

RBSPS Update to BIA - ALCL and “Implant files”

The **Royal Belgian Society of Plastic Surgery (RBSPS)** representing the national members of Plastic Surgery understands the concerns as expressed by the research journalists in the implant files and the last update concerning the ban of high textures implants in France recently.

The RBSPS 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.

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

- BIA-ALCL is an extremely rare condition that is detectable and even curable when presented at early stage.
- Although it is rare, BIA-ALCL seems to occur mainly 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 breast implant.
- No evidenced-based data suggest removal of any implants prophylactically.
- RBSPS 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 breast specialist.
- 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.

- On 21 November 2018, the ANSM (Agence National de Sécurité du Medicament et des produits de santé) in France advised to use smooth implants for cosmetic or reconstructive surgery waiting for the final decision of the experts committee.
- The ANSM will organize a public hearing on 7th and 8th of February 2019 in order to bring a general clarification as to use these implants.
- On 18 December 2018, The ANSM revealed that Allergan failed to obtain the CE mark re-approval by the GMED for Microcell et Biocell textures implants of Allergan.
- The ANSM couldn't identify any immediate risk for patients with the mentioned-above implants.
- The ANSM, as well, the RBSPS recommend an annual control for patients who have breast implants regardless the implant mark or implant shell (textures, smooth, nano surface and polyurethane coated surfaces).
- The RBSPS works closely with the international societies to update our members and patients on the last evolution of the breast implants use and their related risks.
- The RBSPS coordinate constantly available data and information with the our Belgian AFMPS (**Agence Fédérale des Médicaments et des Produits de Santé**) about the BIA-ALCL and patients security.