What to Know About Breast Implants

FDA-approved implants undergo extensive testing before approval to demonstrate reasonable assurance of safety and effectiveness. Still, there are risks associated with all breast implants.

October 23, 2019 By Food and Drug Administration (FDA)

Should I get breast implants? Should they be saline or silicone? Which style? How much monitoring is needed after surgery?

Those are common questions people have when considering breast implants.

That's why the U.S. Food and Drug Administration offers the following information to help people making decisions about breast implants.

Breast implants are medical devices implanted under the breast tissue or chest muscle to increase breast size (augmentation) or to replace breast tissue that has been removed because of cancer or trauma, or that has failed to develop properly because of a severe breast abnormality (reconstruction).

The 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.

The FDA has approved two types of breast implants: saline-filled (salt water solution) and silicone gel-filled. Both have a silicone outer shell and vary in size, shell thickness, shell surface texture, and shape (contour).

Know the Risks of Breast Implants

FDA-approved implants undergo extensive testing before approval to demonstrate reasonable assurance of safety and effectiveness. Still, there are risks associated with all breast implants, including:

- Additional surgeries
- Breast implant associated-anaplastic large cell lymphoma (BIA-ALCL), which is a cancer of the immune system
- Systemic symptoms, commonly referred to as Breast Implant Illness (BII)

- Capsular contracture (scar tissue that squeezes the implant)
- Breast pain
- Rupture (tears or holes in the shell) of saline and silicone gel-filled implants
  - Deflation (with visible change to breast size) of saline filled implants
  - Silent (without symptoms) rupture of silicone gel-filled implants
- Infection

The silicone used for breast implants is different than injectable silicone. Injectable silicone is not FDA-approved for breast augmentation, breast reconstruction, or for any body contouring.

Breast Implants Are Not Lifetime Devices

The longer you have breast implants, the greater the chances are that you will develop complications, some of which will require more surgery.

The life of breast implants varies by person and can't be predicted. That means everyone with breast implants can face additional surgeries, but no one can predict when. Patients can also request additional surgeries to modify the aesthetic outcome, such as size or shape.

Understand Product Labeling for Implants

The FDA advises that people look at the Summary of Safety and Effectiveness Data for each implant to learn about the materials used to construct the device, device characteristics and the fillers used. These summaries have been produced for all approved saline and silicone gel-filled breast implants. The Summary of Safety and Effectiveness Data and the product labeling provide information on the indications for use, risks, warnings, precautions, and studies associated with FDA approval of the device.

They also provide information on how often serious complications occurred. The most serious complications are those that lead to further surgeries, such as ruptures or capsular contracture, or BIA-ALCL diagnosis.

The FDA advises surgeons to give people the full product labeling, including all of the patient information from the manufacturer, for implants. Ask your surgeon for the most recent version of the labeling, and read it carefully. If you have questions about any of this information, ask your surgeon.

Communicate With Your Surgeon

Surgeons evaluate the shape, size, surface texture, and placement of the implant and the incision site for each person. Ask your surgeon questions about his or her experience in performing breast implant surgeries, the surgical procedure, and the ways the implant might affect your life.

Tell your surgeon about previous surgeries and your body's response. For example, discuss whether surgeries resulted in a larger than expected amount of scar tissue. Also, discuss your expectations. These discussions help the surgeon make operative decisions that achieve the desired appearance, including decisions about incision location and size, as well as implant size, material, texture, and placement.

Many people have additional operations to change implant size. To achieve the best results after the first procedure, careful planning and reasonable expectations are necessary.

Know the Long-Term Risks of Breast Implants

The FDA has identified an association between breast implants and the development of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), a type of non-Hodgkin's lymphoma. People who have breast implants may have an increased risk of developing this cancer in the fluid or scar tissue surrounding the implant.

Breast implants have either smooth or textured surfaces (shells). BIA-ALCL develops more frequently in people with textured implants than in those with smooth-surfaced implants. Like other lymphomas, BIA-ALCL is a cancer of the immune system and not of breast tissue.

Some women with implants may have experienced health problems such as connective tissue diseases (such as lupus and rheumatoid arthritis), trouble breastfeeding, or reproductive problems. There is currently insufficient evidence to support an association between breast implants and those diagnoses.

Additionally, some women have also reported health problems, such as fatigue, memory loss, rash, "brain fog," and joint pain. Some patients use the term "breast implant illness" to describe these health problems, and some patients report that their symptoms have improved when the implants were removed. The symptoms and what causes them are poorly understood, and there is currently insufficient evidence to support an association between breast implants and symptoms referred to as BII. But researchers are investigating these symptoms to better understand their origins.

Monitoring Your Breast Implants Is Important

In general, follow your surgeon's instructions on how to monitor your breast implants.

If you notice any unusual signs or symptoms, report them promptly to your surgeon or health care provider. Health care providers and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Also, follow your health care provider's instructions for imaging for screening for breast cancer as this may be different for those patients who had breast augmentation and for those patients who

had breasts reconstruction. If you are making an appointment for mammography, inform the mammography facility that you have breast implants, and ask them what you can expect regarding mammography with breast implants.

Your surgeon or health care provider may also recommend other tests, such as ultrasound or magnetic resonance imaging (MRI). The FDA recommends that patients with silicone implants get regular screenings to detect silent ruptures.

If you have specific questions about breast implants, ask your surgeon or health care provider.

More FDA Resources

The FDA has a web page on breast implants with resources that include:

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

If you have specific questions about breast implants, ask your surgeon or health care provider.

This announcement was originally published on the Food and Drug Administration website.
