Breast Restoration AdVocacy and Education (BRAVE)

Allergan Voluntarily Recalls BIOCELL® Textured Breast Implants and Tissue Expanders

Important Product Safety Information

On July 24, 2019, Allergan announced a voluntary worldwide withdrawal of unused stock of BIOCELL® textured breast implants and tissue expanders from doctors' offices and hospitals, and a suspension of any future sales which is part of the voluntary recall of BIOCELL® textured breast implants and tissue expanders. Natrelle smooth breast implants and MICROCELL® breast implants are not subject to this withdrawal.

Why did Allergan do this?
Allergan took this action following notification by the U.S. Food and Drug Administration (FDA) of their recently updated global safety information. This information showed an association between breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and Allergan BIOCELL® textured breast implants.

At this time, the likelihood of developing BIA-ALCL is thought to be low, occurring in less than 0.03% of patients with BIOCELL® textured breast implants; *however, BIA-ALCL is a serious condition and can lead to death, especially if not diagnosed early or treated promptly.*

What is BIA-ALCL?
BIA-ALCL is not breast cancer—it is a type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL

is found in the scar tissue and fluid near the implant, but in some cases, it can spread throughout the body.

What are the symptoms of BIA-ALCL?
BIA-ALCL symptoms include breast enlargement or hardening, persistent pain, lump in the breast or armpit, or a large fluid collection surrounding an implant. These symptoms have been reported between 6 months and 26 years after implant placement and are typically diagnosed an average of seven (7) to nine (9) years after implant placement.

BIA-ALCL is highly curable if detected early. Prompt diagnosis is key.

What is the likelihood of developing BIA-ALCL?
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What do I need to do if I have BIOCELL® textured breast implants or tissue expanders?
Patients with Allergan BIOCELL® breast implants or tissue expanders should be aware of the following important recommendations from the FDA:

- If you have no symptoms, the FDA does not recommend the removal of these or other types of breast implants due to the low risk of developing BIA-ALCL. However, if you have any questions, talk to a board-certified plastic surgeon.
- Know the symptoms of BIA-ALCL and monitor the area around your breast implants for any changes.
- If you have symptoms, notice anything of concern about your breasts or suspect anything may be wrong with your implants or expanders, please speak with a board-certified plastic surgeon. Evaluation for BIA-ALCL typically involves a physical exam and assessment of the fluid and/or tissue around the breast implant.

It is important to undergo an evaluation to diagnose BIA-ALCL since a confirmed BIA-ALCL diagnosis may change the type of operation that should be performed.

- Based on discussions with your healthcare provider, patients with confirmed BIA-ALCL should undergo implant removal and removal of the surrounding scar capsule, which is a more extensive operation than implant removal alone.

What is a "voluntary recall"?
This means that Allergan, the manufacturer, has willingly agreed to no longer make or sell these types of implants, and will retrieve the product from healthcare professionals. This product withdrawal from the market does not mean your implants need to be removed unless you have specific symptoms. Only unused products that are currently at doctor's offices, hospitals, or surgery centers need to be returned.

It is important to note that the US Food and Drug Administration (FDA) as well as international regulatory agencies do not recommend removal or replacement of textured breast implants or tissue expanders in patients without symptoms.