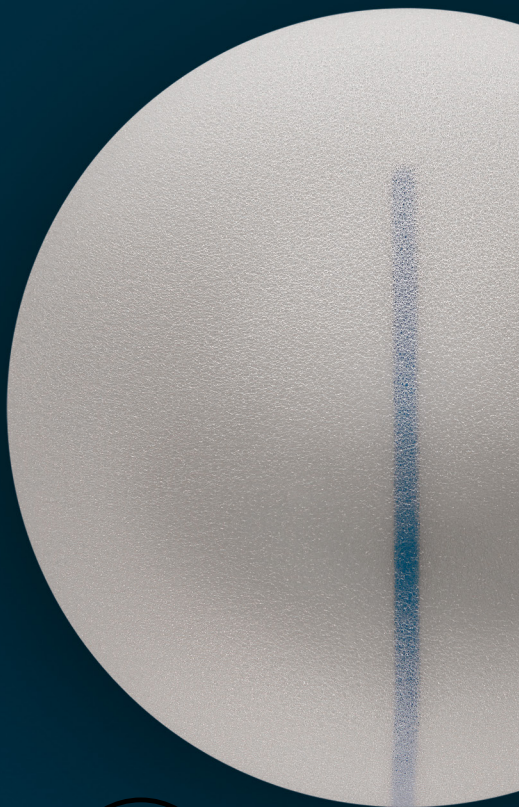


Microthane[®]

Micro-Polyurethane
coated breast implants

Stability and dependability
when you need it most



Made in
Germany

POLYTECH

Microthane® coated vs. silicone textured implants

What is the difference?

POLYTECH Microthane® implants are considered a safe choice, with lower complication rates even in complex cases of radiation treatment, which can dramatically increase the risk of capsular contracture.^{1,2}

- POLYTECH Microthane® implants are coated with a layer of micro-polyurethane foam not comparable to the surface of silicone textured implants
 - A 3D open pore matrix which acts like an internal tissue scaffold allowing true tissue ingrowth, vascularisation and blood flow within and across the surface of the implant
 - Not classified within the ISO 14607 : 2018 standards, the only official standard for implant textures
- Polyurethane implants have proven safety in clinical practice for **more than 4 decades**
- Microthane® is associated with an BIA-ALCL incidence of 1 : 127,000*, compared to an implant average estimate of 1 : 3,000 to 1 : 30,000 across implant types and brands (US FDA)

* September 2020

Indications



Primary augmentation



Revision augmentation



Reconstruction



Mastopexy augmentation

QUALITY MANUFACTURED IN GERMANY

Surgeons recommend Microthane®

Dr. Luísa Magalhães Ramos
Cirurgia Plástica, Lisboa



“As a woman and as a plastic surgeon, I think there is no other option for long lasting results than Microthane® in most of my cases”.

Dr. Constantin Stan
Cronos Med Clinic, Bucharest



“If a family member asked me for an implant recommendation, it would be Microthane®. This is how much I believe in the product”.

Professor Mario Pelle Ceravolo
University of Padua, former President of the Italian Plastic Surgery Society



“I have 35 years’ experience with polyurethane implants. For me there is no implant like it. I am addicted”.

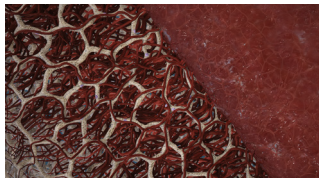
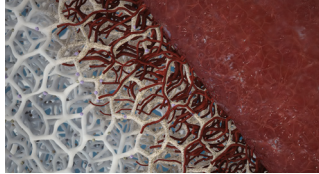
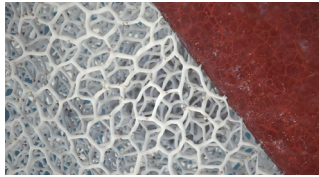


Hear from your peers:
Listen to what your colleagues have to say on Microthane®.
<https://bit.ly/32Pw91J>



FAVOURABLE HEALING

The structure of the micro-polyurethane foam surface breaks the fibrotic pattern and encourages cellular involvement. It re-models the tissue into a sponge like and richly vascularised configuration around the implant.



● Please Login to **MyPOLYTECH** to watch the complete video.

PROMOTING A HIGHLY VASCULARISED CAPSULE

Following implantation, the interaction between the implant and the surrounding tissue will determine the success of the implants acceptance by the patient's body.

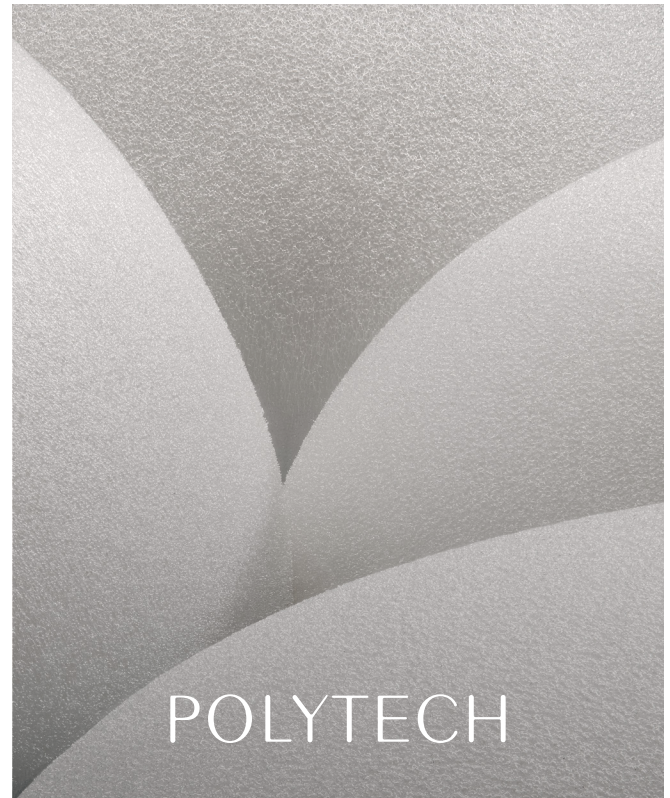
The 3D open pore matrix of the Microthane® surface provides a **safe biofavouring transition** layer into which the healing process can develop.

Progressively, over the course of several weeks, the implant's Microthane® coating will fill with **healthy and highly vascularised tissue**, ensuring the body's immune system is active at the very surface of the implant as well as providing increased adherence and reducing the risk of device rotation and displacement.³

The nature of this tissue interaction with the micro-polyurethane matrix is key:

- In preserving implant shape and position
- In making the implant an integral part of the patients own tissue
- In reducing the risk of capsular contracture³

Polyurethane foam coated implants have measurable advantages over implants with a silicone textured or smooth surface and are not associated with an increased risk of complications.



Outstanding Safety Profile

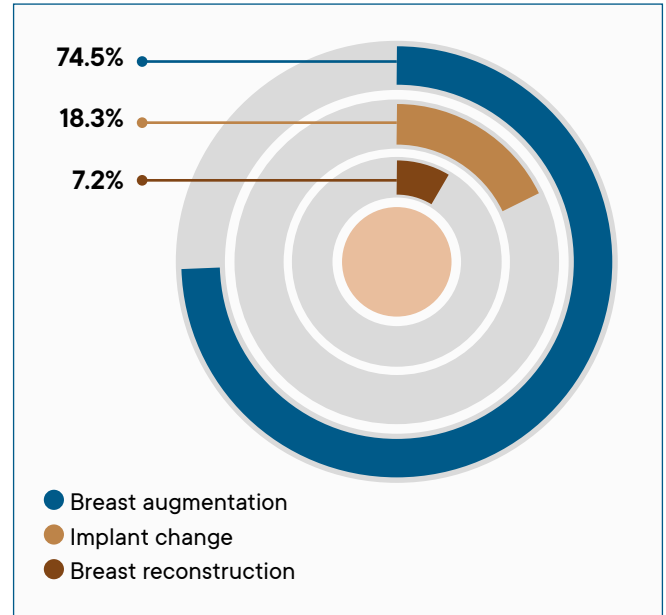
2,113 patients with Microthane® implants observed from 2007 to 2019⁴

- 2,113 patients with a total of 4,094 breast implants undergoing breast augmentation and reconstruction and implant exchange with Microthane® were analysed from 2007 to 2019.
- 74.5% had a breast augmentation.
- Mean volume of Microthane® breast implants: 341ml ± 98ml.
- Only 16.4% of patients had any complication. The safety profile of Microthane® in this survey outperforms all other surfaces.

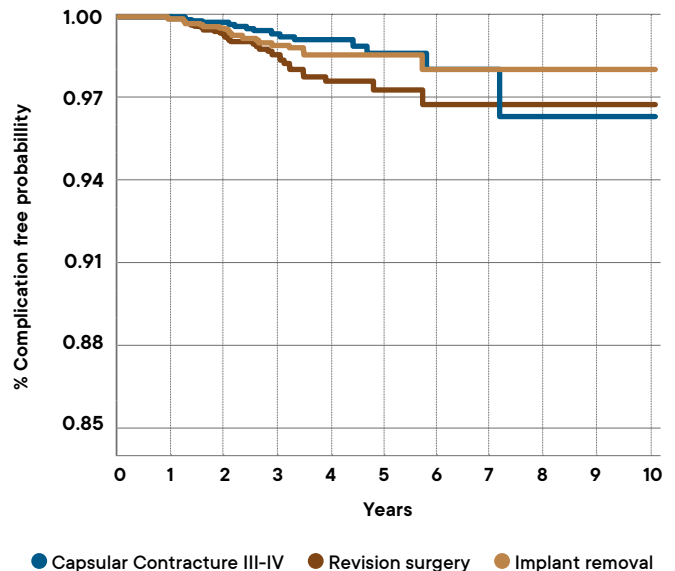
Proportion of complications according to the number of patients (N) who experienced at least one complication in one of the two breast implants.

Type of complication	All Microthane® patients N = 2,113
Capsular contracture Baker grade III-IV	0.7% (15)
Implant removal	1.0% (20)
Seroma	1.0% (22)
Haematoma	1.0% (22)
Open wounds	1.3% (27)
Revision Surgery	1.5% (31)
Hardening / Capsular contracture Baker grade I-II	6.5% (137)
Other	10.7% (227)
Any complication	16.4% (346)

Graph 1: Distribution of patients according to the reason for the operation






















Graph 2: Probability of being complication free over time (based on Kaplan-Meier analysis)



PRODUCT RANGE

POLYTECH offers the Microthane® coating in three different base styles with the following product shapes filled with EasyFit Gel™:

- **Même®**: Round base, Central projection
- **Replicon®**: Round base, Anatomical projection
- **Opticon®**: Short base, Anatomical projection
- **Optimam®**: Oblong base, Anatomical projection

Microthane®	Base Style	PROJECTION			
		Low L	Moderate M	High H	Extra High X
Même®		 30724	 30725	 30726	 30727
Replicon®		 30734	 30735	 30736	 30737
Opticon®		 30744	 30745	 30746	 30747
Optimam®			 30775	 30776	 30777



Diagon\Gel® 4Two Series:

- **AR**: Anatomical projection, Round base
- **AS**: Anatomical projection, Short base

NEW for B-Lite® Lightweight Implants:

- **Même® (RR)**: Round projection, Round base
- **Replicon® (AR)**: Anatomical projection, Round base

Implants of Excellence

The company's trust in the outstanding profile of the product is also reflected in our warranty programme.

Apart from the lifetime rupture replacement, implants coated with Microthane® get replaced in cases of capsular contracture and rotation for lifetime after implantation.

Scan to register



- Please read carefully the Warranty Terms and Conditions on: <https://polytech-health-aesthetics.com/en/warranty>

BIA-ALCL AND IMPLANT SURFACES

- Based on the cumulative unit sales figures up to August 2020, POLYTECH Microthane® implants have a **BIA-ALCL risk of 1 : 127,000**
- Compared with the **current BIA-ALCL risk of 1 : 3,000 to 1 : 30,000**, calculated by the FDA across all implant types and brands, Microthane® has a very low risk
- Published cases of BIA-ALCL with polyurethane foam-covered implants are **associated with another manufacturer**
- Microthane® implants are associated with **lower risk of late seroma, which is a common sign of BIA-ALCL**⁵

Tips for surgeons considering Microthane® implants for the first time

1. Microthane® implants might feel slightly firmer for the first 8–10 months.
2. The incision does not need to be longer than with any other cohesive gel implant.
3. Microthane® implants can be inserted both through the inframammary or the areolar incision. The areolar incision has many advantages with Microthane® implants: more flexibility in the vertical positioning of the implant, full control the anterior surface and of the upper pole of the implant, especially, that the upper pole of the implant lies flat. This will prevent a crease from becoming particularly noticeable when the implant is placed subglandular.
4. The pocket needs to be wide enough for the implant to sit relaxed on the chest wall.
5. Microthane® implants placed in the subglandular plane feel significantly softer and more mobile than those placed in the submuscular plane. The softening of the prostheses takes place in a period of time ranging from 8 months to one year.
6. Due to their excellent and rapid tissue ingrowth characteristics, surgeons can rotate the base of anatomical Microthane® implants to position the point of maximum projection in order to correct specific asymmetries or deformities.

CONCLUSION

When used by experienced surgeons, **POLYTECH** Microthane® implants offer a wide range of benefits:

- Greater tissue adherence
- Reduced risk of capsular contracture
- Long term stability of the clinical results



Sources

1. Pompei S, et al., "Polyurethane Implants in 2-Stage Breast Reconstruction: 9-Year Clinical Experience", Aesthetic Surgery Journal, Volume 37, Issue 2, 1 February 2017, Pages 171-176, doi.org/10.1093/asj/sjw183.
2. Pompei S, Evangelidou D, Arelli F, Ferrante G. 2016. "The Modern Polyurethane-Coated Implant in Breast Augmentation: Long-Term Clinical Experience". Aesthetic Surgery Journal 36(10):1124-1129.
3. Verpaele A, Tonnard P, Experience with the new generation Micro Polyurethane covered Silicone breast implants, www.coupureseminars
4. Implants of Excellence, Annual Survey, 2007-2019, POLYTECH, Data on File
5. Hamdi, M., "Association between breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and polyurethane breast implants, Aaesth. Surg. J. 2019 39 (S1), S49-S:54. <https://doi.org/10.1093/asj/sjy328>

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7. The implant should be positioned exactly where it should stay permanently. This might mean positioning the implant slightly lower than what one would do with a non-polyurethane implant as it does not „settle“.
8. It is important to sit the patient up once the implants are put in situ to ensure the implants are sitting in the correct position.

Using Microthane® implants requires a short learning curve which mainly consists in learning to position the implant meticulously.

In the case of unsatisfactory results

1. The correction of obvious malpositioning or folds is easier before implant integration with the surrounding tissue. Therefore it should be considered within 3–4 weeks or 6 months postoperatively.
2. When explanting a Microthane® implant intracapsularly, please use your fingers to detach the velcro effect between the capsule and the implant.
3. It is not always necessary to perform a complete capsulectomy when replacing a smooth or textured implant with a Microthane® one. It is however important to remove a major part of the capsule to allow tissue ingrowth into the foam.

Recommendations obtained from:



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Dr. Luisa Magalhães Ramos
Lisboa



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