



THE AMERICAN SOCIETY FOR  
AESTHETIC PLASTIC SURGERY, INC.



AMERICAN SOCIETY OF  
PLASTIC SURGEONS

### **ASPS/ASAPS joint advisory: FDA updates website on BIA-ALCL**

The American Society of Plastic Surgeons (ASPS) and the American Society for Aesthetic Plastic Surgery (ASAPS) would like to make members aware of a recent safety communication update to the Food and Drug Administration (FDA) website regarding breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

The March 21 website update acknowledges that while it remains difficult to determine the exact number of BIA-ALCL cases, there have now been 359 medical device reports (MDR) reported to the FDA Manufacturer and User Facility Device Experience (MAUDE) database as of Feb. 1, 2017. Of these MDRs, the FDA reports that 232 included information on the breast implant device, with 203 identified as textured, 28 smooth and one identified as “another surface.” The update also confirms that both silicone gel and saline implants have been reported in cases of BIA-ALCL.

It's important to note that the MAUDE database may contain limited and potentially inaccurate adverse event reports, and does not represent the true number of U.S. cases, as some entries are duplicates and not all cases are confirmed as ALCL. To date, there has been no confirmed smooth surface-only case of BIA-ALCL reported. As of March 21, 2017, 126 unique confirmed U.S. cases of BIA-ALCL have been reported to the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE) database, a collaboration between ASPS, PSF, and the FDA.

The FDA's website update confirms previous ASPS/ASAPS communications, noting that BIA-ALCL remains a rare condition that occurs most frequently in patients who have breast implants with textured surfaces. The report also reiterates that patients should discuss with their health-care provider the benefits and risks of textured-surface versus smooth-surface implants. The FDA highlights the World Health Organization recognition of BIA-ALCL, and standardized diagnosis and treatment guidelines established by the National Comprehensive Cancer Network (NCCN).

The FDA recommends that all cases of BIA-ALCL be reported to the FDA and to the PROFILE registry, at <http://www.thepsf.org/profile>.

For more information on BIA-ALCL, visit [plasticsurgery.org/alcl](http://plasticsurgery.org/alcl) or the FDA website: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>

ASPS and ASAPS are committed to patient safety, advancing quality of care, and practicing medicine based upon the best available scientific evidence. We will continue to monitor and review all new information as it becomes available to keep the plastic surgery community informed.

Please visit the organizations websites for additional info:

ASPS: [plasticsurgery.org/alcl](http://plasticsurgery.org/alcl)

Plastic and Reconstructive Surgery:

<http://journals.lww.com/plasreconsurg/pages/collectiondetails.aspx?TopicalCollectionId=45>.

ASAPS: [surgery.org/professionals](http://surgery.org/professionals)

RADAR (search "ALCL"): [radarresource.org](http://radarresource.org)

FDA:

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>