

Press Release

Faulty Breast Implant Scandal Causes Major Concern Worldwide

Not Affected: Breast Implants „Made in Germany“

Who decides for low cost implants may have to pay dearly in the end

Dieburg, 6 January 2011. BfArM, the German Federal Institute for Drugs and Medical Devices, had already posted an alert in May 2011 regarding the products of the French company PIP (Poly Implant Prothèse)¹. For years, PIP used non-medical grade silicone for the production of breast implants in France. Current media updates report that in the meantime several thousands of women are affected. “30,000 French women will probably have to face removal of their silicone implants – these might cause cancer,” states the German TV station ARD in its evening news². The implants were used for aesthetic purposes as well as for reconstruction after breast cancer.

This is alarming news from a neighbouring country which shows clearly: when using a medical device, quality assurance is crucial.

German quality

German brands enjoy the highest reputation worldwide which equals superior quality and high-level processing. Polytech, the only German breast implant manufacturer has implemented extensive safety test procedures and guarantees the highest quality standard.

“The raw materials we utilize for the shell and gel filling of our implants is certified for long-term implantation. At our production site in Germany, implants are examined after each production step to prevent possible errors or defects. Only when all tests and security checks are passed successfully, the implant is released for sale. In this way, we ensure consistently high quality and safety for the surgeons and patients.”

German standards

POLYTECH Health & Aesthetics is one of the leading manufacturers of implants in Europe. The company is the only German manufacturer of soft-tissue implants. The premises are located in Dieburg (near Frankfurt), and since July 2008, all implants are exclusively produced in Germany. Concentrating the production in Germany assures quality in all areas.

German focus – history shows Polytech’s dedication to excellence

POLYTECH was the first company to receive CE mark for breast implants in 1995. In 2003, the European Community decided that breast implants become a medical device class III product. Also pacemakers, and heart valves are medical device class III products. This means that strong guidelines are to be followed in the production of breast implants. POLYTECH immediately received clearance for their products.

POLYTECH Health & Aesthetics carries the largest product range in the breast implant market with more than 1,500 implant types, both for augmentation and reconstruction. The main focus is on breast implants for women, but also pectoral implants for men as well as implants for the nose, the chin, the calves, the bottom – are offered.

References:

1 www.bfarm.de/DE/Medizinprodukte/riskinfo/empfehlungen/Silikon_Brustimplantate_PIP.html

2 www.tagesschau.de/ausland/pip104.html

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