MENTOR CORPORATION

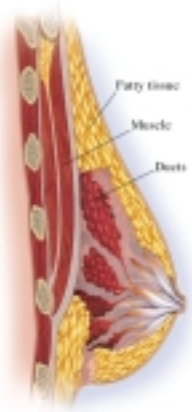
SALINE-FILLED BREAST IMPLANT SURGERY: MAKING AN INFORMED DECISION

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 doctor, 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 salt water solution, through a valve.

In augmentation surgery a breast implant can be placed either over the pectoralis muscle (subglandularly) or partially under this muscle (submuscularly), depending on the thickness of your breast tissue and its ability to adequately cover the breast implant. In reconstruction following mastectomy, a breast implant is most often placed submuscularly. Reconstruction following mastectomy may involve a two-stage

procedure, which includes placement of a tissue expander for several months prior to placement of the breast implant.

The silicone elastomer (rubber) contains the following substances: 1) small amounts (parts per million) of various smaller silicones; 2) small amounts (50 - 100 parts per million) of metals like tin and platinum and very trace amounts of other metals; 3) trace amounts of volatile materials like xylene and other organic compounds; and 4) considerable amounts (approximately 20 parts per hundred) of finely powdered silica that is tightly bound to the silicone rubber pouch.

Are You Eligible for Saline-Filled Breast Implants?

Implants are to be used for females for the following indications:

- 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 doctor 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.

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

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

Who is Not Eligible for Breast Implants?

Implants are contraindicated for women with:

- Existing malignant or pre-malignant cancer of your breast without adequate treatment
- 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:

- 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 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 (*e.g.,* 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 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 suspicious lesions (sores) 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. We will update this brochure with this information and timeframes 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 Implant Are Available from Mentor?

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. 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, Partially Textured (PT) or smooth surface shells. It should be noted that although smooth surface and Siltex-textured surface implants have been evaluated in Mentor's clinical studies, the recently introduced PT implants were not included in these studies.

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

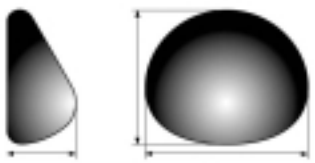
- ***Contour Styles:***
  Style 2700: Siltex® textured shell surface, anterior filling valve, high profile
  Style 2900: Siltex® textured shell surface, anterior filling valve, moderate profile
  Style 5000: Siltex® textured shell surface, anterior filling valve, tall profile
  Style 5000PT: Siltex® partially textured shell surface, anterior filling valve, tall profile

Spectrum® Breast Implant Family (post-operative adjustment of volume):

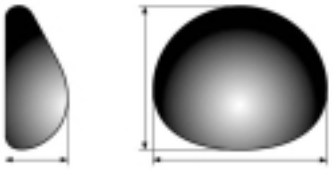
- ***Round Styles:***
  Style 1400: Smooth shell surface, posterior filling valve
  Style 2400: Siltex® textured shell surface, posterior filling valve

- ***Contour Styles:***
  Style 2500: Siltex® textured shell surface, posterior filling valve, high profile
  Style 6000: Siltex® textured shell surface, posterior filling valve, tall profile
  Style 6000PT: Siltex® partially textured shell surface, posterior filling valve, tall profile

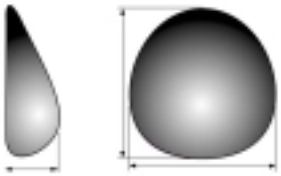
The following diagrams illustrate the high, moderate and tall contour profiles.



Contour, high profile



Contour, moderate profile



Contour, tall profile

What Are the 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 progressively over a period of days and is noticed by loss of size or shape of the implant. 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 necessitate 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. Symptoms range from firmness and mild discomfort, to pain, distortion, palpability of the implant, and/or displacement 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 doctor about severe pain.

- **Additional Surgeries**
  Women should understand there is a high chance they 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. Those who do not 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 doctor should be seen immediately for diagnosis and treatment.

- **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 sexual response or the 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 to biopsy and/or removal of the implant to distinguish them from cancer.

- **Delayed Wound Healing**
  In some cases, the incision site fails to heal 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 are 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 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.

What Are the Risks Based on Mentor's Clinical Studies?

Mentor conducted clinical testing of its saline-filled breast implants to determine the short-term and most common risks of their implants. These were assessed in the following studies:

- Saline Prospective Study (SPS)
- The Large Simple Trial (LST)

The LST was designed to determine the 1-year risk 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, 428 reconstruction patients. 76% of augmentation and 68% of reconstruction patients returned for their 3-year visit. The outcomes of the patients lost to follow-up are not known.

What Is A Cumulative Risk Rate?

The complication risk information obtained from the clinical studies are reported in the form of estimated risk rates for each complication at three years following implant surgery for the SPS, and at one year after implant surgery for the LST Study. These cumulative risk rates describe the risk or chance of developing a first occurrence of a complication in a patient through 3 years for the SPS and through 1 year for the LST. For example, a 1-year cumulative risk rate of 2% for infection means that approximately 2 patients out of 100 will experience at least one infection at some time during the first year after implantation. This 1-year cumulative risk rate does not mean that 2% of the patients still have an infection at one year. Risk rates are reported on both a by-patient and by-implant basis because many patients have two implants.

These risk rates do not provide the risk or chance of developing multiple occurrences of the same complication, nor do they provide information on how long a complication lasted, how severe the complication was, or what treatment (if any) was needed for the complication to resolve. These are issues which you discuss with your surgeon, and which you should understand prior to having an implant.

What Were the 1-Year Cumulative Complication Risk Rates of First Occurrence from the LST?

Complication	1-Year Risk Rate*					
	Augmentation		Reconstruction		Revision	
	By Patient	By Implant	By Patient	By Implant	By Patient	By Implant
Capsular Contracture	5%	3%	29%	23%	15%	10%
Infection	1%	1%	NA	NA	NA	NA
Implant Leakage/Deflation	1%	1%	NA	NA	2%	1%
Implant Removal	4%	3%	10%	8%	6%	5%

NA: Not Available or insufficient data to perform an analysis of risk of that complication.

***** Data on 47% of the patients in the study.

What Were the 3-Year Cumulative Complication Risk Rates of First Occurrence from the SPS?

The cumulative risk rates of first occurrence which occurred in at least 1% of the patients are shown in the following tables, including all levels of severity (mild to severe):

Augmentation

Augmentation Complications	3-Year Risk Rate	
	By Patient N=1264	By Implant N=2526
Wrinkling	21%	20%
Reoperation	13%	10%
Loss of Nipple Sensation	10%	8%
Capsular Contracture III/IV or grade unknown	9%	7%
Implant Removal	8%	6%
Asymmetry	7%	5%
Intense Nipple Sensation	5%	4%
Breast Pain	5%	4%
Leakage/Deflation	3%	2%
Implant Palpability	2%	2%
Infection	2%	1%
Breast Sagging	2%	1%
Scarring Complications	2%	2%

Reconstruction

Reconstruction Complications	3-Year Risk Rate	
	By Patient N=416	By Implant N=572
Reoperation	40%	35%
Loss of Nipple Sensation	35%	32%
Capsular Contracture III/IV or grade unknown	30%	28%
Asymmetry	28%	25%
Implant Removal	27%	24%
Wrinkling	20%	21%
Breast Pain	17%	15%
Infection	9%	8%
Leakage/Deflation	9%	7%
Irritation/Inflammation	8%	6%

Delayed Wound Healing	6%	5%
Seroma	6%	5%
Scarring Complications	5%	4%
Extrusion	2%	2%
Necrosis	2%	1%
Hematoma	1%	1%
Position Change	1%	1%

What Were the Types of Additional Surgical Treatments Performed?

The following table provides of the types of additional surgical treatments that were performed through the 3 years. There were a total of 358 reoperation procedures in augmentation patients and 353 procedures in reconstruction patients (excluding those that were planned reconstruction such as nipple reconstruction) through 3 years. The most common type of additional surgery was removal with replacement.

Augmentation

Type of Additional Surgical Treatment	N = 358 procedures	
	N	%
Implant Removal with Replacement	116	32%
Capsule Related	77	22%
Scar or Wound Revision	67	19%
Reposition Implant	29	8%
Saline Adjustment	27	8%
Mastopexy	23	6%
Implant Removal without Replacement	9	3%
Biopsy/Cyst Removal	6	2%
Breast Reduction or Mastectomy	3	<1%
Nipple Related	1	<1%
Total	**358**	**100%**

Reconstruction

Type of Additional Surgical Treatment	N = 353 procedures	
	n	%
Capsule Related	99	28%
Implant Removal with Replacement	66	19%
Scar or Wound Revision	47	13%
Implant Removal without Replacement	40	11%
Nipple Related	29	8%
Saline Adjustment	23	7%
Reposition Implant	20	6%
Biopsy/Cyst Removal	2	<1%
Breast Reduction or Mastectomy	2	<1%
Mastopexy	1	<1%
Total	**353**	**100%**

What Were the Reasons for Implant Removal?

The following tables detail the main reasons for implant removal among augmentation and reconstruction patients in the SPS on a by-Patient basis. There were 136 augmentation implants and 116 reconstruction implants removed over the 3 years.

Of the 136 implants removed among augmentation patients, 82% were replaced. Of the 116 implants removed among reconstruction patients, 60% were replaced. The most common reason for implant

removal was patient request for a size or shape change for augmentation patients, and was correction of capsular contracture and infection for reconstruction patients.

Augmentation

Main Reason for Augmentation Implant Removal through 3 Years*	N = 136 implants removed	
	n	%
Leakage/Deflation	31	23%
Capsular Contracture	22	16%
Infection	7	5%
Hematoma/Seroma	3	2%
Asymmetry/Wrinkling/Sagging/Scarring	22	16%
Patient Request for Size/Style Change	50	37%
Breast Cancer	1	<1%
Total	**136**	**100%**
* *Patients having more than one reason for implant removal are counted only once using the following hierarchy:* Deflation, Contracture, Infection, Necrosis/Extrusion, Hematoma/Seroma, Asymmetry, Breast Pain, Patient Request, Other		

Reconstruction

Main Reason for Reconstruction Implant Removal through 3 Years*	N = 116 implants removed	
	n	%
Capsular Contracture	30	26%
Infection	30	26%
Leakage/Deflation	25	22%
Asymmetry/Wrinkling/Sagging/Scarring	13	11%
Patient Request for Size/Style Change	7	6%
Necrosis/Extrusion	6	5%
Breast Pain	4	3%
Breast Cancer	1	<1%
Total	**116**	**100%**
* *Patients having more than one reason for implant removal are counted only once using the following hierarchy*: deflation, Contracture, Infection, Necrosis/Extrusion, Hematoma/Seroma, Asymmetry, Breast Pain, Patient Request, Other		

What are the Complication Risk Rates After Implant Replacement?

For those women in the SPS who had an implant removed and replaced and for which there was follow-up information, the cumulative first occurrence risk of complications were higher than for the initial implantation. The cumulative risk rates of first occurrence following implant replacement are shown below on a by implant basis for complications occurring in at least 1% of patients (severity was not assessed).

Augmentation

Complication Following Replacement of Augmentation Implant	3-Year Risk Rate N = 120 implants
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 Complications	2%

Reconstruction

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

What about Systemic or Rare Events?

Connective tissue disease (CTD) and breast disease were reported in some patients through three years after implantation in the SPS. New cases of breast cancer were reported in 2 augmentation patients. The incidence of confirmed new cases of connective tissue disease was in the range of what would be expected based in the literature in a diverse population of this magnitude over a 3 year period, as illustrated by the following table. Unconfirmed reports were based on self-reports by the patients. Confirmed reports were based on a diagnosis by a physician.

Augmentation

Number of Reports of CTD in AUGMENTATION Patients in the SPS Study			
Rheumatic Disease	**No. of Confirmed Reports in Patients**	**No. of Unconfirmed Reports in Patients**	**No. of Reports Expected in Diverse Population**
Osteoarthritis/Rheumatoid Arthritis/Unknown	1	19	4.4 [a]
Osteoarthritis		1	3.4 [b]
Rheumatoid Arthritis	1	3	1.0-1.2 [c]
Arthritis (type unknown)		15	-
Ankylosing spondylitis			0.3[d]
Lupus Erythematosus	1		0.2 - 0.5[e]
Total	2	19[f]	
[a]Combined estimates for osteoarthritis and rheumatoid arthritis. [b]Oliveria et al. 1995 [c]Chan et al. 1993; Dugowson et al. 1991 [d]Kaipainen-Seppanen et al. 1997 [e]Uramoto et al. 1999; McCarty et al. 1995 [f] 2 aug pts had 2 unconfirmed CTDs			

Reconstruction

Number of Reports of CTD in RECONSTRUCTION Patients in the SPS Study			
Rheumatic Disease	**No. of Confirmed Reports in Patients**	**No. of Unconfirmed Reports in Patients**	**No. of Reports Expected in Diverse Population**
Osteoarthritis/Rheumatoid Arthritis/Unknown	4	28	4.4 [a]
Osteoarthritis	2	8	3.4 [b]
Rheumatoid Arthritis		2	1.0-1.2 [c]
Arthritis (type unknown)	1	18	-
Ankylosing spondylitis	1		0.3[d]
Lupus Erythematosus			0.2 - 0.5[e]
Total	4	28[f]	

[a] Combined estimates for osteoarthritis and rheumatoid arthritis.
[b] Oliveria et al. 1995
[c] Chan et al. 1993; Dugowson et al. 1991
[d] Kaipainen-Seppanen et al. 1997
[e] Uramoto et al. 1999; McCarty et al. 1995
[f] 7 recon pts had 2 unconfirmed CTDs

What Are the Benefits of Breast Implants in the SPS?

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. For reconstruction, these outcomes included breast size change. These outcomes were assessed before implantation and at three 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 three years. Of these 283 patients, the average increase in chest circumference was 1.5 inches.

For augmentation patients, 955 out of the original 1264 patients (76%) still had implants and were in the study after three 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 two measured subscales of the Multidimensional Body-Self Relation Questionnaire (MSBRQ) (which measures comfort with your general appearance). For augmentation patients, the Tennessee Self-Concept Scale (which measures self-concept) showed a slight increase at 3 years compared to before implantation.

How Do the Benefits and Risks Information from the Clinical Studies Relate to Me?

While every patient experiences their own individual benefits and risks from the implants, this information indicates that while most women experienced at least one complication over the 3 year period, most women were satisfied with their implants. The chance of additional surgery through 3 years is about 1 in 8 for augmentation and 1 in 2.5 for reconstruction, with implant removal with replacement as the most common reason for additional surgery. The chance of implant removal with or without replacement over 3 years is about 1 in 12 for augmentation and about 1 in 4 for reconstruction.

Other Factors To Consider In Breast Implantation

- **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 or 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:

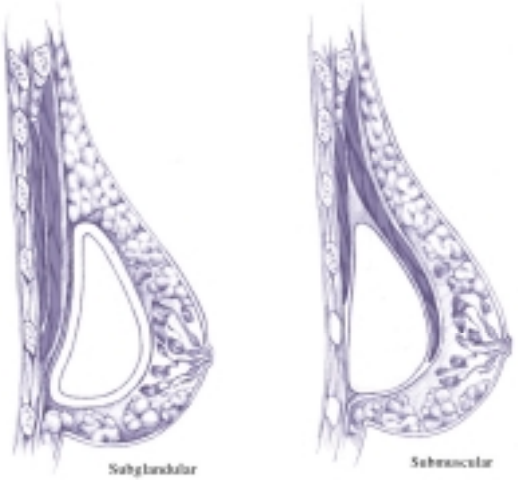
- **Implant Shape and Size**
  Depending on the desired shape you wish to achieve, you and your surgeon may choose a round or contoured implant shape. Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's). You should 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 doctor 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 Mentor implants shows 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?" below).

- **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.

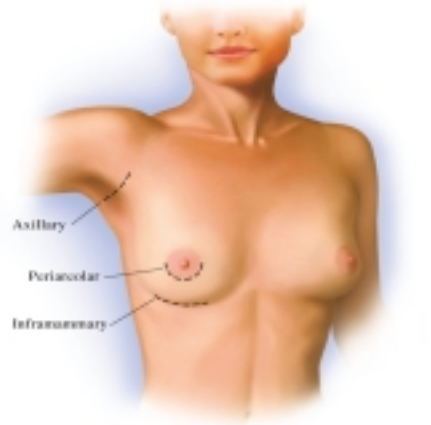
The **subglandular placement** may make surgery and recovery shorter, may be less painful, and may be easier to access for reoperation than the submuscular placement. However, this placement may result in more palpable implants, more capsular contracture, and more difficult imaging of the breast with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

  Augmentation Incision Sites - 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 breastfeed, 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.



Reconstruction Incision Sites - Most implants in breast reconstruction use the mastectomy scar either immediately (during the mastectomy procedure) or after tissue expansion. These issues are discussed below in the special considerations for reconstruction section.

- **Surgical Setting and Anesthesia**

  Augmentation - 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.

  Reconstruction - Reconstruction surgery is usually performed on an inpatient basis in an operating room. General anesthesia is most often used. See the section on special considerations for reconstruction for details regarding immediate versus delayed surgery and other reconstruction options such as use of tissue flaps.

- **Post-operative Care**

  Augmentation - 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.

  Reconstruction - Depending on the type of surgery you have (i.e., immediate or delayed), the post-operative recovery period will vary. See the section on special considerations for reconstruction below.

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

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.

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 is often removed with the breast tissue in mastectomy, the nipple is often reconstructed by using a skin graft from the opposite breast or by 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.

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 Doctor

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.

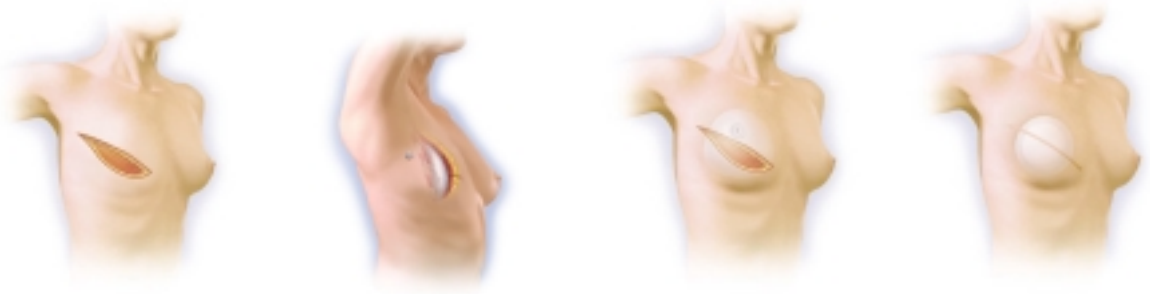
- **Delayed Reconstruction:**
  Two-stage delayed reconstruction with a tissue expander followed several months later by replacement with a breast implant.

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.

- **Two-Stage (Immediate or Delayed) Breast Implant Reconstruction**
  Breast reconstruction with Mentor saline-filled breast implant 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 | Tissue expander with intregal injection dome | Final result with implant

During a mastectomy, the general surgeon often 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 or discomfort after each filling of the expander, which subsides as the tissue expands. 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. 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.

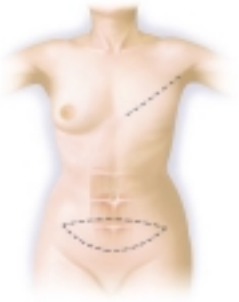
The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap), or it may be removed completely and reattached to the breast area by microsurgical techniques (a free flap). Operating time is generally longer with free flaps, because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

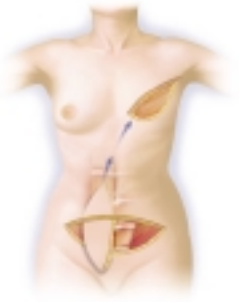
The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap) (which uses tissue from the abdomen) and the Latissimus dorsi flap (which uses tissue from the upper back).

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.

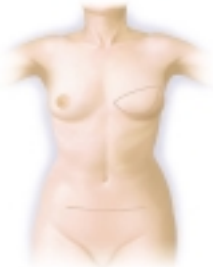
The TRAM Flap (Pedicle or Free)



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

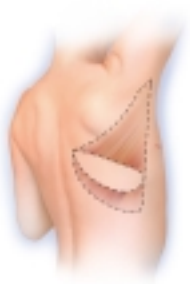


Step 3: Final Result

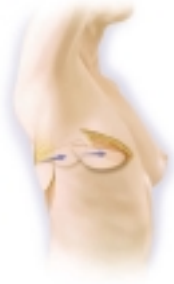
During a TRAM flap procedure, the surgeon removes a section of tissue from your abdomen and moves it to your chest to reconstruct the breast. The TRAM flap is sometimes referred to as a "tummy tuck" reconstruction, because it may leave the stomach area flatter.

A pedicle TRAM flap procedure typically takes 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.

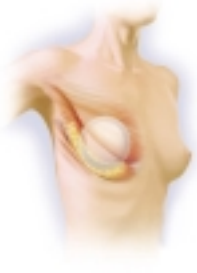
The Latissimus Dorsi Flap With or Without Breast Implants



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



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



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 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.

What Questions Do You Ask Your Surgeon about Breast Augmentation?

The following list of questions may help you to remind you of topics to discuss with your doctor.

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

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 doctor.

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 to 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)?

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 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.

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-INFOFDA (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 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/.

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	cis.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