Saline-Filled Breast Implant Surgery:

Making an Informed Decision

Updated January 2004

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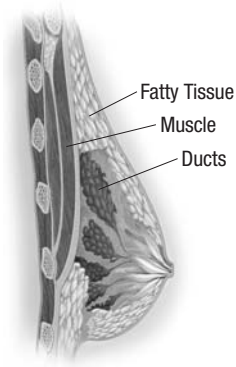
So You're Considering Saline-Filled Breast Implant Surgery

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 Mentor breast implants.

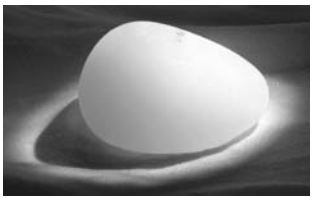
What Gives the Breast Its Shape?

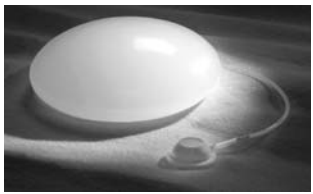
The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. Situated beneath the breast is the pectoralis major muscle or chest muscle. Factors such as pregnancy (when milk glands are temporarily enlarged), rapid weight loss, and the effects of gravity as 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 chest tissues, and then filled with saline, a saltwater solution, through a valve.





Are You Eligible for Saline-Filled Breast Implants?

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

- **Breast Augmentation** — This procedure is done to increase the size and proportions 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.

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 breasts from sagging after pregnancy.
- With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.
- 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.

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

  Reconstruction — 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.

Who Is Not Eligible for Breast Implants?

Implants are not to be used for:

- Women with existing malignant or pre-malignant cancer of your breast without

adequate treatment

- Women with active infection anywhere in your 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 Betadine®*
- Injection through implant shell
- Alteration of the implant
- Stacking of implants: more than one implant per breast per breast pocket

Safety and effectiveness have 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

*Betadine is a registered trademark of Purdue Frederick Company.

Further considerations:

- **Pre-implantation Mammography** — You may wish to undergo a preoperative mammogram and another one at 6 months to 1 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 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, Mentor is monitoring the long-term (i.e., 10 year) chance of implant rupture, reoperation, implant removal, and capsular contracture (hardening of the tissues around the implant). Mentor is also conducting mechanical testing to assess the long-term likelihood of implant rupture. Mentor will update this brochure with this information and time frames later.
- **Capsule Procedures** — 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 Mentor?

Breast implants come in a variety of shapes, surface textures, and sizes. There are 2 types/families of implants filled with saline – one referred to as Saline-Filled and the other referred to as Spectrum™ Implants. The Saline-Filled family of implants has a self-sealing valve located on the front (anterior) of the implant that is used for filling the device. The Spectrum™ family has a valve on the back (posterior) of the implant that allows saline to be added after surgery (postoperative adjustability). The implants are available with Siltex® textured or smooth surface shells.

Below is a description of Mentor 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.

Saline-Filled Breast Implant Family (fixed volume):

- Round Styles:

  Style 1600: Smooth shell surface, anterior filling valve

  Style 2600: Siltex®- textured shell surface, anterior filling valve

  Style 3000: Smooth shell surface, anterior diaphragm valve, high profile

- Contour Styles:

  Style 2700: Siltex®- textured shell surface, anterior filling valve, high profile

  Style 2900: Siltex®- textured shell surface, anterior filling valve, moderate profile

Spectrum™ Breast Implant Family (postoperative adjustment of volume):

- Round Styles:

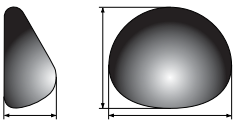
  Style 1400: Smooth shell surface, posterior filling valve

  Style 2400: Siltex® textured shell surface, posterior filling valve

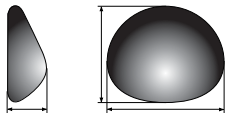
- Contour Styles:

  Style 2500: Siltex® textured shell surface, posterior filling valve, high profile

The following diagrams illustrate the high and moderate contour profiles.

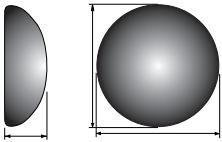


Contour, high profile

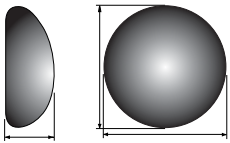


Contour, moderate profile

The following diagrams illustrate the round and the round high profiles.



Round



Round, high profile

What Are 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 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.

- **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 understand 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 sud-

den fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. A doctor 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 calcium deposits from cancer.

- **Delayed Wound Healing**
  In some instances, 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 common complications, there have been concerns with rarer 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 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.
- **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.

Mentor'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 Mentor's saline-filled breast implants. Mentor's clinical studies indicate, for example, that while most women can expect to experience at least one complication at some point through 3 years after implant surgery, most women were satisfied with their implants. The studies also indicate that the chance of additional surgery is 1 in 8 for augmentation patients (with implant removal and replacement as the most common type of additional surgery) and 1 in 2.5 for reconstruction patients (with the most common type of additional surgery being capsule-related). The information below provides more details about the complications and benefits you may experience.

Description of Studies

Mentor conducted clinical testing 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)
- Saline Prospective Study (SPS)

The LST was designed to determine the 1-year rates of capsular contracture, infection, deflation, and implant removal. There were 2,066 augmentation patients, 104 reconstruction patients, and 215 revision patients enrolled. Of these enrolled patients, 47% returned for their 1-year visit.

The SPS was designed as a 3-year study to assess all complications with breast implants as well as patient satisfaction, body image, and self-concept. Patients were followed annually and data through 3 years are available. The SPS enrolled 1,264 augmentation patients and 428 reconstruction patients. Seventy-six (76%) percent of augmentation patients and 78% of reconstruction patients returned for their 3-year visit. The outcomes of the patients lost to follow-up are not known. The SPS results in this brochure represent data through 3 years.

After product approval, Mentor switched data collection to a post-approval study. The post-approval study involves the collection of some safety data from SPS patients through their 10-year post-implantation timepoint. The data are collected from questionnaires that are mailed out to the patients each year. The post-approval data presented includes earlier data shown in the SPS tables with new information added to it. **The 5-year post-approval data are shown in the**

"Augmentation Results from Post-Approval Study" and "Reconstruction Results from Post-Approval Study" sections which follow.

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, 5% or 5 out of 100 augmentation patients experienced capsular contracture at some time within 1 year after implantation. However, this does not mean that 5% of the patients still have capsular contracture at 1 year.

Complications	1-Year Complication Rate*		
	Augmentation	Reconstruction	Revision
Capsular Contracture	5%	29%	15%
Implant Removal	4%	10%	6%
Implant Leakage/Deflation	1%	NA	2%
Infection	1%	NA	NA

NA: Not Available or insufficient data to perform an analysis of risk of the complication.
* Data on 47% of the 2385 patients enrolled in the study.

AUGMENTATION RESULTS FROM SPS

What Were the 3-Year Complication Rates from the SPS for Augmentation Patients?

The 3-year complication rates (including all levels of severity, from mild to severe) are shown from the most common to the least common 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 years after implantation. Some complications occurred more than once for some patients. The most common complication experienced within the first 3 years of implantation was wrinkling (21% or 21 patients out of 100).

Augmentation Complications	3-Year Complication Rate N=1264 Patients
Wrinkling	21%
Additional Operation (Reoperation)	13%
Loss of Nipple Sensation	10%
Capsular Contracture III/IV or grade unknown	9%
Implant Removal	8%
Asymmetry	7%
Intense Nipple Sensation	5%
Breast Pain	5%
Leakage/Deflation	3%
Implant Palpability	2%
Infection	2%
Sagging	2%
Scarring	2%
Hematoma	2%

What Were the Types of Additional Surgical Procedures Performed for Augmentation Patients?

The following table provides a breakdown of the types of surgical procedures that were performed through the 3 years after the initial implantation. There were a total of 358 additional surgical procedures performed in 147 augmentation patients. Of these 147 patients, most reported multiple additional surgical procedures during a single reoperation. The most common type of additional surgical procedure was implant removal with replacement (32% of the 358 procedures).

Type of Additional Surgical Treatment	N=358 procedures
	%
Implant Removal with Replacement	32%
Capsule Related	22%
Scar or Wound Revision	19%
Reposition Implant	8%
Saline Adjustment	8%
Mastopexy	6%
Implant Removal without Replacement	3%
Biopsy/Cyst Removal	2%
Breast Reduction or Mastectomy	<1%
Nipple Related	<1%
Total	**100%**

What Were the Reasons for Implant Removal for Augmentation Patients?

The main reasons for implant removal among augmentation patients in the SPS over the 3 years are shown in the table below. There were 137 implants removed in 87 patients. Of these 137 implants, 82% were replaced. The most common reason for implant removal was patient request for a size or shape change (37% of the 137 implants removed).

Main Reason for Augmentation Implant Removal through 3 Years[1]	N=137 implants removed %
Patient Request for Size/Shape Change	37%
Leakage/Deflation	24%
Capsular Contracture	18%
Wrinkling	5%
Infection	5%
Asymmetry	4%
Hematoma/Seroma	2%
Sagging	2%
Scarring	2%
Cosmetic Revision	2%
Breast Cancer	1%
Total	**100%**

[1]Correction to some rates reported at 3 years. Total number of implants increased by 1.

What Were the Complication Rates After Implant Replacement for Augmentation Patients?

There were 74 augmentation patients who had 120 implants removed and replaced with Mentor implants.

The table below reflects the number of replaced implants (not patients) out of 100 implants associated with the listed complications within 3 years following replacement. For example, there was a reoperation in 16% or 16 out of 100 implants at some time within 3 years after replacement.

Complication Following Replacement of Augmentation Implant	3-Year Complication Rate N=120 implants
Additional Operations (Reoperation)	16%
Wrinkling	15%
Implant Removal	12%
Capsular Contracture III/IV or grade unknown	8%
Leakage/Deflation	4%
Asymmetry	4%
Breast Pain	3%
Hematoma	2%
Scarring	2%

What Were the Breast Disease and CTD Events in Augmentation Patients?

Breast disease and connective tissue disease (CTD) were reported in some patients through 3 years after implantation in the SPS. Although there were 1264 augmentation patients enrolled in the SPS, 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 provided. New cases of breast cancer were reported in 2 augmentation patients.

The table below shows the number of reports of CTD through 3 years after implantation. Some patients may have reported more than one CTD. Confirmed reports were based on a diagnosis by a doctor. Unconfirmed reports were based on self-reports by the patients.

Number of Reports of CTD in AUGMENTATION Patients in the SPS Study		
Connective Tissue Disease	No. of Confirmed Reports	No. of Unconfirmed Reports
Osteoarthritis		1
Rheumatoid Arthritis	1	3
Arthritis (type unknown)		15
Lupus Erythematosus	1	
Total	**2**	**19**[a]
[a]2 aug pts had 2 unconfirmed CTDs		

Without a comparison group of women with similar characteristics (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.

What Were the Benefits from the SPS for Augmentation Patients?

The SPS measured a variety of outcomes that assessed the benefits of the implants. For augmentation, these outcomes included breast size change, as well as satisfaction and comfort with appearance. These outcomes were assessed before implantation and at 3 years after surgery for those patients who still had their original implants.

For augmentation patients, 955 out of the original 1,264 patients (76%) still had implants and were in the study after 3 years. Of these 955 patients, 917 (96%) experienced an increase of at least one cup size at 3 years; the average increase in chest circumference was 2.8 inches. Of the 955 patients still in the study, 860 (90%) indicated being satisfied with the general appearance of their breasts, as measured by the Breast Evaluation Questionnaire (BEQ).

Most augmentation patients who still had their original implants and were still in the study at 3 years exhibited an improvement in the 2 measured subscales of the Multidimensional Body-Self Relation Questionnaire (MBSRQ) (which measures comfort with your general appearance). The Tennessee Self-Concept Scale (which measures self-concept) showed a slight increase at 3 years compared to before implantation.

AUGMENTATION RESULTS FROM POST-APPROVAL STUDY

In terms of patient accountability, of the 1,221 augmentation patients expected for follow-up at 5 years, data were collected for 5%. Of the 1191 augmentation patients expected for follow-up at 7 years, data were collected for 50%. Please note that follow-up rate at 3 years was 76%, which makes the 3-year data more reliable than the 5-year or 7-year data. There was some data reported for 54% of the 1,221 augmentation patients at some time from 3 to 10 years postoperatively. There was some 7-year data reported for 71% of the augmentation patients at some time from 3 to 10 years postoperatively. It is assumed that information obtained at a later time (for example, at 7 years) applies to an earlier time (for example, at 5 years), which counts on patient memory over time. This is not as reliable as information obtained at an earlier time.

The 5-year and 7-year complication rates are shown 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 5 years and 7 years after implantation. The most common complication experienced though 5 years and 7 years of implantation was reoperation (20% or 20 patients out of 100 at 5 years, and 25% or 25 patients out of 100 at 7 years).

Augmentation Complications	5-Year Complication Rate By Patient 5 Years	7-Year Complication Rate By Patient 7 Years
	N=1264	N=1264
Reoperation	20%	25%
Implant Removal	14%	19%
Capsular Contracture III/IV or unknown	10%	11%
Implant Deflation	10%	16%
Breast Pain	7%	12%

The reasons for reoperation through 3, 5 and 7 years are shown below. The reasons for reoperation at 3 years are included below because the original labeling only reported the types of surgical procedures. While there may be some overlap of these two, they are different sets of data. An example of a type of additional surgical procedure is saline adjustment; an example of a reason for reoperation is infection. There were 255 reoperations performed in 146 patients through 3 years. There were 343 reoperations performed in 198 patients through 5 years. There were 464 reoperations in 259 patients at 7 years. There may have been multiple reasons for one reoperation; therefore, the percentages in the table below do not add up to 100%. The most common reason for reoperation through 5 years was patient request for size/shape change (29% of the 343 reoperations). The most common reason for reoperation through 7 years was leakage/deflation (28% of the 464 reoperations). Note that the percentages are smaller for some of the reasons for reoperation because the number of reoperations has gotten bigger.

Reason for Reoperation[1]	3-Years N=255 Reoperations	5-Years N=343 Reoperations	7-Years N=464 Reoperations
Patient Request for Size/Shape Change	33%	29%	24%
Capsular Contracture	19%	17%	15%
Leakage/Deflation[2]	14%	19%	28%
Wrinkling	12%	11%	10%
Asymmetry	10%	8%	6%
Sagging	9%	9%	8%
Hypertrophic Scarring	9%	6%	5%
Hematoma/Seroma	6%	4%	3%
Infection	5%	4%	3%
Cosmetic Revision	5%	4%	3%
Breast Mass/Tumor/Cyst Excision or Biopsy	3%	4%	5%
Breast Pain	1%	1%	1%
Delayed Wound Healing	1%	1%	<1%
Irritation/Inflammation	1%	1%	<1%
Extrusion	1%	1%	<1%
Lymphadenopathy	<1%	<1%	<1%
Contralateral Replacement	0	3%	8%

[1]If there was more than one reason reported per patient, all reasons are included in this table.
[2]Includes reoperations where the reason for reoperation was not reported.

The main reasons for implant removal through 5 years and 7 years are shown below. There were 211 implants removed in 132 patients at 5 years. There were 324 implants removed in 191 patients at 7 years. The most common reason for removal through 5 years was patient request for size/shape change (30% of the 211 implants removed). The most common reason for removal through 7 years was leakage/deflation (38% of

the 324 implants removed). Note that the percentages are smaller for some of the reasons for removal because the number of removals has gotten bigger.

Main Reason for Removal	5-Years N=211 Implants Removed	7-Years N=324 Implants Removed
Patient Request for Size/Style Change	30%	24%
Leakage/Deflation[1]	30%	39%
Capsular Contracture	15%	12%
Wrinkling	6%	6%
Contralateral Replacement	5%	10%
Infection	4%	2%
Asymmetry	3%	2%
Breast Mass or Cancer	2%	1%
Cosmetic Revision	2%	1%
Sagging	1%	1%
Hematoma/Seroma	1%	1%
Hypertrophic Scarring	1%	1%

[1]Includes removals where the reason for the removal was not reported

RECONSTRUCTION RESULTS FROM SPS

What Were the 3-Year Complication Rates from the SPS for Reconstruction Patients?

The 3-year complication rates (including all levels of severity, from mild to severe) are shown from the most common to the least common 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 years after implantation. Some complica-

tions occurred more than once for some patients. The most common complication experienced within the first 3 years of implantation was wrinkling (40% or 40 patients out of 100).

Reconstruction Complications	3-Year Complication Rate N=416 patients
Additional Operation (Reoperation)	40%
Loss of Nipple Sensation	35%
Capsular Contracture III/IV or grade unknown	30%
Asymmetry	28%
Implant Removal	27%
Wrinkling	20%
Breast Pain	17%
Infection	9%
Leakage/Deflation	9%
Irritation/Inflammation	8%
Delayed Wound Healing	6%
Seroma	6%
Scarring	5%
Extrusion	2%
Necrosis	2%
Hematoma	1%
Position Change	1%

What Were the Types of Additional Surgical Procedures Performed for Reconstruction Patients?

The following table provides a breakdown of the types of surgical procedures that were performed through the 3 years after the initial implantation. There were a total of 353 additional surgical procedures in 149 reconstruction patients (excluding those that were planned reconstruction such as nipple reconstruction). Of these 149 patients, most reported multiple surgical procedures during a single reoperation. The most common type of additional surgical procedure was capsule related (28% of the 353 procedures).

Type of Additional Surgical Treatment	N=353 procedures
	%
Capsule Related	28%
Implant Removal with Replacement	19%
Scar or Wound Revision	13%
Implant Removal without Replacement	11%
Nipple Related (unplanned)	8%
Saline Adjustment	7%
Reposition Implant	6%
Biopsy/Cyst Removal	<1%
Breast Reduction or Mastectomy	<1%
Mastopexy	<1%
Total	**100%**

What Were the Reasons for Implant Removal for Reconstruction Patients?

The main reasons for implant removal among reconstruction patients in the SPS over the 3 years are shown in the table below. There were 116 implants removed in 97 patients.

Of the 116 implants removed among reconstruction patients, 60% were replaced. The most common reasons for implant removal were correction of capsular contracture and infection (26% of the 116 implants removed).

Main Reason for Reconstruction Implant Removal through 3 Years[1]	N=116 implants removed
	%
Capsular Contracture	30%
Infection	24%
Leakage/Deflation	22%
Patient Request for Size/Style Change	6%
Necrosis/Extrusion	5%
Asymmetry	4%
Breast Pain	3%
Delayed Wound Healing	2%
Cosmetic Revision	1%
Wrinkling	1%
Breast Cancer	1%
Total	**100%**

[1]Corrections to some rates reported at 3 years. Total number of implants removed did not change.

What Were the Complication Rates After Implant Replacement for Reconstruction Patients?

There were 66 reconstruction patients who had 76 implants removed and replaced with Mentor implants. The table below reflects the number of replaced implants (not patients) out of 100 implants associated with the listed complications within 3 years following replacement. For example, there was a reoperation in 31% or 31 out of 100 implants at some time within the 3 years after replacement.

Complication Following Replacement of Reconstruction Implant	3-Year Complication Rate N=76 implants
Additional Operation (Reoperation)	31%
Leakage/Deflation	23%
Implant Removal	21%
Capsular Contracture III/IV or grade unknown	19%
Asymmetry	17%
Wrinkling	16%
Breast Pain	13%
Infection	5%
Irritation/Inflammation	3%
Seroma	3%
Extrusion	2%
Hematoma	2%
Scarring	2%
Necrosis	1%

What Were the Breast Disease and CTD Events in Reconstruction Patients?

Breast disease and connective tissue disease (CTD) were reported in some patients through 3 years after implantation in the SPS. Although there were 416 reconstruction patients enrolled in the SPS, 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 provided. There were no new cases of breast disease. The table below shows the number of reports of CTD through 3 years after implantation. Some patients may have reported more than one CTD. Confirmed reports were based on a diagnosis by a doctor. Unconfirmed reports were based on self-reports by the patients.

Number of Reports of CTD in RECONSTRUCTION Patients in the SPS Study		
Connective Tissue Disease	No. of Confirmed Reports	No. of Unconfirmed Reports
Osteoarthritis	2	8
Rheumatoid Arthritis		2
Arthritis (type unknown)	1	18
Ankylosing Spondylitis	1	
Total	**4**	**28**[a]
[a]7 recon pts had 2 unconfirmed CTDs		

Without a comparison group of women with similar characteristics (age, race, etc.) and without breast implants, no conclusions can be made about the relationship between breast implants and these CTD events.

What Were the Benefits of the SPS for Reconstruction Patients?

The SPS measured a variety of outcomes that assessed the benefits of the implants. For reconstruction, these outcomes included breast size change. These outcomes were assessed before implantation and at 3 years after surgery for those patients who still had their original implants.

For reconstruction patients, 283 out of the original 416 patients (68%) still had implants and were in the study after 3 years. Of these 283 patients, the average increase in chest circumference was 1.5 inches.

RECONSTRUCTION RESULTS FROM POST-APPROVAL STUDY

In terms of patient accountability, of the 335 reconstruction patients expected for follow-up at 5 years, data were collected for 52%. Of the 309 reconstruction patients expected for follow-up at 7 years, data were collected for 71%. Please note that the follow-up rate at 3-years was 78% which makes the 3-year data more reliable than the 5-year data or 7-year data. There was some 5-year data reported for 73% of the 335 reconstruction patients at some time from 3 to 10 years postoperatively. There was some 7-year data reported for 79% of the reconstruction patients at some time from 3 to 10 years postoperatively. It is assumed that information obtained at a later time (for example, at 7 years) applies to an earlier time (for example, at 5 years), which counts on patient memory over time. This is not as reliable as information obtained at an earlier time.

The 5-year and 7-year complication rates are shown 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 5 years or 7 years after implantation. The most common complication experienced through 5 years was reoperation (43% or 43 patients out of 100). The most common complication experienced through 7 years was reoperation or capsular contracture (50% or 50 patients out of 100).

Reconstruction Complications	5-Year Complication Rate By Patient	7-Year Complication Rate By Patient
	N=416	N=416
Reoperation	43%	50%
Implant Removal	30%	39%
Capsular Contracture III/IV or unknown	29%	49%
Implant Deflation	18%	27%
Breast Pain	16%	29%

The reasons for reoperation through 3, 5 and 7 years are shown below. The reasons for reoperation at 3 years are included below because the original labeling only reported the types of surgical procedures. While there may be some overlap of these two, they are different sets of data. An example of a type of additional surgical procedure is saline adjustment; an example of a reason for reoperation is infection. There were 209 reoperations performed in 149 patients through 3 years. There were 232 reoperations performed in 162 patients through 5 years. There were 279 reoperations performed in 185 patients through 7 years. There may have been multiple reasons for one reoperation; therefore, the percentages in the table below do not add up to 100%. The most common reason for reoperation through 5 years was capsular contracture (29% of the 232 reop-

erations). The most common reason for reoperation through 7 years was casular contracture (31% of the 279 reoperations). Note that the percentages are smaller for some of the reasons for reoperation because the number of reoperations has gotten bigger.

Reason for Reoperation[1]	3-Years N=209 Reoperations	5-Years N=232 Reoperations	7-Years N=279 Reoperations
Capsular Contracture	30%	29%	30%
Asymmetry	22%	20%	17%
Patient Request for Size/Shape Change	16%	16%	15%
Staged Reconstruction	16%	15%	12%
Infection	16%	15%	12%
Leakage/Deflation	13%	15%	19%
Delayed Wound Healing	9%	8%	7%
Breast Pain	8%	7%	7%
Hematoma/Seroma	8%	7%	6%
Scarring	6%	6%	5%
Wrinkling	6%	5%	5%
Extrusion	4%	4%	4%
Necrosis	4%	4%	3%
Cosmetic Revision	4%	4%	3%
Irritation/Inflammation	4%	3%	3%
Breast Mass or Cancer	2%	2%	2%
Valve Malposition	1%	<1%	<1%
Lymphadenopathy	1%	<1%	<1%
Sagging	0%	1%	1%
Contralateral Replacement	0%	<1%	1%
Position Change	0%	0%	<1%

[1]If there was more than one reason reported per patient, all reasons are included in this table. This table excludes patients in which staged reconstruction was the **only** reason for reoperation.

The main reasons for implant removal through 5 years and 7 years are shown below. There were 135 implants removed in 112 patients at 5 years, and 180 implants removed in 142 patients at 7 years. The most common reason for removal though 5

years and 7 years was capsular contracture (29% of the 135 implants removed at 5 years, and 29% of the 180 implants removed at 7 years). Note that the percentages are smaller for some of the reasons for removal because the number of removals has gotten bigger.

Main Reason for Removal	5-Years N=135 Implants Removed	7-Years N=180 Implants Removed
Capsular Contracture	29%	29%
Leakage/Deflation	25%	28%
Infection	21%	16%
Patient Request for Size/Shape/Change	8%	9%
Necrosis Extrusion	5%	4%
Asymmetry	4%	4%
Breast Pain	3%	2%
Breast Mass or Cancer	1%	2%
Delayed Wound Healing	1%	1%
Wrinkling	1%	1%
Cosmetic Revision	1%	1%
Contralateral Replacement	0%	2%
Position Change	0%	1%
Hypertrophic Scarring	0%	1%
Irritation/Inflammation	0%	1%

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 the information in this brochure before deciding whether to have augmentation surgery.

What Questions Do You Ask Your Surgeon about Breast Augmentation?

The following list of questions may help to remind you of topics to discuss with your surgeon:

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 are 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 a surgeon who is experienced with breast augmentation, 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 augmentation 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 augmentation?
6. What is his/her reoperation rate with breast augmentation 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***

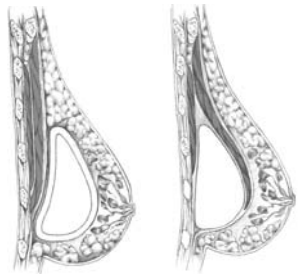
  Depending on the desired shape you wish to achieve, you and your surgeon may choose a round or contoured implant shape. Generally, the larger you want your cup

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 postoperatively. 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 on 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 Mentor implants show no difference in the likelihood of developing capsular contracture with textured implants compared to smooth-surfaced implants (see "Description of Studies" above).
- *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). You should discuss with your surgeon the pros and cons of the implant placement selected for you.

  The **submuscular placement** may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to have 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.



Subglandular Submuscular

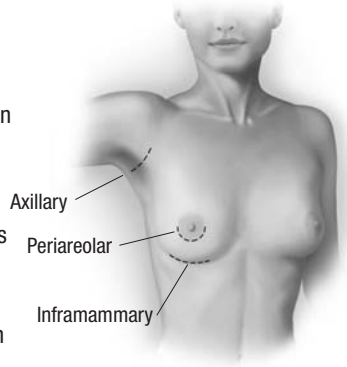
The **subglandular placement** may make surgery and recovery shorter, may be less painful, and may be easier to access for reoperation than the submuscular placement. However, this placement may result in more palpable implants, more capsular contracture, and more difficult imaging of the breast with 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, depending on whether you will be having augmentation or reconstruction.

  There are 3 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 the most concealed, but is associated with a higher likelihood of inability to successfully breast feed, as compared to the other incision sites.
  - Inframammary - This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding.
  - Axillary - This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding.
  - 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 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.

- *Postoperative 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.

Postoperative care may involve the use of a postoperative 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.

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.

Reconstruction Incision Sites

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

Surgical Settings and Anesthesia

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

Breast Reconstruction with Breast Implants

Your surgeon will decide whether your health and medical condition make 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 surgeon, as it may affect the breast reconstruction methods considered for your case.

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 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 of 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.

Stage 1: Tissue Expansion

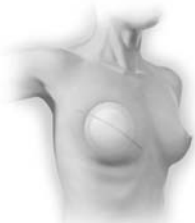
Mastectomy Scar

Expander/Implant with remote injection dome

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 with integral injection dome



Final result with implant

Tissue expander placement usually occurs under general anesthesia in an operating room. Operative time is generally 1 to 2 hours. The procedure may require a brief hospital stay, or be done on an outpatient basis. Typically, you can resume normal daily activity after 2 to 3 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, and 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 4 to 6 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.

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.

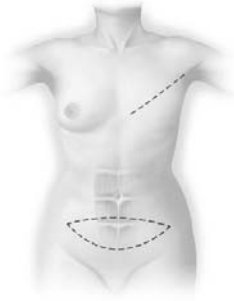
The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap), or it may be removed completely and reattached to the breast area by microsurgical techniques (a free flap). Operating time is generally longer with free flaps because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

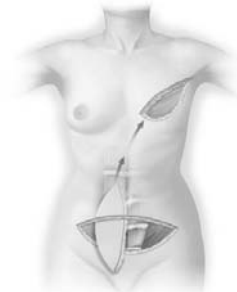
The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap) (which uses tissue from the abdomen) and the Latissimus Dorsi flap (which uses tissue from the upper back).

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.

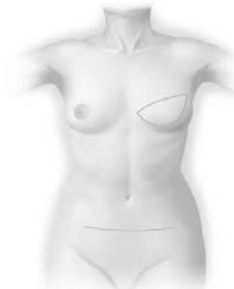
The TRAM Flap (Pedicle or Free)



Step 1: Mastectomy is performed and the donor site is marked



Step 2: The flap of rectus muscle and tissue is funneled to the breast



Step 3: Final Result

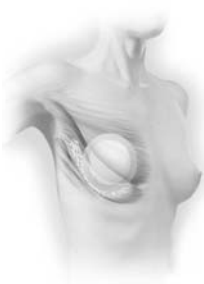
During a TRAM flap procedure, the surgeon removes a section of tissue from your abdomen and moves it to your chest to reconstruct the breast. The TRAM flap is sometimes referred to as a "tummy tuck" reconstruction, because it may leave the stomach area flatter.

A pedicle TRAM flap procedure typically takes 3 to 6 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 2 to 5 days. You can resume normal daily activity after 6 to 8 weeks. Some women, however, report that it takes up to 1 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

Step 1: A skin flap and muscle are taken from donor site in the back.

Step 2: The tissue is tunneled to the mastectomy and used to create a breast mound.



Step 3: An implant can also be used to create the breast mound.

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.

The Latissimus Dorsi flap procedure typically takes 2 to 4 hours of surgery under general anesthesia. Typically, the hospital stay is 2 to 3 days. You can resume daily activity after 2 to 3 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.

- Postoperative Care

Depending on the type of surgery you have (i.e., immediate or delayed), the postoperative 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 Do You Ask Your Surgeon about Breast Reconstruction?

The following list of questions may help to remind you of topics to discuss with your surgeon:

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. For staged reconstruction, 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 (sexual activity or athletic activity)?

Other Factors to Consider In Breast Reconstruction

- ***Choosing a Surgeon***

When choosing a surgeon who is experienced with breast reconstruction, 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 reconstruction 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 reconstruction?
6. What is his/her reoperation rate with breast reconstruction 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 postoperatively. 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 on 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 Mentor implants show no difference in the likelihood of developing capsular contracture with textured implants compared to smooth-surfaced implants (see "What Are the Risks Based on Mentor's Clinical Studies?" above).
- *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.

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 the FDA. You are encouraged to report any adverse events through their health professionals. 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 the FDA's website at **http://www.fda.gov/medwatch/index.html**. You may also call 1-888-463-INFOFDA (1-888-463-6332) from 10:00 a.m.- 4:00 p.m. Eastern Time, Monday through Friday, to receive an additional FDA MedWatch package. **Keep a copy of the MedWatch form completed by your doctor 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 Mentor. For more detailed information on the preclinical and clinical studies conducted by Mentor, you are referred to the Summary of Safety and Effectiveness Data for this product at http://www.fda.gov/cdrh/pdf/p90075b.pdf.

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

Mentor Corporation
1-800-MENTOR8
www.mentorcorp.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
http://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
cancernet.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

Areola - The pigmented or darker colored area of skin surrounding the nipple of the breast.

Asymmetry - Lack of proportion of shape, size and position between the two breasts.

Autoimmune disease - A disease in which the body mounts an "attack" response to its own tissues or cell types. Normally, the body's immune mechanism is able to distinguish clearly between what is a normal substance and what is foreign. In autoimmune diseases, this system becomes defective and 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 - Relating to, or affecting, the right and left breast.

Biopsy - The removal and examination of tissue, cells or fluid from the body.

Breast augmentation - A surgical procedure that increases the size and proportions of a woman's breast.

Breast reconstruction - A surgical procedure that restores the natural breast contour and mass following mastectomy, trauma, or injury.

Capsular contracture - A tightening of the scar tissue surrounding an implant, resulting in firmness or hardening of the breast.

Capsulectomy - Surgical removal of the capsule (scar tissue).

Capsulotomy (closed) - A breakage in the capsule (scar tissue) by massage or compression on the outside of the breast.

Capsulotomy (open) - Incision or opening in the capsule (scar tissue) made by an open surgical approach.

Carcinoma - A malignant (cancerous) tumor.

Congenital anomaly - A deviation from a normal body part, existing at or dating from birth.

Connective tissue disease- A disease or group of diseases affecting connective tissue. The cause of these diseases is unknown. The diseases are grouped together on the basis of clinical signs, symptoms, and laboratory abnormalities.

Deflation/rupture - Leakage of saline solution from the implant, often due to a valve leak or a tear or cut in the implant shell, with partial or complete collapse of the implant.

Delayed reconstruction - Breast reconstruction that takes place weeks, months, or years after a mastectomy.

Displacement - Movement from the usual or proper place.

Epidemiological - Relating to the incidence, distribution and control of disease in a population.

Extrusion - The pressing out of the implant through the surgical wound.

Fibrous tissues - Connective tissues composed mostly of fibers.

Flap - A portion of tissue (which may include muscle, fat and skin) with its blood supply moved from one part of the body to another.

Hematoma - A mass or swelling containing blood.

Immune response - A bodily response to the presence of a foreign substance.

Inframammary - Below the breast.

Inframammary fold/incision - An incision made in the fold below the breast.

In-patient surgery - A surgical procedure in which the patient is required to stay overnight in the hospital.

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 - X-ray examination of the breasts (as for early detection of cancer).

Mastectomy - The removal of breast tissue due to the presence of a cancerous or precancerous growth.

Subcutaneous mastectomy: surgical removal of the breast tissues, but sparing the skin, nipple, and areola.

Total mastectomy: surgical removal of the breast including the nipple, areola, and most of the overlying skin.

Modified radical mastectomy: surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the lymphatic-bearing tissue in the axilla.

Radical mastectomy: surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the pectoral muscles, lymphatic bearing tissue in the axilla, and various other neighboring tissue.

Mastopexy - Plastic surgery to move sagging breasts into a more elevated position.

Necrosis - Death of living tissue.

Oncologist - A doctor specializing in the study of tumors.

Out-patient surgery - A surgical procedure in which the patient is not required to stay in the hospital overnight.

Palpate/palpability - To feel with the hand.

Palpability - Capability of being touched or felt.

Pectoralis - Major muscle of the chest.

Plastic surgery - Surgery intended to repair, restore, or improve the body following trauma, injury, or illness.

Prosthesis - Any artificial device used to replace or represent a body part.

Ptosis - Breast sagging that is usually the result of normal aging, pregnancy, or weight loss.

Rectus abdominus - A long flat muscle extending the whole length of the front of the abdomen (stomach).

Saline - A solution that is made up of water and a small amount of salt. Approximately 70% of an adult's body weight consists of this salt-water solution.

Seroma - Accumulation of fluid in tissue.

Silicone elastomer - A type of silicone that has elastic properties similar to rubber.

Serratus - Muscle located beneath the chest's pectoralis major and minor muscles and the rib cage.

Subglandular placement - Placement underneath the mammary gland and on top of the chest muscle.

Submuscular placement - Placement wholly or partially underneath the pectoralis major (chest) muscle.

Surgical incision - A cut or wound of body tissue made during surgery.

Tissue expander - An adjustable implant that can be inflated with salt water to stretch the tissue at the mastectomy site to create a new tissue flap for implantation of the breast implant.

Transaxillary incision - An incision made across the long axis of the armpit.

Umbilical - Relating to the navel.

Unilateral - Affecting only one side.

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