



DISPOSITIFS MÉDICAUX IMPLANTABLES STÉRILES

Considering the use of silicone breast implants



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Glossary of terms

Asymmetry With regard to breasts, describes imbalance in the proportion, size and shape of the left and right breasts resulting in an unacceptable appearance.

Autoimmune diseases A group of diseases where the body's immune system starts to attack itself.

Breast augmentation Surgery to change the size or enhance the shape of the breasts.

Capsule The scar tissue which forms around a breast implant. This is the body's normal response to the presence of any foreign object.

Capsular contracture Where the capsule surrounding a breast implant tightens. Extreme cases can cause the breast to feel hard and painful. It may also lead to disfigurement where the capsule surrounding one implant contracts and the other does not, or if the capsule contracts unevenly. Women experience different degrees of capsular contracture for reasons as yet unknown.

Closed capsulotomy A procedure to break a contracted capsule by squeezing the breast. The procedure can be extremely painful and may cause implant rupture. It is not recommended and is no longer widely used.

Congenital deformity A deformity that is present from birth.

Connective tissue Fibrous tissue connecting and supporting the body organs and the cells within these organs.

Envelope Outer layer that encloses the contents (saline or silicone gel) of the breast implant. It is usually made of a thick silicone compound.

Gel diffusion Where tiny amounts of silicone gel pass through the intact implant envelope or shell into the surrounding capsule and breast tissue. This silicone gel can also travel to the draining lymph glands.

There is no evidence that this silicone gel can also travel to other body tissues.

Lumen The cavity or channel within a hollow object or tube.

Magnetic Resonance Imaging (MRI) A medical diagnostic technique that creates images of the body using the principles of nuclear magnetic resonance. Utilises radio waves within a magnetic field. Can be used to create images of the breast and surrounding tissues.

Mammogram A special x-ray to detect breast cancers or other breast abnormalities including breast implant rupture. The radiographer should be informed that you have breast implants as special techniques must be used.

Mastectomy A surgical procedure to remove a breast.

Prophylaxis The prevention of disease.

Reconstruction Breast reconstruction refers to the operation performed to create an artificial breast after mastectomy.

Rupture Rupture of an implant refers to a break in the envelope of an implant. The rupture can be a pin-hole sized defect or a large tear of the envelope.

Saline Salt water used to fill saline breast implants and tissue expanders. Saline is absorbed easily by the body if the implant ruptures or leaks. Saline (sodium chloride) is found naturally within the body.

Silicon Silicon is a chemical element occurring in nature. It is the most abundant element in the earth's crust. In various combinations it forms sand, rocks and glass.

Silicone Is a plastic or polymer made partly from silicon. Silicone can come in solid, liquid or gel forms. Silicone breast implants consist of a solid silicone outer shell filled with silicone gel.

Silicone granulomas Are small lumps that sometimes form in breast and other body tissues around leaked silicone from silicone implants.

Tissue expander Is a type of saline breast implant which is used to stretch the skin of the breast. Saline is regularly injected into the expander through a valve under the skin until it stretches enough to allow insertion of a permanent implant. Some tissue expanders are left in the breast permanently as implants.

Ultrasound A medical diagnostic technique in which very high frequency sound is directed into the body and the reflected sound is processed by a computer to produce a photograph or a moving image on a television. Can be used to detect abnormalities of the breast(s).

1. INTRODUCTION

1.1 About the booklet

This booklet has been provided to assist you in learning some basic information about silicone breast implants and specifically implants manufactured by Poly Implants Prothèses. The information in this booklet has been compiled to:

- provide you with information about these implants; and
- give you the information necessary to make an informed choice about breast implants.

The focus of this booklet is silicone gel-filled breast implants because their use has raised considerable health concerns and as a result they have been extensively studied. Specific information relating to Poly Implants Prothèses silicone breast implants is included as appropriate.

It is suggested that you make a note of any questions you have as you read this booklet and discuss these with your surgeon. (See Section: *Suggested questions to ask your Surgeon before surgery* in point 7).

1.2 History of breast implants

In the early 1960s, manufacturers and the medical community developed the silicone gel-filled breast implant to improve the options for women requiring mastectomies or correction of congenital deformities. The original devices had a smooth outer envelope of silicone rubber (elastomer) filled with silicone gel.

In the 1970s, manufacturers sought to improve the second generation silicone-gel-filled breast implants by reducing the thickness of the outer envelope and making the silicone gel more fluid. This outer envelope was prone to rupture and also there was increased diffusion of silicone gel through the intact breast implant envelope. Surgery to remove leaking silicone gel resulted in extensive scarring of patients' chest wall and abdominal wall.

In the 1990s, manufacturers improved the third generation (current) silicone gel-filled breast implants by increasing the thickness of the outer envelope, by adding an inner barrier layer to limit silicone gel diffusion, and by using a thicker silicone gel material which is less likely to migrate into surrounding tissues should rupture occur.

The short-term results of breast implant surgery were so effective that by the 1970s and 1980s an increasing number of women were having cosmetic breast augmentation surgery. Most of the women reported satisfaction with the cosmetic results and many felt an improved sense of self-confidence and self-image.

However, breast implant recipients were not informed about the risks associated with these implants and many women assumed that these devices were lifelong devices that required no ongoing care or examination. Generally, they were unaware of the complications that could arise as the implants aged. In the early 1990s there was growing concern about the safety of silicone gel-filled breast implants. A leading manufacturer of these implants stopped production and some regulatory authorities imposed additional conditions and restrictions on the supply of breast implants. These actions were in response to anecdotal reports of leakage of silicone gel and its spread through the body. At the time, rigorous and systematic studies had not been conducted to establish the safety of these implants. Concerns were raised that the diffusion and/or leakage of the silicone gel was associated with an increase in systemic diseases in women with silicone gel-filled breast implants. There were also widespread

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reports of local problems, such as capsular contracture around the implants that resulted in distortion, hardness, loss of sensation and/or pain.

A review of recent scientific literature has now established that there is no convincing evidence that silicone gel-filled breast implants cause cancer or any classic connective tissue disorder (eg, scleroderma, rheumatoid arthritis or systemic lupus erythematosus). However, there is no doubt that these implants can cause local complications such as capsular contractures which may result in a need for replacement and/or corrective surgery as the implants age.

1.3 Silicon and silicone

Silicon is a chemical element occurring in nature; in fact it is the most abundant element in the earth's crust. In various combinations it forms sand, rocks and glass. Silicones are plastics or 'polymers'. They are complex man-made substances containing silicon, oxygen and other chemical elements. Depending on their structure, silicones can be liquid, gel or solid.

Silicone has been regarded as one of the most compatible materials available for implanting into the human body. Silicones are used in medical devices, medicines and food preparation. All humans carry some silicone in their bodies. Some laboratories claim they can test for the presence of silicone in the blood and urine, but these tests can only show the total amount of elemental silicon. They cannot distinguish between elemental silicon, which occurs naturally in the body, and silicone which may be from breast implants.

Silicone materials have been extensively tested in laboratory studies, as well as clinical studies (which study human health). Much scientific evidence has already been gathered on the basis of the one to two million women who have received breast implants. There has been no epidemiological evidence found associating silicone breast implants with permanent connective tissue disease or cancer.

Silicones have been part of the consumer industry for over 50 years. Because they can be manufactured in various ways, silicones appear in a wide variety of products that most of us use every day. Hairsprays, suntan lotions and moisturising creams are just some of the consumer products that contain one form of silicone called dimethicone.

The application of silicone, whether used as an oil, gel or solid, is equally extensive in the medical field. For example, the lubricating qualities of silicones make them ideal for coating surgical needles and suture thread, as well as the interior surfaces of syringes and bottles used for the storage of blood and intravenous medicines. Protective silicone coatings have also been used in pacemakers and heart valves. Other medical devices utilising silicones include: artificial joints, catheters, drainage systems, facial implants, tissue expanders and breast implants. Silicone products have been shown to be biocompatible (i.e. accepted by the human body without adverse reaction), reliable, flexible, and easy to sterilise, making them an ideal choice for both implantable and non-implantable medical devices.

1.4 Types of breast implants

At present most breast implants are filled with either saline or silicone gel. Currently, there are predominantly three types of breast implants being manufactured:

- Silicone gel-filled implants.
- Saline-filled implants.
- Double lumen implants – silicone gel-filled core and saline-filled periphery.

In all instances the implant contents are enclosed in a dense walled, silicone elastomer envelope. The surface of the envelope may be either textured or smooth.

Over the years, the design, construction and production process of breast implants have been improved by the manufacturers. These improvements are aimed at reducing the risks of capsule formation, gel diffusion and implant rupture. Currently available implants are manufactured under strict quality control guidelines to greatly reduce the possibility of these complications. Regardless of all the controls, manufacturers cannot guarantee that the use of their implants will not lead to complications. Therefore, all potential breast implant recipients should carefully consider the risks and benefits prior to consenting to surgery.

What types of breast implants are available from POLY IMPLANTS PROTHÈSES?

The silicone gel pre-filled breast implants of Poly Implants Prothèses company can have a different shape / profile.

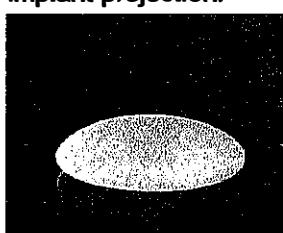
Five different profile types can be found :

- standard profile (S),
- high profile (H),
- extra high profile (EH)
- reconstruction profile (R),
- asymmetrical profile (AR or AL).

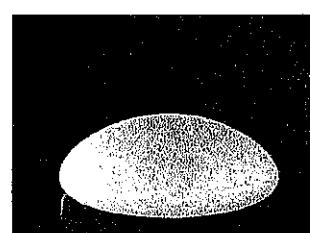
The first three profiles (standard high and extra high) are hemispherical profiles. For a given volume, the main features of the implant are the projection / height and diameter.

To an equivalent volume, a standard profile projection is lower than that of a high profile whereas its diameter is greater.

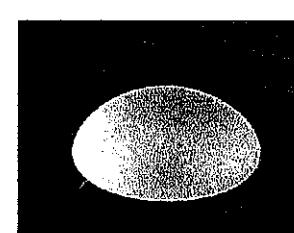
The extra high profile was studied under the basis of the "over-filled" high profile so as to increase the implant projection.



Standard profile

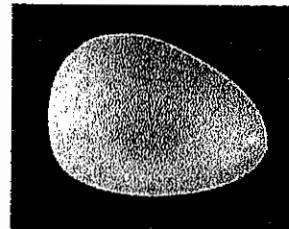


High profile

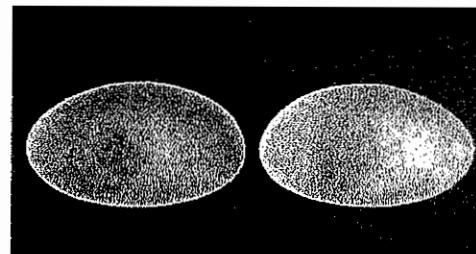


Extra-High profile

Reconstruction profiles have a slightly more complex shape, in so far as the implant shape is closer to that of a breast. That's the reason why the reconstruction profile designation was linked to this type of implant. In case of reconstruction surgery consecutive to the breast removal, this implant type helps filling in the total or almost total absence of mammary gland.

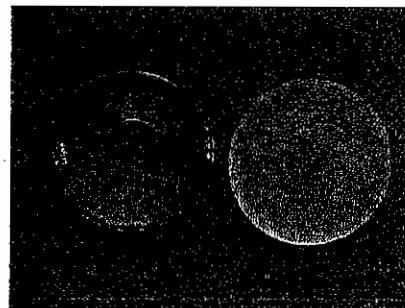


The asymmetrical profiles have no symmetry axis and can be divided into two categories: left side (AL) and right side (AR). This implant shape was studied so as to fit the patient gland, the pectoral muscle and the surrounding fibrous tissues.



The external structure of the high cohesivity gel pre-filled breast implant envelope can be of two types:

- smooth surface (LS),
- textured surface (TX).



In augmentation surgery a breast implant can be placed either over the pectoralis muscle (subglandularly) or partially under this muscle (submuscularly), depending on the thickness of your breast tissue and its ability to adequately cover the breast implant. In reconstruction following mastectomy, a breast implant is most often placed submuscularly.

Reconstruction following mastectomy may involve a two-stage procedure, which includes placement of a tissue expander for several months prior to placement of the breast implant.

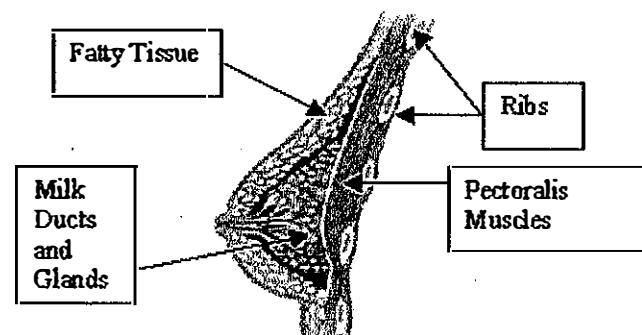
The silicone elastomer (rubber) contains the following substances:

- Small amounts (parts per million) of various smaller silicones;
- Trace amounts of metals (platinum < 10 ppm);
- Trace amounts of volatile materials like xylene and other organic compounds;
- Important quantities (around 10 %) of crystallin silica, inherent to the manufacturing of the silicone rubber.

2. DECIDING TO HAVE BREAST IMPLANTS

2.1 What gives the breast its shape?

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. Situated beneath the breast is the pectoralis major muscle (chest muscle) of the chest wall. Factors such as pregnancy, (when milk glands are temporarily enlarged), rapid weight loss, and the effects of gravity as your age combine to stretch the skin, which may cause the breast to droop or sag.



2.2 Making your decision

This booklet is designed to help you obtain enough information about breast implants from your doctor so that you can make a careful and informed decision about whether to undergo this surgery. You should make sure that all your questions are answered by your surgeon or doctor before you make your decision. In particular, you should ask about other surgical options that do not involve the use of breast implants. You may wish to have a second opinion before you agree to breast surgery. You may also wish to have someone else with you when you talk with your surgeon or doctor.

Your surgeon should give you copies of breast implant information which should include the product information for the attention of patients and surgeons packaged with each device. It is very important that you read this information as it will tell you about the risks associated with the particular implant you are considering.

It is also recommended that you speak with a counsellor about any non-medical issues before you make your decision. Counsellors are available in many women's health centres. Further information can be obtained from other women who have had breast implants, women's health services, and support groups. Information about non-surgical alternatives to breast implants such as breast padding and specially designated bras can be obtained from your State Health Department or Cancer societies and support groups.

After obtaining all the information it is recommended that you think about the risks and benefits of having breast implants for at least 30 days before making a final decision.

2.2.1 Reasons for breast implant surgery

The main reasons for undergoing breast implant surgery are:

- augmentation to increase breast size and/or shape (cosmetic);
- reconstruction following mastectomy;
- replacement of an existing implant for medical or cosmetic reasons;
- correction of a congenital deformity;

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2.2.2 What are important factors for you to consider when deciding to have breast implants

- Whether you are undergoing augmentation or reconstruction, be aware that best implantation may not be a one time surgery. You are likely to need additional surgery and doctor visits over the course of your life.
- Breast implants are not considered live time devices. You will likely undergo implant removal with or without replacement over the course of your life.
- Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast.
- Breast implants may affect your ability to produce milk for breast feeding. Also, breast implants will not prevent your breast from sagging after pregnancy.
- With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.
- For patients who have undergone breast implantation either as a cosmetic or a reconstructive procedure, health insurance premiums may increase, coverage may be dropped, and/or further coverage may be denied. Treatment of complications may not be covered as well. You should check with your insurance company regarding these coverage issues.

2.2.3 Life expectancy of breast implants

Breast implants are artificial devices which will gradually age and wear out, and may eventually need to be removed or replaced. As the time after implant surgery increases, there is a greater risk of implant rupture and gel diffusion. How long the breast implant remains without complications depends on the type of implant inserted, the type of surgery you had and how much physical activity you do. Injury to the breast and excessive repetitive compression of the implant against the chest wall may reduce the life of the implant.

Depending on your age when you have a breast implant, you can expect that the implant may need to be replaced at some time in your life. There are reports that some implant recipients have experienced no problems after 25 years, while others have experienced problems almost immediately after the procedure. Recent studies indicate that the risk of experiencing problems with the breast implant increases significantly 8 to 10 years after the surgery. If you have any problems with the implant, it is recommended that you have your implants checked by your doctor.

2.2.4 Implants following mastectomy

The complications are significantly higher in women who received implants following mastectomy for cancer or cancer prophylaxis than among those who received implants for cosmetic reasons. This is because mastectomy patients are generally older and they have little tissue between the implant and the skin. Furthermore, radiation therapy may affect the skin and underlying tissue.

You have probably already had a mastectomy, involving removal of breast tissue together with skin and the nipple-areola complex. While this medically necessary removal is, or was undoubtedly for the best, like many women in your situation you may feel a great loss.

Living with the diagnosis of breast cancer is difficult, but as many women have proven, the disease is surmountable. Current medical technology offers you many ways to restore your physical and emotional well-being.

Considering what you are going through, the decision to opt for breast reconstruction may be complex, and only you can make that decision. Many women opt for breast reconstruction not only because they want to restore their own familiar curves, but also because it may allow to bring a worrying time to a close. Opting for breast reconstruction can help you make a positive start to a new period of your life. Breast reconstruction techniques have gained momentum in the past few years. Breast implant shapes and other options have also improved considerably. Although reconstruction can never make up for the loss of one's own breast, the results are generally very good.

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2.2.5 Benefits and risks of breast implant surgery

Many women have reported satisfaction with the appearance, size and softness of their breast implants. They have reported that breast implants have improved their self-confidence and self-image, maintained or increased their sense of well-being, have been an aid in their recovery from breast cancer and have reduced emotional stress. Some women have not experienced these benefits. They express dissatisfaction with their breast implants because of capsular contracture (tightening of the scar tissue around the implant), rupture, hardness, pain, etc.

The next section of this booklet details the risks associated with breast implants.

2.2.6 Conditions under which breast implants should not be used

Breast implant manufacturers recommend that in the presence of certain medical conditions, breast implant surgery is not advisable. You should inform your doctor if you have or have had:

- previous unsuccessful breast implant surgery;
- a history of repeated breast cancer or other cancer which has spread;
- an infection or have recently had one;
- painful 'cystic' breasts;
- an allergy to silicone;
- drugs that would interfere with blood clotting; or
- psychological or psychiatric illness.

It is important that you read the product information relating to your particular implant and discuss any concerns you may have with your doctor or surgeon.

2.3 Breast implant surgery

2.3.1 Implant shape and size

Depending on the desired shape you wish to achieve, you and your surgeon may choose a standard or high profile implant shape. Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimetres, or cc's). You should be aware that contoured implants that are placed submuscularly may assume a round shape after implantation.

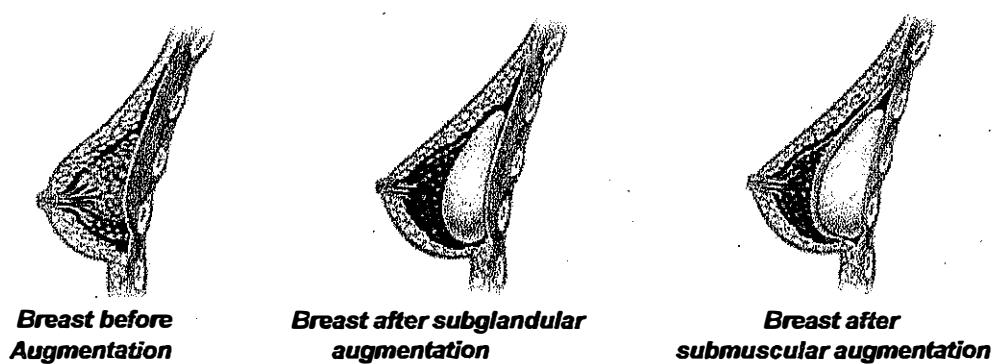
Your surgeon will also evaluate your existing tissue to determine if you have enough to cover the breast implant. If you desire a breast implant size too large for your tissue, the doctor may warn you that breast implant edges may be apparent or visible post-operatively. You may even risk surgical complications. Also, excessively large breast implants may speed up the effects of gravity and result in earlier droop or sag.

2.3.2 Implant placement

The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast glands (subglandular). You should discuss with your surgeon the pros and cons of the implant placement selected for you.

The **submuscular placement** may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to have some re-operation procedures than the subglandular placement. The possible benefits of this placement are that it may result in less palpable implants, less capsular contracture, and easier imaging of the breast with mammography.

The **subglandular placement** may make surgery and recovery shorter, may be less painful, and may be easier to access for re-operation than the submuscular placement. However, this placement may result in more palpable implants, more capsular contracture, and more difficult imaging of the breast with mammography.



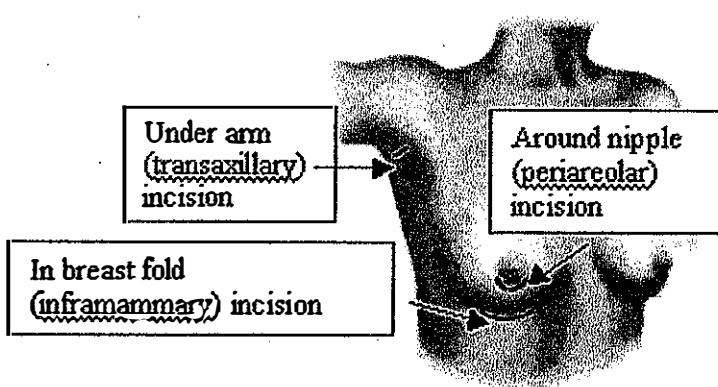
2.3.3 Tissue expanders

If you only have a small area of skin over your breasts, the surgeon may use an implant known as a tissue expander. Generally, tissue expanders are only used in women who have breast implants following mastectomy. The tissue expander is a saline implant where saline is injected into the implant through a valve under the skin over a period of time until the skin stretches enough so that a permanent implant will fit. Tissue expanders come in two types: one type is removed once it becomes fully inflated and a permanent implant is put in place; the other type remains in your breast as a permanent implant once it has been inflated.

2.3.4 Incisions

There are three possible incisions (ie, cuts in the skin) through which a breast implant can be inserted:

- The most common incision is along the crease beneath the breast where it meets the chest wall (inframammary incision).
- Some surgeons prefer to make an incision around the nipple (periareolar incision).
- Other surgeons may prefer an incision in the armpit through which they can gain access to the chest muscle and place the implant either in front or behind that muscle (transaxillary incision).



Before surgery starts, marks are drawn on your skin to show where the cut will be made.

2.3.5 Surgical setting and anaesthesia

Augmentation - Augmentation surgery is usually performed on an outpatient basis, either in a hospital operating room, surgery centre, or surgical suite in the surgeon's office. General anaesthesia is commonly used, and local anaesthesia is also an option. The surgery usually lasts one to two hours. Your surgeon will make an incision and create a pocket for the breast implant. Then, the breast implant will be placed in the pocket, and positioned. Finally, the incision will be closed, usually with stitches, and possibly taped.

Reconstruction - Reconstruction surgery is usually performed on an inpatient basis in an operating room. General anaesthesia is most often used. See the section on special considerations for reconstruction for details regarding immediate versus delayed surgery and other reconstruction options such as use of tissue flaps.

2.3.6 After the operation

It is very likely that you will have a drainage tube in place for a few days to allow any blood or fluid which may collect in the wound to escape.

2.3.7 How long will you be in hospital?

The majority of breast implant surgery is performed as a day surgery procedure, ie, you enter hospital in the morning and go home in the afternoon. However, you may need to stay in hospital for 1-3 days if the surgery is complex or if you have a high risk of developing complications. Your stay may need to be longer if you have any complications after the surgery.

2.3.8 Post-operative care

Augmentation - You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size.

Post-operative care may involve the use of a post-operative bra, compression bandage, or jog bra for extra support and positioning while you heal. At your surgeon's recommendation, you will most likely be able to return to work within a few days, although you should avoid any strenuous activities that could raise your pulse and blood pressure for at least a couple of weeks. Your surgeon may also recommend breast massage exercises.

Reconstruction - Depending on the type of surgery you have (i.e., immediate or delayed), the post-operative recovery period will vary. See the section on special considerations for reconstruction below.

Note: For both augmentation and reconstruction, if you experience fever, or noticeable swelling and/or redness in your implanted breast(s), you should contact your surgeon immediately.

2.4 Surgery complications

There is a slight but important risk of death or brain damage from any general anaesthetic—about one death occurs in every 250,000 anaesthetics given to healthy people.

Other general complications which may occur in breast implant surgery are:

2.4.1 Infection

Infection is possible in any operation, but is more difficult to cure when a foreign object (such as an implant) is introduced into the body. If you develop an infection you will need to see your doctor as soon as possible. You may need to have a further operation to remove the implant until the infection has cleared and then have your implant replaced. Although most infections can be treated successfully, infections can cause serious problems and may result in increased scarring. In a small number of cases these infections may come back.

2.4.2 Scarring

You will have a scar where the surgeon has made the cut into your skin. The position, the length and the type of scar may vary according to a number of factors. Some patients develop red, thick scars known as keloid scars. You should discuss these factors with your surgeon.

2.4.3 Haematoma / Seroma

Haematoma is a collection of blood inside a body cavity, and a seroma is a collection of the watery portion of the blood (in this case, around the implant or around the incision). Postoperative haematoma and seroma may contribute to infection and/or capsular contracture. Swelling, pain, and bruising may result. If a haematoma occurs, it will usually be soon after surgery, however this can also occur at any time after injury to the breast. While the body absorbs small haematomas and seromas, large ones will require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation/rupture can occur from surgical draining if damage to the implant occurs during the draining procedure.

2.4.4 Poor wound healing

Wound healing may take longer if any of the following things happen: infection, bleeding, fluid accumulation, stitches being too tight, too large an implant, diabetes, improper support and pressure against the scar tissue.

2.4.5 A breakdown of skin, known as necrosis

Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

2.4.6 Incorrect implant size, inappropriate location of scars or misplacement of implants

This can happen if the measurement of your chest is not done or not measured accurately. The position, the length and the type of scar may vary according to a number of factors. You should discuss these factors with your surgeon.

2.4.7 Wrinkling of the implant

Visible and palpable wrinkling may occur with saline implants. It occurs more commonly in thin women.

2.4.8 Breast Tissue Atrophy/Chest Wall Deformity

The pressure of the breast implant may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement.

2.4.9 Visible or palpable implants

In women with little breast tissue the implant may be obvious on looking at the breast or it may be easily felt as a foreign object.

2.4.10 Pain

Pain and discomfort occur in the first few days following surgery. Very occasionally severe pain associated with arm movement has been reported. Pain may later occur with the development of capsular contracture.

2.4.11 Rupture/Deflation

Patients should be advised that their implants might rupture, releasing silicone gel or saline, and require replacement or revision surgery. Damage may result in immediate rupture, or may weaken the envelope and result in rupture/deflation post-operatively.

2.4.12 Rotation

Rotation of the implant may occur. Proper placement and pocket dissection reduces the risk of occurrence.

3. ISSUES ASSOCIATED WITH BREAST IMPLANTS

There are risks associated with any device that is implanted. Fewer complications are experienced by women who received implants for cosmetic reasons than by those who received implants following mastectomy for cancer or for cancer prevention.

3.1 Local complications

3.1.1 Capsular formation and contracture

The body's normal response to a foreign body (such as a breast implant) is to form a shell or a capsule of scar tissue around it. This scar tissue may tighten or contract and may cause:

- extreme hardening of the breast;
- pain—ranging from mild discomfort to severe pain;
- extreme sensitivity to touch;
- wrinkling or distortion of the breast; or
- movement or displacement of the implant.

Capsular formation and contracture is the most common local change after implantation. Contractures can occur weeks or years after implantation. The body's response to any foreign object varies greatly from person to person. How much the capsule will contract, if at all, is hard to predict. If the capsule surrounding the implant contracts or shrinks evenly then the breasts will look even, but will be firm. If the capsule contracts unevenly then one or both of the implants may be pushed out of place and the breasts will look uneven. Where excessive capsular contracture occurs, the breast can become hard, look deformed and pain can result. If this happens you may need to have a further operation to have the capsule and/or implant removed.

Other less common results of capsular contracture are increased gel diffusion or rupture of your implants. It is possible that the implant may be pushed through the capsule which surrounds it, but this is rare. Sometimes calcium salt deposits may be found in the capsule. This is called calcification. These deposits may make it difficult to detect early breast cancer on mammography. There is no single cause of capsular contracture. It is believed, however, that many factors can contribute to it, including infection, swelling of the tissue because of bleeding, lack of drainage around the site of the incisions, use of the wrong implant size, implant surface characteristics and the body's reaction to the implant.

The following procedures are used for the treatment of capsular contracture once it occurs:

- 'Open capsulotomy' is a surgical procedure whereby the surgeon cuts the capsule to relieve capsular contracture.
- 'Capsulectomy'. This is a surgical procedure whereby the surgeon removes the scar tissue surgically.
- 'Closed capsulotomy'. A procedure in which the surgeon externally manipulates and squeezes the breast to break down the capsule surrounding the implant. This procedure has been used in the past and is no longer recommended, as it is known to cause the implant to rupture with subsequent escape of silicone gel into the surrounding tissue.

With the first two procedures, even though capsular contracture is relieved, in up to 50 per cent of women the contracture happens again.

3.1.2 Implant rupture and gel leakage

Rupture of your implant **MAY** occur without warning or **MAY** occur as a result of:

- injury;
- normal wear and tear of implant envelope;
- closed capsulotomy (a technique that uses manual pressure to break up fibrous scar tissue around the implant);
- implant age; or
- mammography (breast X-rays).

If a silicone gel implant ruptures, the gel is usually contained within the capsule around your implant. Sometimes, the gel does not remain within the capsule, and may be found in nearby breast tissues. Some of the silicone gel may travel (migrate) to the draining lymph nodes. However, with improved modern implants this migration of silicone is diminished. Current research does not indicate any adverse effects from this 'free' silicone gel, except the presence of some local enlarged lymph nodes. There is no evidence that this silicone gel can also travel to other body tissues. In some cases implant rupture can occur in the absence of any symptoms.

However, when symptoms occur they may include:

- lumps in the breast, or decreased breast size;
- distorted shape of the breast;
- asymmetry; or
- pain (sometimes characterised by burning) or tenderness.

You are advised to see your doctor if you notice these symptoms, or if you think your implant may have ruptured. In such cases, removal of the implant may be necessary. Clinical examination alone is not accurate enough to diagnose a ruptured implant. Rupture and leakage of silicone gel implants can often be seen on mammograms (special X-rays of the breasts). If the mammogram shows that your implant has ruptured it will need to be removed and/or replaced. Other methods for determining whether the implant has ruptured are ultrasonography, computer-aided tomography (CT Scan) and magnetic resonance imaging (MRI). Your doctor would be able to advise you on the best method in your case. While it must be stressed that an implant can rupture any time after insertion, the risk of rupture increases with the age of the implant. Studies have shown that there is an increased risk of rupture 8 to 10 years after implantation. The published figures of rupture rates vary greatly from a low of 5 per cent to a high of 95 per cent depending on how many years after surgery women are checked, age of women with implants in the study, and tests used for rupture diagnosis. Modern implants have a thicker envelope and are filled with a high viscosity silicone to reduce the possibility of rupture.

3.1.3 Gel diffusion

Rupture of the implant is not the only means by which silicone may escape to the surrounding tissues. Silicone may diffuse through the implant envelope in the absence of a tear. Although it is silicone fluid, not the gel, which passes through the intact implant shell, the name 'gel diffusion' or 'gel bleed' has often been used to describe this situation. Although most of this gel diffusion will be absorbed by the capsule surrounding your implant, some of the silicone will be taken up by macrophages which are the 'scavenger' cells of the body's immune system. Normally, these cells try to destroy foreign material such as bacteria. But if the material (such as silicone) cannot be destroyed, it is carried to the lymph glands by the macrophages. It is very difficult to find out how much gel diffusion is occurring from your implant. The microscopic particles of silicone are too small to be detected by mammography, ultrasound, computer-aided tomography (CT Scan) or magnetic resonance imaging (MRI). However,

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these tests can be useful if larger amounts of silicone gel have diffused out of the implant. Your doctor would be able to advise you on the best test in your case.

3.1.4 Granulomas

Where silicone gel leaks into the breast and other nearby body tissues including the lymph nodes, small reactive lumps may sometimes form. If there is a large amount of leaked silicone then larger lumps may form. These lumps are described as granulomas and are usually associated with implant rupture. They are not cancerous but it may be difficult to distinguish them from cancers. Therefore, these breast lumps should be examined by your doctor. This may involve removal of some breast tissue (biopsy) to determine if it is a cancer. Before undergoing a biopsy, you must be sure that your doctor knows that you have or have had breast implants.

3.1.5 Changes in nipple and breast sensation

Any operation on the breast may result in changes in nipple or breast sensation. The breast and nipple may become painfully sensitive or may lose all sensation. In most cases these changes are temporary but in as many as 5 per cent of women, changes in nipple sensation can be permanent. You should discuss this possibility with your surgeon.

3.2 Autoimmune and connective tissue disease

The immune system helps the body recognise and fight infection and toxic and foreign materials. Sometimes the body forms antibodies that react to its own tissues as though they are foreign objects. These antibodies are called autoantibodies (antibody against self). There is a group of disorders, called autoimmune diseases, in which the immune system reacts in this way, eg, systemic lupus erythematosus (SLE), rheumatoid arthritis and scleroderma. Several large studies have failed to establish a link between silicone breast implants and well-defined connective tissue diseases including scleroderma. Even though not many studies have been carried out, current high quality literature suggest that there is no association between breast implants and connective tissue disease-like syndromes (atypical connective tissue diseases). Moreover, it is difficult to define atypical connective tissue diseases. These diseases seem to occur at the same rate in women with or without breast implants, which makes it difficult to decide whether breast implants play a role in the development of such diseases.

Autoimmune disease can cause long-term, serious health problems. Symptoms include pain and swelling of joints; tightness, redness or swelling of the skin; swollen glands or lymph nodes; unusual and unexplained fatigue; swelling of the hands and feet; and unusual hair loss. Generally, people who have these relatively rare connective tissue disorders experience a combination of these and other symptoms. If you experience any of these symptoms you should see your doctor, who will give you a thorough physical examination. Laboratory tests may also be needed. These conditions may occur coincidentally with a breast implant.

3.3 Antibodies

Antibodies to silicone have apparently been detected in silicone implant recipients and in people who had not received medical silicones. These antibody assays (tests) are difficult to do accurately and there are very limited studies on them. Some large, sophisticated research laboratories are able to detect the presence of silicon in the blood, body tissues and urine, but the significance of these test results is unknown. Silicon and silicone are found in many products including food, medicines and

cosmetics. Current testing methods cannot determine whether the silicon came from the implant or another source.

3.4 Calcium deposits in the tissue around the implant

Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery to biopsy and/or removal of the implant to distinguish them from cancer.

3.5 Breast cancer

There is no medical evidence to date to show that women with breast implants have a higher chance of getting cancer, including breast cancer. No studies have established a link between silicone gel-filled breast implants and cancer. Long-term clinical studies are not completed, but the risk of breast implants causing cancer would be extremely small. Breast implants may interfere with mammograms which assist in the early detection of breast cancer.

3.6 Breast feeding and children

There is no medical evidence to show that breast implants interfere with breast feeding. However, breast surgery may affect the shape, function and sensation of the nipple and surrounding breast tissue. This may make it difficult for you to breast feed. It is suggested that you discuss any possible problems with your doctor or midwife.

There have been no studies to show whether silicone from breast implants is present in breast milk, or whether if swallowed, silicone is absorbed by babies or passes through them. There is no evidence that if silicone is absorbed it will cause illness in the child. It is worth noting that silicone is used as a lubricant in syringes and no known complications have been reported amongst diabetic children who are being injected daily.

3.7 Birth defects

There is no evidence that silicone gel-filled breast implants cause birth defects.

3.8 Dissatisfaction with cosmetic results

Dissatisfying results such as wrinkling, asymmetry implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, hypertrophic (irregular, raised scar) scarring, and/or sloshing may occur. Careful surgical planning and technique can minimize but not always prevent such results.

4. LIVING WITH BREAST IMPLANTS

4.1 Breast care

It is very simple to care for your breasts in the first few days after the operation. You will be advised against washing or bathing for the time being. You may still be wearing a supporting bandage, which can be replaced after a few days by a supporting bra.

Once your stitches have been removed, your doctor may instruct you to massage the scar and the breasts gently with cream or lotion (one recommended by your doctor) to prevent the skin from drying out. These are only general guidelines. Every woman is different, so it is important to follow your doctor's specific instructions carefully.

4.2 Checking your implants

All women with breast implants should practise breast self examination and have an annual clinical examination by their doctor. Your doctor may recommend you have a mammogram and/or ultrasound to check your implants, but this is not always necessary. If you have any unusual breast symptoms, you should see your doctor to find out what is causing them and to discuss available treatments. Many women (including women with breast implants) experience symptoms due to normal hormone changes during their menstrual cycle. These symptoms may include discomfort, pain and swelling of parts of the breast. These symptoms do not mean that you have implant problems. However, if you have these symptoms for any length of time you should see your doctor. You should also see your doctor if you notice:

- a lump;
- in-drawing or dimpling of the skin on your breast or nipple;
- a nipple discharge (fluid coming out of the nipple);
- a change in the position or shape of your implant; or
- if you have had a recent injury to your breast.

If your implant has been damaged, it may need to be removed.

4.3 Screening for breast cancer

Although, there is no evidence to date that women with breast implants have a higher risk of getting breast cancer, the risk of developing breast cancer increases with age for all women. Early detection increases the likelihood of successful treatment.

It is recommended that all women practise regular breast self examination and have an annual examination by a doctor. Women over the age of 50 should have a screening mammogram every two years to detect early breast cancer. You should discuss this with your doctor.

4.3.1 Breast self examination

You should perform breast self-examination monthly on your implanted breast. In order to do this effectively, you should ask your surgeon to help you distinguish the implant from your breast tissue. Breast self examination includes looking at your breasts in a mirror both when your chest muscles are tightened by pressing your hands on your hips, and when the muscles are relaxed. Look for any changes in the shape of your breast. Then go over the entire breast, including the 'tail' which reaches up into your armpit, gently 'palpating', that is, pressing the breast against your chest wall and feeling for any lumps or thickening which was not there before. If you notice anything you think has changed, see your doctor.

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Brochures which explain how to perform breast self examination may be obtained from women's health services, your local breast clinic or your doctor. Ideally, you should seek one-to-one instruction from a suitably qualified health worker. You may find it difficult to feel your breast tissue depending on the position of your implant and particularly if the capsule around your implant has contracted.

4.3.2 Clinical examination

Clinical examination by your doctor includes looking at your breasts with your chest muscles tensed and then relaxed, followed by careful 'palpation'. If anything unusual is found, your doctor may suggest you have a mammogram to help in the diagnosis of any changes in your breasts. If you have very little breast tissue lying over your implant, or if you have tightly contracted capsules, mammography is not usually as useful or effective.

4.3.3 Mammography

The most effective way of detecting breast cancer at present is mammography. A mammogram is a special breast X-ray. However, mammography is not as useful in women with breast implants because the implant shows up on the X-ray as a dense shadow which may hide small cancerous tumours. How useful mammograms can be depends on the position of your implant and how far it can be pushed against your chest wall so that your breast tissue can be compressed separately from your implant. This is virtually impossible if you have tightly contracted capsules around your implants. In such cases, mammograms would be of little use. If your breasts are soft, however, and your implant is positioned under your chest muscle, most of your breast tissue can be X-rayed and mammograms can be useful.

To make sure you get the best mammogram possible, it is important that you tell the radiographer (person taking the X-rays) that you have breast implants as special techniques will need to be used to help show as much of your breast tissue as possible. It has been suggested that women older than 30 years of age considering breast implant surgery have mammography before and after implantation. It is especially important for women who are at high risk of developing breast cancer to consider this before having implants. The earlier cancer is detected, the better the chance for a cure. Contact our local Radiologists Association for guidelines for detection of breast cancer in patients with breast implants.

There have been limited studies on the effects of mammography on breast implants. The available information shows that the actual X-ray used in mammography does not cause damage to the implant. However, the pressure applied by the mammography machine could damage the implant, causing rupture or increased gel diffusion. The risk of this is considered to be very small.

4.4 Removal and replacement of implants

A decision to have your implants removed or replaced is a personal decision which should be made in consultation with your doctor or surgeon. In making this decision you should find out the condition of your implant but you should also consider other factors such as:

- your current health;
- any concerns you have about the long term effects of keeping your implants; and
- the possible complications and risks of surgery.

Generally, doctors only recommend removal of implants if you are experiencing specific health problems such as rupture, extreme capsular contracture, constant pain or infection that will not clear up. You may also need to consider whether you should have the capsule which surrounds your implant removed at the same time. If you decide to have your implants removed because of concerns about the effect of silicone on your health, then it may make sense to have the capsule removed as

this is where the silicone is likely to be. However, some doctors say that removal of the capsule is unnecessary and that it increases the chances of bleeding during and immediately after the operation. You should discuss any concerns you have about removal of the capsule including the risks and benefits with your surgeon.

Removal of your implant will also carry the usual risks involved in any operation (eg, bleeding, infection, scarring and the risk associated with anaesthetic). Your implant may also rupture as it is being removed. If your implant has already ruptured prior to the operation, the surgery to remove the escaped silicone gel may also involve the removal of some breast tissue. Other possible surgery includes 'flap reconstruction' which involves taking skin, muscle and other tissue from other parts of your body to build a new breast. This is a complicated procedure and involves lengthy surgery. It is usually only performed where women have had a mastectomy.

Following the removal of your implant, you may have some disfigurement of your breasts, involving loose skin and compacted breast tissue in the area around your nipple. To improve this appearance, a surgical procedure called a mastopexy or breast 'lift' can be performed. There are risks associated with this procedure including infection, bleeding and scarring.

Any problem experienced with your implants should be reported to our Local Health Authority.

5. SPECIAL CONSIDERATIONS FOR BREAST IMPLANTS

5.1 Special Considerations for Breast Augmentation

What Are the Alternatives to Breast Augmentation?

- Accept your breasts as they are;
- Wear a padded bra or external prostheses.

You are advised to wait three to four weeks after reviewing and considering this information before deciding whether to have augmentation surgery.

5.2 Special Considerations for Breast Reconstruction

5.2.1 Should You Have Breast Reconstruction?

Whether you decide to have breast reconstruction depends on your own individual case, medical condition, general health, lifestyle, emotional state, and breast size and shape. You may consider consulting your family, friends, breast implant support groups, and breast cancer support groups to help you in making this decision.

If you are considering breast reconstruction and do not have a plastic surgeon, ask your general surgeon for a referral for the names of experienced, board certified plastic surgeons in your area. Your general surgeon, plastic surgeon, and oncologist should work together to plan your mastectomy and reconstruction procedure to give you the best possible result.

5.2.2 What Are the Alternatives to Breast Reconstruction?

You may choose not to undergo breast reconstruction. In this case, you may or may not decide to wear an external breast form (prosthesis) inside your bra. Breast forms are available in a variety of shapes, sizes, and materials such as foam, cotton, and silicone. Custom prostheses are also available to match the size and shape of your breast.

5.2.3 What Are the Choices in Reconstructive Procedures?

The type of breast reconstruction procedure available to you depends on your medical situation, breast shape and size, general health, lifestyle, and goals. Women with small or medium sized breasts are the best candidates for breast reconstruction.

Breast reconstruction can be accomplished by the use of a prosthesis (a breast implant, either silicone gel or saline-filled), your own tissues (a tissue flap), or a combination of the two. A tissue flap is a section of skin, fat and/or muscle which is moved from your stomach, back or other area of your body, to the chest area, and shaped into a new breast.

Whether or not you have reconstruction with or without breast implants, you will probably undergo additional surgeries to improve symmetry and appearance. For example, because the nipple is often removed with the breast tissue in mastectomy, the nipple is often reconstructed by using a skin graft from the opposite breast or by tattooing the area. Nipple reconstruction is usually done as a separate outpatient procedure after the initial reconstruction surgery is complete.

5.2.4 Breast Reconstruction with Breast Implants

Your surgeon will decide whether your health and medical condition makes you an appropriate candidate for breast implant reconstruction. Women with larger breasts may require reconstruction with a combination of a tissue flap and an implant. Your surgeon may recommend breast implantation of the opposite, uninvolvled breast in order to make them more alike (maximize symmetry) or he/she may suggest breast reduction (reduction mammoplasty) or a breast lift (mastopexy) to improve symmetry. Mastopexy involves removing a strip of skin from under the breast or around the nipple and using it to lift and tighten the skin over the breast. Reduction mammoplasty involves removal of breast tissue and skin. If it is important to you not to alter the unaffected breast, you should discuss this with your plastic surgeon, as it may affect the breast reconstruction methods considered for your case.

5.2.5 The Timing of Your Breast Implant Reconstruction

The following description applies to reconstruction following mastectomy, but similar considerations apply to reconstruction following breast trauma or for reconstruction for congenital defects. The breast reconstruction process may begin at the time of your mastectomy (immediate reconstruction) or weeks to years afterwards (delayed reconstruction). Immediate reconstruction may involve placement of a breast implant, but typically involves placement of a tissue expander, which will eventually be replaced with a breast implant. It is important to know that any type of surgical breast reconstruction may take several steps to complete.

Two potential advantages to immediate reconstruction are that your breast reconstruction starts at the time of your mastectomy and that there may be cost savings in combining the mastectomy procedure with the first stage of the reconstruction. However, there may be a higher risk of complications such as deflation with immediate reconstruction, and your initial operative time and recuperative time may be longer.

A potential advantage to delayed reconstruction is that you can delay your reconstruction decision and surgery until other treatments, such as radiation therapy and chemotherapy, are completed. Delayed reconstruction may be advisable if your surgeon anticipates healing problems with your mastectomy, or if you just need more time to consider your options.

There are medical, financial and emotional considerations to choosing immediate versus delayed reconstruction. You should discuss with your surgeon, plastic surgeon, and oncologist, the pros and cons with the options available in your individual case.

5.2.6 Surgical Considerations to Discuss with your Doctor

Discuss the advantages and disadvantages of the following options with your surgeon and your oncologist:

- **Immediate Reconstruction:**

One-stage immediate reconstruction with a breast implant (implant only).

Two-stage immediate reconstruction with a tissue expander followed by delayed reconstruction several months later with a breast implant.

- **Delayed Reconstruction:**

Two-stage delayed reconstruction with a tissue expander followed several months later by replacement with a breast implant.

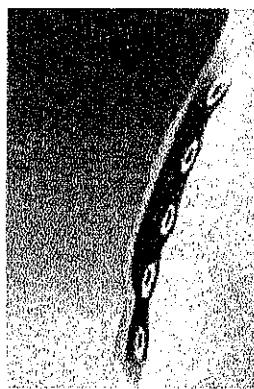
5.2.7 What Is the Breast Implant Reconstruction Procedure?

- **One-Stage Immediate Breast Implant Reconstruction**

Immediate one-stage breast reconstruction may be done at the time of your mastectomy. After the general surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant that completes the one-stage reconstruction.

- **Two-Stage (Immediate or Delayed) Breast Implant Reconstruction**

Breast reconstruction with Poly Implants Prothèses saline pre-filled breast implant usually occurs as a two-stage procedure, starting with the placement of a breast tissue expander, which is replaced several months later with a breast implant. The tissue expander placement may be done immediately, at the time of your mastectomy, or be delayed until months or years later.



Side View. Breast Tissue Removed



Side View. Expander Inserted and Filled

Stage 1: Tissue Expansion

During a mastectomy, the general surgeon often removes skin as well as breast tissue, leaving the chest tissues flat and tight. To create a breast shaped space for the breast implant, a tissue expander is placed under the remaining chest tissues.

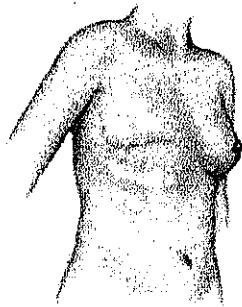
The tissue expander is a balloon-like device made from elastic silicone rubber. It is inserted unfilled, and over time, sterile saline fluid is added by inserting a small needle through the skin to the filling port of the device. As the tissue expander fills, the tissues over the expander begin to stretch, similar to the gradual expansion of a woman's abdomen during pregnancy. The tissue expander creates a new breast shaped pocket for a breast implant.

Tissue expander placement usually occurs under general anaesthesia in an operating room. Operative time is generally one to two hours. The procedure may require a brief hospital stay, or be done on an outpatient basis. Typically, you can resume normal daily activity after two to three weeks.

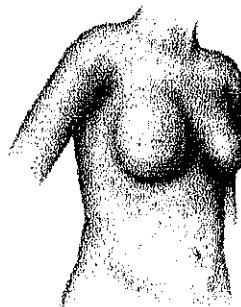
Because the chest skin is usually numb from the mastectomy surgery, it is possible that you may not experience pain from the placement of the tissue expander. However, you may experience feelings of pressure or discomfort after each filling of the expander, which subsides as the tissue expands. Tissue expansion typically lasts four to six months.

Stage 2: Placing the Breast Implant

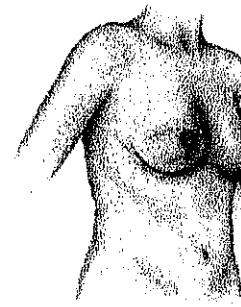
After the tissue expander is removed, the pre-filled breast implant is placed in the pocket. The surgery to replace the tissue expander with a breast implant (implant exchange) is usually done under general anaesthesia in an operating room. It may require a brief hospital stay or be done on an outpatient basis.



Post Mastectomy



Stage 1: Tissue Expander



Stage 2: Breast Implant and Nipple / Areola Reconstruction

Reconstruction Without Breast Implants: Tissue Flap Procedures

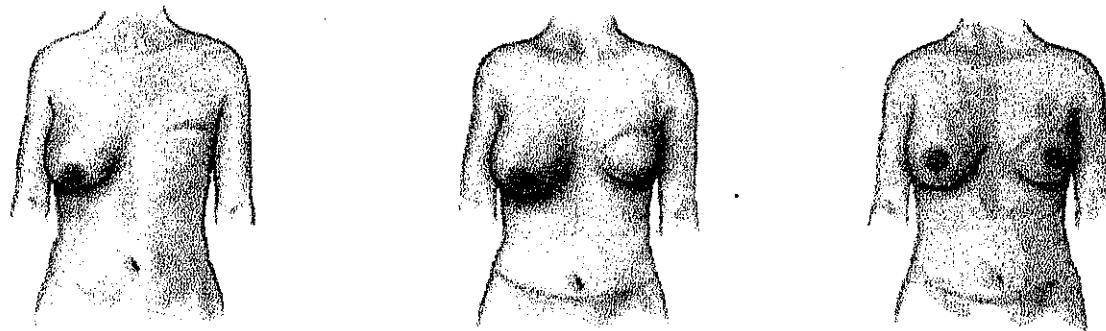
The breast can be reconstructed by surgically moving a section of skin, fat and muscle from one area of your body to another. The section of tissue may be taken from such areas as your abdomen, upper back, upper hip, or buttocks. The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap), or it may be removed completely and reattached to the breast area by microsurgical techniques (a free flap). Operating time is generally longer with free flaps, because of the microsurgical requirements.

Flap surgery requires a hospital stay of several days and generally a longer recovery time than implant reconstruction. Flap surgery also creates scars at the site where the flap was taken and possibly on the reconstructed breast. However, flap surgery has the advantage of being able to replace tissue in the chest area. This may be useful when the chest tissues have been damaged and are not suitable for tissue expansion. Another advantage of flap procedures over implantation is that alteration of the unaffected breast is generally not needed to improve symmetry. The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap) (which uses tissue from the abdomen) and the Latissimus dorsi flap (which uses tissue from the upper back).

It is important for you to be aware that flap surgery, particularly the TRAM flap, is a major operation, and more extensive than your mastectomy operation. It requires good general health and strong emotional motivation. If you are very overweight, smoke cigarettes, have had previous surgery at the flap site, or have any circulatory problems, you may not be a good candidate for a tissue flap procedure. Also, if you are very thin, you may not have enough tissue in your abdomen or back to create a breast mound with this method.

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The TRAM Flap (Pedicle or Free)



Post Mastectomy

TRAM Flap

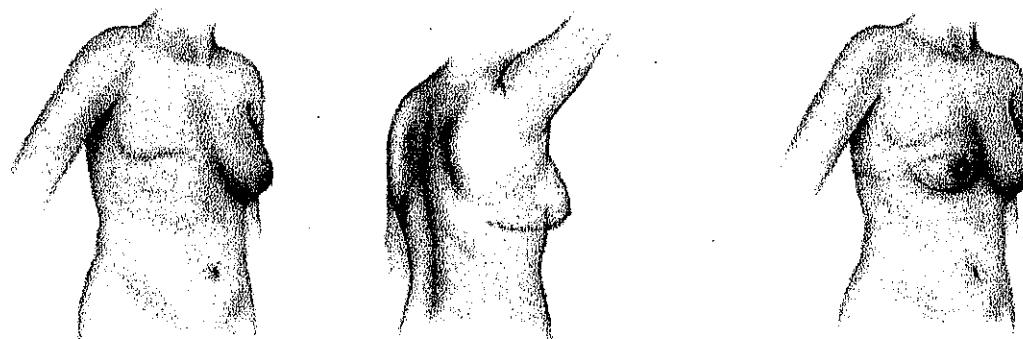
**Final Result with
Nipple / Areola Reconstruction**

During a TRAM flap procedure, the surgeon removes a section of tissue from your abdomen and moves it to your chest to reconstruct the breast. The TRAM flap is sometimes referred to as a "tummy tuck" reconstruction, because it may leave the stomach area flatter. A pedicle TRAM flap procedure typically takes three to six hours of surgery under general anaesthesia; a free TRAM flap procedure generally takes longer. The TRAM procedure may require a blood transfusion. Typically, the hospital stay is two to five days. You can resume normal daily activity after six to eight weeks. Some women, however, report that it takes up to one year to resume a normal lifestyle. You may have temporary or permanent muscle weakness in the abdominal area. If you are considering pregnancy after your reconstruction, you should discuss this with your surgeon. You will have a large scar on your abdomen and may also have additional scars on your reconstructed breast.

The Latissimus Dorsi Flap With or Without Breast Implants

During a Latissimus Dorsi flap procedure, the surgeon moves a section of tissue from your back to your chest to reconstruct the breast. Because the Latissimus Dorsi flap is usually thinner and smaller than the TRAM flap, this procedure may be more appropriate for reconstructing a smaller breast.

The Latissimus Dorsi flap procedure typically takes two to four hours of surgery under general anaesthesia. Typically, the hospital stay is two to three days. You can resume daily activity after two to three weeks. You may have some temporary or permanent muscle weakness and difficulty with movement in your back and shoulder. You will have a scar on your back, which can usually be hidden in the bra line. You may also have additional scars on your reconstructed breast.



Post Mastectomy

**View Showing
Back Scar**

Latissimus Dorsi Flap

6. MEDICAL RECORDS

It is recommended that you obtain information about your implant from your surgeon including your implant product name and product number. It is important that you keep copies of this information as it may be useful in future medical examinations.

A Patient identification card is provided by Poly Implants Prothèses and must be given to the patient after the operation.

The labels that correspond to the implanted prostheses contain most important information (company, reference, lot and serial numbers, volume)

Patient medical records are kept for seven years, and many doctors keep their records for longer periods. If by any chance the information is not available from the doctor's surgery, then a record of the type of implant may have been kept at the hospital where the operation was performed. You will need to phone the Medical Records Department of the hospital to get this information.

7. QUESTIONS

7.1 Commonly asked questions and answers

Below are some commonly asked questions and answers about breast implants.

Q. How long will my implants last?

Breast implants may have a limited life span and may have to be removed and/ or replaced. They will age and may wear out and rupture as a result of an injury such as a fall or knock. An implant may last for only a very short time or for many years. Recent studies indicate that the risk of experiencing problems with the breast implant is much greater 8 to 10 years after the surgery.

Q. What are the alternatives to silicone gel-filled breast implants?

Breast padding and specially designed bras can be used to enhance your appearance without exposing yourself to the risks associated with breast implants. However, if you choose to undergo breast implant surgery, saline filled implants are generally unsuitable in very thin patients with little breast tissue.

Q. Are there any problems with saline implants?

All breast implants, including saline implants, can cause problems. These include capsular contracture (which may involve pain and disfigurement in extreme cases) and implant rupture which will result in further surgery and other possible complications. Wrinkling of the implant is more common with saline implants, especially in very thin patients.

Q. How do I know if my implants have ruptured?

If you have saline implants, your breast will immediately become smaller. You will notice this straight away. The saline from the implant will be absorbed by your body and it will eventually pass out of your body in your urine. If you have silicone implants, a mammogram or ultrasound may show you if your implant has ruptured. The silicone gel from your implant does not flow freely in your body and may be contained within the scar capsule around your implant or may travel to nearby breast and other tissues, sometimes resulting in a palpable lump. If your implant ruptures you will need to have an operation to have it removed.

Q. How can I check to see how much my implants may be leaking?

You can try having a mammogram or ultrasound but there is no guarantee that any leakage (eg, a leak through a hole in the outer shell of the implant) will be picked up. Magnetic resonance imaging may also be able to detect silicone in body tissues. Your doctor should be able to advise you about these services.

Q. How can I check if there is gel diffusion from my implants?

Gel diffusion occurs from all silicone breast implants, but there is no easy way to check to see how much. The tiny particles of silicone gel are too small to be seen by mammography or ultrasound. The particles can be seen under the microscope but you would need to have a large amount of breast tissue surgically removed for examination to be sure how much silicone is present.

Q. Should I have regular mammograms?

If you are over 50, it is recommended you have a mammogram every two years for the early detection of breast cancer.

If you have breast implants this procedure is safe if performed by a trained technician. In theory, the pressure applied by a mammography machine could damage the implant causing rupture or gel diffusion. However, the risk of this is considered to be very small.

Q. Should I have my implants removed or replaced?

Your decision to leave your implants in place or to have them removed or replaced is a personal one. Only you, in consultation with your doctor or surgeon, can make it, but you should weigh up all the benefits and risks.

Doctors generally only recommend removal of implants if you are experiencing specific problems such as extreme capsular contracture, constant pain, infection that will not clear up, or rupture. Other factors to consider are how you feel about your implants, your health, your body image and your concerns about the long term health effects of keeping your implants in.

Q. Is it safe for me to breast feed?

Current information indicates that women with breast implants are able to breast feed. However, there have not been many studies conducted on the effects of silicone on breast fed babies. There is no evidence that silicone from breast implants is present in breast milk, or whether if swallowed, silicone is absorbed by babies or passes through them. There is also no evidence that if silicone is absorbed it will cause illness in the child.

Q. Where can I go if I have problems with my implants?

If you are experiencing problems with your implants or breasts, you should see your doctor or surgeon. You may also want to seek a second opinion. There are also women's health services and support groups for women with breast implants which can provide you with information, support and advice.

7.2 Suggested questions to ask your surgeon before surgery

- Exactly what will be done?
 - What are the expected benefits?
 - What are the risks and common side effects?
 - Is the treatment well recognised or is it experimental?
 - Who will perform the operation?
- Are there any other options available?
- How likely is it that the implant will look and feel as good as I expect?
- What are the likely consequences of the procedure?
- Are there any significant long term physical, emotional, mental, social, sexual or other outcomes which may be associated with the proposed treatment?
- How much time is involved in surgery and recovering from the procedure?
- What are the costs involved, including out of pocket expenses?
- Are there any written information and diagrams that will assist me in understanding the procedures?
- How long do you think this implant will last?
- What is the implant manufacturer's replacement policy should the implant fail?
- Is your surgeon adequately trained to perform this procedure, ie, is he/she a specialist surgeon?

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8. LIST OF CONTACTS

8.1 Cancer groups

Australian Cancer Society	(02) 9380 9022
NSW Cancer Council	(02) 9334 1900
Queensland Cancer Fund	(07) 3258 2200
Anti-Cancer Council of Victoria	(03) 9635 9000
Anti-Cancer Council of South Australia	(08) 8291 4111
Cancer Foundation of WA	(08) 9381 4515
Cancer Council of Tasmania	(03) 6233 2030
Cancer Council of the NT Inc	1800 678 123
ACT Cancer Society	(02) 6262 2222

8.2 WOMEN'S HEALTH OR INFORMATION CENTRES

Look up under "Women's Health or Information Centres" in your local White or Yellow Pages.

8.3 PLASTIC SURGEONS

For information about qualified plastic surgeons in your State or Territory, contact:

Australian Society of Plastic Surgeons (ASPS)
Level 1, 33/35 Atchison Street
St Leonard NSW 2010
Ph: 1300 367 446

8.4 NATIONAL PROGRAM FOR THE EARLY DETECTION OF BREAST CANCER

For information regarding breast cancer screening for women over 50 years contact your nearest Breast Screen Australia branch by calling 13 20 50 for the cost of a local call.