

## Patients: Important Recommendations If You Have Allergan BIOCELL Breast Implants

- If you have no symptoms, we are not recommending the removal of these or other types of breast implants due to the low risk of developing BIA-ALCL. However, if you have any questions, talk to your health care provider.
- Know the symptoms of BIA-ALCL—primarily persistent swelling or pain near the breast implant—and monitor the area around your breast implants for any changes.
- If you experience any of these symptoms or other changes, talk to your health care provider regarding the need for further evaluation. Evaluation for BIA-ALCL typically involves a physical exam, imaging, and/or assessment of the fluid or tissue around the breast implant. It is important to undergo an evaluation to diagnose BIA-ALCL since a confirmed BIA-ALCL diagnosis may change the type of operation that should be performed.
- Based on discussions with your health care provider, patients with confirmed BIA-ALCL should undergo implant removal and removal of the surrounding scar capsule, which is a more extensive operation than implant removal alone.
- As with any implanted device, it is good to keep a record of the device manufacturer, unique device identifier, and implant model name. You may have received this information on a patient device card from your surgeon. If you would like to obtain any of this information, consider asking your surgeon or obtaining the record of your surgery (operative notes) from the facility where it was performed.
- Understand that most cases of BIA-ALCL occur many years after breast implant placement. Talk to your surgeon about your risk of developing BIA-ALCL.
- If you are considering breast implants, please see these [important recommendations](#).

## Addressing Concerns of Patients Who Have Breast Implants

The FDA understands that [the recall] may cause concern to patients who have breast implants, especially those who know they have one of the listed Allergan BIOCELL model implants or may not know the implant's manufacturer or model. The FDA continues to monitor and evaluate reports of adverse events in databases, including external patient registries, and in scientific literature for the incidence of BIA-ALCL across all breast implants and other devices intended for use in the breast. The FDA further notes that the macro-textured implants, like the BIOCELL textured implants manufactured by Allergan, represent less than 5% of breast implants sold here in the U.S. In fact, textured implants account for only 10% of all breast implants sold in the U.S. To fully understand your risk of developing BIA-ALCL, the FDA recommends that patients and healthcare providers follow the FDA's recommendations stated above. More information about BIA-ALCL can be found on the [Breast Implants](#) page and the FDA will continue to update the public about developments in this area.