

POLYTECH

Health & Aesthetics

Quality made in Germany

German Quality Products





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| Welcome |

POLYTECH, founded in 1986, is one of the leading manufacturers of silicone implants in Europe. The company's sales network is spread globally and constantly consolidated. The company offers a broad range of products for plastic, reconstructive and aesthetic surgery.

In July 2008, the company relocated its implant production facilities to the site of its headquarters in Dieburg, Germany – thus becoming Germany's only manufacturer of soft-tissue implants, among them breast implants.

The product range presently consists of more than 1500 implants and expanders.

It is continually extended according to the latest developments and requirements.

The company's focus is directed at breast implants for women; other soft-tissue implants produced are, for example, chest implants for men, implants for the calf and the bottom as well as various other soft-tissue implants.

POLYTECH Health & Aesthetics' philosophy implies that we not only provide our customers and partners with high-quality products, manufactured according to the highest standards, but also offer a high level of support and service.

**Implants made by POLYTECH
Quality made in Germany**

Service | Development | Quality

- ▶ Customer Service
- ▶ Product Development
- ▶ Quality Management







| Customer Service |

It is part of our philosophy to support our customers and partners and to offer comprehensive service to them. In order to achieve this, our field and office staff work closely together and continually improve procedures.

With the long-term experience of our sales and customer service team, we ensure that your inquiries regarding product orders and sales are processed promptly and competently. Additionally, regular product training of our staff ensures the best support for our customers.

Along with our wide product portfolio, we offer extensive information material, ranging from product leaflets and training-DVDs to collections of medical literature. For surgeons, we provide the latest scientific information; specific queries are forwarded directly to the product specialists who process and answer them at short notice.

Storage and shipment of the goods are carried out by qualified staff, fulfilling the requirements of the company's implemented quality management system.





| Product Development |

At POLYTECH Health & Aesthetics, innovation is part of the vision. Especially, since the requirements of the market for plastic, reconstructive and aesthetic surgery are ever increasing and changing constantly. As a medium-sized enterprise, POLYTECH has unique facilities to develop state-of-the-art products. Our department for research and development works in close cooperation with our partners and surgeons to design groundbreaking products.



In Europe, POLYTECH is the only manufacturer of breast implants coated with Microthane® (micropolyurethane foam).

These implants are known to contribute to a considerable reduction of capsular contracture rates. The unique technique of our differential multi-compartment expander allows differentiated anatomical tissue expansion for reconstructive surgery.

Body contouring implants such as gluteus, calf and pectoral implants complete our product range for aesthetic and reconstructive surgery. For more demanding cases in plastic surgery, we additionally offer individual solutions: custom-made implants, which are designed and produced according to the particular patient's needs.

Procedures like development, production, sterilization, quality control, packaging and storage are exclusively accomplished at our headquarters in Germany. From this hub we also organize and control our worldwide sales activities.

| Product Development |





| Quality Control |



The quality controls executed at POLYTECH Health & Aesthetics include tests for rupture resistance of the implant shell (950%), material fatigue and impact resistance (at 45km/h). For many parameters, POLYTECH products fulfill even higher standards than required.

Our comprehensive Quality Management includes in-house blister production under clean-room conditions.



| Quality Management |

POLYTECH Health & Aesthetics has a quality management system in place since the company started business. This ensures that all requirements for a certified company concerning choice of raw materials, product development, manufacturing, sterilization, quality assurance, storage, distribution and customer services are fulfilled.

As one of the first manufacturers in the breast implant business worldwide, POLYTECH implemented the CE-mark for its products. This happened in 1995, meaning POLYTECH fulfilled the medical devices class III quality standards already at this early stage.

In 1994, EN ISO 9001 replaced the previously followed GMP (Good Manufacturing Practice) and GDP (Good Distribution Practice). This ISO standard is the base for the quality management system as established by POLYTECH. In 2003, internal procedures were additionally restructured according to the revised EN ISO 13485, which replaced EN 46001.

At the end of 2004 all manufacturers had to switch to the new standard EN ISO 9001:2000.

In February 2003, the European Commission had decided that breast implants would be reclassified from a class IIb device according to the Council Directive 93/42/EEC (Medical Device Directive) to a higher class III product. Breast implants are now the most rigorously controlled devices within this directive.

Since 1st March 2004 all breast implants sold in the European Community have to have class III approval. POLYTECH received the confirmation of approval for all its breast implants as early as December 2003. This early approval attests to the high quality standards established by POLYTECH and provides reassurance for surgeons and patients alike.

For POLYTECH Health & Aesthetics it is a matter of course to adhere to the highest quality standards and to continually establish new procedures which are in line with the latest requirements. Accordingly, the quality of our products and services is permanently optimized and advances in pace with the growing requirements of the market.



**Implants made by POLYTECH
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Même®



Replicon®



Optimam®



Opticon®

POLYTECH

Health & Aesthetics

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