MEDTECH INSIGHT
CITELINE COMMERCIAL

09 Sep 2022 | **News**

New Cancer Risks Linked To Breast Implants, FDA Warns

by Brian Bossetta

The US FDA has learned of new cancer risks associated with breast implants that differ from cancers the agency has warned about in the past.

The US Food and Drug Administration has learned of new types of cancers associated with breast implants.

In a *safety communication* published 8 September, the FDA said it has received reports of squamous cell carcinoma (SCC) and various lymphomas in the scar tissue that forms around breast implants. These lymphomas, according to the agency, are not the same as the ones in previous alerts which the agency described as "breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)."

Kaveeta Vasisht, the FDA's associate commissioner for women's health, said that while the agency believes the occurrences of carcinoma and the various lymphomas are rare, health care providers and those with – or considering – breast implants should be aware of the cases reported to the FDA.

Vasisht added: "This is an emerging issue, and our understanding is evolving."

After preliminary review of published literature as part of its ongoing monitoring of breast implant safety, the FDA said it knew of fewer than 20 cases of SCC and fewer than 30 of various lymphomas in the capsule around the breast implant.

As of 1 September, the agency has received 10 medical device reports (MDRs) about SCC and 12 about various lymphomas. The reports describe cancers associated with both saline and silicone breast implants.

Some diagnoses, according to the FDA, occurred years after implant surgery, with swelling, pain,

lumps, and skin changes among the reported symptoms.

The agency cautioned, however, that the MDR data received so far were limited and that it was possible some cases had been reported more than once.

As the FDA noted in its safety alert, reports submitted to the agency are just one source it 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.

Breast Implant Patient Preferences Topic Of New FDA Study

By Elizabeth Orr

15 Jun 2022

The US agency's study will look at how the potential cancer risk tied to textured breast implants, as well as other factors, play into how patients decide what type of implants to get.

Read the full article here

The FDA said it will continue to gather and review all available data from these sources to evaluate the occurrence of cancers in the capsule around breast implants.

As it does, the FDA recommends those considering breast implants – or those who already have them – study their risks and benefits.

> ***"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." – US FDA***

Those with breast implants need not change their routine medical care regimens, according to the FDA, but should monitor their implants and notify their surgeons if they notice any changes.

The FDA does not recommend removal of the implants if there are no symptoms.

the agency advises that providers should continue to provide routine care to patients with breast implants, but should be aware of these new cases when examining implant specimens for diagnostic evaluation.

Any cases of SCC, lymphomas, or any other cancers in the capsule around the breast implant

should be reported to the FDA to help the agency better identify and understand the associated risks with these devices.

Both saline and silicone implants – the only two approved for sale in the US – have a silicone outer shell and vary in size, thickness, texture, and shape.

The FDA does not consider breast implants as lifetime devices, and cautions that the longer they are in the body, the more likely they will need to be either be removed or replaced.

The FDA has been looking at the association of BIA-ALCL cancer and breast implants since 2011.

And as recently as October 2021, the agency strengthened its safety requirements for breast implants by mandating surgeons warn patients about the risks prior to implantation and approved new labelling for all implants marketed in the US, including a boxed warning of those potential risks. (Also see "*FDA Strengthens Safety Requirements For Breast Implants*" - Medtech Insight, 28 Oct, 2021.)

As *Medtech Insight* reported then, breast implants have been a cause of concern for some time, and not just because of the risks of developing cancer. Breast implant illness (BII), according to breastcancer.org, has become an established medical term to describe a host of other symptoms many patients have developed after breast augmentation surgery.

BII, also known as autoimmune/inflammatory syndrome induced by adjuvants (ASIA), can occur with any type of implant. Symptoms include joint and muscle pain, chronic fatigue, trouble breathing, difficulty sleeping, hair loss, gastrointestinal issues and anxiety.

Autoimmune and connective tissue disorders, such as lupus, rheumatoid arthritis and scleroderma have also been linked to breast implants.