



Patient Information on Textured ALLERGAN Breast Implants
23 December 2018 – FOR IMMEDIATE RELEASE

Dear patients,

On the 16th of December 2018, the CE certificate for textured breast implants and tissue expanders of the manufacturer ALLERGAN was not extended within the European Union (EU), Iceland, Liechtenstein, Norway and Switzerland. The reason for this is not new scientific findings or studies on the Allergan breast implants, but the fact that additional data on textured breast implants required for the renewal of the CE certificate were not provided on time by the company.

This regulation does not apply to the sale of Allergan breast implants in the USA as they are approved by the US FDA. The CE mark for the Allergan smooth breast implants of this brand has already been renewed and they will continue to be offered in Europe.

Since the French supervisory authority ANSM already suspected a connection with the very rare Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) and the textured implant surfaces at the end of November this year, we would like to inform you about the symptoms of this disorder and its treatment. It is a fact that so far only textured implants of different manufacturers (not only ALLERGAN) have been associated with BIA-ALCL.

If you have a textured implant of any kind and have no symptoms, there is no reason for concern according to the current state of knowledge!

BIA-ALCL Symptoms are:

Acute, painful swelling on one side from a fluid collection around the implant that occurs years after implant surgery.

- Fluid accumulation can occur for a variety of reasons, including BIA-ALCL
- Laboratory testing of the fluid will determine if the rare BIA-ALCL is present
- This Breast Lymphoma is not classified as breast cancer, but as a cancer of the lymphatic system located at the breast with very good treatment options.
- Surgery to remove implant and capsule is the best treatment for BIA-ALCL

At present, about 615 cases of BIA-ALCL are known and documented since 1997 worldwide. There are about 11 million implant patients in the world. Even the most unfavorable statistics show a BIA-ALCL mortality risk that corresponds to the risk of a day's visit to New York City. However, it is important to better understand and study this rare form of breast lymphoma. Thus, studies are already underway by experts globally.

In any case, there is no reason to panic and no reason to have implants removed as a precaution. Patients should continue with their personal breast care, including monthly breast self-examination, mammograms as recommended and an annual visit to your plastic surgeon. If you experience sudden swelling and pain years after implantation, you should immediately contact your board-certified plastic surgeon for evaluation.

As a member of the International Society of Aesthetic Plastic Surgery (ISAPS) we receive updates on this matter on a regular basis so that we can keep you informed if there is any important news.

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