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CDRH Updates Safety Communication for Squamous Cell Carcinoma (SCC) in Scar Tissue around Breast Implants

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Today, the FDA's Center for Devices and Radiological Health (CDRH) provided updates to our September 8, 2022 [Safety Communication](#) about certain rare cancers, specifically squamous cell carcinomas (SCC) and various lymphomas other than BIA-ALCL, observed in the scar tissue (capsule) that forms around breast implants. This update follows our review of the published literature, medical device reports (MDRs) and our ongoing collaboration with external stakeholders and underscores our commitment to share regular updates with the public so that patients may fully consider implant risks with their doctors. In summary, there have been 19 cases of SCC in the capsule around the breast implant reported in literature, including reports for textured and smooth breast implants, and reports for saline and silicone gel filled breast implants. In most cases, people were diagnosed years after initial implant placement. There were 3 reports of death due to the disease in the literature. The FDA is working with multiple stakeholders to gather more information and to ensure that people who are considering or have breast implants are informed about this emerging issue.

The FDA continues to collect and evaluate all available information about SCC, lymphomas, and any other cancers in the capsule around the breast implant. Given these cancers are rare, it is important that health care providers including plastic surgeons, breast surgeons, surgical oncologists, medical oncologists, pathologists and radiologists are aware and consider these potential diagnoses in patients with breast implants. However, CDRH does not recommend removal of breast implants due solely to concerns over the potential for these rare cancers.

CDRH has taken several steps over numerous years to strengthen breast implant safety since the premarket approval of these devices, including diligent postmarket surveillance and evaluation of FDA-mandated manufacturer postmarket studies. This includes collaboration with the American Society of Plastic Surgery-Plastic Surgery Foundation to develop the Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma (ALCL) etiology and Epidemiology ("[The PROFILE registry](#)").

Additionally, in 2019, CDRH convened a [public meeting of the General and Plastic Surgery Devices Advisory Panel](#) to discuss the long-term benefits and risks of breast implants and listen to favorable and unfavorable breast implant experiences of patients and health care providers. In the same year, CDRH directed the voluntary recall of certain breast implants associated with a higher rate of breast implant-associated anaplastic large cell lymphoma.

Subsequently, CDRH [issued guidance](#) that includes a boxed warning, a patient decision checklist, a device description with a list of specific materials used in the device, updated recommendations on screening for device rupture, and a patient implant card in 2020. And in 2021, CDRH [restricted the sale and distribution](#) of all breast implants in the United States to only health care providers and facilities that provide patients with FDA-required risk communication information about breast implants,

including a patient decision checklist that the patient must be given the opportunity to initial and sign and that must be signed by the physician implanting the device.

If a patient with breast implants is experiencing a problem, or a case of SCC, lymphoma or any other cancer in the breast implant capsule is identified, the FDA strongly encourages reporting the details of the case through [MedWatch](#), the FDA Safety Information and Adverse Event Reporting program. Reporting strengthens our understanding related to these rare cases and is crucial for improving device safety. We continue our collaborative efforts with the American Society of Plastic Surgeons (ASPS) and the Plastic Surgery Foundation (PSF) to better characterize these cancers in people with breast implants.

We remain committed to informing the public of important and emerging medical device safety risks and taking appropriate action when necessary for assuring patient safety. We will continue to collaborate with other regulatory authorities, clinical and scientific experts, breast implant registries and patients as a part of our commitment to educate and enhance evidence generation related to all potential risks.

Additional Resources

- [Breast Implants | FDA](#)
- [What to Know About Breast Implants | FDA](#)
- [FDA Issues Final Guidance for Certain Labeling Recommendations for Breast Implants | FDA](#)
- [Breast Implant Postmarket Safety Information | FDA](#)
- [FDA Strengthens Safety Requirements and Updates Study Results for Breast Implants | FDA](#)
- [Premarket Approval \(PMA\) | FDA](#)
- [March 25-26, 2019: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting Announcement - 03/25/2019 - 03/26/2019 | FDA](#)
- [FDA Advises Women with Breast Implants about ALCL - YouTube](#)
- [PROFILE | The Plastic Surgery Foundation \(the-psf.org\)](#)
- [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 | FDA](#)
- [Breast Implants: Reports of Squamous Cell Carcinoma and Various Lymphomas in Capsule Around Implants: FDA Safety Communication | FDA](#)
- [FDA Issues Safety Alert for Squamous Cell Carcinoma and Various Lymphomas in Scar Tissue around Breast Implants | FDA](#)

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