



Things to Consider Before Getting Breast Implants

There are several important things to consider before deciding to undergo any breast implant surgery. Below are some things the FDA thinks you should consider before undergoing breast augmentation, reconstruction or revision surgery.

- The sale and distribution of breast implants are restricted to users and/or facilities that provide information to patients about the risk and benefits of the device prior to its use in the form and manner specified in approval labeling provided by each manufacturer.
- Breast implants are not lifetime devices. The longer you have your implants, the more likely it will be for you to have them removed.
- You should assume that you will need to have additional surgeries (reoperations) because breast implants are not lifetime devices and complications can occur.
- Even if you have complications, the cost of implant removal or implant replacement may not be covered by insurance.
- The longer you have breast implants, the more likely you are to experience complications and adverse outcomes, which may be cosmetically undesirable and irreversible.
- The most common local complications and adverse outcomes are capsular contracture, reoperation and implant removal. Other local complications include rupture or deflation, wrinkling, asymmetry, scarring, pain, and infection at the incision site. For a more complete list of complications and adverse outcomes that may occur for a specific breast implant, you should ask your surgeon for the manufacturer's patient labeling and educational materials or review the relevant labeling.
- Read the manufacturer's patient labeling and other educational materials carefully and discuss any questions you have with your surgeon before deciding.
- There are different shapes, styles and textures of breast implants. Discuss your goals and expectations and the benefits and risks of breast implants with your surgeon.
- If you have your implants removed but not replaced, you may experience changes to your natural breasts such as dimpling, puckering, wrinkling, breast tissue loss, or other undesirable cosmetic changes.
- Breast implants need to be monitored for as long as you have them. If you have silicone gel filled breast implants, your healthcare provider may recommend that you have regular exams using magnetic resonance imaging (MRI) or ultrasound that may not be covered by your insurance, to screen for breast implant rupture and other complications.



- If you notice any abnormal changes in your breasts or implants, you will need to see your health care provider promptly.
- There is a risk of developing a type of cancer called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) in the breast or scar tissue (capsule) surrounding the implant. BIA-ALCL is not breast cancer. Treatment of BIA-ALCL involves removal of the implant and the capsule surrounding the implant. Some patients have also required chemotherapy and/or radiation therapy.
- Although treatable, there is a risk of death for patients diagnosed with BIA-ALCL.
- Some breast implant patients report a variety of systemic symptoms, such as chronic fatigue, brain fog, joint and muscle pain, which may not meet the diagnostic criteria to be categorized as a disease. Patients refer to these symptoms collectively as "breast implant illness (BII)." In some cases, patients report that removal of their breast implants without replacement appears to reverse their symptoms.
- Breast reconstruction often involves the implantation of not only a breast implant device but also a surgical mesh device. Implanting surgical mesh as part of breast implant surgeries has not been approved by the FDA.

For more detailed information about breast implants, visit www.fda.gov/breastimplants.