Allergan Recalls Textured Breast Implants Amid Major Cancer Controversy

All Biocell textured breast implants will be pulled because they may increase the risk for a certain type of blood cancer.

July 25, 2019 By Casey Halter

Irish pharmaceutical giant Allergan is recalling all of its textured breast implant products from U.S. and global markets after several studies have linked them to an increased risk for breast implant–associated anaplastic large-cell lymphoma (BIA-ALCL), a relatively rare type of blood cancer that can be fatal, Medscape reports.

The news came in an official announcement from the U.S. Food and Drug Administration (FDA), which noted in its report that 573 cases of BIA-ALCL and 33 deaths worldwide have been reported in patients who received textured implants following breast augmentation or removal surgery. Of those 573 cases, 481, or 84%, have been attributed to Allergan's implants.

Unlike traditional silicone implants, textured breast implants have rough surfaces instead of smooth ones and are designed to help the body develop scar tissue that sticks to the implant. This makes them less likely to move around inside of the breast post-surgery. Texturing can also help prevent a surgical complication known as capsular contracture, in which scar tissue around a breast implant becomes hard and painful.

Experts say it is still unclear whether the texturing itself is responsible for the cancer or whether there is another explanation for the statistical association with a higher risk for the disease. However, of the hundreds of BIA-ALCL cases linked to textured implants, studies show 845 have been attributed to the Allergan implants specifically.

The recall includes all Biocell textured breast implants made by the company, including Natrelle Saline-Filled breast implants, Natrelle Silicone-Filled breast implants, Natrelle Inspira Silicone-Filled breast implants and Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled breast implants. The recall also includes tissue expanders used by patients prior to breast augmentation or reconstruction surgery.

The worldwide recall will come as no surprise to those in the plastic surgery field. Allergan already

took its textured breast implants off the market in Europe last winter after French regulators ordered a recall. The implants were pulled out of Canadian markets in May 2019.

Included in the FDA's report on the matter is a thorough safety communication outlining the known risk of textured implants and blood cancer and what health care providers and their patients should know when monitoring for symptoms of the disease. The FDA is not recommending that everyone with textured implants get them removed, especially if there are no symptoms. But anyone who experiences symptoms such as persistent swelling or pain near the breast implant or has any concerns should consult his or her health care provider to discuss whether implant removal surgery is warranted.

To read that report, click here.

To learn more about the links between breast implants and cancer, click here.
