Feeling whole again

Basic information on
breast reconstruction

A healthy and well-formed breast plays a part in the positive self-perception of women, it raises their self-confidence and supports a state of well-being.

For patients who had a tumor removed, having a positive attitude is a very important psychological aspect and provides valuable support in coping with the disease. At will of the patient, breast reconstruction may be part of a breast cancer therapy or the treatment concept. In many countries the costs for reconstruction surgery are covered by health insurance.

Nowadays, there exists a wide variety of possibilities for breast reconstruction. Unfortunately, only comparatively few breast cancer patients know about breast reconstruction or the methods available. Therefore, it is our goal to make patients aware of

their possibilities, so they can discuss them with their physician and choose a surgeon who has the necessary experience.

Whatever your personal motivation may be to think about breast surgery, you will have many questions. With this brochure we neither can nor want to replace the advice of a doctor, but it will give you a basic idea and hopefully provide some useful tips. Whether and which type of breast reconstruction makes sense in your particular case is something your doctor will discuss with you in detail.

Breast reconstruction: yes or no? And if yes – at what stage?

According to the Professional Association of German Plastic Surgeons only some 10% of the patients in Germany have plastic surgery to get their breast reconstructed after mastectomy. Equal figures may be found for other European countries. Even less patients opt for reconstruction in non-European countries, especially if breast reconstruction is not covered by health insurance. In fact, the number of breast reconstructions could be much higher, as principally all patients may be reconstructed, even several years after mastectomy.

Whether and when a breast reconstruction is performed depends on several factors: the patient's decision, her physical situation and the medical requirements. Breast cancer patients should discuss this in detail with their physician and find out about the individual options and the pros and cons of their various options.

Basically, a breast reconstruction can be primary / immediate (directly following tumor removal), or secondary / delayed (depending on the patient's situation at least six to twelve months up to several years later, after completion of radiotherapy and chemotherapy). For the patient it is important to be aware of the fact that after reconstruction, corrective measures in the form of further surgical interventions may become necessary.

Different reasons may motivate the affected women to decide for or against reconstruction. For patients who can have a reconstruction, the new breast frequently

promotes a new self-esteem and helps them to cope more easily with the disease. It is important in every case that the women concerned arrive at a decision that is beneficial for the medical prognosis and at the same time for their own body and life.

Surgical techniques for breast reconstruction

Generally, the volume of the breast can be reconstructed in two different ways. One option is to use non-organic materials (for example silicone gel or saline filled silicone implants, plasma expanders) and the other is to use the body's own tissues (such as the muscular flap or from the lower abdomen or the inner thigh). In the first case we speak of prosthetic reconstruction, and in the second of autologous reconstruction.

Autologous reconstruction

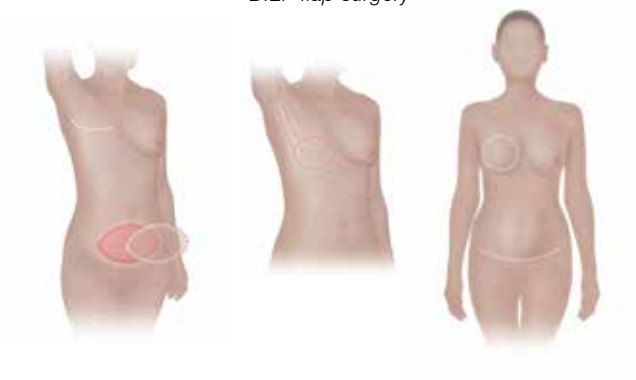
In this type of reconstruction, the surgeon works with the patient's own tissue, taken from elsewhere on the body. Generally speaking, there are two types of flap surgeries: the pedicled flap surgery, where the flap remains connected to its original location, and the more complex free-flap surgery, where the flap is completely removed and then micro-surgically reconnected.

Today, free-flap surgery is widespread. In this type of autologous reconstruction, the flap is completely detached from the body and reinserted micro-surgically

at the target position. Flaps used for this method are: the Gracilis flap from the inner thigh (short operation time and low complication rate), the perforator flap of the Arteria epigastrica (DIEP flap) from the lower abdomen, or the perforator flap of the Arteria glutea superior (SGAP flap) from the upper gluteus area.

In the pedicled flap surgery, the flap remains attached via the blood vessels to its original site at one end. For this type of flap reconstruction, surgeons most often use the Latissimus dorsi or

DIEP flap surgery

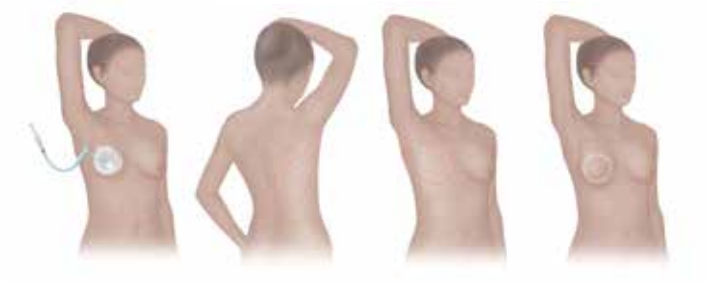


SGAP/IGAP flap surgery

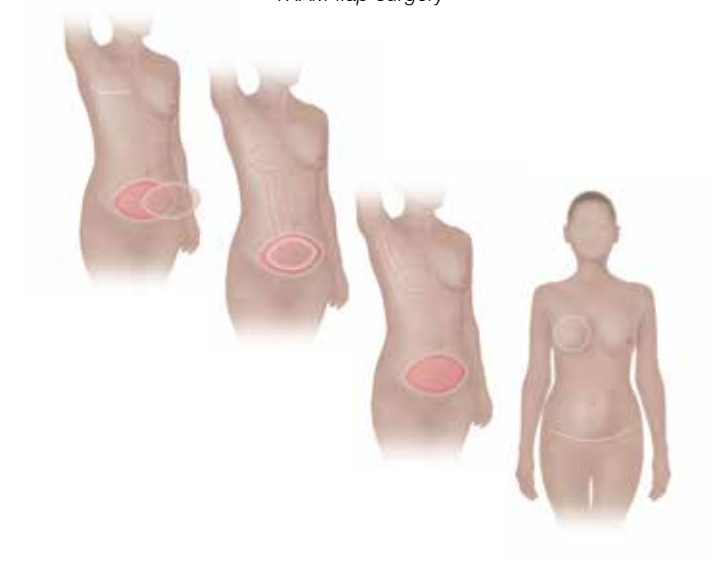
LD flap, a flap of muscle and subcutaneous tissue from the back, or the Transverse rectus abdominis musculocutaneous or TRAM flap, consisting of muscle and subcutaneous tissue from the abdomen.

Autologous reconstruction is often combined with implants, for example if the desired volume of the reconstructed breast cannot be achieved with the

LD flap surgery



TRAM flap surgery



patient's own tissue due to lack of available material. Additionally, acellular dermal matrix (ADM) is used with increasing frequency. ADM is obtained from natural materials and provides a tissue scaffold that supports the regeneration and development of soft tissue – their use can contribute to a positive outcome in breast reconstruction.

Apart from flap surgery, autologous reconstruction is sometimes also performed by means of autologous fat transfer. One has to be aware that in this method, the recoverable volumes are lower than those achievable with implants and that it is not possible to reconstruct a complete breast in this way, just minor defects. Additionally, up to six interventions are required until the desired shape is achieved, since most of the transplanted cells are degraded by the patient's organism.

Prosthetic reconstruction

A prosthetic (or heterologous) breast reconstruction may be performed at different points of time. A primary or immediate reconstruction – i.e. a reconstruction directly after the surgical removal of the cancer – can be performed with practically all patients, depending on the respective tumor biology and extension. If radiation therapy is necessary following the surgery, prosthetic reconstruction may be the source for a higher complication rate and thus should not be considered the first choice.

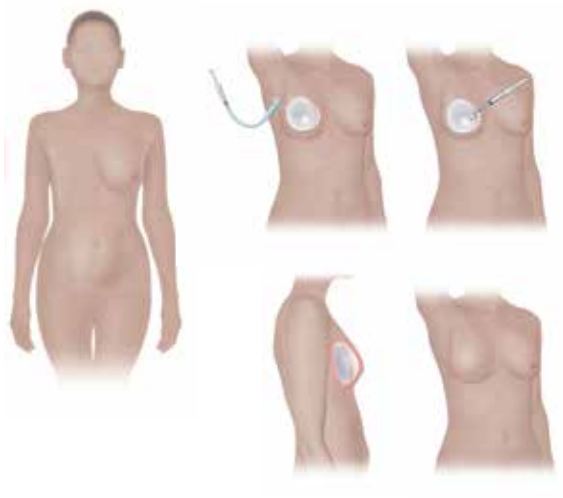
The secondary or delayed reconstruction – i.e. the reconstruction of the breast at a later date – requires several steps: first, the skin must be expanded. To

this effect, a tissue expander is inserted (with a remote or an integrated valve) that allows the skin to be gradually widened until it provides enough tissue. Then, the expander is exchanged against a permanent implant in the desired size.

Immediate reconstruction

The variety of implant shapes available today makes it possible to achieve a very natural result in the reconstructed breast. Advantage over the autologous reconstruction is that the operating costs are often lower. Also, there is less stress on the body because

Delayed reconstruction



no additional scars are created on other parts of the body and no further surgical site needs to be healed by the organism.

Reconstruction of the nipple

Sometimes it may be not possible to save the nipple during tumor resection. In case of a unilateral mastectomy, a way to reconstruct the nipple is to split the nipple of the other breast and build a new one on that. Another possibility is to use tissue from the outer ear or the big toe.

The areola can also be reconstructed from the patient's own tissue, for example using tissue of the inner thigh. However, micropigmentation (a form of tattoo) may be less stressful: after the new nipple is completely healed, a naturally looking areola is pigmented under local anesthesia. This procedure is an outpatient process and painless.

The optimum implant for you

Today, various types of implants are available. However, the distinction between "saline implants" and "silicone implants" is misleading. One thing all manufacturers of all types of breast implants have in common is that the shells are always made of silicone elastomer.

Implants vary in shape, surface and filling. Fillings today consist of isotonic saline solution or silicone gel.

The filling

Silicone gel-filled implants are the most widely used implant type all over the world, both for augmentation and reconstruction. Saline-filled implants are used less often because they feel less natural in the body and come in a very limited range of shapes.

State of the art in implant technology are silicone implants with a filling of a highly cross-linked, cohesive silicone gel. In these, the cross-linking of the gel preserves its anatomical shape and a "memory" effect lets the implant revert to its original shape when deformed.

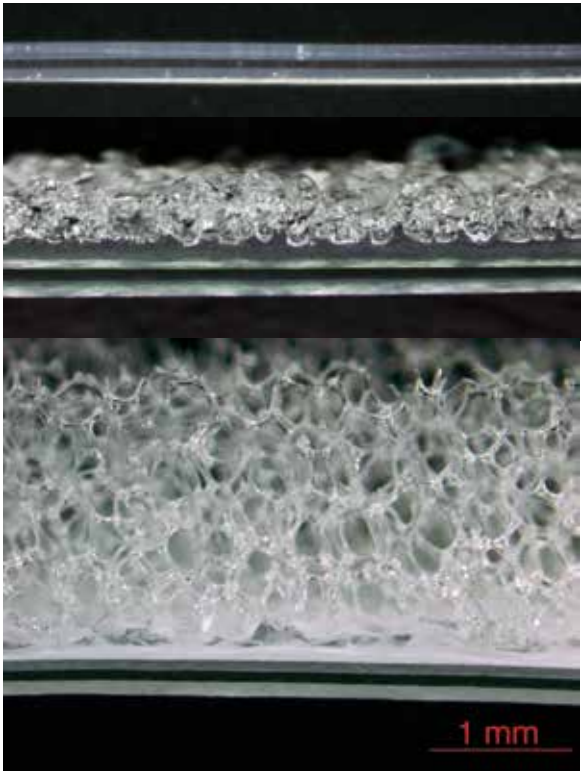
Cut implant showing the highly cross-linked, coshesive silcone gel filling

Todays implants are much safer than the implants of earlier generations.[40-42] This is due to the fact that the significantly improved implant shells have a diffusion barrier that prevents gel particles from migrating into the surrounding tissue. In addition, the low molecular weight components in the highly crosslinked and cohesive gel filling have been drastically reduced. The so-equipped implants will not bleed in case of an injury and are even cut resistant.

The surface

Available implants are equipped with surfaces that are smooth, textured or coated with micropolyurethane foam (Microthane®). The reason for the development of various shell surfaces is the reaction of the organism to a foreign body.

The natural reaction of the human organism towards a foreign body that has invaded its integrity is to form a fibrous capsule around it. In the course of this reaction, the capsule can contract. This contraction



Cuts of implant shells with different surfaces:
top - smooth, center - textured, down - Microthane® covered
(30-fold enlarged)

may lead to a deformation of the implant and painful tissue hardening. This adverse effect is called capsular contracture.

The tendency of a connective tissue capsule to contract is significantly influenced by the orientation of its constituting fibers. The more regularly the fibers are spread, the greater the risk of capsular contracture. This is exactly what happens with smooth-walled implants. In order to avoid the formation of such a capsule around the implant, the implant surface is roughed up by texturization or by covering it with Microthane®. This provokes a more chaotic growth of fibers around the implant. As a result, the fibers are restricted in their tendency to contract.

The capsular contracture rates for textured implants compared to smooth-walled implants may be reduced by half and with Microthane® covered implants even to below 3% (see p.17, "Fighting Capsular Contracture").

The shape

The shape of breast implants is defined by the following parameters: the base, i.e. the side with which the implant rests on the rib cage; the profile, which can be centered (with the highest point in the center above the base) or anatomical (with the highest point in the lower third); and the projection (the curvature), which can be low, moderate, high or extra high.

Breast implant manufacturers have developed different shapes, which can be grouped into two basic types:

a) implants with a round base and a centered profile

b) implants with a round / short / oblong base and an anatomical profile

Evenly curved implants with a centered profile are suitable for the reconstruction of a more youthful breast, whereas the anatomical or teardrop shaped implants have the natural curved shape of a adult woman's breast.

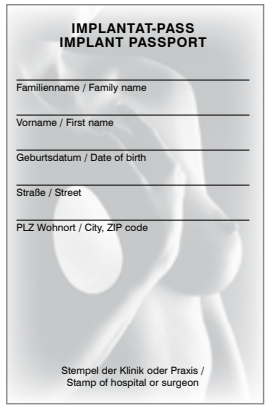
The base of the implants is variable in form and size, as are the profile and projection. This diversity is required in order to do justice to the individual shapes of women's bodies. In a detailed consultation, your doctor will take the time to discuss your options with you and find the optimum implant for you.

Implant life period

As each organism reacts differently to a foreign body, there are no generally accepted recommendations regarding the time implants may stay in the body. Some statements claim that studies indicated an average implant life period of 10 years – these studies, however, refer to implants that were manufactured in the 1980s.[43, 44] Because of the advanced technical development and the resulting improved quality of today's implants, a distinct individual extension of this period can be observed. To be on the safe side, you should have your implants checked once or twice a year by your physician.

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. Deciding for POLYTECH Health & Aesthetics implants and the programme Implants of Excellence means you choose the highest product quality combined with highest personal safety.

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



After implantation surgery, you will receive an implant passport from your physician. This passport has been part of every POLYTECH implant delivery since 1995. Please always carry this document with you, 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.

Implants and breast cancer

Extensive studies found that a breast implant has no effect on the incidence of breast cancer. [25-29] Even after implants were inserted, it is possible to use mammography or sonography for locating tumors. In special cases, magnetic resonance imaging may complement the diagnosis.[22-24, 50, 51]

Fighting capsular contracture – implants covered in Microthane®

Especially with elective operations, such as breast augmentation and breast reconstruction, the adverse effects caused by the operation should be as few as possible. The most common adverse effect of breast implant surgery is capsular contracture.

Around each foreign body – as for example implants, – the human organism forms a fiber capsule. The capsule's behavior can be influenced by the surface of the implants. In some cases the body develops a capsular contracture, i.e. the fibers around the implant contract. Capsular contracture can be classified into four stages, called Baker Grade I, II, III and IV. Contractures grade I and II do not have to be operated because they are neither painful, nor alter the aesthetic result to a burdensome degree. In case of grade III and IV contractions, surgery should be considered, because then the capsule becomes visible and deforms the implant, apart from causing pain for some patients.

Implants covered in Microthane®

Implants with a coating of micropolyurethane foam (Microthane®) have been developed to reduce the incidence of capsular contracture. In extensive clinical studies over a follow-up period of two decades, a large number of patients, the capsular contracture rates where observed (only Baker grade III and IV contractures were considered). According to the results, the capsular contracture rate with micropolyurethane-foam covered implants inserted in virgin tissue is 0 to 9% compared to 9 to 50% for other implants. In most of the extensive studies, a capsular contracture rate of 0 to 3% for micropolyurethane-foam implants is indicated.

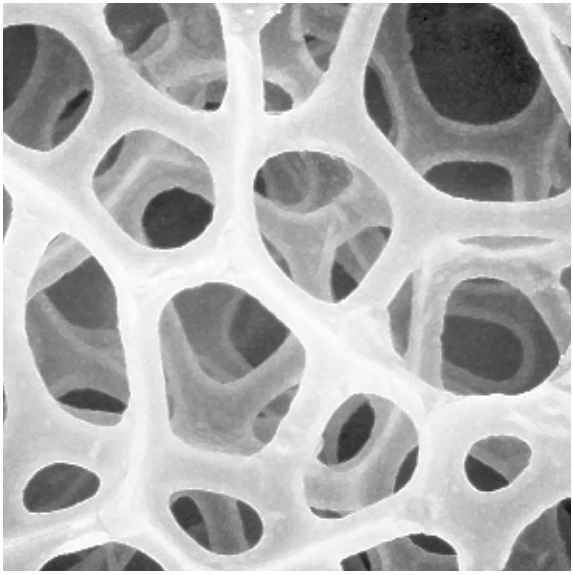
The Kaplan-Meier analysis of an extensive long-term study from the USA confirmed the significant reduction in the risk of capsular contracture with micropolyurethane-foam implants for a period of up to 10 years after implantation. Statistics show that 8 years post implantation, the rate of capsular contracture with micropolyurethane-foam implants compared to textured implants is 15% lower, compared with smooth-walled implants it is 30% lower.[48]

The reduced rate is due to the tissue ingrowth into the structure of the micropolyurethane foam. Through this active healing of the tissue, not a single capsule is formed around the implant, as it happens with smooth-walled and textured implants, but numerous small capsules whose contractive forces neutralize each other.

The fixation of the implant in the tissue combined with its filling of highly cross-linked and cohesive silicone gel result in a natural look, touch, and

movement of the reconstructed breast. Also, rotation or dislocation of the implant is prevented. The low contracture rate also allows placing the implants in front of the pectoral muscle, which ensures very aesthetic results for augmentation and breast reconstruction.

For reconstructions in general, no rules can be set up regarding implant positioning. (For example: in front or behind the pectoral muscle). This is due to the fact that this decision crucially depends on the individual patient's situation. Your doctor will determine together with you which implant positioning will produce the best result in your case.



Structure of the Microthane® cover under the electron microscope

Expert advice and the right questions

Please remember that breast reconstruction is a surgical procedure; this means that not even a specialized surgeon is able to guarantee a successful outcome. Of course, the experience and skill of the surgeon have a decisive impact on the outcome of the surgery. Therefore, it is important to take your time to find a surgeon you can trust. You may find assistance in your search at Breast Cancer Care organizations in your country.

A good source for addresses of competent doctors are professional associations and patient support groups. In some countries, there are breast health centers where you may find assistance. Maybe friends and acquaintances have gained experience you can refer to. In some hospitals and clinics you may look at images of former patients or can even make contact with them or support groups of former breast cancer patients.

During the primary interview, you should not hesitate to ask your surgeon about his experience regarding breast reconstruction. A good surgeon will schedule enough time for a detailed consultation and examine you thoroughly. S/he will not make unrealistic promises about the result to be expected and will not push you to make fast decisions.

A thorough preliminary examination includes questions about the cancer treatments you had, existing allergies, chronic diseases, consumption of anticoagulant drugs, the tendency to increased scarring, and other influencing factors. Possibly it may be advisable to seek a second or third opinion.

Our tip: Make a list of all your remaining questions before the interview, discuss them with your surgeon during consultation, and take your time afterwards to make your final decision.

Following you will find a list of possible questions:

- How long have you practiced as a plastic surgeon?
- How often have you performed the planned surgery within the last 12 months? Can I see your gallery of before-and-after photos?
- May I talk to patients of yours who have had this surgery?

And in case of a breast reconstruction with implants:

- What size and what form would you choose for my implants? Why?
- How will you proceed? Why?
- What surface will my implants have? Why?
- What implants do you use (manufacturer)? Why?
- What are the expectations of how the implants will look and function after the surgery?
- How long will I have the implants?
- What are the complications and what are your complication rates with this surgery?

- What examinations will you perform to determine whether I can have the intervention? (A thorough preliminary examination should include questions about your medical history, existing allergies, chronic diseases, intake of anticoagulants, the tendency for increased scarring, etc.)

- What type of anesthesia will you use? Will I tolerate the anesthesia well? What can be the side effects and consequences?

- Will my health insurance cover all costs of the intervention? If not, what additional costs will I have to deal with and why?

- Can I have a look in the operating room and the recovery room?

- How many days do I have to take off? How long will it take until I will have fully regenerated?

- What aftercare is required? How often should I come for follow-up?

- Is cancer screening possible after an implantation?

- Do I have to expect any restrictions after the surgery? (for example regarding sports)

Do not hesitate to discuss your questions with your surgeon. You should be very clear about your decision in favour of or against the surgery. The better informed you are of your options, the more satisfied you will be with the result.

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:

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