EASAPS / ESAPS

Statement on BIA-ALCL and Recall of Allergan Breast Implants

EASAPS/ESAPS main goal is to serve European Societies of Aesthetic Plastic Surgery and their members as well as to promote patient safety in the different fields of our specialty.

Background: Media as well as social media put a considerable amount of attention to the medical condition, defined as Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). BIA-ALCL is a very rare malignant disease observed in patients with textured breast implants operated on for benign or reconstructive purposes.

December 2018:

Allergan`s Biocell and Microcell implants lacked renewal of certification at the European market.

April 2019:

France banned all macro-textured Implants and polyurethane implants due to BIA-ALCL risks.

Canada banned Allergan Biocells

July 2019:

Australia announced plans to suspend 25 models of textured implants.

No other countries followed this initiative.

Allergan now recalls textured breast implants worldwide in response to U.S. FOOD and Drug Administration. FDA published new data showing that Allergan textured implants were linked to most cases of BIA-ALCL as 481 out of 573 unique cases identified worldwide were diagnosed with Allergan products. FDA states that patients with Allergan BIOCELL textured implants have a six times higher risk of BIA-ALCL compared to textured implants from other manufacturers, although FDA continues to monitor the other devices in the Market. The above FDA decision was prompted by an increasing number of deaths from known 9 cases in February 2019 to 33 deaths in July 2019.

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The total number of known 334 BIA-ALCL cases is presumably underreported and EASAPS/ESAPS will continuously gather information from member societies on the occurrence of BIA-ALCL cases throughout Europe. It must be emphasized that altogether this is a very rare complication, that is curable if detected early.

We also co-work with ICOBRA, as we see a huge benefit of unified breast registry data. Templates from well-organized and functioning registries are available without any costs for European countries without breast implant registry and EASAPS is ready to inform you how to get them. We strongly support all European Breast implant registry initiatives!

Is there any need to remove breast implants?

Patients with breast implants without any symptoms do not need to remove or replace their implants, this advice is for all implants textured or smooth, Allergan or other brand. To the best of our knowledge, there is no evidence-based data or international recommendations to undergo surgery for prophylactic reasons.

In case of acute seroma of the breast pocket, palpation of a nodule, redness or breast pain it is mandatory to make an appointment with a plastic- or breast surgeon. EASAPS/ESAPS highly recommends yearly follow-up investigations of patients with breast implants. Most patients are anxious because of mass media reports and need qualified objective information from their operating plastic surgeon. Facebook and Instagram reports are not qualified medical information sources for our patients.

EASAPS/ESAPS aims to provide as objective information as possible and works with national and international qualified medical scientific sources.

As leaders in all what concerns Aesthetic Plastic Surgery in Europe we are available for Surgeons, Public and Societies.