

Textured breast implant recall: What you need to know

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Ever since the Food and Drug Administration recalled textured breast implants in late July, the phone has not stopped ringing at the office of Orlando plastic surgeon Dr. Kendall Peters.

"We tell them what the FDA is recommending. We tell them that we're not putting in any new ones, and that the FDA is not recommending that we take them out," said Kendall, who practices at the Center for Plastic & Reconstructive Surgery.

On July 24, the FDA recalled Allergan BIOCELL textured [breast implants](#) because of the increased risk of anaplastic large cell lymphoma, also called BIA-ALCL. The agency said data analysis showed that the risk of developing the cancer with Allergan's implants was nearly 6 times the risk of developing the cancer from textured implants manufactured by other companies.

"The continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences and potentially death from BIA-ALCL," the FDA wrote

on Aug. 2.

The recall was based on reports of 573 cases of anaplastic large cell lymphoma worldwide, including 33 deaths. Of all the cases, 481 had Allergan breast implants at the time of diagnosis, according to the FDA.

Allergan has since started removing the breast implants from the market. The agency also advised doctors to stop using the breast implants and return their inventory to the company.

The odds of developing anaplastic large cell lymphoma are still low, but diagnosis is serious and can lead to death if the cancer isn't diagnosed early.

Textured implants make up less than 10% of all breast implants sold in the U.S., and the FDA is still trying to determine if the risk of anaplastic large cell lymphoma is only associated with specific models of textured breast implants or all of them.

In an interview, Dr. Peters answered our questions about the recent recall and implications for patients.

Q: What do we know about anaplastic large cell lymphoma?

A: We didn't know a lot about anaplastic large cell lymphoma until probably in the last 10 years. Initially, there were only some 20 reported cases in the literature. We know that it's not a cancer of the breast tissue. It's a cancer of the capsular tissue that forms around the breast implant. So it's actually a lymphatic cancer. It's a type of non-Hodgkins lymphoma.

Q: What are the main symptoms of anaplastic large cells lymphoma?

A: I happened to find one case in my practice several years ago. It's usually not a lump. It's

usually someone who out of the blue develops swelling or enlargement of the breast because of the build up of fluid around the breast implant. So the whole breast gets really big and swollen. That's the most common symptom. Now I've had a lot of patients who have had that problem and we've done the appropriate testing and found that it's not anaplastic large [cells](#) lymphoma. So again, this is extremely rare.

The symptoms also usually appear a year or several years after the breast implant. Everything is fine and all of a sudden this happens. And it's not subtle.

Q: How do you test for it?

A: You generally aspirate some of the fluid and then test the fluids for different markers for the cancer.

Q: So are you testing more patients after the recall?

A: Absolutely. Every time somebody swells, the first thing I think is that I have to make sure it's not anaplastic large cell lymphoma.

Q: What's the treatment for this type of cancer?

A: There have been only 33 deaths from this lymphoma so it's very treatable. Usually it's just removing the scar tissue that forms around the implant and the implant. So it's generally a surgical solution. There have been situations where there have been more aggressive forms and the patients have had to do chemotherapy and radiation therapy.

Q: What are textured implants used for?

A: There are some benefits to using the texturing in persons who have thin tissues or poor elasticity of the skin. In [breast](#) construction, I've found that textured implants are particularly beneficial because there's a big open pocket and the texturing helps the [implant](#) to adhere to the tissue a little better. Also, the teardrop-shape implants have been traditionally textured up to this point because you don't want them to turn upside down or

sideways.

Q: The FDA has recalled textured implants only from one manufacturer. There are still others available in the market. Are you using them?

A: I'm no longer using textured implants. I'm going back to smooth implants until this gets sorted out. I think this phenomenon is somehow related to texturing. So I would not feel comfortable personally using any kind of textured implants right now until the research is done. If it's my family member, I would err on the side of caution and go with something that has a smooth surface right now.

Q: How are you advising patients?

A: The FDA is not recommending that we replace textured implants if patients have no symptoms. It's because anaplastic large cell [lymphoma](#) is so rare and the likelihood of someone developing it is so low that it doesn't make sense to take everyone back to the operating room.

Breast implants have been around a really long time. They're one of the most implanted devices in the body, including hips and knees and heart valves. So I don't think this needs to incite panic. It's a very rare form of cancer.

More information: If you're thinking about getting breast implants, check this list for important advice: www.fda.gov/medical-devices/br...breast-implants—If you have questions about the recall, email DICE@FDA.HHS.gov or call 800-638-2041.

To see a list of recalled breast implants, visit www.fda.gov/medical-devices/sa...ts-requests-allergan

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