

Feeling whole again

Patient Information on
Breast Reconstruction

Made in
Germany

POLYTECH

INTRODUCTION

A healthy and shapely breast plays a positive part in a woman's body image, and can promote a state of well-being. Unfortunately, recent studies show that one in eight women will develop breast cancer during their lifetime¹. Breast cancer is still the most common cancer in women (apart from skin cancer)¹. For many patients who have undergone prophylactic mastectomy or had a tumour removed, breast reconstruction may be part of the healing process. It can help improve their self-confidence and self-esteem, and improve quality of life.

Whatever your motivation for breast surgery is, you will have many questions. This leaflet will provide basic information about the possibilities of breast reconstruction and the wide variety of choices available, as well as the benefits and disadvantages. Please note this leaflet does not replace the advice of breast surgeons, and you will need to discuss your case in detail with them.

BREAST RECONSTRUCTION: YES OR NO?

Breast reconstruction is a procedure that is carried out to restore breast shape and replace breast tissue that is lost during a mastectomy or lumpectomy. The goal is to create breasts that look symmetrical, close to the original appearance and shape, and as natural as possible.

Whether or not a breast reconstruction is performed depends on several factors: your personal decision, your physical condition and medical requirements. It is important that you understand every option available for breast reconstruction. Having the right information as a starting point for a full and frank discussion with your doctor can help you in the journey to reconstruction.

BENEFITS OF BREAST RECONSTRUCTION

Different reasons may motivate you to decide for or against reconstruction. The benefits of a reconstructed breast may include:

- ▶▶ Increased self-confidence and self-esteem²
- ▶▶ A way to cope with breast cancer³
- ▶▶ An improved symmetry of your breast
- ▶▶ Avoiding the choice between external prostheses or a flat chest



DISADVANTAGES OF BREAST RECONSTRUCTION

There are several disadvantages and problems that may occur with breast reconstruction that need to be taken into account before making a decision to go ahead⁴:

- ▶▶ Not all breast reconstruction procedures are a total success, and the result might not look like you expected
- ▶▶ Additional corrective surgeries may be necessary and the revision rate is higher than in augmentation breast surgery
- ▶▶ Surgery will leave scars on your breast and, in case of autologous reconstruction, in any areas tissue was taken from to create your new breast
- ▶▶ A reconstructed breast will not feel the same as a natural breast
- ▶▶ In order to achieve symmetry between the reconstructed breast and the healthy one, reduction or enlargement of the latter may be necessary

See the section of 'Risks and complications of an implant' for more information on the complications that you may encounter in case of breast reconstruction with implants. It is important that you consider the risks and the benefits of each procedure, in order to reach a decision that is beneficial for your medical prognosis, your physical and mental health, and your personal circumstances. While cost should not be your primary driver, different procedures have different costs. You should discuss in detail with your surgeon the different techniques and implants available, and their respective pros and cons, as well as the options that are covered by your local health service or insurance.

AT WHAT STAGE IS BREAST RECONSTRUCTION PERFORMED?

Breast reconstruction can take place at two different times, depending on your medical condition, planned therapy, and where possible on your wishes:

- 1 Immediate breast reconstruction is performed during the same surgery, following a prophylactic subcutaneous mastectomy or a tumour removal
- 2 Delayed breast reconstruction is performed not only after mastectomy or lumpectomy surgery, but also after the radio- or chemotherapies that follow such surgery, and can take place from 6 to 12 months up to several years later

The choice between immediate or delayed breast reconstruction is often determined by the need to undergo therapies that may negatively affect the outcome of reconstruction.

SURGICAL TECHNIQUES FOR BREAST RECONSTRUCTION

Generally, the breast volume can be reconstructed in two different ways:

- ▶▶ Autologous reconstruction uses your body's own tissues, such as a muscular flap from the lower abdomen or the inner thigh or the gluteal region
- ▶▶ Implant-based reconstruction uses non-organic materials, such as silicone gel-filled or silicone implants and breast tissue expanders

AUTOLOGOUS RECONSTRUCTION

In autologous reconstruction, the surgeon works with your own tissue taken from another part of your body. Autologous breast reconstruction can be performed immediately or delayed by the surgeon. Generally, there are two types of flap surgeries:

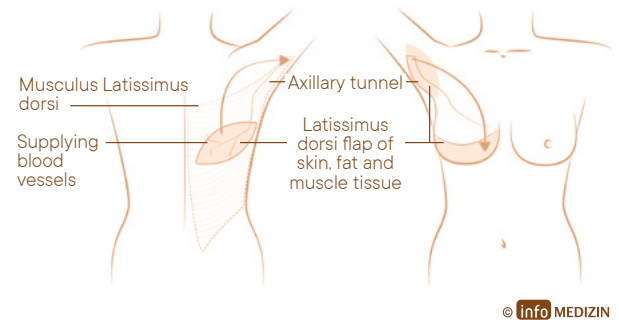
- ▶▶ Pedicled flap surgery, in which the flap remains attached via the blood vessels to its original site at one end. For this type of flap reconstruction, surgeons often use the Latissimus dorsi or LD flap, a flap of muscle and subcutaneous tissue from the back, or the Transverse rectus abdominis musculocutaneous flap or TRAM flap, consisting of muscle and subcutaneous tissue from the abdomen, or the Gracilis flap or PAP-(Profunda Artery Perforator-) flap from the inner thigh.
- ▶▶ Free-flap surgery, which is more complex and the flap is completely removed from the donor site and then micro-surgically reconnected in the breast area.

Today, free-flap surgery is a very common procedure. Flaps used for this method are:

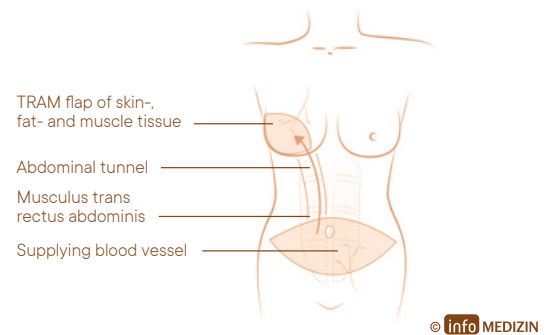
- The Deep Inferior Epigastric Perforator flap, or DIEP flap, from the lower abdomen
- The Superior or Inferior Gluteal Artery perforator flap – SGAP or IGAP flap – from the gluteal area

Different types of flap have different indications, operation times and complication rates.

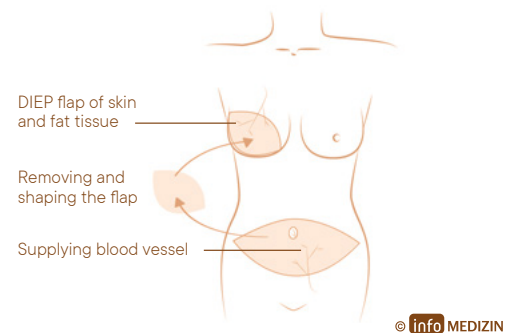
Breast reconstruction – LATISSIMUS DORSI flap



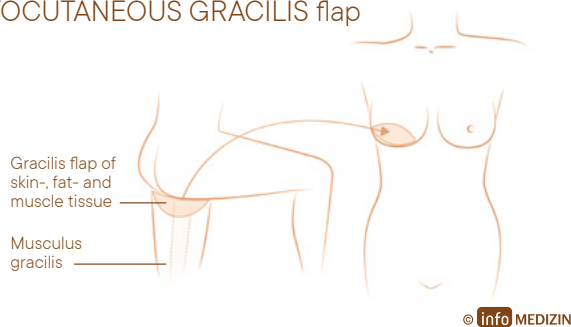
Breast reconstruction – Tram flap



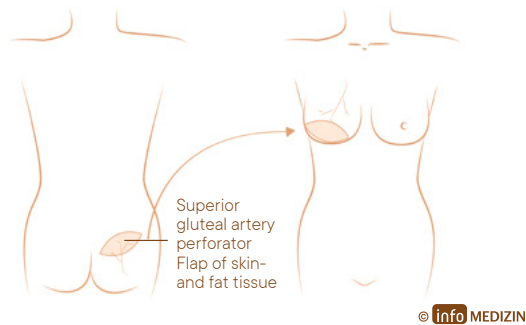
Breast reconstruction – DIEP flap



Breast reconstruction – MYOCUTANEOUS GRACILIS flap



Breast reconstruction – S-GAP flap



Autologous reconstruction is often combined with implants, for example if the desired volume of the reconstructed breast cannot be achieved with the patient's own tissue.

The use of an Acellular Dermal Matrix (ADM) or Meshes is also becoming more frequent. These are obtained from natural or synthetic materials and provide a scaffold that supports the regeneration and development of the soft tissue, contributing to a positive outcome in breast reconstruction.

Apart from flap surgery, autologous reconstruction is sometimes also performed using fat transfer. Only minor defects in the breast can be corrected by using this technique, as the volume of fat obtained is lower than the volume that may be achieved with implants and it is not possible to reconstruct a complete breast. Autologous fat reconstruction might require several follow-up surgeries until the desired shape is achieved, because many of the transplanted cells tend to be destroyed by the body.

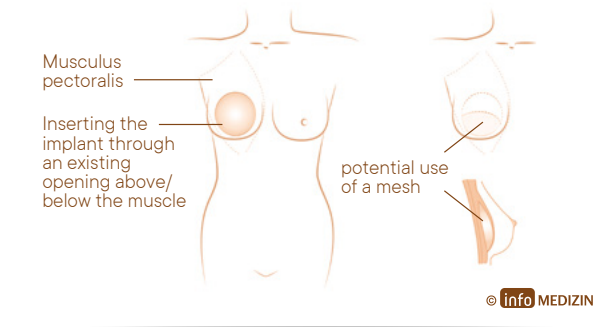
IMPLANT-BASED RECONSTRUCTION

Breast surgery with implants can be immediate or delayed.

Nearly all patients are suitable for immediate reconstruction with breast implants, but the decision depends on the tumour biology and amount of reconstruction needed. If radiation therapy is necessary following the initial surgery, this may increase the complication rate with breast implants and therefore immediate reconstruction should not be the first choice.

Delayed reconstruction requires several steps. Firstly, the skin must be expanded using a tissue expander. A tissue expander is a special type of temporary implant that is inserted unfilled, and is then filled with saline solution via a remote or an integrated valve over the course of several weeks, to slowly expand the skin until there is enough tissue to insert a permanent implant. Then, the expander is replaced with the permanent implant in the desired size.

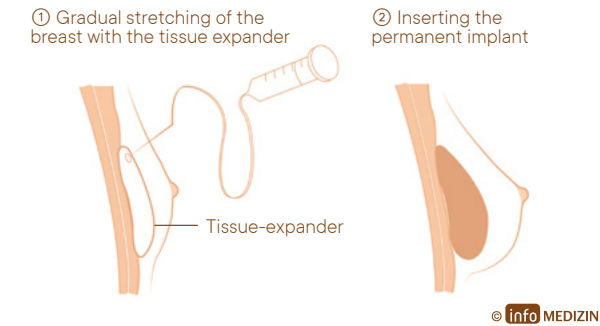
Immediate breast reconstruction with implants – After mastectomy



The variety of implant shapes available today makes it possible to achieve a very natural look.

Please note that Breast implants are not lifetime devices. An implant may have to be removed or replaced, with no guarantee of a satisfactory cosmetic outcome from any reoperation. Complications may lead to one or more reoperations, and the risks of a reoperation are higher than the risks of the first surgery.

Delayed breast reconstruction with expanders



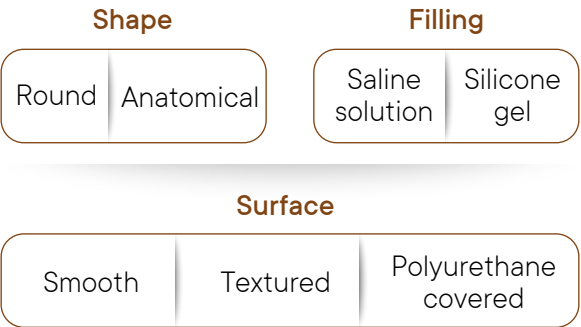
RECONSTRUCTION OF THE NIPPLE

Sometimes it may be not possible to save the nipple during removal of the tumour. When only one breast has been removed, the nipple can be reconstructed by using half of the nipple of the other breast. Tissue grafts from the outer ear or the big toe can also be used to reconstruct the nipple.

The areola on the breast can be reconstructed from the patient's own tissue, for example using tissue of the inner thigh. As an alternative, a naturally-looking areola may also be tattooed onto the breast.

WHICH IS THE BEST IMPLANT FOR ME?

If you are considering breast reconstruction with implants, you are probably asking yourself this question. Today, there are many different types of breast implants on the market. The one thing that is common to all types of breast implants is that surface and filling are available in a wide variety:



►► THE SHAPE

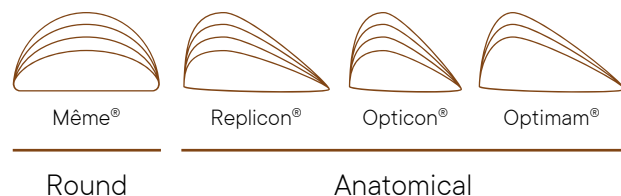
While it is common to refer to breast implants as merely round or anatomical, it is more accurate to define the shape of breast implants by the following features:

- Base, which is the side with which the implant rests on the rib cage and can be round, short or oblong
- Profile, which can be round or dome-shaped or anatomical or teardrop-shaped
- Projection means how much the breast implant extends forward in front of your chest. It generally can be low, moderate, high or extra high

Implants with a round profile are generally considered suitable for the reconstruction of a more youthful breast, as they tend to fill out the upper pole of the breast in favour of an accentuated décolleté, whereas the anatomical or teardrop shaped implants have the natural curved shape of an adult woman's breast.

In addition to the different bases, profiles and projections, implants are available in different volumes, or sizes. This diversity is required in order to accommodate different body types and breast shapes. In a detailed consultation, your doctor will take the time to discuss your options and find the implant that is most suitable for you.

The shapes of POLYTECH implants:

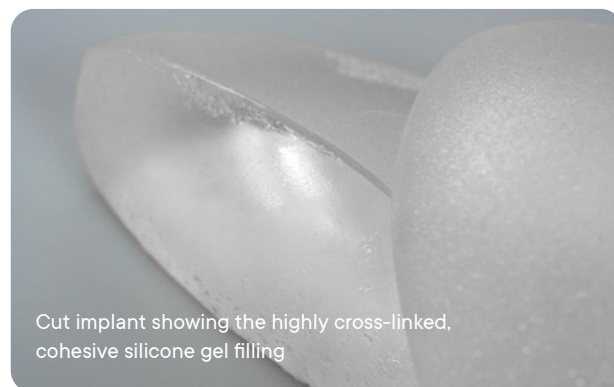


►► THE FILLING

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 far less often because they tend to feel less natural and come in a limited range of shapes.

State of the art implant technology, also offered by POLYTECH, has allowed the production of silicone implants to be filled with a highly cross-linked, cohesive silicone gel. In these, the cross-linking of the gel preserves its form. These types of implants also revert to their original shape when touched or moderately pressed.

Today's implants are much safer than the implants of earlier generations due to the significantly improved manufacturing standards. All implants have a diffusion barrier that minimizes the risk of small silicone molecules to migrate into the surrounding tissue. In addition, the low molecular weight components in the highly crosslinked and cohesive gel filling have been drastically reduced. If these implants are damaged, they will not leak in case of rupture.



»» THE SURFACE

Breast implants are available with a smooth, textured or micro-polyurethane foam-coated surface. Why is that?

The first breast implants were manufactured in the 1960s and had a smooth surface. A polyurethane foam covering was introduced in the 1970s to minimize the event of capsular contracture as well as implant dislocation and rotation. Textured implants were introduced in the late 1980s, to mimic the effect of the polyurethane layer.

What is capsular contracture? As part of the body’s natural reaction, a capsule of connective tissue is formed around any foreign body inserted into the tissue, including around breast implants. 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, and so to the shape of the breast. Additionally, the capsule can become very hard and cause pain. Capsular contracture is the most common complication of breast implant surgery and is classified using the Baker scale (see the section Risks and complications with breast implants).

Baker scale for capsular contracture

Grade I	The breast is normally soft and appears natural
Grade II	The breast is a little firm and appears natural
Grade III	The breast is firm and appears abnormal
Grade IV	The breast is hard, painful to the touch, and appears abnormal

A capsular contracture may never occur, or it may occur after weeks, months or years. It cannot be predicted if or when a capsular contracture will occur and, if it does, how pronounced it may be.

Capsular contracture rates, as well as rates of other complications such as rotation and dislocation, vary in relation to the implant surface⁵:

	Smooth implants	Textured implants	Polyurethane-covered implants
Capsular contracture rate	30 - 50%	15 - 30%	0 - 9%

In most of the large studies, the capsular contracture rate for polyurethane-foam-covered implants is as low as 0-3%⁵.

Recent studies have shown that POLYTECH Microthane® implants are a safe choice for breast reconstruction, and have lower complications even in cases of radiation treatment, which is known to dramatically increase the risk of capsular contracture⁶.



RISKS AND COMPLICATIONS WITH BREAST IMPLANTS

Complications are unfavourable evolutions or consequences of a disease, a health condition, a therapy or a procedure. The goal of surgery is to have as few complications as possible and the surgeon will try to minimize them, however, breast reconstruction is associated with risks and complications. We have compiled a list of the most common complications, with an explanation and, where appropriate, with recommendations.

■ Capsular contracture or capsular fibrosis

When any foreign body is placed inside an organism, the physiological reactions include metabolism, expulsion or isolation. In the latter case, a capsule is formed around the foreign body, which is what happens with breast implants in the human body. This capsule can tighten around the implant and contract. The 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 its occurrence rates vary according to implant surface. A significant capsular contracture will result in implant removal.

■ Seromas

Seromas develop as an accumulation of serous fluid around the implant, which can lead to pain and excessive swelling of the breast(s). Several reasons can cause seromas: intra-operative or post-operative traumatization, excessive post-operative mobility of the implant or infection. Possible treatments: compression, drainage or implant removal, if necessary. Seromas may develop early, immediately after surgery, or late, occurring several months after surgery. See the section on Anaplastic Large-Cell Lymphoma.

■ Pain

Pain may occur in the operated area as well as in the chest muscle, shoulder or arm after breast surgery. Continuous pain may be due to improperly sized or placed implants. Over-sized implants, capsular contracture as well as irritations due to excessive implant movement, may provoke pain. Please consult your surgeon immediately to clarify the cause of pain following an operation.

■ Reddening of the skin or “rash”

This complication can be observed in a low percentage of patients. This reddening of the skin should not be confused with an infection. It differs from an infection by itching and the absence of systemic infection symptoms. It usually occurs 7 to 10 days after the implantation and can last 2 to 3 weeks. The use of steroids may be necessary.

■ Chest wall deformity

The rib cage may be deformed due to the pressure exerted by the implant.

■ Calcification

Benign calcification around the implant is possible.

■ Infections

Infections may present with fever and/or inflammation. Infections in connection with breast implants are very rare: 0.114%⁷. Infections with unclear aetiology that occur after breast implantation surgery should be treated immediately. The use of antibiotics, drainage or implant removal may be necessary. Not all infections can be treated while the implant remains in the body. The “toxic shock” syndrome has been reported in extremely rare cases in connection with breast implants.

■ Inflammation or irritation

Reactions of the body to an infection or injury showing as redness, swelling, pain.

■ Implant rupture

Failure of the integrity of the implant shell. Implant damage (intraoperatively, e.g. by too short incisions, by surgical instruments, or postoperatively, e.g. in case of punctures, biopsies etc.), trauma or material fatigue are, in our opinion, the most frequent reasons. After rupture of a gel-filled implant, the consistency of the silicone gel prevents diffusion. However, it is not guaranteed that the gel remains a complete entity. Ruptures may be noticeable (symptomatic ruptures) or not (silent ruptures). Magnetic resonance imaging (MRI) is the most effective method for detecting silent rupture of silicone gel-filled breast implants. If a rupture is diagnosed the implant should be replaced.

■ Permeation of silicone

All modern breast implants are equipped with special barrier layers to prevent the diffusion of silicone particles through the shell. While the passage of low molecular weight silicone components through the shell of the implant cannot be completely excluded, the small amounts of gel remain within the tissue capsule that physiologically grows around the implant⁸.

■ Granuloma

Granulomas are accumulations of cells of the immune system (inflammation), which may result from an implant rupture or from silicone permeation. Granulomas of an unknown origin may require a biopsy or implant removal.

■ Swelling of the axillary lymph nodes

Lymph nodes are small structures located all over the body around blood vessels. They are part of the lymphatic system of the body. They can swell and become tender or painful in cases of a local infection, an infection affecting the whole body, cancer or immune disorders. Axillary lymph nodes are the lymph nodes located in the armpit and which drain the breast area of fluid. Some patients with breast implants have been found to have enlarged lymph nodes in the armpit. This is referred to as lymphadenopathy. It has been reported to occur in women with both ruptured and intact silicone gel breast implants. If an enlarged lymph node becomes painful, it may need to be surgically removed. You should immediately report any painful or enlarged lymph nodes to your doctor.

BREAST CANCER

The extensive studies available show that women with breast implants are not subject to a higher risk of breast cancer than women without breast implants⁹. In other words, a breast implant has no influence on the occurrence of breast cancer. While scientists do discuss the theoretical risks of this disease with implants, breast cancer as a direct result of breast implants has not been observed in humans.

It is important that you undergo all the usual breast examinations, such as self-examination, the annual preventive medical check-up at the doctor's and possible imaging procedures (mammary

sonography, tomosynthesis, mammogram, magnetic resonance imaging (MRI)) to detect possible breast cancer. Modern imaging techniques such as sonography, MRI or computer tomography (CT) help to find tumours at an early stage¹⁰.

Make sure to self-examine your breasts at regular intervals. For post-operative self-examination, your surgeon should instruct you on how to distinguish between the implant and your own tissue to enable you to detect nodules 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 painful. If you find any changes, please consult a surgeon.

BIA-ALCL

Reports from regulatory agencies and medical literature have shown an association between breast implants and the development of ALCL, resulting in the term BIA-ALCL or Breast Implant-Associated Anaplastic Large Cell Lymphoma. This means that women with breast implants may have a small increased risk in developing ALCL. There are several different estimates of the risk of developing BIA-ALCL.

The vast majority of cases in literature concern patients with history of use of textured implants.

ALCL is currently classified as a form of non-Hodgkin's lymphoma (NHL) – a cancer of the immune system. It typically presents as a late seroma – the accumulation of liquid within the capsule – but it may also occur with the formation of a mass. The symptoms may occur well after the surgical incision has healed, often years after implant placement, but there are known cases with a shorter time of occurrence.

ALCL is a rare but serious type of cancer. There are documented cases of death due to the spreading of the disease out of the capsule. When detected early and timely treated, this disease has a positive prognosis. In most patients, it is treated successfully with surgery to remove the implant and surrounding scar tissue, but for some patients chemotherapy and radiation therapy may be necessary.

It is very important that you continue to attend regular check-ups and perform self-examination. If symptoms such as swelling, pain or a lump in the implant region occur, you should immediately inform your doctor.

If you have breast implants and have no symptoms, you do not need to do anything, but you should continue to routinely monitor your breast implants and follow your routine medical care. Removing the implants is not recommended in women with no symptoms without a confirmed diagnosis of BIA-ALCL.

SCREENING DIAGNOSTICS

Silicone implants can interfere with screening techniques and may have a falsifying effect on results, but special techniques have been devised to reduce these limitations.

In addition, invasive methods for diagnosis and treatment such as biopsies could potentially damage the shell of the implant and lead to implant removal.

Make sure you inform in advance the physician and the medical staff involved about the presence of your implants so that they may suggest the most suitable screening method and perform examination with the appropriate technique.

Please note MRI examinations are contra-indicated when using certain expanders in a two-stage breast reconstruction. Ensure you inform the doctor or technician if you have an expander or if you will need to undergo MRI during your reconstruction process.

YOU AND YOUR SURGEON

Please remember that breast reconstruction is a surgical procedure; this means that even a specialized surgeon may not guarantee a successful outcome. Of course, the experience and skill of the surgeon will have an impact on the outcome of the surgery. Therefore, it is important to take your time to find a surgeon you can trust.

Breast Cancer Care organizations may help you find a surgeon in your area. A good source for addresses of reconstruction specialists are professional associations and patient support groups. In some countries, there are breast health centres that

may help you with your search. Maybe friends and acquaintances have experience of a surgeon and can provide a recommendation. In some hospitals and clinics, you may look at images of former patients or even make contact with them to ask questions.

During your consultation with your surgeon, you should not hesitate to ask them about their experience of breast reconstruction. A good surgeon will schedule enough time for a detailed consultation and examine you thoroughly. They will not make any unrealistic promises about the expected result and will not push you to make a quick decision.

A thorough preliminary examination includes questions about the cancer treatments you have received or will receive, allergies, chronic diseases, drugs that you are taking, tendency for increased scarring, and other factors that could influence the outcome of surgery. You should receive thorough answers to your questions and feel free to seek a second or third opinion.

WHAT QUESTIONS SHOULD YOU ASK THE SURGEON?

Make a list of all your questions before your appointment, discuss them with your surgeon during consultation, and take your time afterwards to make your final decision.

FOLLOW-UP AFTER SURGERY

Once you have undergone surgery, you should take advantage of all check-up appointments offered by your surgeon and have at least an annual check of your breast implants.

For more information, please see our brochure: *A Breast implant for me* or visit POLYTECH on www.polytech-health-aesthetics.com



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