



CONSIDERING SILICONE
GEL-FILLED BREAST IMPLANTS?

While every effort has been made by Inamed Corporation to ensure the accuracy of the information contained in this booklet, Inamed Corporation accepts no responsibility and/or liability for errors or omissions. The information contained herein, has been compiled from studies into silicone gel-filled implants and from generally accepted practices. Due to the on-going research into the safety of silicone gel-filled implants, you should discuss with your surgeon, all known risks and benefits of silicone gel-filled breast implant surgery, prior to your surgery.

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**Informed Consent Forms to implant silicone gel-filled breast implants (Surgeon and Patient Copies) -
For Australian use only.**

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 the Inamed Corporation. 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 general information relating to 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 McGhan 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 6.2: Suggested questions to ask your surgeon before surgery).

1.2 General information about breast implants

a) What is a breast implant?

A breast implant consists of a silicone elastomer shell casing or envelope that is usually filled with silicone gel or a cohesive gel that has a shape retaining memory. Implants can also be filled with saline solution. Silicone gel and saline (salt-water) solution are the best known, most extensively researched fillers and most commonly used. Your doctor can tell you more about each filler.

Not only are there choices in fillers, but the shell or envelope can vary also. The surface may be rough (also known as textured) or smooth. Capsule formation is a normal physiological reaction, which occurs around any implanted device, such as a hip prosthesis, an artificial heart valve or a breast implant. With breast implants the capsule sometimes contracts after it forms, resulting in a hard and painful breast. Improvements in device design and surgical techniques have contributed to declining rates of capsular contracture. Low rates are associated with submuscular placement of the implant and with textured implants. A smooth surfaced implant lacks this feature, and may be associated with a greater risk of capsular contracture when placed subglandularly.

Over the years, the design, construction and production process of breast implants have been improved. 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. Therefore, all potential breast implant recipients should carefully consider the risks and benefits prior to consenting to surgery.

b) 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. This outer envelope was prone to rupture and also there was diffusion of silicone gel through the intact envelope.

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, not enough was known 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 1990's there was a 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.

Today, 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 (e.g. scleroderma, rheumatoid arthritis or systemic lupus erythematosus). However, there is no doubt that these implants can cause local complications such as capsular contracture, 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 intra-

venous 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 McGhan and CUI breast implants

Currently there are predominantly three types of breast implants being manufactured by Inamed Corporation:

1. Silicone gel-filled implants.
2. Saline-filled implants.
3. Double lumen implants – saline-filled core and silicone gel-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.

As every woman is unique, implants also exist in different shapes and sizes to suit their varied needs. Some implants are round, while others are shaped more like a teardrop, closely resembling the natural shape of a breast (called anatomical).

Round implants will make the upper part of your breasts fuller. Anatomical implants on the other hand, are shaped more like a teardrop and follow the body's natural contour. This gives your breasts a more natural shape.

Both types of implants can increase the size of your breasts. You should decide in consultation with your surgeon, which implant would suit you best, and achieve the look you desire.

a) Details of McGhan Gel and Gel/Saline-filled breast implants provided by Inamed Corporation:

40 McGhan INTRASHIEL™ Gel-Filled,
Smooth Round, Standard Profile Breast Implant
Size range: 140-360g



45 McGhan INTRASHIEL™ Gel-Filled,
Smooth Round, High Profile Breast Implant
Size range: 120-400g



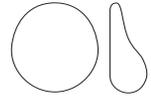
110 McGhan INTRASHIEL™ BIOCELL™
Gel-Filled, Textured Round, Moderate Profile Breast Implant
Size range: 90-510g



120 McGhan INTRASHIEL™ BIOCELL™
Gel-Filled, Textured Round, High Profile Breast Implant
Size range: 180-650g



150 (Full Height and Short Height) McGhan
 BioDIMENSIONAL™, INTRASHIEL™ BIOCELL™ Expandable
 Gel/Saline-Filled Textured Breast Implant with Adjustable Inner Lumen
Size ranges:
 Full Height: 230/250-720/760cm³
 Short Height: 135/145-625/655cm³

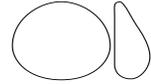


**McGhan Style 410 BioDIMENSIONAL™, INTRASHIEL™,
 BIOCELL™ Textured Cohesive Gel-Filled Breast Implant**

FL Full Height, Low Projection
Size range: 140-320g



FM Full Height, Moderate Projection
Size range: 155-670g



FF Full Height, Full Projection
Size range: 160-740g



ML Moderate Height, Low Projection
Size range: 125-285g



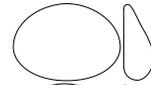
MM Moderate Height, Moderate Projection
Size range: 160-450g



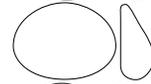
MF Moderate Height, Full Projection
Size range: 140-640g



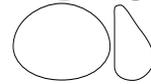
LL Low Height, Low Projection
Size range: 135-300g



LM Low Height, Moderate Projection
Size range: 140-320g

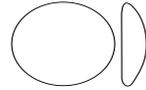


LF Low Height, Full Projection
Size range: 125-595g

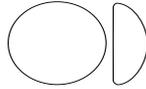


b) Details of CUI Gel-filled breast implants provided by Inamed Corporation:

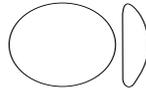
MLP CUI Style MLP Low Profile MicroCell™ Textured,
DRIE™ Silicone Gel-Filled Breast Implant
Size range: 110-380g



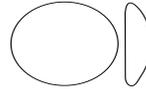
MHP CUI Style MHP High Profile MicroCell™ Textured,
DRIE™ Silicone Gel-Filled Breast Implant
Size range: 100-410g



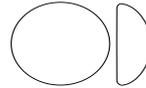
CML CUI Style CML Low Profile MicroCell™ Textured,
DRIE™ Silicone Cohesive Gel
Size range: 080-800g



SLD CUI Style SLD Low Profile Smooth, DRIE™
Silicone Gel-Filled Breast Implant
Size range: 110-500g



SHD CUI Style SHD High Profile Smooth, DRIE™
Silicone Gel-Filled Breast Implant
Size range: 100-500g



2. DECIDING TO HAVE BREAST IMPLANTS

2.1 What is a breast?

The breast is made up of fatty tissue, glandular tissue, milk ducts, blood vessels, nerves and lymph ducts covered with skin. Below the breast lies the pectoralis major muscle. A breast implant can be placed either partially under or over this muscle, depending on the thickness of your breast tissue and its ability to adequately cover the breast implant.

It is the fatty tissue that makes the breast soft and gives it its shape. The shape also depends on the elasticity of the skin. Young breasts are composed of a lot of glandular tissue and a little fatty tissue, which is why they are firm. The glandular tissue gradually makes way for fatty tissue, which is much less firm. This is why breasts become a little flabbier in the course of time. Pregnancy and breast-feeding also affect the shape of the breasts. As you get older, gravity will cause the upper part of your breasts to become "emptier", which means that the breasts droop more. Breasts contain no muscle tissue, so there is no point in doing exercises in order to enlarge them.

2.2 Making your decision

The information given here should help you to 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 your surgeon or doctor answers all your questions before you make your decision (see Section 6.2: Suggested questions to ask your surgeon before surgery). 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 Documents 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 will also give you information on our Product Replacement Policy (Returned Goods Policy) in case anything goes wrong with the implant after your surgery. You will be asked to sign a Consent Form as part of your decision making process. You should ensure that you fully understand this information and that you keep a copy in a safe place for future reference. A Consent Form is supplied in duplicate at the back of this booklet for Australian use only. You must complete and sign both copies and retain one for your records. The surgeon will keep a copy of the Consent Form also.

Each device is also packaged with a Patient Identification Card (ID Card), which you should complete and retain for future reference.

It is also recommended that you speak with a counsellor about any non-medical issues before you make your decision. Counsellors should be 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 local Health Department or Cancer Societies and support groups.

Breast implant surgery is known to provide psychological satisfaction to patients. Breast implantation is an elective procedure and you must be well counselled on the risk to benefit relationship. 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.

a) 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.

b) Factors to consider when making your decision

- What are the risks of surgery (i.e. anaesthetic, haemorrhage, infection, etc.)?
- 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

c) 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 have 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, 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. For these reasons, you should be aware that you might need to undergo surgery on your breasts again for some reason related to your breast implants.

If you have any problems with the implant (see Section 3: Risks associated with breast implants) it is recommended that you have your implants checked by your doctor. You should be aware that breast implants should not be considered lifetime devices.

d) 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.

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.

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.

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 them 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.

(i) Types of reconstruction

There are various ways to reconstruct the breast. Here again, the choice you make depends on a variety of personal details such as your state of health, the shape and size of your breasts, your remaining skin and tissue, your wishes and your lifestyle. In breast reconstruction, every situation is unique after all, you are unique. Breast reconstruction can be carried out with the aid of a breast implant, by using your own tissue, or a combination of the two.

(ii) The timing of reconstruction

The question of whether reconstruction is carried out in the same operation as the mastectomy (immediate) or at a later stage (delayed) very much depends on your personal situation. Immediate reconstruction means that the procedure begins at the same time as the mastectomy. Delayed reconstruction can be carried out weeks or even years afterwards. It is important to know that, whichever method of reconstruction you choose, it may involve various stages before the end result is achieved.

(iii) Immediate reconstruction

One advantage of immediate reconstruction is that when you wake up from the anaesthetic, the reconstruction process has already begun. This means that you avoid the experience of having only one breast, or none, if the mastectomy was performed on both breasts. Another advantage of immediate reconstruction is that it means one less time undergoing anaesthesia and surgery. In addition, costs may be reduced when the first stage of reconstruction is combined with the mastectomy. At the same time, you should realise that the length of time the operation takes is increased and there is slightly greater risk of complications. Moreover, the time required for you to accept the reconstructed breast and for convalescence may be longer than in the case of reconstruction at a later stage.

(iv) Delayed reconstruction

One advantage of delayed reconstruction, is that you give yourself time to make a good, well-considered decision. In fact, you can work on your recovery in two phases. You can begin by concentrating entirely on follow-up treatment, such as radiotherapy, chemotherapy, or both. You will also need time to cope with the whole course of the disease, a process that will require a great deal of energy. After this phase, you can prepare yourself for the restoration of your natural body contours.

Your surgeon will discuss with you the best timing depending on your situation and your wishes. Allow plenty of time for these discussions. The decision to have breast reconstruction carried out is an important one, leading into a new phase of life.

There are medical, financial and emotional considerations to choosing immediate versus delayed reconstruction. Talk to your surgeon about the options relevant to your situation.

e) 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 tissue around the implant), rupture, hardness, pain, etc. Section 3 of this booklet details the risks associated with breast implants.

f) 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" (lumpy) breasts;
- ptotic (drooping) breasts where the nipple falls below the inframammary fold, without mastopexy (breast lift surgery);
- advanced fibrocystic disease (condition common in women that is characterised by pain and multiple cysts in the breast) considered to be pre-malignant without mastectomy;
- 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 concern you may have with your doctor or surgeon. The specific product information will be provided to you by the surgeon and will be explained to you, as it contains a lot of medical detail.

2.3 Breast implant surgery

a) Placement

The breast implant is placed either partially or totally under the pectoralis major muscle (submuscular) or on top of the muscle and under the glands (subglandular). The surgeon, in consultation with you, will choose the location depending on your physical characteristics.



Breast before
augmentation



Breast after subglandular
augmentation



Breast after submuscular aug-
mentation

b) 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 an 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 (McGhan Style 150).

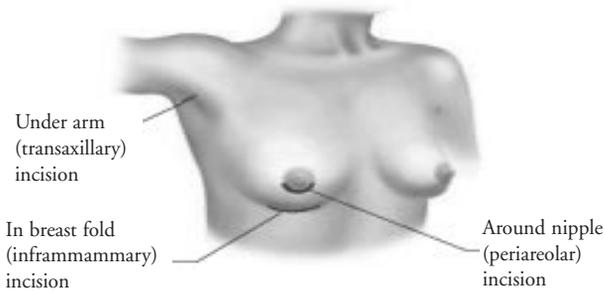
The McGhan Style 150 implant has an adjustable saline-filled inner lumen surrounded by a silicone gel-filled outer lumen. In most cases, the McGhan Style 150 breast implant eliminates the need for patients to undergo additional expander exchange surgery. Uniquely controlled expansion to the lower area provides complimentary results with a natural shape.

c) Incisions

There are three possible incisions (i.e. cuts in the skin) through which a gel-filled breast implant can be inserted (the incision site chosen will depend on the size of the implant being 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.



d) Anaesthetic

Breast implant surgery is performed under general anaesthetic, i.e. you will be unconscious during the procedure, or local/regional anaesthetic, i.e. you will be awake. The type of anaesthetic will depend on the anaesthetist, the surgeon and you. All anaesthetics carry a risk and you should discuss these risks with the anaesthetist.

e) Preparing for the operation

Smoking – smoking can decrease your wound healing ability so your doctor will probably advise you to stop smoking or provide you with further information on how smoking may affect your chances of a successful operation.

f) How long will you be in hospital?

The majority of breast implant surgery is performed as a day surgery procedure, i.e. you enter the 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.

g) 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.

The McGhan Style 150 has a remote injection site, which is attached to the implant via a tube. This remote injection site reliably allows for long-term device adjustability. The remote injection site can be removed if needed.

h) 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.

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:

a) 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. Capsular contracture may be related to infection in the area surrounding the implant.

b) 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 may develop a thick, red scar known as a keloid scar. It is not always possible to predict which patients will develop these keloid scars. You should discuss these factors with your surgeon.

c) 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.

d) 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 or if you are a smoker.

e) A breakdown of skin, known as necrosis

This may occur 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.

- f) **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.
- g) **Wrinkling of the implant**
Visible and palpable wrinkling may occur with all implants, especially saline-filled types. It occurs more commonly in thin women.
- h) **Visible or palpable implants**
In women with little breast tissue the implant may be obvious when looking at the breast or it may be easily felt as a foreign object. Submuscular placement should be advised in these cases.
- i) **Pain**
As expected following any invasive surgical procedure, pain of varying intensity and duration may occur following breast implant surgery. In addition, improper implant size, implant placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. Very occasionally severe pain associated with arm movement has been reported. Pain may later occur with the development of capsular contracture. Unexplained pain must be promptly investigated by the surgeon.
- j) **Rupture/deflation**
Patients should be advised that their implants might rupture, releasing silicone gel or saline, and require replacement or revision surgery. The saline-filled lumen of the double lumen implant (McGhan Style 150) may also deflate, resulting in slight asymmetry and require revision surgery. Damage may result in immediate rupture, or may weaken the envelope and result in rupture/deflation post-operatively.
- k) **Rotation**
Rotation of the implant may occur. Proper placement and pocket dissection reduces the risk of occurrence.

3. RISKS ASSOCIATED WITH BREAST IMPLANTS

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

3.1 Local complications

a) 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 tissue around it. This 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 more 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 incision, 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.
- A 'capsulectomy' is a surgical procedure whereby the surgeon removes the tissue surgically.
- A 'closed capsulotomy' is 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, it can reoccur. The recurrence rate for capsular contracture is unknown. Generally there is a higher rate of capsular contracture and recurrence of capsular contracture, following a second surgical procedure. Improvements in device design and surgical techniques have contributed to declining rates of capsular contracture. The current risk of clinically significant capsular contracture is approximately 10%. Low rates are associated with submuscular placement of the implant and with textured implants.

b) Implant rupture and gel leakage

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

- Injury;
- Normal wear and tear of implant envelope;
- Closed capsulotomy (a technique that uses manual pressure to break up fibrous tissue around the implant – no longer a recommended technique but it may be used in some circumstances);
- Implant age;
- Mammography.

If a silicone gel implant ruptures, the gel is usually contained within the capsule around the implant. Sometimes the gel does not remain within the capsule and may be found in nearby breast and other body tissues. Some of the silicone gel may travel (migrate) to other parts of the body, including the 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.

In some cases implant rupture can occur in the absence of any symptoms. However, when symptoms occur they may include:

- Lumps in the breast;
- 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 some 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. Your doctor will 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% to a high of 95% 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. Improvements in device design, manufacture and surgical techniques have contributed to the lower rates of rupture/deflation reported in recent studies. The rupture/deflation rates are dependent on many factors as listed above.

c) Gel diffusion

Rupture of the implant is not the only means by which silicone may escape to the surrounding tissues. Silicones may diffuse through the implant envelope in the absence of a tear. Although it is only the silicone fluid component of 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 will be able to advise you on the best test in your case.

Advancements in implant technology and design have improved shell features, thereby reducing gel diffusion. McGhan INTRASHIEL™ and CUI DRIE™ shells feature a patented barrier coat between two layers of silicone elastomer to minimise gel diffusion.

d) 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, your doctor should examine these breast lumps. This may involve removing 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 had breast implants.

e) Changes in nipple and breast sensation

Any operation may result in changes in nipple or breast sensation. The breast and nipple may become painfully sensitive or may lose all pleasurable sensation. In most cases these changes are temporary but in as many as 1 in 7 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 to recognise and fight infection, toxic and foreign material. 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, e.g. 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 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 tissue 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. As yet neither the FDA (Food and Drug Administration), nor the European Ministries of Health, have approved any of these detection tests, and they have indicated that the results of these tests should be treated with caution.

3.4 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.

You should be aware that breast implants may interfere with mammograms, which assist in the early detection of breast cancer (see section on Mammography). Therefore, it is extremely important that you have regular checkups to detect cancer early.

Breast cancer occurs in tissues rich in ducts and glands, and may spread throughout the body. About one in every ten women develops breast cancer in her lifetime. Because of the safety issues surrounding silicone in medical devices and the incidence rates of breast cancer in the human population, questions have been raised concerning increased risks of developing breast cancer for women with breast implants. Several clinical studies have demonstrated that the likelihood of developing breast cancer does not appear to increase following the use of silicone breast implants. There is no scientific evidence that women with silicone gel-filled (or saline-filled) mammary implants are more susceptible to cancer than other women.

3.5 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. Studies indicate that there is no evidence to show an increased risk of connective tissue disease in children of women with breast implants.

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 showing that if silicone is absorbed it will cause illness in the child.

3.6 Birth defects

There is no evidence that silicone gel-filled breast implants cause birth defects. A review of the published literature indicates that studies in animals that have evaluated silicone materials for birth defects or other reproductive effects have shown a lack of such activity.

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 practice 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 discuss available treatments.

Many women (including women with breast implants) experience symptoms due to normal hormonal 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;
- 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 practice 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.

a) Breast self-examination

All women should examine their breasts each month. Breast self-examination includes looking at your breast 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', i.e. 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.

b) Clinical examination

Clinical examination by your doctor includes looking at your breasts with your chest muscle 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.

c) 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. Some devices may also have orientation marks, which may be misdiagnosed as small tumours.

How useful mammograms are 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 your local Radiologists Association for information and guidelines on detecting 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 one, 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 facts 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 extreme capsular contracture, constant pain, infection that will not clear up, or rupture.

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 leaked silicone is likely to be. However, some doctors say that the 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 (e.g. 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, surgical procedure called mastopexy or 'breast lift' can be performed. There are risks associated with this procedure including infection, bleeding and scarring.

You should report any problems experienced with your implants, to your Local Health Authority (see also Section 5.2: Reporting adverse events).

4.5 Recovery

You will normally be able to return to work or resume your usual day-to-day activities after a few days. Your surgeon will probably advise you to try to avoid stress for the first few weeks, and in any case you should avoid activities, which could increase your pulse rate and raise your blood pressure. Your surgeon can give you more specific tips, geared to your own personal situation, on what is best for you to ensure a successful recovery.

4.6 Worried? Contact your doctor

If anything happens and worries you, such as a raised temperature, a visible swelling, reddened skin on the breast or any of the other complications listed in this booklet then contact your surgeon immediately.

5. OTHER IMPORTANT INFORMATION

5.1 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. Inamed Corporation provides a Patient Identification Card with each of its implants that must be given to the patient and contains details of the type of implant obtained (the style, reference number, serial number, lot number etc.). This card should be retained as part of your records.

Patient medical records are kept for several years. 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.

5.2 Reporting adverse events

If you are living in Australia and the intended surgical procedure is for the replacement of an existing breast implant, you should complete a Problem Reporting Form and send it to the Regulatory Authority in Australia. A Problem Reporting Form can be obtained from your doctor or local health clinic.

5.3 Informed consent

An important part in taking the decision to have a silicone breast implant is to sign an Informed Consent Form. Your doctor will provide you with an Informed Consent Form, which is included in the product packaging. If you are receiving your implant in Australia, you should complete and sign the duplicate Consent Forms provided at the back of this booklet. You should retain the patient copy for your records, while the surgeon will retain the surgeon copy.

It is important that you take at least 30 days to read and consider the information provided to you by your surgeon before you decide to complete the Informed Consent Form.

A further Informed Consent Form will be required by the hospital as part of the general procedures for surgery.

5.4 Checklist

To assist you in your decision making process, a checklist is included in Section 7 of this booklet. It is recommended that you complete the checklist to make sure that you have considered all the necessary information to assist you in your decision to have silicone gel-filled breast implants.

6. QUESTIONS

6.1 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. Breast implants should not be considered lifetime devices.

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 an alternative to gel-filled implants. These 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 contraction (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 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 your leakage (e.g. 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 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 years of age, it is recommended that 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 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. How much will it cost for me to have breast implants?

The cost of breast implant surgery 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 (e.g. costs for further surgery).

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.

6.2 Suggested questions to ask your surgeon before surgery

You should question your surgeon before surgery to ensure that you understand all about your surgery. The following is a list of some useful questions you could ask:

- What type of surgery will I have?
- What benefits can I expect to have?
- What type of risks and side effects can I expect?
- Is this a standard surgical procedure or is it experimental?
- Who will perform the surgery?
- What alternative treatments could I have?
- What are the chances of not achieving the desired outcome?
- What are the consequences of the procedure?
- What are the expected long-term outcomes of the procedure (e.g. physical, emotional, mental, social, sexual, etc.)?
- How long will the surgery take?
- How long will it take to recover from the surgery?
- How long will I have to stay in hospital?
- How much will the surgery cost and what additional expenses can I expect to have?
- Are there any leaflets describing the procedure in a simplified way using drawings?
- How long will it be before I have to replace my implants?
- What is the manufacturer's replacement policy in the event that the device fails?
- What is the surgeon's qualification, is he qualified to perform the procedure?
- What is the surgeon's specialist area?
- How much experience do you have using the different methods?
- Do you have photos taken of patients before and after reconstruction/augmentation so that I can get an idea of the results that are possible with each method?
- What results do you think can be achieved for me?
- What will the scar be like?
- Can I expect changes in the course of time and what will they be?
- Is it possible to talk to other patients about their experiences?
- Which different types of breast implants can I choose from, and what are the advantages and disadvantages of each?

You should ask the surgeon about any special questions or concerns you may have.

7. CHECKLIST

- I have read the Inamed Corporation booklet *Considering Silicone Gel-Filled Breast Implants?*
- I have asked the surgeon questions and received satisfactory answers.
- I have read other information regarding breast implants.
- My doctor has described the process, complications, risks and benefits to me.
- My doctor has gone through the detailed product information relating to the implants best suited to me.
- I have signed the duplicate Informed Consent Form relating to the implantation of the silicone gel-filled breast implants and have kept the patient copy.
- I have completed the Patient Identification Card and have it in my records.
- I have arranged for time off work to allow for post-operative care and healing.

Glossary of Terms

Asymmetry: Imbalance in the proportion, size and shape of the left and right breasts.

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 breast through the use of breast implants.

Capsule: The 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 contracts. 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 silicone elastomer.

Fibrocystic Disease: Condition common in women that is characterised by pain and multiple cysts in the breast.

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 other body tissues, particularly through the body's lymphatic system.

Inframammary Fold: The crease at the base of the mammary gland (breast) and the chest wall.

Lumen: Interior space or cavity, for example, the inside of a breast implant or tube.

Magnetic Resonance Imaging (MRI): Technology to detect breast cancers or other abnormalities in the breast including breast implant rupture and leakage. The technique involves the use of radio waves to take pictures of sections of body tissue.

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 after diagnosis of breast cancer.

Mastopexy: Breast lift. 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.

Prophylaxis: The prevention of disease; preventive treatment.

Ptosis/Ptotic Breasts: Prolapse/Drooping of the breast.

Reconstruction: Breast reconstruction refers to the operation performed to create a new breast after mastectomy.

Rupture: Rupture of an implant refers to a break in the envelope of an implant. The rupture can be a pinhole 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.

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 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.

Ultrasound: Is the use of ultrasonic waves to detect abnormalities including rupture of breast implants.

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**McGhan & CUI Silicone Breast Implants
Informed Consent to implant silicone gel-filled breast implants
Information for patients, considering gel-filled breast implants**

As a patient already determined eligible for silicone gel-filled breast implants, you should receive an Inamed Corporation booklet called *Considering Silicone Gel-Filled Breast Implants?*. This booklet contains information about the risks involved before surgery is scheduled, so that you have time to review and discuss the information, including any unfamiliar medical terms with your surgeon. You must decide whether you are willing to accept the risks along with the benefits of breast implant surgery. The risks and benefits may vary, depending on you, the patient, and the specific procedure performed.

You should discuss with your surgeon any previous unsuccessful surgery, infections, psychological or psychiatric illness, painful "cystic" breasts, a history of repeated breast cancer or other cancer, which has spread, or if you have taken any drugs that would interfere with blood clotting.

It is recommended that you speak with a counsellor about any non-medical issues before you make your decision.

It is recommended that after you have obtained all the information that you should take at least 30 days to think about the risks and benefits of having breast implants before making a final decision.

ADDITIONAL INFORMATION AVAILABLE

In addition to the booklet, your surgeon may wish to discuss aspects of the information provided, with you before surgery:

- Alternatives to breast implant surgery;
- The detailed product information we have provided in our product inserts;
- The risks and benefits of the specific surgical procedure(s) to be performed.

Patient details:

Name:

Date of birth:

Address:

.....

.....

Previous implant(s): Yes No Type:.....

Implant date:

Surgeon name:.....

Institution:

Address:.....

.....

Reason for implant(s):

.....
.....

I have read and believe that I understand all the information presented to me including the information provided in the *Considering Silicone Gel-Filled Breast Implants?* Booklet from Inamed Corporation 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 surgeon and I have chosen will be performed using silicone gel-filled breast implant(s). I also understand that periodic medical check-ups are required and that the implant(s) have a limited life span.

I have received a copy of the Inamed Corporation *Considering Silicone Gel-Filled Breast Implants?* Booklet and other information regarding my implant(s) on (date).

I have taken days to consider this information.

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).

.....

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:

**TGA,
Conformity Assessment Branch,
PO Box 100,
Woden ACT 2606.**

Surgeon Copy

FOR AUSTRALIAN USE ONLY

**McGhan & CUI Silicone Breast Implants
Informed Consent to implant silicone gel-filled breast implants
Information for patients, considering gel-filled breast implants**

As a patient already determined eligible for silicone gel-filled breast implants, you should receive an Inamed Corporation booklet called *Considering Silicone Gel-Filled Breast Implants?* This booklet contains information about the risks involved before surgery is scheduled, so that you have time to review and discuss the information, including any unfamiliar medical terms with your surgeon. You must decide whether you are willing to accept the risks along with the benefits of breast implant surgery. The risks and benefits may vary, depending on you, the patient, and the specific procedure performed.

You should discuss with your surgeon any previous unsuccessful surgery, infections, psychological or psychiatric illness, painful "cystic" breasts, a history of repeated breast cancer or other cancer, which has spread, or if you have taken any drugs that would interfere with blood clotting.

It is recommended that you speak with a counsellor about any non-medical issues before you make your decision.

It is recommended that after you have obtained all the information that you should take at least 30 days to think about the risks and benefits of having breast implants before making a final decision.

ADDITIONAL INFORMATION AVAILABLE

In addition to the booklet, your surgeon may wish to discuss aspects of the information provided, with you before surgery:

- Alternatives to breast implant surgery;
- The detailed product information we have provided in our product inserts;
- The risks and benefits of the specific surgical procedure(s) to be performed.

Patient details:

Name:

Date of birth:

Address:

.....

.....

Previous implant(s): Yes No Type:

Implant date:

Surgeon name:

Institution:

Address:

.....

Reason for implant(s):

.....
.....

I have read and believe that I understand all the information presented to me including the information provided in the *Considering Silicone Gel-Filled Breast Implants?* Booklet from Inamed Corporation on risks and benefits of silicone gel-filled breast implants. I have had an opportunity to ask questions of

Dr.....

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.....

Patient Signature

.....

Witness Signature

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Surgeon/Physician Signature

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If the intended surgical procedure is for the replacement of an existing breast implant, please complete a problem reporting form and send to:

**TGA,
Conformity Assessment Branch,
PO Box 100,
Woden ACT 2606.**

Patient Copy

Device Technologies Australia Pty. Ltd.
Locked Bag 521, Frenchs Forest
NSW 1640, Australia
Tel: 61.2.1800 804 006
Fax: 61.2.1800 999 323
website: www.device.com.au

