Mount Sinai

Breast Implant Recall Announcement

Mount Sinai Health System has been informed by the U.S. Food and Drug Administration (FDA) of a nationwide recall of a breast implant product.

In late July 2019, the FDA requested that Allergan, the manufacturer of a specific type of textured breast implant, recall specific models of its textured breast implants from the U.S. market due to the risk of BIA-ALCL (breast implant-associated anaplastic large cell lymphoma). According to the FDA, the overall incidence of BIA-ALCL appears to be relatively low (less than 0.03 percent of patients).

The FDA and other health authorities have not recommended removal or replacement of textured breast implants or tissue expanders in asymptomatic patients at this time.

Patients who want more information should contact their plastic surgeon about the applicability of this recall to them, as well as about risks, alternatives, and benefits of maintaining versus removing the implant. Medical information from the implant manufacturer can be obtained at 1-800-678-1605, option 2, or at IR-Medcom@allergan.com. Additional information can also be found at the following sites:

- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergan-voluntarily-recalls-biocellr-textured-breast-implants-and-tissue-expanders#recall-announcement

- https://www.allergan.com/medical-aesthetics/biocell-product-safety-alert