

## Breast Implant Associated ALCL (BIA-ALCL)

(From FDA.gov) In **2011**, the FDA identified a possible association between breast implants and the development of anaplastic large cell lymphoma (ALCL), a rare type of non-Hodgkin's lymphoma.

At that time, the FDA knew of so few cases of this disease that it was not possible to determine what factors increased the risk. In a [report](#) summarizing the Agency's findings, we emphasized the need to gather additional information to better characterize ALCL in women with breast implants.

Since 2011, we have strengthened our understanding of this condition and concur with the [World Health Organization designation](#) of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as a rare T-cell lymphoma that can develop following breast implants. The exact number of cases remains difficult to determine due to [significant limitations in world-wide reporting and lack of global implant sales data](#). At this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces.

We continue to collect and evaluate information about ALCL in women with breast implants.

On an ongoing basis, In **2016**, there were several advances in the description of the disease and treatment recommendations. These are described below:

- The [World Health Organization](#) recognized breast implant-associated anaplastic large cell lymphoma as a rare T-cell lymphoma that can develop following breast implants.
- Professional organizations including the [Plastic Surgery Foundation](#) and the National Comprehensive Cancer Network (NCCN) published information to help physicians understand the disease and provide diagnosis and treatment.
- Regulatory bodies outside the United States issued communications on BIA-ALCL.
  - The Australian Therapeutic Goods Administration (TGA) [reported](#) a detailed analysis of the 46 confirmed cases of BIA-ALCL in Australia, including 3 deaths. TGA estimated the risk of developing BIA-ALCL to be between 1-in-1000 and 1-in-10,000 women with breast implants.
  - The French National Agency for Medicines and Health Products Safety (ANSM) asked manufacturers of textured breast implants to perform [biocompatibility testing](#) (testing to determine how living tissues react to textured implants) and to report their findings within a year.

The following provides a summary of what is currently known about BIA-ALCL. (from the American Society of Plastic Surgery, **2017**)

- Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a rare 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.<sup>1</sup>
- The lag time between implant insertion to diagnosis of BIA-ALCL has been from 2 to 28 years, with a median of 8 years.
- No cases of BIA-ALCL have been definitively associated with patients who have only had smooth implants. However, it is not possible to exclude the appearance of BIA-ALCL in association with smooth implants at this time.
- The association of BIA-ALCL 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, although the number of cases to date remain too low to make any significant distinctions between the various forms of texturing.
- 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. Diagnosis is based on ultrasound-guided fine needle aspiration of the peri-implant fluid, which is assessed with immunohistochemistry for CD 30-positive and ALK-negative T-cell lymphocytes.
- PET-CT and MRI scans are investigations performed following a positive diagnosis. Mammograms are not helpful.
- 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](http://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.<sup>2</sup>
- 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 submit a case to PROFILE, go to [ThePSF.org/PROFILE](http://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](http://www.accessdata.fda.gov).