

MEMORIAL

— PLASTIC SURGERY —

August 23, 2019

RE: IMPORTANT NOTICE REGARDING BIOCELL TEXTURED BREAST IMPLANTS AND TISSUE EXPANDERS

As a patient of our practice, we would like to share the recent reports regarding an uncommon condition called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). BIA-ALCL is not a breast cancer, but rather a type of lymphoma that develops in the fluid or tissue immediately around the breast implant. At this time, data supports the likelihood of developing this condition as extremely low. This rare condition affects approximately 1:16,000 - 1:30,000 patients, with reports of only 573 unique cases worldwide that were found in patients who have or had a history of textured breast implants.

Please know that it is extremely rare to have textured breast implants placed in a cosmetic setting at our practice. If you are a cosmetic breast augmentation patient, smooth breast implants were most likely used and this notice does not apply to you. If you are an implant-based reconstructive patient however, it is highly likely that a textured implant was placed following your mastectomy due to the numerous advantages. Patients who do not have their implant card information, or are unsure of what type of breast implant was used in their procedure may contact our office to retrieve this information.

In July of 2019, the Food & Drug Administration (FDA) issued a notice instructing Allergan, a breast implant manufacturer, to recall its Allergan BIOCELL textured breast implants and tissue expanders from the market due to the higher occurrence of BIA-ALCL in patients who have, or have had, these specific implant devices. This global recall does not affect Allergan's NATRELLE smooth or MICROCELL breast implants and tissue expanders. To date, there have been no confirmed cases of breast implant-associated anaplastic large cell lymphoma in women who have only had "smooth surface" breast implants and we have seen no indication of BIA-ALCL in any of our cosmetic or reconstructive patients.

Due to the rarity of this condition, the FDA does not currently recommend the removal of textured implants unless a patient is experiencing symptoms or has been diagnosed with BIA-ALCL. The initial presenting symptom is typically a distinct swelling or change in size of the breast that is seen to present itself approximately 8-10 years, on average, after implantation. Other symptoms may include the breast hardening, persistent pain, lump in the breast or armpit, or a large fluid collection surrounding the implant that usually affect only one side but can occur to both breasts.

BIA-ALCL is a very curable condition in most patients but can become serious when left untreated. In most patients, BIA-ALCL is treated successfully with surgery to remove the implant and the scar tissue surrounding it, but some patients may require additional treatment such as radiation or chemotherapy. Patients who are experiencing any of these symptoms or have any concerns regarding BIA-ALCL are encouraged to contact our office so we can help answer any of your questions and determine if further evaluation or testing is necessary. We would also like to remind our patients of the importance of ongoing breast health surveillance, including self-breast exams and mammograms scheduled by your physician.

For more information about BIA-ALCL, please feel free to contact our office so we can help answer any of your questions.

Sincerely,

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