Textured Breast Implants & the FDA recall

What To Know & What to ask your health care providers & more importantly, how to decide if you want to have or keep your implants

On July 24, 2019, the FDA (US Food and Drug Administration) requested that Allergan recall specific models of its textured breast implants and tissue expanders from the U.S. market due to an increased risk of patients with these specific implants developing BIA-ALCL (breast implant-associated anaplastic large cell lymphoma.) Allergan did then voluntarily move forward with a worldwide recall of their BIOCELL textured breast implant products and tissue expanders that are specified in the FDA link here. https://www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue#list You'll see that the link lists the recalled implants in the medical device section of the FDA website as breast implants are considered medical devices. The concerns regarding certain implants has been reported in the news for over a year and in an effort to inform our survivor community, . The speakers/panelists were: Steven Nagel, MD, FACS, Surgical Oncologist and Medical Officer with the US Food and Drug Administration, Andrew Warheit, MD, Diagnostic Radiologist and Medical Director, Breast Center at St. Peter's Hospital, Danielle Krol, MD, Medical Oncologist, US Food and Drug Administration. An event podcast is available for the Q&A portion of the event at *https://tolife.org/education-and-resources/educational-programs/beat-odds*. A brief summary of some of the program and information is outlined below.

BIA-ALCL is a rare form of Non-Hodgkin's Lymphoma It's important to know that not all implants from Allergan are on the recall list and that other companies make textured implants that are also not on the recall list. Accordingly, if you already have an implant you'll want to verify what type you have (either by looking at an identification card that you have and/or contacting the plastic surgeon who performed your surgery) and then verifying your implant information with the recall list to determine whether your implant is on the recall list. You may be wondering why the FDA specifically asked Allergan to recall their products. The FDA asked only Allergan to voluntarily recall the specified implants because they determined that these implants (and tissue expanders) posed an increased risk of BIA_ALCL to patients over other implants that are not on the recall list. The FDA is not recommending removal for patients without any symptoms but they do provide information "5 Things to Know About Breast Implants" (summarized below but the full information is at this link: *https://www.fda.gov/consumers/consumer-updates/what-know-about-breast-implants*). Additionally, the following link provides information about various forms of breast implants as well as potential complications: *https://www.fda.gov/medical-devices/breast-implants/risks-and-complications-breast-implants.*

Dr. Andrew Warheit (Diagnostic Imaging with Breast Implants) provided a compelling presentation addressing types of monitoring for survivors with implants, including imaging such as mammography, ultrasound and MRI. He also discussed timing of monitoring and encouraged survivors to speak with their health care providers to determine the best monitoring approach for their own health situation.

Of the extensive references provided in Dr. Nagel's talk, one may provide the most concise answer to the question "What do I need to know about this?" The FDA publication "What to Know About Breast Implants" summarizes facts and concerns about implants, including discussion points to be explored during the decision process about reconstruction. The FDA publication suggests the following (presented here in summary)

1. Recognize that breast implants are not considered lifetime devices.

Like any other device or appliance, implants age and can develop problems. An implant's lifetime varies by individual and is impossible to predict. The longer implants are in place, the more likely that problems will eventually arise. An implant may last 20 – 30 years but that is not the norm.

2. Review Product Labeling

All approved saline and silicone gel filled implants come with a Summary of Safety and Effectiveness Data (SSED). Summaries provide information on indications for use of the implant, risks, warnings, precautions and studies associated with FDA approval. Look for information about serious complications that may require further surgeries. The FDA advises health care providers to give patients full product labeling and for patients to read it carefully.

3. Communicate with your surgeon.

Each patient is different and each surgery must be evaluated by the surgeon based on unique characteristics and preferences including size, type and placement of implants.

Patients should ask questions about the procedure, likely and unlikely outcomes, the healing process and living with an implant over time. Surgeons should be told about previous surgeries and any complications, such as more extensive scar tissue than expected, to help inform the surgical decision making. Many patients will have additional surgeries to change implant size. Careful planning and reasonable expectations help to achieve the best possible results from the first procedure.

4. Learn about long-term risks.
Breast implants approved in the U.S. can be filled with either saline or with silicone gel. They come in different sizes and shapes and have either smooth or textured surfaces (shells). As noted earlier, the FDA has identified an association between breast implants and BIA-ALCL, a type of non-Hodgkin's lymphoma. BIA-ALCL appears to develop more frequently in individuals with textured implants than in those with smooth-surfaced implants.

Some women with implants may have experienced health problems including connective tissue diseases (such as lupus and rheumatoid arthritis), trouble breast-feeding, or reproductive problems, but current evidence does not support a link between implants and these conditions.

5. Know that monitoring is important.
Follow your health care provider's instructions on how to monitor your breast implants and promptly report any unusual signs or symptoms.

Also, follow your provider's instructions for routine mammography screening for breast cancer. When you make your appointment, be sure to inform the mammography facility that you have breast implants so enough time is scheduled for your mammogram. Your provider may recommend other tests, such as magnetic resonance imaging (MRI). The FDA recommends that people with silicone implants get MRI screenings to detect silent ruptures three years after their surgery and every two years after that.

A *To Life!* Perspective
Digesting all this safety information when someone is trying to determine whether to have reconstruction and if so, what type, is challenging. It is no so when it has been years since your implant reconstruction and you want to know whether you should have it removed and possibly replaced. At the end of the day, after any or all reconstruction options are presented by medical providers based on your appropriate medical circumstances, it may boil down to personal preference. Some people want autologous tissue reconstruction, some really like the look and feel of silicone implants, and some prefer saline implants. Some survivors prefer not to have reconstruction and instead use prosthesis and bras. Others prefer to do nothing at all post mastectomy. At *To Life!* we are here to provide information and give you the tools to make your best educated but very personal decision.