

# BIA-ALCL

is a rare lymphoma that has only been reported in patients with a history of textured breast implants. Here are some important numbers and what they mean:

457

The FDA reports that there are 457 unique medical device reports that meet the pathologic criteria of BIA-ALCL

5%

of those 457 cases, 5% were smooth implant reports all of which were previously mixed with textured implants or had no historical information available

9

the FDA reports 9 deaths. These are part of the 17 known deaths worldwide from BIA-ALCL. Of these deaths, none of the patients had the implants completely removed and were delayed in receiving any treatment

265

265 suspected/confirmed United States cases have been reported to the PROFILE registry which is a joint collaboration between the FDA and ASPS/PSF to prospectively track BIA-ALCL patients. ASPS is now aware of 688 unique cases worldwide with 17 disease-related deaths over 30 countries.

**1:3,817-  
30,000**

The current lifetime risk of BIA-ALCL is estimated to be 1:3,817 - 1:30,000 women with textured implants based upon current confirmed cases and textured implant sales data over the past two decades.

**1400**

There are 1,400 patients per year diagnosed with 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.

**12.7%**

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% of the market.

**93%**

93% of patients are disease free at 3 years, which is an excellent prognosis when treated appropriately.

**30**

For a suspected patient with a delayed seroma (>1 year), 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.