2004 Update

Making An Informed Decision

Saline-Filled Breast Implant Surgery

INAMED AESTHETICS

Introduction

TO THE PATIENT

The information contained in this booklet, Making an Informed Decision, Saline-Filled Breast Implant Surgery, is designed to provide you with an understanding of the risks and benefits of surgery with saline-filled breast implants, as well as provide an overview of the experience of patients in INAMED clinical studies.

Please review this information to ensure your preoperative consultation is effective and comprehensive. Make notes about issues that you would like to further discuss with your plastic surgeon, and ask questions. Give yourself time to consider your choices and proceed with surgery only after you are satisfied that the decision is right for you.

TO THE HEALTHCARE PROFESSIONAL

Discussion of the content of this document is an important part of the informed decision making process for the patient. Please take time to familiarize yourself with the information presented here and incorporate it into your pre-operative discussion.

For your convenience, a signature block is provided as a means of documenting the preoperative discussion in the patient's file.

After removing the signature block, please give this book to the patient for her records.

Saline-Filled Breast Implant surgery

I have reviewed the information presented in Making an Informed Decision, Saline-Filled Breast Implant Surgery. My concerns and questions have been addressed by my doctor, and I have considered alternatives to surgery, including use of external prostheses.

I am choosing to proceed with saline-filled breast implant surgery.

Patient Name _____

Patient Signature _____

Date _____

Surgeon Name _____

Surgeon Signature _____

Date _____

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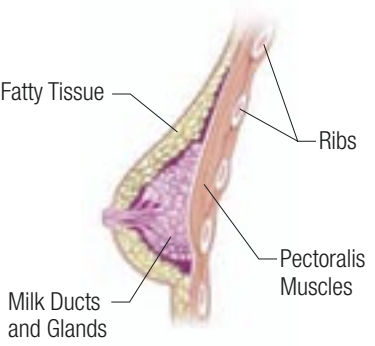
So You're Considering Saline-Filled Breast Implant Surgery…

The purpose of this brochure is to assist you in making an informed decision about breast augmentation and breast reconstruction surgery. This educational brochure is set up to help you talk with your surgeon, as well as provide you with general information on breast implant surgery and give you specific details about INAMED Saline-Filled Breast Implants.

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 (chest 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.



What is a Saline-Filled Breast Implant?

A breast implant is a sac (implant shell) of silicone elastomer (rubber), which is surgically implanted under your tissues, and then filled with sterile saline, a salt water solution, through a valve.

What Are Important Factors for You to Consider When Deciding to Have Saline-Filled Implants?

- Whether you are undergoing augmentation or reconstruction, be aware that breast implantation may not be a one time surgery. You are likely to need additional surgery and surgeon visits over the course of your life.
- Breast implants are not considered lifetime devices. You will likely undergo implant removal with or without replacement over the course of your life.
- Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast.
- Breast implants may affect your ability to produce milk for breast feeding. Also, breast implants will not prevent your breast 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.
- For patients who have undergone breast implantation either as a cosmetic or a reconstructive procedure, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should check with your insurance company regarding these coverage issues.

Are You Eligible for Saline-Filled Breast Implants?

Implants are to be used for females for the following indications (procedures):

Breast Augmentation

This is done to increase the size and proportion of a woman's breasts. **A woman must be at least 18 years old for breast augmentation.**

Breast Reconstruction

This procedure is done to restore a woman's breast shape after a mastectomy or injury that resulted in either partial or total loss of the breast(s), or to correct a birth defect.

Who is Not Eligible for Breast Implants?

Implants are not to be used for:

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

What are Contraindications, Warnings, and Precautions for You to Consider?

Surgical practices that are contraindicated in breast implantation because they may damage the shell and cause deflation/rupture:

- Placement of drugs/substances inside the implant other than sterile saline
- Any contact of the implant with Povidone-Iodine
- Injection through the implant shell
- Alteration of the implant
- Stacking of implants (more than one implant per breast)

Safety and Effectiveness has not been Established in Patients with the Following Conditions:

- Autoimmune diseases such as lupus and scleroderma
- Conditions that interfere with wound healing and blood clotting
- A weakened immune system (for example, currently receiving immunosuppressive therapy)
- Reduced blood supply to breast tissue

Further considerations:

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

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.

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, INAMED is monitoring the long term (10 year) chance of implant rupture, reoperation, implant removal, and capsular contracture (hardening of the tissues around the implant). INAMED is also conducting mechanical testing to assess the long-term likelihood of implant rupture. As new information becomes available, INAMED will issue an updated version of this brochure.

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.

What Types of Breast Implants Are Available from INAMED Aesthetics?

Breast implants come in a variety of shapes, surface textures, and sizes. All currently available INAMED Aesthetics implants have a selfsealing (diaphragm) valve that is used for filling the device. Depending on the style, the filling valve may be located on the front (anterior) or the back (posterior) of the implant. Below is a description of INAMED Aesthetics breast implant styles. Be sure to familiarize yourself with the different features of breast implants and to discuss the most appropriate type(s) of implants for you with your surgeon.

Round Breast Implants:

Style 68: Smooth shell surface, anterior filling valve, low, moderate, and high profile

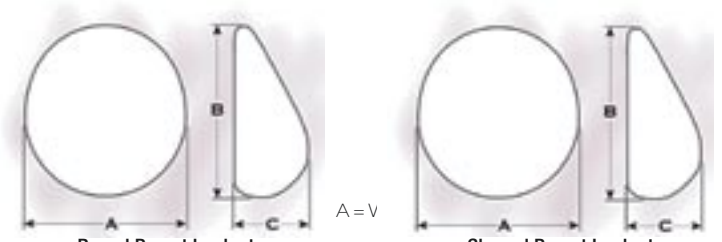
Style 168: BIOCELL® Textured shell surface, anterior filling valve, moderate profile

Shaped Breast Implants:

Style 163: BIOCELL® Textured shell surface, posterior filling valve, full height, full projection

Style 363: BIOCELL® Textured shell surface, anterior filling valve, low height, full projection

Style 468: BIOCELL® Textured shell surface, anterior filling valve, full height, moderate projection



Round Breast Implant | Shaped Breast Implant

What Are the Potential Breast Implant Complications?

Undergoing any surgical procedure may involve the risk of complications such as the effects of anesthesia, infection, swelling, redness, bleeding, and pain.

In addition, there are potential complications specific to breast implants. These complications include:

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/rupture.

Deflated implants require additional surgery to remove and to possibly replace the implant.

Capsular 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 may be 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). 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.

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.

Additional Surgeries

You should 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. Also, problems such as deflation, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. 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.

Dissatisfaction with Cosmetic Results

Dissatisfying results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, hypertrophic (irregular, raised scar) scarring, and/or sloshing may occur. Careful surgical planning and technique can minimize but not always prevent such results.

Infection

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. 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 for this condition.

Hematoma/Seroma

Hematoma is a collection of blood inside a body cavity, and a seroma is a collection of the watery portion of the blood (in this case, around the implant or around the incision). Postoperative hematoma and seroma may contribute to infection and/or capsular 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 require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation/rupture 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
At this time it is not known if a small amount of silicone may diffuse (pass through) from the saline-filled breast implant silicone shell and may find its way into breast milk. If this occurs, it is not known what effect it may have on the nursing infant. Although there are no current methods for detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone–filled gel implants when compared to women without implants.

With respect to the ability to successfully breast feed after breast implantation, one study reported up to 64% of women with implants who were unable to breast feed compared to 7% without implants. The periareolar incision site may significantly reduce the ability to successfully breast feed.

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.

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.

Necrosis
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.

Breast Tissue Atrophy/Chest Wall Deformity
The pressure of the 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.

In addition to these complications, there have been concerns with certain systemic diseases, of which you should be aware:

Connective Tissue Disease

Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature with small numbers of women with implants. A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants. However, a lot of women with breast implants believe that their implants caused a connective tissue disease.

Cancer

Published studies indicate that breast cancer is no more common in women with implants than those without implants.

Second Generation Effects

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.

INAMED's Clinical Studies

Although you will experience your own risks (complications) and benefits following breast implant surgery, this section describes the specific complications and benefits of Inamed saline-filled breast implants. Inamed's studies indicate, for example, that most women can expect to experience at least one complication at some point through 5 years after implant surgery. The studies also indicate that the chance of additional surgery through 7 years is 3 in 10 for augmentation patients and about 1 in 2 for reconstruction patients. The information below provides more details about the complications and benefits you may experience.

Description of Studies

INAMED conducted clinical studies of its saline-filled breast implants to determine the short-term and most common complications as well as benefits of their implants. These were assessed in the following studies:

- The Large Simple Trial (LST)
- The 1995 Augmentation Study (A95)
- The 1995 Reconstruction Study (R95)
- The Post Approval Survey Study (PASS)

The Large Simple Trial was designed to determine the 1-year rates of capsular contracture, infection, implant leakage/deflation, and implant replacement/removal. There were 2,333 patients enrolled for augmentation, 225 for reconstruction, and 317 for revision (replacement of existing implants). Of these enrolled patients, 62% returned for their 1-year follow-up visit.

The A95 and R95 Studies were designed as 5-year studies to assess all complications as well as patient satisfaction, body image, body esteem, and self concept. Patients were followed annually and data through 3 years (with partial 4 year data) were presented to FDA for PMA approval. After PMA approval, INAMED transitioned data collection to a post-approval study. The first phase of this postapproval study consisted of completion of the A95 and R95 Studies, with collection of all risk/benefit information through 5 years.

The A95/R95 sections of the brochure include original data presented to FDA for PMA approval along with the 5-year post-approval study data. The data presented through 5 years includes earlier data shown in the tables with new information added to it.

The Post Approval Survey Study was designed to collect long-term safety data from A95/R95 patients from 6-10 years post-implant. The data are collected from surveys that are mailed out to the patients each year. The PASS Study data are shown within both the Reconstruction

and Augmentation Sections following the A95/R95 data. The data presented through 7 years includes earlier data shown in the tables with new information added to it.

What Were the 1-Year Complication Rates from the LST?

The table below shows the complication rates for augmentation, reconstruction, and revision patients through 1 year. The rates reflect the number of patients out of 100 who experienced the listed complication. For example, 7% or 7 out of 100 augmentation patients experienced capsular contracture at some time within 1 year after implantation. However, this does not mean that 7% of patients still have capsular contracture at 1 year.

Complication	1-Year Complication Rate*		
	Augmentation	Reconstruction	Revision
Capsular Contracture III/IV	7%	13%	12%
Implant Removal	6%	14%	8%
Leakage/Deflation	4%	3%	5%
Infection	2%	6%	3%

*Data on 62% of the 2875 patients enrolled in the study

Breast Augmentation Results from A95 Study

What Were the Follow-Up Rates from the A95 Study?

The A95 Study enrolled 901 augmentation patients, with 77% returning for their 3-year follow-up visit. Of those A95 patients expected to be seen for their 5-year follow-up visit, 81% returned and were evaluated.

Augmentation: What Were the Complication Rates from the A95 Study?

The 3-year and 5-year complication rates are shown from the most common 5-year rate to the least common 5-year rate in the table below. The rates reflect the number of augmentation patients out of 100 who experienced the listed complication at least once within the first 3 and 5 years after implantation. Some complications occurred more than once for some patients. The two most common complications experienced within the first 5 years of implantation were reoperation (26% or 26 patients out of 100) and breast pain (17% or 17 patients out of 100).

Complications	N = 901 Patients	
	3-Year** Complication Rate	5-Year Complication Rate
Additional Operation (Reoperation)	21%	26%
Breast Pain*	16%	17%
Wrinkling*	11%	14%
Asymmetry*	10%	12%
Implant Palpability/Visibility*	9%	12%
Implant Replacement/Removal for Any Reason	8%	12%
Capsular Contracture	9%	11%
Intense Nipple Sensation*	9%	10%
Loss of Nipple Sensation*	8%	10%
Implant Malposition*	8%	9%
Intense Skin Sensation*	7%	8%
Scarring Complications	6%	7%
Leakage/Deflation	5%	7%
Irritation/Inflammation*	3%	3%
Seroma	3%	3%
Hematoma	2%	2%
Skin Rash	2%	2%
Capsule Calcification*	1%	2%
Delayed Wound Healing*	1%	1%
Infection	<1%	1%

Note: * These complications were assessed with severity ratings. Only the rates for moderate, severe, or very severe (excludes mild and very mild ratings) are shown in this table.

** As reported in original PMA submission.

Augmentation: What Were the Types of Additional Surgical Procedures Performed?

The following table provides a breakdown of the types of surgical procedures that were performed through 4 and 5 years after implantation. Through 5 years, there were 224 patients who had one or more additional operations after the initial implantation (reoperations), for a total of 293 reoperations. These reoperations involved one or more surgical procedures, for a total of 463 surgical procedures. Examples of multiple procedures during a single reoperation 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 5 years was implant removal with replacement (34% of the 463 procedures performed).

Type of Surgical Procedures	N = 901 Patients	
	Through 4 Years* % (N = 402 Surgical Procedures)	Through 5 Years % (N = 463 Surgical Procedures)
Implant Removal With Replacement**	30%	34%
Capsule Procedure	19%	19%
Add/Remove Saline	11%	11%
Scar Revision/Wound Repair	9%	9%
Removal of Excess Fluid	7%	6%
Mastopexy	7%	6%
Reposition Implant	5%	5%
Biopsy/Lump Removal	4%	5%
Implant Removal Without Replacement	3%	2%
Removal of Skin Lesion/Cyst	2%	2%
Exploration of Breast Area or Implants	2%	1%
Skin Related Procedure	1%	1%
Nipple Related Procedure (Unplanned)	<1%	<1%
Total	**100%**	**100%**

* As reported in original PMA submission with additional data clarification.

** Some removals were replaced with a INAMED implant, while others were replaced with a non-INAMED implant.

Augmentation: What Were the Reasons for Reoperation?

The reasons for reoperation through 4 and 5 years are shown below. The reasons for reoperation 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 reoperation is implant malposition.

There were 257 reoperations performed in 204 patients through 4 years. There were 293 reoperations performed on 225 patients through 5 years. The most common reason for reoperation through 5 years was deflation (18% of the 293 reoperations).

Reasons for Reoperation	4-Years % (N=257 Reoperations)	5-Years % (N=293 Reoperations)
Implant Deflation	18%	18%
Capsular Contracture	18%	18%
Patient Choice	15%	15%
Hematoma/Seroma	10%	9%
Implant Malposition	9%	10%
Lump/Mass/Cyst	8%	9%
Scarring	7%	7%
Asymmetry	5%	5%
Ptosis	5%	6%
Add/Remove Saline	5%	5%
Delayed Wound Healing	2%	1%
Unsatisfactory Nipple Result	2%	2%
Wrinkling	2%	3%
Infection	1%	1%
Skin Lesion/Cyst	1%	1%
Capsule Calcification	0%	<1%
Breast Pain	<1%	<1%
Implant Extrusion	<1%	<1%
Implant Palpability	<1%	1%
Irritation	<1%	<1%

* Total is greater then 100% because some reoperations were performed for multiple reasons.

Augmentation: What Were the Reasons for Implant Removal?

The following table details the primary reasons for implant removal in the A95 Study over the 5 years. Through 5 years, there were 166 devices removed in 98 patients. Of these 166 devices, 156 were replaced and 10 were not. The most common reason for implant removal through 5 years was patient request for a size or style change (42% of the implants removed).

Primary Reason for Implant Removal	Through 4 Years* % (N = 132 Implants Removed)	Through 5 Years % (N = 166 Implants Removed)
Patient Choice	43%	43%
Leakage/Deflation	33%	33%**
Capsular Contracture	10%	10%
Wrinkling	5%	4%
Asymmetry	3%	2%
Breast Pain	2%	2%
Implant Malposition	2%	1%
Infection	1%	1%
Implant Extrusion	1%	1%
Damage to Implant During Surgery	1%	1%
Implant Palpability/Visibility	0%	4%
Total	**100%**	**100%**

* As reported in original PMA submission with additional data clarification.

** Includes 1 implant removal where the reason for removal is unknown.

Augmentation: What Were the Complication Rates After Implant Replacement?

There were 78 patients in the A95 Study who had 126 implants removed and replaced with INAMED implants. The table below reflects the number of replaced implants (not patients) out of 100 implants associated with the listed complications within 2 and 3 years following replacement. For example there was capsular contracture in 8% or 8

out of 100 implants at some time within 3 years after replacement. The complications reported following implant replacement were restricted to the same ones collected in the Large Simple Trial, LST (refer to page 11).

Complication Following Replacement of Augmentation Implant(s)	2-Year Complication Rate* % (N = 108 Implants)	3-Year Complication Rate % (N = 126 Implants)
Removal/Replacement	5%	18%
Leakage/Deflation	9%	9%
Capsule Contracture III/IV	7%	8%
Infection	1%	3%

* As reported in original PMA submission.

Augmentation: What Were the Breast Disease and CTD Events?

Breast disease and connective tissue disease (CTD) were reported in some patients through 5 years after implantation in the A95 Study. Although there were 901 patients enrolled in the A95 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.

There were 81 reports of breast disease through 5 years. Of these 81 reports, 7 are new since year 4. Additionally, 2 unknown outcome reports at year 4 were found to be false reports and were removed from the year 5 numbers, and the remaining 7 unknown outcome patients at year 4 were recategorized into benign. The reports of breast disease through 4 and 5 years are summarized in the following table.

Breast Disease Observation	No. of Patient Reports Through 4 Years*	No. of Patient Reports Through 5 Years
Benign	66	80
Malignant	1	1
Unknown Outcome	7	0

* As reported in original PMA submission with additional data clarification:
Benign includes 22 additional reports and unknown outcome (includes 2 fewer reports).

The table below shows the number of patients reported to have CTD through 4 and 5 years after implantation. Confirmed reports were based on a diagnosis by a doctor. Unconfirmed reports were based on self-reports by the patients. There were 20 reports of CTD through 5 years. Of the 20 reports, 11 are new since year 4 (2 confirmed, 9 unconfirmed). Additionally, 3 unconfirmed reports at year 4 were found to be false reports and were removed from the year 5 numbers.

Connective Tissue Disease	Through 4 Years*		Through 5 Years	
	No. of Confirmed Reports	No. of Unconfirmed Reports	No. of Confirmed Reports	No. of Unconfirmed Reports
Graves' Disease	2	0	3	0
Hyperthyroiditis	1	2**	2	1
Lupus Erythematosus and/or Rheumatoid Arthritis	0	3	0	1
Thyroiditis	0	2	0	4
Chronic Fatigue Syndrome or Fibromyalgia	2	0	2	4
Inflammatory Bowel Disease	0	0	0	1
Raynaud's Phenomenon, Graves' Disease, Hyperthyroiditis, and Rheumatoid Arthritis	0	0	0	1**
Seronegative Spondylarthritis	0	0	0	1
Total	**5**	**7**	**7**	**13**

* As reported in original PMA submission.

** Patient was recategorized at 5-year timepoint.

Augmentation: What Were the Benefits?

The benefits of saline-filled breast implants in the A95 Study were assessed by a variety of outcomes, including bra cup size change, patient satisfaction, body image, body esteem, and self concept. These outcomes were assessed for patients with both original and replacement saline devices before implantation and at 3 years after surgery, except for bra size and satisfaction. Bra size was measured within the first year and a half after surgery. Satisfaction was measured at every follow-up visit through 5 years.

859 of the original 901 patients (95%) at 18 months were included in an analysis of cup size (5% did not provide data because pre/post measurements were not obtained or replacement/removal occurred prior to obtaining a post measurement). Of these 859 patients, the following shows the percentage of patients experiencing various changes in cup size:

- Increase by 1 cup size: 38%
- Increase by 2 cup sizes: 49%
- Increase by 3 cup sizes: 9%
- No Increase: 4%

683 of the original 901 patients (76%) were included in an analysis of satisfaction at 5 years (24% were not included because satisfaction data was not obtained or implant replacement/removal occurred prior to 5 years). Of these 683 patients, 95% indicated being satisfied with their breast implants at 5 years.

Before implantation, augmentation patients scored higher (better) than the general U.S. female population on the SF-36 and MOS-20 scales, which measure general health-related quality of life. After 3 years, augmentation patients showed a worsening in their SF-36 and MOS-20 scores. The following two scales showed no change over the 3 years: The Tennessee Self Concept Scale (which measures overall self concept) and The Body Esteem Scale (which measures overall self esteem related specifically to one's body). The Rosenberg Self Esteem Scale (which measures overall self esteem) showed a slight improvement over the 3 years. The Semantic Differential Scale (which measures attitudes about your breasts compared to attitudes about yourself) showed that patients experienced an increased positive attitude towards their breasts compared to themselves over the 3 years.

Breast Augmentation Results from Post Approval Survey Study (PASS)

The section above summarizes the data collected through 5 years. This section focuses on the augmentation data collected through the PASS, which involved mail-in surveys. The following tables present results through 7 years. Of the women expected to return completed surveys for the 7-year post-implantation study interval, data were collected for 85% of the augmentation patients.

Augmentation: What Were the Complication Rates from the PASS Study?

The 7-year complication rates are shown from the most common to the least common. The rates reflect the number of augmentation patients out of 100 who experienced the listed complication at least once within the first 7 years after implantation. The most common complication experienced through 7 years was reoperation (30%, 30 out of every 100 patients).

Complication	7-Year Complication Rate N = 901 Patients
	Rate (%)
Reoperation	30%
Breast Pain	25%
Capsular Contracture	16%
Implant Removal	15%
Implant Deflation	10%

Augmentation: What Were the Reasons for Reoperation?

The reasons for reoperation through 7 years are shown below. The reasons for reoperation 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 reoperation is implant malposition.

There were 343 reoperations performed in 261 patients through 7 years. The most common reason for reoperation through 7 years was implant deflation (19% of the 343 reoperations).

Reasons for Reoperation	7-Year % (N = 343 Reoperations)
Implant Deflation	19%
Patient Choice	18%
Capsular Contracture	16%
Lump/Mass/Cyst	13%
Implant Malposition	9%
Hematoma/Seroma	8%
Scarring	6%
Ptosis	6%
Add/Remove Saline	5%
Asymmetry	4%
Wrinkling	2%
Implant Palpability	2%
Unsatisfactory Nipple Result	2%
Delayed Wound Healing	1%
Infection	1%
Skin Lesion/Cyst	<1%
Breast Pain	<1%
Capsule Calcification	<1%
Implant Extrusion	<1%
Irritation	<1%

*Total is greater than 100% because some reoperations were performed for multiple reasons.

Augmentation: What Were the Reasons for Implant Removal?

The following table details the primary reasons for implant removal in the PASS Study through 7 years. Through 7 years, there were 213 devices removed from 124 patients. The most common reason for implant removal was patient choice (42% of the implants removed).

Primary Reason for Implant Removal	Through 7 Years % (N = 213 Implants Removed)
Patient Choice	42%
Implant Deflation	32%
Capsular Contracture	9%
Wrinkling	4%
Implant Malposition	4%
Implant Palpability/Visibility	3%
Asymmetry	3%
Breast Pain	1%
Iatrogenic Injury	<1%
Infection	<1%
Implant Extrusion	<1%
Breast Mass/Lump/Cyst	<1%
Total	**100%**

*As reported in original PMA submission with additional data clarification.
**Includes 1 implant removal where the reason for removal is unknown.

Augmentation: What Was the Satisfaction Rate at 7 Years?

Eighty-Seven percent (87%) of the patients who provided satisfaction scores indicated being satisfied with their breast implants at 7 years post-implant.

Breast Augmentation Considerations

Special Considerations for Breast Augmentation

What Are the Alternatives to Breast Augmentation?

- Accept your breasts as they are
- Wear a padded bra or external prostheses

You are advised to wait a week after reviewing and considering this information before deciding whether to have augmentation surgery.

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 breast feeding?
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 procedure and what results are reasonable for me?

Other Factors to Consider in Breast Augmentation

Choosing a Surgeon

When choosing an experienced surgeon who is experienced with breast implantation, you should know the answers to 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 on the world wide web.
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?

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

Implant Shape and Size

Depending on the desired shape you wish to achieve, you and your surgeon may choose a round or contoured implant shape. Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's). You should be aware that contoured implants that are placed submuscularly (under your chest muscle) may assume a round shape after implantation.

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.

Surface Texturing

Textured surface implants were designed to reduce the chance of capsular contracture. Some information in the literature with small numbers of patients suggests that surface texturing reduces the chance of severe capsular contracture, but clinical information from studies of a large number of women with INAMED implants shows no difference in the likelihood of developing capsular contracture with textured implants compared to smooth surfaced implants. .

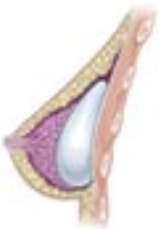
Palpability

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 glands (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.

Breast before augmentation



Breast after subglandular augmentation

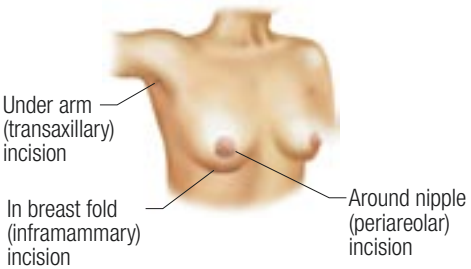
Breast after submuscular augmentation

The submuscular placement may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to have some reoperation procedures 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 reoperation 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 Sites

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

Periareolar

This incision is 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.

Umbilical/endoscopic

This incision site has not been studied and is not recommended.

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 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.

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 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.

Insurance

Insurance does not cover breast augmentation and may not cover reoperation (additional surgery) and additional surgeon's visits following augmentation.

Breast Reconstruction Results from R95 Study

Reconstruction: What Were the Follow-Up Rates from the R95 Study?

The R95 Study enrolled 237 reconstruction patients, with 71% returning for their 3-year follow-up visit. Of those R95 patients expected to be seen for their 5-year follow-up visit, 80% returned and were evaluated.

Reconstruction: What Were the Complication Rates from the R95 Study?

The 3-year and 5-year complication rates are shown from the most common 5-year rate to the least common 5-year rate in the table below. The rates reflect the number of reconstruction patients out of 100 who experienced the listed complication at least once within the first 3 and 5 years after implantation. Some complications occurred more than once for some patients. The two most common complications experienced within the first 5 years of implantation were reoperation (45% or 45 patients out of 100) and asymmetry (39% or 39 patients out of 100).

Complications	N = 237 Patients	
	3-Year** Complication Rate	5-Year Complication Rate
Additional Operation (Reoperation)	39%	45%
Asymmetry*	33%	39%
Capsular Contracture	25%	36%
Implant Replacement/Removal for Any Reason	23%	28%
Wrinkling*	23%	25%
Implant Palpability/Visibility*	20%	27%
Breast Pain*	15%	18%
Loss of Nipple Sensation*	12%	18%
Implant Malposition*	12%	17%
Irritation/Inflammation*	7%	7%
Leakage/Deflation	6%	8%
Intense Skin Sensation*	6%	6%
Scarring Complications	6%	6%
Infection	5%	6%
Capsule Calcification*	5%	5%
Seroma	4%	4%
Skin/Tissue Necrosis	4%	4%
Delayed Wound Healing*	3%	3%
Implant Extrusion	3%	3%
Skin Rash	3%	3%
Hematoma	1%	1%

Note: * These complications were assessed with severity ratings. Only the rates for moderate, severe, or very severe (excludes mild and very mild ratings) are shown in this table.

** As reported in original PMA submission.

Reconstruction: What Were the Types of Additional Surgical Procedures Performed?

The following table provides a breakdown of the types of surgical procedures that were performed through 4 and 5 years after implantation. Through 5 years, there were 100 patients who had one or more additional operations after the initial implantation (reoperations), for a total of 126 reoperations. These 126 reoperations involved one or more surgical procedures, for a total of 159 surgical procedures. Examples of multiple procedures during a single reoperation include implant replacement for both breasts or a capsule procedure and mastopexy on the same breast. This table does not include the 282 planned nipple reconstruction and nipple/areolar tattoo procedures that occurred through 4 years. Only the 151 unplanned procedures through 4 years and the 159 unplanned procedures through 5 years are included in the table. The most common type of unplanned additional surgical procedure through 5 years was implant removal with replacement (31% of the 159 procedures performed).

Type of Surgical Procedures	N = 237 Patients	
	Through 4 Years* % (N = 151 Surgical Procedures)	Through 5 Years % (N = 159 Surgical Procedures)
Implant Removal With Replacement**	30%	31%
Scar Revision/Wound Repair	19%	19%
Capsule Procedure	12%	8%
Implant Removal Without Replacement	11%	13%
Add/Remove Saline	6%	6%
Removal of Excess Fluid	5%	4%
Biopsy/Lump Removal	5%	4%
Reposition Implant	4%	4%
Skin Related Procedure	4%	4%
Nipple Related Procedures (unplanned)	2%	2%
Other Procedures***	2%	2%
Removal of Skin Lesion/Cyst	1%	2%
Total	**100%**	**100%**

* As reported in original PMA submission with additional data clarification.

** Some removals were replaced with a INAMED implant, while others were replaced with a non-INAMED implant.

*** Through 4 years, other procedures were liposuction, placement of a stacked implant. Through 5 years, other procedures were liposuction, placement of a stacked implant.

Reconstruction: What Were the Reasons for Reoperation?

The reasons for reoperation through 5 years are shown below. The reasons for reoperation 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 reoperation is implant malposition.

There were 117 reoperations performed in 94 patients through 4 years. There were 125 reoperations performed in 99 patients through 5 years. The most common reason for reoperation through 5 years was capsular contracture (27% of the 125 reoperations).

Reason for Reoperation	4-Years % (N = 117 Reoperations)	5-Years % (N = 125 Reoperations)
Capsular Contracture	27%	27%
Asymmetry	21%	20%
Patient Choice	11%	10%
Implant Malposition	10%	9%
Scarring	9%	8%
Lump/Mass/Cyst	8%	8%
Implant Deflation	8%	9%
Infection	7%	7%
Tissue/Skin Necrosis	5%	5%
Hematoma/Seroma	5%	5%
Breast Pain	5%	5%
Implant Extrusion	4%	4%
Add/Remove Saline	4%	3%
Wrinkling	3%	4%
Implant Palpability	2%	2%
Delayed Wound Healing	2%	2%
Unsatisfactory Nipple Result	<1%	<1%
Skin Lesion/Cyst	<1%	2%
Total	131%	130%

*Total is greater than 100% because some reoperations were performed for multiple reasons.

Reconstruction: What Were the Reasons for Implant Removal?

The following table details the primary reasons for implant removal in the R95 Study over the 5 years. Through 5 years, there were 70 devices removed in 62 patients. Of these 70 devices, 49 were replaced and 21 were not. The most common reason for implant removal through 5 years was capsular contracture (31% of the 70 implants removed).

Primary Reason for Implant Removal	Through 4-Years* % (N = 62 Reoperations)	Through 5-Years % (N = 70 Reoperations)
Capsular Contracture III/IV	26%	31%
Patient Choice	23%	21%
Leakage/Deflation**	16%	17%
Infection	10%	10%
Implant Extrusion	6%	6%
Implant Malposition	6%	4%
Other***	3%	4%
Wrinkling	3%	3%
Asymmetry	3%	1%
Recurrent Breast Cancer	3%	1%
Total	100%	100%

* As reported in original PMA submission with additional data clarification.

** Includes removals where the reason for removal was unknown.

*** Through 4 years, other reasons were abnormality of CT scan at mastectomy site, poor tissue expansion due to radiation. Through 5 years, other reasons were abnormality of CT scan at mastectomy site, poor tissue expansion due to radiation, second stage breast reconstruction.

Reconstruction: What Were the Complication Rates After Implant Replacement?

There were 37 patients in the R95 Study who had 40 implants removed and replaced with INAMED implants. The table below reflects the number of replaced implants (not patients) out of 100 implants associated with the listed complications within 2 and 3 years following replacement. For example there was capsular contracture in 34% or 34 out of 100 implants at some time within 3 years after replacement. The complications reported following implant replacement were restricted to the same ones collected in the Large Simple Trial, LST (refer to page 11).

Complication Following Replacement of Reconstruction Implant(s)	2-Year Complication Rate* % (N = 40 Implants)	3-Year Complication Rate* % (N = 40 Implants)
Capsular Contracture III/IV	33%	34%
Removal/Replacement	26%	27%
Leakage/Deflation	5%	10%
Infection	7%	3%

* As reported in original PMA submission with correction to capsular contracture rate.

Reconstruction: What Were the Breast Disease and CTD Events?

Breast disease and connective tissue disease (CTD) were reported in some patients through 5 years after implantation in the R95 Study. Although there were 237 patients enrolled in the R95 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.

There were 99 reports of breast disease through 5 years. Of these 99 reports, 7 are new since year 4. Additionally, 1 unknown outcome report was recategorized at 5 years. The reports of breast disease through 4 and 5 years are summarized in the following table.

Breast Disease Observation	No. of Patient Reports Through 4 Years*	No. of Patient Reports Through 5 Years*
Benign	72	75
Malignant	19	24
Unknown Outcome	1	0

* As reported in original PMA submission with additional data clarification: Benign includes 61 additional reports.

The table below shows the number of patients reported to have CTD through 4 and 5 years after implantation. Confirmed reports were based on a diagnosis by a doctor. Unconfirmed reports were based on self-reports by the patients. There were 5 reports of CTD through 5 years. Of the 5 reports, 4 are new since year 4 (all unconfirmed). Additionally, 4 unconfirmed reports at year 4 were found to be false reports and were removed from the year 5 numbers.

Connective Tissue Disease	Through 4 Years*		Through 5 Years	
	No. of Confirmed Reports	No. of Unconfirmed Reports	No. of Confirmed Reports	No. of Unconfirmed Reports
Graves' Disease	1	0	1	0
Lupus Erythematosus and/or Rheumatoid Arthritis	0	1	0	3
Inflamatory Bowel Disease	0	1	0	0
Thyroiditis	0	2	0	1
Total	**1**	**4**	**1**	**4**

* As reported in original PMA submission.

Reconstruction: What Were the Benefits?

The benefits of saline-filled breast implants in the R95 Study were assessed by a variety of outcomes, including patient satisfaction, body image, body esteem, and self concept. These outcomes were assessed for patients with both original and replacement saline devices before implantation and at 3 years after surgery, except for satisfaction which was measured at every follow-up visit through 5 years.

137 of the original 237 patients (58%) were included in an analysis of satisfaction at 5 years (42% were not included because satisfaction data was not obtained or implant replacement/removal occurred prior to 5 years). Of these 137 patients, 89% indicated being satisfied with their breast implants at 5 years.

Before implantation, reconstruction patients scored higher (better) than the general U.S. female population before implantation on some SF-36 scales, which measure general health-related quality of life. After 3 years, reconstruction patients showed an improvement in some of their SF-36 and MOS-20 scores. The following three scales showed no change over the 3 years: The Tennessee Self Concept Scale (which measures overall self concept), The Rosenberg Self Esteem Scale

(which measures overall self esteem), and The Body Esteem Scale (which measures overall self esteem related specifically to one's body). The Semantic Differential Scale (which measures attitudes about your breasts compared to attitudes about yourself) showed that patients experienced an increased positive attitude towards their breasts compared to themselves over the 3 years.

Breast Reconstruction Results from Post Approval Survey Study (PASS)

The section above summarizes the data collected through 5 years. This section focuses on the reconstruction data collected through the PASS, which involved mail-in surveys. The following tables present through 7 years. Of the women expected to return completed surveys for the 7-year post-implantation study interval, data were collected for 83% of the reconstruction patients.

Reconstruction: What Were the Complication Rates from the PASS Study?

The 7-year complication rates are shown from the most common to the least common. The rates reflect the number of reconstruction patients out of 100 who experienced the listed complication at least once within the first 7 years after implantation. The most common complication experienced through 7 years was reoperation (49%, 49 out of every 100 patients).

Complication	7-Year Complication Rate N = 237 Patients
	Rate (%)
Reoperation	49%
Capsular Contracture	43%
Implant Removal	31%
Breast Pain	26%
Implant Deflation	12%

Reconstruction: What Were the Reasons for Reoperation?

The reasons for reoperation through 7 years are shown below. The reasons for reoperation 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 reoperation is implant malposition.

There were 138 reoperations performed in 107 patients through 7 years. This does not include planned reoperations like nipple procedures. The most common reason for reoperation through 7 years was capsular contracture (25%).

Reasons for Reoperation	7-Year % (N = 138 Reoperations)
Capsular Contracture	25%
Asymmetry	18%
Implant Deflation	12%
Patient Choice	12%
Implant Malposition	9%
Lump/Mass/Cyst	9%
Scarring	8%
Infection	7%
Breast Pain	4%
Hematoma/Seroma	4%
Tissue/Skin Necrosis	4%
Implant Extrusion	4%
Wrinkling	4%
Add/Remove Saline	4%
Implant Palpability	2%
Delayed Wound Healing	1%
Skin Lesion/Cyst	1%
Unsatisfactory Nipple Result	1%
Cancer	<1%
Ptosis	<1%

*Total is greater than 100% because some reoperations were performed for multiple reasons.

Reconstruction: What Were the Reasons for Implant Removal?

The following table details the primary reasons for implant removal through 7 years. Through 7 years there were 81 implants removed from 69 patients. The two most common reasons for implant removal were implant deflation and capsular contracture (50% of the implants removed).

Primary Reason for Implant Removal	Through 7 Years % (N = 81 Implants Removed)
Implant Deflation	25%
Capsular Contracture	25%
Patient Choice	24%
Infection	9%
Implant Extrusion	5%
Other*	5%
Implant Malposition	4%
Wrinkling	3%
Asymmetry	3%
Total	100%

*Other reasons as reported by the physician were: Recurrent Carcinoma (n=1), Abnormality on CT Scan at Mastectomy Site (n=1), Tissue expansion Went Poorly Due to Radiation (n=1), Second Stage Breast Recon (n=1)

Reconstruction: What Was the Satisfaction Rate at 7 Years?

Eighty-eight percent (88%) of the patients who provided satisfaction scores indicated being satisfied with their breast implants at 7 years post-implant.

Breast Reconstruction Considerations

Special Considerations for Breast Reconstruction

Should You Have Breast Reconstruction?

Whether you decide to have breast reconstruction depends on your own individual case, medical condition, general health, lifestyle, emotional state, and breast size and shape. You may consider consulting your family, friends, breast implant support groups, and breast cancer support groups to help you in making this decision.

If you are considering breast reconstruction and do not have a plastic surgeon, ask your general surgeon for a referral for the names of experienced, board certified plastic surgeons in your area. Your general surgeon, plastic surgeon, and oncologist should work together to plan your mastectomy and reconstruction procedure to give you the best possible result.

What Are the Alternatives to Breast Reconstruction?

You may choose not to undergo breast reconstruction. In this case, you may or may not decide to wear an external breast form (prosthesis) inside your bra. Breast forms are available in a variety of shapes, sizes, and materials such as foam, cotton, and silicone. Custom prostheses are also available to match the size and shape of your breast.

What Are the Choices in Reconstructive Procedures?

The type of breast reconstruction procedure available to you depends on your medical situation, breast shape and size, general health, lifestyle, and goals. Women with small or medium sized breasts are the best candidates for breast reconstruction.

Breast reconstruction can be accomplished by the use of a prosthesis (a breast implant, either silicone gel or saline-filled), your own tissues (a tissue flap), or a combination of the two. A tissue flap is a section of skin, fat and/or muscle which is moved from your stomach, back or other area of your body, to the chest area, and shaped into a new breast.

Whether or not you have reconstruction with or without breast implants, you will probably undergo additional surgeries to improve symmetry and appearance. For example, because the nipple and areola are usually removed with the breast tissue in mastectomy, the nipple is usually reconstructed by using a skin graft from another area of the body or the opposite breast, in addition to tattooing the area. Nipple reconstruction is usually done as a separate outpatient procedure after the initial reconstruction surgery is complete.

Breast Reconstruction with Breast Implants

Your surgeon will decide whether your health and medical condition makes you an appropriate candidate for breast implant reconstruction. Women with larger breasts may require reconstruction with a combination of a tissue flap and an implant. Your surgeon may recommend breast implantation of the opposite, uninvolved breast in order to make them more alike (maximize symmetry) or he/she may suggest breast reduction (reduction mammoplasty) or a breast lift (mastopexy) to improve symmetry. Mastopexy involves removing a strip of skin from under the breast or around the nipple and using it to lift and tighten the skin over the breast. Reduction mammoplasty involves removal of breast tissue and skin. If it is important to you not to alter the unaffected breast, you should discuss this with your plastic surgeon, as it may affect the breast reconstruction methods considered for your case.

Reconstruction Incision Sites

Most implants in breast reconstruction use the mastectomy scar either immediately (during the mastectomy procedure) or after tissue expansion.

Surgical Setting and Anesthesia

Reconstruction surgery is usually performed on an inpatient basis in an operating room. General anesthesia is most often used.

The Timing of Your Breast Implant Reconstruction

The following description applies to reconstruction following mastectomy, but similar considerations apply to reconstruction following breast trauma or for reconstruction for congenital defects. The breast reconstruction process may begin at the time of your mastectomy (immediate reconstruction) or weeks to years afterwards (delayed reconstruction). Immediate reconstruction may involve placement of a breast implant, but typically involves placement of a tissue expander, which will eventually be replaced with a breast implant. It is important to know that any type of surgical breast reconstruction may take several steps to complete.

Two potential advantages to immediate reconstruction are that your breast reconstruction starts at the time of your mastectomy and that there may be cost savings in combining the mastectomy procedure with the first stage of the reconstruction. However, there may be a higher risk of complications such as deflation with immediate reconstruction, and your initial operative time and recuperative time may be longer.

A potential advantage to delayed reconstruction is that you can delay your reconstruction decision and surgery until other treatments, such as radiation therapy and chemotherapy, are completed. Delayed reconstruction may be advisable if your surgeon anticipates healing problems with your mastectomy, or if you just need more time to consider your options.

There are medical, financial and emotional considerations to choosing immediate versus delayed reconstruction. You should discuss with your surgeon, plastic surgeon, and oncologist, the pros and cons with the options available in your individual case.

Surgical Considerations to Discuss with your Surgeon

Discuss the advantages and disadvantages of the following options with your surgeon and your oncologist:

Immediate Reconstruction:

One-stage immediate reconstruction with a breast implant (implant only).

Two-stage immediate reconstruction with a tissue expander followed by delayed reconstruction several months later with a breast implant.

Delayed Reconstruction:

Two-stage delayed reconstruction with a tissue expander followed several months later by replacement with a breast implant.

What Is the Breast Implant Reconstruction Procedure?

One-Stage Immediate Breast Implant Reconstruction

Immediate one-stage breast reconstruction may be done at the time of your mastectomy. After the general surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant that completes the one-stage reconstruction. In reconstruction following mastectomy, a breast implant is most often placed submuscularly.

Two-Stage (Immediate or Delayed) Breast Implant Reconstruction

Breast reconstruction usually occurs as a two-stage procedure, starting with the placement of a breast tissue expander, which is replaced several months later with a breast implant. The tissue expander placement may be done immediately, at the time of your mastectomy, or be delayed until months or years later.

Side View, Breast Tissue Removed

Side View, Expander Inserted and Filled

Stage 1: Tissue Expansion

During a mastectomy, the general surgeon removes skin as well as breast tissue, leaving the chest tissues flat and tight. To create a breast shaped space for the breast implant, a tissue expander is placed under the remaining chest tissues.

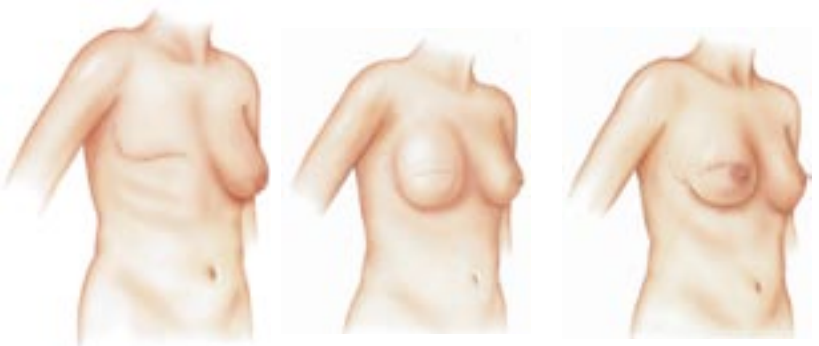
The tissue expander is a balloon-like device made from elastic silicone rubber. It is inserted unfilled, and over time, sterile saline fluid is added by inserting a small needle through the skin to the filling port of the device. As the tissue expander fills, the tissues over the expander begin to stretch, similar to the gradual expansion of a woman's abdomen during pregnancy. The tissue expander creates a new breast shaped pocket for a breast implant.

Tissue expander placement usually occurs under general anesthesia in an operating room. Operative time is generally one to two hours. The procedure may require a brief hospital stay, or be done on an outpatient basis. Typically, you can resume normal daily activity after two to three weeks.

Because the chest skin is usually numb from the mastectomy surgery, it is possible that you may not experience pain from the placement of the tissue expander. However, you may experience feelings of pressure, tightness or discomfort after each filling of the expander, which subsides as the tissue expands but may last for a week or more. Tissue expansion typically lasts four to six months.

Stage 2: Placing the Breast Implant

After the tissue expander is removed, the unfilled breast implant is placed in the pocket, and then filled with sterile saline fluid. In reconstruction, following mastectomy, a breast implant is most often placed submuscularly. The surgery to replace the tissue expander with a breast implant (implant exchange) is usually done under general anesthesia in an operating room. It may require a brief hospital stay or be done on an outpatient basis.



Post Mastectomy | **Stage 1: Tissue Expander** | **Stage 2: Breast Implant and Nipple/Areola Reconstruction**

Breast Reconstruction Without Implants: Tissue Flap Procedures

The breast can be reconstructed by surgically moving a section of skin, fat and muscle from one area of your body to another. The section of tissue may be taken from such areas as your abdomen, upper back, upper hip, or buttocks.

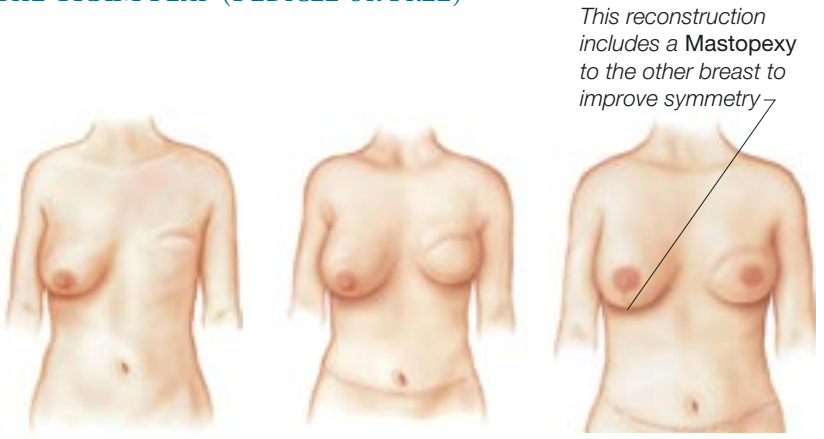
The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap), or it may be removed completely and reattached to the breast area by microsurgical techniques (a free flap). Operating time is generally longer with free flaps, because of the microsurgical requirements.

Flap surgery requires a hospital stay of several days and generally a longer recovery time than implant reconstruction. Flap surgery also creates scars at the site where the flap was taken and on the reconstructed breast. However, flap surgery has the advantage of being able to replace tissue in the chest area. This may be useful when the chest tissues have been damaged and are not suitable for tissue expansion. Another advantage of flap procedures over implantation is that alteration of the unaffected breast is generally not needed to improve symmetry.

The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap) (which uses tissue from the abdomen) and the Latissimus dorsi flap (which uses tissue from the upper back).

It is important for you to be aware that flap surgery, particularly the TRAM flap, is a major operation, and more extensive than your mastectomy operation. It requires good general health and strong emotional motivation. If you are very overweight, smoke cigarettes, have had previous surgery at the flap site, or have any circulatory problems, you may not be a good candidate for a tissue flap procedure. Also, if you are very thin, you may not have enough tissue in your abdomen or back to create a breast mound with this method.

The TRAM Flap (Pedicle or Free)



Post Mastectomy | **TRAM Flap** | **Final Result and Nipple/Areola Reconstruction**

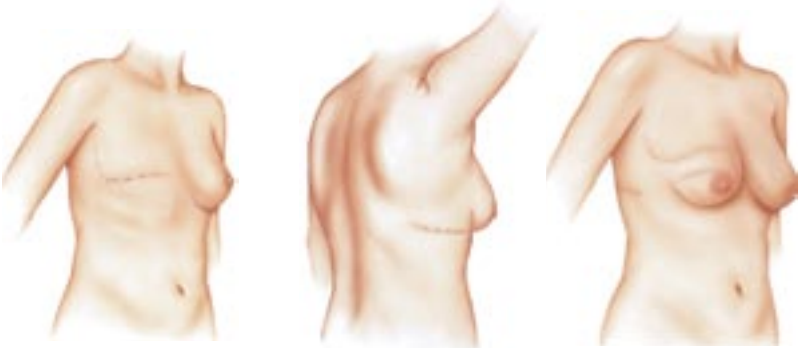
During a TRAM flap procedure, the surgeon removes a section of tissue from your abdomen and moves it to your chest to reconstruct the breast. The TRAM flap is sometimes referred to as a "tummy tuck" reconstruction, because it may leave the stomach area flatter.

A pedicle TRAM flap procedure typically takes three to six hours of surgery under general anesthesia; a free TRAM flap procedure generally takes longer. The TRAM procedure may require a blood transfusion. Typically, the hospital stay is two to five days. You can resume normal daily activity after six to eight weeks. Some women, however, report

that it takes up to one year to resume a normal lifestyle. You may have temporary or permanent muscle weakness in the abdominal area. If you are considering pregnancy after your reconstruction, you should discuss this with your surgeon. You will have a large scar on your abdomen and may also have additional scars on your reconstructed breast.

The Latissimus Dorsi Flap With or Without Breast Implants

During a Latissimus Dorsi flap procedure, the surgeon moves a section of tissue from your back to your chest to reconstruct the breast. Because the Latissimus Dorsi flap is usually thinner and smaller than the TRAM flap, this procedure may be more appropriate for reconstructing a smaller breast.



Post Mastectomy **View Showing Back Scar** **Latisimus Dorsi Flap and Nipple/Areola Reconstruction**

The Latissimus Dorsi flap procedure typically takes two to four hours of surgery under general anesthesia. Typically, the hospital stay is two to three days. You can resume daily activity after two to three weeks. You may have some temporary or permanent muscle weakness and difficulty with movement in your back and shoulder. You will have a scar on your back, which can usually be hidden in the bra line. You may also have additional scars on your reconstructed breast.

Post-Operative Care

Depending on the type of surgery you have (i.e., immediate or delayed), the post-operative recovery period will vary.

Note: If you experience fever, or noticeable swelling and/or redness in your implanted breast(s), you should contact your surgeon immediately.

What Questions Should You Ask Your Surgeon about Breast Reconstruction?

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

1. What are all my options for breast reconstruction?
2. What are the risks and complications of each type of breast reconstruction surgery and how common are they?
3. What if my cancer recurs or occurs in the other breast?
4. Will reconstruction interfere with my cancer treatment?
5. How many steps are there in each procedure, and what are they?
6. How long will it take to complete my reconstruction?
7. How much experience do you have with each procedure?
8. Do you have before and after photos I can look at for each procedure and what results are reasonable for me?
9. What will my scars look like?
10. What kind of changes in my implanted breast can I expect over time?
11. What kind of changes in my implanted breast can I expect with pregnancy?
12. What are my options if I am dissatisfied with the cosmetic outcome of my implanted breast?
13. Can I talk with other patients about their experiences?
14. What is the estimated total cost of each procedure?
15. How much will my health insurance carrier cover, especially any complication that may require surgery?
16. How much pain or discomfort will I feel, and for how long?
17. How long will I be in the hospital?
18. Will I need blood transfusions, and can I donate my own blood?
19. When will I be able to resume my normal activity (or sexual activity, or athletic activity)?

Other Factors to Consider in Breast Reconstruction

Choosing a Surgeon

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

1. How many breast reconstruction 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 on the world wide web.
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?

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

Implant Shape and Size

Depending on the desired shape you wish to achieve, you and your surgeon may choose a round or contoured implant shape. Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's). You should be aware that contoured implants that are placed submuscularly may assume a round shape after implantation.

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.

Surface Texturing

Textured surface implants were designed to reduce the chance of capsular contracture. Some information in the literature with small numbers of patients suggests that surface texturing reduces the chance of severe capsular contracture, but clinical information from studies of a large number of women with Inamed implants shows no difference in the likelihood of developing capsular contracture with textured implants compared to smooth surfaced implants.

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.

Insurance

Most insurance covers the first breast reconstruction operation. Insurance coverage for reoperation procedures or additional surgeon's visits following reconstruction may not be covered, depending on the policy.

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. You are encouraged to report any adverse events through your health professional. Although reporting by physicians or other health professionals is preferred, women may also report any serious problem directly through the 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. 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, use MedWatch form 3500 which may be obtained through FDA's website at http://www.fda.gov/medwatch/index.html. You may also call 1-888-463-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.

What Are Other Sources of Additional Information?

General Resources about Implants:

Upon request, you will be provided with a copy of the Directions for Use (package insert). You can request a copy from your surgeon or from INAMED Aesthetics. For more detailed information on the preclinical and clinical studies conducted by INAMED, you are referred to the Summary of Safety and Effectiveness Data for this product at http://www.fda.gov/cdrh/pdf/p990074.html

You will be given a device identification card with the style and serial number of your breast implant(s).

INAMED Aesthetics
1-800-624-4261
www.InamedAesthetics.com

Institute of Medicine Report on the Safety of Silicone Implants
www.nap.edu/catalog/9618.html

Food and Drug Administration
1-888-INFO-FDA or 301-827-3990
www.fda.gov/cdrh/breastimplants/

Breast Reconstruction Resources

The following list of resources may help you to find more information and support for your breast reconstruction decision.

National Cancer Institute
1-800-4-CANCER
www.nci.nih.gov/

American Cancer Society (Reach to Recovery)
1-800-ACS-2345
www.cancer.org/

Y-ME National Organization for Breast Cancer Information and Support
1-800-221-2141
www.y-me.org/

Glossary of Medical Terms

Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	A lack of proportion of shape, size and position on opposite sides of the body.
Autoimmune Disease	A disease in which the body mounts an "attack". Disease 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 produces antibodies against normal parts of the body, causing tissue injury. Certain diseases such as rheumatoid arthritis and scleroderma are considered to be autoimmune diseases.
Axillary	Pertaining to the armpit area.
Bilateral	Pertaining to both the left and right breast.
Biopsy	Removal and examination of sample tissue for diagnosis.
Breast Augmentation	Enlargement of the breast by surgical implantation of a breast implant or patient's own tissue.
Breast Reconstruction	Surgical restoration of natural breast contour and mass following mastectomy, trauma or injury.
Capsular Contracture	Tightening of the tissue surrounding a breast implant which results in a firmer breast.
Capsulectomy	Surgical removal of the entire capsule surrounding a breast implant.

Capsulotomy	Closed Capsulotomy: Compression on the outside of the breast to break the capsule and relieve contracture. Open Capsulotomy: 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 are unknown. The diseases are grouped together on the basis of clinical signs, symptoms, and laboratory abnormalities.
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.
Displacement	Shifting in the original position.
Epidemiological	Pertaining to the cause, distribution and control of disease in populations.
Extrusion	A breast implant or tissue expander being pressed out of the body.
Fibrous Tissue	Tissue resembling fibers.
Hematoma	A swelling or mass of blood (usually clotted) confined to an organ, tissue, or space and caused by a break in a blood vessel.
Immune Response	The reaction of the body to substances that are foreign or are interpreted as being foreign.
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.
In-Patient Surgery	Surgery performed in a hospital requiring an overnight stay
Latissimus Dorsi	Two triangular muscles running from the spinal column to the shoulder.
Mammaplasty	Plastic surgery of the breast.
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.
Mastectomy	Surgical removal of the breast. Subcutaneous Mastectomy: Removal of breast tissue, preserving the skin and nipple. Partial Mastectomy: Removal of primary tumor and a wide margin of tissue, may include the overlying skin and the muscle fibrous tissue (fascia) underlying the tumor. Total (Simple) Mastectomy: Removal of breast tissue and the nipple; sometimes accompanied by armpit (axillary) node dissection. Modified Radical Mastectomy: Removal of breast tissue, nipple, and fascia of chest (pectoralis) muscle with axillary node dissection.
Mastopexy	Plastic surgery to move 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.
Oncologist	A specialist in the branch of medicine dealing with the study and treatment of tumors.
Out-Patient Surgery	Surgery performed in a hospital or surgery center not requiring an overnight stay.
Palpate/Palpability	To feel with the hand.
Pectoralis	The major muscle of the chest.
Plastic Surgery	Surgery intended to improve, restore, repair, or reconstruct portions of the body following trauma, injury or illness.
Prosthesis	An artificial device used to replace or represent a body part.
Ptosis	Sagging of the breast usually due to normal aging, pregnancy or weight loss.
Rectus Abdominus	Major abdominal (stomach) muscle.
Saline	A solution of sodium chloride (salt) and water.
Seroma	Localized collection of serum, the watery portion of blood, that resembles a tumor.
Serratus	Muscle located beneath the chest's pectoralis major and minor muscles and the rib cage.
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 prepectoral or retromammary placement.
Submuscular Placement	Placement of the breast implant under the chest (pectoralis) muscle, or under the pectoralis and serratus muscles. Also called retropectoral or subpectoral placement.
Surgical Incision	Cut made in tissue for surgical purposes.
Transaxillary Incision	Incision across the long axis of the armpit (axilla).
Umbilical	Relating to the navel.
Unilateral	Affecting only left or right breast.

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