Microthane®
Implant cover of medical-grade micropolyurethane foam for low capsular contracture rates and few adverse effects

Implants manufactured by POLYTECH – QUALITY made in Germany

POLYTECH health & aesthetics
Implants covered in medical-grade micropolyurethane foam for low capsular contracture rates and few adverse effects

One of the principal considerations for any elective operation like breast reconstruction or augmentation, is to minimize the number of adverse events. The most common complication occurring with breast-implant surgery is capsular contracture.

The first implants with a shell covered in medical-grade micropolyurethane foam certified for longerm implantation have been developed in the 1960s. The goal was 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 grade III and IV) have been determined. The capsular contracture rate for micropolyurethane-foam 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 micropolyurethane-foam 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 micropolyurethane-foam covered implants for up to 10 years after implantation. The statistics show that after 8 years the capsular contracture rate with micropolyurethane-foam covered implants compared to textured implants is 15% lower, and even 30% lower compared to smooth implants\(^2\).

Data collected by POLYTECH as part of their market surveillance show a 6-fold lower risk for capsular contracture after eight years in-situ for POLYTECH implants with micropolyurethane-foam cover (brand name Microthane\(^3\)).

The low capsular contracture rate is histologically 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. Around smooth and textured implants the fibres grow in a single large capsule. In contrast and due to microencapsulation of the polyurethane foam, the thus covered implants encourage the growth of numerous microcapsules around the foam structure, whereby contractile forces are neutralized.

Additionally, the tissue fixation of the implants covered in micropolyurethane foam ensures that these remain in the position they were placed during the surgery and ensures a longterm stable result. Implant dislocation and rotation occur in very rarely. In combination with the highly cross-linked silicone gel, these implants provide for a natural look, feeling and motion of the augmented breast. The low capsular contracture rate also permits prepectoral implantation and thus allows the creation of pleasing aesthetic results for the augmentation and reconstruction of the breast.

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 consistency 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 micropolyurethane-foam 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.
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 micropolyurethane-foam covered implants are better protected against capsular contracture for up to 10 years after implantation. Additionally, the average period until reoperation after implant insertion is longer than with smooth or textured implants. Due to the tissue ingrowth into the micropolyurethane foam, implant dislocation and rotation occur only very rarely.

All advantages of micropolyurethane-foam covered implants combined drastically reduce the total complication rate for the patient.

Literature:
2) Handel, 2006;
3) Szycher & Siciliano, 1991;
4) Food and Drug Administration, 1995; 5) Wilson, 1979
Microthane®
the micropolyurethane surface manufactured by POLYTECH Health & Aesthetics

The POLYTECH Health & Aesthetics brand name for our micropolyurethane-foam covered shell surface is Microthane® – an acronym created from the word »micropolyurethane«. At the end of the 1980, POLYTECH started distributing micropolyurethane-covered breast implants and in the 1990s we became manufacturers; in 2008, the complete production was relocated to Germany. In close cooperation with surgeons, we continually optimized our Microthane® implants. Currently, POLYTECH is the only European manufacturer of breast implants offering breast implants with this type of surface.

With regard to Microthane®, POLYTECH had always been able to refer to earlier studies on breast implants covered in micropolyurethane foam, especially regarding histology, since the material used for the cover was basically the same. Nevertheless, specific studies on Microthane® were commissioned and their results have been published at the end of 2016. They confirm that Microthane® implants produce very low rates of capsular contracture and complications in both primary breast augmentation and 2-stage reconstruction.

In the first study on the modern polyurethane implant in breast augmentation, a total of 131 patients with 255 implants were evaluated in a retrospective study. Data were compiled from postoperative follow-up sessions at 2 weeks; 1, 3, 6, and 12 months; and annually thereafter (median follow-up 110 months). Rates of various complications, including capsular contracture, were determined. Capsular contracture Baker grade III or IV developed in 1.2% and postoperative hematoma occurred in 2 implanted breasts (0.8%).

In the second study, the authors determined the incidence of capsular contracture following 2-stage breast reconstruction using Microthane® implants, with and without radiation therapy. They retrospectively reviewed the records of 92 patients who received 115 Microthane® implants and compared rates of capsular contracture over time for irradiated and nonirradiated groups. The median follow-up time for patients was 103.3 months. The overall cumulative incidence of capsular contracture at 9 years was 8.1%. The 9-year cumulative incidence was 10.7% in the irradiated and 5.5% nonirradiated group. Radiation therapy increases the risk of high-grade capsular contracture with textured or smooth implants.7 As a consequence, it is discussed in professional circles whether implants are usable at all in these cases. Microthane® implants, however, are associated with a much lower incidence of capsular contracture following 2-stage breast reconstruction, even when radiotherapy is performed; therefore, they provide an excellent option for these patients.

POLYTECH Health & Aesthetics offers Microthane® implants in four different basic shapes: Même® (round), Replicon® (anatomical round), Opticon® (anatomical short), Optimam® (anatomical oblong). All of these follow a modular design of four projections – low, moderate, high, extra high – and in 18 sizes, respectively. Also available is the DiagonGel® 4Two series, which comes in two shapes: anatomical round and anatomical oval (short).

5) Stefano Pompei, MD, Dora Evangelidou, MD, MRM, Floriana Arelli, MD, Gianluigi Ferrante, MD, MSc: The Modern Polyurethane-Coated Implant in Breast Augmentation: Long-Term Clinical Experience. Published: 18 October 2016
6) Stefano Pompei, MD, Floriana Arelli, MD, Lara Labardi, MD, Fabio Marcasciano, MD, Dora Evangelidou, MD: Polyurethane Implants in 2-Stage Breast Reconstruction: 9-Year Clinical Experience. Published: 09 December 2016