swissmedic

Breast implant associated-anaplastic large cell lymphoma (BIA-ALCL) – updated information

13 February 2019

In November 2018 Swissmedic provided information about breast implant associated-anaplastic large cell lymphoma (BIA-ALCL), noting that the majority of known cases of BIA-ALCL had been observed in patients with textured implants. However, no controlled clinical trials have been performed to compare uniform groups of patients with smooth and textured implants so far. There is thus no scientific evidence to date of a causal relationship between use of a specific breast implant and the development of BIA-ALCL. The cause of and mechanism by which BIA-ALCL develops have not been identified yet.

Swissmedic therefore contacted the association Swiss Plastic Surgery in order to obtain further clarification of the available information. The association sent Swissmedic the following statement (link to German document):
https://plasticsurgery.ch/fileadmin/user_upload/plasticsurgery/public/dokumente/news_40-2018-3_D.pdf (page 6)

Based on the information currently available, Swiss Plastic Surgery recommends using smooth implants rather than textured implants where permitted by the clinical situation.

In addition, the French regulatory authority ANSM (National Agency of Medicine and Health Products) organised a hearing of various groups affected by ALCL (patients, patient advocacy organisations, healthcare professionals, professional associations, representatives of industry and the authorities) on 7 and 8 February 2019. An initial summary of the outcome can be found here: Conclusions of the ad hoc specialist scientific committee "Public hearing on the place and use of textured breast implants in aesthetic and reconstructive surgery" (in French).

The ANSM reached the same conclusion: that smooth implants should be used in preference to textured implants.

The following recommendations were also issued:

- The need for a standardised classification of the different surfaces of breast implants at the European level
- Provision of detailed information to patients about these medical devices, the possible alternatives to textured breast implants and the necessary follow-up care for patients
- Systematic provision of information to all healthcare professions that treat or monitor patients with implants about the risks associated with breast implants and specifically about BIA-ALCL (greater vigilance is required with substantial periprosthetic effusions, reddening of the breast, increased volume, palpable masses or lymph nodes, ulcerations or a change in the patient's general condition)
- Greater transparency on the part of the manufacturers and a guarantee of the quality and safety of their medical devices

The committee does not, however, recommend preventive removal of textured implants.

Swissmedic · Hallerstr. 7 · 3012 Bern Switzerland · www.swissmedic.ch · Tel. +41 58 462 02 23 · Fax +41 58 462 02 12

In view of the growing awareness of the issue and the rising number of internationally confirmed cases of BIA-ALCL, Swissmedic advises individuals who are considering breast implants or who present for follow-up of their breast implants to discuss the risks and benefits of an intervention of this type with their surgeon as a matter of urgency. **If you have health concerns relating to breast implants, you should talk to a medical professional.**

Reminder: all cases of ALCL must be reported to Swissmedic and to the BI-ALCL global registry and, from 2019, to the breast implant registry. (The registry will be made available by Swiss Plastic Surgery in early 2019. The members of this association will be informed by e-mail.)

Contact

Swissmedic, Swiss Agency for Therapeutic Products / Medical Devices Division / Hallerstrasse 7 / 3012 Bern / Switzerland
Tel.: +41 58 462 02 23
Fax: +41 58 462 76 46
Internet: www.swissmedic.ch/md
E-mail: medical.devices@swissmedic.ch