

**Important Information For Women About
IDEAL IMPLANT® Saline-Filled Breast Implants**
December 2008

**CAUTION: Investigational device. Limited by Federal law to
investigational use.**

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Glossary

Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	Lack of proportion of shape, size, and/or 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.
Biocompatible	The condition of being compatible with living tissues or systems without being toxic.
Biopsy	The removal and examination of tissues, cells, or fluid from the body.
Breast augmentation	A surgical procedure to increase breast size. For this document, it refers to placement 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 replacement augmentation.
Breast evaluation Questionnaire (BEQ)	A questionnaire intended to measure self-esteem and body image related to breast satisfaction among breast surgery patients.
Breast implant	An internal artificial device or implant intended to replace the breast.
Breast mass	A lump or body in the breast.
Calcification	Process of hardening by calcium salts.
Capsule	Scar tissue that forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in a capsule contracture.
Capsule contracture	A tightening of the tissue capsule surrounding an implant, resulting in firmness or hardening of the breast and in squeezing of the implant if severe. Capsule contracture is

graded by Baker Classification. Class III or IV are the most severe. Class III often results in the need for additional surgery (subsequent operation) because of pain and possibly abnormal appearance. Class IV usually results in the need for additional surgery (subsequent operation) because of pain and unacceptable appearance. Class II may also result in the need for additional surgery. Capsule contracture is a risk for implant rupture. Below is a description of each Baker Class:

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

When an implant deflates and gets smaller, the capsule begins to contract, sometimes within days. For this reason, prompt replacement of a deflated implant may avoid the need for additional procedures to enlarge a contracted capsule.

Capsulectomy	Surgical removal of the scar tissue capsule around the implant.
Capsulorrhaphy	Surgical modification of the scar tissue capsule around the implant.
Capsulotomy (closed)	An attempt to tear the scar tissue capsule around the implant to enlarge the space for the implant, by pressing or pushing on the outside of the breast. This method does not require surgery, but is a known risk for rupture of the implant and is contraindicated.
Capsulotomy (open)	Surgical incision into the scar tissue capsule around the implant, usually to enlarge the space for the implant.
Congenital anomaly	An abnormal development in part of the body.
Connective tissue disease/disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system. Connective tissue diseases (CTDs) that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.
Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Contralateral	Opposite side.

Core Study	The primary clinical study of augmentation and replacement augmentation patients to support the approval of the premarket approval (PMA) application. Safety and effectiveness data are collected yearly through 10 years.
Deflation	Loss of saline from within the implant because of a failure in the implant shell. The saline is absorbed by the body over a few days as the implant deflates and the breast gets smaller. If a deflated implant is replaced promptly, before the capsule contracts, the procedure may be done using local anesthesia in the area of the original incision, rather than with general anesthesia or intravenous sedation.
Delayed wound healing	Delayed progress in the healing of an open wound.
Displacement	Movement of the implant from the usual or proper place.
Epidemiological	Relating to the science of explaining the relationships of factors that determine disease frequency and distribution.
Extrusion	Skin breakdown with the pressing out of the implant through the surgical wound or skin.
Fibromyalgia	A disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue.
Fibrous tissues	Connective tissues composed mostly of fibers.
Hematoma	A collection of blood within a space.
Hypertrophic scarring	An enlarged scar remaining after the healing of a wound.
Immune response	A bodily response to the presence of a foreign substance.
Infection	Invasion with microorganisms (for example, bacteria, viruses). An infection usually results in fever, swelling, redness, and/or pain.
Inflammation	The response of the body to infection or injury that is characterized by redness, swelling, warmth, pain and/or loss of function.
Inframammary fold	The crease at the base of the breast and the chest wall.
Inframammary incision	An incision made in the fold below the breast.

Inpatient surgery	A surgical procedure in which the patient is required to stay overnight in the hospital.
Investigational device	A medical device that has not been approved by FDA for general sale and use.
Lactation	The production and secretion of milk by the breast glands.
Lymphadenopathy	Enlargement of the lymph node(s).
Malposition	Implant malposition or displacement is when the implant is not in the correct spot in the breast. This could have been due to incorrect placement of the implant during the surgery or due to shifting of the implant position over time.
Mammary	Pertaining to the breast.
Mammography	A type of X-ray examination of the breasts used for detection of cancer.
Mammoplasty	Plastic surgery of the breast.
Mastopexy	Plastic surgery to move sagging breasts into a more elevated position.
Necrosis	Death of cells or tissues.
Outpatient surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight.
Palpate	To feel with the hand.
Palpability	The ability to feel the implant.
Pectoralis	Major muscle of the chest.
Periareolar	Around the darkened or pigmented area surrounding the nipple of the breast.
Plastic surgery	Surgery intended for the improvement of appearance of the body.
Post-operatively	After surgery.
Primary breast augmentation	The first time a breast implant is placed for the purpose of breast augmentation.
Ptosis	Breast sagging that is usually the result of normal aging, pregnancy, or weight loss.

Replacement augmentation	Refers to surgical removal and replacement of breast implants that were placed originally for primary breast augmentation.
Rheumatological disease/disorder	A variety of diseases involving connective tissue structures of the body, especially the joints and fibrous tissue. These diseases are often associated with pain, inflammation, stiffness, and/or limitation of motion of the affected parts. Can include autoimmune diseases. Fibromyalgia is a rheumatological disorder.
Saline	A solution that is made up of water and a small amount of salt.
Scar revision	A surgical procedure to improve the appearance of a scar.
Seroma	A build-up of the watery portion of the blood in a tissue location.
SF-36 questionnaire	A questionnaire intended to measure health-related quality of life. It includes questions that measure physical, mental, and social health.
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
Subglandular placement	Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.
Submuscular placement	Placement of a breast implant wholly or partially underneath the chest muscle.
Subsequent operation	An additional surgery after your first breast implantation.
Surgical incision	A cut made to body tissue during surgery.
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Symptomatic	Any evidence or sign of disease or disorder reported by the patient.
Systemic	Pertaining to or affecting the body as a whole.

Important Information for Women about IDEAL IMPLANT® Saline-Filled Breast Implants

1. Considerations for IDEAL IMPLANT Saline-filled Breast Implant Augmentation

The purpose of this booklet is to help you in making an informed decision about having breast implants for augmentation (breast enlargement) or replacement of your existing saline-filled or silicone gel-filled augmentation implants. This booklet is not intended to replace consultation with your surgeon. This educational booklet is set up to provide you with information about risks and benefits of IDEAL IMPLANT saline-filled breast implants.

Please read this entire booklet 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.

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. The chest muscle (pectoralis major muscle) is located beneath the breast. 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.

It is important to realize that implants are used to make the breast larger. The implants alone may not adequately lift the breast, or correct the effects of pregnancy, weight loss, or skin stretching. Your surgeon may suggest additional procedures, such as mastopexy, to help achieve improved breast lift.

1.2 What is the IDEAL IMPLANT Saline-Filled Breast Implant?

The IDEAL IMPLANT is a round, smooth-surface, saline-filled breast implant that is supplied sterile in a double wrapped packaging system. It was developed so women can have the option of a breast implant that is unlike the current saline-filled implants or the current silicone gel-filled implants.

The IDEAL IMPLANT is made from the same materials as standard saline-filled breast implants. However, while standard saline-filled implants have a single shell made from successive cross-linked layers of silicone elastomer, the IDEAL IMPLANT has three to five shells of slightly increasing size. There is an inner shell with a valve in the posterior patch for filling an inner lumen. Surrounding this are one to three unattached, perforated shells. Finally, surrounding these perforated shells, is an outer shell with an anterior

valve for filling an outer lumen. The inner and outer lumens are filled with saline after the implant has been placed in a submuscular or subglandular pocket.

The internal structure of the IDEAL IMPLANT was designed to restrict movement of the saline filler. In addition, this internal structure was designed to support the upper pole and edge. The fill volumes were established so that when placed on a convex surface, the edge of the implant is low.

1.3 Are You Eligible for IDEAL IMPLANT Saline-Filled Breast Implants?

You must meet all of the Inclusion Criteria and meet none of the Exclusion Criteria to be eligible to participate in the clinical trial of the IDEAL IMPLANT.

Inclusion Criteria – you must:

- Be a genetic female, 18 years of age or older.
- Be a US citizen and primarily reside within 100 miles of the investigator.
- Have an email address.
- Be undergoing one of the following:
 - bilateral primary breast augmentation, and have dissatisfaction with your breast size and wish breast enlargement
 - bilateral replacement augmentation, and have had previous augmentation with silicone gel-filled or saline-filled implants.
- Agree to sign the Informed Consent which includes HIPAA authorization.
- Agree to sign a Medical Records Release form.
- Agree to comply with post-operative instructions.
- Agree to follow the procedures for explant analysis including to authorize return of the implant to Ideal Implant Incorporated if the implant is explanted.
- Agree to comply with follow-up requirements including email contacts, visits, and questionnaires.

Exclusion Criteria - you must not:

- Plan to become pregnant within six months of the procedure.
- Have nursed a child within three months of study enrollment.
- Have a condition that could compromise or complicate wound healing.
- Have a diagnosis of active cancer of any type.
- Have ever been diagnosed with breast cancer.
- Have pre-malignant breast disease.
- Have an infection or abscess anywhere in the body.
- Have tissue characteristics incompatible with an implant, such as inadequate tissue cover or compromised vascularity.
- Have any condition, or be under treatment for any condition which, in the opinion of the investigator, may constitute an unwarranted surgical risk.
- Have anatomic or physiologic abnormality that could lead to significant post-operative adverse events.
- Have unrealistic/unreasonable expectations of the procedure results.

1.4 Important Factors You Should Consider When Choosing the IDEAL IMPLANT.

- Breast implants are not lifetime devices, and breast implantation is likely not a one-time surgery. You will likely need additional unplanned surgeries on your breasts because of complications or unacceptable cosmetic outcomes. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures. When you have your implants replaced (replacement augmentation), your risk of future complications increases compared to first time (primary) augmentation surgery.
- Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implants removed and not replaced, you may experience unacceptable dimpling, puckering, wrinkling or other cosmetic changes of the breast, which can be permanent.
- Breast implants may affect your ability to breast feed, either by reducing or eliminating milk production.
- Breast implants may not last a lifetime. Failure of the inner shell and/or the outer shell can occur due to wear from stresses or manipulations during daily routines such as vigorous exercise, contact athletics, manual massage or intimate physical contact. Inner shell failure does not decrease implant fullness, outer shell failure slightly decreases implant fullness that may or may not be noticeable, and failure of both shells significantly decreases implant fullness that is noticeable. Either inner shell failure or outer shell failure will cause the implant to feel different. If this is a cosmetic concern, removal, with or without replacement, may be recommended. For failure of both the inner shell and the outer shell (deflation), removal, with or without replacement, should be performed.
- With breast implants, routine screening mammography for breast cancer will be more difficult. If you are of the proper age for mammography screening, you should continue to undergo routine mammography screening as recommended by your primary care physician. The implant may interfere with finding breast cancer during mammography. Because the breast and implant are squeezed during mammography, damage may occur to the inner shell, the outer shell or both shells causing the implant to feel different and/or possibly deflate. More x-ray views are necessary for women with breast implants; therefore, you will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays. Be sure to inform the mammography technologist that you have implants.
- You should perform an examination of your breasts every month for cancer screening; however, this may be more difficult with implants. You should ask your surgeon to help you distinguish the implant from your breast tissue. Any new lumps may be evaluated with a biopsy, as appropriate. If a biopsy is performed, care must be taken to avoid injuring the implant.
- After undergoing breast augmentation surgery (either primary or replacement), your health insurance premiums may increase, your insurance coverage may be dropped,

and/or future coverage may be denied. Treatment of complications may not be covered as well. You should discuss the complete extent of your insurance coverage with your insurance company before undergoing surgery.

- You should inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.
- Ideal Implant Incorporated will continue its ongoing Core Study through ten years to further evaluate the long-term safety and effectiveness of this product.
- It is important that you read this entire booklet because you need to understand the risks and benefits and to have realistic expectations of the outcome of your surgery.

2. Potential Breast Implant Complications

Undergoing any type of surgical procedure involves risks (some serious) such as the effects of anesthesia, infection, swelling, redness, bleeding, pain, and even death, which need to be balanced against the benefits of the breast augmentation surgery. There are potential complications specific to breast implant surgery and breast implants, as described below.

2.1 Major Surgery and Anesthesia Related Risks

All surgical procedures have a small risk of complications inherent to the surgery itself and to anesthesia. These include:

- Anesthesia complications including allergic reactions and anaphylaxis
- Cardiac complications such as arrhythmia, myocardial infarction
- Pulmonary complications such as aspiration, atelectasis, pneumonia
- Pulmonary embolus
- Deep venous thrombosis
- Neurologic complications such as stroke, pressure neuropathy
- Death

2.2 Breast Implant Related Risks

- **Capsule contracture**

The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant and is called capsular contracture. Capsular contracture is more common following infection, hematoma and seroma. It is also more common with subglandular placement (behind the mammary gland and on top of the chest muscle). Symptoms range from mild firmness and mild discomfort to severe pain, distorted shape, palpability of the implant, and/or movement of the implant.

Additional surgery is needed in cases where pain and /or firmness is severe. This surgery ranges from removal of the implant capsule tissue to removal and possibly replacement of the implant itself. Capsular contracture may happen again after these additional surgeries.

- **Capsule calcification and calcium deposits**

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

- **Wrinkling/scalloping**

Wrinkling and/or scalloping of the implant shell may occur. If the overlying tissue is thin, they may be palpable and/or visible. Folds in the implant shell may cause thinning and erosion of the overlying tissue, with possible extrusion of the implant. Also, folds may cause shell damage resulting in deflation of the implant.

- **Spontaneous failure of the inner shell**

Failure of the inner shell of the implant does not cause a decrease in implant fullness, but the implant will feel different (e.g. the edge may feel thicker and more palpable than previously). If this occurs, you should have the implant evaluated by your plastic surgeon. If there is a cosmetic concern, removal, with or without replacement, may be recommended.

- **Spontaneous failure of the outer shell**

Failure of the outer shell of the implant deflates just the outer cavity. This causes a slight decrease in implant fullness that may or may not be noticeable, but the implant will feel different (e.g. the edge may feel thicker and more palpable than previously). The saline is absorbed by the body. If this occurs, you should have the implant evaluated by your plastic surgeon. If there is a cosmetic concern, removal, with or without replacement, may be recommended.

- **Spontaneous deflation**

Failure of the inner and outer shells deflates both the inner and outer cavities. This causes a significant decrease in implant fullness that makes the breast appear noticeably smaller. The saline is absorbed by the body. If this occurs, you should have the implant removed, with or without replacement. If the deflated implant is replaced promptly, before the capsule contracts, the procedure may be done using local anesthesia in the area of the original incision, rather than general anesthesia or intravenous sedation.

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 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 be aware that the breast implant may wear out over time and deflate.

- **Seroma**

A seroma is an accumulation of fluid around an implant. Symptoms may include swelling and pain. A seroma may contribute to infection or subsequent capsule contracture. The body will absorb small amounts of fluid, but large amounts may have to be drained surgically and may result in a small scar. Implant deflation can occur from surgical draining if damage to the implant occurs during the draining procedure.

- **Breast tissue atrophy/chest wall deformity**

The pressure of a breast implant may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement.

- **Interference with mammography**

The implant may interfere with finding breast cancer during mammography and also may make it difficult to perform mammography. 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 the additional x-rays.

- **Dissatisfaction with cosmetic result**

Dissatisfying 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.

Subsequent operation related to presence of implants - Women should understand there is a high chance they will need to have a subsequent operation at some time related to an implant problem such as capsule contracture, spontaneous deflation, wrinkling or seroma. Many women decide to have the implants replaced, but some women do not. Those who do not may have cosmetically unacceptable dimpling and/or puckering of the breast following implant removal. Implant replacement increases the risk of complications such as capsule contracture and the need for subsequent operations.

2.3 Breast Procedure Related Risks

- **Hematoma/bleeding**

A hematoma is an accumulation of blood around an implant. 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. A hematoma may contribute to infection or subsequent capsule contracture. The body will absorb small amounts of blood, but large amounts may have to be drained surgically and may result in a small scar. Implant deflation can occur from surgical draining if damage to the implant occurs during the draining procedure.

- **Wound infection (not peri-prosthetic)**

Infection can occur with any surgery. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. An infection may be limited to the skin and breast tissue (not peri-prosthetic) or may involve the implant (peri-prosthetic). In rare instances, toxic shock syndrome has been noted after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, diarrhea, vomiting, dizziness, fainting and/or sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment for this condition.

- **Wound healing delay, tissue necrosis, dehiscence (no exposure)**

In some cases, the incision fails to heal normally. Necrosis is the formation of dead tissue 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.

- **Peri-prosthetic infection (no exposure)**

An infection may involve the implant (peri-prosthetic). 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.

- **Septicemia**

Severe infection on rare occasions can result in septicemia, an infection that spreads in the blood stream throughout the body.

- **Implant exposure/extrusion**

Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.

- **Skin scar unsatisfactory**

Any incision in the skin will leave a scar that is permanent. While plastic surgical techniques make this as inconspicuous as possible, some women have skin that results in more conspicuous or thick (hypertrophic) scars and/or pigment changes no matter how the incision is repaired. Such scars may be of cosmetic concern.

- **Mastopexy unsatisfactory**

A breast uplift procedure (mastopexy) may result in unsatisfactory elevation of the breast tissue, position of the nipple, breast shape and/or skin scars.

- **Implant position unsatisfactory (malposition)**

An implant may be placed in an unsatisfactory position at the implantation procedure or may shift to an unsatisfactory position over time due to gravity, scarring, capsule contracture, stretching and/or thinning of tissues.

- **Persistent breast 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.

- **Nipple/breast sensitivity change**

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.

- **Lactation problem**

Breast surgery, including breast biopsy and implantation, can have an adverse effect on the adequacy of a woman's milk supply, although many women with breast implants have nursed their babies successfully.

- **Lymphadenopathy**

Infection can result in enlargement of regional lymph nodes (lymphadenopathy).

Subsequent operation related to surgical procedure for implant placement -

Women should understand there is a chance they will need to have subsequent operations at some time related to problems from the surgical procedure for implant placement. Examples include control of bleeding or treatment of an infection.

2.4 Other Reported Conditions and Risks

- **Dissatisfaction with implant size selected – bilateral**

At any time following implantation, the patient and/or surgeon may become dissatisfied with the size of the implants selected before or at the time of surgery. Changing the size of the implants requires a subsequent operation and also may involve a procedure to adjust the size of the implant capsules.

- **Dissatisfaction with implant size selected - unilateral (asymmetry)**

At any time following implantation, the patient and/or surgeon may become dissatisfied with the symmetry of size of the breasts due to the size of the implants selected before or at the time of surgery. Changing the size of one or both implants requires a subsequent operation and also may involve a procedure to adjust the size of one or both implant capsules.

- **Trauma to implant – surgical procedure**

Damage to the outer shell or both shells causing the implant to feel abnormal and possibly deflate may result accidentally from surgical instruments during procedures such as breast biopsy or needle aspiration of a cyst.

- **Trauma to implant – external**

Damage to the outer shell, the inner shell or both shells causing the implant to feel abnormal and possibly deflate may result from external trauma such as from an automobile airbag or the compression required for mammography.

- **Breast ptosis - after implant placement procedure due to pregnancy, weight change and/or breast size change**

Breast ptosis (droop) is caused by the effects of gravity over time, the effects of pregnancy, change in weight and/or change in breast size. Breast ptosis may be present before or become apparent after implantation. Correction requires a subsequent operation.

- **Breast lesion – benign**

There is no evidence of increased risk of benign breast tumors associated with breast implants.

- **Breast lesion – malignant**

Published studies indicate that breast cancer is no more common in women with implants than those without 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 of 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. However, a lot of women with breast implants believe that their implants caused a connective tissue disease.

- **Reproduction problem**

There have been concerns raised regarding potential damaging effects on children born of mothers with implants. A review of the published literature on this issue suggests that the information is insufficient to draw definitive conclusions.

- **Suicide**

An increased rate of suicide has been reported in women with breast implants. The reason for this is unknown, but some studies have found an increased history of psychiatric problems prior to surgery.

Subsequent operation unrelated to presence of implant or surgical procedure for implant placement - Women should understand there is a chance they will need to have subsequent operations at some time for problems unrelated to the implant or the surgical procedure for implant placement. Examples include change in implant size or replacement due to trauma to the implant.

3. Surgical Considerations for Breast Augmentation

3.1 What Are the Alternatives to Breast Augmentation with IDEAL IMPLANT Saline-Filled Breast Implants?

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 FDA-approved silicone gel-filled or standard saline-filled implants.

For replacement augmentation patients, alternatives may include:

- No replacement.
- Removal without replacement.
- Removal and replacement with FDA-approved silicone gel-filled or standard saline-filled implants.

3.2 Choosing a Surgeon

When choosing a surgeon who is experienced with breast augmentation, you should know the answers to the following questions:

- How many breast augmentation procedures does he/she perform per year?
- How many years has he/she performed breast augmentation procedures?
- Is he/she board certified, and if so, with which board?
- In which state(s) is he/she licensed to practice surgery? (Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients, either by request or on the Internet.)
- What is the most common complication he/she encounters with breast augmentation?
- What is his/her re-operation rate with breast augmentation, and what is the most common type of re-operation he/she performs?

3.3 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, not in cup sizes), because this depends on the size and shape of the individual woman's chest.

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

3.4 Implant Placement

The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast glands (subglandular). You should discuss with your surgeon the advantages and disadvantages of the implant placement selected for you, as described in the Table below.

Comparison between Submuscular versus Subglandular Placement

Submuscular Placement	Subglandular Placement
Recovery may be longer	Recovery may be shorter
May be more painful	May be less painful
Re-operation may be more difficult	Re-operation may have easier access
Less visible and palpable implants	More visible and palpable implants
Less likelihood of capsule contracture	Greater likelihood of capsule contracture
Easier imaging during mammography	More difficult imaging during mammography
May be preferable if you have thin or weakened breast tissue	May not be recommended if you have thin or weakened breast tissue

3.5 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: around the nipple (periareolar), within the breast fold (inframammary) or under the arm (axillary).

- **Periareolar** – This incision is the most concealed, but is associated with a higher likelihood of breast feeding difficulties, as compared to the other incision sites.
- **Inframammary** – This incision is generally less concealed than periareolar and associated with less breast feeding difficulties than the periareolar incision site. It is also the most commonly used incision site at the present time, and is felt to give the best access to and control of the breast implant pocket.
- **Axillary** – This incision is less concealed than periareolar and associated with less breast feeding difficulties than the periareolar incision site. If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive (very small) instruments, to create a “pocket” for the breast implant.
- **Umbilical** – This belly button incision avoids a scar on the breast, but the approach is more difficult and may increase the risk of damage to, and unexpected location of, the implant.

3.6 Additional Procedures at the Time of Breast Augmentation

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

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

3.7 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.

3.8 Surgical Setting and Anesthesia

Augmentation surgery is usually performed 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 1 to 2 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.

3.9 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 for at least a couple of weeks you should avoid any strenuous activities that could raise your pulse and blood pressure. 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.

4. The Saline-filled Breast Implants Available from Ideal Implant Incorporated

Approximate Dimensions and Volumes

Catalogue Number	Size cc	Diameter* mm	Projection* mm	Inner Lumen	Outer Lumen			Total Implant Volume		
					Low	Mid	High	Low	Mid	High
44 – 184	184	99.5	31.2	122cc	33	47	61cc	184	198	212cc
44 – 210	210	104.0	32.2	142	35	51	67	210	226	242
44 – 238	238	108.5	33.2	165	38	56	74	238	256	274
44 – 265	265	112.5	34.2	188	40	60	79	265	285	304
44 – 295	295	116.0	35.2	188	55	76	97	295	316	337
44 – 325	325	119.5	36.2	212	58	82	105	325	349	372
44 – 360	360	123.0	37.2	236	64	89	114	360	385	410
44 – 390	390	126.5	38.2	261	66	93	121	390	417	445
44 – 425	425	129.5	39.2	288	69	96	124	425	452	480
44 – 460	460	132.5	40.2	317	71	101	131	460	490	520
44 – 495	495	135.5	41.2	344	75	107	140	495	527	560
44 – 530	530	138.5	42.2	344	92	125	158	530	563	596
44 – 565	565	141.5	43.2	373	90	125	160	565	600	635
44 – 600	600	144.5	44.2	403	87	124	161	600	637	674

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*measured on a convex surface at minimum fill in the outer lumen

5. How to Report Problems with Your Implant

The Food and Drug Administration (FDA) requires that serious injuries (defined as those that need medical or surgical intervention to prevent permanent damage) be reported by hospitals if they are aware of the serious injuries. If you believe that you have experienced one or more serious problems related to your breast implants, you are encouraged to report the serious problem(s) through your health professional to the FDA.

6. Limited Warranty

The Ideal Implant Incorporated Breast Implant Limited Warranty provides lifetime replacement and limited financial assistance in the event of inner shell failure, outer shell failure and/or deflation, subject to certain conditions as described in the Breast Implant Limited Warranty literature. For more information, please contact Ideal Implant Incorporated at 214-492-2500.

Other Sources of Additional Information

Upon request, you will be provided with a copy of the Instructions for Use. You can request a copy from your surgeon or from Ideal Implant Incorporated. The Instructions for Use has many undefined medical and technical terms because it contains information directed only to the surgeon.

If you should decide to get breast implants, you will be given a Patient Implant Card with the catalogue number and serial number of your breast implant(s). This will be given to you right after your surgery. It is important that you keep this card because you may need to refer to that information at a later date.

For additional information or questions about Ideal Implant Incorporated breast implants, please call 214-492-2500.

Food and Drug Administration
1-800-INFO-FDA or 240-276-3103

You can find important information in the FDA breast implant consumer handbook, which is available through the phone number provided above.

American Society of Plastic Surgeons
www.plasticsurgery.org

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