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Information for reconstructive and aesthetic plastic surgery

Issue 02/2007

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Who Defines the Meaning of Quality?

or

What does "quality" actually mean?

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Who Defines the Meaning of Quality?

or

What does "quality" actually mean?

by Oliver Bögershausen, PhD, Manager Regulatory Affairs and Quality Manager at POLYTECH Health & Aesthetics GmbH

First of all, I would like to define the term „quality“, which is often used without the one using it knowing its actual meaning.

Basic definitions of quality:

- Quality is the **compliance of the actual state with the target state**, i.e. the fulfillment of requirements and expectations (among others those of the customer)
- Quality is also defined according to the degree of **compliance with given requirements**.

Which requirements are significant? Who is setting the rules? The patient? The attending physician? The legislator? The judge? I don't know. However, one thing is certain: each of them will **define different requirements** and consequently have a **different perception of quality**.

The term „quality“ itself does not imply any classification, although it is commonly applied in an appraising way. In the day-to-day language, however, the term „quality“ is often used as a synonym for „excellence“. For this reason, we are often talking about „good“ or „bad“ quality. If a customer buys a product and it complies with the customer's intended purpose of use, he, by common usage, will call it a product of „good quality“. This **subjective**, customer-related perception of „quality“ is very difficult to conceive, as there may be strong **individual** differences.

In fact, the term „quality“ established itself in economic life as a general measure of value, expressing the adequacy of a product. This perception is for instance clearly demonstrated in the expression „high-quality work“. This term is

frequently applied within a trans-sectoral system ensuring the quality of the individual sectoral results. The coordination of planning, supervision and control of all corresponding activities is called **Quality Management**. All efforts combined result in a „quality product“.

POLYTECH Health & Aesthetics has been operating a quality management for many years, duly certified according to the current standards EN ISO 9001:2000, ISO 13485:2003 and Annex II of the Medical Device Directive 93/42/EEC.

Wherever quality can be defined according to measurable quantities, it is frequently called **„technical quality“**. This refers for example to properties like breaking strength, resilience, longevity, etc.

According to the standard EN ISO 9000:2005, **quality is the degree to which a set of inherent characteristics fulfils given requirements**. In this way quality indicates the extent up to which a product complies with the existing requirements. The term „quality“ can be used with adjectives, such as bad, good or excellent. „Inherent“, as opposed to „assigned“, means existing in something, especially as a permanent characteristic.

Breast implants manufactured by POLYTECH Health & Aesthetics are complying with all requirements stipulated by regulatory acting organizations in Europe. This is, amongst others, proven by the certification of the products.



According to the standard EN ISO 9000, it is **not the price of a product that is crucial for its quality**, but its compliance with all product-related requirements. This means that not only the **objectively measurable properties** and specifications of the manufacturer but also the **subjective expectations** of the customers have to be met.

Given this situation, it is obvious that it is hardly possible, for instance for a judicial authority, to weigh the quality of our breast implants against the quality of breast implants of other manufacturers, as it is impossible to objectify the subjective requirements of the individual customer (physician, patient). Usually, the customer himself is unable to formulate his requirements in an adequate form.

It is only the objectively measurable technical quality of the products that can be assessed. In this case, the characteristics concerning the safety and compliance with the intended purpose for the patient are crucial for breast implants. In Europe it is the Medical Device Directive (MDD) that regulates these characteristics and the corresponding compliance.

Other important documents for the assessment of the technical quality are:

- the communication from the Commission on the community and national measures in relation to breast implants (COM(2001) 666 final);
- the Commission Directive 2003/12/EC on the reclassification of breast implants;
- the standard EN ISO 14607, which defines the technical requirements for breast implants.

The discussion on the safety of breast implants that had started at the end of the nineties, finally resulted in a re-classification of breast implants to class-III medical devices. This means that political parties were of the opinion that breast implants are a similar risk to patients like, for example, artificial heart valves. On account of this re-classification, manufacturers had to prove the compliance (the corresponding technical quality) of their products

with the stricter requirements according to the now applicable, considerably tighter regulations.

In December 2003, POLYTECH Health & Aesthetics was the first manufacturer of breast implants who succeeded in obtaining the certification of their breast implants according to the stricter requirements.

This certification per se is a clear proof of the first-class technical quality of breast implants from POLYTECH Health & Aesthetics.

In the course of the reform of the basic legal principles for medical devices in Europe, the medical device directive (MDD) had been created in 1993. Just as in 2003, POLYTECH Health & Aesthetics had acted as a pioneer then, and in 1995 we were the first manufacturer to obtain the certification of our breast implants – several years ahead of the expiry of the corresponding transition period.

All tests to prove the compliance with the requirements as stipulated in the subject documents were executed by independent testing laboratories and the defined values were consistently exceeded.

POLYTECH Health & Aesthetics aim is to win the customer's favor through the quality of our products. Accordingly, we do not define the quality of our products producing undue and non-significant comparisons of single characteristics that, considered individually, do not determine the product quality.

► **Dieburg 2008.** True to our quality standards, we relocated implant production to Germany in 2008. This way, our customers can be assured that only the highest standards are applied, quality controls are stringent and our products are of consistent superior quality.

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

POLYTECH

Health & Aesthetics

In a woman's life, the shape, size and health of her breast are an important issue. A beautiful breast is good for female self-confidence. Today, breast reconstruction and augmentation are among the most-performed procedures in plastic surgery.

Insights derived from extensive studies inspired us at POLYTECH Health & Aesthetics to specialize in textured and micropolyurethane-coated breast implants. According to the present state of the art, these implants are the optimal choice for your patients' well-being and safety.

Breast implants from POLYTECH Health & Aesthetics are CE-marked as medical devices. Regular testing demonstrates that the quality of our implants always meets the norms and exceeds the requirements of many of the standards.

POLYTECH Health & Aesthetic offers patients the possibility to register with the program **Implants of Excellence**. It includes an extended lifetime warranty and continuous information on mammary implants.

Deciding for POLYTECH Health & Aesthetics implants and promoting the program **Implants of Excellence** means you choose superior product quality combined with high personal safety for your patients.

For further information please refer to our website. There, you can also take a look at how and where our implants are manufactured:

www.polytech-health-aesthetics.com

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