



Breast Implants

An Information Update

2000

September 2000

Dear Reader:

The Food and Drug Administration (FDA) is pleased to provide you the newly revised breast implant consumer handbook entitled, "Breast Implants – An Information Update – 2000."

This handbook contains the latest information about breast implants to assist you in making an informed decision about whether or not to have breast implants.

It includes topics such as availability of breast implants, potential risks, answers to the most frequently asked questions by consumers, reporting of serious problems, chronology of FDA activities related to breast implants, and breast implant resource groups.

We hope the information in this breast implant handbook will be helpful to you. You may duplicate it for further distribution without permission.

The Consumer Affairs Staff of FDA's Office of Health and Industry Programs (OHIP) is responsible for answering breast implant calls and distributing the breast implant handbook. For specific information on how to obtain a copy of this handbook or to talk to a Consumer Affairs Specialist, refer to the *Breast Implant Resource Groups* section.

This breast implant consumer handbook, along with other breast implant information, may also be obtained by visiting FDA's website at <http://www.fda.gov/cdrh/breastimplants/>.

If you have any comments regarding the breast implant handbook, please write to us at FDA, Office of Device Evaluation, Division of General, Restorative, and Neurological Devices, 9200 Corporate Boulevard, HFZ-410, Rockville, MD 20850.

Sincerely yours,

David W. Feigal, Jr. M.D., M.P.H.
Director
Center for Devices and Radiological Health

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INTRODUCTION

FDA was given the responsibility for regulating medical devices, such as breast implants, under a law called the Medical Device Amendments of 1976. The law requires manufacturers of new medical devices to show that the devices are safe, effective, and properly labeled before they are allowed on the market. Devices in use before the 1976 law, including saline-filled and silicone gel-filled breast implants, were allowed to stay on the market. However, the law directed FDA to eventually require scientific evidence of the safety and effectiveness of many of these pre-1976 devices.

There are three types of breast implants, all of which are intended for breast augmentation, breast reconstruction, and/or revision (i.e., replacement) of a breast implant. The saline-filled implant has an external silicone shell and is filled with sterile saline (salt water). The silicone gel-filled implant also has an external silicone shell but is filled with silicone gel. An alternative breast implant may have a different shell material and/or a different filler.

While many women believe breast implants cause debilitating systemic illnesses, such as autoimmune disease, this is not proven at this time. However, most women with breast implants will experience some local complications such as rupture, pain, capsular contracture (a tightening of the scar tissue or capsule the body forms around the breast implant), disfigurement, and serious infection. These may lead to nonsurgical medical treatments and repeat surgeries.

Well before the date of surgery, you should take the time to carefully read and consider the information provided in the patient labeling and the device package insert. You should discuss any questions you have with your doctor before you make your decision.

Additionally, the following are important factors for you to consider when deciding to have implants:

1. Whether you are undergoing augmentation or reconstruction, be aware that breast implants are not considered lifetime devices and that breast implantation may not be a one-time surgery. You are likely to need additional surgery(ies) and doctor visits over the course of your life. You are also likely to have surgery to remove the implant with or without replacement sometime over the course of your life.
2. 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, loss of breast tissue, or other cosmetic changes of the breast.
3. Breast implants may affect your ability to breast feed. Also, breast implants will not prevent your breast from sagging after pregnancy.
4. With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.
5. Breast implant surgery and/or treatment of complications may not be covered by your health insurance. You should check with your insurance company regarding these coverage issues because, for some women, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied.

STATUS / AVAILABILITY OF IMPLANTS

Status of Silicone Gel-Filled Breast Implants

On April 10, 1991, FDA asked the manufacturers to submit evidence in a premarket approval (PMA) application that silicone gel-filled breast implants were safe and effective. However, they were unable to provide FDA with this information. Without enough data on safety and effectiveness, FDA determined that silicone gel-filled breast implants could not be approved. Therefore, silicone gel-filled breast implants were removed from the open market. However, silicone gel-filled implants are available to women through the following FDA-approved studies:

- an adjunct study
- an investigational device exemptions (IDE) study

An adjunct study is a study developed for continued availability of silicone-gel breast implants for a public health need. In April 1992, after a careful evaluation of the public health need, the alternatives to silicone gel-filled breast implants, and the risks, FDA concluded that silicone gel-filled breast implants should continue to be available for women seeking breast reconstruction or revision of an existing breast implant.

Accordingly, the adjunct study was developed to make silicone gel-filled breast implants available for reconstruction and revision patients and to collect short-term complication data. Eligible women include those who have had breast cancer surgery, a severe injury to the breast, a birth defect that affects the breast, or a medical condition causing a severe breast abnormality. Additionally, those who need to have an existing implant replaced for medical reasons, such as rupture of the implant, are also eligible. Women who want silicone gel-filled implants for breast augmentation (cosmetic reasons) cannot be enrolled in the adjunct studies. According to the adjunct study protocols, each woman will be followed for at least five years.

An IDE study is a clinical study that must be reviewed and approved by FDA to help assure that the resulting data will be meaningful and that patients will not be exposed to unreasonable risks. Under the law, FDA cannot acknowledge the existence of any study conducted under the IDE unless the manufacturer publicly announces the existence of the study. Likewise, FDA cannot release the results of studies conducted under an IDE unless the manufacturer has made the data publicly available. Generally, these IDE study data are used as the basis for a future application to market the device. Women participating in an IDE study would receive their implants for the uses described in the study protocol/plan. Each woman who participates in an IDE study must give informed consent, and an Institutional Review Board (IRB) must oversee the study. An IRB is composed of scientists, health professionals, and community members who do not have a bias as to the outcome of the study.

To date, both Mentor Corporation and McGhan Medical have adjunct and IDE studies approved by FDA. For further information on enrolling into one of these studies, contact your doctor or the manufacturer (see [Breast Implant Resource Groups](#) section for manufacturer contact information).

Status of Saline-Filled Breast Implants

The manufacturers of saline-filled breast implants were notified by FDA in January 1993 that the agency would require data on their products' safety and effectiveness. While the manufacturers were conducting the required studies, saline-filled breast implants remained on the market.

On August 19, 1999, FDA asked the manufacturers to submit evidence in a PMA that saline-filled breast implants were safe and effective. On March 1-3, 2000, FDA's General and Plastic Surgery Devices Panel met to review PMAs for saline-filled breast

implants manufactured by Mentor Corporation, McGhan Medical, and Poly Implant Protheses (PIP). The Panel voted to recommend approval of Mentor Corporation and McGhan Medical's saline-filled breast implants and to recommend disapproval of PIP's implants. On May 10, 2000, FDA granted approval of Mentor's and McGhan's PMAs.

To date, all other manufacturers' saline-filled breast implants are considered investigational.

If you want to receive an implant other than Mentor and McGhan's, you must enroll in an IDE study. To enroll in an IDE, contact your doctor or the manufacturer (see *Breast Implant Resource Groups* section for manufacturer contact information).

Status of Alternative Breast Implants

Currently, there are no alternative breast implants approved for marketing. As an investigational device, an alternative breast implant can be made available only through an IDE study.

To date, there is one approved IDE for an alternative breast implant called the Trilucent™; however, there is no new patient enrollment in this IDE. Refer to the *Frequently Asked Questions* section for more information.

THE SURGERY

General Description of Breast Implant Surgery

Breast implant procedures can be performed on an outpatient (not hospitalized) basis or at a hospital. Breast implant surgery can be done under local anesthesia (only breast area numbed) or under general anesthesia (put to sleep). Breast implant surgery can last from one to several hours depending on whether the implant is inserted behind (submuscular) or in front of (subglandular) the chest muscle and whether surgery is performed on one or both breasts. If the surgery is done in a hospital, the length of the hospital stay will vary according to the type of surgery, the development of any postoperative complications, and your general health. It may also depend on the type of coverage your insurance provides. Before surgery, your doctor should discuss with you the extent of surgery, the estimated time it will take, and the choice of drugs for pain and nausea.

Your Expectations - Reconstruction or Augmentation

Your consideration of breast implants, for reconstruction or for augmentation, should be based on realistic expectations of the outcome. You may also want to talk with women who have had this surgery at least a year ago by the same surgeon. Keep in mind, however, that there is no guarantee that your results will match those of other women.

Your results will depend on many individual factors, such as

- your overall health
- chest structure and body shape
- healing capabilities (which may be hindered by radiation and chemotherapy, smoking, alcohol, and various medications)
- bleeding tendencies/likelihood

- prior breast surgery(ies)
- possibility of infection
- the skill and experience of the surgical team
- the type of surgical procedure
- the type and size of implant

You will be given general or local anesthesia, and in most cases, antibiotics. The surgery may last from 1-2 hours for augmentation to several hours for reconstruction or revision.

Scarring is a natural outcome of surgery, and your doctor can describe the location, size, and appearance of the scars you can expect to have. For most women, scars will fade over time to thin lines, although the darker your skin, the more prominent the scars are likely to be. You should ask your doctor about the types of surgical procedures, where your scar will be, and what to expect after surgery.

Postoperative Care

Your doctor should describe the usual postoperative (after surgery) recovery process, the possible complications that can arise, and the expected recovery period. Following the operation, as with any surgery, some pain, swelling, bruising, and tenderness can be expected. These complications may last for a month or longer, but they should disappear with time.

Medications for pain and nausea can be prescribed. Some women may experience bleeding and some may experience fever, warmth, or redness of the breast, or other symptoms of infection. These symptoms should be reported immediately to your doctor. You should be told about wound healing and how to care for your wound. Drains may be used for a few days.

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 doctor'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 doctor may also recommend breast massage exercises.

Ask your doctor about a schedule of follow-up examinations, limits on your activities, precautions you should take, and when you can return to your normal routine. (If you are enrolled in a clinical study, your doctor should give you a schedule for follow-up examinations set by the study plan.)

Special Surgical Concerns for Women with Breast Cancer

The following issues should be considered for women with breast cancer:

- The physical and cosmetic results with breast implants may be affected by chemotherapy, radiation therapy, or any other factor that significantly alters the healing process.
- Skin necrosis (cell death) may occur because circulation to the remaining tissue has been changed by a mastectomy (breast removal). Also, skin necrosis may be increased as a result of radiation treatment.
- It usually takes more than one operation to achieve the desired cosmetic outcome, especially if this procedure includes building a new nipple.

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 breast implant, 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, after your breast has healed from the original implant surgery, you may want to build a new nipple and darken the areola (skin around the nipple). This procedure can usually be performed on an outpatient basis. Ask your doctor to explain the various ways this can be done, such as using a skin graft from the opposite breast or by tattooing the area.

Ask your doctor about the pros and cons of each implant technique. If you decide to have reconstruction for one breast, you may need to think about surgery on the other breast to achieve a similar appearance.

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 surgeon, as it may affect the breast reconstruction methods considered for your case.

Timing of 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

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.

Breast Implant Reconstruction Procedures

- **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

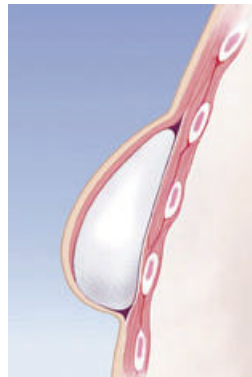
surgeon will then implant a breast implant that completes the one-stage reconstruction.

- **Two-Stage (Immediate or Delayed) Breast Implant Reconstruction**

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



**Side View. Breast
Tissue Removed**



**Side View. Expander
Inserted and Filled**

- **Tissue Expansion**

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.

- **Placing the Breast Implant**

After the tissue expander is removed, the breast implant is placed in the pocket. The surgery to replace the tissue expander with a breast implant (implant exchange) is usually done under general anesthesia in an operating room. It may require a brief hospital stay or be done on an outpatient basis.



Post Mastectomy



Stage 1: Tissue Expander



**Stage 2: Breast Implant
and Nipple/Areola Reconstruction**

Breast Reconstruction Without Implants: Tissue Flap Procedures

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

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

Flap surgery requires a hospital stay of several days and generally a longer recovery time than implant reconstruction. Flap surgery also creates scars at the site where the flap was taken and 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)**

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.



Post Mastectomy



TRAM Flap



**Final Result with
Nipple/Areola Reconstruction**

- **The Latissimus Dorsi Flap With or Without Breast Implants**

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

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



Post Mastectomy



View Showing Back Scar



Latissimus Dorsi Flap

BREAST IMPLANT RISKS

The Institute of Medicine (IOM) completed its independent, unbiased review of all past and ongoing scientific research study of silicone breast implant safety in June 1999.¹ Among the major findings from this study were that local complications with silicone breast implants were the primary safety issue with breast implants, that these have not been well studied, and that information on these complications is crucial for women deciding whether or not they want breast implant surgery. The IOM report said:

“First, reoperations and local and perioperative [right after surgery] complications are frequent enough to be a cause for concern and to justify the conclusion that they are the primary safety issue with silicone breast implants. Complications may have risks themselves, such as pain, disfigurement, and serious infection and they may lead to medical and surgical interventions, such as reoperations, that have risks. Second, risks accumulate over the lifetime of the implant, but quantitative data on this point are lacking for modern implants and deficient historically. Third, information concerning the nature and the relative high frequency of local complications and reoperations is an essential element of adequate informed consent for women undergoing breast implantation.”

There are risks or complications associated with any surgical procedure, such as the effects of anesthesia, infection, swelling, redness, bleeding, and there are complications specific to breast implants. These complications are described below.

¹ Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}

1. Capsular Contracture

Capsular contracture is when the scar tissue or capsule that normally forms around the implant tightens and squeezes the implant. It may be more common following infection, hematoma (collection of blood), and seroma (collection of watery portion of blood). There are four grades of capsular contracture - Baker Grades I through IV.

The Baker grading is as follows

Grade I	the breast is normally soft and looks natural
Grade II	the breast is a little firm but looks normal
Grade III	the breast is firm and looks abnormal (visible distortion)
Grade IV	the breast is hard, painful, and looks abnormal (greater distortion)

Additional surgery may be needed to correct the capsular contracture. 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 this additional surgery.

In a prospective clinical study of saline-filled breast implants conducted by Mentor, the cumulative, 3-year, by patient rates of a first occurrence of capsular contracture Grades III and IV were 9% for the 1264 augmentation patients and 30% for the 416 reconstruction patients. In a prospective clinical study of saline-filled breast implants conducted by McGhan, the cumulative, 3-year, by patient rates of a first occurrence of capsular contracture Grades III and IV were 9% for the 901 augmentation patients and 25% for the 237 reconstruction patients.

A randomized controlled study comparing silicone gel-filled and saline-filled implants in women undergoing reconstruction reported a 54% contracture rate of Baker Grades III and IV in the silicone gel group after 6 months.²

A retrospective study by Gabriel et al. indicated that 131 of 749 (17.5%) women had at least one surgical procedure over an average of 7.8 years because of capsular contracture.³ This would not include capsular contracture that may have been severe but did not result in surgery. This study included women who had implants for cosmetic and reconstruction purposes, most of whom had silicone gel-filled breast implants.

2. Deflation/Rupture/Leakage

Breast implants **are not lifetime devices** and cannot be expected to last forever. Some implants deflate or rupture in the first few months after being implanted and some deflate after several years; others are intact 10 or more years after the surgery.

- a. Silicone Gel-Filled Breast Implants - When silicone gel-filled implants rupture, some women may notice decreased breast size, nodules (hard knots), uneven appearance of the breasts, pain or tenderness, tingling, swelling, numbness, burning, or changes in sensation. Other women may unknowingly experience a rupture without any symptoms (i.e., “silent rupture”). Magnetic resonance imaging (MRI) with equipment specifically designed for imaging the breast may be used for evaluating patients with suspected rupture or leakage of their silicone gel-filled implant.

² Asplund, O. Capsular contracture in silicone gel and saline-filled breast implants after reconstruction. *Plast Reconstr Surg* 1984;73:270-5.

Silicone gel which escapes the fibrotic capsule surrounding the implant may migrate away from the breast. The free silicone may cause lumps called granulomas to form in the breast or other tissues where the silicone has migrated, such as the chest wall, armpit, arm, or abdomen.

Plastic surgeons usually recommend removal of the implant if it has ruptured, even if the silicone is still enclosed within the scar tissue capsule, because the silicone gel may eventually leak into surrounding tissues. If you are considering the removal of an implant and the implantation of another one, be sure to discuss the benefits and risks with your doctor.

FDA completed a retrospective study on rupture of silicone gel-filled breast implants.⁴ This study was performed in Birmingham, Alabama and included women who had their first breast implant before 1988. Women with silicone gel-filled breast implants had a MRI examination of their breasts to determine the status of their current breast implants. The 344 women who received a MRI examination had a total of 687 implants. Of the 687 implants in the study, at least two of the three study radiologists agreed that 378 implants were ruptured (55%). This means that 69% of the 344 women had at least one ruptured breast implant. Of the 344 women, 73 (21%) had extracapsular silicone gel in one or both breasts. Factors that were associated with rupture included increasing age of the implant, the implant manufacturer, and submuscular rather than subglandular location of the implant. A summary of the findings of this study is also available on FDA's website at

<http://www.fda.gov/cdrh/breastimplants/studies/biinterview.pdf> and
<http://www.fda.gov/cdrh/breastimplants/studies/birupture.pdf>.

³ Gabriel SE, Woods JE, O'Fallon WM, Beard CM, Kurland LT, Melton LJ. Complications leading to surgery after breast implantation. *New Engl J Med* 1997; 336:679-682.

⁴ Brown SL, Middleton MS, Berg WA, Soo MS, Pennello G. Prevalence of rupture of silicone gel breast implants in a population of women in Birmingham, Alabama. *American Journal of Roentgenology* 2000;175:1-8.

Robinson et al. studied 300 women who had their implants for 1 to 25 years and had them removed for a variety of reasons.⁵ Visible signs of rupture in 51% of the women studied were found. Severe silicone leakage (silicone outside the implant without visible tears or holes) was seen in another 20%. Robinson et al. also noted that the chance of rupture increases as the implant ages.

Other studies indicate that silicone may escape the capsule in 11-23% of rupture cases.^{6,7,8,9}

- b. Saline-Filled Breast Implants – Saline-filled 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. You should also be aware that the breast implant may wear out over time and deflate. Additional surgery is needed to remove deflated implants.

In a prospective clinical study conducted by Mentor, the cumulative, 3-year, by patient rates of a first occurrence of deflation were 3% for 1264 augmentation

⁵ Robinson OG, Bradley EL, Wilson DS. Analysis of explanted silicone implants: a report of 300 patients. *Ann Plast Surg.* 1995; 34:1-7.

⁶ Vinnik CA. Migratory silicon - clinical aspects. *Silicone in Medical Devices - Conference Proceedings.* 1991 February 1-2; Baltimore, MD: U.S. Department of Health and Human Services, FDA Publication No. 92-4249 (p.59-67).

⁷ Duffy MJ, Woods JE. Health risks of failed silicone gel breast implants: a 30-year clinical experience. *Plast Reconstr Surg* 1994;94:295-299.

⁸ Berg WA, Caskey CI, Hamper UM, Kuhlman JE, Anderson ND, Chang BW, Sheth S, Zerhouni EA. Single- and double-lumen silicone breast implant integrity: Prospective evaluation of MR and US criteria. *Radiology* 1995;197:45-52.

⁹ Gorczyca DP, Schneider E, DeBruhl ND, Foo TKF, Ahn CY, Sayre JW, Shaw WW, Bassett LW. Silicone breast implant rupture: Comparison between three-point Dixon and fast spin-echo MR imaging. *AJR* 1994;162:305-310.

patients and 9% for 416 reconstruction patients. In a prospective clinical study conducted by McGhan, the cumulative, 3-year, by patient rates of a first occurrence of deflation were 5% for the 901 augmentation patients and 6% for the 237 reconstruction patients.

A retrospective study of saline breast implants by Gutowski et al. indicates that 10.1% of women followed for an average of 6 years had at least one implant deflated.¹⁰

For silicone gel and saline-filled implants, some causes of rupture or deflation include

- damage by surgical instruments during surgery
- overfilling or underfilling of the implant with saline solution (specific only to saline-filled breast implants)
- capsular contracture
- closed capsulotomy (described below)
- stresses such as trauma or intense physical manipulation
- excessive compression during mammographic imaging
- placement through umbilical incision site
- injury to the breast
- normal aging of the implant
- unknown/unexplained reasons

Closed capsulotomy is a technique used to relieve capsular contracture. It involves manually squeezing the breast to break the hard capsule. This has been implicated as a possible cause of breast implant rupture. Closed capsulotomy is not recommended by breast implant manufacturers.

3. 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 your implant(s) due to problems such as deflation, capsular contracture, infection, shifting, and calcium deposits. Many women decide to have the implants replaced, but some women do not. Those who do not have their implants replaced may have cosmetically undesirable dimpling and/or puckering of the breast following removal of the implant.

In a prospective clinical study of saline-filled breast implants conducted by Mentor, the cumulative, 3-year, by patient rates of a first occurrence of additional surgeries were 13% for the 1264 augmentation patients and 40% for the 416 reconstruction patients. In a prospective clinical study of saline-filled breast implants conducted by McGhan, the cumulative, 3-year, by patient rates of a first occurrence of additional surgeries were 21% for the 901 augmentation patients and 39% for the 237 reconstruction patients.

A retrospective study by Gabriel et al. shows that 24% of women with breast implants experience adverse events resulting in surgery during the first five years after implantation (silicone and saline implants were studied together).¹¹ According to this study, about 1 in 3 women getting breast implants for reconstruction may need a second surgery within five years, and about 1 in 8 women getting breast implants for augmentation may need a second surgery within five years. These additional surgeries may result in the loss of breast tissue.

¹⁰ Gutowski KA, Mesna GT, Cunningham BL. Saline-filled Breast Implants: A Plastic Surgery Educational Foundation Multicenter Outcomes Study. *Plastic Reconstructive Surgery*. 1997 (100): 1019-27.

¹¹ Gabriel SE, Woods JE, O'Fallon WM, Beard CM, Kurland LT, Melton LJ. Complications leading to surgery after breast implantation. *New Engl J Med* 1997; 336:679-682.

4. Pain

Women may feel pain of varying severity (degrees) and duration (length of time) 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 if you have pain.

5. 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.

Additionally, for saline-filled implants that have a valve, you also might be able to feel the valve of the implant with your hand.

Repeated surgeries to improve the appearance of the breasts and/or to remove ruptured or deflated prostheses may result in an unsatisfactory cosmetic outcome.

6. 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 has cleared up.

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.

7. Hematoma/Seroma

Hematoma is a collection of blood inside a body cavity, and seroma is a collection of the watery portion of the blood 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.

8. 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. (Refer to the *Other Illnesses* section for more information on breast feeding.)

9. 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 remove the implant to

distinguish these deposits from cancer. Calcium deposits may be felt as nodules (hard knots) under the skin around the implant.

10. Delayed Wound Healing

In some cases, the incision site fails to heal normally or takes longer to heal.

11. Extrusion

An unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion of the implant, which is when the breast implant comes through the skin. The additional surgery needed to correct this complication can result in unacceptable scarring or loss of breast tissue.

12. 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 and/or 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.

13. 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.

14. Interference with Mammography

Interference with mammography due to breast implants may delay or hinder the early detection of breast cancer either by hiding suspicious lesions (wounds or injuries or tumors) or by making it more difficult to include them in the image. Implants increase the difficulty of both taking and reading mammograms. Some women who undergo reconstruction will have some breast tissue remaining, and some have all of their breast tissue removed. It is important that a woman with breast tissue remaining continue to have mammography of that breast, as well as of the other breast, to detect breast cancer.

Mammography requires breast compression (hard pressure) that could contribute to implant rupture. In addition to special care taken by the technologist to reduce the risk of implant rupture during this compression, other techniques are used to maximize what is seen of the breast tissue during mammography. These techniques are called breast implant displacement views, Eklund displacement views, or Eklund views, after the radiologist who developed them. These special implant displacement views are done in addition to those views done during routine mammograms.

Because of the extra views and time needed, women with implants should always inform the receptionist or scheduler that they have breast implants when making an appointment for mammography. They should also tell the radiology technologist about the presence of implants before mammography is performed. This is to make sure that the technologist uses these special displacement techniques and takes extra care when compressing the breasts to avoid rupturing the implant.

The displacement procedure involves pushing the implant back and gently pulling the breast tissue into view. Several factors affect the success of this special technique in imaging the breast tissue in women with breast implants. The location of the implant,

the hardness of the capsular contracture, the size of the breast tissue compared to the implant, and other factors may affect how well the breast tissue can be imaged.

Also, a radiologist may find it difficult to distinguish calcium deposits in the scar tissue around the implant from a breast tumor when he or she is interpreting the mammogram. Occasionally, it is necessary to remove and examine a small amount of tissue (biopsy) to see whether or not it is cancerous. This can frequently be done without removing the implant.

15. Galactorrhea

Sometimes after breast implant surgery, you may begin producing breast milk. In some cases, the milk production stops spontaneously or when medication is given to suppress milk production. In other cases, removal of the implant(s) may be needed.

OTHER ILLNESSES

Some women with breast implants have reported health problems that they believe are related to their implants, but most studies of these illnesses have failed to show an association with breast implants. There also have been concerns about possible, but unproven, effects on health.

Most of the health concerns about breast implants are related to silicone gel. Even if a silicone gel-filled breast implant does not rupture, small amounts of the silicone fluid or oil may bleed out of the implant and migrate into the surrounding tissue. There has been concern that this escaped silicone fluid or oil might cause harmful effects, including connective tissue disease and related disorders and/or cancer.

These other illnesses are discussed below.

1. Connective Tissue Diseases (CTDs) and Related Disorders

The body's immune system is the network of cells that protect against infectious diseases. Antibodies are one type of substance the body produces to fight off infectious agents. CTDs and related disorders of the body's immune system are related to the connective tissues of the body, which include fibrous tissues, cartilage, and bone that support body structures and bind body parts together. Some CTDs are autoimmune diseases that occur when a woman's immune system attacks her own cells as if they were foreign.

Defined autoimmune diseases include

- lupus
- rheumatoid arthritis
- polymyositis

- dermatomyositis
- progressive systemic sclerosis or scleroderma

Disorders that are not autoimmune include

- fibromyalgia
- chronic fatigue syndrome

Some women with breast implants have experienced the diseases and/or disorders listed above, as well as a variety of signs and symptoms that could be related to the immune system. However, this is not considered a defined disorder.

These signs and symptoms include

- pain and swelling of joints
- tightness
- redness or swelling of the skin
- swollen glands or lymph nodes
- unusual or unexplained fatigue
- swelling of the hands and feet
- excessive hair loss
- memory problems
- headaches
- muscle weakness or burning

Signs and symptoms such as these may be present in women without CTD or related disorders or without breast implants. Individual cases alone cannot scientifically prove or disprove a connection between CTDs and related disorders and breast implants.

Some doctors and women have thought that these signs and symptoms are part of a new disease which is related to silicone and have called the disease "human adjuvant disease," "silicone related syndrome," "atypical disease," or other names. The IOM report stated "The diagnosis of this condition could depend on the presence of a number of symptoms that are nonspecific and common in the general population. Thus, there does not appear to be even suggestive evidence of a novel [new] syndrome in women with breast implants." So, it is unclear at this time whether the signs and symptoms experienced by these women are related to their implants. In some cases, women have reported fewer symptoms after the implants were removed. In other cases, there was no change in signs and symptoms after the implants were removed.

Studies have shown that some women with silicone gel-filled breast implants produced antibodies to their own collagen (a connective tissue protein), but we do not know how often these antibodies occur in the general population, and there are no data that show these antibodies cause CTDs and related disorders.^{12,13,14} There are reports of women with implants who have other autoantibodies. However, the presence of these antibodies does not mean that a woman has an increased risk of actually developing a CTD or related disorder.

Several other studies of women with breast implants have been completed recently. These studies provide substantial, but not complete information, about the lack of a possible association between breast implants and CTDs. For example:

¹²Wolf LE, Lappe M, Peterson RD, et al. Human immune response to polydimethylsiloxane (silicone): screening studies in a breast implant population. *FASEB J* 1994;7:1265-1268.

¹³Tueber SE, Rowley MJ, et al. Anti-collagen antibodies are found in women with silicone breast implants. *J Autoimmunity* 1993;6:357-377.

¹⁴Rowley MJ Cook AD, et al. Antibodies to collagen: comparative epitope mapping in women with silicone breast implants, system lupus erythematosus and rheumatoid arthritis. *J Autoimmunity* 1994; 7:775-789.

- A study by Gabriel et al. of breast implants and CTDs, conducted at the Mayo Clinic, compared the medical records of 749 women with breast implants in Olmsted County, Minnesota, with a similar group of women from the same area who did not have implants.¹⁵ The researchers concluded that there was no increased risk of defined CTD and related disorders among the women with breast implants.
- A study by Englert et al., conducted in Australia, found no increase in scleroderma, a connective tissue disease whose possible connection to breast implants had been the source of some concern.¹⁶
- A study by Sanchez-Guerrero, conducted at the Harvard Medical School, included 1183 women with silicone gel-filled, saline, double lumen, polyurethane coated and 56 unknown breast implants.¹⁷ This study found no increase in CTDs.
- A 1996 study by Hennekens et al., also conducted at the Harvard Medical School, is the largest study to look at the past experiences of women with breast implants.¹⁸ Almost 400,000 women (nearly 11,000 with breast implants) completed questionnaires for the study. The study showed a small but statistically significant increase in the risk of all CTDs reported by women with breast implants. The study indicated that over a 10-year-period, women with breast implants were 1.24 times more likely to report having a CTD or related disorder than women without breast implants. The increase in risk applies to all of the CTDs and related disorders taken together. When calculated individually,

¹⁵ Gabriel SE, O'Fallon WM, Kurland LT, Beard CM, Woods JE, Mellon LJ. Risk of connective-tissue diseases and other disorders after breast implantation. *N Engl J Med* 1994; 330:1697-1702.

¹⁶ Englert HJ, Brooks P. Scleroderma and augmentation mammoplasty--a casual relationship? *Aust NZ J ME* 1994;24:74-80.

¹⁷ Sanchez-Guerrero J, Colditz GA, Karlson EW, Hunder DJ, Speizer FE, Liang MH. Silicone breast implants and the risk of connective-tissue diseases and symptoms. *New Engl J Med* 1995;322:1666-1670.

however, the risk for each of these diseases was not statistically significant.

According to this study, having breast implants did not increase the risk of getting any one of these CTDs and related disorders when they are considered individually.

When considered together, these studies indicate that the risk of developing a typical or defined CTD or related disorder due to having a breast implant is low.

None of the studies described above can completely resolve the question of whether silicone gel-filled breast implants increase the risk of CTDs and related disorders. Without a group of women without implants who are of similar age, health, and social status and followed for a long time (such as 10-20 years), a relationship between implants and these diseases cannot conclusively be made. Also, except for the Hennekens study, none of the studies has been large enough to rule out the possibility that the implants could cause CTD or a related disorder in a small subset of women who have them. Because these studies were largely designed to find out whether women with the implants had certain well-defined CTDs and related disorders, they also cannot exclude the possibility that some women with implants might develop other signs and symptoms related to the immune system that are not a defined CTD. In other words, these studies do not resolve the question of whether the variety of signs and symptoms some women report might be related to their implants.

¹⁸ Hennekens CH, Lee I-M, Cook NR, Hebert PR, Karlson EW, LaMotte F, Manson JE, Buring JE. Self-reported breast implants and connective-tissue diseases in female health professionals. *JAMA* 1996;275:616-621.

2. Cancer

The IOM report indicates that breast cancer is no more common in women with implants than those without implants.¹⁹

At this time, there is no scientific evidence that silicone gel-filled breast implants can increase the risk of other cancers in women, but this possibility cannot be completely ruled out because the studies to evaluate the risk of other cancers have not been done.

About 10% of women with breast implants received the polyurethane foam-coated type until they were taken off the market in 1991 because of concerns that the coating might increase the risk of breast cancer. This coating released small quantities of the chemical called TDA (2,4-toluenediamine) that has been shown to cause cancer in animals. Because of this concern, the manufacturer of the coated implants, Bristol-Myers Squibb Company, analyzed the urine of women with these devices for TDA.²⁰ Researchers found TDA in the urine but in such tiny amounts that the risk of cancer from the polyurethane foam-coated implants is only about 1 in a million over a woman's lifetime. Therefore, it is unlikely that even 1 of the estimated 110,000 women who got the polyurethane foam-covered implants will get cancer as a result of exposure to the TDA. This study supports FDA's recommendation that women with polyurethane foam-covered breast implants should not have them removed based solely on concerns about cancer from TDA.

Concerns have also been raised about whether the TDA from the polyurethane-coated implants could increase the risk of cancer to a nursing infant. FDA required the

¹⁹ Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}

²⁰ Hester TR Jr, Ford NF, Gale PJ, Hammett JL, Raymond RH, Turnbull D, Frankos VH, Cohen MB. Measurement of 2,4-toluenediamine in the urine and serum samples from women with Meme or Replicon breast implants. *Plast Reconstr Surg*, 1997;100:1291-1298.

manufacturer to analyze mother's milk for TDA, but the manufacturer was unable to get enough lactating women with these implants to conduct a valid study.

3. Breast Feeding

Women of childbearing age who want to breast feed should be aware of the negative impact of breast implants on breast feeding.

One concern is the ability to successfully breast feed after breast implantation. Some women who undergo breast augmentation can successfully breast feed and some cannot. Women who undergo a mastectomy will be unable to breast feed on the affected side due to loss of breast tissue and glands that produce milk.

One study by Hurst reports that up to 64% of 42 women with implants were unable to breast feed compared to 7% of 42 women without implants.²¹ This is the highest reported range in the literature. While there have been no definitive studies regarding this issue, having an implant may significantly affect your ability to breast feed.

It is not known if a small amount of silicone may pass from the silicone shell of an implant 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 by Semple et al. measuring *silicon* (one component in silicone) levels showed the same levels in breast milk from women with silicone gel-filled implants when compared to breast milk from women without implants.²²

²¹ Hurst NM. Lactation after augmentation mammoplasty. *Obstet Gynecol* 1996;87:30-34

²² Semple JL, Lugowski SJ, Baines CJ, Smith DC, McHugh A. Breast milk contamination and silicone implants: preliminary results using silicone as a proxy measurement for silicone. *Plast Reconstr Surg* 1998;102:528-533.

4. Effects on Children

Concerns have been raised about the potential damaging effects on children born of mothers with implants. The IOM report said that the information is insufficient or flawed to draw definite conclusions about this issue²³. In other words, it is not known what effect breast implants may have on a fetus and the nursing infant.

5. Other

There is some concern, but little information, about possible risks from the silicone material of the shell from the saline-filled and silicone gel-filled breast implants.

Another concern relates specifically to saline-filled breast implants. Questions have been raised about the potential for the saline to become contaminated (not sterile) with fungus or bacteria and to be released into the woman's body if her implant deflates or ruptures or if the valve leaks. However, saline-filled implants are now generally filled from a bag and tubing rather than from an open bowl, which should reduce the risk of this complication. Also, the manufacturers have advised doctors against adding any antibacterial, antiseptic, or cleansing agent to the saline as it may decrease the strength of the implant shell.

²³ Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}

SPECIFIC ISSUES TO CONSIDER

In the *Introduction* section, factors for you to consider when deciding whether or not to have breast implants were provided. Additionally, the previous sections describe the risks and other illnesses of breast implants. The following are additional issues for you to consider in your decision making process, including questions to ask your surgeon.

OTHER FACTORS TO CONSIDER IN BREAST IMPLANTATION

1. Choosing a Surgeon -

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

- a. How many breast augmentation or reconstruction implantation procedures does he/she perform per year?
- b. How many years has he/she performed breast implantation procedures?
- c. Is he/she board certified, and if so, with which board?
- d. 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.
- e. What is the most common complication he/she encounters with breast implantation?
- f. What is his/her reoperation rate with breast implantation and what is the most common type of reoperation he/she performs?

When you have answers to these questions, you will have a better idea of the technical qualifications of your surgeon.

2. 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 the pectoralis major 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 an implant size too large for your tissue, your surgeon may warn you that breast implant edges may be apparent or visible post-operatively. You may even risk surgical complications. Also, excessively large breast implants may speed up the effects of gravity and result in earlier droop or sag.

3. Surface Texturing

Textured surface implants were designed to reduce the chance of capsular contracture. Some studies with small numbers of women suggest that surface texturing reduces the chance of severe capsular contracture, but studies of a large number of women with saline-filled implants show no difference in the likelihood of developing capsular contracture with textured implants compared to smooth surfaced implants.

4. Palpability

The following may cause implants to be more palpable (more easily felt)

- textured implants
- larger implants
- subglandular placement (on top of the muscle and under the breast glands)

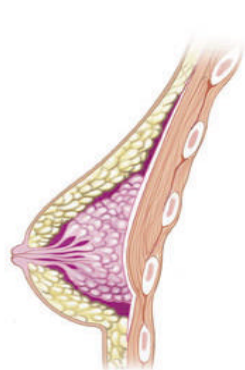
- smaller amount of skin/tissue available to cover the implant

5. Implant Placement

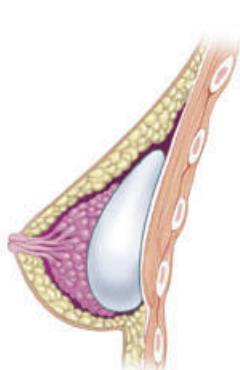
The breast implant can be placed either submuscularly or subglandularly. You should discuss with your surgeon the pros and cons of the implant placement selected for you.

Submuscular Placement Possible Results	Subglandular Placement Possible Results
Surgery may be longer	Surgery may be shorter
Recovery may be longer	Recovery may be shorter
Reoperation may be more difficult	May provide easier access for reoperation
Less palpable implants	More palpable implants
Easier imaging in mammography	More difficult imaging in mammography

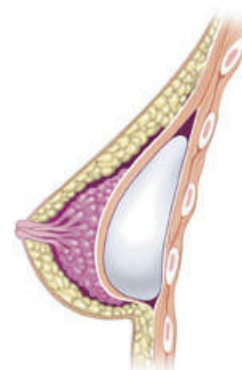
The sketches below show the differences between subglandular and submuscular placement of your implant compared to a breast before augmentation.



Breast before augmentation



**Breast after
subglandular augmentation**

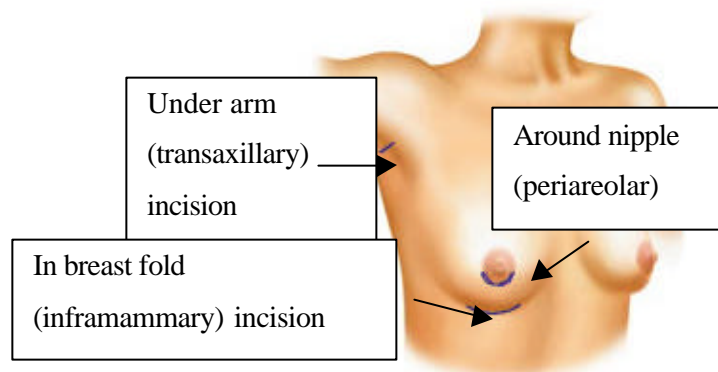


**Breast after
submuscular augmentation**

6. Incision Sites

Augmentation Incision Sites – The three common incision sites are under the arm (axillary), around the nipple (periareolar), or within the breast fold (inframammary). If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive (very small) instruments, to create a "pocket" for the breast implant.

- Periareolar – This incision is most concealed but is associated with a higher likelihood of inability to successfully breast feed, as compared to the other incision sites.
- Inframammary – This incision is less concealed than periareolar but associated with less difficulty with breast feeding than the periareolar incision site.
- Axillary – This incision is less concealed than periareolar but associated with less difficulty than the periareolar incision site when breast feeding.
- Umbilical/endoscopic – This incision site 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.

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.

As a note, the saline-filled implant is typically inserted empty and then filled with saline to permit the smallest possible incision.

QUESTIONS TO ASK YOUR SURGEON ABOUT BREAST AUGMENTATION

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

1. What are the risks and complications associated with having breast implants?
2. How many additional operations of my implanted breast(s) can I expect over my lifetime?
3. How will my breasts look if I choose 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?

QUESTIONS TO ASK YOUR SURGEON ABOUT BREAST RECONSTRUCTION

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

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

FREQUENTLY ASKED QUESTIONS

What information should I get for my records?

If you are going to receive a breast implant, there are several important items of information you should have for your personal records before your surgery.

- **Patient information:** This may be in the form of a brochure, an information sheet, or an informed consent document.

For the approved saline-filled breast implants made by Mentor and McGhan, there are patient informed decision brochures that are available through your doctor, Mentor or McGhan, or on FDA's website at <http://www.fda.gov/cdrh/breastimplants>. These brochures describe the approved uses for those implants, factors to consider in your decision, risks, clinical results, etc. The brochures are to assist you in making your decision about whether or not to have these saline-filled breast implants.

To date, for all other breast implants other than Mentor's or McGhan's saline-filled implants (whether saline-filled or silicone gel-filled), you must be enrolled in a FDA-approved clinical study called an IDE study to receive the implant in the U.S. Additionally, you must sign the IDE informed consent document before surgery. The informed consent document for an IDE study describes the purpose of the clinical study, the risks associated with breast implants, etc. **It is advisable that you obtain a copy of the informed consent document from your doctor well in advance of your surgery so that you may better understand the risks involved and ask questions.** This should be kept as part of your records.

Note that the informed consent document described above is required for you to participate in an IDE study. This should not be confused with a standard consent form that a hospital requires to be signed by any patient.

Aside from the informed consent document required to participate in an IDE study, the patient labeling for the Mentor and McGhan saline-filled breast implants and this consumer handbook provide additional information for you to consider in your decision about whether or not to have breast implants.

- **Package insert:** You should also ask for a copy of the manufacturer's package insert for the breast implant you will receive. Each package insert contains important information about the precautions to be taken and the risks associated with the specific brand of implant. You should use this insert as a basis for discussion about the surgery with your doctor, and keep it for future reference.
- **Manufacturer's device sticker:** A copy of the sticker identifies the brand of the implant you will receive, its size, and the manufacturer's lot number. This data should be part of your personal medical record. It will be useful if you should have problems following surgery or seek care from another health care provider. Therefore, you should seek this information as soon as possible because doctors and hospitals do not keep medical records forever.
- **Insurance coverage:** Breast implant surgery (whether breast reconstruction or augmentation) and/or treatment of complications may not be covered by your health insurance. You should check with your insurance company regarding these coverage issues because, for some women, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Before surgery, be sure to get, in writing, answers from your insurance company to these questions, at minimum:

- ⇒ Does my policy cover the costs of the implant surgery, the implant, the anesthesia, and other related hospital costs? To what extent?
- ⇒ Does it cover removal and/or replacement of the implants if this becomes necessary? To what extent?
- ⇒ Does it cover the cost of detecting or treating a complication as a result of either the implant or the reconstruction? To what extent?
- ⇒ Will there be an increase in my insurance premium? To what extent?
- ⇒ Will future coverage be affected? To what extent?

Note that policies on coverage may change from year to year due to numerous reasons.

Should I tell other doctors in the future about my implants?

Yes. Whenever you give a medical history, be sure to inform the doctor that you have breast implants, just as you would tell him or her about other previous surgical procedures.

Do I need to get regular mammograms?

Women with breast implants who are in an age group where routine mammograms are recommended should be sure to have these examinations at the recommended regularly scheduled times. (Those who have had breast cancer surgery on both breasts should ask their doctors whether mammograms are still necessary.) However, women should be aware that breast implants may interfere with the detection of cancer and that

mammograms do not detect implant ruptures or leakage. The *Breast Implant Risks* section discusses rupture/leakage and the method of detection of rupture/leakage.

What about the Trilucentä (soybean oil-filled) implants?

The Trilucent™ is a breast implant with a silicone shell filled with purified soybean oil. LipoMatrix Inc., a subsidiary of Collagen Aesthetics, Inc. (DBA Collagen Corporation) was the former owner of this IDE. Now AEI Inc. (a company owned by Inamed) is the owner of this IDE. About 470 women (about 200 of who are in the U.S.) were enrolled in an IDE study to evaluate the safety and effectiveness of the implant. In 1997, the manufacturer stopped enrolling new patients into the IDE study. The IDE patients are being evaluated, and no new clinical studies are planned for this breast implant.

While these implants were never approved for marketing in the U.S., they were approved for marketing in Europe. The Medical Device Agency (MDA), the British equivalent of the FDA, removed the Trilucent™ implant from the market in the United Kingdom in March 1999 as a result of their investigation of reported adverse events. Their concern was that breakdown products of the soybean oil filler in Trilucent™ implants removed from some women were significantly different than the breakdown products predicted during preclinical testing. These breakdown products could result in some substances that are biologically active (react with body tissues), the toxic effects of which have not been adequately evaluated, but which could be cancer-causing. The MDA recommended that a woman with the Trilucent™ breast implant should consult her general practitioner or the doctor who performed the initial implantation. The MDA also advised that a woman should seek her doctor immediately if she notices unusual breast swelling or inflammation associated with a Trilucent™ breast implant.

After more research, in June 2000, the MDA issued a Hazard Notice entitled, “Trilucent™ Breast Implants: Recommendation to Remove” and a statement entitled, “Statement on the Safety of Trilucent Breast Implants.” Both are available on MDA’s website at <http://www.medical-devices.gov.uk>. Based on new toxicology information provided by AEI Inc. and reviewed by the Independent Advisory Group set up by MDA, the MDA recommended several immediate actions for women implanted with the Trilucent™ breast implants in the U.K. Among these actions, women were advised to have their Trilucent™ breast implants removed and to avoid pregnancy and breast-feeding while they still are implanted with their Trilucent™ implants. FDA worked with McGhan Medical (a company owned by Inamed and responsible for the U.S. clinical study) to develop a plan to contact all patients in the U.S. IDE study and request that they come in for an evaluation and for a discussion of the MDA findings and recommendations. Additional information from McGhan is available at <http://www.mcghan.com/trilucent/mcghan%20release.html> and <http://www.trilucentinfo.com/>. If you have questions regarding the Trilucent™ implant, you should contact McGhan (refer to *Breast Implant Resource Group* section).

Is there a test to detect silicone in the body or to determine if an individual is sensitive to silicone?

Currently, there are no FDA-approved tests to detect silicone in the body or to determine whether a woman's immune system is sensitive to any component of silicone breast implants.

Determining that silicon or silicone is present in body fluids does not indicate whether a person is sensitive to these substances or at risk for any specific disease. (Silicon is an element that is one component of the polymer silicone and is one of the most abundant elements on the earth. Everyone is exposed to silicon.) Some researchers reportedly

have developed a test that can detect antibodies to silicone in blood; however, the proven accuracy and usefulness of the test has not been determined. Some researchers have also reported that a test called the Anti-Polymer Antibody Assay may be able to distinguish signs and symptoms of disease ranging from mild to severe in women with implants. However, the biologic basis for the assay has not been established. The test remains to be proven as accurate, and, at this time, the clinical usefulness of the test results has not been determined.

Even if such antibodies were detected, the importance would be unclear. Antibodies to silicone would not necessarily mean that silicone is harmful or that a person would necessarily have an adverse reaction to it. Some researchers have also reportedly developed a test to detect if a woman's immune system is sensitive to silica, a component found in silicone breast implants. The accuracy of this test also has been questioned, and it is not clear at this time whether the results of this test have clinical usefulness.

Even if simple techniques to detect silicone were available, they might not be useful in detecting a rupture because small amounts of silicone oil ordinarily bleed even from intact implants. Further, because silicone is found in food and many other products, including commonly used medicines and cosmetics, the tests would not easily determine whether the silicone came from the implant or another source.

REPORTING OF SERIOUS PROBLEMS / MEDWATCH

What is MedWatch?

MedWatch, the FDA Medical Products Reporting Program, is designed to

- educate all health professionals about the critical importance of being aware of, monitoring for, and reporting adverse events and problems to FDA and/or the manufacturer
- ensure that new safety information is rapidly communicated to the medical community thereby improving patient care

These MedWatch databases consist of information from adverse event and product problem reports that FDA receives from manufacturers, user facilities, distributors, importers, and the general public.

These databases of adverse reports are most useful as an early warning system when the hazards of a device are previously unknown. FDA also uses these databases to follow trends with particular devices and look for signals that further follow-up could be needed.

What is an adverse event?

An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported when the patient outcome is:

- **Death:** Report if the patient's death is suspected as being a direct outcome of the adverse event.
- **Life-threatening injury or illness:** Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death.
- **Hospitalization:** Report if admission to the hospital or a longer hospital stay results because of the adverse event.
- **Disability:** Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function or structure, physical activities, or quality of life.
- **Birth Abnormality:** Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child.
- **Medical or surgical intervention:** Report if you suspect that the use of a medical product resulted in a condition that required medical or surgical intervention to prevent permanent impairment or damage to a patient.

What is a product problem?

Product problems (a defective or malfunctioning device problem) should be reported when there is a concern about the quality, performance, or safety of any medication or device. Problems with product quality may occur during manufacturing, shipping, or storage.

They include

- product contamination
- defective parts
- poor packaging or product mix-up
- questionable stability
- device malfunctions
- labeling concerns

With drugs, the pharmacist is often the first to recognize a product quality problem. Nurses are often the first to recognize a problem with a medical device. These suspicions should be reported to FDA through MedWatch.

How many reports of adverse events or product problems has FDA received?

From 1985 until January 2000, FDA received 127,770 adverse reaction reports for silicone gel-filled breast implants. During the same time period, FDA received 65,720 adverse reaction reports for saline-filled implants. (There may be some duplicate reports.) The greater number of reports for silicone gel-filled implants does not necessarily mean that there are more problems with this type of implant but may reflect that more women received silicone gel-filled implants than saline-filled implants. There were 1712 additional summary reported problems in which the type of implant was unknown.

As of January 2000, FDA received 123 reports of deaths reportedly related to breast implants. The reports are not confirmed by autopsy, and they do not show that breast implants necessarily caused the deaths. In fact, in some cases, the actual cause of death was not specified. A few of the reports related the cause of death to the surgical procedure for implants. This included problems with anesthesia during surgery, deaths

from surgical complications such as hemorrhage (heavy blood loss), or infection. The reports did not show that the implants themselves caused the reported deaths.

There were a few reports of women dying of the complications of diseases such as cancer or CTDs (e.g., rheumatoid arthritis). However, because these illnesses occur in people with and without the implants, there is no evidence that the implant actually caused the illnesses or the deaths. According to the scientific studies done so far, women do not have a significantly greater risk of illness, including scleroderma, rheumatoid arthritis and cancer, or death if they have breast implants (refer to the *Other Illnesses* section).

How are serious adverse events and device problems reported to the FDA?

Serious adverse events and product problems should be reported to the FDA either directly or through the manufacturer of the product.

User facilities (such as hospitals, nursing homes, etc.), under the Safe Medical Device Act of 1990 (SMDA), are legally required to report suspected medical device-related deaths to both FDA and the manufacturer, if known, and serious injuries to the manufacturer or to FDA if the manufacturer is unknown. Health professionals within a user facility should become familiar with their institution's procedures for SMDA reporting. Within a user facility, reporting deaths and serious injuries that occur with the use of medical devices is required by federal law and regulation. Meanwhile, reporting adverse events and product problems with medications (drugs and biologics) and special nutrition, although considered vital, is strictly voluntary.

Consumers and healthcare professionals should use the MedWatch program for reporting significant adverse events with medical products.

If you believe that you have experienced one or more serious problems related to your breast implants, we encourage you to have your healthcare professional report the problem(s) to the FDA. Although reporting by physicians or other health professionals is preferred, you may also report any serious problem directly through the MedWatch voluntary reporting system. If you are participating in a study, you should be reporting problems to your doctor so that information will be included in the study. However, if you wish, you may also report a serious problem directly to MedWatch. You should identify the study that you are participating in so that your problem report can be included in the appropriate database.

If you are a healthcare professional, call 1-800-332-1088 to receive a form or to report by phone.

If you are a consumer, call 1-888-463-INFOFDA (1-888-463-6332), from 10:00am – 4:00pm Eastern Time, Monday through Friday, to receive an FDA MedWatch Package. Ask your doctor to complete the MedWatch form and keep a copy of the completed form for your records.

For you to report a serious adverse event or device problem directly to FDA, use MedWatch form 3500. This form may be obtained through FDA's website at <http://www.fda.gov/medwatch/index.html>. Instructions for completing this form are located at <http://www.fda.gov/medwatch/report/consumer/instruct.htm>.

Mail the completed form to MedWatch, FDA Medical Products Reporting Program, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852-9787, or fax it to 1-800-332-1088.

The following information should be included in a MedWatch report

- the event or problem, described in detail
- the manufacturer, model, and brand name of the implant
- whether it is silicone gel or saline filled
- the year implanted and (if this applies) the year removed
- implant position/placement and size
- the reason implanted and the reason for removal (if this applies)
- diagnosis by your doctor (please include only information confirmed by a doctor's diagnosis)
- names of implanting and diagnosing doctors
- whether silicone has migrated, and if so, where and how this has been confirmed
- number of surgeries

You may attach records or other supporting material to the completed MedWatch form if you think it will be helpful to FDA.

Every voluntary report is read individually and reviewed by a health professional at FDA, who sends the reporter an acknowledgment letter. FDA will not contact you again unless we need additional information. The report is analyzed, coded, and used to assist FDA in taking regulatory actions. FDA will follow-up on unusual adverse events. The data are evaluated for trends every few months and used as background information for studies of adverse events with breast implants.

CHRONOLOGY OF FDA BREAST IMPLANT ACTIVITIES

- May 28, 1976: The Medical Device Amendments were enacted, giving FDA authority to regulate medical devices such as breast implants, which were already on the market.
- July 23, 1976: The FDA General and Plastic Surgery Devices Panel (referred to as the Panel) recommended that breast implants be placed in class II, requiring general controls and performance standards. As a note, under the law, there are three regulatory categories for medical devices. Class I devices are usually simple devices whose risks can be controlled by labeling and the manufacturing process. Class II devices require additional measures, called special controls, to control risks. Special controls may include performance standards, postmarket surveillance studies, user education, or other measures. If there is a lack of information about whether a device is safe and effective, it is put into class III, and the highest level of premarket review is required. Class III devices include innovative (creative), medical breakthrough, and new technology devices, as well as devices with poorly established or questionable safety and effectiveness.
- January 19, 1982: Because of some reports of adverse events in the medical literature, FDA announced a proposal to place breast implants in class III. Class III devices have strict controls for safety and effectiveness.
- June 24, 1988: FDA classified all breast implants into class III. After a prescribed waiting period of 30 months, FDA could require the submission of premarket approval applications (PMAs) in which manufacturers present data showing the safety and effectiveness of these devices.

- January - March 1989: An unpublished study showed that polyurethane foam, which was used as a coating on certain types of silicone gel-filled breast implants, would degrade and release 2-toluene diamine (TDA), a chemical known to cause cancer in animals, under conditions of high temperature and alkalinity. FDA requested specific information from the manufacturer about the chemical make up and safety testing of polyurethane foam. Shortly afterwards, the manufacturer of polyurethane-coated breast implants removed them from the market.
- May 17, 1990: FDA issued a proposed 515(b) regulation (call for safety and effectiveness data) in the *Federal Register* on silicone gel-filled implants.
- February 1-2, 1991: FDA sponsored a *Conference on Silicone in Medical Devices*. This was an exchange of scientific information and views on the applications of silicone in medical devices.
- April 10, 1991: FDA published a final 515(b) regulation in the *Federal Register* that required manufacturers of silicone gel-filled implants to submit PMAs with data showing the safety and effectiveness of the implants by July 9, 1991.
- June 1991: FDA required the manufacturer of polyurethane-coated implants to conduct research on the material. In taking this action, FDA made the first use of new postmarket surveillance authority under the Safe Medical Devices Act of 1990.
- July 31, 1991: The Panel reviewed FDA's risk assessment of polyurethane foam coating. The Panel found that the risk of cancer, if any, appears small and would very likely be outweighed by the surgical risk involved in removing a polyurethane-coated implant.

- August 22, 1991: FDA determined that PMAs submitted by three manufacturers of silicone gel-filled implants did not contain sufficient data to warrant a full review.
- September 26, 1991: FDA issued a Notice in the *Federal Register* requiring distribution of information to patients on the risks associated with saline-filled and silicone gel-filled breast implants.
- November 12-14, 1991: FDA convened the Panel to consider whether the PMA data received from the manufacturers was sufficient to establish that the silicone gel-filled implants are safe and effective. Despite the lack of data, the Panel voted unanimously (complete agreement) to advise FDA that the implants filled a public health need for breast reconstruction and revision for medical or surgical reasons and that the implants should continue to be available while the manufacturers collected additional data.
- January 6, 1992: FDA called for a voluntary moratorium (delay) on the use of silicone gel-filled implants until new safety information could be thoroughly reviewed by the Panel.
- February 18, 1992: The Panel met again to review new information on silicone gel-filled implants. This included case reports of autoimmune diseases, information not included in the manufacturers' original submissions to FDA, and evidence that some early models may have leaked excessively.
- March 19, 1992: Dow Corning withdrew from the silicone implant market but continued to supply gel to one implant manufacturer.
- April 16, 1992: FDA lifted the voluntary moratorium on breast implants. FDA also announced its decision to allow silicone gel-filled implants on the market only

under controlled clinical studies for reconstruction after mastectomy, correction of congenital deformities, or replacement of ruptured silicone gel-filled implants due to medical or surgical reasons. Until these clinical studies could be submitted and reviewed, FDA authorized temporary limited distribution of silicone gel-filled implants for reconstructive patients on an urgent need basis with a very detailed informed consent form. FDA denied applications for using silicone gel-filled breast implants for augmentation but planned that the manufacturers would later conduct clinical trials that would include a limited number of augmentation patients (the stage 3 or core studies).

- July 24, 1992: FDA approved Mentor Corporation's stage 2 (or adjunct study protocol) for silicone gel-filled implants for reconstruction and revision only.
- December 1992: Dow Corning announced that it would no longer make five implant grades of silicone for sale after March 31, 1993, but that it would continue to manufacture 45 other medical grades of silicone materials.
- January 8, 1993: FDA published a 515(b) proposal in the *Federal Register* calling for safety and effectiveness data for saline-filled implants. The proposal provided for a 60-day comment period.
- June 2, 1994: FDA sponsored a Part 15 Hearing on saline breast implants to hear testimony from all interested parties concerning the timing of the agency's review of the safety and effectiveness of saline-filled breast implants. FDA promised to make a decision by the end of the year.
- July 15, 1994: FDA granted conditional approval of an IDE pilot study of 50 patients for a breast implant filled with a purified form of soybean oil (Trilucent™ implant).

- October 21, 1994: FDA sponsored the workshop *Alternatives to Silicone Breast Implants*. The workshop provided a forum for FDA to present draft guidance concerning testing requirements for alternative breast implants.
- December 23, 1994: FDA issued a Talk Paper describing the types of studies required to demonstrate the safety and effectiveness of saline breast implants and the date the studies are expected to be completed. Preclinical data were submitted throughout 1995. Final clinical data were expected by early 1999.
- April 20, 1995: FDA updated the patient information sheet (entitled “Information for Women Considering Saline-Filled Breast Implants”) on the risks of saline-filled breast implants that manufacturers give to physicians who, in turn, provide them to patients considering implant surgery.
- January 11, 1996: FDA sent a letter to current and potential manufacturers of silicone gel-filled breast implants detailing the type of information needed for core studies (stage 3 studies) of the silicone gel-filled implants for augmentation, reconstruction, and revision patients.
- September 4, 1996: FDA cleared Poly Implants Protheses (PIP) for marketing of saline-filled breast implants through the 510(k) process.
- September 19, 1996: FDA received a Citizen's Petition from the Y-Me National Breast Cancer Organization and other related organizations requesting that the FDA ease restrictions on the availability of silicone gel-filled breast implants for women who choose reconstruction after a mastectomy and who have other special medical needs.

- February 11, 1997: FDA received a Citizen's Petition from implant recipients (who reported significant problems with their silicone implants) requesting that the FDA revoke permission granted to manufacturers to make silicone gel-filled breast implants available to women with breast cancer and women who previously had implants.
- May 20, 1997: FDA cleared Hutchinson International for marketing of saline-filled breast implants through the 510(k) process.
- October 15, 1997: FDA sent letters in response to the two Citizen's Petitions dated 9/19/96 and 2/11/97. The FDA responded to both petitioners that we do not, at this time, have sufficient information to change the current regulatory policy on silicone gel implants.
- 1997: The Department of Health and Human Services (DHHS) asked the Institute of Medicine (IOM) to conduct an independent, unbiased review of all past and ongoing scientific research regarding the safety of silicone breast implants. A committee of experts in relevant scientific and clinical areas was asked to evaluate past and ongoing studies of the relationship, if any, between implants and systemic disease; assess the biologic and immunologic effects of silicone and other chemical components of breast implants; assess the impact of breast implants, if any, on the offspring of women with implants; and assess the accuracy of mammograms.
- Spring 1998: The FDA completed a study to assess the rupture rate of silicone gel-filled breast implants.
- March 30, 1998: FDA approved McGhan Medical's Stage 2 (or adjunct study) protocol for silicone gel-filled breast implants for reconstruction and revision only.

- May 6, 1998: Mentor Corporation and its subsidiary, Mentor Texas, signed a consent decree of permanent injunction, promising that the company would manufacture its breast implants in compliance with the Quality System Regulation. The Quality System Regulation is critical in helping to assure that medical devices are consistently high in quality and are safe and effective. FDA permitted Mentor to continue marketing its breast implants because the deficiencies in Mentor's manufacturing process were not shown to result in a significantly increased risk to women who received this company's breast implants.
- June 5, 1998: FDA approved McGhan Medical's IDE study for silicone gel-filled breast implants for augmentation, reconstruction, and revision for a limited number of patients at a limited number of sites.
- November 12, 1998: FDA received a Citizen's Petition from Hyman, Phelps & McNamara requesting that FDA either withdraw the proposed rule calling for PMAs or PDPs for the saline-filled breast implant or reopen the comment period to allow interested persons to address the information that has become available since the publication of the 1993 proposed call for PMAs or PDPs. This petition was denied.
- February 1, 1999: FDA cleared Silimed, LLC for marketing of their pre-filled and inflatable saline-filled breast implants through the 510(k) process.
- June 22, 1999: The IOM released a comprehensive review of the published literature and ongoing studies on both saline-filled and silicone gel-filled breast implants entitled "Safety of Silicone Breast Implants." The IOM made a clear distinction between local complications and systemic health concerns. The IOM determined that there was insufficient evidence to establish that either or both types of breast implants cause systemic health effects, such as autoimmune disease, and

that there were no new health or safety issues associated with the use of both types of implants. The IOM also concluded that local complications are “the primary safety issue with silicone breast implants.” These local complications include rupture, pain, capsular contracture, disfigurement, and serious infection, which may lead to medical interventions and repeat surgeries. For more information, refer to <http://books.nap.edu/catalog/9602.html> for the IOM report, *Safety of Silicone Breast Implants*, and to <http://books.nap.edu/catalog/9618.html> for the consumer booklet on the IOM study, *Information for Women about the Safety of Silicone Breast Implants*.

- June 30, 1999: FDA received a Citizen's Petition from Anne Stanswell requesting that FDA ban the use of the silicone gel-filled breast implants. This petition was denied.
- October 1999: FDA issued a draft guidance entitled, “Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses.” This guidance is for saline, silicone gel, and alternative breast implants and is intended to replace FDA’s other guidances for individual types of breast implants.
- August 19, 1999: FDA published a final 515(b) regulation in the *Federal Register* that required manufacturers of saline-filled implants to submit PMAs with data to establish the relative safety and effectiveness of the implants within 90 days.
- March 1-3, 2000: Panel meeting was held to discuss the safety and effectiveness data submitted in PMAs from Mentor, McGhan, and PIP. The Panel recommended that Mentor and McGhan’s PMAs be approved with conditions and that the PIP PMA be disapproved. Additionally, a day of this Panel meeting was dedicated towards obtaining public input on patient labeling.

- May 10, 2000: FDA granted approval of Mentor's and McGhan's saline-filled breast implant PMAs. The clinical trials conducted by Mentor and McGhan on saline-filled breast implants provided data on the types and rates of local complications experienced by patients. These complication data are provided in the patient labeling available on our FDA website at <http://www.fda.gov/cdrh/breastimplants>. The 3-year cumulative risk rates are also summarized in our May 10, 2000 press release available at <http://www.fda.gov/bbs/topics/NEWS/NEW00727.html>. Despite complications experienced by some women, the majority of those women still in the McGhan and Mentor studies after three years reported being satisfied with their implants; however, this does not include women who had their implants removed due to problems and were dropped from the studies. To date, all other saline-filled breast implants are considered investigational.
- August 2, 2000: FDA approved Mentor's IDE study for silicone gel-filled breast implants for augmentation, reconstruction, and revision for a limited number of patients at a limited number of sites.

BREAST IMPLANT RESOURCE GROUPS

The following list provides sources of information and organizations involved in breast implant issues. The list is provided for information purposes only and does not constitute an endorsement by the FDA of the information or recommendations they may provide. At the end of this section is federal government contact information.

MANUFACTURERS

Current Manufacturers of Silicone Gel-Filled Implants:

McGhan Medical Corporation
700 Ward Drive
Santa Barbara, CA 93111-2936
1-800-862-4426

Mentor Corporation
5425 Hollister Avenue
Santa Barbara, CA 93111
1-800-525-0245

Former Manufacturers of Silicone Gel-Filled Implants:

Baxter Healthcare Corporation
1385 Centennial Drive
Deerfield, IL 60015
1-800-323-4533

Bioplasty, Inc.
1385 Centennial Drive
St. Paul, MN 55113
1-800-328-9105

Dow Corning Corporation
P.O. Box 994
Midland, MI 48686-0994
1-800-442-5442

Medical Engineering Corporation
(A Bristol-Myers Squibb Company)
2317 Eaton Lane
Racine, WI 53404
414-632-3717

Porex Technologies
500 Bohannon Road
Fairburn, GA 30213
1-800-241-0195

Surgitek (replaced by Medical Engineering Corp.)
3037 Mt. Pleasant Street
Racine, WI 53404

Current Manufacturers of Saline -Filled Implants:

McGhan Medical Corporation
700 Ward Drive
Santa Barbara, CA 93111
1-800-862-4426

Mentor Corporation
5425 Hollister Avenue
Santa Barbara, CA 93111
1-800-525-0245

Cosmetic Surgery Suppliers (CSS)
CSS Implants Division
2088 Idlewood Road, Suite #2A
Tucker, GA 30084
1-800-525-7752

Poly Implants Protheses/USA
9831 East Evergreen St.
Miami, FL 33157
888-700-9831

Hutchison International, Inc.
7949 Jefferson Highway
Baton Rouge, LA
225-927-6800

Silimed, L.L.C.
802 Easy Street
Garland, TX 75042
888-423-7600

Novamed Medical Products Manufacturing, Inc.
623 Hoover Street N.E.
Minneapolis, MN 55369
612-378-1437

Former Manufacturer of Saline -Filled Implants:

PMT Corporation
1500 Park Road
Chanhassen, MN 55317
1-800-626-5463

PHYSICIAN, NURSING, and INDUSTRY GROUPS

American Academy of Allergy & Immunology
611 East Wells Street
Milwaukee, WI 53202
414-272-6071
Fax: 276-3349

American Academy of Clinical Toxicology
Kansas State University
Comparative Toxicology Laboratories
Manhattan, KS 66506-5606
785-532-4334
Fax: 785-532-4481
Fred Oehme

American Academy of Cosmetic Surgery
401 N. Michigan Ave.
Chicago, IL 60611-4267
312-527-6713
Fax: 312-644-1815
Website: <http://www.cosmeticsurgery.org>
Email: aacs@spa.com

American Academy of Nurse Practitioners
P.O. Box 40130
Washington, D.C. 20016
202-966-6414
Fax: 202-966-2856
Dr. Jan Towers

American Association for Clinical Chemistry
2101 L Street, N.W.
Washington, D.C. 20037-1526
202-835-8744
Fax: 202-887-5093
Email: jrhame@aacc.org

American Association for Neurological Surgeons
22 South Washington Street, Suite 100
Park Ridge, IL 60068
708-692-9500
Fax: 708-692-2589
Email: bhr@aans.org

American College of Chest Physicians
3300 Dundee Road
Northbrook, IL 60062
847-498-1400
Fax: 847-498-5460
Email: chestp@aol.com

American College of Obstetricians & Gynecologists
409 12th Street, S.W.
Washington, D.C. 20024
202-863-2511
Fax: 202-488-3985
Email: kbryant@acog.com

American College of Osteopathic Ob/Gyn
900 Auburn Road
Pontiac, MI 48342
248-332-6360
Fax: 248-332-4607
Jaki Britton

American College of Radiology
1891 Preston White Drive
Reston, VA 22091
703-648-8904
Fax: 703-836-0567

American College of Surgeons
633 N. St. Claire Street
Chicago, IL 60611
312-202-5000
Fax: 312-202-5001
Website: <http://www.facs.org>

American Gastroenterological Association
6900 Grove Road
Thorofare, NJ 08086
609-848-9218
Fax: 609-853-5991

American Hospital Association (AHA)
Capitol Place, Building #3
50 F. Street N.W., Suite 1100
Washington, D.C. 20001
202-638-1100
Fax: 202-626-2345 (main receptionist desk)
Fax: 202-626-4630 (Fax directly to Dr. Bentley)
James D. Bentley, Ph.D., Senior Vice President for Policy

American Medical Association
515 North State St.
Chicago, IL 60610
312-464-4370
Fax: 312-464-5896
Website: <http://www.ama-assn.org>

American Medical Women's Association
801 N. Fairfax St.
Alexandria, VA 22314
703-838-0500
Fax: 703-549-3864
Eileen McGrath

American Nurses Association
Suite 100W
600 Maryland Ave., S.W.
Washington, D.C. 20024-2571
202-554-4444 x270
Fax: 202-651-7001
Website: <http://www.nursingworld.org>

American Physical Therapy Association
1111 North Fairfax Street
Alexandria, VA 22314
703-684-2782
Fax: 703-706-8519

American Public Health Association
1015 15th Street, N.W.
Washington, D.C. 20005
202-789-5600
Fax: 202-789-5661

American Society for Aesthetic Plastic Surgery
11081 Winners Circle, Suite 200
Los Alamitos, CA 90710
888-272-7711
Fax: 562-799-1098
Website: www.surgery.org

American Society for Microbiology
1325 Massachusetts Avenue, N.W.
Washington, D.C. 20005
202-737-3600
Fax: 202-737-0233
Email: amelnick@asmusa.org

American Society of Clinical Oncology
225 Reinekers Lane, Suite 650
Alexandria, VA 22314 USA
703-299-1058 or 888-282-2552

American Society of Plastic Surgeons
444 E. Algonquin Road
Arlington Heights, IL 60005
1-800-635-0635
Fax: 847-228-7099
Website: <http://www.plasticsurgery.org>

American Society of Plastic and Reconstructive
Surgical Nurses
East Holly Avenue, Box 56
Pitman, NJ 08071-0056
609-256-2340
Fax: 609-489-7463
Website: <http://asprsn.inurse.com/>

American Urological Association
1120 North Charles Street
Baltimore, MD 21201
410-727-1100
Fax: 410-223-4370
Email: aua@auanet.org

Association of Reproductive Health Professionals
2401 Pennsylvania Avenue, N.W., Suite 350
Washington, D.C. 20037
202-466-3825
Fax: 202-466-3826
Wayne Shields, President & CEO

Chemical Specialty Manufacturers Association
(CSMA)
1913 I Street, N.W.
Washington, D.C. 20006
202-872-8110
Fax: 202-872-8114
Ralph Engel, President

College of American Pathologists
325 Waukegan Road
Northfield, IL 60093
708-446-8800
Fax: 708-446-8807

Emergency Care Research Institute (ECRI)
5200 Butler Pike
Plymouth Meeting, PA 19462
610-825-6000
Fax: 610-834-1275
Joel Nobel, President

Food and Drug Law Institute (FDLI)
1000 Vermont Avenue, N.W., Suite 200
Washington, D.C. 20005
202-371-1420
Fax: 202-371-0649
Email: comments@FDLI.org (comments)
Email: JSA@FDLI.org (announcements)
John C. Villforth, President

Health Industry Manufacturers Association (HIMA)
1200 G. Street, N.W., Suite 400
Washington, D.C. 20005
202-783-8700
Fax: 202-783-8750
Email: database@himanet.com
Alan H. Magazine, President

Health Resources Services Assoc./OWH
5600 Fishers Lane, Rm. 14-25
Rockville, MD 20857
301-443-8695
Fax: 301-443-8587

Medical Alley
1550 Utica Avenue, South
Minneapolis, MN 55416
612-542-3077
Fax: 612-542-3088
Thomas Meskan, Executive Director

Medical Device Manufacturers Association (MDMA)
1900 K Street, N.W. Ste. 300
Washington, D.C. 20006
202-496-7150
Fax: 202-496-7756
Email: snorthrup@medicaldevices.org
Stephen J. Northrup, Executive Director

National Black Nurses Association
8630 Fenton St. Suite 330
Silver Spring, MD 20910
301-589-3200
Fax: 301-589-3223
Millicent Gorham

National Medical Association
1012 10th St., N.W.
Washington, D.C. 20001
202-347-1895
Fax: 202-842-3293
Website: <http://www.nmanet.org/>
Yolanda Flemming

CONSUMER GROUPS

AMC Cancer Research Center
1600 Pierce St.
Denver, CO 80214
1-800-525-3777

American Cancer Society
1599 Clifton Rd. NE
Atlanta, GA 30329
1-800-ACS-2345
Website: <http://www.cancer.org>

Arthritis Foundation
PO Box 7669
Atlanta, GA 30357-0069
404-872-7100, x6350
1-800-283-7800
Website: <http://www.arthritis.org>

Boston Women's Health Book Collective
P.O. Box 192
West Somerville, MA 02144
617-625-0277
Fax: 617-625-0294

Breast Cancer Action
55 New Montgomery Suite 323
San Francisco, CA 94105
415-243-9301
Barbara Brenner

Cancer Hope Network
231 North Avenue West
Westfield, NJ 07090-1420
1-877-HOPENET

The Cancer Letter
P.O. Box 9905
Washington, D.C. 20016
202-362-1809
Fax: 202-362-1681
Kristen Goldberg

CANDO (Chemically Associated/Neurological Disorders)
P.O. Box 682633
Houston, TX 77268-2633
281-444-0662
Fax: 281-444-5468
Email: keeling.m@worldnet.att.net

Center for Women Policy Studies
1211 Connecticut Avenue, Suite 312
Washington, D.C. 20036
202-872-1770
Fax: 202-296-8962
Leslie Wolfe

Central Texas Silicone Implant Support, Inc.
1900A Gracy Farms Lane
Austin, TX 78758
Phone & Fax: 512-837-5254
Email: jcraig@realtime.net

Children Afflicted by Toxic Substances (CATS)
413 Fort Salonga Road
Northport, NY 11768
631-757-4829
Fax: 631-757-4872
Email: catstoxic@aol.com

Coalition of Silicone Survivors (COSS)
P.O. Box 129
Broomfield, Co 80038-0129
970-506-9288
Fax: 970-506-9288
Email: coss1@uswest.net
Lynda Roth

Command Trust Network
256 South Linden Drive
Beverly Hills, CA 90212

Humantics Foundation for Women
Breast Implants: Recovery & Discovery
1380 Garnet #444
San Diego, CA 92109
858-270-0680
Email: ilena@san.rr.com
and ilena2000@hotmail.com
Website: <http://www.info-implants.com/Quebec/Espoir/03.html> and
<http://www.toxic-exposure.com>
Ilena Rose

Implant Information Foundation
P.O. Box 2907
Laguna Hills, CA 92653

International Cancer Alliance for Research and Education
4853 Cordell Avenue, Suite 11
Bethesda, MD 20814
301-654-7933
Dave Hankins

Kentucky Women's Health Network
P.O. Box 5471
Louisville, KY 40255-0471
502-897-2774
Fax: 502-893-6200
Email: mtbears@worldnet.att.net

Lupus Foundation of America
1300 Piccard Drive, Suite 200
Rockville, MD 20850
1-800-558-0121
Fax: 301-670-9486
Email: lupusinfo@aol.com

National Alliance of Breast Cancer Organizations
9 East 37th St., 10th Floor
New York, NY 10016
212-889-0606
Fax: 212-939-1213
Email: Nabco.info@aol.com
Website: <http://www.nabco.org/>
Amy Langer

National Asian Women's Health Org. (NAWHO)
250 Montgomery St., Suite 1500
San Francisco, CA 94104
415-989-9747
Fax: 415-989-9758
Jennifer Stoll-Hadaya

National Association for Women's Health
300 N. Adams, Suite 328
Chicago, IL 60606-5101
312-786-1468
Fax: 312-786-0376
Email: fbloom@nawh.org
Felicia Bloom

National Black Women's Health Project
600 Pennsylvania Ave., S.E. Suite 310
Washington, D.C. 20003
202-543-9311
Fax: 202-543-9743
Email: nbwhp@nbwhp.org
Website: <http://www.nbwhp.org/>
Julia Scott

National Breast Cancer Coalition
1707 L St., N.W. Suite 1060
Washington, D.C. 20036
202-296-7477
Jennifer Levin

National Breast Implant Task Force
P.O. Box 210503
West Palm Beach, FL 33414
561-791-2625
Fax: 561-791-4419

National Center for Policy Research for Women and Families
1444 Eye Street, N.W., Suite 900
Washington, D.C. 20005
202-216-9507
Website: <http://www.cpr4womenandfamilies.org/>
Diana Zuckerman, Ph.D., Executive Director

National Chronic Fatigue Syndrome and Myalgia Association
P.O. Box 18426
Kansas City, MO 64133
816-931-4777

National Council of Negro Women
633 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
202-737-0120
Fax: 202-737-0476
J. Lawrence Miller

National Women's Health Network
514 Tenth Street, N.W., Suite 400
Washington, D.C. 20004
202-347-1140
Fax: 202-347-1168
Website: <http://www.womenshealthnetwork.org/>
Cindy Pearson

National Women's Health Resource Center
120 Albany St. Suite 820
New Brunswick, NJ 08901
202-537-4702
Fax: 301-320-3762
Beth Battaglino, Director of Marketing

Plaintiffs' Liaison Council
2008 Second Avenue, N.
Birmingham, AL 35203
205-252-6784
Fax: 205-252-0423
Email: dburchfield@breastimplant.org

Planned Parenthood
1120 Connecticut Avenue, N.W., Suite 461
Washington, D.C. 20036
202-785-3351
Fax: 202-296-2318
Jacquelyn Lendsey, VP Public Policy

Public Citizen Health Research Group
1600 20 St., N.W.
Washington, D.C. 20009
202-588-1000
Website: <http://www.citizen.org/>

Scleroderma Foundation
89 Newbury St
Danvers, MA 01923
1-800-722-HOPE
Fax: 978-750-9902
Email: sfinfo@scleroderma.org
Website: <http://www.scleroderma.org/>

The Silicone Survivors Support Network
P.O. Box 117
Fairhope, AL 36532
334-928-7731

The Society for Women's Health Research
1828 L St., N.W. Suite 625
Washington, D.C. 20036
202-223-7009
Fax: 202-833-3472
Connie Tomber

Toxic Discovery Network, Inc.
1906 Grant Lane
Columbia, MO 65203
573-445-0861
Fax: 573-445-0861
Email: toxicdiscovery@plateauconsulting.com or
breastimplantinfo@plateauconsulting.com
Website:
[http://www.plateauconsulting.com/toxicdiscoverynet
work/](http://www.plateauconsulting.com/toxicdiscoverynetwork/)
Kathy Keithley Johnston, RN, Breast Implant
Consultant

Toxic 2 KIDS
915 Rustic Drive
Macon, MO. 63552
660-385-4621
Fax: 660-385-3289
On-line Newsgroup: toxic2kids@egroups.com
Website:
[http://www.plateauconsulting.com/toxicdiscoverynet
work/toxickids.html](http://www.plateauconsulting.com/toxicdiscoverynetwork/toxickids.html)
Chair: Cindy Fuchs-Morrissey –
Fuchs/Morrissey@hotmail.com
Co-Chair: Ed Brent – brentko@mindspring.com

United Silicone Survivors of the World, Houston
Chapter
12615 Misty Valley
Houston, TX 77066
281-448-9760 or 281-444-4796
Fax: 281-448-4330
Email: Keeling.m@worldnet.att.net

WASP-Wisconsin
Chetek, WI 54728
715-924-3691

Y-ME National Breast Cancer Organization
212 West Van Buren
Chicago, IL 60607-3908
1-800-221-2141
Fax: 312-294-8597
Website: <http://www.y-me.org/>

FEDERAL GOVERNMENT

The Consumer Affairs Staff of FDA's Office of Health and Industry Programs (OHIP) is responsible for answering breast implant calls and distributing the breast implant handbook.

To receive a copy of the breast implant handbook, please call 1-888-463-6332. When prompted, press 1, press 3, press 1, press 6, and then press 2 for the handbook (or 1 to hear the latest information on breast implants). The breast implant handbook may also be obtained by visiting FDA's website at <http://www.fda.gov/cdrh/breastimplants/indexbip.html>.

The Consumer Affairs Staff at OHIP is available Monday through Friday, 8:00am to 4:30pm Eastern Time. To contact the Consumer Affairs Staff, use one of the following options:

- *Call 301-827-3990.*
To speak to a Consumer Affairs Specialist during business hours, press 5. To request information outside of business hours, press 4 and leave a message.
- *Call 1-888-463-6332.*
When prompted, press 1, press 3, press 2, press 4, and press 1. Then, to speak to a Consumer Affairs Specialist during business hours, press 5, or to request information outside of business hours, press 4 and leave a message.
- *Fax 301-443-9535.*
- *Email DSMA@cdrh.fda.gov.*

Additional information may be found by visiting another FDA website at <http://www.fda.gov/cdrh/consumer/index.shtml>. Click on "Products Regulated" on the left side, then click on "B" and scroll down to "Breast Implants."

The following is additional federal government contact information:

Food and Drug Administration
Office of Consumer Affairs
5600 Fishers Lane, Rm. 16-59
Rockville, MD 20857
1-888-INFO-FDA

Food and Drug Administration
Office of Women's Health
5600 Fishers Lane, Rm. 14-62
Rockville, MD 20857

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs
HFZ-210
1350 Piccard Drive
Rockville, MD 20850

Food and Drug Administration
Center for Devices and Radiological Health
Division of Mammography Quality and Radiation
Programs
1350 Piccard Drive, HFZ-240
Rockville, MD 20850

Institute of Medicine
National Academy of Sciences
Committee on the Safety of Silicone Breast Implants
2101 Constitution Ave., N.W.
Washington, D.C. 20418
202-334-1318
Fax: 202-334-2939
Website: <http://www.nas.edu/>

National Cancer Institute
Office of Cancer Communications
Building 31, Room 10A-24
9000 Rockville Pike
Bethesda, MD 20892
1-800-4-CANCER (226237)

National Institute of Health/OWH
Office of Research on Women Health
Bldg. 1, Room 201
1 Center Drive
Bethesda, MD 20892
301-402-1770
Fax: 301-402-1798
Vivian Pinn

Medicare Hotline
1-800-MEDICARE

CURRENT BIBLIOGRAPHIES

The National Library of Medicine (NLM) offers publications in its Current Bibliographies in Medicine (CBM) series free-of-charge through the World Wide Web. Bibliographies in the CBM series are produced by staff of NLM's Reference Section in collaboration with subject specialists from the National Institutes of Health and elsewhere. Each bibliography is prepared by searching a variety of online databases and covers a separate topic of current interest. The result is a subject-categorized list of citations to the recent literature, primarily journal articles and books. CBMs may be retrieved from the Library's Web site at <http://www.nlm.nih.gov/pubs/resources.html>.

The IOM report, *Safety of Silicone Breast Implants*, is available for sale from National Academy Press, 2101 Constitution Avenue, N.W., Box 285, Washington, DC 20055 or call 800-624-6242 or 202-334-3938 or through the web at <http://books.nap.edu/catalog/9602.html>. The IOM report may also be read at the same website for free. A consumer booklet on the IOM study, *Information for Women about the Safety of Silicone Breast Implants*, can be purchased from the National Academy of Sciences on their website at <http://books.nap.edu/catalog/9618.html> or read at the same website for free.

FDA FREEDOM OF INFORMATION

We sincerely hope that the information in this packet has been of help to you. If you need more information, please submit a written request to the FDA Freedom of Information Staff.

The Freedom of Information Act (FOIA) allows anyone to request FDA records. However, under FOIA, information that is deemed exempt from disclosure may not be released to the public. Examples of this type of information typically include: preclinical or clinical data from ongoing, completed or discontinued studies; mechanical drawings; chemical compositions; etc. For instance, FDA cannot acknowledge the existence of an investigational study unless we know that the manufacturer has gone public with that information. Even then, in most cases, no details of that study can be given per FDA regulations. We are not denying any request; however, this clarification is provided so that you do not have unrealistic expectations on what information you can obtain through FOIA.

To access additional information on FOIA, to check to see if the information you want is already on FDA's website, to find out about FDA public reading rooms, and to access the complete handbook for requesting information through FOIA, please go to our website at <http://www.fda.gov/cdrh/foicdrh.html>

If you want to request information under FOIA, you must submit a written request to the following address:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857
Fax: 301-443-1726
Voice Mail Message: 301-827-6500

The letter should include your name, address and telephone number, as well as a statement of the desired records, identified as specifically as possible. A request for specific information that is releasable to the public can be processed much more quickly than a request for all information on a particular subject. There are fees for searching and reviewing the information plus a charge of 10 cents per page. You are billed after your request for information has been filled.

If you have submitted a FOIA request and you have questions relating to its status, please write to:

Freedom of Information Staff (HFZ-82)
Center for Devices and Radiological Health
Food and Drug Administration
2094 Gaither Road
Rockville, MD 20850
Fax: 301-594-4792

Breast implant documents involving our recent PMA approvals for two saline-filled breast implants may be of interest to you. For example, the Summary of Safety and Effectiveness (SSE) for each PMA may be obtained through FOIA. However, the transcripts for the March 1-3, 2000 Panel meeting for these saline-filled breast implants, as well as the patient labeling, for these implants are already available on our website at <http://www.fda.gov/cdrh/breastimplants/>.

Note: As an alternative source of information on breast implants, you should be aware that there is a comprehensive collection of FDA breast implant documents handled by the Plaintiffs' Liaison Counsel, which is independent from FDA and its FOIA Staff. Upon the order of Judge Pointer, FDA released all relevant breast implant information that we had up to February 1993. If the information you are seeking occurred before this date, you should consider contacting the Plaintiffs' Liaison Counsel at the telephone number or address below.

While FDA formerly referred to this comprehensive collection as the “Pointer Compendium,” the Plaintiffs’ Liaison Counsel stated that you should refer to that collection as “those documents produced by FDA to the national depository in the national breast implant litigation MDL926.”

This comprehensive collection of documents, along with an objective index allowing a requestor to access these documents, is available on CD. The collection includes items such as

- material related to advisory panel meeting in 1991 and 1992
- *Federal Register* notice for silicone gel-filled implants
- correspondence and meeting minutes concerning silicone and breast implants
- public statements issued by FDA
- FDA meeting minutes discussing elements of informed consent for silicone gel-filled implants
- documents related to compliance with FDA-imposed requirements
- documents in FDA field offices
- administrative files concerning breast implant manufacturers
- 10 PMA applications for silicone gel-filled breast implants as well as correspondence and other related materials
- FDA filings in breast implant-related litigation
- testimony prepared for Congressional hearings regarding silicone gel implants
- material related to IND 2702 (Dow Corning’s early investigation into soft tissue augmentation with silicone fluid injections)

The Plaintiffs’ Liaison Counsel may also be contacted for general assistance and information on breast implant litigation.

Please be aware that there will be independent charges assessed for this information also. Questions on the specific contents of this comprehensive collection or requests for specific records are to be directed to:

Plaintiffs' Liaison Counsel
2008 2nd Avenue
Birmingham, Alabama 35203
205-252-6784
Fax: 205-252-0423