2%
Wrinkling/scalloping (excludes mild severity)	3.8%	12.0%
Spontaneous deflation*	4.8%	3.3%
Seroma	0.3%	2.9%
Breast tissue atrophy/chest wall deformity	0.3%	0.0%
Dissatisfaction with cosmetic results	4.1%	8.9%
Hematoma/bleeding	1.8%	0.0%
Wound healing delay/tissue necrosis/dehiscence	1.3%	1.0%
Wound infection	1.3%	1.0%
Implant exposure/extrusion	0.0%	2.0%
Skin scar unsatisfactory	1.5%	3.9%
Mastopexy unsatisfactory	1.5%	0.0%
Implant position unsatisfactory (malposition)	2.6%	1.0%
Persistent breast pain	0.3%	1.1%
Mastitis not requiring treatment	0.5%	0.0%
Inadequate milk supply	0.3%	1.1%
Lymphadenopathy	0.3%	0.0%
Dissatisfaction with implant size selected	3.0%	3.9%
Breast ptosis - after implant procedure	0.5%	4.1%
Breast lesion – benign	1.5%	4.1%
Breast lesion – malignant	0.5%	0.0%

*Rates for Subsequent breast operation, Implant removal and Spontaneous deflation are 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. The other 36 primary augmentation subjects and 10 revision augmentation subjects received an early design of the implant which is not being manufactured, and therefore were excluded from the complication rates for these 3 events.
** 155 Primary Augmentation patients and 47 Revision Augmentation patients experienced at least one complication or reoperation through 2 years.

3.3 What were the Types of Additional Surgical Procedures Performed?

Table 4 provides a breakdown of the types of surgical procedures that were performed through 2 years after implantation. Through 2 years, there were 51 Primary Augmentation patients who had one or more additional operations after the initial implantation (subsequent breast operations), for a total of 63 subsequent breast operations. These subsequent breast operations involved one or more surgical procedures for a total of 114 surgical procedures. Through 2 years, there were 22 Revision Augmentation patients who had one or more additional operations after the initial implantation (subsequent breast operations), for a total of 34 subsequent breast operations. These subsequent breast operations involved one or more surgical procedures for a total of 62 surgical procedures. Examples of multiple procedures during a single subsequent breast operation include implant replacement for both breasts or a capsule procedure and mastopexy on the same breast. The most common type of additional surgical procedure through 2 years for Primary Augmentation patients was implant removal with replacement (23.7% of the 114 procedures performed). The most common type of additional surgical procedure through 2 years for Revision Augmentation patients was fill volume adjustment (24.2% of the 62 procedures performed).

Table 4 - Types of Subsequent Surgical Procedures through 2 Years*		
Procedure	**Primary Augmentation (N=114)**	**Revision Augmentation (N=62)**
Capsule procedure (e.g., release, excision, plasty)	10.5% (12/114)	19.4% (12/62)
Reposition a malpositioned implant	6.1% (7/114)	0.0% (0/62)
Explantation		
No immediate replacement with any implant	0.9% (1/114)	8.1% (5/62)
With replacement using new IDEAL IMPANT	23.7% (27/114)	11.3% (7/62)
With replacement using other manufacturer implant	14.0% (16/114)	22.6% (14/62)
Evacuate hematoma/control bleeding	2.6% (3/114)	0.0% (0/62)
I&D and/or debridement	0.9% (1/114)	0.0% (0/62)
Skin scar revision and/or secondary would closure	2.6% (3/114)	3.2% (2/62)
Mastopexy – primary or revision	14.0% (16/114)	1.6% (1/62)
Treatment of breast lesion (e.g., open biopsy, lumpectomy)	1.8% (2/114)	0.0% (0/62)
Fill volume adjustments	19.3% (22/114)	24.2% (15/62)
Other	3.5% (4/114)**	9.7% (6/62)***

* 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. Subsequent breast operations were performed in 51 primary augmentation patients and 22 revision augmentation patients.
** Mastectomy and fat grafting to breasts.
*** Excise skin, fat transfer to breasts and replace implants.

3.4 What were the Reasons for Subsequent Breast Operations?

The reasons for subsequent breast operations through 2 years are shown below in Table 5. The reasons for subsequent breast operation may overlap with the types of surgical procedures performed, but they are two different sets of data. An example of a type of additional surgical procedure is repositioning of an implant; an example of a reason for subsequent breast operation is implant malposition.

There were 63 subsequent breast operations performed in 51 Primary Augmentation patients through 2 years. The most common reason for subsequent breast operation through 2 years was spontaneous deflation (25.4% of the 63 subsequent breast operations). There were 34 subsequent breast operations performed in 22 Revision Augmentation patients through 2 years. The most common reason for subsequent breast operation through 2 years was implant exposure/extrusion (23.5% of the 34 subsequent breast operations).

Table 5 - Primary Reasons for Subsequent Breast Operation through 2 Years, 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 different reasons, the primary reason will be selected following the reasons matching the collected categories as close as possible to the FDA guideline hierarchy.
* 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.

3.5 What were the Reasons for Implant Removal?

Table 6 shows the reasons for implant removal over 2 years. Through 2 years, there were 44 implants removed from 27 Primary Augmentation patients. The most common reason for implant removal through 2 years was spontaneous deflation (36.4% of the implants removed). Through 2 years, there were 26 implants removed from 14 Revision Augmentation patients. The most common reasons for implant removal through 2 years were patient dissatisfaction with implant size or patient dissatisfaction with cosmetic result (each 23.1% of the implants removed).

Table 6 - Primary Reasons for Implant Removal through 2 Years, 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)
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.
* 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.

3.6 What were the Complication Rates after Implant Replacement?

Among the Primary Augmentation patients, there were 28 implants removed and replaced with IDEAL IMPLANTS. Table 7 below reflects the number of replaced implants (not patients) out of 100 implants associated with the listed complications following replacement. For example there was wound infection in approximately 4% or 4 out of 100 Primary Augmentation implants at some time within 2 years after replacement. Among the Revision Augmentation patients, there were 9 implants removed and replaced with IDEAL IMPLANTS. The table below reflects the number of replaced implants (not patients) out of 100 implants associated with the listed complications within 2 years following replacement. For example there was capsular contracture in 11% or 11 out of 100 Revision Augmentation implants at some time within 2 years after replacement. There were no new adverse events reported among patients who had their implants removed and not replaced.

Table 7 - 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% (0/28)	11.1% (1/9)
Wrinkling/scalloping	0% (0/28)	11.1% (1/9)
Dissatisfaction with cosmetic results	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.		

3.7 What were the Other Reported Conditions?

Breast disease and signs and symptoms of connective tissue disease (CTD) were reported in some patients through 2 years after implantation. Although there were 502 patients enrolled in the Core Study, not every patient returned for each follow-up visit. Therefore, the percentage of patients with these events cannot be determined. Only the number of events can be reported. Without a comparison group of women with similar characteristics (such as age, race, etc.) and without breast implants, no conclusions can be made about the relationship between breast implants and these breast disease and CTD events.

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.

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

Patients underwent a screening for connective tissue disorders at each follow-up visit. Approximately 1 of out 100 Primary Augmentation patients and 5 out of 100 Revision Augmentation patients were referred to a board certified Rheumatologist through 2 years after implantation. 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.

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.

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

3.8 What were the Benefits?

The benefits of IDEAL IMPLANT Structured Breast Implants were assessed by a variety of outcomes, including change in chest circumference, patient and surgeon satisfaction with the outcome of the surgery, and patient satisfaction with the appearance of their breasts. These outcomes were assessed for patients with both Primary Augmentation and Revision Augmentation before implantation and at 2 years after surgery, except for change in chest circumference, which was assessed at 1 year after surgery for Primary Augmentation patients only.

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.

Patients completed the Breast Evaluation Questionnaire (BEQ), which measures how satisfied patients were with the appearance of their breasts before and after surgery while fully dressed and not fully dressed, and satisfaction with certain aspects of their breasts, such as size, shape and firmness. Primary Augmentation and Revision Augmentation patients reported improvements in how satisfied they were with the appearance of their breasts, both fully and not fully dressed, and their physical attributes, such as size and shape.

Patients and physicians reported their satisfaction with the overall cosmetic outcome of surgery (Table 8). 370 of the original 399 Primary Augmentation patients were included in an analysis of satisfaction at 2 years. 91 of the original 103 Revision Augmentation patients were included in an analysis of satisfaction at 2 years.

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).
Satisfaction based upon analyses of subjects with final design of the baffle shell: N=391 for Primary Augmentation Cohort and N=100 for Revision Augmentation Cohort.

Before implantation, Primary Augmentation and Revision Augmentation patients scored higher (better) than the general US female population on the SF-36 scales, which measures general health-related quality of life. After 2 years, augmentation patients showed a worsening in their SF-36 scores.

4.0 Surgical Considerations for Breast Augmentation

4.1 What Are the Alternatives to Breast Augmentation with IDEAL IMPLANT?

For primary augmentation patients, alternatives may include:

- Accept your breasts as they are and have no surgery
- Wear a padded bra or external prostheses
- Have mastopexy surgery (breast lift) without an implant
- Have surgery with silicone gel-filled implants
- Have fat injections

For revision augmentation patients, alternatives may include:

- Accept your breasts as they are and have no surgery
- Wear a padded bra or external prostheses
- Removal of implants without replacement
- Have surgery with silicone gel-filled implants
- Have fat injections

You are advised to wait at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary augmentation surgery. In the case of a revision augmentation; however, your surgeon may find it medically advisable to perform surgery sooner.

4.2 What Questions Should You Ask Your Surgeon about Breast Augmentation?

The following list of questions may help you to remind you of topics to discuss with your surgeon. You may have additional questions as well.

1. What are the risks and complications associated with having breast implants?
2. How many additional operations on my implanted breast(s) can I expect over my lifetime?
3. How will my breasts look if I decide to have the implants removed without replacement?
4. What shape, size, surface texturing, incision site, and placement site is recommended for me?
5. How will my ability to breast feed be affected?
6. How can I expect my implanted breasts to look over time?
7. How can I expect my implanted breasts to look after pregnancy? After breastfeeding?
8. What are my options if I am dissatisfied with the cosmetic outcome of my implanted breasts?
9. What alternate procedures or products are available if I choose not to have breast implants?
10. Do you have before and after photos I can look at for each option?
11. Do you think my expectations are reasonable?

Early in the consultation process, be sure to speak directly to your surgeon about your expectations and desired results, as well as what you can expect regarding the length of the surgery, your recovery, and any risks and potential complications of the surgery.

4.3 Choosing a Surgeon

When choosing a surgeon who is experienced with breast implantation, you should ask the following questions.

1. How many breast augmentation implantation procedures does he/she perform per year?
2. How many years has he/she performed breast implantation procedures?
3. Is he/she board certified, and if so, with which board?
4. In which states is he/she licensed to practice surgery? Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients either by request or online.
5. What is the most common complication he/she encounters with breast implantation?
6. What is his/her reoperation rate with breast implantation and what is the most common type of reoperation he/she performs?

4.4 What are the Choices and Options Associated with the Surgery?

IDEAL IMPLANT Structured Breast Implants

The IDEAL IMPLANT is available in 14 sizes (Table 9). Each size can be adjusted within a specified volume range at the time of surgery, by varying the amount saline used to fill the implant. This size adjustability can be useful when the breasts are not symmetrical in size. The IDEAL IMPLANT is round and has a smooth surface. If a textured surface or shaped implant is desired, then it is not an appropriate choice.

Table 9 - IDEAL IMPLANT Sizes

Size	Volume Range
210 cc	210 - 235 cc
240 cc	240 - 270 cc
270 cc	270 - 305 cc
300 cc	300 - 340 cc
335 cc	335 - 375 cc
370 cc	370 - 415 cc
405 cc	405 - 455 cc
440 cc	440 - 495 cc
475 cc	475 - 535 cc
515 cc	515 - 580 cc
555 cc	555 - 625 cc
595 cc	595 - 670 cc
635 cc	635 - 710 cc
675 cc	675 - 755 cc

IDEAL IMPLANT on a curved surface simulating the curve of the chest wall

Familiarize yourself with the following options in breast implant surgery and be prepared to discuss with your surgeon the following issues:

Implant Size

Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's). Your surgeon will also evaluate your existing tissue to determine if you have enough to cover the breast implant. If you desire a breast implant size too large for your tissue, the surgeon may warn you that breast implant edges may

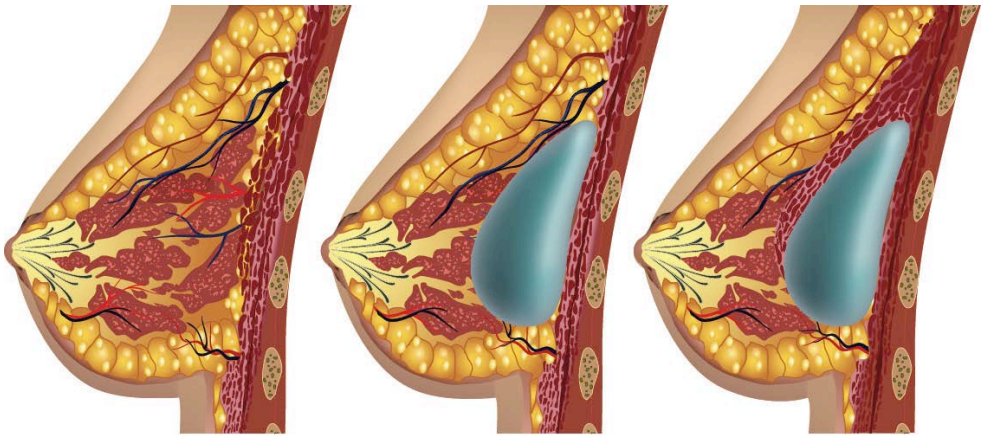
be apparent or visible post-operatively. You may even risk surgical complications. Also, excessively large breast implants may speed up the effects of gravity and result in earlier droop or sag.

Palpability

The following may cause implants to be more palpable (more easily felt): textured implants, larger implants, subglandular placement, and the amount of skin/tissue available to cover the implant.

Implant Placement

The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast gland (subglandular) depending on the thickness of your breast tissue and its ability to adequately cover the breast implant. You should discuss with your surgeon the pros and cons of the implant placement selected for you.



The submuscular placement may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to have a subsequent breast procedure than the subglandular placement. The possible benefits of this placement are that it may result in less palpable implants, less capsular contracture, and easier imaging of the breast with mammography.

The subglandular placement may make surgery and recovery shorter, may be less painful, and may be easier to access for a subsequent breast operation than the submuscular placement. However, this placement may result in more palpable implants, more capsular contracture, and more difficult imaging of the breast with mammography.

Incision Site

To permit the smallest possible incision, the implant is typically inserted empty, and then filled with saline. You should discuss with your surgeon the pros and cons for the incision site specifically recommended for you.

There are three common incision sites: within the breast fold (inframammary), around the nipple (periareolar), or under the arm (axillary). If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive (very small) instruments, to create a “pocket” for the breast implant. A fourth incision site around the belly button (peri-umbilical) was not studied and should not be used. This approach may cause damage to the implant.

Periareolar

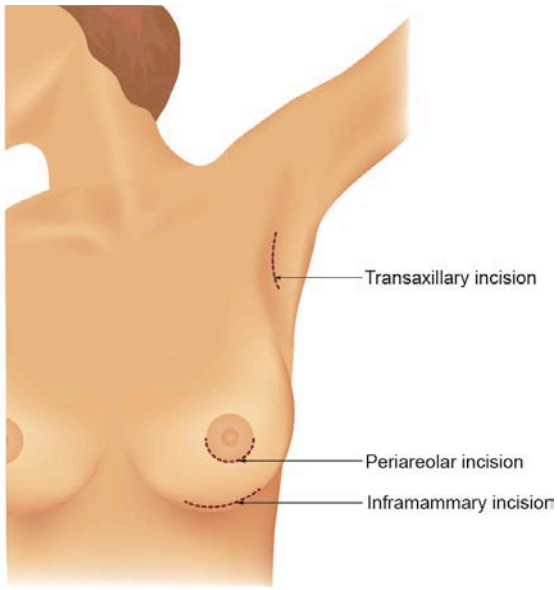
This incision is the most concealed, but is associated with a higher likelihood of inability to successfully breast feed, as compared to the other incision sites.

Inframammary

This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding.

Axillary

This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding.



Other Procedures at the Time of the Breast Augmentation

Your surgeon may recommend having other cosmetic procedures during the same surgery to get the best results from your breast implants. In some cases, breast implants alone may not give you the results you want. If you have previously lost a lot of weight, been pregnant, or breast-fed, you may have sagging, stretched, or extra skin that is not completely filled out by breast tissue. To remove the excess skin from your breast tissue, your doctor may recommend doing a breast lift (mastopexy) to one or both breasts.

During mastopexy, excess skin is usually removed from around the nipple area and lower part of the breast. Stitches are used to close the incision. This procedure lifts the breast tissue, raises the nipple location, and tightens the skin over the breast tissue. There is more scarring and possibly a longer recovery time than if just have implants placed. Mastopexy and breast augmentation may be done at the same time, or as separate procedures. Your doctor can discuss the risks and benefits of this procedure with you.

Surgical Setting and Anesthesia

Breast augmentation surgery is usually preformed on an outpatient basis, either in a hospital operating room, surgery center, or surgical suite in the surgeon's office. General anesthesia is commonly used, and local anesthesia is also an option. The surgery usually lasts one to two hours. Your surgeon will make an incision and create a pocket for the breast implant. Then, the breast implant will be placed in the pocket, filled, and positioned. Finally, the incision will be closed, usually with stitches, and possibly taped.

4.5 Post-operative Care

You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size. Post-operative care may involve the use of a special post-operative bra, compression bandage, or jog bra for extra support and positioning while you heal. At your surgeon's recommendation, you will most likely be able to return to work within a few days, although you should avoid any strenuous activities that could raise your pulse and blood

pressure for at least a couple of weeks. Your surgeon may also recommend breast massage exercises. Note: If you experience fever, or noticeable swelling and/or redness in your implanted breast(s), you should contact your surgeon immediately.

Following breast augmentation, you should continue breast self examination to monitor your breasts and breast implants. If you have pain, lumps, hardening, swelling, or changes in shape, report these to your surgeon. To protect your implants, you should make sure that any health care provider treating you knows that you have breast implants. If they do not know, they could damage them by accident during a procedure, such as a breast biopsy.

5.0 Additional Information

5.1 If You Experience a Problem, Should You Report It?

If you believe that you have experienced a serious problem(s) related to your breast implants, you should have your health professional report the problem(s) to FDA and/or to Ideal Implant Incorporated. You are encouraged to report any adverse events through your health professional. Women may also report any serious problem directly through the FDA's MedWatch voluntary reporting system. An adverse event is serious and should be reported when it results in an initial or prolonged hospitalization, disability, congenital anomaly, or medical or surgical intervention to prevent lasting damage. This information reported to MedWatch is entered into databases to be used to follow safety trends (patterns) of a device and to determine whether further follow-up of any potential safety issues related to the device is needed.

To report to FDA, use MedWatch form 3500 which may be obtained through FDA's website at fda.gov/medwatch/index.html. You may also call 1-888-INFO-FDA (1-888-463-6332), from 10:00am – 4:00pm Eastern Time, Monday through Friday, to receive an additional FDA MedWatch Package. Keep a copy of the MedWatch form completed by your surgeon for your records. To report to Ideal Implant Incorporated, call 214-492-2500.

5.2 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.

5.3 What are Other Sources of Additional Information?

Upon request, you will be provided with a copy of the Instructions for Use (package insert). You can request a copy from your surgeon or from Ideal Implant Incorporated. For more detailed information on the preclinical and clinical studies conducted by Ideal Implant Incorporated, you are referred to the Summary of Safety and Effectiveness Data (SSED) for this product at fda.gov/cdrh/pdf/p120011.html. You will be given a Patient Implant Card with the serial number of your breast implant(s).

Food and Drug Administration
1-800-INFO-FDA or 301-827-3990
fda.gov/breastimplants

Ideal Implant Incorporated
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7.0 Index

Acknowledgement

I have reviewed the information presented in *Making an Informed Decision, IDEAL IMPLANT® Structured Breast Implant for Breast Augmentation Surgery.* My concerns and questions have been addressed by my doctor, and I have considered alternative to surgery, including use of external prostheses.

I am choosing to proceed with IDEAL IMPLANT breast augmentation surgery.

Patient Name _____

Patient Signature _____

Date _____

Surgeon Name _____

Surgeon Signature _____

Date _____

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Print date: 8-1-15