

# POLYTECH

press release

Medical / MedTech

POLYTECH Health & Aesthetics GmbH

## **Breast Aesthetics Company POLYTECH Releases Official Statement Following the French Health Authority Decision**

POLYTECH Health & Aesthetics GmbH, an international leader in Breast Aesthetics, released today its official response following the ANSM decision to ban several textured implants and polyurethane implants from the French market.

Dieburg, Germany, April 4<sup>th</sup> 2019. POLYTECH Health & Aesthetics, an international leader in breast aesthetics and the only German manufacturer of breast implants, released today its official response following the French *Agence Nationale de Sécurité du Médicament* (ANSM) recent decision to ban what it considers macro-textured implants and polyurethane-coated implants from the French market.

The decision is based on a possible association between textured breast implants and the development of BIA-ALCL (breast implant-associated anaplastic large cell lymphoma).<sup>1</sup> The new directive indicates that moving forward, smooth implants and those implants that according to the ANSM's own classification are micro-textured - to which POLYTECH's MESMOsensitive® counts - is approved for use in France.<sup>2</sup> The company will continue to sell their POLYsmooth® and MESMOsensitive® surfaces in France.

POLYTECH has officially expressed its objections to the conclusions of the ANSM despite the fact that microtextured and smooth implants are an integral part of the company's portfolio. The ANSM decision is not based on any scientific proof and surgeons and their patients in France will now be offered very limited options, that may not allow them to achieve a safe and optimal surgical result. The company does completely agree with the findings and statements of more than 22 international Plastic & Aesthetic European Societies in more than 20 countries.

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POLYTECH has recently broadened its product range and now offers the B·Lite® lightweight implant with a smooth surface, as a unique and excellent alternative for surgeons and patients. The company will also continue to offer their textured and PU coated implants, which according to numerous scientifically valid clinical studies are safe, and allow for lower rates of the most common complications.

"As a leading manufacturer of breast implants, it is our obligation to educate both surgeons and patients on the subject of BIA-ALCL, with evidence-based information, recent medical publications and our gathered knowledge," stated Wolfgang Steimel, POLYTECH's CEO, at the official ANSM hearing. "Even as it is a very rare complication, we take the appearance of BIA-ALCL very seriously. However, we believe that a ban of textured and polyurethane-coated implants is a false decision in terms of the overall patient safety, when it is based on the currently available facts" Mr. Steimel adds.

POLYTECH also had the opportunity to present its position through the official industry representative of the *Federal Association of Medical Technology e.V. Germany* (BvMed), Mrs. Elke Vogt.

"As we review the information gathered to date, there is no clear scientific evidence of an association between BIA-ALCL and a specific implant surface", Mr. Steimel continues. "According to the available information, it is impossible to rule out any implant type, including smooth implants, from a possible association with the occurrence of BIA-ALCL". This is confirmed by a recent update from the FDA dated February 6, 2019, that recorded a number of BIA-ALCL cases with smooth only implants.<sup>3</sup>

According to the FDA, there are approximately 660 recorded cases of BIA-ALCL, with a seemingly higher occurrence in textured implants. However, in thirty percent of the recorded cases there is no information on the type of implant concerned.<sup>4</sup> A study by Loch Wilkinson et al. is often quoted as reporting fifteen cases of BIA-ALCL with polyurethane implants.<sup>5</sup> However, these cases occurred with polyurethane-implants manufactured by a different manufacturer, that lost its CE mark in 2015. While the current BIA-ALCL risk is calculated by the FDA as between 1:3,000 and 1:30,000<sup>6</sup> the risk with POLYTECH implants is of 3:1,100,000 implants sold, and the specific risk related to Microthane® is less than 1:160,000.

The overall data on BIA-ALCL to date, is based on the reported cases and not on prospective, controlled trials, as required by evidence-based medicine.

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"The ban on textured implants will, in our view, lead to a significant increase in the number of reoperations due to higher capsular contracture rates. Even though the French authority does not recommend, nor even suggest the explantation of the banned implants, patients may feel compelled to undergo reoperation and exchange their textured implants with smooth implants for fear of potential consequences - for which there is no scientific proof. The risks implied by a re-operation, or by anaesthesia, are per se higher than the BIA-ALCL risk according to published data." Mr. Steimel added.

"We believe that patient education should be transparent, not only in regards to BIA-ALCL, but for all possible complications. Patients education will enable them to make informed choices about their procedure and implant type" Mr. Steimel concluded. "The different European authorities expressed their expectation that patient education and transparent information regarding BIA-ALCL and other possible complications, will become a priority primarily for the surgeons, but also for manufacturers. We are already taking steps to make evidence-based information available to the public."

## **About the POLYTECH Portfolio**

The POLYTECH breast implant portfolio includes a wide variety of shapes and sizes, in four different surfaces: smooth, two different types of textures and implants coated with polyurethane-foam (PU): marketed since the beginning of the 1970's, the PU-foam that coats the implant is a three-dimensional matrix that has a different mechanical and biological interaction with the surrounding tissue compared with textured implants. Historically, textured implants were developed in the 1980's to mimic the shape and benefits of PU-coated implants. It is a very common conceptual error to consider PU-coated implants as textured implants. The mechanisms related to tissue adhesion and fibrous capsule formation are fundamentally different from textured implants: this tissue interaction with the polyurethane fibres is key to the low rates of capsular contracture.<sup>7</sup>

## **About POLYTECH**

With a global footprint in over 75 countries, POLYTECH Health & Aesthetics GmbH is an international leader in the development and production of silicone implants. Founded in 1986 in Dieburg, Germany, the company focuses on breast implants, used in both reconstructive and aesthetic plastic surgery. POLYTECH is the only German manufacturer of soft tissue implants. All products are developed exclusively at the company headquarters in Germany,

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and are manufactured under clean room conditions. The company employs over 250 people.  
For more information visit <https://polytechhealth.com/en>

\* POLYTECH products are not sold in the US.

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