

This brochure provides useful information on Breast Implant Anaplastic-Associated Large Cell Lymphoma (BIA-ALCL):

- What it is
- Symptoms
- Testing options
- Diagnosis
- Treatment

BIA-ALCL is a 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.

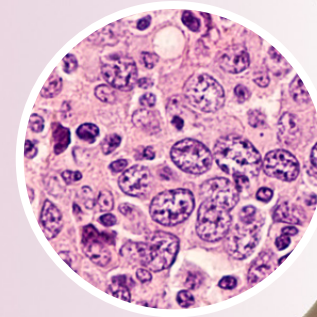
An individual's risk for developing BIA-ALCL may depend on the type of textured implant placed and the length of time a woman has an implant. It is possible to catch the disease early.



The American Society of Plastic Surgeons (ASPS) and The Plastic Surgery Foundation (PSF) are helping plastic surgeons identify safe, effective treatments for their patients through the Plastic Surgery Registries Network (PSRN). ASPS and PSF collaborate on several PSRN registries with specialists, manufacturers and government leaders who play important roles in patient safety.

WHAT PATIENTS NEED TO KNOW

Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL)



AMERICAN SOCIETY OF
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BIA-ALCL DIAGNOSIS

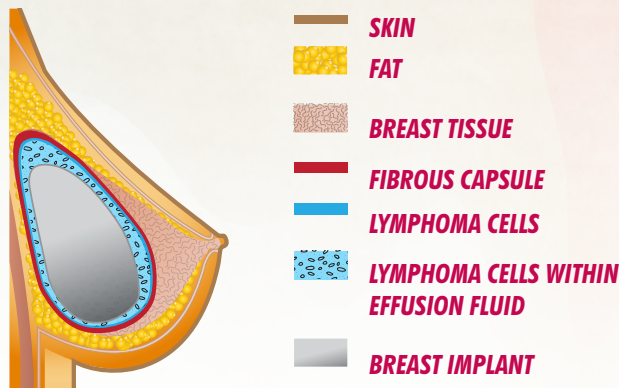
BIA-ALCL SYMPTOMS

Common symptoms include breast enlargement, pain, asymmetry, lump in the breast or armpit, overlying skin rash, hardening of the breast, or a large fluid collection typically developing more than one year after receiving an implant.

Have you been diagnosed with BIA-ALCL?

Receiving the diagnosis of BIA-ALCL may cause anxiety and frustration but women should know that not all cancers are equal. When caught early, this disease is not usually aggressive.

ASPS endorses BIA-ALCL guidelines established by the National Comprehensive Cancer Network (NCCN), which defines diagnosis and treatment based on proven methods to treat the disease.



Treatment of BIA-ALCL

When a woman is diagnosed with BIA-ALCL, her physician will refer her for a PET/CT scan to look for any disease that may have spread throughout the body. Any spread of the disease determines the stages, which is important for treatment.

For patients with BIA-ALCL only around the implant, surgery is performed to remove the breast implant and the scar capsule around the implant.

Patients with more advanced forms of BIA-ALCL may have disease in their lymph nodes, in their bones and/or organs. These patients require further treatment with chemotherapy.

Have you developed symptoms?

Women who develop these symptoms should see their physician to be evaluated with a physical exam and further testing. Patients with BIA-ALCL symptoms will receive an ultrasound or a magnetic resonance imaging (MRI) of the symptomatic breast to evaluate for fluid or lumps around the implant and in the lymph nodes.

If fluid or a mass is found, patients will require a needle biopsy with drainage of the fluid to test for BIA-ALCL. This fluid will be tested for CD30 immune staining (CD30IHC) performed by a pathologist. Testing for CD30IHC is required to confirm a diagnosis or rule out BIA-ALCL. Fluid collections ruled out by CD30IHC for BIA-ALCL will be treated as typical seromas by a physician. Most insurance companies confirm coverage for both testing and treatment of BIA-ALCL, regardless of whether the patient received cosmetic or reconstructive implants; patients should review plans for their individual coverage. There is no testing or screening for women without symptoms.

After Treatment

Following removal of the disease, patients are commonly followed for two years with imaging tests in three- to six-month appointments. Disease re-occurrence is rare after surgical removal for early disease. The FDA recommends that all cases be reported to the ASPS PROFILE registry so that BIA-ALCL may be tracked and followed to better understand and prevent this disease.

For further information, recommended BIA-ALCL resources are available:

- The Plastic Surgery Foundation: www.thepsf.org/PROFILE
- The American Society of Plastic Surgeons: www.plasticsurgery.org/alcl
- MD Anderson Cancer Center: www.mdanderson.org/cancer-types/implant-associated-anaplastic-large-cell-lymphoma.html
- The US FDA: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProstheti>

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