

5 Things to Know About Breast Implants

Should I get breast implants? Are there alternatives? Will they need to be replaced?

And if you decide to get implants, there are even more questions. Saline or silicone? What style? How much monitoring is needed?

Researching breast implants can be overwhelming and confusing. The Food and Drug Administration (FDA) has online tools available to help women sort through the information and provides questions to consider before making the decision.

Know the basics

FDA has approved implants for increasing breast size in women, for reconstruction after breast cancer surgery or trauma, and to correct developmental defects. Implants are also approved to correct or improve the result of a previous surgery.

A number of studies have reported that a majority of breast augmentation and reconstruction patients are satisfied with the results of their surgery.

FDA has approved two types of breast implants for sale in the U.S.: saline (salt water solution)-filled and silicone gel-filled. Both have a silicone outer shell and vary in size, shell thickness and shape.

Know the risks

Silicone implants sold in the U.S. are made with medical-grade silicone. These implants undergo extensive testing to establish reasonable assurance of safety and effectiveness. Nonetheless, there are risks



associated with all breast implants, including:

- additional surgeries
- capsular contracture—scar tissue that squeezes the implant
- breast pain
- rupture (tears or holes in the shell) with deflation of saline-filled implants
- silent (without symptoms) rupture of silicone gel-filled implants

FDA experts suggest five things women should know about breast implants.

1. Breast implants are not lifetime devices. The longer a woman has them, the greater the chances that she will develop complications, some of which will require more surgery. The patient can also request additional surgeries to modify the aesthetic outcome, such as size or shape.

“The life of these devices varies according to the individual,” says Gretchen Burns, a nurse consultant at FDA’s Center for Devices and Radiological Health (CDRH). “All women with implants will face additional surgeries—no one can tell them when.” While a few women have kept their original implants for 20-30 years, “that is not the common experience.”

2. Research products. Review the patient labeling. FDA advises that women look at the Summary of Safety and Effectiveness Data (SSED) for each implant to learn about their characteristics and the fillers used. SSEDs have been produced for all approved saline (www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm258564.htm) and silicone gel-filled (www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm063871.htm)

breast implants. These summaries provide information on the indications for use, risks, warnings, precautions, and studies associated with FDA approval of the device. Look at the frequency of serious complications found in the SSED. The most serious are “those that lead to further surgeries, such as ruptures or capsular contracture,” says Tajanay Ki, a biomedical engineer in CDRH.

FDA advises health care providers to give women the full labeling (www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm063743.htm)—all of the patient information from the manufacturer—for an implant. Ask your surgeon for the most recent version of the labeling. You should have at least 1-2 weeks to review the information before making a decision, but with some reconstruction or revision surgery cases, it may be advisable to perform surgery sooner.

3. Communicate with the surgeon. Surgeons must evaluate the shape, size, surface texture and placement of the implant and the incision site for each woman. Ask the surgeon questions about his or her professional experience, the surgical procedure, and the ways the implant might affect an individual’s life.

Also, tell the surgeon about previous surgeries and your body’s response—for example, whether surgeries resulted in excessive scar tissue—and discuss your expectations. This helps the surgeon make operative decisions that achieve the desired appearance (i.e., incision location and size, implant size and placement). Many women undergo reoperation to change implant size. To achieve

optimal results after the first procedure, careful planning and reasonable expectations are necessary.

4. Learn about long-term risks. Some women with breast implants have experienced connective tissue diseases, lactation difficulties or reproductive problems. However, current evidence does not support an association between breast implants and these conditions. FDA has identified a possible association between breast implants and the development of anaplastic large cell lymphoma (ALCL), a rare type of non-Hodgkin’s lymphoma. Women who have breast implants may have a very small but increased risk of developing ALCL in the fluid or scar tissue surrounding the implant. Like other lymphomas, ALCL is a cancer of the immune system and not of breast tissue.

5. Monitoring is crucial. FDA recommends that women with breast implants:

- promptly report any unusual signs or symptoms to their health care providers, and
- report any serious side effects to MedWatch (www.fda.gov/Safety/MedWatch/HowToReport), FDA’s safety information and adverse event reporting program.

Furthermore, women with silicone implants should get MRI screenings to detect silent ruptures three years after their surgery and every two years after that. Insurance may not cover these screenings.

Burns recommends that women with breast implants continue to perform self-examinations and get

mammograms to look for early signs of cancer. “Just because you have implants doesn’t mean you can ignore other breast health recommendations,” she says.

FDA’s Online Resources

FDA has a breast implants web page (www.fda.gov/breastimplants) with resources that include:

- Links to patient information and data for each product.
- Information about risks and complications
- Questions to ask health care professionals regarding breast implant surgery
- Contact information for manufacturers of FDA-approved breast implants and related professional organizations

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