



# Breast Implant Information Booklet

4th edition



**Australian Government**  
Department of Health and Ageing  
Therapeutic Goods Administration

# **Breast Implant Information Booklet**

## **4th edition**

This booklet has been prepared to provide guidance for persons considering the use of silicone gel-filled breast implants. These implants are associated with potential long-term risks and complications. The TGA recommends that you consider the information provided for a period of 30 days before making a final decision.

Produced by the  
Therapeutic Goods Administration  
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## Glossary of terms

<b>Asymmetry</b>	With regard to breasts, describes imbalance in the proportion, size and shape of the left and right breasts resulting in an unacceptable appearance.
<b>Autoimmune diseases</b>	A group of diseases where the body's immune system starts to attack itself.
<b>Breast augmentation</b>	Surgery to change the size or enhance the shape of the breasts.
<b>Capsule</b>	The scar tissue which forms around a breast implant. This is the body's normal response to the presence of any foreign object.
<b>Capsular contracture</b>	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.
<b>Closed capsulotomy</b>	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.
<b>Congenital deformity</b>	A deformity that is present from birth.
<b>Connective tissue</b>	Fibrous tissue connecting and supporting the body organs and the cells within these organs.
<b>Envelope</b>	Outer layer that encloses the contents (saline or silicone gel) of the breast implant. It is usually made of a thick silicone compound.

<b>Gel diffusion</b>	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.
<b>Lumen</b>	The cavity or channel within a hollow object or tube.
<b>Magnetic Resonance Imaging (MRI)</b>	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.
<b>Mammogram</b>	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.
<b>Mastectomy</b>	A surgical procedure to remove a breast.
<b>Prophylaxis</b>	The prevention of disease.
<b>Reconstruction</b>	Breast reconstruction refers to the operation performed to create an artificial breast after mastectomy.
<b>Rupture</b>	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.
<b>Saline</b>	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.

<b>Silicon</b>	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.
<b>Silicone</b>	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.
<b>Silicone granulomas</b>	Are small lumps that sometimes form in breast and other body tissues around leaked silicone from silicone implants.
<b>Tissue expander</b>	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.
<b>Ultrasound</b>	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

## About the booklet

This booklet on silicone gel-filled breast implants 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. It should be noted, however, that the rates for local complications, immediate surgical complications and anaesthetic complications are similar for both saline-filled breast implants and silicone gel-filled breast implants.

Today there are different expectations about communication and more recognition of the duty to inform women and to check their assumptions and knowledge – hence the publication of this booklet.

This booklet has been written with the help of women who have had breast implants, nurses, general practitioners, plastic surgeons, immunologists, radiologists, implant manufacturers, government regulators, legal and consumer groups.

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* on page 33)

## 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

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 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.

## **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:

1. Silicone gel-filled implants.
2. Saline-filled implants.
3. 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.

## **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.



## 2. Deciding to have breast implants

### **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 (See Section: *Suggested questions to ask your Surgeon before surgery* on page 33). 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 manufacturer's information sheet. 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 may also give you information on the manufacturer's legal liability in case anything goes wrong with your implant after your surgery. This information may have a consent section for you to sign. You should ensure that you fully understand this information and that you keep a copy in a safe place.

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 designed bras can be obtained from your State health department or cancer societies and support groups (see Section: *List of contacts* on page 35).

**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.**

## **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; and
- correction of a congenital deformity.

## **Factors to consider when making your decision**

- Are breast implants the best option for you?
- What complications may follow insertion of breast implants?
- The implants may need to be replaced in the future.
- What are the risks of surgery (eg. anaesthetic, haemorrhage, infection, scarring etc)?

## **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 (see Section: *Risks associated with breast implants* on page 13), it is recommended that you have your implants checked by your doctor.

## **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.

## **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 wellbeing, 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.

## **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. These conditions are generally described in the manufacturer's product information. 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.

## **Breast implant surgery**

### **Placement**

An implant is placed behind your breast tissue either in front of or behind your chest muscle. The surgeon, in consultation with you, will choose the location depending on your physical characteristics.

### **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.

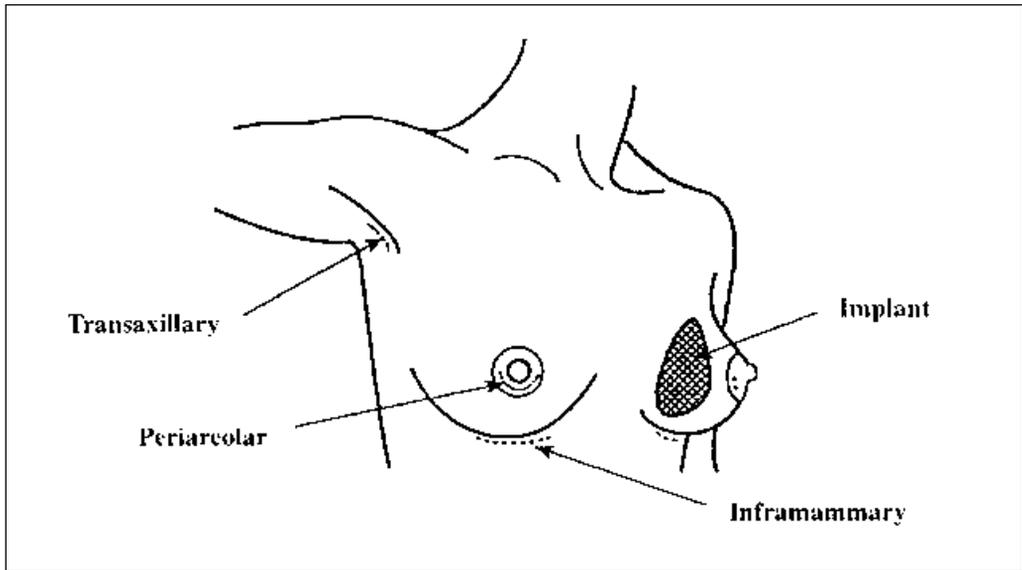
The tissue expander is a saline implant where saline is injected into the implant through a valve under the skin over a period of time until the skin stretches enough so that a permanent implant will fit. Tissue expanders come in two types: one type is removed once it becomes fully inflated and a permanent implant is put in place; the other type remains in your breast as a permanent implant once it has been inflated.

### **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.



*Implant incision location*

## **Anaesthetic**

A general anaesthetic is almost always given for breast implant surgery; in other words, you will be unconscious during the procedure. A local or regional anaesthetic can also be given for breast implant surgery. You should be aware that the anaesthetic itself adds a slight but important risk to the whole procedure.

## **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.

## **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.

## **Post-operative care**

It is important that you discuss your care after the operation with your surgeon as the wound may take several weeks to heal.

## **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:

### **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.

### **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.

### **Bleeding and haematoma formation**

Bleeding can occur after any operation. It usually happens soon after surgery and this is why the surgeon may use drainage tubes for a short time. A haematoma or blood clot may also form where the implant has been placed. If this happens, the haematoma may disappear by itself or you may need to have it surgically removed.

## **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.

## **A breakdown of skin, known as necrosis**

This may be due to thinness of the skin flap over the implant or trauma to the skin during surgery. Sometimes this may require removal of the implant.

## **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.

## **Wrinkling of the implant**

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

## **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.

## **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.

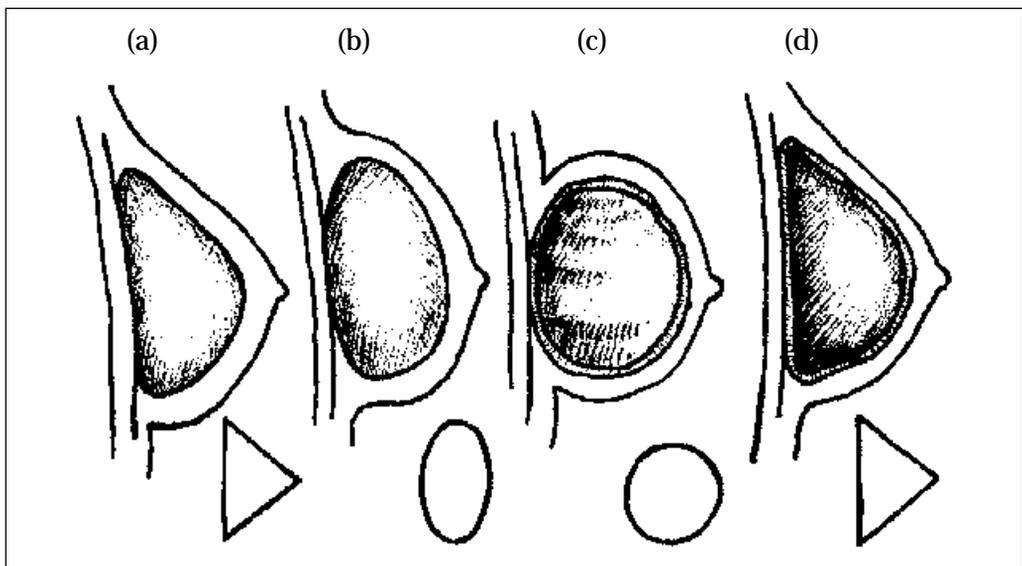


### 3. Issues associated with breast implants

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.

#### Local complications

##### Capsular formation and contracture



*The gradual changes that may occur from contracture formation around a breast implant.*

- a. The initial triangular-cone form.*
- b. Contraction of the fibrous capsule forms an ovoid form.*
- c. Continued contraction and thickening of the capsule produces buckling at the top and a rounded form.*
- d. Opening of the capsule and releasing the tension restores the original triangular-cone form.*

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.

### **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.

## **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, 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.

## **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.

## **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.

## **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.

## **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.

## **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 (See Section on *Mammography* on page 22).

## **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.

## **Birth defects**

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



## 4. Living with breast implants

### 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.

### 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.

## **Breast self examination**

All women should examine their breasts each month. 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. 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.

## **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.

## **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. The Royal Australasian College of Radiologists (RACR) has set out guidelines for detection of breast cancer in patients with breast implants. Written guidelines exist at the State/ Territory level for screening women presenting with breast implants at BreastScreen Australia services.

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.

BreastScreen Australia provides free screening mammograms every two years for women over the age of 50. Screening mammograms are for women who do not have any symptoms of breast disease. If you detect a change in your breast such as a lump, nipple discharge or dimpling of the skin, you should see your doctor as soon as possible.

The results of screening women in the age group 40-49 years indicates a small but significant reduction in mortality when asymptomatic women in this age group are screened regularly. For women under 40, there is no evidence of benefit from screening mammography. BreastScreen Australia services are not intended for use by women to check the condition of their breast implants.

## **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.

The TGA operates an Incident Reporting Scheme (see Section: *List of contacts* on page 35) where you should report any problems you have had with your implants. This will help the TGA track the types of problems experienced with individual implant types.

## 5. Other important information

### Costs of breast implants

Medicare benefits are payable in relation to the following medical services:

- The insertion of breast implants where surgery is required for medical reasons, eg, following mastectomy or for significant breast deformity.
- The removal and/or replacement of your implants where clinically indicated. In view of the concerns with silicone breast implants, Medicare benefits are payable for their removal and replacement whether or not there is a clinical indication.
- Tests for autoimmune disorders if you are experiencing symptoms of these disorders.

Medicare will not assist with the costs listed below. It is recommended that you find out the total cost of any procedure or treatment before having it performed. If you have private health insurance, your insurer may pay some of these costs. You should find out whether your private health insurance will cover these costs.

- The costs for surgery to insert the implants, or for reconstructive surgery following the removal of implants, where the surgery is performed for cosmetic purposes, ie, to improve the appearance of your breasts. These costs can be quite high, and would include the cost of the anaesthetic and any assistance at the operation.
- The cost of the actual implant device.
- The costs of health screening services (eg, mammography, ultrasound, magnetic resonance imaging) where you are not showing actual symptoms but just want to have a routine check of your implants.

In general, the costs of any surgery will depend on where your surgeon chooses to perform the operation and whether you go into hospital as a public or private patient. If the operation is performed in a private hospital or if you are treated as a private patient in a public hospital, the costs may be high.

Private patients in either public or private hospitals are required to meet accommodation and all other charges by the hospital, either personally or through private health insurance.

For services covered by Medicare benefits, a rebate of 75 per cent of the Medicare Benefits Schedule fee applies for services given to private patients in hospital, with private health funds meeting the 25 per cent 'patient gap' for insured patients. However, where doctors charge above the Schedule fee, the patient has to pay for any additional amounts charged.

## **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.

The law requires that records be 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.

## **Australian regulation of breast implants**

Breast implants are regarded as therapeutic goods under the terms of the *Therapeutic Goods Act (1989)*, which came into effect on 15 February 1991. With the implementation of the Therapeutic Goods Act (1989), breast implants along with other devices were entered on the Australian Register of Therapeutic Goods (ARTG) as 'grandfather status' low risk (Listable) devices. Entry on the ARTG is necessary to allow legal supply of devices in Australia.

In July 1991, following reports of local and systemic complications and growing concerns regarding their safety, the TGA advised all suppliers of silicone gel-filled breast implants that these devices would be changed from low risk (Listed) devices to high risk (Registrable) devices. Manufacturers and suppliers were informed that adequate data supporting the safety of silicone gel-filled breast implants would need to be supplied to the TGA by 31 January 1992, if they wished to continue marketing these devices. At the time, no manufacturer or supplier had such information and as a result there were no

silicone gel-filled breast implants on the ARTG until 29 June 2001, at which time a manufacturer of silicone gel-filled breast implants satisfactorily demonstrated their quality, safety and efficacy. Silicon gel-filled breast implants from various manufacturers are now available in Australia.

Over the last five years numerous large scale studies on the effects of silicone gel-filled breast implants have been conducted. Many of the earlier concerns about silicone gel-filled implants have been resolved and are reflected in this booklet.

Prior to entry on the ARTG, silicone gel-filled breast implants could not legally be supplied in Australia, except on an individual patient use (IPU) basis. There are now no restrictions on the supply and use of **approved** silicone gel-filled breast implants in Australia. Unapproved silicone gel-filled breast implants cannot be legally supplied in Australia, except on an individual patient use (IPU) basis, where it can be shown that the patient has a demonstrated clinical need for the unapproved silicone gel-filled breast implant, that the patient is likely to benefit from the use of the unapproved silicone gel-filled breast implant and that no approved silicone gel-filled breast implant is suitable.

Products to be sold in Australia generally must have been approved by the TGA after an evaluation of their quality, safety and efficacy.

The TGA operates an Incident Reporting Scheme (see Section: *List of Contacts* on page 35) where you can report any problems you have or have had with your implants. This will help the TGA track the types of problems experienced with individual implant types.



## 6. 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.

Medicare will pay 75 per cent of the Medicare Benefits Schedule fee for the removal and replacement of breast implants regardless of whether there is a medical reason for this surgery.

### **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. How much will it cost for me to have breast implants?**

The costs of breast implant surgery are not covered by Medicare unless the operation is for correction of a breast deformity or following a mastectomy. What you will have to pay will depend on where the operation is performed and whether you have private health insurance. There may also be other costs once you have implants (eg, costs for further surgery). See page 25 of the booklet for further information.

### **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. (See Section: *List of contacts* on page 35).



## 7. Suggested questions to ask your surgeon before surgery

To obtain information on breast implant surgery from your surgeon, the following questions based on the National Health and Medical Research Council's *General Guidelines for Medical Practitioners on Providing Information to Patients* may be useful:

- 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?

Any additional queries and concerns should also be raised with your surgeon.



## 8. List of contacts

### Cancer groups

The Cancer Council Australia	(02) 9036 3100
The Cancer Council New South Wales	(02) 9334 1900
Queensland Cancer Fund	(07) 3258 2200
The Cancer Council of Victoria	(03) 9635 9000
The Cancer Council of South Australia	(08) 8291 4111
The Cancer Council of Western Australia	(08) 9212 4333
The Cancer Council of Tasmania	(03) 6233 2030
The Cancer Council NT	(08) 8297 4888
The Cancer Council ACT	13 11 20

### Women's Health or Information Centres

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

### Plastic surgeons

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

Australian Society of Plastic Surgeons (ASPS)  
33 Atchison Street  
St Leonards NSW 2065  
Ph: (02) 9437 9200

### 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.

## **Commonwealth government**

### **Medical Device Incident Report Investigation Scheme (IRIS)**

If you experience difficulties with your implant(s), you are encouraged to report those difficulties to the TGA via the Medical Device Incident Report Investigation Scheme. This will help the TGA track the types of problems experienced with individual implant types. For information contact:

Reply Paid 32  
Medical Device Incident Report Investigation Scheme  
PO Box 100  
Woden ACT 2606  
Phone: 1800 809 361  
Email: iris@health.gov.au

For information about the supply of breast implants contact:

Information Officer  
Medical Devices  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2609  
Ph : 1800 020 653

For medical advice from TGA's perspective, contact:

Head Clinician Section  
Medical Devices  
Phone: (02) 6232 8679

An electronic copy of this booklet can be viewed and downloaded from the following Internet site:

<http://www.tga.gov.au/devices/devices.htm>

Copies of this booklet are available from:

The Publications Officer  
Therapeutic Goods Administration  
Fax: (02) 6232 8616  
Phone: 1800 020 653

## 9. Acknowledgments

This document was produced as an update to two booklets:

- *Breast Implant Information Booklet*, published by the Australian Government Publishing Service, 1995; and
- *IPU Information Booklet*, published by the Therapeutic Goods Administration, March 1993.

This information booklet contains extracts from:

1. Consent to implant silicone gel-filled breast implants. An article published by the Federal Food and Drug Administration (FDA) of the USA (1992).
2. *Reported complications of silicone gel-filled breast implants: An epidemiologic review: Annals of Internal Medicine* (Volume 124, Number 8; 15 April 1996)—Barbara G Silverman, S Lori Brown, Roselie A Bright, Ronald G Kaczmarek, Janet B Arrowsmith-Lowe and David A Kessler.
3. *Complications leading to surgery after breast implantation: The New England Journal of Medicine* (March 6, 1997)—Sherine E Gabriel, John E Woods, W Michael O'Fallon, Mary Beard, Leonard T Kurland, L Joseph Melton III.
4. *Successful treatment of some fibrous envelope contractures around breast implants: Plastic and reconstructive surgery* (August 1972)—Bromley S Freeman.
5. *Silicone Breast Implants' possible link to atypical rheumatic disease: MD-D-I Reports—'The Gray Sheet'; 14 April 1997.*
6. *Rupture of silicone-gel breast implants: causes, sequelae, and diagnosis: The Lancet* (Vol 350. November 22, 1997)—S Lori Brown, Barbara G Silverman, Wendie A Berg.
7. *Do silicone breast implants cause connective tissue disease? There is still no clear evidence that they do: BMJ* (Vol 316. 7 February 1998). Cyrus Cooper and Elaine Dennison.

If you have any suggestions for future reprints of this Booklet, please write to:

The Chief Clinical Advisor  
Medical Devices  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606

## Consent to implant silicone gel-filled breast implants

### Patient details

Name	<input type="text"/>		
Date of birth	<input type="text"/>		
Address	<input type="text"/>		
Previous implant(s)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Type <input type="text"/>
Implant date	<input type="text"/>	Type	<input type="text"/>
Surgeon name	<input type="text"/>		
Institution name	<input type="text"/>		
Institution address	<input type="text"/>		
Reason for implant(s)	<input type="text"/>		

I have read and believe that I understand all the information presented to me including the information provided by the Therapeutic Goods Administration (TGA) on risks and benefits of silicone gel-filled breast implants. I have had an opportunity to ask questions of Dr

and all my questions have been answered to my complete satisfaction.

I understand that the procedure my doctor and I have chosen will be performed using a silicone gel-filled breast implant(s). I also understand that periodic medical checkups are required and that the implants have a limited lifespan.

I have received a copy of the TGA information and other information regarding my implant(s). I understand that the TGA does not give any assurance of the safety of silicone gel-filled breast implants. I also understand that my name and address and information about my implant(s) may be kept on an implant register. I will keep the surgeon informed by mail of any change in my name and address.

After carefully considering all these factors, I consent to the use of silicone-gel filled breast implant(s).

<input type="text"/>	<input type="text"/>	<input type="text"/>
Patient Signature	Witness Signature	Surgeon/Physician Signature

I also understand that, in addition to this form, I must sign a separate consent form for the surgical procedure.

If the intended surgical procedure is for the replacement of an existing breast implant, please complete a problem reporting form and send to the Chief Clinical Advisor, Medical Devices, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606.

# Patient Information and Identification Record

## Silicone Gel-filled Breast Implant(s)

Record date	<input type="text"/>
Patient Hosp No.	<input type="text"/>
Patient's name	<input type="text"/>
Patient's address	<input type="text"/>
Institution	<input type="text"/>
Surgeon's name	<input type="text"/>
Surgeon's address	<input type="text"/>

	Left Side	Right Side
Type of implant	<input type="text"/>	<input type="text"/>
Manufacturer	<input type="text"/>	<input type="text"/>
Brand name	<input type="text"/>	<input type="text"/>
Catalogue number	<input type="text"/>	<input type="text"/>
Style number	<input type="text"/>	<input type="text"/>
Lot number	<input type="text"/>	<input type="text"/>
Volume	<input type="text"/>	<input type="text"/>
Date of surgery	<input type="text"/>	<input type="text"/>
Site of incision	<input type="text"/>	<input type="text"/>
Placement subpectoral	<input type="text"/>	<input type="text"/>
Submammary	<input type="text"/>	<input type="text"/>

**Note: Provide patient with a copy of this record.**