EASAPS
EUROPEAN ASSOCIATION OF SOCIETIES OF AESTHETIC PLASTIC SURGERY
The Voice of Aesthetic Plastic Surgery

www.easaps.org

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Press Release of EASAPS

ANSM (agence national de sécurité du medicament et des produits de santé) stated April 3th, 2019 that macrotextured and surface-coated polyurethane implants from different labels are prohibited in France.

EASAPS opinion is that this is an regrettable decision that is not based on scientific data.

We need evidenced-based and statistically convincing studies for proper patient information on adverse events and the rare disease of ALCL.

EASAPS believes that non-conflicted unbiased reporting of all data of national breast implant registries should be globally aligned. This is in line with the opinion of FDA. The FDA´s General and Plastic Surgery Devices Panel organized a hearing on implant safety during March 25-26, 2019. Particular emphasis was brought forward for data collection in national breast implant registries. FDA supported and recognized national breast implant registries for independent post-market surveillance. Patients´ perspectives and input in terms of PROMS are important aspects to be included in national breast implant registries. EASAPS promotes and supports all efforts to start or harmonize European registries. EASAPS patient safety committee will set first priority for supporting proper and realistic information for patients considering implant-based breast surgery. Signed informed consents also with information concerning the low risk of BIA-ALCL, are highly recommended to all European countries.

We strongly believe in what we presented in our press release of dec 2018:

> *EASAPS and the other scientific communities in plastic surgery all over the world have been focusing on Breast Implant Associated Anaplastic Large Cell Lymphoma BIA-ALCL for over 5 years and recommend that decisions regarding implant surgery in general and breast implant surgery in particular to follow guidelines based on scientific evidence rather than emotions.*

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Looking at all scientific data on BIA-ALCL available as of december 2018, EASAPS comes to the following conclusions:

- *BIA-ALCL is an extremely rare condition that is detectable and curable.*
- *BIA-ALCL seem to occur in women who at some point had a textured implant.*
- *Textured implants may still be indicated in both cosmetic and reconstructive cases in order to give the best possible results or the least overall risk of complications.*
- *Information on BIA-ALCL should be included in the preoperative information of any patient receiving a textured breast implant.*
- *No evidenced-based data suggest removal of any implants prophylactically.*
- *EASAPS has no data to support banning of any of the certified breast implants currently used in Europe.*
- *Patients with breast implants without any symptoms need to do nothing.*
- *Unexpected swelling of the breast or a lump in the breast need to be examined by your plastic surgeon or another medical doctor.*
- *Specific recommendations on the use of textured/smooth implants may vary between the different European countries based on their health authorities' recommendations. Plastic surgeons in charge of implant-based indications should follow national recommendations until international consensus is obtained and implemented.*

22 European Aesthetic Plastic Surgery Societies of 20 countries that we were able to reach support these conclusions.
International collaboration with other Societies and countries continues to stay informed of the current scientific status of this disease and other diseases that might be related to breast implants. We will keep patients and our colleagues up to date.