FDA Breast Implant Consumer Handbook

2004

June 2004

Dear Reader:

The Food and Drug Administration (FDA) is pleased to provide you the newly revised "FDA Breast Implant Consumer Handbook – 2004." This replaces the previous version of the 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 the status of breast implants, potential complications, issues to consider, timeline of FDA activities related to breast implants, and breast implant resource groups.

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

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

You may also be interested in joining the Breast Implant Listserv to receive emails about upcoming events, panel meetings, frequently asked questions, etc. associated with breast implants. You may join the Breast Implant Listserv by visiting FDA's website at http://www.fda.gov/cdrh/breastimplants/.

We hope the information in this handbook will be helpful to you. You may duplicate the information for further distribution. If you have any comments regarding this handbook, please email us through the link at the bottom of FDA's website at http://www.fda.gov/cdrh/breastimplants/ or 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,

Samie Allen
FDA Breast Implant Team Leader
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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GLOSSARY

Below are brief definitions for some of the words used in this handbook.

Adjunct study	Clinical study for silicone gel-filled breast implant to address a public health need for reconstruction and revision patients. The status of the implants in an adjunct study is investigational.
Asymmetry	Uneven appearance between a woman's breasts in terms of size, shape, or breast level.
Augmentation	Includes cosmetic uses, such as to increase breast size or for ptosis (sagging or drooping of the breast) or asymmetry. Augmentation is one of three indications (clinical uses) for breast implants.
Breast pain	Pain in the nipple or breast area. See the **Local Complications & Reoperations** section for more details.
Breast pocket	A pocket surgically created to hold the implant.
Breast tissue atrophy	Thinning and shrinking of the skin.
Calcification/ calcium deposits	Hard lumps under the skin around the implant. These can be mistaken for cancer during mammography, resulting in additional surgery, either to biopsy the lumps or to remove the implant.
Capsular contracture	Scar tissue or capsule that normally forms around the implant, which tightens or squeezes the implant. There are four grades of capsular contracture ranging from grade I (breast is normally soft and looks natural) to grade IV (breast is hard, painful, and looks abnormal). See the **Local Complications & Reoperations** section for more details.
Chest wall deformity	When the chest wall or underlying rib cage appears deformed following removal of the implants and breast tissue.
Delayed wound healing	Incision site fails to heal normally or takes longer to heal.
Extracapsular rupture	Rupture of silicone gel-filled breast implant in which the silicone gel is outside of the fibrous scar capsule that forms around the implant.

Extrusion	Skin breakdown with the implant appearing through the skin.
Galactorrhea	Inappropriate breast milk production that may occur after breast implant surgery. In some cases, the milk production stops by itself or after receiving medicine to stop milk production. In other cases, the implant(s) may need to be removed to treat this complication.
Granuloma	Non-cancerous lumps that can form when certain body cells surround foreign material, such as silicone. Like any lump, it should be evaluated to distinguish it from a lump that might be cancerous.
Hematoma	Collection of blood inside a body cavity. Swelling, pain, and bruising may result. If a hematoma occurs, it will usually be soon after surgery; however, it can also occur at any time after injury to the breast. While the body absorbs small hematomas, large ones may require the placement of surgical drains for proper healing. A small scar can result from surgical draining.
Iatrogenic injury/damage	Injury/damage to the tissue or implant due to surgical instruments either during the operation, during a reoperation, during implant removal, or during breast procedures while the implant is in place (e.g., cyst aspiration or hematoma drainage).
Infection	Can occur with any surgery when wounds are contaminated with micro-organisms such as bacteria or fungi. 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. Another implant may be placed after the infection is gone.
Inframammary	Within the breast fold.
Inflammation/ irritation	Swelling of the breast area, usually with redness.
Intracapsular rupture	Rupture of silicone gel-filled breast implant in which the silicone gel remains contained within the fibrous capsule.
Investigational	Not approved, in general terms. For breast implants, this means not PMA-approved.

Investigational Device Exemption (IDE)	Clinical study performed to collect clinical data on a device to support approval of a marketing application. Approval of an IDE study does not mean approval to market the implant. The status of a device in an IDE study is investigational.
Local complications	Complications that occur in the breast or chest area.
Malposition/ displacement	When the implant is placed incorrectly during the initial surgery or when the implant has moved/shifted from its original position. Shifting can be caused by many factors, such as gravity, trauma, poor initial placement, and capsular contracture.
Mastectomy	Partial or complete removal of the breast.
Mastopexy	Surgical procedure to raise and reshape sagging breasts. Women may also have this surgery after an implant is removed and not replaced.
Necrosis	Formation of dead tissue around the implant. Factors associated with increased necrosis include infection, use of steroids in the surgical breast pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.
Nipple/breast sensation changes	An increase or a decrease in the sensation in the nipple or breast. This change can vary in degree and may be temporary or permanent. It may affect comfort while nursing or sexual response. See the **Local Complications & Reoperations** section for more details.
Palpability/ visibility	Palpability is when the implant can be felt through the skin. Visibility is when the implant can be seen through the skin, such as the valve on a saline-filled breast implant or the edge of an implant.
Periareolar	Around the nipple.
Premarket approval (PMA)	Application for marketing a device. FDA must approve the PMA for the device to be sold on the market in the U.S.

Prospective study	Study in which people are exposed to a medical intervention, such as breast implants, and then observed over time to determine how effective and safe the intervention is. The outcome is not known when a prospective study is started. Medical evaluations are performed before and after the intervention so that the outcome of the intervention can be measured.
Ptosis	Sagging/drooping of the breast.
Reconstruction	Includes non-cosmetic uses such as post-mastectomy, a severe injury to the breast, a birth defect that affects the breast, or a medical condition causing a severe breast abnormality. Reconstruction is one of three indications (clinical uses) for breast implants.
Redness/ bruising	Bleeding at operative site that causes discoloration and varies in degree and length of time. This is expected following breast implant surgery or breast procedures.
Reduction mammoplasty	Surgical procedure to reduce breast size.
Removal	Removal of the implant, with or without replacement. See the **Local Complications & Reoperations** section for more details.
Reoperation	Any additional surgery performed to the breast or chest area. See the **Local Complications & Reoperations** section for more details.
Retrospective study	Study that begins after a medical intervention, such as breast implant surgery, has occurred. Therefore, it looks backward in time at events complications that happened in the past. For instance, a group of women with breast implants may be identified and then asked to allow researchers to review their medical records to obtain information on complications that they had. Women might also be asked to respond to a survey or interview about whether or not they had complications with their implants. The problem with this type of study is that it assumes that if there was a problem, it would be in the medical record or that someone would remember it accurately.
Revision	This is replacement of an existing breast implant. Revision is one of three indications (clinical uses) for breast implants.

Rupture/ deflation	Hole or tear in the shell of the implant that allows for loss of the filler material from the shell. See the **Local Complications & Reoperations** section for more details.
Scarring	Formation of tissue at the incision. All wounds heal by the formation of a scar. The degree of scarring varies from person to person, and skin type is an important factor for the development of scars. If the scarring becomes irregular and raised, it is called hypertrophic scarring. This may leave a visible, permanent scar. The keloid, a severe type of hypertrophic scar, generally does not fade or flatten with time.
Seroma	Collection of the watery portion of the blood around the implant or around the incision. Swelling, pain, and bruising may result. While the body absorbs small seromas, large ones will require the placement of surgical drains for proper healing. A small scar can result from surgical draining.
Silent rupture	Rupture of a silicone gel-filled breast implant that happens without a visible change or feel by the woman and is not evident by a physical examination by the doctor.
Silicone	Silicone is a man-made material that can be found in several forms such as oil, gel, or rubber (elastomer). The exact make-up of silicone will be different depending on its use. See the **Device Description** section for more details.
Subglandular	When the implant is placed under and within the breast glands but on top of the chest muscles.
Submuscular	When the implant is placed underneath the chest muscles.
Toxic Shock Syndrome	Rare, but life-threatening bacterial infection that may occur after surgery. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and sunburn-like rash. **A doctor should be seen immediately for diagnosis and treatment if toxic shock syndrome is suspected.**
Transaxillary	Under the arm.
Unsatisfactory style/size	Patient or doctor is not satisfied with the overall look based on the style or size of implant used.

Wrinkling/ rippling	Wrinkling of the implant that can be felt or seen through the skin.
510(k)	Application for marketing a device. In the past, breast implants were reviewed under the 510(k) process. However, they are now reviewed under the PMA process.

INTRODUCTION

The three basic types of breast implants are saline-filled, silicone gel-filled, and alternative (e.g., soybean oil) implants. Breast implants are designed for treatment of augmentation, reconstruction, and revision patients. While many women believe breast implants cause illnesses, such as autoimmune disease, this is not proven at this time. However, most women with breast implants will experience local complications, such as pain, capsular contracture, and rupture/deflation. You may need to have nonsurgical treatments or reoperations to treat local complications. Breast implants do NOT last a lifetime. You should be prepared for long-term follow-up, reoperations to treat complications, and personal financial costs.

Before you make your decision whether or not to get breast implants, it is very important that you:

- read the information in this handbook
- read the patient labeling for the approved saline-filled breast implants at FDA's website (http://www.fda.gov/cdrh/breastimplants/) to learn about the types and rates of complications seen with breast implants
- read the specific patient labeling or informed consent documents for the breast implants for which you are gathering information[1]
- collect specific information from your insurance company and your doctor to estimate personal financial costs (see below)
- have a realistic expectation of the outcome (see below).

[1] Patient labeling is the general term used for the patient information provided for approved breast implants. An informed consent document, on the other hand, is the format for providing patient information to all investigational (not approved) breast implants under clinical studies. Refer to the **Status/Availability** section for more details.

After obtaining all of the information that is recommended and getting answers to your questions, you should give yourself adequate time to determine whether or not to get breast implants.

Personal Financial Costs – Breast implant surgery and treatment of complications may not be covered by your health insurance. Typically, insurance companies will not cover breast augmentation or any reoperations and additional doctor visits following augmentation. However, most insurance companies cover the first breast reconstruction operation. Insurance coverage for reoperation procedures or additional doctor visits following reconstruction may not be covered, depending on your insurance policy.

Aside from insurance coverage specific to your surgery, you need to find out about how breast surgery will affect your health insurance, as a whole. **For some women, companies may increase premiums, drop coverage, or deny future coverage following breast implant surgery or following complications from the breast implants or surgery.** Policies on coverage may also change from year to year.

Before surgery, be sure to get, in writing, answers from your insurance company to the following questions, at a 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 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?

In addition to collecting information from your insurance company, you should also ask your doctor to provide cost information such as:

- What are the costs of getting breast implants (the implants, the anesthesia, the surgery, etc.)?
- What are the costs for follow-up visits?
- What are the costs for detecting or treating a complication, especially treatment that involves a reoperation, such as implant removal with or without replacement?
- What is the specific manufacturer warranty for the implants that you are gathering information on?

Realistic Expectations: Your decision whether or not to get breast implants should be also based on realistic expectations of the outcome. 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 (including age), chest structure, breast/nipple shape and position, skin texture, healing capabilities (which may be slowed by radiation and chemotherapy treatment, smoking, alcohol, and various medications), tendency to bleed, prior breast surgery(ies), surgical team's skill and experience, type of surgical procedure, and type and size of implant.

DEVICE DESCRIPTION

Breast implants may vary in shell surface (smooth versus textured), shape (round or shaped), profile (how far it sticks out), volume (size), and shell thickness. The primary parts of most breast implants are a shell (otherwise known as the envelope or lumen), a filler, and a patch to cover the manufacturing hole.

With respect to the shell design, while most breast implants are single lumen (just the shell), some breast implants are double lumen (one shell inside another shell). With respect to the filler, some breast implants are manufactured with a fixed volume of filler, some are filled during the operation, and some allow for adjustments of the filler volume after the operation.

It should be noted that tissue expanders, which are silicone shells filled with saline, are regulated by FDA in a different way than breast implants. This is because tissue expanders are intended for general tissue expansion for a maximum of 6 months, after which, they are to be removed. Because of this, the design specifications (e.g., thinner shell) and preclinical testing recommendations are different for tissue expanders than for breast implants. Tissue expanders are not to be confused with the third type of double lumen silicone gel-filled breast implants described in the **Silicone Gel-Filled Breast Implants** section below. The third type of double lumen silicone gel-filled breast implant is a permanent implant (not intended to be removed) that allows for limited tissue expansion but is regulated by FDA as a breast implant. See that section for more details.

Below is information specific to saline-filled, silicone gel-filled, and alternative breast implants.

Saline-Filled Breast Implants

The three types of saline-filled breast implants are as follows:

- One type is a single lumen implant that is filled during the operation with a fixed volume of saline through a valve. There are no adjustments of the saline volume after the operation.
- A second type is a single lumen implant that is filled during the operation with saline through a valve. This type of implant allows for adjustments of the saline volume after the operation.
- A third type is a single lumen implant that is prefilled by the manufacturer with a fixed volume of saline. There are no valves for filling during the operation or for adjustments of the saline volume after the operation.

The silicone rubber shell for a saline-filled breast implant has the following general composition:

- cured polymeric (large) silicones
- approximately 20% of finely powdered silica that is tightly bound to the silicone polymers
- small amounts of smaller silicones
- minute amounts (parts per million) of metals, including a metal catalyst (usually tin, zinc, or platinum) (A catalyst is something that causes a change in material.)
- traces of readily evaporating materials (volatiles), such as xylene and other organic compounds.

The filler is sterile saline that should conform to United States Pharmacopeia (USP) standards for Normal Physiological Saline (injection grade).[2]

Silicone Gel-Filled Breast Implants

The three types of silicone gel-filled breast implants are as follows:

- One type is a single lumen implant that is prefilled by the manufacturer with a fixed volume of silicone gel.
- A second type is a double lumen implant with (1) an inner lumen prefilled by the manufacturer with a fixed volume of silicone gel and (2) an outer lumen that is filled during the operation with a fixed volume of saline through a valve.
- A third type is a double lumen implant with (1) an outer lumen prefilled by the manufacturer with a fixed volume of silicone gel and (2) an inner lumen that is filled during the operation with saline through a valve. This type of implant allows for adjustments of the saline volume after the operation.

A silicone gel-filled breast implant has a silicone rubber shell with the same general composition as shown in the **Saline-Filled Breast Implants** section above.

The filler is silicone gel that has the general composition of:

- silicone oil
- cured polymeric (large) silicones
- small amounts of uncured large and smaller silicones

[2] As a note, one concern that relates specifically to saline-filled breast implants is the potential for the saline to become contaminated (not sterile) with fungus or bacteria and then released into the woman's body if her implant ruptures/deflates or if the valve leaks. However, saline-filled implants are now generally filled from a bag and tubing rather than from an open bowl, and this procedure may reduce the risk of this complication.

- minute amounts (parts per million) of metals, including a metal catalyst (usually platinum). (A catalyst is something that causes a change in material.)

Alternative Breast Implants

An alternative breast implant typically has a silicone rubber shell with a filler other than saline or silicone gel. The filler material may or may not be a gel. An alternative breast implant may also have an alternative shell other than one made from silicone rubber.

STATUS / AVAILABILITY

Saline-Filled Breast Implants

Prior to August 1999, saline-filled breast implants were sold on the market either as preamendments devices (they were on the market prior to May 1976) or as 510(k)-cleared devices. In August 1999, FDA issued a regulation that required that all saline-filled breast implants be PMA-approved to be sold on the market. However, those companies that had a preamendments or 510(k)-cleared saline-filled breast implant and submitted their PMA within 90 days of the August 1999 regulation were allowed to keep their device on the market until the final decision/actions were made in May 2000. Since May 2000, a saline-filled breast implant must be PMA-approved to be sold on the market.[3]

On May 10, 2000, FDA approved Mentor Corporation's and Inamed Corporation's (formerly McGhan Medical) saline-filled breast implant PMAs. As of the date of this handbook, these are the only two companies with **PMA-approved** saline-filled breast implants.

Except for two PMA-approved saline-filled breast implants, all other saline-filled breast implants are considered investigational devices because they are not PMA-approved. For a woman to receive an investigational saline-filled breast implant in the U.S., she must enroll in an investigational device exemption (IDE) study.

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. IDE studies may include augmentation, reconstruction, and/or revision patients. The number of patients and the number of sites are limited in IDE

[3]A completed product development protocol (PDP) application is an alternative to an approved PMA for all types of breast implants. However, to date, no companies have pursued the PDP route to marketing for these devices; thus, PDPs are not discussed further in this handbook.

studies. In addition, each woman who participates in an IDE study must give informed consent.[4] The safety and effectiveness data collected in an IDE study are used to support a future PMA.

Silicone Gel-Filled Breast Implants

Prior to 1991, silicone gel-filled breast implants were sold on the market as either preamendments devices (they were on the market prior to May 1976) or as 510(k)-cleared devices. In April 1991, FDA issued a regulation that required that all silicone gel-filled breast implants be PMA-approved to be sold on the market. However, those companies that had a preamendments or 510(k)-cleared silicone gel-filled breast implants and submitted their PMA within 90 days of the April 1991 regulation were allowed to keep their device on the market until the final decision/actions were made in April 1992. Since April 1992, a silicone gel-filled breast implant must be PMA-approved to be sold on the market.

As of the date of this handbook, no company has PMA approval for a silicone gel-filled breast implant. Therefore, all silicone gel-filled breast implants are considered investigational. For a woman to receive a silicone gel-filled breast implant in the U.S., she must enroll in an IDE study or an adjunct study.

An IDE study is described in the **Saline-Filled Breast Implants** section above.

An adjunct study is different from the IDE study in terms of its purpose and study design. In April 1992, FDA determined that the silicone gel-filled breast implant PMAs submitted in 1991 did not include adequate safety data to support PMA approval. However, FDA believed that there was a public health need to have breast implants

[4] Note that the informed consent document required for a patient to participate in an IDE study should not be confused with a standard surgical consent form that a hospital requires to be signed by any surgical patient.

available for reconstruction and revision patients. Therefore, companies that had not withdrawn their PMAs prior to the April 1992 decision were given the opportunity to submit an adjunct study protocol, for FDA approval, to address the public health need. Only Mentor Corporation and Inamed Corporation received approvals for their adjunct studies.

Adjunct studies are limited to reconstruction and revision patients. Women who want silicone gel-filled implants for augmentation (cosmetic reasons) cannot be enrolled in an adjunct study. New reconstruction and revision patients are continuously being enrolled in the adjunct studies because there is no limit on the number of patients or the number of sites. Each woman who participates in an adjunct study must give informed consent.[5] The safety data collected in an adjunct study are used as supplemental data to support a future PMA.

Alternative Breast Implants

All alternative breast implants are reviewed through the PMA process because they are post-amendments devices (not on the market prior to May 1976). As of the date of this handbook, there are no alternative breast implants approved for marketing. Therefore, all alternative breast implants are considered investigational devices. To receive an alternative breast implant in the U.S., you must enroll in an IDE study (see the **Saline-Filled Breast Implant** section above).

Refer to the **Timeline of Breast Implant Activities** section to see which companies have IDE studies for their breast implants.

[5] Note that the informed consent document required for a patient to participate in an adjunct study should not be confused with a standard surgical consent form that a hospital requires to be signed by any surgical patient.

LOCAL COMPLICATIONS & REOPERATIONS

The Institute of Medicine (IOM) completed its independent review of past and ongoing scientific research of silicone [both saline-filled and silicone-gel filled] breast implant safety in June 1999.[6] Below are some of the major findings from the IOM report.

- Local complications are the primary safety issue with breast implants because they are frequent enough to be a concern.
- Local complications accumulate over the lifetime of the implant, and they have not been well studied.
- Information on local complications is crucial for women deciding whether or not they want breast implants.

Key points to consider whether you are undergoing breast augmentation, reconstruction, or revision:

- Breast implants will not last a lifetime. Either because of rupture or other complications, you will likely need to have the implants removed.
- You are likely to need additional doctor visits and reoperations because of one or more complications over the course of your life.
- You are likely to have the implants removed, with or without replacement, because of one or more complications over the course of your life.
- Many of the changes to your breast following implantation may be cosmetically undesirable, as well as irreversible (cannot be undone).

[6] Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}. Also available through IOM website at www.iom.edu.

- If you later choose to have your implants removed, you may experience unacceptable dimpling, puckering, wrinkling, loss of breast tissue, or other undesirable cosmetic changes of the breast.

Potential local breast implant complications are bulleted below. You may need non-surgical treatments or reoperations (including removal of your implant) to treat any of these local complications. Potential local complications include, but are not limited to:

- Asymmetry
- **Breast pain**
- Breast tissue atrophy
- Calcification/calcium deposits
- **Capsular contracture**
- Chest wall deformity
- Delayed wound healing
- Extrusion
- Galactorrhea
- Granuloma
- Hematoma
- Iatrogenic injury/damage
- Infection, including Toxic Shock Syndrome
- Inflammation/irritation
- Malposition/displacement
- Necrosis
- **Nipple/breast sensation changes**
- Palpability/visibility
- Ptosis
- Redness/bruising
- **Rupture/deflation**
- Scarring
- Seroma
- Unsatisfactory style/size
- Wrinkling/rippling

Refer to the **Glossary** at the front of this handbook for a brief definition of each of the complications bulleted above. If you need more explanation, you should ask your doctor **before** you make your decision whether or not to get breast implants.

Below is a more detailed discussion of reoperation, removal, and the four **bolded** local complications bulleted above.

Reoperation

As stated above, it is likely that you will need to have one or more reoperations over the course of your life because of local complications from breast implants.

Reasons for reoperations could include any of the potential local complications bulleted above, such as capsular contracture, wrinkling, asymmetry, rupture/deflation, implant malposition, etc.

The type of surgical procedure(s) performed during the reoperation depends on the local complication involved. More than one procedure may be performed in a single reoperation. Examples of the types of surgical procedures that may be performed in a reoperation include:

- implant removal with or without replacement
- capsule procedure (e.g., removal or surgical release of the capsule)
- scar or wound revision (e.g., surgical removal of excess scar tissue)
- drainage of a hematoma (e.g., inserting a needle or tube through the skin to drain the collection of blood)
- repositioning of the implant (e.g., surgically opening the incision and moving the implant)
- biopsy/cyst removal (e.g., inserting a needle through the skin or cutting through the skin to remove a lump).

Multiple reoperations to either improve the appearance of the breasts, to remove ruptured/deflated implants, or both may result in an unsatisfactory cosmetic outcome.

A retrospective study by Gabriel, et al. showed that 24% of women with breast implants had complications resulting in a reoperation during the first five years after implantation (silicone and saline implants were studied together).[7] According to this study, about 1 in 3 women getting breast implants for reconstruction needed a reoperation within five years, and about 1 in 8 women getting breast implants for augmentation needed a reoperation within five years.

Prospective studies of saline-filled breast implants approved by FDA in May 2000 showed reoperation rates of 13-21% at 3 years and 20-26% at 5 years for augmentation patients. The same studies showed reoperation rates of 39-40% at 3 years and 43-45% at 5 years for reconstruction patients.[8,9]

Removal

Removal of the implant(s), with or without replacement, is one type of surgical procedure that may be performed in a reoperation. As stated above, you are likely to have your implant removed at some time over the course of your life because of one or more local complications.

Reasons for removal could include any of the potential local complications bulleted above, such as capsular contracture, wrinkling, asymmetry, unsatisfactory size/style, etc. Many women decide to have the implants replaced, but some women do not. Women who do not have their implants replaced may have cosmetically undesirable dimpling, puckering, or sagging of the breast following removal of the implant, or both. Recall that some health insurance companies may not cover implant removal or implant replacement even though the first implant surgery was covered by health insurance.

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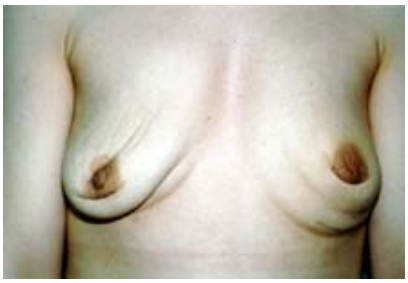
[7] Gabriel SE, Woods JE, O'Fallon WM, Beard CM, Kurland LT, Melton LJ. Complications leading to surgery after breast implantation. New Engl J Med 1997; 336:679-682.
[8] Inamed patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.
[9] Mentor patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.

Prospective studies of saline-filled breast implants approved by FDA in May 2000 showed implant removal rates of 8% at 3 years and 12-14% at 5 years for augmentation patients. The same studies showed implant removal rates of 23-27% at 3 years and 28-30% at 5 years for reconstruction patients.[10,11]

In a retrospective study of augmentation patients with silicone gel-filled breast implants, 303 of 907 (33%) of women reported that they had at least one reoperation in which their implant(s) were removed or replaced.[12] The average time to removal, as reported by those who remembered the date of their surgery, was 11.5 years.

Photograph 1 below shows the same 29-year-old woman in Photograph 3 (see the **Capsular Contracture** subsection below) one year after removal of her silicone gel-filled breast implants without replacement.[13] Women with large implants, particularly those inserted subglandularly (under and within the breast glands but on top of the chest muscles), may have a major cosmetic deformity if they choose not to replace them or to undergo additional reconstructive surgery.

Photograph 1: Implant removal without replacement in augmentation patient.



[10] Inamed patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.
[11] Mentor patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.
[12] Brown SL, Pennello G. Replacement surgery and silicone gel breast implant rupture: Self-report by women after mammoplasty. Journal of Women's health & Gender Based Medicine, 2002;11:255-264. A summary of the findings of this study is also available on FDA's website at http://www.fda.gov/cdrh/breastimplants/.
[13] Photograph courtesy of Walter Peters, Ph.D., M.D., F.R.C.S.C., University of Toronto.

Rupture/Deflation

Breast implants do not last a lifetime. Some breast implants rupture/deflate[14] in the first few months after being implanted and some deflate after several years. Others may take 10 or more years to rupture/deflate.

The following surgical practices are contraindicated (not recommended) for the approved saline-filled breast implants because they are known to cause rupture/deflation:

- closed capsulotomy (technique used to relieve capsular contracture involving manually squeezing the breast to break the hard capsule)
- placement of drugs/substances inside the implant other than sterile saline
- any contact of the implant with Betadine®[15]
- injection through the implant shell
- alteration of the implant
- stacking of the implants (more than one implant per breast pocket).

In addition to the surgical practices above that have been shown to cause rupture/deflation of saline-filled breast implants, there are other reasons for rupture/deflation of breast implants. Companies are currently studying what these other reasons are.

[14] Although the term rupture is used for all types of implants, the term deflation is typically used only for saline-filled breast implants.
[15] Betadine is a registered trademark of Purdue Frederick Company.

Some possible reasons for rupture/deflation of breast implants include:

- normal aging of the implant
- damage by surgical instruments
- too much handling during surgery
- damage by procedures to the breast, such as biopsies and fluid drainage
- compression during mammographic imaging
- stresses such as trauma or intense physical pressure
- capsular contracture
- overfilling or underfilling of saline-filled breast implants
- placement through an umbilical (belly button) incision site because it involves too much handling of the implant.

Doctors usually recommend removal of the implant if it has ruptured, regardless of whether it is saline-filled or silicone gel-filled.

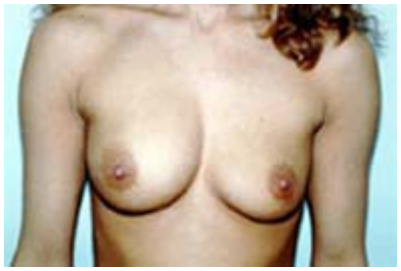
Rupture/Deflation of Saline-Filled Breast Implants – Saline-filled breast implants rupture/deflate when the saline solution leaks either through an unsealed or damaged valve or through a break in the implant shell. Implant deflation usually happens immediately but sometimes it happens slower over a period of days. Deflation of saline-filled breast implants is noticed by a loss of size or shape of the implant.

The IOM report[16] stated that the deflation rate reported in the medical literature across studies was 7% at 7 years. The IOM report also stated that earlier saline-filled breast implant models had more frequent deflations than modern models. The IOM estimated that 1-3% of modern saline-filled breast implants would have ruptured by the first year and that this rate would increase over time. The modern models show a 5-10% rupture rate after 10 years, according to one study.

Prospective studies of saline-filled breast implants approved by FDA in May 2000 showed rupture/deflation rates of 3-5% at 3 years and 7-10% at 5 years for augmentation patients. The same studies showed rupture/deflation rates of 6-9% at 3 years and 8-18% at 5 years for reconstruction patients.[17,18]

Photograph 2 below shows a 30-year-old woman's left saline-filled breast implant deflation.[19] The suspected cause was the leaf-valve design of the implant, which is no longer being used by manufacturers.

Photograph 2: Deflation in augmentation patient.



[16] Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}. Also available through IOM website at www.iom.edu.
[17] Inamed patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.
[18] Mentor patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.
[19] Photograph courtesy of Walter Peters, Ph.D., M.D., F.R.C.S.C., University of Toronto.

Rupture/Deflation of Silicone Gel-Filled Breast Implants - Because silicone gel is thicker than saline, when a silicone gel-filled breast implant ruptures, the gel may remain contained within the fibrous capsule. This is called an intracapsular rupture. An intracapsular rupture is usually a silent rupture, which means that it happens without a visible change or feel by the woman and is not evident by a physical examination by the doctor. Because the woman and her doctor will not see or feel any changes with a silent rupture, a magnetic resonance imaging (MRI) examination is needed to determine whether or not a silent rupture has happened. MRI with equipment specifically designed for imaging the breast is currently the most sensitive method for detecting rupture of a silicone gel-filled breast implant in women with silent ruptures.

With some silicone gel-filled implants ruptures, women may notice a decreased breast size, a change in breast implant shape, hard lumps over the implant or chest area, an uneven appearance of the breasts, pain or tenderness, tingling, swelling, numbness, burning, or changes in sensation. Ruptures of this type are called symptomatic (show symptoms) and are usually extracapsular (gel outside the fibrous capsule). However, some extracapsular ruptures can be silent (show no symptoms).

Silicone gel that escapes the scar capsule surrounding the implant may migrate away from the breast. The free silicone gel may cause lumps called granulomas to form in the breast or in other tissues where the silicone gel has migrated, such as the breast tissue, chest wall, armpit, or arm. Silicone gel may also migrate to distant organs such as the liver. Migrated silicone gel may be difficult or impossible to remove.

The IOM report[20] stated that rupture rates reported in the medical literature across studies ranged from 0.3-77%. This large range of rupture rates is due to the different types and models of implant, varying durations of implantation, different types of groups of women studied, and other factors. The IOM report also stated that extracapsular gel (gel outside

[20] Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}. Also available through IOM website at www.iom.edu.

the fibrous capsule) was present in about 12-26% of gel-filled ruptures reported in the medical literature. The IOM estimated that less than 10% of modern silicone gel-filled breast implants would have ruptured by five years and that rupture rate would continue to increase over time.

FDA reported a retrospective study on rupture of silicone gel-filled breast implants.[21] This study included augmentation women who had breast implants before 1988. There were 344 women (with 687 implants) who had a MRI examination of their breasts to determine whether or not there was evidence of rupture of their implants. Of the 687 implants in the study, 378 implants (55%) were ruptured. This means that 69% of the 344 women had at least one ruptured breast implant. Of the 265 women with at least one rupture, 73 (21%) had extracapsular (outside the capsule) silicone gel in one or both breasts. Factors that were associated with rupture included the age of the implant, the specific manufacturer of the implant, and the surgical placement (submuscular versus subglandular) of the implant.

Marotta, et al.[22] reviewed numerous publications on over 9,770 silicone implants that were removed and concluded that 26% of implants were ruptured by 3.9 years, 47% were ruptured by 10.3 years, and 69% were ruptured by 17.8 years. Marotta, et al. also reported that shells from removed silicone gel-filled breast implants were considerably weaker than shells before implantation.

Holmich, et al. 2001[23] reported on a group of 271 women, with 533 augmentation breast implants, who had MRI evaluations for rupture. These women had breast implantation

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[21] Brown SL, Middleton MS, Berg WA, Soo MS, Pennello G. Prevalence of rupture of silicone gel breast implants revealed on MR imaging in a population of women in Birmingham, Alabama. American Journal of Roentgenology 2000;175:1-8. A summary of the findings of this study is also available on FDA's website at http://www.fda.gov/cdrh/breastimplants/.

[22] Marotta JS, Goldberg EP, Habal MB, Amery DP, Martin PJ, Urbaniak DJ, Widenhouse CW. Silicone gel breast implant failures: Evaluation of properties of shells and gels for explanted prostheses and meta-analysis of literature rupture data. Ann Plast Surg 2002;49:227-247.

[23] Holmich, LR, et al. Prevalence of silicone breast implant rupture among Danish women. Plast Reconstr Surg. 2001; 108(4):848-858.

before 1996 and were randomly selected from four plastic surgery clinics in Denmark. The authors found that, overall, 26% of implants in 36% of the women examined were found to be ruptured, and an additional 6% of implants were possibly ruptured. This is the minimum rupture rate for this group because there were problems with performance of the MRI at one of the study sites. Of the ruptured implants, 22% were extracapsular, and these ruptures were significantly associated with a history of closed capsulotomy.

In a follow-up study by Holmich, et al.[24], this group of women had another MRI two years later. Over the 2-year period, the MRI evaluations showed that 17% of the implants were definitely or possibly ruptured.

According to the IOM report[25], the diagnosis of rupture of a gel-filled breast implant is important because the release of silicone gel and fluid into the tissues may result in local complications. An intracapsular rupture may become extracapsular, and both are generally agreed to indicate the need for removal of the implant. The rupture rate over time (both intracapsular and extracapsular) of modern silicone gel-filled breast implants is currently not well characterized. The silent rupture rate over time is not known for modern silicone gel-filled breast implants.

[24] Holmich, LR, et al. Incidence of silicone breast implant rupture. Arch Surg. 2003; 138:801-806.
[25] Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}. Also available through IOM website at www.iom.edu.

Capsular Contracture

Capsular contracture happens when the scar tissue or capsule that normally forms around the implant tightens and squeezes the implant. It can happen to one or both of the implanted breasts.

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
Grade IV	the breast is hard, painful, and looks abnormal.

Capsular contracture may be more common following infection, hematoma, and seroma. However, it is not known for sure why capsular contracture happens. The literature also discusses other factors, such as a textured implant surface and submuscular placement of the implant, which may decrease the capsular contracture rate.

A reoperation may be needed to correct capsular contracture, usually for grade III or IV capsular contracture. The surgical procedures range from removal of the implant capsule tissue with or without replacement of the implant itself. Capsular contracture may happen again after this reoperation.

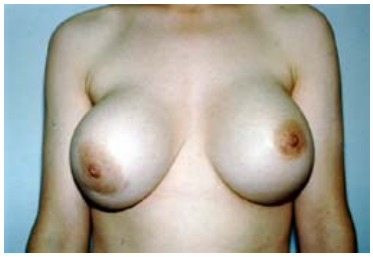
The IOM report[26] stated that, for studies involving both silicone gel-filled and saline-filled breast implants, the capsular contracture rates were 36-81% for silicone-gel filled breast implants and 8-41% for saline-filled breast implants.

[26] Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}. Also available through IOM website at www.iom.edu.

Prospective studies of saline-filled breast implants approved by FDA in May 2000 showed rates of grade III or IV capsular contracture of 9% at 3 years and 10-11% at 5 years for augmentation patients. The same studies showed rates of grade III or IV capsular contracture of 25-30% at 3 years and 29-36% at 5 years for reconstruction patients.[27,28]

Photograph 3 below shows grade IV capsular contracture in the right breast of a 29-year-old woman seven years after subglandular placement of 560cc silicone gel-filled breast implants.[29]

Photograph 3: Capsular contracture in augmentation patient.



Breast Pain

Women may feel pain of varying degrees and length of time following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain. You should tell your doctor if you have pain.

The IOM report[30] stated that pain is one of the primary reasons for implant removal and replacement even though few studies included in the medical literature report information about pain.

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[27] Inamed patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.
[28] Mentor patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.
[29] Photograph courtesy of Walter Peters, Ph.D., M.D., F.R.C.S.C., University of Toronto.
[30] Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}. Also available through IOM website at www.iom.edu.

Prospective studies of saline-filled breast implants approved by FDA in May 2000 showed breast pain rates of 5-16% at 3 years and 7-17% at 5 years for augmentation patients. The same studies showed breast pain rates of 15-17% at 3 years and 16-18% at 5 years for reconstruction patients.[31,32]

Nipple and Breast Sensation Changes

Sensation (feeling) in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensation to no sensation in the nipple or breast following surgery. Changes in sensation can be temporary or permanent and may affect sexual response or the ability to nurse a baby. (Refer to the **Specific Issues to Consider** section for more information on breast feeding.)

Prospective studies[33,34] of saline-filled breast implants approved by FDA in May 2000 showed the following changes with regard to nipple and breast sensation for augmentation:

- intense nipple sensation in 5-9% of women at 3 years and in 10% of women at 5 years
- loss of nipple sensation in 8-10% of women at 3 years and in 10% of women at 5 years
- intense skin sensation in 7% of women at 3 years and in 8% of women at 5 years.

[31] Inamed patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.
[32] Mentor patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.
[33] Inamed patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.
[34] Mentor patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.

The same prospective studies[35,36] of saline-filled breast implants approved by FDA in May 2000 showed the following changes with regard to nipple and breast sensation for reconstruction:

- loss of nipple sensation in 12-35% of women at 3 years and in 18% of women at 5 years
- intense skin sensation in 6% of women at 3 years and in 6% of women at 5 years.

[35] Inamed patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.
[36] Mentor patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.

DISEASES

Some women with breast implants have reported health problems that they believe are related to their implants, but most studies of these diseases 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 the body reacting to a foreign material, such as silicone gel. These diseases are discussed below.

Connective Tissue Diseases (CTDs) and Related Disorders

These are a group of diseases and disorders related to the immune system and to the connective tissue of the body (e.g., muscle, tendon, bone, etc.) that supports body structures and binds body parts together. 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.

The cause of CTDs is unknown. Some CTDs have autoimmune characteristics in that a woman's immune system attacks her own cells as if they were foreign.

CTDs with autoimmune characteristics include:

- lupus
- rheumatoid arthritis
- polymyositis
- dermatomyositis
- progressive systemic sclerosis or scleroderma.

CTDs without autoimmune characteristics include:

- fibromyalgia
- chronic fatigue syndrome.

Some women with breast implants have experienced the diseases or disorders listed above, as well as a variety of signs and symptoms that could be related to the immune system or to the connective tissues of the body. However, these signs and symptoms are not considered a defined disease or 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 those bulleted above, may be present in women without CTD or related disorders or in women 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[37] 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 or not the signs and symptoms

[37] Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}. Also available through IOM website at www.iom.edu.

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.[38,39,40] There are reports of women with implants who have a variety of autoantibodies. (Autoantibodies are antibodies that your body makes that accidentally target your own tissues.) However, the presence of these autoantibodies does not mean that a woman has an increased risk of actually developing a CTD or related disorder.

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. However, these studies have not been large enough to resolve the question of whether or not breast implants slightly increase the risk of CTDs or related disorders. Researchers must study a large group of women without breast implants who are of similar age, health, and social status and who are followed for a long time (such as 10-20 years) before a relationship between breast implants and these diseases can conclusively be made.

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[38]Wolf 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.
[39] Tueber SE, Rowley MJ, et al. Anti-collagen antibodies are found in women with silicone breast implants. J Autoimmunity 1993;6:357-377.
[40] Rowley 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.

There have been reports of women with fibromyalgia following breast implants, and a preliminary study conducted by FDA[41] found an association between self-reported fibromyalgia and extracapsular rupture diagnosed by MRI. However, this association has not been repeated in a similar study based on a large group of Danish women[42] and the weight of the epidemiological evidence published in the literature does not support an association between fibromyalgia and breast implants.

Cancers

The IOM report[43] indicates that breast cancer is no more common in women with breast implants than those without breast implants. While not conclusive, cancer rates have been reported to be slightly higher for some types of cancers. Cancers rates that have been higher in more than one study are lung and vulva. Because these cancers may be related to other factors that were not examined in these studies (such as smoking) these studies are not conclusive.

More information on cancer and breast implants is available at the National Cancer Institute website at:

- http://www.nci.nih.gov/newscenter/silicone-othercancers
- http://www.nci.nih.gov/newscenter/silicone-mortality
- http://www.nci.nih.gov/newscenter/siliconebreast.

[41] Brown, et al. Assn of SBI rupture and BI. Clin Rheumatol. 2002; 4(4);293-298.
[42] Holmich, et al. Self-reported diseases and symptoms by rupture status among unselected Danish women with cosmetic silicone breast implants. Plast Recon Surg. 2003; 111(2):723-732.
[43] Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}. Also available through IOM website at www.iom.edu.

Neurological Symptoms/Diseases

Some women with breast implants have reported that they have neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking or remembering things) or diseases (such as multiple sclerosis) related to their implants. Several studies have indicated that women with implants are not at an increased risk of being hospitalized with neurological disease compared to other women. The IOM report[44] found no basis for thinking that women with implants were more likely to have neurological diseases or symptoms.

Since the IOM report, Winther, et al.[45] published additional follow-up of the Danish group of 1,653 women with cosmetic breast implant surgery at private clinics in Denmark compared to a comparison group of 1,736 women who underwent other types of cosmetic procedures. No increased risks for neurological disorders were found in the breast implant patients. However, it should be noted that these studies are limited in that rare disorders cannot be addressed.

[44] Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}. Also available through IOM website at www.iom.edu.
[45] Winther, JF, et al. Neurological disease among women with silicone breast implants in Denmark. Acta Neurol Scand 2001; 103:93-96.

SPECIFIC ISSUES TO CONSIDER

Mammography

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. 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 remaining breast tissue continue to have mammography of that breast, as well as of the other breast, to detect breast cancer. (Those who have had breast cancer surgery on both breasts should ask their doctors whether mammograms are still necessary.)

Women should be aware that breast implants may interfere with the detection of cancer and that breast compression (hard pressure) during mammography may cause implant rupture/deflation.

Interference with mammography by 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 (x-ray, ultrasound). Implants increase the difficulty of both taking and reading mammograms.

Mammography requires breast compression, which could contribute to implant rupture. According to the FDA adverse event database, there were 41 reported cases of breast implant rupture during mammography reported between 1992 and 2002.[46] An additional 17 cases of rupture during mammography were reported in the medical literature.

[46] Brown SL, Ferlo Todd J, Luu H-MD. Breast implant adverse events during mammography: reports to the Food and Drug Administration. Journal of Women's Health 2004; 13:1-8. A summary of the findings of this study is also available on FDA's website at http://www.fda.gov/cdrh/breastimplants/.

In addition to special care taken by the radiological 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, named for the radiologist who developed the techniques. 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 radiological technologist about the presence of implants before mammography is performed. Then, the radiological technologist will use these special displacement techniques and take extra care when compressing the breasts to avoid rupturing the implant.

The displacement procedure involves pushing the implant back and pulling the breast tissue into view. Several factors that may affect the success of this special technique in imaging the breast tissue in women with breast implants include the location of the implant, the hardness of the capsular contracture, and the amount of the breast tissue compared to the implant size.

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

As a last note, FDA does not consider mammograms an adequate means of detecting implant rupture/deflation for silicone gel-filled breast implants. As described in the **Local Complications & Reoperations (Rupture/Deflation of Silicone Gel-Filled Breast Implants)** section above, FDA believes that MRI is currently the best method for detecting implant rupture for silicone gel-filled breast implants.

Breast Feeding

Women of childbearing age should know that they may not be able to 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.

The IOM report[47] said that women with either silicone gel-filled or saline-filled breast implants showed lactation insufficiency (not enough milk) ranging from 28-64%. The periareolar approach (incision cite is around the nipple) was the factor most associated with lactation insufficiency.

Having a breast implant may also influence a woman's decision about whether or not she will try to breast feed, particularly if she has capsular contracture or is worried about problems with the implants.[48]

Effects on Children

There are two concerns associated with the effects on children:

- the safety of the milk from mothers with breast implants for breast feeding children
- the effects of silicones and other chemicals on children born of mothers with breast implants (second-generation effects).

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. There are no current methods for detecting *silicone* levels in breast milk.

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[47] Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}. Also available through IOM website at www.iom.edu.

[48] Strom SS, Baldwin BJ, Sigurdson AJ, Schusterman MA. Cosmetic saline breast implants: a survey of satisfaction, breast-feeding experience, cancer screening, and health. Plast Reconstr Surg 1997;100:1553-1557.

The IOM report[49] said that there is convincing evidence that infants breast-fed by mothers with breast implants receive no higher *silicon* intakes from breast milk than infants breast-fed by mothers without breast implants. (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.)

Concerns have been also raised about the potential damaging effects on children born of mothers with implants. The IOM report[50] said that the information is insufficient or flawed to draw definite conclusions about this issue. In other words, it is not known what effect breast implants may have on an unborn baby (fetus) and the nursing infant.

Several studies since the IOM report have suggested that the risk of birth defects overall is not increased in children born after implant surgery.[51,52] These studies are comforting, but, because they are small and of short duration, they cannot rule out a very small risk.

Suicide

Several recent studies have found a slight increase in deaths due to suicide among women with cosmetic breast implants.[53,54,55] The reason for this increase is unknown although some suggest that this may be due to underlying psychological problems in women who

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[49] Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}. Also available through IOM website at www.iom.edu.
[50] Safety of Silicone Breast Implants. Institute of Medicine National Academy Press, Washington, D.C. 2000. {IOM Report}. Also available through IOM website at www.iom.edu.
[51] Kjoller K, Friis S, Signorello LB McLaughlin JK, Blot WJ, Lipworth L, Mellemkjaer L, Winther J, Olsen J. Health outcomes in offspring of Danish mothers with cosmetic breast implants. Ann Plast Surg 48;238-245, 2002.
[52] Signorello LB, Fryzek JP, Blot WJ, McLaughlin JK, Nyren O. Offspring health risk after cosmetic breast implantation in Sweden. Ann Plast Surg 46:279-286, 2001.
[53] Brinton LA, Lubin JH, Burich MC, Colton T, Hoover RN. Mortality among augmentation mammoplasty patients. Epidemiology 2001;12:321-326.
[54] Koot VCM, Peeters PHM, Granath F, Grobbee DE, Nyren O. Total and cause specific mortality among Swedish women with cosmetic breast implants: prospective study. BMJ 326;527-528.
[55] Pukkala E, Kulmala I, Hovi S-L, Hemminki E, Keskimäki I, Lipworth L, Boice JD, McLaughlin JK. Causes of death among Finnish women with cosmetic breast implants, 1971-2001. Ann Plast Surg 2003;51:339-342.

get breast implants for cosmetic reasons.[56,57] Others have suggested that women may be distressed because of the burden of breast implant complications.[58]

Gel Bleed

A concern related specifically to silicone-gel filled breast implants is that small amounts of the silicone fluid or oil may bleed through the shell and travel into the surrounding tissue. This escaped silicone fluid or oil might cause local complications. There is inadequate information to determine whether or not gel bleed is a problem because there have been no studies that measure the amount of gel bleed and relate it to local complications.

Platinum

Platinum is a metal used in the manufacture of some breast implants. Recent scientific literature indicates that the platinum leaches (leaks) from these implants and is present in the surrounding tissue.[59] Because certain chemical forms of platinum can cause allergic reactions, there has been concern that platinum that leaches from the implants may be harmful. FDA scientists reviewed the currently available studies from the medical literature on platinum and breast implants and did not find evidence that leached platinum causes illness in women with breast implants.[60]

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[56] Pukkala E, Kulmala I, Hovi S-L, Hemminki E, Keskimäki I, Lipworth L, Boice JD, McLaughlin JK. Causes of death among Finnish women with cosmetic breast implants, 1971-2001. Ann Plast Surg 2003;51:339-342.
[57] Joiner TE. Does breast augmentation confer risk of or protection from suicide. Aesthetic Surgery Journal, 2003.
[58] Zuckerman D. Mortality in Swedish women with cosmetic breast implants. BMJ 2003;326:1266.
[59] Flassbeck D, Pfleiderer B, Klemens P, Heumann KG, Eltze E, and Hirner AV. Determination of siloxanes, silicone, and platinum in tissues of women with silicone gel-filled implants."Anal Bioanal Chem (2003) **375**: 356-362.
[60] Arepelli S, Bezebah S, Brown SL, Allergic reactions to platinum in silicone breast implants. J Long-Term Effects Medical Implants 2002; 299-306.

Silicone Sensitivity

Currently, there are no FDA-approved tests to detect silicone in the body or to determine whether or not 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 claim to have 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 claimed that a test called the Anti-Polymer Antibody Assay (APA) is able to distinguish signs and symptoms of disease ranging from mild to severe in women with implants. However, a recent report[61] failed to find an increased level of APA activity in women who had silicone breast implants and health complaints compared with healthy women without implants. The accuracy of this test, the clinical usefulness of the test results, and the biological basis for the assay has not been established.

Even if antibodies to silicone 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.

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[61] De Jong, WH, Kallewaard, M, Goldhoorn, CA, Verhoef, CM, Bijlsma, WJ, Schouten, JSAG, and Van Loveren, H. Long-term exposure to silicone breast implants does not induce antipolymer antibodies; *Biomaterials* **25** (2004) 1095-1103.

Recent published results[62] indicate that silicon and certain silicones found in breast implants are present in tissues surrounding these implants. However, the results do not provide evidence that either silicon or the detected silicones are responsible for adverse immunological (or other toxic) reactions to breast implants. One or more of the silicones found in these studies are also found in food and many other products, including commonly used medicines and cosmetics. Therefore, exposure to these silicones from other sources is widespread. Although there is continued interest in potential adverse reactions to silicones, the current scientific information does not provide convincing evidence of adverse immunological effects.

Polyurethane Foam-Coated Breast Implants

This section is applicable to those women who received a polyurethane foam-coated breast implant.

Until the polyurethane foam-coated breast implants were taken off the market in 1991 because of concerns that the coating might increase the risk of breast cancer, about 10% of women with breast implants received the polyurethane foam-coated type of breast implant. The polyurethane foam 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 polyurethane foam-coated implants, Bristol-Myers Squibb Company, analyzed the urine of women with these devices for TDA.[63] Researchers found TDA in the urine but in such tiny amounts that the risk of

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[62] Flassbeck, D, Pfleiderer, B, Klemens, P, Heumann, KG, Eltze, E, and Hirner, AV. Determination of siloxanes, silicone, and platinum in tissues of women with silicone gel-filled implants; *Anal Bioanal Chem* **375** (2003) 356-362.

[63] 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.

cancer from the polyurethane foam-coated implants is only about one in a million over a woman's lifetime. Therefore, it is unlikely that even one 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 foam-coated implants could increase the risk of cancer to a nursing infant. FDA required the company to analyze mother's milk for TDA, but the company was unable to get enough lactating women with these implants to conduct a valid study.

Trilucent™ Breast Implants

This section is applicable to those women who received Trilucent™ breast implants.

The Trilucent™ is an alternate breast implant that consists of a silicone shell filled with purified soybean oil. Although the Trilucent™ breast implants were once part of an IDE study, which is now closed, the Trilucent™ breast implants were never approved for marketing in the U.S. They were, however, approved for marketing in Europe. The Medical Device Agency (MDA), the British equivalent of the FDA, removed Trilucent™ breast implants 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™ breast implants could cause cancer.

In June 2000, the MDA issued a hazard notice recommending women to consider having their Trilucent™ breast implants removed and to avoid pregnancy and breast-feeding while they still are implanted with their Trilucent™ breast implants. The MDA hazard notice is available on MDA's website at http://www.medical-devices.gov.uk.

A recently published study of explanted Trilucent™ breast implants indicated that all explanted implants showed evidence of shell deterioration, probably because the lipid in the Trilucent™ filler interacts with and weakens the shell.[64] This may contribute to rupture of these implants. Also, high levels of the breakdown products were found in all Trilucent™ breast implants tested.

Additional information from Inamed Corporation is available at http://www.inamed.com/con_info/us/con_information.html.

[64] Kirkpatrick WNA, Jones BM. The history of Trilucent implants, and a chemical analysis of the triglyceride filler in 51 consecutively removed Trilucent breast prostheses. Brit J Plast Surg 2002;55:479-489.

BREAST IMPLANT SURGERY & RELATED ISSUES

Choosing a Surgeon

When choosing a surgeon who is experienced with breast implantation, we recommend that you find out the answers to the following questions:

- In which states is he/she licensed to practice surgery? Note that some state medical licencing boards provide information on disciplinary action and malpractice claims/settlements to prospective patients either by request or on the internet.

- Is he/she board certified, and if so, with which board?

- How many breast augmentation, reconstruction, or revision surgeries does he/she perform per year?

- How many years has he/she performed breast implantation surgeries?

- What are the most common complications he/she encounters with patients after breast implantation?

- What is his/her reoperation rate with breast implants 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.

Choosing an Implant

You should consider the following when you and your surgeon are discussing implant options.

Implant Status – Whether or not an implant is PMA-approved or investigational (not PMA-approved) should be something you consider (see the **Status/Availability** section for details). An implant that is investigational means you will need to be part of a clinical study to get these implants. In addition, the surgeon of your choice may work with only specific breast implants.

Shape and Size - Depending on the desired shape and size you wish to achieve, you and your surgeon may choose a round or contoured implant shape of appropriate size (volume). You should be aware that contoured implants that are placed submuscular (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.

Implant Surface - 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. However, other studies of a large number of women with saline-filled implants show no difference in the likelihood of developing capsular contracture with textured implants when compared to smooth-surfaced implants.

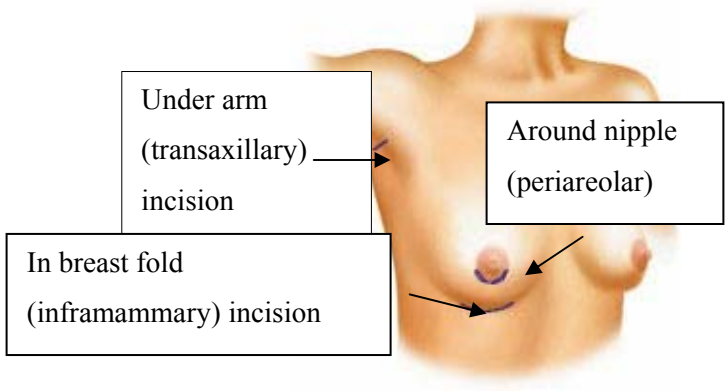
Implant Palpability/Visibility - The following may cause implants to be more palpable (more easily felt) or more visible: textured implants; larger implants; subglandular placement; and smaller amount of skin/tissue available to cover the implant.

Choosing the Surgical Incision Site

You should discuss the pros and cons for each incision site you are considering with your surgeon. Your surgeon may recommend an incision site for you depending on whether you will be having augmentation or reconstruction.

Augmentation Incision Sites – The three common incision sites are under the arm (transaxillary), around the nipple (periareolar), or within the breast fold (inframammary). The sketch below shows each of these incisions sites.[65]

- Transaxillary – This incision is less concealed than periareolar but associated with less difficulty than the periareolar incision site when breast feeding.
- 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.



The umbilical/endoscopic incision site is not recommended by companies.

[65] Sketch from Inamed patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.

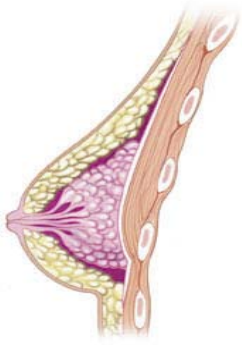
Reconstruction Incision Sites - Most implants in breast reconstruction use the mastectomy scar either immediately during the mastectomy procedure or after tissue expansion.

Choosing the Type of Implant Placement

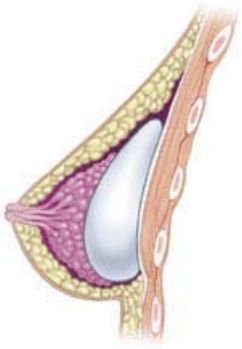
The breast implant can be placed either submuscularly or subglandularly. You should discuss with your surgeon the pros and cons of the implant placement selected for you.

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 during mammography exam	More difficult imaging during mammography exam

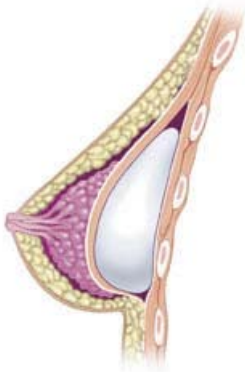
The sketches below show the differences between subglandular and submuscular placement of your implant compared to a breast before augmentation.[66]



Breast before augmentation



Breast after subglandular augmentation



Breast after submuscular augmentation

[66] Sketches from Inamed patient labeling at FDA's website at http://www.fda.gov/cdrh/breastimplants/.

General Description of Breast Implant Surgery

Breast implant surgery can be performed on an outpatient (not in the hospital) basis or in a hospital. It can be done under local anesthesia (only the breast area is numbed) or under general anesthesia (put to sleep or not aware of having surgery).

Breast implant surgery can last from one to several hours depending on your particular case (your condition, implant choice, incision site, implant placement, etc.).

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 (after surgery) complications, and your general health. The length of the hospital stay 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 treatment for pain and nausea.

After the Surgery

Your doctor should describe the usual postoperative recovery process, the possible complications that can arise, and the expected recovery period. Following the operation, as with any surgery, you can expect some pain, swelling, bruising, and tenderness. These complications may last for a month or longer, but they should disappear with time. In addition, scarring is a natural outcome of surgery. Ask your doctor to 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.

Your doctor may prescribe medications for pain and nausea. Some women may experience bleeding and some may experience fever, warmth, or redness of the breast, or other symptoms of infection. You should report these symptoms immediately to your doctor. Your doctor should tell you about wound healing and how to care for your wound. Drains may be used for a few days.

You may need 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, including exercising. (If you are enrolled in a clinical study, your doctor should give you a schedule for follow-up examinations set by the study plan.)

Choices in Reconstructive Procedures

The type of breast reconstruction procedures available to you depends on your medical situation, breast shape and size, general health, lifestyle, and goals. You can have your breast reconstructed with a breast implant, a tissue flap (your own tissues), or a combination of the two. If you have breast reconstruction, with or without breast implants, you will probably undergo several reoperations 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, your doctor may suggest surgery on the other breast to achieve a similar appearance.

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 affects the healing process.
- Skin necrosis may occur because blood circulation to the remaining tissue has been changed by a mastectomy. Radiation treatment may also increase skin necrosis.
- It usually takes more than one operation to achieve the desired cosmetic outcome, especially if the reconstruction procedures include building a new nipple.
- Breast reconstruction is an optional procedure and is not needed to treat the cancer.

Breast Reconstruction with Breast Implants

The following information applies to reconstruction following mastectomy. However, similar considerations apply to reconstruction for breast trauma or congenital defects.

Your doctor will decide whether your health and medical condition makes you an appropriate candidate for breast reconstruction with breast implants. Women with larger breasts may require reconstruction with a combination of a tissue flap and an implant.

Your doctor may recommend a breast implant, reduction mammoplasty (breast reduction), or a mastopexy (breast lift), of your opposite, uninvolved breast to improve symmetry with your reconstructed breast. Reduction mammoplasty involves removal of breast tissue and skin. 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. If it is important to you not to alter the unaffected breast, you should discuss this with your doctor because it may affect the breast reconstruction procedures considered for your case.

The breast reconstruction process may begin at the time of your mastectomy (immediate reconstruction) or weeks to years afterwards (delayed reconstruction).

Immediate reconstruction is one-stage or two-stage reconstruction.

- 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 insert a breast implant under the skin where breast tissue was removed.

- Two-stage reconstruction is more typical. The first stage is a breast tissue expander placed, at the time of your mastectomy, to stretch your skin and create a pocket for a breast implant. Tissue expansion typically lasts four to six months. The tissue expander is then replaced several months later with a breast implant.

This is considered immediate reconstruction because the tissue expander is placed at the time of mastectomy.

Delayed reconstruction is a two-stage reconstruction starting with a breast tissue expander placed months or years later, which is then replaced several months later with a breast implant. This is considered delayed reconstruction because the tissue expander is placed after the mastectomy site has healed.

It is important to know that the one and two-stage references do not mean the number of surgeries involved. You should expect that any type of breast reconstruction will take several steps to complete. It could take months to years before your reconstruction is complete.

Two potential advantages to immediate reconstruction are that your breast reconstruction starts at the time of your mastectomy and that you may save money when you combine the mastectomy with the first stage of the reconstruction. However, with immediate reconstruction, there may be a higher risk of complications, such as rupture/deflation, as well as longer initial operation and healing times.

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 the pros and cons with the options available in your individual case with your surgeon, plastic surgeon, and oncologist.

Breast Reconstruction with Tissue Flaps

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

The most common types of tissue flaps are:

- the TRAM (transverse rectus abdominus musculocutaneous) flap that uses tissue from the lower abdominal area
- the Latissimus Dorsi flap that uses tissue from the upper back.

Flap surgery has the advantage of using your own tissue to construct a new breast. However, it is important for you to be aware that flap surgery, particularly TRAM flap surgery, is a major operation and more extensive than your mastectomy operation or breast implant surgery. 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 at the flap site to construct a breast mound.

Tissue flaps, in general, can be moved to the reconstruction site by one of two methods. The first method is when the flap is left attached to the muscle and blood vessels and tunneled under the skin to the reconstruction site. The second method is when the flap is completely removed and then transferred to the reconstruction site and reattached by microsurgery. More specifically, the TRAM flap can be done by either of these two methods while the Latissimus Dorsi flap procedure involves only the first method. In addition, for TRAM flap surgery, your surgeon may also need to build you a new belly button after the lower abdominal area is reshaped.

Flap surgery requires a hospital stay of several days and generally a longer recovery time than breast implant reconstruction. While you can resume normal daily activity after several weeks, some women report that it takes up to one year to resume a normal lifestyle.

Flap surgery also creates scars at the site where the flap was taken and possibly additional scars on the reconstructed breast. You may also have some temporary or permanent decreased muscle strength at the flap site.

As a special note regarding the TRAM flap procedure, if you are considering pregnancy after your reconstruction, you should discuss with your surgeon how this procedure may affect your abdominal muscle strength. In addition, although abdominal tissue feels like breast tissue to the touch, the nerves are cut during the surgery, so there may be little feeling or sensitivity in your breast. Also, you should know that a surgeon can take tissue from your abdomen only once. If you later need a mastectomy of your second breast and want to have a tissue flap procedure, then the tissue will have to come from another site, such as your back.

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 surgeon. You may have additional questions as well.

1. What are the risks and complications associated with having breast implants?
2. How many additional operations 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 surgeon. You may have additional questions as well.

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

RESOURCE GROUPS

All resource group information, except for FDA's Consumer Affairs Staff contact information, has been moved online to the "Breast Implant Resource Groups" webpage.

Visit FDA's breast implant website for this and other up-to-date information, available at: http://www.fda.gov/cdrh/breastimplants/.

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FDA's Consumer Affairs Staff

The Consumer Affairs Staff is a consumer resource to answer breast implant calls and distribute the breast implant consumer handbook. To contact the Consumer Affairs Staff, use one of the following options:

- *Call:* 301-827-3990

  This is a direct line to the Consumer Affairs Staff.

- *Call:* 1-888-463-6332

  This toll free number involves a series of prompts that leads to the Consumer Affairs Staff. The messages at each level at this toll free number change frequently, so specific numbers are not given. However, we provide the following tips. The first prompt to listen for is to talk to someone regarding a regulated product. Afterwards, listen for the prompts regarding talking to someone or obtaining information regarding medical devices. This should lead you to the Consumer Affairs Staff.

- *Email:* dsmica@cdrh.fda.gov

- *Write to:* Food and Drug Administration, Office of Health and Industry Programs, Consumer Affairs Staff, 1350 Piccard Drive, HFZ-210, Rockville, MD 20850.

- *Website:* www.fda.gov/cdrh/consumer.

TIMELINE OF 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 (the Panel) recommended that breast implants be placed in class II, requiring general controls and performance standards. 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, new technology devices, and 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 PMAs in which manufacturers present data showing the safety and effectiveness of these devices.

- January 6, 1989: FDA published a notice of intent to require submission of PMAs for saline-filled and silicone gel-filled breast implants.

- 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 (high pH). FDA requested specific information from the manufacturer about the chemical make up and safety testing of polyurethane foam. Shortly afterwards, the manufacturer of polyurethane foam-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 breast 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 breast implants to submit PMAs with data showing a reasonable assurance of safety and effectiveness of the implants by July 9, 1991.

- June 1991: FDA required the company of polyurethane foam-coated breast 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 breast implant.

- August 22, 1991: FDA determined that PMAs submitted by three companies of silicone gel-filled breast 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 companies was sufficient to establish that the silicone gel-filled breast 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 companies collected additional data.

- January 6, 1992: FDA called for a voluntary moratorium (delay) on the use of silicone gel-filled breast 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 companies' 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 company.

- April 16, 1992: FDA lifted the voluntary moratorium on breast implants. FDA also announced its decision to allow access to silicone gel-filled breast implants 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 the these clinical studies (adjunct 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 companies would later conduct clinical trials that would include a limited number of augmentation patients (core or IDE studies).

- July 24, 1992: FDA approved Mentor Corporation's adjunct study protocol for silicone gel-filled breast implants for reconstruction and revision patients 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 breast implants.

- June 2, 1994: FDA sponsored a Part 15 Hearing on saline-filled 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 a draft guidance document for 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-filled 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 companies give to physicians who, in turn, provide them to patients considering implant surgery.

- January 11, 1996: FDA sent a letter to companies of silicone gel-filled breast implants detailing the type of information needed for core studies (IDE studies) of the silicone gel-filled breast implants for augmentation, reconstruction, and revision patients.

- September 4, 1996: Poly Implants Protheses (PIP)'s 510(k) for their saline-filled breast implants was cleared for marketing by FDA.

- 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. FDA denied this petition.

- February 11, 1997: FDA received a Citizen's Petition from CanDo Organization requesting that the FDA revoke permission granted to companies to make silicone gel-filled breast implants available to women with breast cancer and women who previously had implants. FDA denied this petition.

- May 20, 1997: Hutchinson International's 510(k) for their saline-filled breast implants was cleared for marketing by FDA.

- 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 biological and immunological 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: FDA completed a study to assess the rupture rate of silicone gel-filled breast implants.

- March 30, 1998: FDA approved Inamed Corporation's adjunct study protocol for silicone gel-filled breast implants for reconstruction and revision patients only.

- May 6, 1998: Mentor Corporation and its subsidiary, Mentor Texas, signed a consent decree of permanent injunction, promising to 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 Corporation to continue marketing its breast implants because the deficiencies in Mentor Corporation'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 Inamed Corporation's IDE study for silicone gel-filled breast implants for a limited number of augmentation, reconstruction, and revision 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. FDA denied this petition.

- February 1, 1999: Silimed's 510(k) for their pre-filled and inflatable saline-filled breast implants was cleared for marketing by FDA.

- June 22, 1999: The IOM released a comprehensive report 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, which include rupture, pain, capsular contracture, disfigurement, and serious infection, may lead to medical interventions and repeat surgeries.

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.

- 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. FDA denied this petition.

- October 1999: FDA issued a draft guidance document entitled, "Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses." This guidance document was for saline, silicone gel, and alternative breast implants and replaced FDA's previous three guidance documents for the 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 breast implants to file PMAs or completed PDPs within 90 days. The PMAs or PDPs were to include data showing a reasonable assurance of safety and effectiveness of the implants. One of the reasons for the time span between the January 1993 proposed call for PMAs/PDPs and this final one was to give companies time to collect data on their preamendments or 510(k)-cleared saline-filled breast implants.

- December 17, 1999: FDA approved Silimed's IDE study for saline-filled breast implants for a limited number of augmentation, reconstruction, and revision patients at a limited number of sites.

- March 1-3, 2000: FDA convened a Panel meeting to review a PMA submitted by Mentor Corporation, Inamed Corporation, and PIP for their saline-filled breast implants and make a recommendation to the FDA whether the PMAs are approvable. The Panel recommended that Mentor Corporation's and Inamed Corporation's PMAs be approved with conditions and that the PIP PMA be disapproved. Additionally, a day of this Panel meeting was dedicated to obtaining public input on patient labeling. The transcript for this Panel meeting is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=184.

- April 28, 2000: FDA approved PIP's IDE study for saline-filled breast implants for a limited number of augmentation, reconstruction, and revision patients at a limited number of sites.

- May 10, 2000: FDA granted approval of Mentor Corporation's and Inamed Corporation's saline-filled breast implant PMAs. Both PMAs included data on the types and rates of local complications experienced by patients. The 3-year complication 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 Inamed Corporation and Mentor Corporation studies after three years reported being satisfied with their implants.

  Both PMAs were approved for females for the following indications: breast augmentation (a woman must be at least 18 years old) and breast reconstruction. The approval letter, the labeling at the time of approval, and the Summary of Safety and Effectiveness (SSED) are available at http://www.fda.gov/cdrh/pdf/p990075.html for Mentor Corporation and at http://www.fda.gov/cdrh/pdf/p990074.html for Inamed Corporation.

Updated clinical data from Mentor Corporation's and Inamed Corporation's ongoing postapproval studies for these PMAs are available in the patient labeling on FDA's website at http://www.fda.gov/cdrh/breastimplants, as well as on the websites for both companies.

- May 26, 2000: FDA approved Hutchison's IDE study for saline-filled breast implants for a limited number of augmentation, reconstruction, and revision patients at a limited number of sites.

- August 2, 2000: FDA approved Mentor Corporation's IDE study for silicone gel-filled breast implants for a limited number of augmentation, reconstruction, and revision patients at a limited number of sites.

- September 8, 2000: FDA approved Inamed Corporation's IDE study for more-cohesive (firmer) silicone gel-filled breast implants for a limited number of augmentation and reconstruction patients at a limited number of sites.

- June 29, 2001: FDA approved Mentor Corporation's IDE study for more-cohesive (firmer) silicone gel-filled breast implants for a limited number of augmentation, reconstruction, and revision patients at a limited number of sites.

- July 18, 2001: FDA approved Mentor Corporation's IDE study for saline/silicone gel-filled breast implants for a limited number of reconstruction patients at a limited number of sites. These implants have an inner lumen filled with saline and an outer lumen filled with silicone gel.

- August 13, 2001: FDA issued an updated breast implant guidance document entitled, "Guidance for Saline, Silicone Gel, and Alternative Breast Implants." This version replaced the October 1999 version.

- September 5, 2002: FDA approved Silimed's IDE study for silicone gel-filled breast implants for a limited number of augmentation, reconstruction, and revision patients at a limited number of sites.

- December 30, 2002: Inamed Corporation submitted a PMA for their silicone gel-filled breast implants.

- February 11, 2003: FDA issued an updated breast implant guidance document entitled, "Guidance for Saline, Silicone Gel, and Alternative Breast Implants." This version replaced the August 2001 version.

- April 29, 2003: FDA approved CSS' IDE study for saline-filled breast implants for a limited for a limited number of augmentation, reconstruction, and revision patients at a limited number of sites.

- May 14, 2003: FDA approved Inamed Corporation's IDE study for saline/silicone gel-filled breast implants for a limited number of augmentation, reconstruction, and revision patients at a limited number of sites. These implants have an inner lumen filled with saline and an outer lumen filled with silicone gel.

- August 22, 2003: Consent Decree with Mentor Corporation was vacated by court. Mentor satisfied FDA's requirement that Mentor's Irving, Texas facility be in continuous compliance for at least five years with the FDA's current good manufacturing practices requirements.

- October 14-15, 2003: FDA convened a Panel meeting to review a PMA submitted by Inamed Corporation for a silicone gel-filled breast implant and to make a recommendation to the FDA whether the PMA is approvable. The PMA included data collected in their core clinical study (the IDE), as well as information from the larger adjunct study, medical device reports from a variety of databases, and

published scientific literature. Approximately 120 members of the public also were afforded an opportunity to address the Panel. The Panel voted nine to six to recommend approval of the PMA with certain conditions.
A copy of the Panel meeting agenda, Panel package, Panel roster, FDA slides, brief summary of Panel meeting, and complete transcript are available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=388.

- November 3, 2003: FDA received a Citizen's Petition from Kim Gandy, Sidney Wolfe, M.D., and Cynthia Pearson requesting the FDA to stop the review of the Inamed Corporation silicone gel-filled breast implant PMA until the information described in their petition was provided. FDA denied the petition because FDA is required to complete the review of an outstanding application and make a decision.

- November 18, 2003: FDA received a Citizen's Petition from Marlene Keeling requesting the FDA to stop the review of any silicone gel-filled breast implant PMA until the information described in their petition was provided. FDA denied the petition because FDA is required to complete the review of an outstanding application and make a decision.

- December 12, 2003: Mentor Corporation submitted a PMA for their silicone gel-filled breast implants.

- January 7, 2004: As noted on their website at http://www.inamed.com, Inamed Corporation announced that they received a "Not Approvable" letter from FDA for their silicone gel-filled breast implant PMA and that the letter outlines the additional information that Inamed Corporation must provide prior to the FDA's further review of its PMA. FDA cannot discuss the specific details of that letter because it is considered confidential material.

- January 13, 2004 (pre-publication release date of January 8th): FDA issued an updated (and in draft) guidance document entitled, "Saline, Silicone Gel, and Alternative Breast Implants." The substantive new recommendations in the draft guidance document involve mechanical testing, modes and causes of rupture, clinical study information, postapproval requirements, and labeling. A copy of the draft guidance document is available at http://www.fda.gov/cdrh/ode/guidance/1239.pdf. FDA also issued a press release regarding this guidance document. The press release is available at http://www.fda.gov/bbs/topics/NEWS/2004/NEW01003.html. After the comment period, the guidance document will be finalized and then replace the February 2003 version.

MEDWATCH

MedWatch is the FDA's program for reporting serious complications and problems with medical products, such as drugs and medical devices. MedWatch data include voluntary and mandatory (required) reports by consumers and others. MedWatch data are most useful as an early warning system when the hazards of a device are previously unknown. FDA also uses these data to follow trends with particular devices and look for signals that further follow-up could be needed.

If you have experienced one or more serious problems related to your breast implants, you may ask you healthcare provider (for example, nurse or doctor) to report the problem(s) to the manufacturer or to FDA. If you are participating in a study, you should report all problems to your doctor so that information will be included as part of the study data.

If you want more information, please visit the MedWatch website at http://www.fda.gov/medwatch or call 1-800-332-1088.

FREEDOM OF INFORMATION

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; and specific chemical compositions. In addition, FDA cannot acknowledge the existence of an IDE study unless we know that the company 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/foi/foia2.htm. You may also obtain FOIA information by calling 1-888-INFO-FDA (1-888-463-6332). FDA may charge a fee for completing a FOIA request.