Breast Implants: Reports of Squamous Cell Carcinoma and Various Lymphomas in Capsule Around Implants: FDA Safety Communication

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The U.S. Food and Drug Administration (FDA) is informing the public about reports of cancers, including squamous cell carcinoma (SCC) and various lymphomas, in the scar tissue (capsule) that forms around breast implants. The various lymphomas reported are not the same as the lymphomas described in previous FDA Communications as Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). The FDA learned about these reports through our continual postmarket review of breast implants and our ongoing collaboration with external stakeholders.

After preliminary review of published literature as part of our ongoing monitoring of the safety of breast implants, the FDA is aware of less than 20 cases of SCC and less than 30 cases of various lymphomas in the capsule around the breast implant. As of September 1, 2022, the FDA has received 10 medical device reports (MDRs) about SCC related to breast implants and 12 MDRs about various lymphomas related to breast implants. The FDA recognizes the limitations of MDR data, including that reports do not necessarily represent unique cases. Reports submitted to the FDA are just one source the FDA uses to monitor the safety of medical devices, in addition to mandated postmarket studies, published literature, and real-world data from registries and claims databases. The FDA will continue to gather and review all available data from these sources to evaluate the occurrence of cancers in the capsule around breast implants.

While the FDA believes that occurrences of SCC or various lymphomas in the capsule around the breast implant may be rare, health care providers and people who have or are considering breast implants should be aware that cases have been reported to the FDA and in the literature. Currently, the incidence rate and risk factors for SCC and various lymphomas in the capsule around the breast implants are unknown. When breast implant information was provided, there have been literature reports of SCC and various lymphomas in the capsule around the breast implants for both textured and smooth breast implants, and for both saline and silicone breast implants. In some cases, people were diagnosed after years of having breast implants. Some of the reported signs and symptoms included swelling, pain, lumps or skin changes.

This is an emerging issue and our understanding is evolving. For this reason, the FDA is asking health care providers and people with breast implants to report cases of SCC, lymphomas, or any other cancers around the breast implant to the FDA.

Recommendations for People who Have or Are Considering Breast Implants

- If you are considering breast implants (/medical-devices/breast-implants/things-consider-getting-breast-implants) or if you have them, learn more about the risks and benefits of breast implants (/medical-devices/implants-and-prosthetics/breast-implants).
- If you have breast implants, you do not need to change your routine medical care or follow-up.
- Be aware that cases of SCC and various lymphomas in the capsule around the breast implant have been reported.
- Monitor your breast implants for as long as you have them. If you notice any abnormal changes in your breasts or implants, promptly talk to your surgeon or health care provider.
- If you do not have symptoms, the FDA does not recommend the removal of breast implants because of this safety communication.
- If you have breast implants and experience a problem, the FDA encourages you to file a report through MedWatch (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home), the FDA Safety Information and Adverse Event Reporting program. Your report, along with information from other sources, can provide information that helps improve patient safety.

Currently, these recommendations do not change or affect the recommendations (/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl) previously provided by the FDA on BIA-ALCL.

Recommendations for Health Care Providers

- Continue to provide routine care and support to your patients with breast implants.
- Be aware that cases of SCC and various lymphomas in the capsule around the breast implant have been reported.
- When examining breast implant specimens (for example, seroma, capsule, devices) for diagnostic evaluation, characterize all findings and potential diagnoses.
- Report cases of SCC, lymphomas, and any other cancers in the capsule around the breast implant to the FDA. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Currently, these recommendations do not change or affect the recommendations (/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl) previously provided by FDA on BIA-ALCL.

Device Description

Breast implants (/medical-devices/implants-and-prosthetics/breast-implants) are medical devices implanted under the breast tissue or chest muscle to increase breast size (augmentation) or to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality (reconstruction). They are also used in revision surgeries, which seek to correct or improve the result of an original surgery.

There are two types of breast implants approved for sale in the United States: saline-filled and silicone gel-filled. Both types have a silicone outer shell. They vary in size, shell thickness, shell surface texture, and shape (contour). Breast implants are not lifetime devices. The longer you have your implants, the more likely it will be for you to have them removed or replaced.

FDA Actions

The FDA is continually evaluating the postmarket safety of approved breast implants and communicating about the risks associated with these devices. Since 2011, the FDA has been collecting and evaluating information about BIA-ALCL. The FDA will collaborate with other regulatory authorities, clinical and scientific experts, manufacturers, and breast implant registries, to gather all available information about SCC, lymphomas, and any other cancers in the capsule around the breast implant. We will continue to communicate to the public on significant findings as new information and analyses become available.

Reporting Problems with Your Device

If you think you had a problem with your device, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.