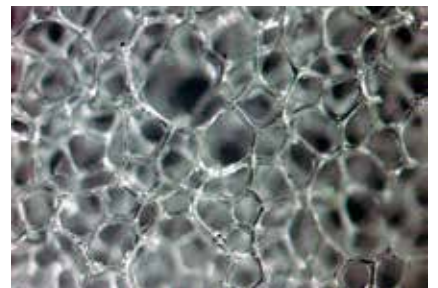


Microthane®

Implant cover of medical-grade micro-polyurethane foam for low capsular contracture rates and few adverse effects



Implants made by POLYTECH – QUALITY made in Germany



POLYTECH
health & aesthetics 

Microthane® CE 0483

The POLYTECH micropolyurethane-foam implant cover

One of the principal considerations for any elective operation, e. g. breast reconstruction or augmentation, is to minimize the number of complications. The most common complication of breast-implant surgery is capsular contracture.

Implants covered with Microthane® (micropolyurethane foam) have been developed to minimize the capsular contracture rate. In extensive clinical studies over the past twenty years reviewing large numbers of patients, the capsular contracture rates (Baker classification III and IV) have been determined. The capsular contracture rate for Microthane®-covered implants in virgin tissue is 0 to 9% compared to 9 to 50% for other implants. In most of the large studies, the capsular contracture rate for Microthane®-covered implants is as low as 0 to 3%¹⁾. An extensive long-term study carried out in the United States using the Kaplan-Meier survival analysis confirms the significant reduction of the risk for capsular contracture with Microthane®-covered implants for up to 10 years after implantation. The statistics show that after 8 years the capsular contracture rate with Microthane®-covered implants compared to textured implants is 15% lower. It is even 30% lower compared to smooth implants²⁾.

The low capsular contracture rate is attributed to the ingrowth and micro-encapsulation of the fibroblasts in the polyurethane-foam matrix (fig. 2). Due to the active healing process, a linear capsular contracture (fig. 1) and the resulting disfigurement of the implant are drastically reduced. In contrast to smooth and textured implants around which a single large capsule is created, the Microthane®-covered implants – due to microencapsulation of the polyurethane foam – encourage the growth of numerous microcapsules around the foam, whereby contractile forces are neutralized.

The tissue fixation and the highly cross-linked silicone gel provide a natural feeling to the breast. Implant dislocation and rotation occur in such a low frequency that POLYTECH offers a 10-year warranty against these adverse events. The low capsular contracture rate also allows the prepectoral implantation and allows a pleasing aesthetic result for the augmentation and reconstruction of the breast.

Due to the positive effect of tissue ingrowth, the foam is not visible at first sight after explantation. The polyurethane foam can only be made visible again when the capsule has been enzymatically degraded (fig. 3 and 4)³⁾!

In 1995, the American health authority “Food and Drug Administration” announced that the estimated excess cancer risk due to micropolyurethane-foam covered implants is less than one in one million over a woman’s lifetime⁴⁾. This figure indicates that there exists no significant danger according to standard risk analysis⁵⁾. The general risk to suffer from breast cancer is, according to the WHO statistics, one in nine.

Summary

Patients with Microthane® implants are better protected against capsular contracture for up to 10 years after implantation. Additionally, the average period until reoperation after Microthane® implant insertion is longer than with smooth or textured implants. Due to the Microthane® implants' tissue ingrowth, implant dislocation and rotation very rarely occur.

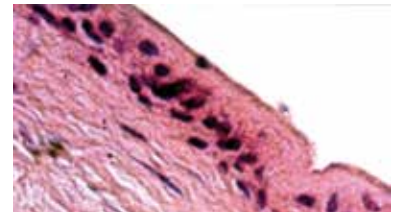
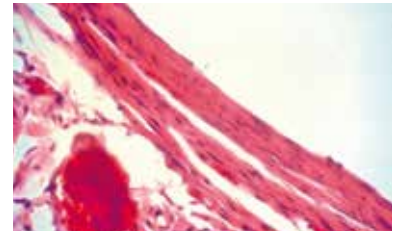
All advantages of Microthane® implants combined drastically reduce the total complication rate for the patient.

Literature:

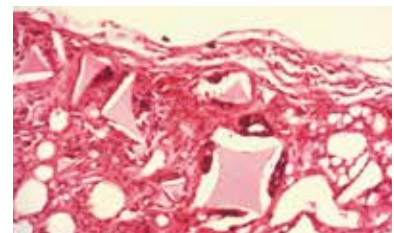
- 1) Handel, 1991; Pennisi, 1990; Shapiro, 1989; Hester et al., 2001; Baudelot, 1989; Gasperoni, 1992; Hermann, 1984; Eyssen, 1984; Schatten, 1984; Artz, 1988; Vázquez, 2007
2) Handel, 2006; 3) Szycher & Siciliano, 1991; 4) Food and Drug Administration, 1995; 5) Wilson, 1979

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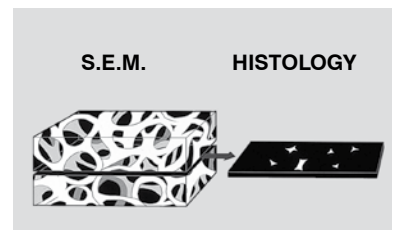
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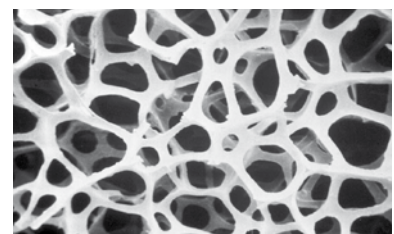
1 Passive healing:
Using smooth-walled silicone implants (fig. top), a capsule with low vascularization is formed around the foreign body. The contractile forces squeeze the implant and the originally soft consistence is lost; the breast becomes harder and is eventually deformed. This also happens with textured implants (fig. down), though the fibrotic pattern of the capsule is slightly fractured.



2 Active healing:
The structure of the Microthane® surface breaks the fibrotic pattern and actively encourages cellular involvement. It re-models the tissue into a sponge-like and richly vascular configuration around the implant.



3 On the left side, the three dimensional structure of Microthane® foam is shown as it could be seen through a scanning electron microscope (SEM). When sectioned for a histological study, the structure appears fragmentary even though it is complete.



4 Microthane® foam freed from tissue by enzymes 9 years after implantation.