整形外科中心
Plastic & Reconstructive Surgery Centre

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

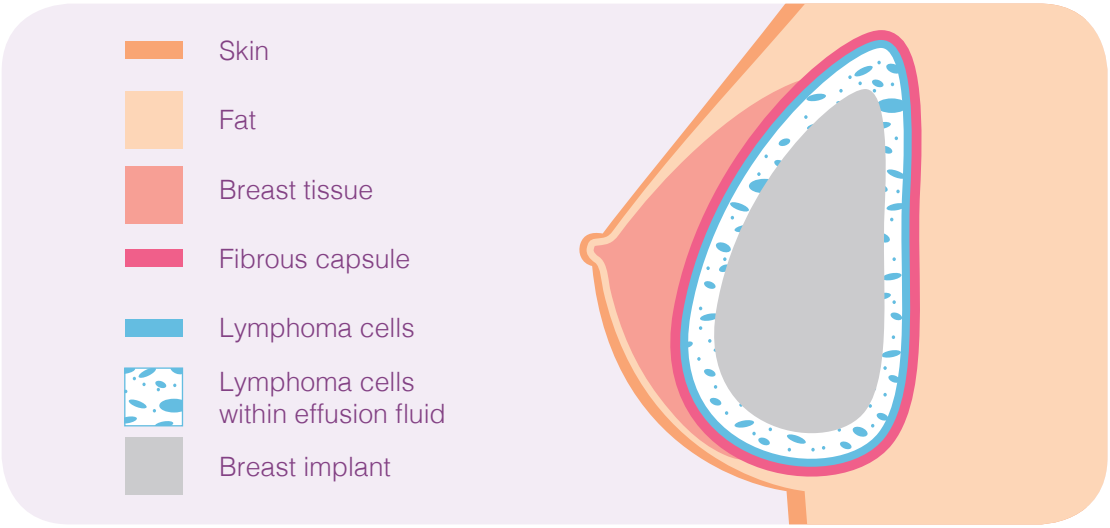
The following updates are provided in response to the recent medical device safety alert issued by the Department of Health related to the discontinued production and recall of Allergan BioCell breast implants.

According to the recommendations of the Food and Drug Administration (FDA), removal of the breast implants in question are not required in the absence of BIA-ALCL symptoms. Patients with this type of breast implant should be aware of the latest development and not be overly worried. They are advised to have them checked once a year. For enquiries, please contact the Centre or your doctor.

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

It is a type of lymphoma which develops within the capsule that forms naturally around the implant. It is a very rare condition and if it occurs, is very treatable in its early stages. Until now, BIA-ALCL has been relatively unexplored and is not considered to be breast cancer. Approximately 35 million implants have been sold since 1997, with around 570 cases of this disease documented.

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



Are specific implants affected?

Many breast implants have a textured surface and have been used by surgeons worldwide. Only textured implants have been reported to be associated with the risk of BIA-ALCL among all types of implants manufactured by different companies. It is important to know that there have been no confirmed cases of BIA-ALCL associated with patients with smooth-surface implants. The reasons remain unclear.

Of the 573 cases of BIA-ALCL, 481 are reported to have Allergan BioCell textured breast implants at the time of diagnosis, according to FDA. Allergan has stopped the production of this implant envelope.

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Are FDA[i] and Australia's Therapeutic Goods Administration[ii] (TGA) asking me to have my implants removed?

It has been specifically stated that removal or replacement of textured implants in patients who have no symptoms is not recommended or suggested due to the low risk of developing BIA-ALCL.

What symptoms should I be looking for?

Unlike breast cancer, BIA-ALCL most commonly presents with swelling of one breast. Other less common symptoms include hardening of the breast, an unusually persistent rash, fluid collections/seromas, or a palpable mass in the breast or armpit – all easily identified by you. If you have any of these symptoms, please call to schedule an appointment for an examination and if needed, further tests. An ultrasound can detect the presence of fluid, and if present, a small amount can be aspirated with a needle and tested. Should tests called CD30 and ALK be positive, a diagnosis of BIA-ALCL will be considered. If the tests are negative, the fluid collection is considered benign. Benign fluid collections, known as seromas, are not uncommon around breast implants. It is important to differentiate them from those associated with ALCL.

How serious is BIA-ALCL?

When BIA-ALCL is diagnosed and treated early, it is usually curable. Of the 573 cases in the world, there have been 33 deaths. Deaths associated with BIA-ALCL are thought to have resulted from delayed diagnosis or inappropriate treatment. The single most important intervention to prevent advanced BIA-ALCL is regular monitoring and early detection.

What if the tests confirm BIA-ALCL?

In most patients, BIA-ALCL is curable with surgery alone – removing the textured implants and the capsule. Radiation or chemotherapy is not required in most cases. For enquiries, please contact the Centre or your doctor.

What if I do not have any symptoms?

To our knowledge, there is no medical agency or health ministry that recommends removal of your textured breast implants at this time. Should you develop any signs or symptoms mentioned above, you should make an appointment for evaluation.

Please continue to have your breast implants checked routinely, usually every year. You may schedule a consultation at any time.

If you have any further concerns or would like to schedule an evaluation, please contact the Centre for an appointment.

Source of Information:

i. The U.S. Food and Drug Administration
https://www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue

ii. Australia's Therapeutic Goods Administration
https://www.tga.gov.au/alert/allergan-macro-textured-breast-implants-and-tissue-expanders

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