

Updated BIA-ALCL FAQ's

Over the past several months, textured breast implants have been in the news. On July 24, 2019 the FDA requested that the Allergan company voluntarily recall its Biocell textured implants: <https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan>. You may receive information directly from Allergan. I am writing to provide additional information and to discuss what action, if any, is appropriate.

What is BIA-ALCL? “Breast Implant Associated Anaplastic Large Cell Lymphoma”, (BIA-ALCL), is a rare form of lymphoma. It is not a cancer that develops in the breast. There are many types of lymphomas. This type of lymphoma develops within the capsule that forms naturally around the implant.

Why Just the Allergan BioCell Textured Implants? Some breast implants have a textured surface. The texturing of the Biocell implants is different from the texturing of other implants and has been associated with the highest risk of BIA-ALCL. It is important to know that there have been NO confirmed cases of BIA-ALCL associated with smooth implants.

Is Allergan's Recall like an Automotive Safety Recall? No. There are several different types of FDA recalls. Unlike an automotive recall that seeks to replace the “recalled” part, this type of recall is simply a withdrawal of Biocell implants from future use. The term is a little confusing, but it is the term that the FDA chooses to use. The “recall”, in other words, is directed at Allergan, not at you, the patient, or at your implants.

Is Allergan Or The FDA Asking Me To Have My Implants Removed? No, just the opposite. The FDA specifically stated that it does not recommend removal or replacement of Allergan BioCell textured implants in patients who have no symptoms.

Why Did Allergan Withdraw Its BioCell Textured Implants? Although there are manufacturers of textured implants other than Allergan, the FDA analysis found that the risk of a BIA-ALCL diagnosis with Allergan products is approximately six times higher than that of other types of texture. 84% of the 573 reported cases have been linked to Allergan BioCell textured products. The diagnosis of BIA-ALCL is rare; the best estimate is thought to be approximately 1:3,000, although some centers have reported higher incidences.

How Serious Is BIA-ALCL? When BIA-ALCL is detected and treated early it is usually curable. Of the 573 cases in the world, there have been 33 deaths. Deaths associated with BIA-ALCL are thought to have resulted from delayed diagnosis or inappropriate treatment. The single most important intervention to prevent advanced BIA-ALCL is regular monitoring and early detection.

What Symptoms Should I Be Looking For? Unlike breast cancer, BIA-ALCL most commonly presents with swelling of one breast. Other less common symptoms include hardening of the breast, an unusually persistent rash or a palpable mass in the breast or armpit – all easily identified by you. If you have any of these symptoms, please call to schedule an appointment for

an examination and if needed, further tests. An ultrasound can detect the presence of fluid, and if present, a small amount can be aspirated with a needle and tested. Should this be positive for tests called CD30 and ALK, a diagnosis of BIA-ALCL will be considered. If the tests are negative, the fluid collection is considered benign. Benign fluid collections, known as seromas, are not uncommon around breast implants so it is important to differentiate them from those associated with ALCL.

What If The Tests Confirm BIA-ALCL? In most patients, BIA-ALCL is curable with surgery alone – removing the textured implants and the capsule. Consultations with other medical specialists may be recommended but in most cases there is no need for radiation or chemotherapy.

What If I Do Not Have Any Symptoms? The FDA recommends that you do not remove your BioCell textured breast implants at this time. Should you develop any of the signs or symptoms mentioned above, you should make an appointment for evaluation. You are the patient, however, and you do have the option of removing your BioCell implants, with or without replacement with smooth implants.

What Will Surgery Cost? You will be responsible for all operating room, anesthesia and surgeon fees for having your BioCell textured implants removed and for any additional surgery you may select, such as a breast lift or fat transfer. In some cases, Allergan will provide the smooth implants without charge if you desire to have the implants exchanged. This warranty at this time is limited to surgeries performed in the next two years or until July 24, 2021.

Where Can I Find More To Read? Additional information on ALCL and Allergan’s recall can be found here:

- FDA letter 5/3/2019 Summarizing recent FDA committee findings and recommendations: <https://www.fda.gov/news-events/press-announcements/statement-fda-principal-deputy-commissioner-amy-abernethy-md-phd-and-jeff-shuren-md-jd-director-fdas>
- FDA Reports of Breast Implant Associated Anaplastic Large Cell Lymphoma <https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma>
- FDA Safety Communication to Patients 7/24/2019 <https://www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue>

If you have any further concerns and would like to meet with me, please contact my office for an appointment at 518-786-1700 or e-mail me at Info@capekplasticsurgery.com. I look forward to hearing from you.