

SEVEN KEY
CONSIDERATIONS
FOR LYMPHOMA
PATIENTS WHO
HAD BREAST
IMPLANTS

RECENT STUDIES HAVE FOUND A LINK BETWEEN BREAST IMPLANTS AND THE OCCURRENCE OF A RARE TYPE OF LYMPHOMA YEARS LATER.

If you or someone you love has recently been diagnosed with anaplastic large cell lymphoma and had breast implantation surgery in the past, it is crucial that you understand your medical and legal options. In this guide, we will discuss seven key considerations for lymphoma patients who have had breast implantation surgery.



NEW RESEARCH INDICATES A CONNECTION BETWEEN TEXTURIZED BREAST IMPLANTS AND A SLIGHTLY INCREASED OCCURRENCE OF ANAPLASTIC LARGE CELL LYMPHOMA (ALCL).

Recently, the Food and Drug Administration (FDA) updated an earlier study concluding that there was an identifiable link between breast implants and a very rare form of cancer: anaplastic large cell lymphoma. As this type of lymphoma is linked to breast implants, the FDA calls it breast implant-associated anaplastic large cell lymphoma, or "BIA-ALCL."

According to the FDA, "all of the information to date suggests that women with breast implants have a very low but increased risk of developing anaplastic large cell lymphoma compared to women who do not have breast implants."

While the exact number of cases of BIA-ALCL has been difficult to determine because of limited worldwide reporting, the FDA said that it had received 359 reports of the cancer and that nine women died from the disease.

Most of the women who were diagnosed with BIA-ALCL were diagnosed because fluid had collected around a breast implant (called a seroma) years after the implant was placed. In some cases, testing the

seroma fluid led to the diagnosis. In other cases, BIA-ALCL was diagnosed after a mass was found in the breast or because the tissue capsule tightened (called capsular contracture) and caused discomfort or cosmetic problems.

The FDA report further noted that the risk of BIA-ALCL is higher in women who have textured implants, which have a bumpy surface, as opposed to smooth implants.

However, it's important to note that the FDA emphasized the risk of developing BIA-ALCL is extremely low, and that based on the current data, the potential for contracting the disease is still too low to generally caution against breast implantation.

2 WHAT IS ANAPLASTIC LARGE CELL LYMPHOMA (ALCL)?

According to the Lymphoma Research Foundation, Anaplastic large cell lymphoma (ALCL) is a rare type of non-Hodgkin lymphoma (NHL), and one of the subtypes of T- Cell lymphoma. Put more simply, it is a rare type of blood cancer where cells called lymphocytes (white blood cells that usually fight infection), build up in unhealthy quantities in lymph nodes.

ALCL comprises about one percent of all NHLs, and approximately 16 percent of all T-Cell lymphomas. A diagnosis of ALCL requires taking a biopsy (small sample of tumor tissue or abnormal skin tissue) and looking at the cells under a microscope. Additional tests may be conducted to give physicians more information about the disease and how far it has spread in the body. These can include blood tests, a CT scan, a PET scan, a MRI scan and bone marrow biopsy.

ALCL can initially appear in the skin covering and surrounding the breast, in other regions of skin, in the lymph nodes or in organs throughout the body (considered "systemic"). ALCL that appears in the skin is most often called primary cutaneous ALCL,

and it typically has a less aggressive disease course throughout the body's organs than the systemic type.

The characteristics of primary cutaneous ALCL include the appearance of solitary or multiple raised red skin lesions that do not go away and may ulcerate or itch. Primary cutaneous ALCL extends beyond the skin to lymph nodes or organs in only about 10 percent of cases.

Patients with systemic ALCL are divided into two groups based on whether the cancer involves a specific type of protein called ALK: "ALK-positive" and "ALK-negative." Treatment options for each of these groups vary, as described below.

MEDICAL THEORIES AND RESEARCH ON THE CONNECTION BETWEEN TEXTURIZED BREAST IMPLANTS AND BREAST IMPLANT-ASSOCIATED ANAPLASTIC LARGE CELL LYMPHOMA (BIA-ALCL)

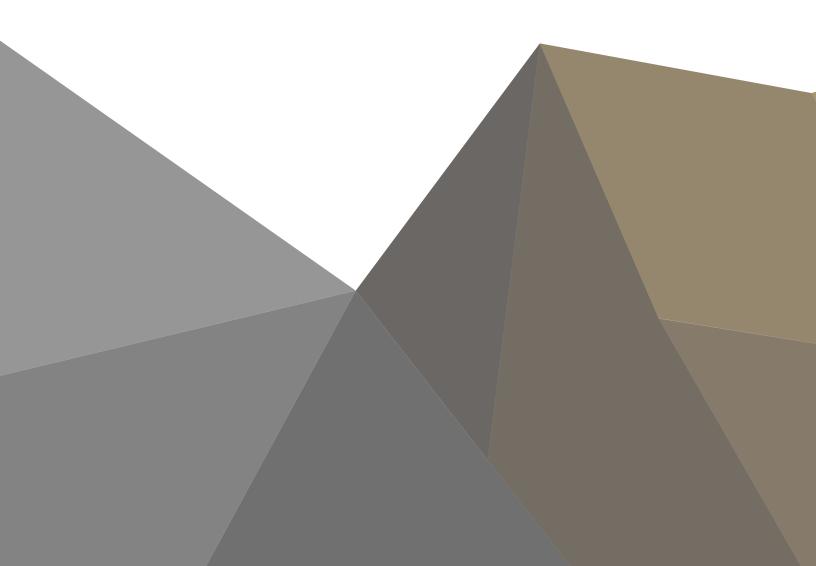
BIA-ALCL occurs most frequently in patients who have breast implants with textured surfaces. It has occurred with both silicone and saline implants and in patients who have had breast implantation surgery for both breast cancer reconstruction and cosmetic purposes.

Recently, the FDA updated a study concluding that there was an identifiable link between breast implants and BIA-ALCL, noting that the agency received 359 reports of the cancer and nine reports of women dying from the cancer.

Overall, the FDA concluded from the data that women with breast implants had a low, but increased risk of developing ALCL as compared to women without breast implants.

TREATMENT OPTIONS FOR WOMEN DIAGNOSED WITH BREAST IMPLANT-ASSOCIATED ANAPLASTIC LARGE CELL LYMPHOMA (BIA-ALCL)

ALK-positive ALCL responds well to standard chemotherapy treatments, putting most patients into long-term remission. In contrast, while most people with ALK-negative ALCL initially respond to treatment as well, the disease is more likely to relapse (return) within five years. A kind of chemotherapy called CHOP is used for both ALK-positive and ALK-negative ALCL. The therapy gets its name for the first letters of the drugs it uses: Cytoxan, hydroxydaunorubicin, Oncovin, and prednisolone. If the cancer doesn't respond to CHOP, the patient may get another drug called brentuximab vedotin (Adcetris).



Sometimes, ALK-negative patients are treated more aggressively, often with a stem cell transplant after remission.

This procedure is complicated and risky, and usually only done when other treatments have failed. Doctors inject stem cells into the patient's body to encourage it to grow new cancer-free cells. The stem cells come from the patient's own body or from a closely matched donor.

For primary cutaneous forms of ALCL, treatment may also include radiation, which uses high-energy rays to kill cancer cells, and surgery to remove the tumors. Chemotherapy is attempted with cutaneous ACLC when the cancer is present on multiple areas of skin.

5 LEGAL OPTIONS FOR WOMEN DIAGNOSED WITH ANAPLASTIC LARGE CELL LYMPHOMA (BIA-ALCL), WHO PREVIOUSLY HAD BREAST IMPLANTATION SURGERY

If you are suffering from BIA-ALCL, you may have a strong legal case against the manufacturer of your implants or the physician who performed the surgery. Generally, BIA-ALCL lawsuits make claims for some combination of the following:

- · Defective design and/or manufacturing
- · Failure to warn
- Negligence

These lawsuits typically seek compensation for medical expenses, lost wages, and pain and suffering. If you have been diagnosed with BIA-ALCL, it is imperative that you speak with a qualified attorney who will protect your rights.

OVERVIEW OF PRODUCT LIABILITY LAW AND POTENTIAL COMPENSATION AVAILABLE IN SUCCESSFUL CASES

If a breast implant ends up being defective, you most likely will have grounds for a lawsuit. There are several types of lawsuits that can be filed against wrongful parties in an ALCL case:

Lawsuits Against the Manufacturer

The majority of lawsuits based on defective breast implants involve the injured person (the "plaintiff") suing the manufacturer of the breast implants (the "defendant"). Typically, a case against the manufacturer will be a product liability case and will include claims of strict liability, failure to warn, breach of express or implied warranties, negligence and even fraud.

In a strictly liability claim, a plaintiff (you) only needs to prove that the manufacturer sold the breast implant in a dangerous condition, the manufacturer intended the implant to reach the consumer (you) unaltered, and you were injured by the implant's dangerous condition.

In a failure to warn claim, you must prove the manufacturer knew or should have known about a particular risk inherent in the breast implant but failed to provide you with an adequate warning.

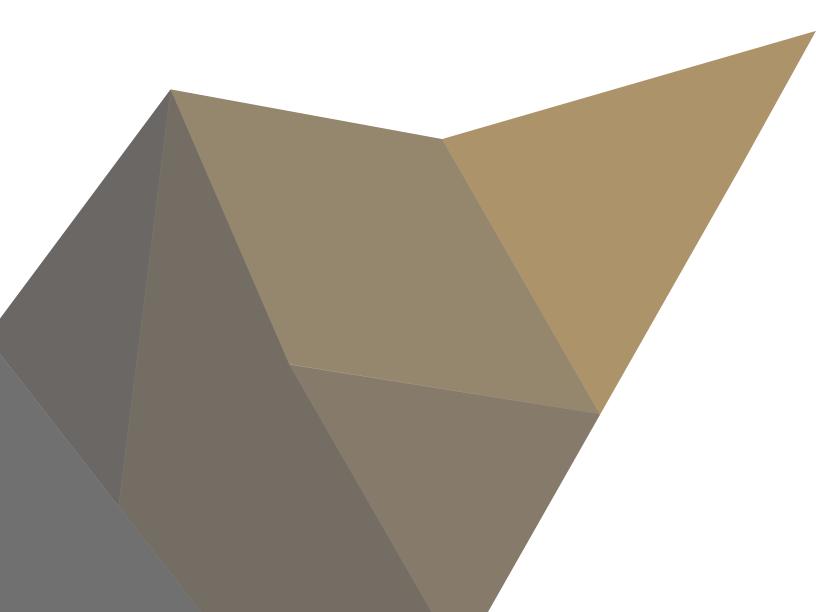
A warranty (which can be either express or implied), is a guarantee that the product will perform in a certain way or will conform to certain standards. If the breast implant unexpectedly ruptures, leaks or becomes deformed, you can claim that it did not meet the purposes for which it was purchased and that there was a breach of warranty.

A case against a breast implant manufacturer may also involve a negligence claim. To win your negligence claim you will need to prove:

- The defendant owed the plaintiff a duty of reasonable care under the circumstances
- The defendant's actions "breached" (i.e. did not meet) the duty of reasonable care owed
- The defendant's breach was the main or only cause of the plaintiff's injuries
- The plaintiff actually suffered some kind of injury

Class Action Settlements

There may be a type of lawsuit called a class action lawsuit in place to provide compensation to consumers who have been injured by a defective breast implant. If you think you've been injured by a defective breast implant, you may not need to sue to get a recovery, but to "join a class" of similarly affected persons instead.



7 WHAT YOU SHOULD DO IF YOU HAVE BEEN DIAGNOSED WITH BREAST IMPLANT-ASSOCIATED ANAPLASTIC LARGE CELL LYMPHOMA (BIA-ALCL).

If you or a loved one has breast implants and were later diagnosed with BIA-ALCL, you need an attorney with specific experience dealing with such cases and the proper resources to help you recover your damages. Filing a product liability or medical malpractice claim requires an in-depth understanding of the law and the evidence required to prove your case.

At Allan Berger & Associates, we have years of experience in winning high settlements and verdicts for clients who have been injured due to defective medical devices and medical malpractice. During an initial consultation, we will review your records and determine whether you may have a viable claim. Then, we will begin devising a comprehensive strategy to help you and your family recover the compensation you are entitled to.

We are on your side and know exactly what to do to get justice for you. Additionally, we understand the emotional turmoil and devastation that cancer can bring upon

a family. The knowledgeable and skilled attorneys at Allan Berger & Associates are here to fight this battle for you. For a complimentary consultation, contact us today at (504) 526-2222.

To learn more about ALCL, you can visit the following resources:

https://www.lymphoma.org/aboutlymphoma/nhl/alcl/

https://www.fda.gov/medical-devices/breast-implants/breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl





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