

Joined ISAPS ESAPS Statement

3 May 2019

U.S. FDA Allows Continued Sales of Textured-Surface Breast Implants

FDA announces new efforts to protect women's health and ensure the safety of breast implants:

Maryland, USA, May 2, 2019 – The American Food and Drug Administration (FDA) issued a statement on Thursday in regards to the March 2019 public advisory hearing on breast implants and the related risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). They announced new steps aimed at providing women with the necessary information regarding breast implants.

The FDA has evaluated the body of available evidence regarding the safety and risks of breast implants, including an in-depth review of study data, medical device reports, scientific literature, and public discussions, in addition to hosting a public advisory committee meeting on the topic in March. The FDA concluded that there was not enough data-supported evidence supporting a ban on textured-surface breast implants, but believes that women and providers should be adequately informed of the risk of BIA-ALCL and made aware that the risk is higher with the use of textured implants, albeit still low.

"This decision by the FDA is consistent with the position of ISAPS that a ban of textured and polyurethane-coated implants is an improper decision in terms of overall patient safety, when based on the currently available data." explains Dr. Dirk Richter, President of the International Society of Aesthetic Plastic Surgeons.

Together with his European colleague Dr. Ivar van Heijningen, President of the European Association of Societies of Aesthetic Plastic Surgery, EASAPS, they stand by the following important points:

- *BIA-ALCL is an extremely rare condition that is detectable and curable.*
- *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.*
- *We have no data to support banning of any of the certified breast implants currently used.*

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- *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 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.*

About EASAPS – The European Association of Societies of Aesthetic Plastic Surgery represents all 53 National Societies within geographical Europe consisting of plastic surgeons with an interest in aesthetic plastic surgery. The Association focuses on providing all European Plastic Surgeons with information that is pertinent to them. Patient safety and education are of prime importance in this collaboration.

About ISAPS – The International Society of Aesthetic Plastic Surgery (ISAPS) is the world's leading professional body for board-certified aesthetic plastic surgeons. Founded in 1970, ISAPS provides an open forum for the exchange of aesthetic plastic surgery knowledge worldwide. The Society offers its' members up-to-date training and continuing education, and sponsors and endorses scientific meetings regularly throughout the world. Today, ISAPS' membership includes the world's most respected aesthetic and reconstructive surgeons from 107 countries

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