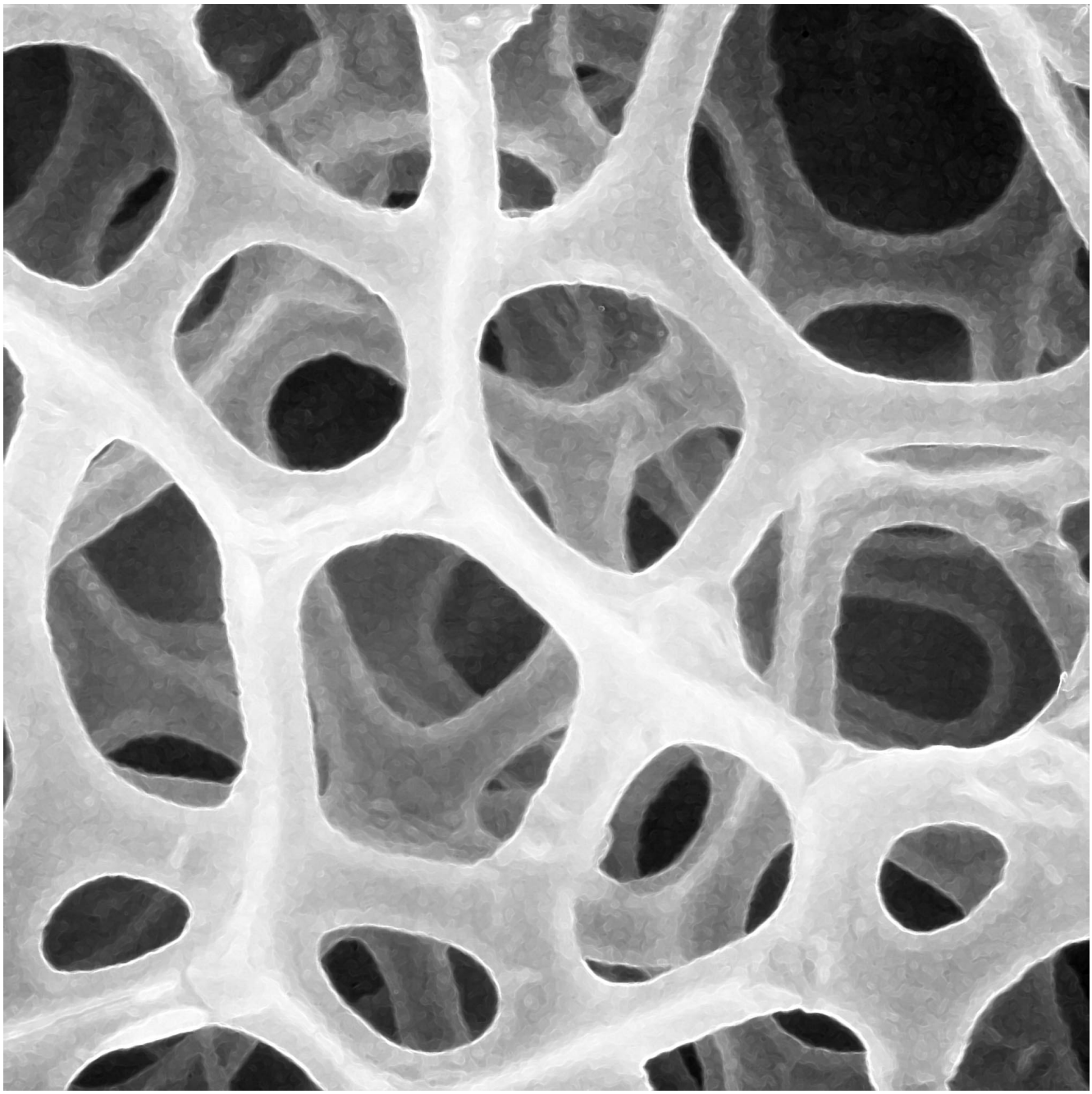
MPS
MicroPolyurethane-foam-Surface

- Low capsular contracture rate
- Low total complication rate

POLYTECH SILIMED EUROPE GmbH

Positional integrity of the **M**icro**P**olyurethane-foam-**S**urfaced (**MPS**) mammary implants is guaranteed through the active ingrowth of the fibrotic tissue into the MPS-Matrix.



MicroPolyurethane-foam-Surface

One of the principle considerations for any elective operations, e.g. breast reconstruction or augmentation is to minimize the number of complications.

The most common complication of breast implant surgery is capsular contracture. **M**icro**P**olyurethane-foam-**S**urfaced (MPS) implants have been developed to minimize the capsular contracture rate.

In extensive clinical studies over the past twenty years reviewing high numbers of patients, the capsular contracture rate (Baker classification III-IV) has been determined: Considering the available literature the capsular contracture rate for MPS implants in virginal tissue is 0-9% in comparison to 9-50% for other implants. In most of the large studies[1)] the **capsular contracture rate for MPS implants is as low as 0-3%**. The low capsular contracture rate is attributed to the ingrowth and microcapsulation 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. The tissue fixation and the highly crosslinked silicone gel give a natural feeling to the breast.

The low capsular contracture rate also allows the prepectoral implantation and allows a pleasing aesthetic result for the augmentation and reconstruction of the breast.

The common misunderstanding of the appearance of polyurethane foam upon explantation is caused by the positive effect of ingrowth of tissue into the foam; **the polyurethane foam can only be made visible again when the capsule has been enzymatically degraded** (fig. 3, 4)[2)]!

The possible degradation of polyurethane foam has been extensively researched, with particular interest to 2,4-toluenediamine (TDA). Hydrolyses-[3)] and biodegradation-(enzymatic) studies[2)] show, that a minimal amount of TDA can be released without endangering the patient (realistic assumptions indicate a daily dose of 0.01 mg/kg body weight)[4)]. In 1995 the American health authority “Food and Drug Administration” announced that **the cancer risk due to MicroPolyurethane-foam-Surfaced implants is less than one in one million,** over the lifetime of the patient. This figure represents no significant danger according to the standard risk analysis[5)]. In relation to the „normal“ risk of breast cancer, that, according to the WHO-statistics is one in nine, the possible extra risk due to the use of **M**icro**P**olyurethane-foam-**S**urfaced implants is drastically reduced.

Summary

The major advantage of MicroPolyurethane-foam-Surfaced implants is the low capsular contracture rate, therefore the total complication rate is drastically reduced.

The high number of scientifically based arguments and clinical experiences support the efficiency of this product concept.

Literature:

1) Handel, 1991; Pennisi, 1990; Shapiro, 1989; Hester et al., 2001; Baudelot, 1989; Gasperoni, 1992; Hermann, 1984; Eyssen, 1984; Schatten, 1984; Arzt, 1988 2) Szycher & Siciliano, 1991 3) Amin, 1993 4) Kerrigan, 1989 5) Wilson, 1979 (Literature is available from POLYTECH SILIMED Europe GmbH).

ZERT Zertifiziertes QM-System DIN EN ISO 9001 Reg. Nr. 95014

mdc

CE 0483

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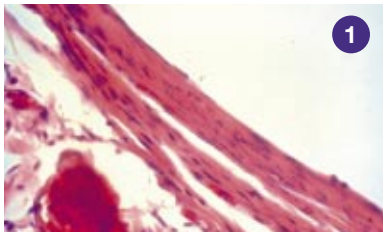
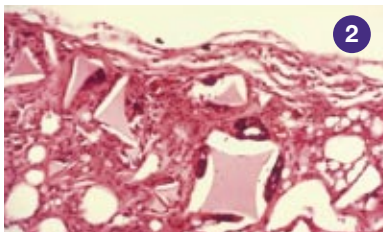


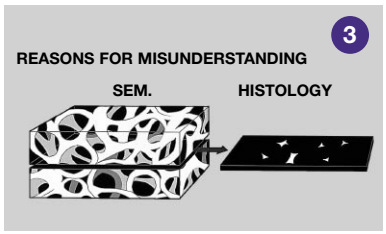
Passive healing:

Using smooth-walled silicone implants a capsule with low vascularization is formed around the foreign body. The contractile forces squeeze the implant. The originally soft consistence is lost; the breast becomes harder and is eventually deformed.

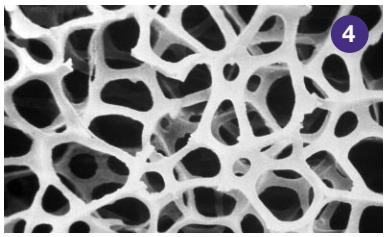


Active healing:

The micropolyurethane structure 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.



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



Micropolyurethane foam freed from tissue by enzymes 9 years after implantation.