# UPDATE: Reports of Squamous Cell Carcinoma (SCC) in the Capsule Around Breast Implants - FDA Safety Communication

Español (/medical-devices/safety-communications/actualizacion-sobre-reportes-de-carcinoma-de-celulas-escamosas-en-la-capsula-alrededor-de-los)

**Update: March 22, 2023**

As of March 22, 2023, health care providers can submit case reports of SCC, various lymphomas, and any other cancers in the capsule around breast implants to the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma (ALCL) Etiology and Epidemiology (PROFILE) (https://www.thepsf.org/research/registries/profile) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) Registry, a collaborative effort between the American Society of Plastic Surgeons (ASPS), the Plastic Surgery Foundation (PSF), and FDA. Health care providers can continue to submit case reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) (/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl) to PROFILE as well.

The FDA reviews data from the PROFILE registry on an ongoing basis to gather all available information on cancers in the capsule around breast implants, and will keep the public informed on significant findings as new information becomes available.

The FDA continues to recommend that health care providers also report (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm) all cases of SCC, various lymphomas, BIA-ALCL and any other cancers in the capsule around the breast implant to the FDA.

**Date Issued: March 8, 2023**

The U.S. Food and Drug Administration (FDA) is providing an update on reports of squamous cell carcinoma (SCC) in the scar tissue (capsule) that forms around breast implants. Previously, on September 8, 2022, the FDA released a safety communication (/medical-devices/safety-communications/breast-implants-reports-squamous-cell-carcinoma-and-various-lymphomas-capsule-around-implants-fda) informing the public of reports of cancers, including SCC and various lymphomas, in the capsule that forms around breast implants. The various lymphomas are not the same as the lymphomas described previously by the FDA as Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) (/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl).

This update includes information from the FDA's review of literature and medical device reports (MDRs). The FDA is aware of 19 cases of SCC in the capsule around the breast implant from published literature. There have been reports in the literature of deaths from progression of the disease. While the FDA continues to believe that occurrences of SCC in the capsule around the breast implant may be rare, the cause, incidence and risk factors remain unknown.

Health care providers and people who have or are considering breast implants should be aware that cases of SCC and various lymphomas in the capsule around the breast implant have been reported to the FDA and in the literature. The FDA continues to ask health care providers and people with breast implants to report cases of SCC,

lymphomas, or any other cancers around breast implants to the FDA. In addition, we continue to collaborate with other regulatory authorities, scientific experts, breast implant manufacturers and registries to gather all available information on cancers in the capsule around breast implants.

## Recommendations for People who Have or Are Considering Breast Implants

The FDA continues to recommend the following:

- 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 (other than BIA-ALCL) 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 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 solely due to concern related to the risk of developing SCC or various lymphomas.
- 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 FDA on Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL).

## Recommendations for Health Care Providers

The FDA continues to recommend the following:

- Continue to provide routine care and support to your patients with breast implants.
- Be aware that cases of SCC and various lymphomas (other than BIA-ALCL) 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.

### Updated Recommendations for Health Care Providers

- Include information about SCC and various lymphomas in the capsule around the breast implant in your discussions with people who have or are considering breast implants.
- For patients who have been diagnosed with SCC or various lymphomas in the capsule around the breast implant, develop an individualized treatment plan in coordination with a multidisciplinary team of experts including surgical oncology, plastic surgery, breast surgery, radiology, oncology, and pathology.
- Report (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=professional.reporting1) all 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.

- Please include the following information in the report, if known:
  - Clinical presentation and breast implant history
  - Imaging studies performed
  - Pathology of the capsule tissue
  - Treatment therapy
  - Outcomes

Currently, these recommendations (/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl) do not change or affect the recommendations previously provided by FDA on Breast Implant Associated Anaplastic Large Cell Lymphoma (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 (reconstruction) due to cancer or trauma, or that has failed to develop properly due to a severe breast abnormality. Breast implants 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 (/medical-devices/breast-implants/risks-and-complications-breast-implants).

## Results from FDA Review of Published Literature

After review of published literature including abstracts and full articles through January 2023, the FDA is aware of 19 cases of SCC in the capsule around breast implants. Of the 19 literature cases, 17 were reported in females or women, 1 was reported in a male or man, and there was no available information for 1 case. Patients' ages at time of diagnosis ranged from 40 years to 81 years. The majority of cases involved swelling and/or pain of the breast as symptoms. Other reported symptoms included lumps and skin discoloration. Breast implants, when reason for implant was available, had been placed for breast reconstruction and augmentation.

In general, the diagnosis was established by pathology examination of the capsule tissue. Imaging studies were often used in the diagnostic workup such as computed tomography (CT) of the chest, or magnetic resonance imaging (MRI) of the breast, or CT in combination with positron emission tomography (PET) as a PET-CT. The diagnosis of SCC in the capsule around the breast implant occurred approximately 7 to 42 years (when data was available) after initial implant placement. SCC was located in the capsule around the breast implant often in the posterior aspect (behind the implant) without being present in the breast tissue. Three reports of death due to the disease were reported in the literature.

### Table 1. Summary of 19 Cases of SCC in the capsule around breast implants reported in Literature

| | | SCC (Cases = 19 from literature*) | |
|---|---|---|---|
| | | n | % ** |
| **Age at time of Diagnosis (years)** | **Median** | 53.5 years | |
| | **Range** | 40-81 years | |
| | **No age specified (# of cases)** | 1 | |
| **Sex or Gender*** ** | **Female or woman** | 17 | 90% |
| | **Male or man** | 1 | 5% |
| | **Not specified** | 1 | 5% |
| **Type of Implant at the time of diagnosis** | **Silicone** | 9 | 47% |
| | **Saline** | 7 | 37% |
| | **Not specified** | 3 | 16% |
| **Texture of Implant at the time of diagnosis** | **Textured** | 4 | 21% |
| | **Smooth#** | 4 | 21% |
| | **Foam±** | 1 | 5% |
| | **Not specified** | 10 | 53% |
| **Time from initial Implant to SCC Diagnosis (years)** | **Range (approximation only‡)** | 7-42 years | |
| | **Not specified (# of cases)** | 2 | |
| **Reason for Implant** | **Reconstruction** | 5 | 26 % |
| | **Augmentation** | 11 | 58 % |
| | **Not specified** | 3 | 16 % |

| | | | |
|---|---|---|---|
| **Clinical presentation (breast)∆** | **Breast swelling/pain** | 17 | 90 % |
| | **Erythema or Skin discoloration** | 5 | 26 % |
| | **Peri-implant Mass/lump** | 2 | 11 % |
| | **Other** | 2 | 11 % |
| | **Not specified** | 1 | 5 % |

*** Case refers to SCC reported per breast**

**** Percentage in terms of the total 19 cases**

***** Sex or Gender terms in the table are based on the information as provided in the literature.**

**# In the 4 cases of SCC with smooth implants at the time of diagnosis, 2 have a history of prior implants of unknown texture, 1 has a history of textured implant, and 1 has a history of one smooth implant and no known textured implant.**

**± The term "foam covered" in the table is based on the information as provided in the literature.**

**‡ The range in years is approximation only. In some cases, there was a range of years reported for when the first breast implant was placed.**

**∆ For some cases, more than one clinical presentation was reported.**

In summary, there have been reports in the literature of SCC in the capsule around the breast implant for both textured and smooth breast implants, and for both saline and silicone breast implants, when implant information was available. In most cases, people were diagnosed years after initial implant placement.

## Results from FDA Review of MDRs

As of January 15, 2023, the FDA has received 24 medical device reports (MDRs) about SCC related to breast implants. The FDA recognizes the limitations of MDR data, including duplicate reporting of cases within the MDRs, and between the MDRs and the literature. Therefore, MDRs do not necessarily represent unique cases. In addition, the incidence of SCC in the capsule around breast implants cannot be determined from this reporting system alone due to potential under-reporting, duplicate reporting of events, and the lack of information about the total number of patients who have breast implants. Based on review of the MDRs, the information described about SCC related to breast implants is similar to information from the literature for patient age, implant type, reason for implant, time to diagnoses, and clinical presentation.

MDRs 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 databases.

## FDA Actions

The FDA continues to collect and evaluate all available information about SCC, lymphomas, and any other cancers in the capsule around the breast implant. We are collaborating with other regulatory authorities, clinical and scientific experts, professional societies, manufacturers, and breast implant registries, to increase awareness of SCC in the capsule around the breast implant. In addition, the FDA is working with breast implant manufacturers to help ensure that patients receive and understand information about this emerging issue. The FDA continues 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 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.

## Publications


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4. Zomerlei, T. A., et al. "Primary Squamous Cell Carcinoma Arising from a Breast Implant Capsule." Plastic and Reconstructive Surgery. Global Open. 2015 Jan; 3(12), e586.
5. Olsen, D. L., et al. "Breast implant capsule-associated squamous cell carcinoma: a report of 2 cases" Human Pathology. 2017 Sept;67, 94–100.
6. Buchanan, P. J., et al. "Primary Squamous Cell Carcinoma Arising From a Breast Implant Capsule: A Case Report and Review of the Literature." Aesthetic Surgery Journal. 2018 Jun;38(7).
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11. Zikiryakhodzhaev AD., et al. "GG Breast implant capsule associated squamous cell carcinoma: case report." Malignant Tumors. 2020 Oct;(4):30-37.
12. Goldberg, M. T., et al. "Squamous Cell Carcinoma Arising in Breast Implant Capsules." Annals of Plastic Surgery. 2021 March 1;86(3), 268–272.
13. Liu, Z., et al. "Breast prosthetic implant-associated Squamous Cell Carcinoma: A case report and Literature Review." (Preprint, Version 1) Research Square. 2021 January 8.
14. Soni, S. E., et al. "Breast Implant Capsule-Associated Squamous Cell Carcinoma during Pregnancy: A Mimicker of Breast Implant-Associated Anaplastic Large-Cell Lymphoma." Plastic and Reconstructive Surgery. 2022 Oct 1;150(4), 926e–928e.
15. Whaley, R. D., et al. "Breast Implant Capsule-Associated Squamous Cell Carcinoma: Report of 2 Patients." International journal of surgical pathology. 2022 Dec;30(8), 900–907

16. Vorstenbosch J., et al. "Clinical Implications and Management of Non-BIA-ALCL Breast Implant Capsular Pathology." Plastic and Reconstructive Surgery. 2023 Jan;1 151(1):20e-30e.

17. Xia, Z., et al. "Breast implant-associated squamous cell carcinoma in a male patient: A case report and review of the medical literature." Frontiers in Surgery. 2023 Jan;10: 983611.

## 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.