What to consider before getting breast implants:
New guidelines from the FDA

Undergoing implant surgery is a big decision and one that many patients with breast cancer consider. At Yale Cancer Center and our Smilow Cancer Hospital Breast Centers, a team of oncology professionals is available to help you and your loved ones throughout your breast cancer treatment. Our surgeons are nationally known leaders in the field of breast cancer surgery, and are experienced in the latest surgical advances and innovative techniques. Our breast surgeons and plastic surgeons work hand-in-hand to assure the best possible results and quality of life after breast cancer surgery.

We want to keep you informed of new regulations regarding breast implants. On Oct. 27, 2021, the US Food and Drug Administration (FDA) added several new safety requirements for the use of breast implants. These guidelines are intended to help make sure that you receive and understand the benefits and risks of breast implants so that you can make informed decisions about breast reconstruction surgery options.

The new actions put into place by the FDA include:

**Labeling breast implants with a “boxed warning” label**
Similar to warnings on some medications, a boxed warning is information written inside a text box, which is noticeable and easy to read.

The information in the breast implant boxed warning states that:
- Breast implants are not considered to be lifetime devices. They may need to be replaced at some point in the future.
- The chance of developing complications increases over time.
- Some complications will require more surgery.
- Breast implants have been associated with the development of a cancer of the immune system called Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). This cancer occurs more commonly with textured breast implants than smooth implants.
- Patients with breast implants may experience systemic symptoms such as joint pain, muscle aches, confusion, fatigue and autoimmune diseases.
Providing a Patient Decision Checklist
The FDA now requires that implant manufacturers sell breast implants only to healthcare providers who thoroughly review the risks of breast implant surgery using a Patient Decision Checklist. The checklist helps organize the key information the surgeon will discuss with you before surgery to help you decide whether to undergo the procedure.

As part of this process, you and your plastic surgeon are required to sign the checklist in several places before you can schedule implant reconstruction surgery. A copy of the signed checklist will be placed in your chart. It will also be given to you for your records.

Information covered in the checklist includes:
- Considerations for a successful breast implant candidate
- Risks of undergoing breast implant surgery
- Importance of physician education, training and experience
- Risk of BIA-ALCL
- Risk of other systemic symptoms associated with breast implants
- Discussion of options other than breast implant surgery, as appropriate

Other required information
The FDA guidance also recommends that all patients receive the following information:
- Screening recommendations for detecting a rupture in silicone gel-filled breast implants
- Device material/manufacturing descriptions, including chemicals that may be released by breast implants
- A patient device card

What is the risk of developing cancer from a breast implant?
There are two types of implants:
- ones with a smooth shell
- ones with a textured shell

The risk of developing BIA-ALCL is associated more often with textured breast implants. However, patients with smooth breast implants have also been diagnosed with BIA-ALCL.

Estimates for the risks of developing BIA-ALCL in patients with textured implants ranges from 1 in 3,000 patients to 1 in 30,000. For patients who have textured implants, there is currently no evidence to suggest that removing the implants eliminates the risk of BIA-ALCL. The FDA, American Society of Plastic Surgeons, and the American College of Surgeons do not recommend removing textured breast implants to prevent BIA-ALCL. However, if a patient has symptoms of BIA-ALCL, treatment involves removal of the implant and the capsule surrounding the implant. Some patients have also required chemotherapy and/or radiation therapy.
How can you decide whether breast reconstruction surgery is right for you?
We work closely together with our patients to make individualized treatment plans. Breast reconstruction can be a physically and emotionally rewarding option for a woman who has lost a breast due to cancer or another disease.

Through the use of various plastic surgery techniques, our goal is to restore the appearance, symmetry and size of the breast to near normal shape. Reconstruction of a breast can help to improve your self-image, self-confidence and quality of life after lumpectomy or mastectomy.

When considering breast reconstruction, it is important to evaluate your goals and reasonable expectations. At the time of your consultation, several options will be discussed with you. These options may include flat closure with external prosthesis (if desired), implant reconstruction or autologous reconstruction.

Our healthcare providers routinely discuss the benefits and risks of breast implants when considering breast reconstruction options. If you do choose reconstruction surgery, you will receive additional information about all aspects of your procedure and ways to enhance your recovery. Our goal remains to create a plan together with you and support you as you choose the best option for yourself.

To read more about what things to consider before getting a breast implant, please visit the FDA website for additional information:

https://www.fda.gov/consumers/consumer-updates/what-know-about-breast-implants