FDA NEWS RELEASE

FDA takes action to protect patients from risk of certain textured breast implants; requests Allergan voluntarily recall certain breast implants and tissue expanders from market

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Español (/news-events/press-announcements/la-fda-actua-para-proteger-las-pacientes-del-riesgo-que-conllevan-ciertos-implantes-de-seno)

The U.S. Food and Drug Administration today took significant action to protect women from breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) by requesting that Allergan, the manufacturer of a specific type of textured implant, recall specific models of its textured breast implants from the U.S. market due to the risk of BIA-ALCL. Following the agency's request, Allergan has notified the FDA that it is moving forward with a worldwide recall of their BIOCELL textured breast implant products, including: Natrelle Saline-Filled breast implants, Natrelle Silicone-Filled breast implants, Natrelle Inspira Silicone-Filled breast implants, and Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled breast implants. The recall also includes tissue expanders used by patients prior to breast augmentation or reconstruction, including Natrelle 133 Plus Tissue Expander and Natrelle 133 Tissue Expander with Suture Tabs. The recall helps ensure that unused products are removed from suppliers and doctors' offices. The agency also issued a safety communication (/medical-devices/safety-communications/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan) today for patients with breast implants, patients considering breast implants and their health care professionals outlining the known risks and what steps patients should consider when monitoring for symptoms of BIA-ALCL, including swelling and pain in their breasts. The safety communication also lists information about all models and style numbers included in the recall.

"Although the overall incidence of BIA-ALCL appears to be relatively low, once the evidence indicated that a specific manufacturer's product appeared to be directly linked to significant patient harm, including death, the FDA took action to alert the firm to new evidence indicating a recall is warranted to protect women's health," said FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D. "The FDA has been diligently monitoring this issue since we first identified the possible association between breast implants and ALCL in 2011 and, at that time, communicated to patients and providers that there is a risk for women with breast implants, more frequently occurring in women with textured implants, for developing this disease. Since that time, we have worked to increase awareness and encourage reporting of all cases to the FDA so that we could continue to monitor this potential safety signal. As this issue and the science have continued to develop, we have been monitoring the reports in databases, including external patient registries, and in scientific literature. Based on new data, our team concluded that action is necessary at this time to protect the public health. We will continue to monitor the incidence of BIA-ALCL across other textured and smooth breast implants and tissue expanders as well as other devices intended for use in the breast. If action is needed in the future, we will not hesitate to do what is necessary to protect patients."

In a table updated today on the agency's BIA-ALCL webpage (/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma), the FDA provides the new total of 573 unique cases globally of BIA-ALCL and 33 patient deaths, which reflect a significant increase in known cases of BIA-ALCL since the agency's last update earlier this year (/news-events/press-announcements/statement-binita-ashar-md-fdas-center-devices-and-radiological-health-agencys-continuing-efforts) —an increase of 116 new unique cases and 24 deaths. Specifically, of the 573 unique cases of BIA-ALCL, 481 are attributed to Allergan implants. Of the 33 patient deaths the FDA is reporting today, 12 of the 13 patients for which the manufacturer of the implant is known, are confirmed to have an Allergan breast implant at the time of their BIA-ALCL diagnosis. These cases include new data reported to the agency since the public advisory committee meeting in March. Based on the currently available information, including the newly submitted data, our analysis demonstrates that the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately six times the risk of BIA-ALCL with textured implants from other manufacturers marketing in the U.S.

The table on the FDA's website summarizes the cases, along with a breakdown of important information such as breast implant surface texture, patient's age at diagnosis, time from last implant to diagnosis, and other details to give patients and health care professionals the most complete information possible about the known factors impacting these unique cases and deaths. The FDA is continuing to evaluate these additional case reports and will make this information available on its database of adverse event reports within the next few weeks.

The FDA has taken multiple steps to better understand the safety and risks of breast implants and to help strengthen the evidence generated to help inform its regulatory actions in this area, including sharing updates with the public (as recently as February (/news-events/press-announcements/statement-binita-ashar-md-fdas-center-devices-and-radiological-health-agencys-continuing-efforts) 2019 and via a public advisory committee meeting in March (/advisory-committees/advisory-committee-calendar/march-25-26-2019-general-and-plastic-surgery-devices-panel-medical-devices-advisory-committee)) and encouraging patients and health care professionals to report adverse events to the agency. This voluntary recall is a direct result of the agency's comprehensive efforts to improve the quality of data collected and analyzed, and the FDA's ongoing work to evaluate all available safety information.

"We understand that today's news may be alarming to some patients with breast implants. In the safety communication issued today, we're providing actionable information for individuals with specific breast implants and their health care professionals. The FDA does not recommend removal for patients without symptoms due to potential risks, but we provide helpful information for patients and providers to consider when discussing next steps," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "Moving forward, we are committed to continuing to share updates with patients about this issue. We will continually evaluate any new information and may, as a result, take action regarding other breast implants, if warranted. In addition, we are continuing our assessment to determine whether the risk of developing BIA-ALCL is limited to specific models of textured, or all textured breast implants. We continue to advise women and health care professionals that the use of breast implants is associated with a risk of developing BIA-ALCL and that the risk is greater with textured implants."

Textured breast implants overall are less common in the U.S. compared to other countries and specifically, macro-textured implants (the type of textured implant that Allergan manufactures) represent less than 5% of all breast implants sold in the U.S. Although this type of textured breast implant may represent a small

proportion of the U.S. market, the continued availability of Allergan BIOCELL textured breast implants pose a public health risk to patients. Today's action by the FDA is similar to other actions initiated by France, Canada and Australia, where the use of textured implants is much higher, sometimes as high as 80% of their market share. These countries have also initiated or taken actions to prompt the recall or removal of certain textured breast implants (including certain breast implants sold by Allergan) from the market.

In addition to the voluntary recall announced today, the FDA is initiating other actions to ensure that all women who consider breast implants have the information they need to have thoughtful and balanced discussions with their health care professional on the benefits and risks of breast implants based on clear information reflecting the most current understanding of their safety. For example, as previously discussed, the agency is considering recommendations for changes to the labeling of breast implants, which could include a boxed warning and a patient decision checklist to help women consider the benefits and risks of breast implants.

The FDA will continue to focus on gathering available evidence to help inform future regulatory actions and assure that women and health care professionals are informed of the risk of BIA-ALCL as they consider breast implants. To this end, the agency has requested that all breast implant manufacturers provide quarterly trending analyses of adverse events, including BIA-ALCL, and require reporting individual events in the adverse event database for devices and in existing registries. The FDA will continue to analyze all available information regarding risks associated with breast implants, routinely update the BIA-ALCL analysis published on our website and take additional actions when and where necessary.

The FDA is committed to protecting the health of women and providing as much information as possible to ensure they and their health care professionals know the benefits and risks of these devices, and that women have the most complete information available to make these important decisions about their health care.

Link to FDA Recall (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergan-voluntarily-recalls-biocellr-textured-breast-implants-and-tissue-expanders)

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Related Information

Patients with questions about the recall

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