

## Silicone Gel Breast Implants

Silicone gel breast implants have been available in the United States for decades – going back to a time when medical devices didn't require approval by the Food and Drug Administration (FDA). In 1992, after evaluating existing research on the safety and efficacy of silicone implants, the FDA took them off the general use market because it found that the manufacturers had not done adequate research to show that the products were reasonably safe.

In 2005 the FDA approved two silicone gel breast implants even though FDA scientists had concluded that neither company provided sufficient data to answer questions on the safety of the products and the agency's outside scientific advisors had recommended against approval of one of the applications. This decision culminated a 15 year-long struggle between the FDA and the implant manufacturers who resisted calls for long-term studies of the device. The National Women's Health Network does not believe that silicone breast implants have been shown to be safe for long-term use.

The FDA has asked implant manufacturers to inform women receiving implants that they will need regular MRI exams (which women will have to pay for out of their own pocket) to detect rupture, and to keep the clinical trials going until they have collected 10 years worth of data. (The approvals were based on 2-3 years of data.) These measures could help protect women's health and answer important outstanding questions about the safety of silicone gel breast implants, however, the FDA has an extremely weak track record when it comes to ensuring that conditions such as these are met.

### Silicone Gel Implants Cause Known Health Problems

The studies that the companies have conducted have shown that even in the first few years after women receive silicone gel breast implants, they experience high rates of complications and health problems.

- After just three years, 20 percent of augmentation patients and 46 percent of reconstruction patients had to have additional surgeries because of complications such as infection, hematoma (a collection of blood or fluid around the implant), loss of breast sensation, and the formation of scar tissue around the implant that can result in painful misshapen breasts.
- Women who received implants for augmentation experienced significant increases in muscle and joint pain, muscle weakness, fatigue and other signs and symptoms of connective tissue disease within two years. Prior to getting implants, these were healthy women, with an average age of 34.

A study conducted by FDA scientists found a significant link between silicone gel implants and fibromyalgia, a disorder that causes pain and fatigue in the muscles, tendons and ligaments. A National Cancer Institute study found that women with implants had increases in cancers of the brain, respiratory tract, cervix and vulva. And a Finnish study found that women who have implants for breast augmentation are three times more likely to commit suicide than women without implants. Some have suggested that this is because women who get implants have lower self-esteem than other women. But that does not explain why suicide rates are higher for women with implants than for women who undergo other types of plastic surgery who also have been found to have lower self-esteem. Additionally, implants interfere with accurate mammography readings. Although there are ways to minimize this interference, approximately thirty percent of the breast tissue will still be obscured in women with implants.

### Silicone Gel Implants Break

Breast implants do not last forever. Some break within the first few months of being implanted, and some last more than 15 years. A study conducted by researchers at the FDA found that the majority of women with implants had a broken implant within 15 years, and the likelihood of rupture tends to increase over time. Despite the FDA's official regulatory guidance asking implant manufacturers to gather data that would allow them to estimate how many implants will rupture over the expected lifetime of the device, neither company has provided more than 3 years of rupture data. For a device that will remain inside a woman's body for the rest of her life, this is simply not enough.

### Silicone Gel Implants May Cause Unknown Health Problems

There are still many unanswered questions about the damage that silicone gel implants may cause. When silicone implants break, silicone gel is released into the body. The long-term effects that this has on a woman's health have not been adequately researched.

Women with silicone breast implants have reported a variety of autoimmune diseases, including scleroderma, rheumatoid arthritis, and lupus. While some studies that concluded that breast implants do not cause autoimmune disease, most of that research has focused on women who had implants for a few months or a few years, and these studies have tended to include small numbers of women. Since these diseases are rare and take many years to develop and be diagnosed, it is not possible for studies of small groups of women who have implants for a short period of time to determine if implants increase the long-term risks of getting these diseases.

Researchers have suggested that exposure to toxins in silicone gel may be the trigger that causes women who are

predisposed to autoimmune disease to develop it. Silicone gel has been found to migrate to distant parts of the body and to lymph nodes, and evidence suggests it may remain there for at least several years. Some scientists have theorized that silicone gel in the lymph system could result in the development of autoimmune disease. The bottom line is that we do not know enough about the long-term potential for disease associated with silicone gel implants. Additionally, according to the Institute of Medicine (IOM) women who have had any kind of breast surgery, including implant surgery, are three times more likely to have an inadequate supply of milk for breastfeeding. Concerns have been raised about the safety of breastfeeding with implants, and there isn't enough information about the health of children breastfed by women with implants to answer mothers' questions or lay the concerns to rest.

### The Economic Burden of Implants

Because most implants will eventually break or cause health problems, women with implants are likely to need additional surgeries to remove or replace their implants. According to a study published in the New England Journal of Medicine, one in four women who get implants will require additional surgery. While the initial implant surgery is usually covered by health insurance for mastectomy patients, costs associated with additional surgeries may not be covered and are less likely to be covered for augmentation patients. There are loan packages available to finance the costs of the initial surgery (approximately \$4,000-\$6,000) for a woman whose insurance does not cover it, but she may find herself stuck with future surgical costs that she did not plan for. The cost of removing or replacing implants can be higher than the cost of getting implants in the first place. Some women have to live with deflated, leaky implants and painful, misshapen breasts because they cannot afford to have their implants removed.

### More Resources on Silicone Gel Implants

- [Beauty and the Breast](#) is a blog space led by consumer advocates Sybil Goldrich and Mary McDonough. The blog explores safety issues that surround breast implants as well as some of the fundamental questions about the meaning of beauty, self worth and the role of women in today's society.
- [Breast Intentions](#) is designed to fully inform women about breast implants before they make the decision to get them. The website is produced and maintained by Command Trust Network and In the Know. The founders of these two organizations, Sybil Goldrich and Mary McDonough, also lead the [Beauty and the Breast blog](#).
- [The Implant Information Project](#) is a web site sponsored by the National Research Center for Women & Families designed for girls and women considering breast implants, and for those who already have implants and want more information. The website gives helpful information about breast augmentation and breast reconstruction. Individuals can contact The Implant Information Project with specific questions directly via phone # (202) 223-4000 or email [iaib@breastimplantinfo.org](mailto:iaib@breastimplantinfo.org).
- [Toxic Discoveries](#) produces educational materials and information concerning chemical injury and medical device failure, including breast implants.

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