

A breast implant for me?

Information leaflet on breast augmentation



POLYTECH

A BREAST IMPLANT FOR ME?

Being happy with the appearance of your body can positively affect your self-image, your self-confidence, and your quality of life. Aesthetic surgery, such as breast augmentation, can make a significant contribution to your self-confidence.

There are many possibilities for augmentation, contour correction or enlargement of the breast. Regardless of your personal motivation for choosing breast surgery, you will probably have many questions about this subject. On the following pages, we have gathered information about breast implants and some answers to questions you may have on your mind.

However, like any surgical procedure, plastic surgery should be thoroughly considered. The following leaflet provides answers to some frequently asked questions. To date, breast augmentation is one of the most frequently performed procedures in plastic surgery. Breast implants have been in use since the early 1960s. Since then, millions of women have opted for breast augmentation and also reconstruction with silicone gel-filled implants.

Breast implants have constantly improved over the years due to physicians, manufacturers and patients collaborating together.

The insights gained inspired us at POLYTECH Health & Aesthetics to become specialists in breast implants coated with micropolyurethane foam. With over 45 years

of experience in breast augmentation surgery, we know that micropolyurethane breast implants significantly reduce complications associated with breast implant surgery. The POLYTECH brand name for this type of implant surface is Microthane®.

WHAT IS SILICONE?

In medicine, silicone (not to be confused with silicon, the crystalline material which microelectronics are made of) is used as a component of numerous products, e.g. probes, catheters, coatings of puncture needles and pacemakers, gloves and wound dressings. In soft-tissue surgery, silicone implants are used for body contour correction.

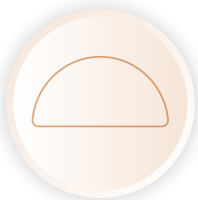
The first production process for silicone polymers was patented in 1958. Silicone, or as chemists call it, dimethylpolysiloxane, is produced as silicone elastomer, silicone gel and silicone oil. Silicone is everpresent in our daily lives; as anti-foaming agents for cooking, as water-repellent for clothing, as electrical insulation, as anti-acids for the stomach, as carrier spray in anti-perspirants, etc. Silicone does not contain any additives, especially no softeners. Extensive studies have not provided evidence of allergic reactions to silicone.

ARE THERE VARIOUS TYPES OF IMPLANTS?

Yes, there is a great variety of implants. Our goal at POLYTECH is to support the diversity in appearance of women. This is why we manufacture a wide range of silicone implants. The projection can be defined by four different profiles: low, moderate, high and extra high. Each implant type and profile is available in up to 18 different sizes (and in at least two different surfaces). The resilient and highly resistant shell of our implants consists of several layers of silicone and a diffusion barrier. This barrier layer prevents the gel from permeating through the shell into the surrounding tissue.

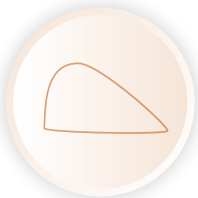


There are four implant types:



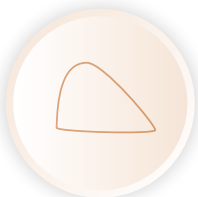
Mème®

a silicone gel-filled implant with a round base and central projection



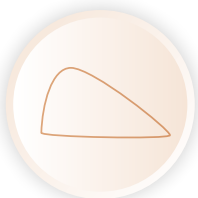
Replicon®

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

WHICH IMPLANT FILL MATERIALS ARE AVAILABLE?

For many years, silicone gel and saline solution have been successfully used as filling materials for implants. Implants filled with highly cross-linked silicone gel authentically mimic natural soft breast tissue replacement. The silicone gel used by POLYTECH is form-stable and returns to its original shape after moderate compression. A section through any of our implants shows the soft yet cohesive texture of the gel. In terms of feel & movement, a silicone gel-filled implant imitates the natural breast.

WHY ARE THERE VARIOUS IMPLANT SURFACES ON THE MARKET?

As part of the body's natural reaction, a capsule is formed around any foreign body inserted into the tissue, including breast implants. In certain cases, this capsule can contract. The contraction can deform 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 its occurrence is related to the implant surface.



Breast implants cut in two, showing the highly cohesive silicone gel

The first breast implants were manufactured in the 1960s and had a smooth surface. Since the mid-1970s, micropolyurethane-covered implants have been in use. Textured implants were introduced in the late 1980s. Currently three different surfaces are available.

Even though surgical techniques for breast augmentation have improved, Microthane® micropolyurethane-covered implants offer impressively low capsular contracture rates of 0 – 3% compared to the 30% of smooth implants.¹⁻³

The first in-house evaluations indicate that the capsular contracture rate of the friction minimized, microtextured MESMO®-sensitive surface might be similar to that of Microthane®. Standard-Textured implants also provide a clearly lower risk (15%) of capsular contracture compared to smooth implants (30%).⁴⁻⁷ For these reasons, POLYTECH specialise in implants with micropolyurethane and textured surfaces.

ARE TESTS PERFORMED TO ENSURE THE SAFETY OF THE IMPLANTS?

Yes, constantly. Throughout 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 very strict regulations.

See below two examples of the tests we perform regularly:



Fatigue test: In this test we simulate the dynamic forces working on the breast implants in the chest of a woman jogging. According to the standard, two million cycles are required. This corresponds to a weekly running distance of 10 km over a period of 10 years. According to the guidelines, the shell must not show any defect after this test. We perform up to 36 million cycles which is equivalent to a weekly running distance of 180 km for 10 years (more than 4 marathons per week) or 10 km per week for 180 years.

Elongation test: In this test we check the ability of the shell to resist deformation without causing damage. The minimum elongation stipulated is 450%. Our shells achieve up to 850%.

CAN AN IMPLANT CHANGE MY PHYSICAL APPEARANCE?

Yes, and most of the time this is the intention of plastic surgery. Whilst oncological factors and treatment must be taken into consideration when using breast implants for reconstruction, a result which replicates the natural look, movement and feel of the breast can be achieved.⁸⁻¹² Similarly, contour correction and breast augmentation may improve your appearance and body confidence.

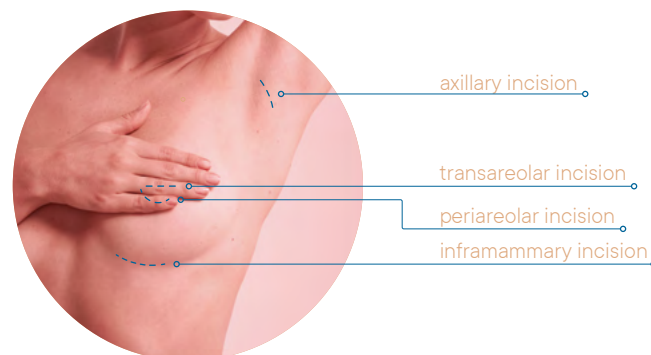
ARE THERE DIFFERENT TYPES OF SURGICAL PROCEDURES?

Yes, there are various options available. We suggest you consult an experienced and qualified surgeon if you want to know more about the surgical techniques in breast augmentation. Your surgeon is the specialist and will explain the different methods and possible risks of the procedures.

WHICH INCISIONS ARE USED FOR AN AUGMENTATION?

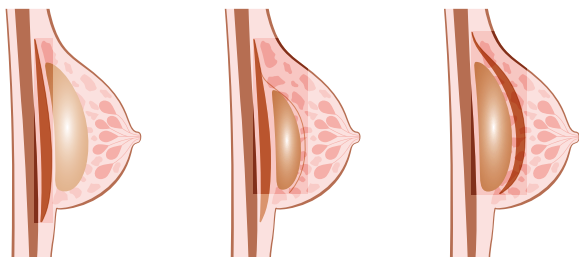
The surgical incision chosen by your surgeon depends on the results of your examination. Incisions can be located in the armpit (axillary incision) or around the areola area (periareolar, transareolar incision). The most common approach for implant insertion is the incision in the mammary fold beneath the breast (inframammary incision).

Access routes for implant placement:



WHERE IS THE IMPLANT POSITIONED?

For augmentation, the implant can be positioned either directly behind the breast tissue (sub-glandularly), under the fascia of the muscle (sub-fascially) or under the pectoral muscle (sub-pectoral/sub-muscular). Your physician will advise you which placement technique is best for your situation. POLYTECH silicone implants are naturally soft and adapt naturally to the body, whether positioned subglandularly 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 used also in women who have breast implants. Modern imaging techniques such as sonography, MRI or CT help to find tumors at an early stage.¹³⁻¹⁷

WHAT ARE THE RISKS AND POSSIBLE COMPLICATIONS?

Like any surgical procedure, breast augmentation entails risks, and complications may occur. As with all surgical procedures there are potential risks from both the anaesthesia and from the surgery, such as the possibility of infection or pain. The following information will help you to make an informed decision.

WHAT SHOULD I EXPECT AFTER MY IMPLANT SURGERY?

In the worst cases complications arising from breast implant surgery can include: asymmetry, implant dislocation, increased scarring, incorrect implant position, sensory disturbances, palpable implant edges, infection, capsular fibrosis and capsular contracture. You should always discuss the possible risks and outcomes with your physician prior to breast surgery.

CAN IMPLANT-RELATED INFECTION OCCUR?

Infections associated with breast implants are extremely rare.¹⁸ Infections of unknown aetiology that occur after implantation should be treated as quickly as possible. Use of antibiotics, drainage or implant removal followed by implant exchange after the infection has been successfully treated may be required. Not all infections can be treated with the implant remaining in place. "Toxic shock" syndrome has been noted in isolated cases in connection with breast implants.

DO MICROPOLYURETHANE-COVERED BREAST IMPLANTS HAVE HIGHER RISKS OF INFECTION COMPARED TO OTHER BREAST IMPLANTS?

No, not at all.¹⁸ Several studies show that there is no increased risk for infection with micropolyurethane-coated implants.

HOW WILL MY BODY REACT TO THE IMPLANT?

The formation of a capsule of connective tissue around an implant is a normal reaction to a foreign body. The undesired tightening of this capsule (capsular contracture or capsular fibrosis) can result in changes to the shape as well as to the position of the implant. A capsular contracture may never occur

at all, or it may occur after weeks, months or years. It cannot be said with certainty, when or how pronounced a capsular contracture may be. A significant capsular contracture (Baker grade III or IV) can be identified when there is severe deformity of the breast and also pain that ultimately results in implant removal. Because of possible damage to the product, we advise against closed capsulotomy. Should your physician nevertheless perform a manual capsulotomy, damage to the implant must be avoided by using an imaging technique.

DO BREAST IMPLANTS INCREASE THE RISK OF BREAST CANCER?

The extensive studies currently available show that women with breast implants are not subject to a higher risk of breast cancer than women without breast implants.¹⁹⁻²³ In other words, a breast implant has no influence on the occurrence of breast cancer. Breast cancer as a direct result of smooth, textured or micropolyurethane-covered implants has not been observed in human beings nor in studies on animals. Nonetheless, scientists discuss theoretical risks.²⁴⁻²⁵

WHAT IS BIA-ALCL?

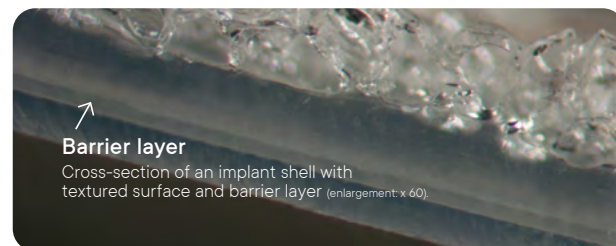
BIA-ALCL (Breast Implant Associated Anaplastic Large-Cell Lymphoma) is a subtype of lymphoma that may arise in connection with breast implants. It is not breast cancer, and it is very rare: its incidence is 33 in 1 million lifetime risk for women with breast implants,²⁶ compared to breast cancer with a lifetime risk of 1 in 8 women (with or without implants).²⁷ If it develops, it happens between 8 to 25 years after implant placement.²⁶ The reason why it develops is still unknown, but it has become easy to diagnose and to treat effectively with an excellent prognosis.

IS THERE A LINK BETWEEN AUTOIMMUNE DISEASES AND BREAST IMPLANTS?

Extensive independent studies have shown no connections between silicone gel-filled breast implants and autoimmune disease.²⁸⁻³⁴

CAN SILICONE GEL PERMEATE THROUGH THE IMPLANT SHELL?

Permeation of low molecular weight silicone gel through the intact implant shell cannot be completely excluded, but the gel usually remains within the capsule. In contrast to previous generations of implants, only negligible traces of gel can be found in the connective tissue capsule around current day implants. This is due to the significantly improved quality of the implant shells that are now equipped with a diffusion barrier preventing gel permeation (see image below).



Furthermore, the high degree of cross-linking of the filler gel³⁵⁻³⁷ and the significant reduction of its level of low molecular weight components contribute to the high quality of POLYTECH implants.

CAN THE IMPLANTS WRINKLE?

POLYTECH implants are adequately filled. Company data show a very low reports of wrinkling. Possible complications can occur when there is incorrect choice of implant size, implant position or insufficient tissue coverage. These can include wrinkling, papable implant edges and implant compression.

WHAT SHOULD I DO IN CASE OF PERSISTENT PAIN?

Persistent pain is usually caused by an incorrect size or positioning of an implant. This symptom may be caused by an implant that is too large, by capsular contracture, or by irritation based on excessive mobility of the implant. Pain may occur postoperatively in the area of the surgery as well as in the pectoral muscles and the arm when the arm and shoulder are moved. Please consult your surgeon as quickly as possible to clarify pain following an operation.

HOW LONG DOES AN IMPLANT LAST?

Every body reacts individually to a foreign body; therefore it is not possible to give a standard response to the lifetime of an implant. The expected lifespan was assessed by evaluating clinical data from other silicone breast implants that are considered equivalent. Technical advances have resulted in improved quality and a significant reduction in the incidence of implant ruptures compared to earlier generation implants. Of course, the likelihood of an implant rupture increases with the age of the implant. Based on a variety of studies using MRI, the rupture frequency varies from 0.5% – 7.7% three years after implantation and rises up to 9.3% six years after implantation. Another study reported an 8% rupture rate for a mean for the worst case scenario, as they are based on imaging results for both confirmed and undetermined ruptures.

The results include a variety of study cohorts (e.g. primary and secondary augmentations and reconstructions). Therefore the lifetime rate of POLYTECH implants can be estimated to be approximately 90% after 10 years.³⁸⁻⁴⁰ Abnormal stress and excessive movement or trauma to the tissue surrounding the implant may result in implant rupture (rupture of the implant shell) and necessitate for implant removal.

In the unlikely case of a shell rupture, any leaking gel will be contained by the connective tissue capsule, which forms naturally around the implant. Factors that can result in a rupture of the implant shell include damage to the implant shell due to surgical procedures, normal material fatigue of the implant shell, mammographies and complications of capsular contracture.

An implant rupture may occur unexpectedly and you may not notice it. Therefore, you should attend the follow-up examinations recommended by your physician. In case of an implant rupture, we always recommend an implant exchange.

WHAT ARE THE INTERVALS FOR FOLLOW-UP EXAMINATIONS AFTER IMPLANTATION?

Your surgeon should check the implant every six months or annually. Please note that breast implants have a limited lifespan. An implant may need to be removed or replaced, which will then require additional surgery.

WHAT DO I HAVE TO TAKE INTO CONSIDERATION AFTER HAVING BREAST IMPLANTATION?

After your implant surgery, you will receive an implant passport from your surgeon. This passport has been part of every POLYTECH breast implant box since 1995. Please always carry this document with you, so the information concerning the type and size of your implants is available if needed. Also, for your own safety you should inform your physicians and the person performing your mammography about your implants.

SHOULD I SELF-EXAM FOR BREAST CANCER SYMPTOMS?

Make sure to self-examine your breasts at regular intervals. For post-operative self-examination, your physician should instruct you on how to distinguish between the implant and your own tissue to enable you to detect tumours yourself. Do not just touch your breasts, also look for swelling, redness and inflammation, as well as any breast deformities, even if these are not yet painful. If you find any changes, please consult a physician.

DOES AN IMPLANT COMPROMISE THE ABILITY TO BREASTFEED?

The ability to breastfeed can be impaired by breast surgery, regardless of implants. However, the ability to breastfeed is generally preserved in women with breast implants. In any case, you should discuss your desire to breastfeed with your physician before breast surgery as this may affect the choice of implant position. There is no evidence that breast implants pose a health risk to infants.

WHY IS IT NECESSARY TO WORK WITH PHYSICIANS?

1 Follow-up examinations

You should have your physician check your implants twice a year. Please undergo all the usual breast examinations, such as self-examination and possible imaging procedures (mammary sonography, tomosynthesis, mammography, magnetic resonance mammography (MRI) to detect possible breast cancer. Please inform the radiologist that you have a breast implant before a mammography is performed. Ask them to document the pressure on your breast resulting from the compression during a mammography.

2 Planned surgery in the thorax (chest) area

Please inform the physician or surgeon about your implants if thoracic surgery is planned so that appropriate care can be taken during the procedure.

3 Suspected complications

Please consult a physician if you suspect complications, due to excessive pressure or force to the breast, e.g. during extreme sports activities, intensive massages or from safety belts in traffic accidents.

4 Use of topical medication

Please consult your physician or pharmacist before using a topical medication such as steroid ointment, shortly after your operation or also in case of complications

HOW DO I PREPARE FOR THE CONSULTATION WITH MY SURGEON?

Breast augmentation is an elective surgical intervention based on your personal decision. It is therefore important to be well informed before surgery. It may be helpful to prepare in advance a list of questions. Here are some suggestions:

- What implant size and shape would you as my surgeon suggest? Why?
- Which incision will you use? And where will the implant be placed? Why?
- 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. no exercise or reduced physical activities)

On our website you can access our Surgeon Checklist, which lists these questions and more for the consultation with your surgeon. Your surgeon will give you a thorough examination and offer extensive advice. Do not hesitate to discuss your questions. Before you proceed with you surgery ensure you fully understand all the potential risks and complications discussed during your consultation.

POLYTECH Health & Aesthetics breast implants, combined with our IMPLANTS OF EXCELLENCE programme offer you as a patient product quality combined with a high level of personal safety. Breast implants by POLYTECH Health & Aesthetics are certified as medical devices. Regular tests show that the quality of the implants meets, and in many cases exceeds, the requirements of these standards. With the IMPLANTS OF EXCELLENCE programme you benefit from a specialised service for your personal safety.

Notes

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