

Safety Communication

Safety of textured breast implants

Background:	<p>Recently, SFDA has issued a field safety notice of Allergan Textured Breast Implants and Tissue Expanders (SG-1902-08-H). Later on, further evaluation has been conducted to evaluate the safety of textured breast implants in general, which enable deriving the following recommendations.</p>
Recommendation/Actions:	<p>SFDA highly recommends healthcare providers to:</p> <ul style="list-style-type: none"> • discuss BIA-ALCL with their patients at the initial consultation, and they are greatly encouraged to include the association between BIA-ALCL and textured implants in the informed consent, especially those having, or planning to have, textured breast implants. • discuss BIA-ALCL signs and symptoms with patients who decide to select textured breast implant. • provide patients with the implant ID card for future references. • facilitate routine follow-up visits with their patients, every two years, for the first 6 years, and in a yearly basis afterwards. • follow the recommended diagnostic procedures, including the ultrasound guided aspiration and cytological analysis, with any suspected BIA-ALCL case, especially those cases that demonstrate a sudden and unexplained seroma AND/OR a sudden asymmetry in the patient breast. Note: when sending fluid for cytology, healthcare providers should consider asking for identification of cytological markers CD30-positive and ALK-negative T-cell lymphocytes. • keep in mind that most experts advise using a smooth or micro-textured implant for new implant recipients. • track their patients to be able to reach them for any sudden warning that relate to their implants.

Also patients who consider to implant textured breast implants, or those who already have implanted the device are recommended to consider the following:

- Breast implant is not a lifetime device, but the longer you have the implant, the most likely you are to experience local complications and adverse outcomes. However, the new generation of breast implants preserve safer products that could last for a longer time with minimal risks.
- BIA-ALCL is a rare disease, but studies show that its symptoms appear in a period of 8-10 years (median interval from implantation to diagnosis is 9.2 years). Therefore, the longer you have the implant, the more caution you should be to do a routine medical follow-up regarding any sudden pain, lumps, swelling or recent asymmetry in the breast.
- Educate yourself about breast implants before agreeing to surgery, and upon your agreement to have a breast implantation, plan for a routine follow-up for a long period of time, considering the suggested period of replacing the device as per directed by your healthcare provider.
- BIA-ALCL is believed to be developed more frequently in individuals with textured implants than in people with smooth-surfaced implants. Before getting breast implants, make sure to talk to your health care provider about the benefits and risks of both textured-surface and smooth-surfaced implants.
- In case you have a breast implant, there is no need to panic or to change your routine medical follow-up. Also, keep in mind that you should expect swelling and pain right after the surgery. However, if you noticed changes in the way your breast looks or feels after your recovery, or at any time afterward, make sure to talk to your healthcare provider.
- Remember to keep your implant ID for future references.

- Make sure to report any adverse event you notice regarding your implant through the National Center for Medical Devices Reporting (NCMDR) system:
<https://ncmdr.sfda.gov.sa>
- or Saudi Vigilance System
<https://ade.sfda.gov.sa/>