

A
breast implant
– for me?

Information
on breast
enhancement

A breast implant – for me?

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. Nowadays, you have the choice between various possibilities for breast reconstruction, contour correction and augmentation.

Apart from your personal reasons for breast surgery, you certainly might have a lot of questions about the subject. On the following pages we will provide some information on breast implants and try to answer some of the questions which might be of concern.



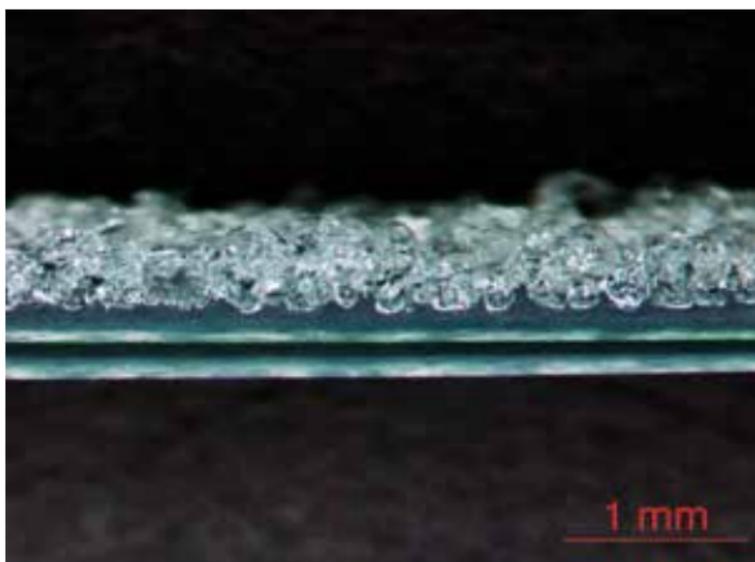
Today, breast reconstruction and augmentation are among the most-performed types of procedures in plastic surgery. Breast implants have been in use since the early 1960s. In the meantime, more than three million women have opted for the implantation of silicone gel-filled implants. The implants have constantly been improved due to the constructive cooperation between patients, physicians and manufacturers.

As a consequence, these insights inspired us at POLYTECH Health & Aesthetics to become specialists for breast implants coated with micropolyurethane (Microthane®). According to the present state of the art, these implants are the optimal choice for your well-being and safety.

What is silicone?

In medical science, silicone is used as a component of numerous products, e.g. probes, catheters, coatings of puncture needles and pace makers, gloves and wound dressings. In soft-tissue surgery, silicone implants are used for body contour correction.

The first production process for silicone polymers was patented in 1958. Silicone or, as chemists call it, dimethylpolysiloxane, is produced as silicone elastomer, silicone gel and silicone oil. We encounter silicone every day: as anti-foaming agents for cooking, as water-repellent for clothing, as electrical insulation, as anti-acids for the stomach, as carrier spray in anti-per-spirants, as the shine in cosmetics, etc. Silicone does not contain any additives, especially softeners. Intensive studies have not provided evidence of allergic reactions to silicone.



Cross-section of an implant shell with textured surface (enlargement: x 30)

Are there different types of implants?

Yes, there exists a great variety of implants. Our goal at POLYTECH Health & Aesthetics is to do justice to the individual appearance of women. This is why we manufacture a wide range of silicone implants which offer a large scope for contour correction. There are four different basic models:

- M^ême[®] – a silicone-gel filled implant with a round base and central projection



- Replicon[®] – a silicone-gel filled implant with a round base and anatomical projection (maximum projection in the lower half)



- Opticon[®] – a silicone-gel filled implant with a short base and anatomical projection



- Optimam[®] – a silicone-gel filled implant with an oblong base and anatomical projection



The projection in turn can be defined in four different profiles: low, moderate, high and extra high. Every of these combinations is available in 18 different sizes (and in two different surfaces, see p. 5).

The resilient and highly resistant shell of our implants consists of several layers of silicone and is additionally equipped with a diffusion barrier preventing gel to permeate through the shell into the surrounding tissue.

Which filling materials are available?

For many years, silicone gel and saline solution have been proven to be the filling materials of choice for implants. Implants filled with highly cross-linked silicone gel present the state of the art for soft tissue replacement.



A breast implant cut in two, showing the highly cross-linked, cohesive silicone gel

The silicone gel used by us at POLYTECH Health & Aesthetics is form-stable and returns to its original shape after moderate compression. When cut in two, the gel in our implants shows its soft but cohesive consistency. In terms of tactility and movement it corresponds to the natural breast.

What is the reason for the existence of different implant surfaces?

Due to a natural reaction of the host organism, a capsule is formed around all foreign bodies inserted into the tissue, implants included. This capsule can close tightly around the implant and contract. This contraction deforms the implant shape and thus the shape of the breast. Additionally, the capsule can become very hard and cause pain. This complication is referred to as "capsular contracture" and the rate of its occurrence is related to the implant surface. The first implants were manufactured in the 1960s and had a smooth surface. Since the middle of the 1970s, micropolyurethane-coated implants have been in use. Textured implants were introduced at the end of the 1980s. At present, implants with these three different surfaces are available.

Independently of improved operating techniques for implantations, micropolyurethane-coated implants result in impressively low capsular contracture rates of 0–3% compared to 30% with smooth implants.⁴⁵⁻⁴⁷ Textured implants also produce a clearly lower risk (15%) of capsular contracture compared to smooth implants (30%).^{4, 16-18} These are the reasons for POLYTECH Health & Aesthetics to specialise in implants with micropolyurethane and textured surfaces.

A re tests performed to ensure the safety of the implants?

Yes, constantly. All over Europe, the Medical Device Directive and other international standards stipulate precise requirements for breast implants. Materials, product development, production, quality control, sterilisation and packaging are subject to strict regulations.

Following two examples for the tests we perform regularly:

Fatigue test. In this test we check the dynamic forces working on the breast implants in the chest of a jogging woman. According to the Standard, 2 million cycles are required. This corresponds to a weekly mileage of 10km over a period of 10 years. The shell may not show any defect after this test. We do up to 36 million cycles with our implants remaining intact. This corresponds to a weekly mileage of 180km over a period of 10 years or a weekly mileage of 10km over a period of 180 years.

Elongation test. In this test we check the ability of the shell to resist deformation without wearing out. The maximum elongation stipulated is 450% , our shells achieve up to 950%, more than twice the required value.

C an an implant change my physical appearance?

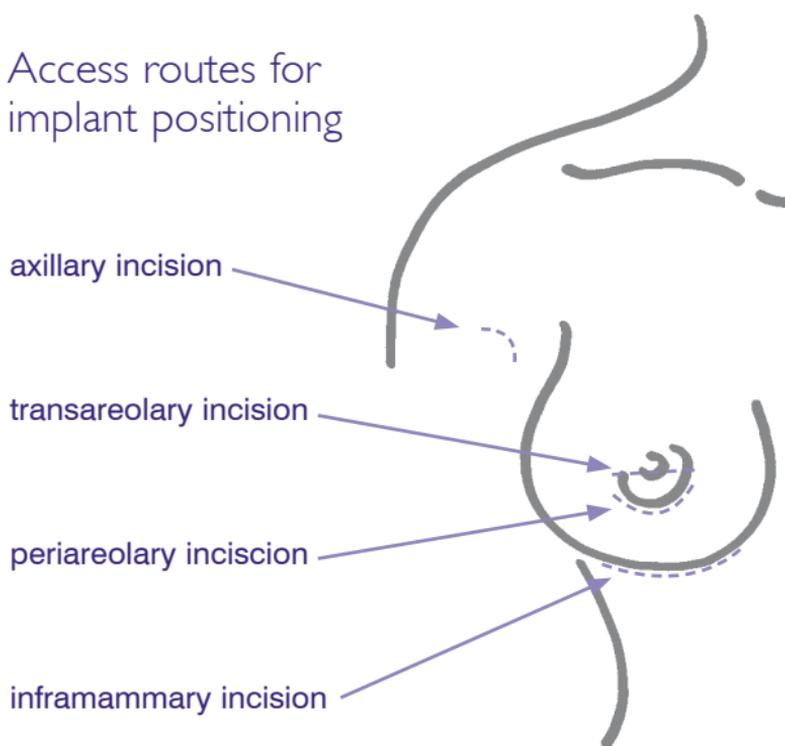
Yes, and most of the time, this is exactly the objective of plastic surgery. A breast implant can give a

very natural look and feel to the reconstructed breast. Obviously, the oncological aspects play a role in this context.^{19-21,48,49} Contour correction and augmentation can improve your looks according to your specific wishes.

A re there different surgical procedures?

Yes, a good many of them. We suggest you consult your physician if you want to know more about the surgical techniques practised in breast reconstruction and augmentation. Your physician is the specialist and she/he will explain to you individually the different methods and possible risks of the procedures.

Access routes for implant positioning



Which incisions are used for an augmentation?

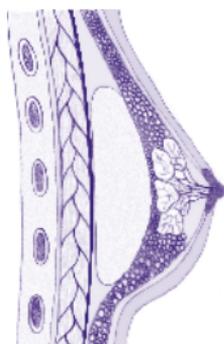
The access which is chosen by your surgeon depends on the results of his examination of your body.

Incisions can be located in the armpit (axillary incision) or in the mamillary area (periareolar, transareolar incision). The most common access for implant insertion is an incision in the mammary fold beneath the breast (inframammary incision).^{see page 7}

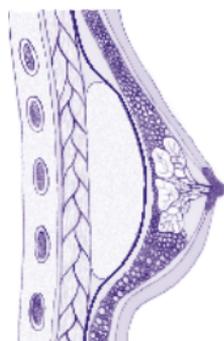
Where is the implant positioned?

For augmentation, the implant can either be positioned directly behind the glandular tissue (sub-glandular), under the fascia of the muscle (sub-fascial) or under the pectoral muscle (sub-pectoral / sub-muscular). In reconstruction, the positioning depends very much on the oncological aspects. Your physician will advise you which positioning of the implant is best for you.

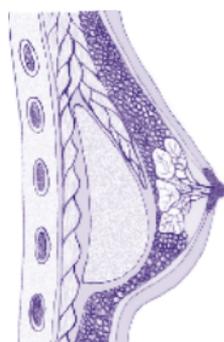
POLYTECH Health & Aesthetics implants with their filling of naturally soft, highly cross-linked silicone gel fit naturally to the body, whether positioned sub-glandularly or sub-muscularly.



sub-glandular



sub-fascial



sub-muscular

Does cancer screening work after an implantation?

Mammography makes it possible to locate tumors. Using a special technique, the Eklund Technique, mammography can be conducted with women having breast implants. Modern imaging techniques like sonography, MRI or CT help to find tumors early.^{22-24,50,51}

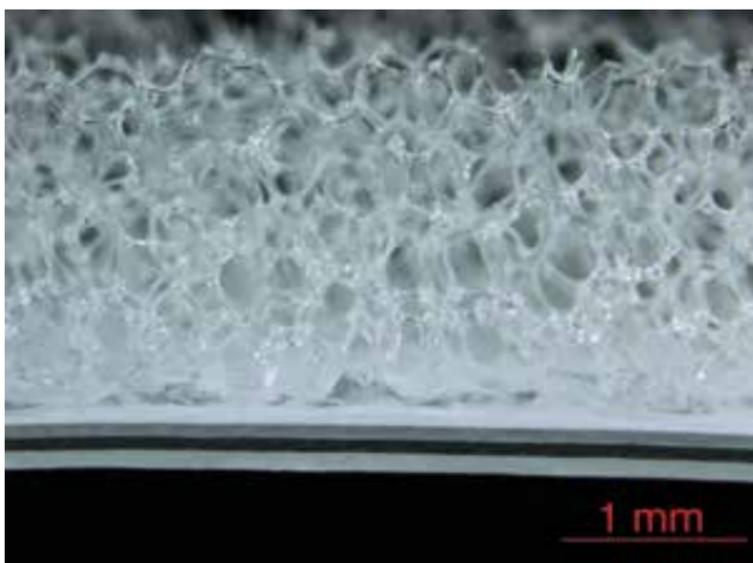
What influence do breast implants have on cancer occurrence?

In extensive studies, it was evaluated that women with breast implants are not subject to a higher risk of breast cancer than women without such implants.²⁵⁻²⁹

A breast implant has no influence on the occurrence of breast cancer. Breast cancer due to smooth, textured or micropolyurethane-coated implants has not been observed in human beings nor in studies on animals. Independently of this situation, scientists discuss theoretical risks.^{30, 31}

Do micropolyurethane-coated implants induce a greater infection risk than other implants?

No, not at all.³² Several studies show that there exists no increased risk for infection with micropolyurethane-coated implants.



Cross-section of an implant shell with Microthane® surface (enlargement: x 30)

Is there a link between autoimmune diseases and breast implants?

No. No plausible link between silicone gel-filled implants and autoimmune diseases has been observed.³³⁻³⁹

Can silicone gel permeate through the implant shell?

In contrast to previous generations of implants, only negligible traces of gel can be found in the connective tissue capsule of state-of-the-art implants. This is due to the significantly improved quality of the implant shells now equipped with a diffusion barrier preventing gel permeation. Also, the highly cross-linked, cohesive filler gel⁴⁰⁻⁴² and the reduction to an absolute minimum of low-molecular-weight silicone gel contribute to the high quality level of POLYTECH Health & Aesthetic implants.

How long does an implant last?

Each host organism shows an individual reaction to a foreign body. In the past, studies referring to saline and thin-shell implants have shown an average life span of ten years for breast implants in general.^{43,44} Modern implant technology combined with improved quality results in a distinct, individual expansion of this period. POLYTECH Health & Aesthetic offers patients the possibility to register with the programme **Implants of Excellence**. It includes an extended lifetime exchange warranty in case of shell rupture and continuous information on our mammary implants.

Deciding for POLYTECH Health & Aesthetics implants and the programme **Implants of Excellence** means you choose the highest product quality combined with highest personal safety. Breast implants from POLYTECH Health & Aesthetics are CE-marked

Implants of Excellence



The extended warranty program for breast implants made by POLYTECH Health & Aesthetics at:

www.polytechhealth.com

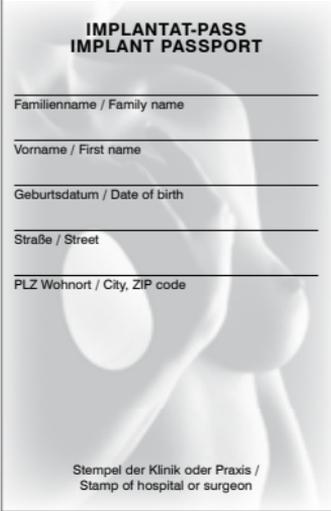
as medical devices. Regular testing demonstrates that the quality of our implants always meets the norms and exceeds the requirements of many of the standards. With the extended warranty for POLYTECH Health & Aesthetics implants you will enjoy lifetime benefits and additional personal safety.

What are the intervals for follow-up examinations after implantation?

The implants should be controlled semi-annually or annually by your physician.

What do I have to take into consideration after having had an implantation?

After insertion of the implants, you will receive an **implant passport** from your physician. This passport is part of every POLYTECH implant delivery since 1995. Please carry this document with you always, so the information concerning the type and size of your implants is available when needed. Also, you should inform the person performing your mammography about your implants as well as any physician you see for treatment.



**IMPLANTAT-PASS
IMPLANT PASSPORT**

Familienname / Family name

Vorname / First name

Geburtsdatum / Date of birth

Straße / Street

PLZ Wohnort / City, ZIP code

Stempel der Klinik oder Praxis /
Stamp of hospital or surgeon

How do I prepare for the consultation with my surgeon?

The reconstruction or augmentation of the breast is a voluntary surgical intervention based on your personal decision. It may be helpful to prepare in advance a list of questions for your surgeon, i.e.

- ▶ What implant size and form would you as my surgeon suggest? Why?
- ▶ Where will the incision be located? And where the implant? Why?
- ▶ How long will it take until the healing is complete?
- ▶ How many days should I take off? When can I get back to work?
- ▶ Is there anything I need to be aware of after the operation? (e.g. physical cutbacks in sports), etc.

Via the Download Center on our website you can access our "Checklist Surgeon", which lists these questions and more for the consultation with your surgeon.

Your surgeon will give you a thorough examination and extensive advice. Do not hesitate to discuss your questions with her/him. You should be very clear about your decision in favour of or against the surgery. This decision is very personal and will always be your own!

For further information as well as the list of the studies referred to in this brochure, please go to our website. There, you can also take a look at how and where your implants are manufactured:

www.polytech-health-aesthetics.com

Implants made by POLYTECH
– QUALITY made in Germany



POLYTECH Health & Aesthetics GmbH

Alzheimer Str. 32 | 64807 Dieburg | Germany

phone +49 (0)6071 9863-0 | fax +49 (0)6071 9863-30

eMail info@polytechhealth.com

www.polytech-health-aesthetics.com

Implants made by POLYTECH
– QUALITY made in Germany