

Information for Women

Considering Silicone-Filled Breast Implants



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To the Patient

McGhan Medical encourages all women considering breast implant surgery to read this brochure, as well as the package insert for this device, and discuss the possible risks and benefits of the surgery with her physician before surgery is scheduled. McGhan Medical is committed to informing patients of the possible risks and benefits of breast implant surgery, as well as other surgical alternatives available. We have provided a list of resources at the end of this brochure that may help you find more information and support for your decision to have breast implant surgery.

For some women, breast implants can improve their quality of life. Some breast cancer survivors believe that getting breast implants can be an important part of their recovery. However, other women find external breast forms to be satisfactory. Reconstruction options include breast implants or surgery using tissue from a patient's own abdomen, back, or buttocks to form a new breast. This surgery requires sufficient fat tissue and a longer operation, and like any other procedure, it is not always successful. For each woman, whether her goal is augmentation or reconstruction, the benefits may be different. With your physician's advice, you must decide whether or not you wish to accept the possible risks in order to achieve the expected results.

Breast implant surgery presents the same general risks associated with anesthesia as any other surgery. After the surgery, there are other special risks related to silicone-filled breast implants. (The McGhan Medical package insert gives additional, more detailed information. You can get the package insert from your physician.)

Availability of Implants

On April 10, 1991, FDA asked the manufacturers to submit evidence that silicone-filled breast implants were safe and effective. However, much of the information was not available. This did not necessarily mean that the breast implants were unsafe, but it did mean that FDA could not, as the law requires, confirm their safety.

With insufficient data on safety and effectiveness, FDA determined that silicone-filled breast implants could not be approved and could not be marketed for the purpose of breast augmentation in healthy women. However, under the law, FDA may extend its review period of devices already on the market if the agency determines that a continued availability of the device is necessary for the public health. In April 1992, after a careful evaluation of the public health need, the alternatives to silicone-filled breast implants, and the known, potential and suspected risks, FDA reached the conclusion that silicone-filled breast implants should continue to be available for women seeking breast reconstruction because of their public health need.

Because there are FDA concerns about the possible short-term and long-term effects of silicone-filled breast implants, FDA has limited access to these devices to women who are enrolled in a clinical study sponsored by the manufacturer and approved by FDA. Each patient must give informed consent, and the study must be overseen by an Institutional Review Board. An Institutional Review Board is composed of unbiased scientists, health professionals and community members who oversee and protect patients participating in a clinical study.

How to Enroll in a Study on Silicone-Filled Breast Implants

To enroll in a study on silicone-filled breast implants, you must meet certain criteria. You should first contact the physician you choose to perform your breast implant surgery. A list of participating physicians can be obtained by calling McGhan Medical at 800.624.4261. The physician will determine your eligibility for the study and contact McGhan Medical to make the necessary arrangements. The physician must certify to McGhan Medical that you qualify for the breast implant, then make the necessary arrangements with McGhan Medical. You or your physician may contact McGhan Medical directly at 800.624.4261 for further information.

Your Expectations

Your consideration of breast implants should be based on realistic expectations of the outcome. To help you get an idea of what results may be possible, request “before and after” pictures of patients who have had this surgery from your physician. Keep in mind, however, that there is no guarantee that your results will match those of other women.

Your results will depend on many individual factors, such as your overall health, chest structure and body shape, healing capabilities (which may be hindered by radiation and chemotherapy, smoking, alcohol and various medications), bleeding tendencies, prior breast surgery(ies), infection, skill and experience of the surgical team, and the type of surgical procedure.

Most Common Risks

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

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

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

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

FDA completed a retrospective study on rupture of silicone gel-filled breast implants.¹ This study was performed in Birmingham, Alabama and included women who had their first breast implant before 1988. Women with silicone gel-filled breast implants had a MRI examination of their breasts to determine the status of their current breast implants. The 344 women who received a MRI examination had a total of 687 implants. Of the 687 implants in the study, at least two of the three study radiologists agreed that 378 implants were ruptured (55%). This means that 69% of the 344 women had at least one ruptured breast implant. Of the 344 women, 73 (21%) had extracapsular silicone gel in one or both breasts. Factors that were associated with rupture included increasing age of the implant, the implant manufacturer, and submuscular rather than subglandular location of the implant. A summary of the findings of this study is also available on FDA's website at <http://www.fda.gov/cdrh/breastimplants/studies/biinterview.pdf> and <http://www.fda.gov/cdrh/breastimplants/studies/biruptere.pdf>.

Robinson et al. studied 300 women who had their implants for 1 to 25 years and had them removed for a variety of reasons.² Visible signs of rupture in 51% of the women studied were found. Severe silicone leakage (silicone outside the implant without visible tears or holes) was seen in another 20%. Robinson et al. also noted that the chance of rupture increases as the implant ages.

Other studies indicate that silicone may escape the capsule in 11-23% of rupture cases.^{3,4,5,6}

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

- 2 Robinson OG, Bradley EL, Wilson DS. Analysis of explanted silicone implants: a report of 300 patients. *Ann Plast Surg*. 1995; 34:1-7.
- 3 Vinnik CA. Migratory silicon - clinical aspects. *Silicone in Medical Devices - Conference Proceedings*. 1991 February 1-2; Baltimore, MD: U.S. Department of Health and Human Services, FDA Publication No. 92-4249 (p.59-67).
- 4 Duffy MJ, Woods JE. Health risks of failed silicone gel breast implants: a 30-year clinical experience. *Plast Reconstr Surg* 1994;94:295-299.
- 5 Berg WA, Caskey CI, Hamper UM, Kuhlman JE, Anderson ND, Chang BW, Sheth S, Zerhouni EA. Single- and double-lumen silicone breast implant integrity: Prospective evaluation of MR and US criteria. *Radiology* 1995;197:45-52.
- 6 Gorczyca DP, Schneider E, DeBruhl ND, Foo TKF, Ahn CY, Sayre JW, Shaw WW, Bassett LW. Silicone breast implant rupture: Comparison between three-point Dixon and fast spin-echo MR imaging. *AJR* 1994;162:305-310.

Capsular Contracture. The scar tissue or capsule that normally forms around the breast implant may tighten and squeeze the breast implant. This is called capsular contracture. Over several months to years, some women have had changes in breast shape, hardness, or pain as a result of this contraction. Although this seems to occur to some extent in most women with breast implants, there are no reliable data on how often this happens. If these conditions are severe, more surgery may be needed to correct or remove the breast implants.

Making Breast Cancer Harder to Find. The breast implant could interfere with finding breast cancer during mammography. It may “hide” suspicious-looking patches of tissue in the breast, making it difficult to interpret results. The breast implant may also make it difficult to perform mammography. Since the breast is squeezed during mammography, it is possible for a breast implant to rupture during the procedure. It is essential that every woman who has a breast implant tell her mammography technologist before the procedure. The technologist can use special techniques to minimize the possibility of rupture and to get the best possible views of the breast tissue. Because more x-ray views are necessary with these special techniques, women with breast implants will receive more radiation than women without breast implants who receive a normal exam. However, the benefit of the mammogram in finding cancer outweighs the risk of additional x-rays.

Other Known Risks

Calcium Deposits in the Tissue Around the Breast Implant. Calcium deposits may form in the tissue around a breast implant and may cause pain and hardening of scar tissue. In some cases, these deposits may need to be surgically removed.

Additional Surgeries. You should understand there is a fairly high chance you will need to have additional surgery at some point to replace or remove the breast implant. Also, problems such as rupture, capsular contracture, infection, shifting and calcium deposits can require removal of the breast implants. Discuss the risk of these additional surgeries with your physician. Many women decide to have the breast implants replaced, but some women do not.

Infection. Infection can occur with any surgery. The frequency of infection with breast implant surgery is not known, but as a prospective patient, you should ask your physician what his or her experience has been. 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 foreign bodies present (such as breast implants) 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. After the infection is treated, a new breast implant can usually be put in.

Hematoma. A hematoma is a collection of blood inside the body (in this case, around the breast implant or around the incision). Swelling, pain, and bruising may result. The chance of getting a hematoma is not known, but if you are considering breast implants you should ask your physician about his or her experience. If a hematoma occurs, it will usually be soon after surgery. (It can also occur at any time after injury to the breast.) Small hematomas are absorbed by the body, but large ones may have to be drained surgically for proper healing. Surgical draining causes scarring, which is minimal in most women.

Delayed Wound Healing. In rare instances, the breast implant can stretch the skin abnormally, depriving it of blood supply and allowing the breast implant to push out through the skin. This complication usually requires additional surgery.

Changes in Nipple or Breast Sensation. Changes in sensation may result from breast implant surgery. These changes may be temporary or permanent. They may affect sexual response and the response of the nipple during breast feeding.

Shifting of the Breast Implant. Sometimes an implant may shift from its initial placement, giving the breasts an unnatural look. If the breast implant shifts, it may become possible to feel the breast implant through the skin. Other problems with appearance could include incorrect breast implant size, visible scars, uneven appearance, and wrinkling of the breast implant.

Unknown Risks

In addition to these known risks, there are unanswered questions about silicone-filled breast implants. For example, can the breast implants bring on symptoms of auto-immune diseases such as lupus, scleroderma, and rheumatoid arthritis? Can they bring on neurological symptoms similar to multiple sclerosis in some women? Can the breast implants increase the risk of cancer?

Connective Tissue and Related Disorders. These illnesses include autoimmune disorders such as lupus, scleroderma, and rheumatoid arthritis, as well as disorders such as fibromyalgia and chronic fatigue syndrome. Some women with breast implants have experienced these disorders as well as a variety of symptoms that could be related to the immune system. However, these symptoms may be present **without** breast implants or connective tissue disease. It is unclear at this time whether the signs and symptoms experienced by these women are related to their breast implants. In some cases, women have reported a reduction in symptoms after their

breast implants were removed; in other cases, there was no change in symptoms after their breast implants were removed.

Several human studies have been completed recently, which provide substantial, but not complete, information about any possible link between breast implants and immune-related disorders. These studies provide reassurance that the risk of developing a connective tissue disease due to breast implants is not high. Taken together, these studies tell us that the vast majority of women with breast implants will not develop defined immune-related disorders from their breast implants.

Breast-Feeding and Children. At this time it is not known what effect breast implants have on lactation. Any breast surgery may impair breast feeding. A woman with breast implants who has questions about risks while pregnant or breast feeding should consult her physician.

Cancer. At this time, there is no scientific evidence that women with silicone-filled breast implants are more susceptible to cancer than other women. Two large studies have shown no increase in the incidence of breast cancer in women with breast implants for either augmentation or reconstruction. However, the possibility has not been ruled out and further research is being conducted. Lifetime effects are currently unknown.

Resources

The following list of resources may help you find more information and support to help you make an informed decision on breast implant surgery:

National Cancer Institute	1-800-4-CANCER
American Cancer Society (Reach to Recovery)	1-800-ACS-2345
American Society of Plastic Surgeons	1-800-635-0635
Food and Drug Administration	1-888-INFO-FDA
Food and Drug Administration <i>Breast Implant Information Update</i>	FDA, Office of Consumer Affairs 5600 Fishers Lane, HFE-1 Rockville, MD 20861
McGhan Medical Corporation <i>Choices in Breast Reconstruction</i> <i>What is Silicone?</i>	1-800-624-4261

In Closing

This pamphlet is not meant to take the place of consultation with your physician or the McGhan Medical package insert for this device, which contains important information on silicone-filled breast implants. We encourage you to review all the materials available to you and discuss the risks and benefits of breast implant surgery, as well as your expectations, with your physician.

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