



AMERICAN SOCIETY OF PLASTIC SURGEONS

BIA-ALCL Physician Resources

BIA-ALCL Resources

Summary and Quick Facts

The following provides a summary of what is currently known about BIA-ALCL.

- Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is an uncommon and treatable type of T-cell lymphoma that can develop around breast implants. BIA-ALCL is not a cancer of the breast tissue itself.
- BIA-ALCL should continue to be discussed with any patient considering breast implants as part of the informed-consent process.¹
- The lag time between current implant insertion to diagnosis of BIA-ALCL has been from 0.8-27 years, with a mean of 9.75 years.
- No cases of BIA-ALCL have been reported with patients who have only had smooth implants in case series, case reports or registries. However, it is not possible to exclude the appearance of BIA-ALCL in association with smooth implants at this time. The FDA confirms that all confirmed cases worldwide either have a history of a textured device or an incomplete clinical history available for review.
- The association of BIA-ALCL and textured implants may be related to the increased surface area of the texturing; however, this has not yet been definitively proven. The variation in surface texturing among manufacturers may mean there are variable risks for the development of BIA-ALCL.
- The disease has been associated with both silicone and saline implants in aesthetic as well as reconstructive patients.
- The majority of patients present as a delayed seroma, but also present with symptoms of mass, skin rash, fever and night sweats and lymphadenopathy. Diagnosis is based on ultrasound-guided, fine-needle aspiration of the peri-implant fluid, which is assessed with immunohistochemistry for CD 30-positive large anaplastic T-cell lymphocytes.
- PET-CT is performed following a positive diagnosis. Mammograms are not helpful for evaluating lymphoma, but are important for the evaluation of breast cancer.

- Consideration should be given to a multidisciplinary approach including, when required, an oncological breast surgeon and an oncologist specializing in lymphoma.
- Incomplete capsular resection has been associated with both recurrence and significantly lower survival.
- The majority of patients can be cured of their disease by bilateral total capsulectomy and implant removal. Rare patients will present with a mass and have an increased risk of requiring radiotherapy and chemotherapy. Treatment approach should follow international guidelines established by the National Comprehensive Cancer Network (NCCN) for BIA-ALCL, available at nccn.org.
- Current treatment recommendation is for bilateral complete capsulectomy and implant removal, as a small number of women have had contralateral disease found incidentally.²
- The FDA recommends that any suspected or confirmed cases of BIA-ALCL be reported to the PROFILE registry, the MAUDE database and the device manufacturer. To report a case to PROFILE, go to ThePSF.org/PROFILE. To submit a case to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database, which collects medical device reports (MDRs) of suspected device-associated deaths, serious injuries and malfunctions, visit www.accessdata.fda.gov.
- For more information: visit PlasticSurgery.org/ALCL or search "ALCL" on RADAR.

1. Clemens MW, Jacobsen ED, Horwitz ST. 2019 NCCN Consensus Guidelines on the Diagnosis and Treatment of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). *Aesthetic Surgery Journal*, 39(1), 2019, Pages S3-S13.

2. Clemens MW, Brody GS, Mahabir RC, Miranda RN. How to Diagnose and Treat Breast Implant-Associated Anaplastic Large Cell Lymphoma. *Plast Reconstr Surg*. 2018 Apr;141(4):586e-599e. doi: 10.1097/PRS.00000000000004262.

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BIA-ALCL RESOURCES

- ▶ [BIA-ALCL Summary and Quick Facts \(08/2019\)](#)
- ▶ [BIA-ALCL By The Numbers \(08/2019\)](#)
- ▶ [Allergan Announces Worldwide Recall of Biocell Textured Implants \(07/2019\)](#)
- ▶ [BIA-ALCL Sample Letter To Patients \(07/2019\)](#)

- ▶ [BIA-ALCL Safety Advisory \(06/2019\)](#)
- ▶ [Free Educational Brochure: What Patients Need to Know \(03/2018\)](#)
- ▶ [ASPS Literature on BIA-ALCL](#)
- ▶ [ASPS Recommended Insurance Coverage Criteria for Third-Party Payers](#)
- ▶ [BIA-ALCL NCCN Guidelines \(Free Registration\)](#)
- ▶ [Free CME Class on BIA-ALCL](#)
- ▶ [Informed Consent Language \(02/2019\)](#)
- ▶ [PRS BIA-ALCL Supplement](#)
- ▶ [BIA-ALCL Patient Resources](#)



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