

Plastic Surgery NEWS

AMERICAN SOCIETY OF
PLASTIC SURGEONS

SPECIAL BULLETIN

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FDA to issue safety signal on ALCL & breast implants

Today the Food and Drug Administration (FDA) issued a communication to inform health care practitioners and the public about a possible association between breast implants and anaplastic large cell lymphoma (ALCL). Although ALCL is extremely rare, the FDA believes that women with breast implants may have a very small but increased risk of developing the condition. ASPS has been actively engaged with the FDA on this matter. The Society is collaborating with the Agency to develop a centralized registry to collect more information on existing case reports and any new cases that may be identified going forward.

The Agency has posted two resources on its website. The first is a Safety Communication which provides a summary of the issue, recommended actions for physicians and patients, and how to report information to the FDA. The second is a more detailed report of the FDA's preliminary findings and analyses on ALCL in women with breast implants.

Following the signing of a Confidential Disclosure Agreement with the Agency, ASPS was asked by the FDA to comment on both documents.

Working both internally and with outside scientific experts, ASPS provided extensive comments, some of which are reflected in the final documents.

The FDA has provided the following links to their documents:

- FDA Medical Device Safety Communication: Reports of Anaplastic Large Cell Lymphoma (ALCL) in Women with Breast Implants at www.fda.gov/MedicalDevices/Safety/Alerts&Notices/ucm240000.htm.
- Anaplastic Large Cell Lymphoma (ALCL) In Women with Breast Implants: Preliminary FDA Findings & Analyses at www.fda.gov/MedicalDevices/Products&MedicalProcedures/Implants&Prosthetics/BreastImplants/ucm239996.htm.

The FDA has issued a press release ([link to press release](#)) and is conducting a media conference call and stakeholder call today. ASPS is executing an aggressive media relations campaign to represent plastic surgery's view and minimize potential false alarms for patients and consumers.

ASPS has posted additional resources for members and consumers on its website.

The Society is determined to work collaboratively with the FDA to ensure that plastic surgery patients, consumers and ASPS members are provided the information they need to make informed decisions. PSM