



THE AMERICAN SOCIETY FOR AESTHETIC PLASTIC SURGERY, INC.

Member FAQs: Latest Information on ALCL:

The Food and Drug Administration (FDA) has recently updated the public information on its website about breast implant associated anaplastic large cell lymphoma (BIA-ALCL). We have known about this disease for quite some time and the FDA has been providing updates since 2011.

What is breast implant associated-anaplastic large cell lymphoma (BIA-ALCL)?

- A rare type of lymphoma that develops adjacent to breast implants
- It usually develops as a swelling of the breast 3 to 14 years after the insertion of breast implants, which is due to fluid collecting around the implant or it can present as a lump in the breast or armpit

BIA-ALCL is not breast cancer

- BIA-ALCL develops in the fluid around breast implant and is usually contained by the fibrous capsule around implants it does not develop in the breast tissue

What are the symptoms of BIA-ALCL?

- The most common symptom is a persistent swelling of the breast but can include other symptoms such as a lump in the breast or armpit
- These symptoms develop between three and 14 years following the insertion of breast implants and most commonly around eight years
- The swelling of the breast is due to fluid accumulating around the implant
- The lymphoma develops around the breast implant in the fluid and in most cases is contained within the fibrous capsule the body makes around the implant and is not in the breast tissue itself

What is the risk of developing BIA-ALCL?

- The current risk is estimated to be 1 in 30,000. However, there has never been a documented case in a patient with only a smooth implant.
- Because this is a rare disease it is difficult to be certain about the absolute risk of developing this disease
- The risk of breast cancer is about one in eight women

Are some women more at risk than others?

- It is not possible to predict who will develop BIA-ALCL
- It has occurred in women who have breast implants for cosmetic reasons and also for breast reconstruction
- It has occurred in women with both saline implants and silicone implants

How is BIA-ALCL diagnosed?

- If a woman develops swelling of the breast which has an implant they are sent for an ultrasound scan and if fluid is detected this will be removed and tested for BIA-ALCL
- Specific tests are asked for to exclude or diagnose BIA-ALCL (cytology and CD30)
- Most fluid collections around breast implants are not BIA-ALCL but proper testing will be able to tell them apart
- Mammograms are not useful in diagnosing BIA-ALCL
- In confirmed cases MRI and PET/CT scans may be performed to help stage the disease

Should women with breast implants be screened for BIA-ALCL?

- At this point expert opinion is that women without symptoms or changes in their breasts do not need regular ultrasound scan.
- breast implants are not lifelong devices. If there are changes in your breasts associated with breast implants and especially if there is general swelling or a lump you should have a breast examination and this may need to be investigated further

What is the treatment of BIA-ALCL?

- The majority of cases are cured with the removal of implants and the fibrous capsule around them from both breasts.
- The majority of patients require no additional treatment.
- All known cases where there were no delays in diagnosis have resulted in 100% cure at this time.

Should breast implants be removed just in case?

- Breast implants are not lifelong devices and in general all will need to be removed or replaced at some point
- The most common reasons for implant removal or replacement are capsular contracture, implant migration, implant rupture
- Without symptoms or signs of BIA-ALCL routine implant removal is not required unless there are other concerns

Do we know what causes BIA-ALCL?

- Bacteria have been identified within the lymphoma and around implants in affected breasts
- There is accumulating evidence that a long-term inflammatory response to the presence of these bacteria is one of the factors that may cause of BIA-ALCL
- There may also be genetic factors involved for individual women
- We are continuing to investigate this disease to improve our understanding

Are there ways to make breast implant surgery safer?

- There is accumulating evidence that bacteria are associated with other complications of breast implant surgery as well such as the risk for capsular contracture which does not lead to cancer
- Infection control standards are extremely important in breast surgery to ensure best outcomes and Specialist Plastic Surgeons are expertly trained to ensure the highest standards of patient safety and lowest risk of infection.
- A 14 point plan (Deva, AK, Adams Jr., WP, Vickery, K. The role of bacterial biofilms in device-associated infection." *Plast Reconstr Surg* 132(5): 1319-1328, 2013) has been developed for surgeons to help reduce the risk of infection in breast implant surgery
- The 14 point plan outlines various steps that can be undertaken during surgery to minimize the bacterial load around the implant.
- These steps have been proven to lower capsular contracture rates
- Not all of the 14 points are applicable in every circumstance but each of the steps can be added

What should I tell patients who are concerned about their breast implants?

- Contact your surgeon
- If you have swelling of the breast associated with a breast implant you may need a referral for an ultrasound to remove some fluid for testing and this will be able to determine if BIA-ALCL is present (Immunohistochemistry is performed to identify a T-cell lymphoma that is positive for the CD30, and cytology).
- Most breast swelling that occurs after breast implants is not due to BIA-ALCL however it does needs to be excluded

Can new breast implants be inserted when BIA-ALCL is treated?

- Yes. Smooth implant have been replace at a delayed interval in treated patients as well as immediately in some cases.

Where can I get more information?

[FDA.gov](https://www.fda.gov), [Surgery.org](https://www.surgery.org), [plasticsurgery.org](https://www.plasticsurgery.org)

What should I tell my patients who are considering breast implants?

- Women who are considering breast implant surgery should discuss the risks and benefits of the procedure with their Plastic Surgeon including the risks of BIA-ALCL. If a patient is using a smooth implant the risk of BIA-ALCL is currently zero.
- There are different implant types available and implant selection needs to consider the risks and benefits of specific choices.
- Implant selection will be different from one person to the next.
- Breast implants are not lifetime devices and women with breast implants should all consider that they will require revision or replacement of the breast implants at some time

I have angry patients asking why I used textured implants in the first place...

- Many surgeons use textured implants because there is evidence to suggest that in certain situations they may reduce the chances of capsular contracture (scar tissue build-up) or help to keep an implant in position. Some textured implants have among the best data for rupture and longevity. For many years gummy bear implants were only available with textured surfaces.