



POLYTECH

i n f o r m e d[®]

Issue 01/2012

Information for reconstructive and aesthetic plastic surgeons

For medical staff only. Do not hand out to the untrained public.

© Polytech Health & Aesthetics GmbH, Dieburg, Germany

Why are Microthane[®] polyurethane covered breast implants the best available choice?

POLYTECH

i n f o r m e d[®] is a service offered by::

POLYTECH Health & Aesthetics GmbH
Altheimer Str. 32 | 64807 Dieburg | Germany

Tel. +49 (0)6071 98 63 0
Fax +49 (0)6071 98 63 30

eMail: info@polytechhealth.com
www.polytech-health-aesthetics.com



Clarification of a Perceived Cancer Risk with Polyurethane Covered Implants in the UK

by Patrick O'Leary, PhD

Given the fact that many women with breast implants are extremely worried by the media coverage regarding the allegedly defective French implants, it is questionable whether the unearthing of outdated and irrelevant information concerning polyurethane helps to clarify the situation.

An article from the Daily Mail, UK cited an internal document from Nuffield Health Bristol Hospital indicating that the doctors in their service should not use polyurethane covered implants. They should quarantine these implants and wait for clarification. This was not a position paper or an indictment on polyurethane by Nuffield, but a conservative position waiting for further clarification on polyurethane. This information, taken out of context from the yellow press, caused a stir amongst some women who thought there was a new cancer risk for breast implants.

The facts are that Nuffield was performing an assessment of breast implants due to the PIP implant scandal. In their review, they found an outdated statement from the MHRA (British FDA), that indicated that polyurethane could break down to 2,4 TDA, a carcinogen for cancer prone rodents. This is an old statement from the 1990's and was a figment of the manner in which the assay was performed. In this old test, polyurethane is put into high acid or base and

subjected to high heat. In this process the polyurethane is broken down and TDA is generated which was never there prior to the test. It was just generated during the test preparation procedure. In 1995 the FDA published a position paper that states the chances of contracting cancer from polyurethane are less than 1:1,100,000. This is the statistical equivalent of something being unsterile after a validated sterilization process by autoclaving.

The MHRA subsequently approved polyurethane covered implants for sale in the UK market. The MHRA has recently reiterated their approval position on polyurethane covered implants in the UK market on 31. January 2012.

Microthane[®] coated breast implant



Microthane[®] is a registered trademark of POLYTECH Health & Aesthetics, Germany



Facts about Polyurethane covered breast implants

- ▶ Polyurethane has been used in many medical and surgical devices since the early 1950's and continues to be used today. In all this time, **NO PUBLISHED CLINICAL reports or information has linked polyurethane or any of its breakdown products with cancer in humans.**
- ▶ One published paper in 1991, Chan et al, reported that 2,4 TDA (a breakdown products that under certain circumstances can be derived from polyurethane) can cause a carcinoma in a cancer prone white rat species. This one publication has been revisited and heavily criticized by an FDA study of 1993. The fact remains that **NO LINK BETWEEN 2,4 TDA and cancer in HUMANS has ever been shown.**
- ▶ In 1995 after extensive investigation, the FDA concluded that polyurethane breast implants should not be removed from patients that have these implants and that the risk of polyurethane (if any) is less than 1 in 1.1 million over the lifetime of the patient. Polyurethane continues to be used successfully in a variety of medical and surgical products throughout the world today.

- ▶ Polyurethane surface breast implants have been used since 1968. Since that time, over 114 peer review published medical papers have all shown that polyurethane surface breast implants have a reported lower capsular contraction rate (the largest complication in breast implant surgery) than normal silicone surface implants. Not one single publication has indicated that polyurethane surface implants **INCREASES** complications in patients. To reduce complications in patients that receive breast implants **MUST BE** the primary concern of all surgeons, clinics, hospitals and health authorities.
- ▶ More than 80,000 polyurethane covered breast implants are implanted each year around the world.

Conclusion: The cancer risk due to polyurethane breast implants has been determined by the FDA to be so low that it is scientifically irrelevant. In the interest of a low complication rate the use of breast implants with polyurethane-foam coating represents the best alternative and does not expose patients to any significant additional risk.



Lateral view of an implant shell with Microthane[®] coating

→ Polyurethane-foam coating, ca. 2mm

→ Silicone shell with barrier layer



In the Pursuit of Safety: Breast Implants "made in Germany"

For ordering the brochure please contact:
info@polytechhealth.com

POLYTECH

Health & Aesthetics

POLYTECH Health & Aesthetics GmbH
Alzheimer Str. 32 | 64807 Dieburg | Germany
fon ++49 (0)6071 9863-0 | fax ++49 (0)6071 986330
eMail: info@polytechhealth.com
www.polytech-health-aesthetics.com