AMERICAN SOCIETY OF PLASTIC SURGEONS

Health Policy

BIA-ALCL Physician Resources

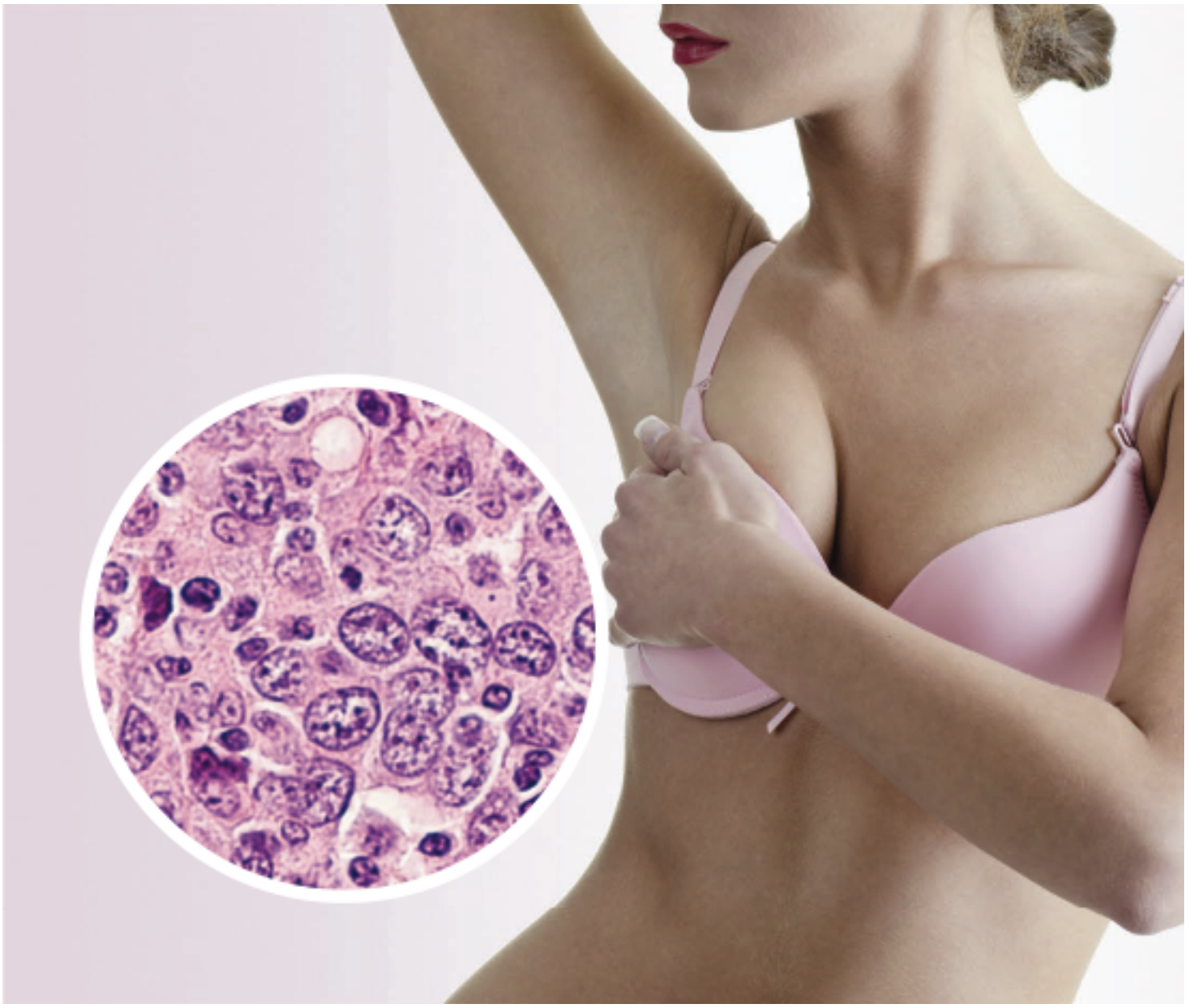
Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is an uncommon and highly treatable type of lymphoma that can develop around breast implants. BIA-ALCL occurs most frequently in patients who have breast implants with textured surfaces. The current lifetime risk of BIA-ALCL is estimated to be 1:2,207 - 1:86,029 based upon variable risk with different manufacturer types of textured implants. Since the initial case report in 1997, ASPS now recognizes approximately 288 cases in the US and a total of 735 worldwide as of August 5, 2019.

Most of the patients who have developed BIA-ALCL receive an excellent prognosis following surgical removal of the breast implants and the surrounding scar tissue capsule. Continued follow-up after any breast implant surgery is suggested and important for patient health, but patients who notice pain, lumps, swelling, fluid collections or unexpected changes in breast shape, including asymmetry, should contact their plastic surgeon. In most cases, women

diagnosed with BIA-ALCL observed changes in the look or feel of the area surrounding the implant greater than one year after their initial surgical sites were fully healed, and on average eight to ten years after receiving textured implants.

Patients undergoing plastic surgery procedures, aesthetic or reconstructive, should be thoroughly informed of the potential risks and possible complications known to be associated with the procedure, and any device used in that procedure. In the cases where a diagnosis of BIA-ALCL is made, surgical treatment is essential for the management of the disease. Some patients with more advanced disease may require further treatment such as chemotherapy.

FDA updates website on BIA-ALCL



The American Society of Plastic Surgeons (ASPS) 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 July 24th, 2019 FDA website update acknowledges that while it remains difficult to determine the exact number of BIA-ALCL cases, after thorough review there have now been **573 unique confirmed cases worldwide which included 33 known deaths**. Majority of these cases involved a textured device at the time of BIA-ALCL diagnosis or demonstrate a clinical history of

a textured device at some time prior. The update also confirms that both silicone gel and saline implants have been reported in cases of BIA-ALCL. The FDA noted that a majority (481 reports) of cases were associated with Allergan breast implants and therefore **requested a voluntary recall** of Allergan Biocell surface devices within the US. Allergan subsequently responded with a worldwide **recall** of their Allergan Biocell textured implants and expanders.

As of August 5, 2019, 288 suspected/confirmed U.S. cases of BIA-ALCL have been reported to the **P**atient **R**egistry and **O**utcomes **F**or breast **I**mplants and anaplastic large cell **L**ymphoma Etiology and **E**pidemiology (PROFILE) Registry, a joint collaboration between ASPS, PSF and the FDA.

The FDA's website update confirms previous ASPS communications, noting that BIA-ALCL remains an uncommon disease 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**.

For more information on BIA-ALCL, visit **PlasticSurgery.org/ALCL** or the **FDA website**.

ASPS is 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 »**
- **Plastic and Reconstructive Surgery »**
- **FDA »**

Last updated on August 5, 2019. Video published February 23, 2018.

PROFILE REGISTRY

ASPS/PSF and FDA are collaborating to conduct research and develop a Breast Implant-Associated ALCL Registry, the PROFILE Registry, to increase the scientific data on ALCL in women with breast implants.

Report Your Case

PROFILE DATA SUMMARIES

- **PROFILE Manuscript**
- **PROFILE and FDA Data Comparison (07/2019)**

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**

ASPS POSITION STATEMENTS

- ASPS/ASAPS Joint Advisory: FDA Updates Website On BIA-ALCL (03/2017)
- Position Statement: Breast Implant Specimens and Pathology

FDA RESOURCES

- The FDA Takes Action to Protect Patients from Risk of Certain Textured Breast Implants
- Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma
- 5 Things to Know About Breast Implants