

16. February 21

B-Lite® Temporary Certificate Suspension

Dear Valued Customer,

As a leading manufacturer of world-class breast implants, the POLYTECH Group takes any questions regarding our products very seriously. We are committed to ensuring that our products comply not only with our own high quality and safety standards but also with all required industry standards.

Recently the presence of B-Lite® filling material was identified on the surface of B-Lite® implants. The integrity of our shells was at no point questioned. Our analysis identified that a droplet of filling material containing gel and microspheres touched the outer surface of the shell during manufacturing. These findings do not pose a risk to patients' safety. As a responsible manufacturer we voluntarily halted B-Lite® shipments, while we work together with our notified body Medical Devices Certification GmbH (MDC) to address this issue.

We have been informed by MDC that one of our B-Lite® certificates has been temporarily suspended. This is a standard procedure.

Please note that POLYTECH implants are not impacted, and continue to be available to you and your patients.

The health and safety of patients is paramount to the POLYTECH Group and we continue to be confident in the safety of our products. We value the trust placed in us by our customers and want to reassure you that we are doing our utmost to resolve the current situation.

Microspheres are used throughout the body in many medical procedures, including direct injection into tissues and the bloodstream. They do not pose a safety risk. Additionally, the microspheres identified on the surface of B-Lite® implants are covered by a veil of cured silicone which further strengthens their adherence to the implants' surface.

Our B-Lite® breast implants have gone through the most rigorous research, development and testing over 10 years prior to introduction. Since then, our B-Lite® implants have exceeded every required industry test prior to, and post market. Tens of thousands of implants have been used by surgeons in more than 50 countries in the last 7 years. In fact, our clinical experience to date shows that B-Lite® implants have an outstanding safety profile, superior to other existing implants.

POLYTECH

We apologise that we cannot supply B-Lite® at this time and for the inconvenience this might cause. We can reassure you that we are working closely with MDC to ensure a swift resolution of the situation.

The temporary suspension lasts for three (3) months, so please consider we may not be able to supply you with B-Lite® during this period of time. If there is a change, we will notify you immediately. In the meantime, you might consider a POLYTECH implant as an alternative if you feel this would be appropriate for your patients. Your trust in B-Lite® and POLYTECH is not something we take for granted. We will work with you to find the best solution for you and your patients should you wish to opt for alternative POLYTECH implants.

We are confident that we will be able to resume supply in the near future bringing to you and your patients the unique benefits of B-Lite®, the first and only lightweight breast implant. We will of course keep you informed and please do not hesitate to reach out should you have any queries on this matter.



Wolfgang Steimel
CEO