



# POLYTECH and AMSilk Announce Start of Joint International Clinical Study for Silk-Coated Medical Implants

Dieburg and Munich, February 27, 2018 – AMSilk GmbH, the world's first industrial supplier of synthetic silk biopolymers for medical devices, is partnering with POLYTECH Health & Aesthetics GmbH, the leading manufacturer of soft-tissue silicone implants, to begin the clinical study *POSIS*, the first-in-human clinical safety testing of silk-coated silicone SILKline® breast implants in Europe. The study, which started with several patients in the first week at a number of medical universities in Austria, may be extended to further European countries for comprehensive testing.

POLYTECH's silicone breast implants have been available to international customers for many decades, and demand has recently reached an all-time high, with the company selling over 200.000 silicone implants in 2016. As part of POLYTECH's quality control system, all implants are produced under stringent quality guidelines and fulfill maximum safety requirements. To ensure consistent quality, the implants are produced manually, and are checked after each production step according to the highest standards.

The partnership with AMSilk GmbH marks the first time that bioengineered silk will be inside the human body. AMSilk's unique silk coating forms a thin and flexible physical protein interface between the silicone surface of POLYTECH's implant and the surrounding tissue. The body recognizes the physical protein interface as a natural surface, leading to a much better biocompatibility. In preclinical studies, SILKline® silk-coated silicone breast implants resulted in superior tolerability. Therefore, it is expected that minor postoperative complications and minimization of sometimes painful side effects that accompany traditional implants (e.g. capsular fibrosis) will occur.

"With the new SILKline® implants, POLYTECH plans to further increase the safety and tolerability standards of our products," said Wolfgang Steimel, CEO of POLYTECH. "Working with AMSilk enables us to provide our customers the





newest and best technology available to support patients' wellbeing and satisfaction, combined with the objective to reduce complications with real innovative technology."

Added Jens Klein, CEO of AMSilk: "Through our multi-year partnership with the experts at POLYTECH, we've created a new and groundbreaking product for the medical devices market. The SILKline® implants are the first product providing our silk coating in the medical device sector – but other products utilizing the extraordinary biocompatibility of our silk coatings will soon follow."

#### **About POLYTECH**

POLYTECH Health & Aesthetics was founded in 1986 in Dieburg (Hessen). Today, the company is an international market leader regarding implant advancement and manufacturing. POLYTECH's portfolio of superior medical devices includes more than 2,000 variations of breast implants for women, soft-tissue implants for men as well as calf and gluteus implants. This range is complemented by custom-made implants, tissue expanders, compression bras and scar-therapy products. More than 230 employees in the units of development, manufacturing, quality control, sales and marketing ensure that POLYTECH remains the number one regarding implant quality and safety made in Germany.

## www.polytech-health-aesthetics.com

#### **About AMSilk**

AMSilk GmbH is the world's first industrial supplier of synthetic silk biopolymers and has its headquarters in Planegg near Munich, Germany. AMSilk high-performance biopolymers have the unique functional properties of the natural product they are based on. The organic high-performance material can be used in multiple ways, and is especially suited for medical devices as well as for personal care products. AMSilk high-performance biopolymers give such products unique properties. Among other things, the polymers are biocompatible, safe and robust.

#### www.amsilk.com





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