

25. Oktober 19

Dear Surgeons, dear Partners,

As you know, POLYTECH is the only German breast implants manufacturer and is present in over 75 countries worldwide.

Today, POLYTECH is one of the world's leading companies in the field of the development and production of silicone implants. Indeed, our Company provides the surgeons with the largest portfolio of breast implants with

- smooth implants (POLYsmooth®),
- two types of microtextured implants (MESMO® and POLYtxt®),
- polyurethane (PU) coated implants (Microthane®),
- B-Lite® implants.

OUR POLYSMOOTH®, MESMO® AND POLYTXT® IMPLANTS ARE REGULARLY ALLOWED AND AVAILABLE IN THE AUSTRALIAN MARKET, AND OR MICROTHANE® IMPLANTS MAY STILL BE PURCHASES BY SURGEONS ON A SPECIAL ACCESS BASIS.

PU implants have been consistently related to minimal risk of capsular contracture, seroma and other common complications over time, with scientific literature as support since more than four decades¹⁻⁷.

Less than one month ago, the Australian Therapeutic Goods Administration (TGA) proposed a temporary suspension of several manufacturers' breast implants because of an increasing concern related to the development of breast implant associated - anaplastic large cell lymphoma (BIA-ALCL). Among these breast implants, we found surprisingly also our Microthane® implants.

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This TGA's decision was really unexpected as **in Australia there is**

- **only 1 primary case of seroma-only disease associated with the insertion of Microthane® implants** ⁸.

Even in the rest of the world,

- Microthane® implants show a **very low rate of BIA-ALCL** ^{9,10}, and the same is true also with POLYtxt® implants.
- **No cases of BIA-ALCL have been associated, to date, with our POLYsmooth®, microtextured MESMO® and B-Lite implants.**

The BIA-ALCL risk rate calculated in the recent literature for PU implants is only based on Silimed cases and sales in Australia. This risk calculation is more than doubtful, as it takes into account only the PU implants sold by Silimed, excluding in the denominator the sales figures of Surgitek and POLYTECH. Therefore, **the general risk for PU implants is overestimated** ^{8,11}.

Although Silimed, Surgitek and POLYTECH implants are covered with the same PU foam, there are known differences in the manufacturing quality ^{9,10} which could explain the different incidence rate of BIA-ALCL: 23 cases with Silimed PU implants, 1 case with POLYTECH PU implants and 1 case with Surgitek PU implants in Australia ⁸.

We have also skepticism regarding the TGA's assertion that

- **1 single case of BIA-ALCL can be considered sufficient for suspending the sales of Microthane® in Australia.**

If this assertion is true, then

- **why other Companies with more than 1 case of BIA-ALCL and an increase of the number of cases over the last year have not been suspended?**

Despite the rare incidence of BIA-ALCL with POLYTECH breast implants, we take very seriously this disease. We have been monitoring for more than 10 years the **post-marketing performance** of all our implants and we actively collaborate with expert researchers around the world in order to maintain the high level of quality of our implants, having as our main care and goal the **health of the women**.

In the meantime, we commit our **close collaboration to the TGA** and other governmental authorities in order to contribute to the efforts to find the cause of BIA-ALCL, which to date is not known.

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We promise to **share all the new information** with our partners, surgeons and patients, and, should the incidence of BIA-ALCL have a significant increase in the future, we will withdraw immediately the concerned product from the market.

Please do not hesitate to contact us for any clarification.

Sincerely,



Wolfgang Steimel, CEO
POLYTECH health & Aesthetics GmbH

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