# BIA-ALCL Resources

## By the numbers, and what they mean

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On August 20, 2020, the U.S. Food and Drug Administration (FDA) released a safety communication updating the current understanding of BIA-ALCL, the number of known worldwide cases and calling for a voluntary Class I device recall of higher-risk devices. Many members have expressed confusion over much of the data surrounding BIA-ALCL. The purpose of this document is to discuss and bring clarity to some of the figures surrounding this rare disease.

## 733

The recent BIA-ALCL update reported that the FDA has been made aware of 733 medical device reports (MDRs) for BIA-ALCL cases worldwide related to breast implants. This is in comparison previous FDA reports of 573 unique and pathologically confirmed cases in July 2019, 660 medical device reports (MDRs) in March 2019, 414 MDRs in March 2018, 359 MDRs in March 2017, 258 MDRs in January 2016 and 64 MDRs in January 2011. When a manufacturer was listed, the FDA reports 90.4% of world cases involved an Allergan implant, 7.3% Mentor implants, 1.5% Sientra implants, and 0.9% other manufacturers. Importantly, the FDA does not recommend the prophylactic explantation of implants without the diagnosis of BIA-ALCL. Prophylactic procedures such as implant exchange or capsulectomy have not been shown to mitigate future risk of disease.

## 4.5%

The recent FDA update of 733 reports included 28 (5.3 percent) smooth implant reports. This is similar to last year's update of 26 (4.5 percent) smooth implants, 30 (7 percent) in 2018, 28 (8 percent) in 2017, and 11 (4 percent) in 2016. Very important, in the 28 cases of smooth implants, 10 have unknown prior history of implants, 8 have a history of textured implants, and 9 have a history of prior implants with an unknown texture, and 1 had a history of smooth implants. Keep in mind with these MDR reports, the FDA “cannot confirm that the reported implant history is complete.” There were no reports of cases associated with tissue expanders but there is one tissue expander report to the PROFILE registry. **To date, no purely clinical history of purely smooth-surface devices and BIA-ALCL has ever been confirmed in any series, registry or case report with a detailed history.** The FDA confirms that BIA-ALCL is predominantly associated with textured surface implants.

## 36

The FDA reports 36 unique deaths worldwide. While seroma is the most common presentation for all BIA-ALCL cases (53%), a capsular mass was the most common presentation among the deaths (39%) likely indicating more advanced and invasive disease.

## 166

166 confirmed United States cases have been reported to the PROFILE registry. The PROFILE registry is a joint collaboration between the FDA and ASPS/PSF to prospectively track BIA-ALCL patients. Based upon a global network of international plastic surgery societies sharing tracking of cases, ASPS is now aware of 885 unique cases worldwide.

## 1:355-86,029

The current published lifetime risk of BIA-ALCL is estimated to be a range of 1:355-1:86,029 based upon variable risk with different manufacturer types of textured implants. US Epidemiology was reported in 2017 with an overall textured implant risk of 1:30,000 Importantly, this was an average number across both Allergan and Mentor textured implants which were demonstrated to have a 6:1 ratio. BIA-ALCL cases from the Allergan prospective CA/CARE trial have been reported to demonstrate a risk of 1:2,207 with Allergan Biocell. This year, researchers in Australia and New Zealand reported a 1:3,345 risk with Allergan Biocell and a 1:86,029 risk with Mentor Siltex. Worldwide clusters of disease have been reported and importantly represent heightened disease awareness and excellent long-term surveillance at these centers. Unfortunately a growing narrative exists of misattributing clusters to “lapses in surgical technique” and “poor institutional hygiene” without any supportive data, which chastens surgeons and discourages the reporting of cases. To date, no operative strategy has been shown to decrease or affect the future risk of BIA-ALCL.

## 1,400

There are 1,400 patients per year diagnosed with ALCL. ALCL is a family of diseases from the very aggressive systemic ALCL to the indolent lymphoproliferative disorder primary cutaneous ALCL. For the first time in 2016, the World Health Organization added BIA-ALCL as a provisionally recognized lymphoma to the family of existing ALCL. It is important to differentiate BIA-ALCL from primary lymphoma of the breast which is predominantly a B-cell lymphoma with an incidence of approximately 1:4 million. ALK+ disease and B cell pathology should be concerning for primary lymphoma of the breast rather than BIA-ALCL.

## <5%

Approximately 550,000 total breast implants are placed per year in the U.S. Of these, approximately 70,000 textured breast implants are placed, representing 12.7 percent of the market as of 2017. In March 2019, the FDA reported that this market share may have recently decreased to less than 5%.

## 93%

93 percent of patients are disease free at 3 years follow-up, which is an excellent prognosis when treated appropriately. The National Comprehensive Cancer Network defines optimal treatment which is total capsulectomy and implant removal for most patients with disease confined to the capsule (35 percent of patients) or a resectable mass (40 percent of patients). Advanced disease with lymph node metastasis (14 percent of patients) or organ metastasis (1 percent of patients) may require further treatment with chemotherapy using either CHOP anthracycline based-protocol and/or targeted immune therapy with brentuximab vedotin. Radiation therapy is only reserved for local unresectable disease such as into the chest wall and mediastinum. Advanced disease is the end of the spectrum of cancer stages, and these patients substantiate the World Health Organization classification of BIA-ALCL as a lymphoma and not benign or lymphoproliferative.

## 30

For a suspected patient with a delayed seroma (>1 year), a minimum of 50ml fluid should be aspirated and sent for CD30 immunohistochemistry, cytology and flow cytometry. CD30 is the main diagnostic test that must be performed on the seroma fluid as routine pathology or H&E staining can frequently miss the diagnosis.

**Page last updated on October 1, 2020*