



Well-Known Data Re-Assessed

by Dr. Oliver Bögershausen

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Intentionally or unintentionally, Microthane[®] covered implants are associated by our competitors with hazards for patients.

Let us briefly recall some of the facts:

In 1989, Chris Batich published an analysis concerning polyurethane foam in the Journal of Biomedical Materials Research. In this study, he reported on large quantities of TDA (toluene diamine). The analysis was carried out using gas chromatography combined with mass spectrometry (GC/MS) and in addition referring to TDA as a well-known toxic, carcinogenic substance.

In his analysis, Batich hydrolyzed one gram of polyurethane foam by heating the sample in 10 ml NaOH (sodium hydroxide) in a Teflon-coated reaction vessel overnight to 150°C. The extract contained 2,4-TDA.

The test arrangement used by Batich is not appropriate to prove a release under physiological in vivo conditions in the human organism or under the conditions of an accelerated aging in vi-tro, as the combination of high temperature and extremely alkaline pH also contains a chemical component in addition to the physical one. This is rather a matter of chemically destroying a material.

In his article "What Will Historians Say?", published in 1991, Jack C. Fisher, M.D. (San Diego) makes the following statement:

Widely quoted is the experimental study by Cardy in 1979 reporting tumors, both benign and malignant, following exposure of the Fischer 344 rat to orally administered TDA. This is a rodent strain (CDF[F-344]Cr1132) known since 1932 to be highly susceptible to spontaneous and chemically induced cancer. For example, spontaneous tumor incidence as high as 90 percent has been reported. Liver cancer is one of the many malignancies described in the Fischer 344 rat. These are bioengineered species, and historical and biologic fact that no one should forget.

TDA was administered to the Fischer rat in doses that transcend clinical experience, i.e., at suprahuman dosage and for the majority segment of the host's lifespan. How then can we fool ourselves or the historians of the next century that we have conducted studies that will have lasting valid meaning? We cannot!

Quote of Jack C. Fisher (Santa Fe Congress, 24th August 1993):

You can feed the Fischer rat peanut butter and it will have the same effect of developing cancer.

During the discussions between 1989 to 1992 on the safety and efficacy concerning the use of such products, these arguments were hotly debated among others within the scope of the warranty legislation in the United States and were used as an efficient source of income by lawyers of big law offices. In the meantime, the safety of silicone gel as an implant component has been proven, and also the arguments put



forward against polyurethane, which could not be scientifically supported, were clearly refuted. In 1995, also the FDA supported this opinion and published a statement concerning the safety of polyurethane-covered implants.

Since its first use in 1968 until today, Microthane® has positively contributed to the aesthetic and reconstructive shaping of the female breast by achieving significantly improved, long lasting results for the patients.

5 good reasons for breast implants made by POLYTECH

1. Accumulated expertise since the company's foundation in 1986 with a proven Quality Management.
2. First company to obtain the C€ mark for a breast implant, i.e. early application of the class III standards for medical devices and building of the corresponding knowhow. Medical devices class-III certification for breast implants since December 2003 as one of the first manufacturers worldwide.
3. Close cooperation with surgeons, especially of our Research&Development team, provides for the widest range of the most advanced products to satisfy the specific needs of the patient, surgeon, and society. POLYTECH offers the largest selection of shapes, sizes, projections, gel structures, and surfaces in the breast implant market.
4. Specialization and focus on one field of expertise: breast implants. We pride ourselves in the quality of our products and in our craftsmanship. That is why we offer a lifetime warranty in case of shell rupture on all our breast implants.
5. POLYTECH is an open company: We invite surgeons to come to visit us in Dieburg, Germany, any time!



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