MINISTRY OF HEALTH
MANATŪ HAUORA

Silicone Gel Breast Implants

Therapeutics Section
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CONTENTS

DISCLAIMER

This information booklet was prepared by the Compliance Team of the Ministry of Health's Therapeutics Section to assist women to make an informed choice about the use of silicone gel breast implants.

While every care has been taken in the preparation of the information contained in this booklet, the Ministry of Health is not responsible for the results of any act or omission, done or omitted in reliance, in whole or in part, on the basis of that information, nor for any error or omission from the booklet.

ACKNOWLEDGEMENTS

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PREFACE

This is the second edition of this booklet. The information it contains is not significantly different from that in the first edition, but it is presented in greater detail. It also includes advice for women who already have breast implants.

If you are considering breast implants, or already have breast implants, the Ministry of Health believes that you should read the following information about the possible risks involved.

The use of breast implants is not endorsed by the New Zealand Government, whether through the Ministry of Health or otherwise, and the safety of such implants cannot be confirmed or refuted.

Please read the information carefully and be prepared to ask your surgeon questions. Your surgeon should have additional information for you about the operation and about the types of implants available. Make sure you have fully discussed any concerns that you may have before consenting to the operation.

After reviewing the information and discussing concerns with your doctor and others, you must decide for yourself whether to accept the risks in order to achieve the expected benefits. It is very important that you understand fully what is involved before consenting to the operation.

If you decide to have breast implants, you should advise your surgeon whether you wish your name, address and details of the implant(s) to be recorded on a register. The intention of this register is to make it easier to inform you of any significant new information about the safety of your implant(s). The Ministry of Health has requested that members of the New Zealand Association of Plastic and Reconstructive Surgeons, and the New Zealand Breast Surgery Section of the Royal Australasian College of Surgeons each maintain a register of their own patients. You should ask your surgeon whether they hold such a register.

Arrangements have been made to keep surgeons informed through their professional organisations of significant new information on the safety of breast implants so that they may then pass this information on to the patients on their register.

You may choose not to have your name on the register being kept by your surgeon. If you do this you may not be contacted with new information about your implant.

Please keep this information booklet which contains your copy of the declaration and register entry (if appropriate). If you change your name or your address, you will be responsible for telling your surgeon so that the register can be amended.

INFORMATION ABOUT BREAST IMPLANTS

The following is information from the Food and Drug Administration (FDA) of the United States of America about breast implants. It contains information for women considering breast implants and recommends a number of questions they should discuss with their surgeons. There is also advice for women who already have breast implants.

Footnotes have been added to clarify and to explain the situation in New Zealand.

SILICONE GEL-FILLED IMPLANTS

Under the law,[1] FDA's job in regulating medical devices such as breast implants is to be sure they are safe and effective before they are marketed. To do that, FDA requires manufacturers of new devices that might be risky to submit scientific evidence showing they are safe and effective.

Breast implants were already on the market when FDA began to regulate medical devices in 1976. Like other devices in this category, they were allowed to remain in use, with the understanding that FDA would later go back and require the manufacturers to submit scientific evidence of safety and effectiveness, just as they would do if the devices were brand new.

When FDA asked the manufacturers of silicone gel-filled breast implants to submit this scientific evidence, it became apparent that much of the information was not available. This does not necessarily mean that the implants are unsafe. But it does mean that FDA cannot vouch for their safety. This is why FDA decided to remove gel-filled implants from the market and allow them to be used only in controlled clinical studies.[2]

The adverse effects associated with silicone gel-filled breast implants can be divided into two categories: known effects, which are experienced by some women and are clearly associated with these devices, and possible effects, which might exist but have not been proven.

[1]In the USA.

[2]In New Zealand gel-filled implants have not been withdrawn from the market. The Ministry of Health is monitoring the situation internationally regarding breast implants and has produced this booklet to inform women considering breast implants of the issues and risks, and to provide information for women with existing breast implants.

KNOWN RISKS

At this point, the manufacturers of the implants have not been able to supply FDA with the actual percentage of women who experience these effects. Future studies should help to answer this question.

Capsular contracture

The most common of the known risks is capsular contracture, a tightening of scar tissue that normally forms around the implant. The tightened scar tissue can squeeze the implant, causing pain, hardening of the breast or changes in its appearance. Capsular contracture can also make the detection of breast cancer more difficult. If capsular contracture becomes a problem, the doctor may have to remove the scar tissue surgically.

Calcium deposits in tissue around the implant

Calcium deposits can also form in surrounding tissue, and this too can cause pain and hardening.

Granulomas

These are non-cancerous lumps that can form when certain body cells surround a tiny droplet of silicone. It may be difficult to distinguish granulomas from other potentially cancerous lumps, unless they are removed and examined, or biopsied, to determine if they are cancerous.

Rupture of the implant

There is also the possibility that an implant may rupture, allowing the gel filling to be released into the surrounding tissue. The implant can break due to injury or normal wear over time, releasing the silicone gel filling. The silicone gel may migrate to the surrounding breast tissue and other parts of the body. The effects of this silicone are not fully understood at this time.

Implants can rupture without any noticeable symptoms. Some women have reported a burning sensation or a loss of breast shape. Women are advised to see their doctor if they notice these symptoms, or if they think their implant may have ruptured.

Interference with mammography

Breast implants also may delay detection of early breast cancer by "hiding" suspicious lesions in the breast during mammography. It is especially important for women who are at high risk[3] of developing breast cancer to consider this before having implants.

Since the breast is compressed during mammography, it is possible for an implant to rupture.

Before the mammography examination, women should tell the radiographer that they have implants. The radiographer should take special care when compressing the breast to avoid implant rupture. Also, an experienced radiographer should know how to push the implant away from the breast tissue to get the best possible view of the tissue. Even when this special technique is used, some breast tissue may be missed. Also, women are subject to additional radiation and higher costs because more x-ray views are needed for women with implants.

Also, it may be difficult to distinguish any calcium deposits formed in the scar tissue around the implant from a tumour when interpreting the mammogram.

Changes in nipple and breast sensation

Other known effects include temporary or permanent changes in nipple or breast sensation due to the surgery. There can be increased or decreased sensation. Some women have reported that after implant surgery their breasts feel numb, while others reported intense pain.

Interference with breast feeding

The surgical implantation of a device into the breast may interfere with a woman's ability to nurse her baby. Previous surgery, such as that for a mastectomy or for a previous breast implant, already may have interfered with a woman's ability to breast feed.

If the problems are severe, the implants may have to be removed permanently.

[3]High risk is defined in the Ministry of Health policy on the lower age limit for screening mammography as having one or more of the following:

- a strong family history of breast cancer (a mother or sister with premenopausal breast cancer or bilateral cancer),
- previous breast cancer,
- breast histology demonstrating an at risk lesion, eg atypical hyperplasia.

POSSIBLE RISKS

The *possible* risks are chiefly related to silicone gel that may escape from the implant and reach distant parts of the body. This can happen if the implant ruptures, or when tiny amounts of silicone leak or "sweat" through an intact implant. (This is also referred to as "gel bleed".)

Autoimmune-like disorders

It has been suggested that even the very small amounts of silicone that "sweat" through the implant could cause certain autoimmune-like disorders such as lupus, scleroderma and rheumatoid arthritis in some women.

Some physicians have reported that a few of their patients have developed arthritis-like diseases after receiving breast implants. But there is no conclusive evidence at present that women with breast implants have an increased risk of developing autoimmune-like disorders. In other words, women with breast implants who have developed such diseases may have done so regardless of their implants.

Some recent animal research studies have reinforced the ideas that there might be a link between silicone gel and effects on the immune system. For example, some studies have shown that silicone gel of the type used in breast implants can increase antibody production in these animals. However, these studies cannot prove a connection between silicone and immune system effects because they were intentionally designed to stimulate the animals' immune systems through the injection of other substances.

Another study has shown that some women with breast implants produced antibodies against their own collagen (a connective tissue protein), but it is not known whether this might increase their risk of actually developing an autoimmune-like disorder.

More research will be needed before it is known whether studies like these are relevant to women with breast implants. Some of this research is already under way.

Cancer

Another question is whether the silicone in breast implants can increase the risk of cancer. There is no evidence that this is the case, although the possibility cannot be totally ruled out. Studies presently under way should provide an answer to this question within the next few years.

There is a special question about silicone gel-filled breast implants that are coated with polyurethane foam. About 10 percent of women with implants have this type.[4] The coating was intended to reduce the risk of capsular contracture. These implants are no longer being used because it was found that the polyurethane coating can chemically break down under laboratory conditions to release very small amounts of a substance called 2-toluene-diamine (TDA), which can cause cancer in animals.

It is not known whether there is an increased risk of cancer from the TDA in women with this type of implant. At present, there is not enough evidence to justify having polyurethane-coated breast implants removed because of concerns about cancer.

Concerns have also been raised about whether TDA from the polyurethane-coated implants could find its way into breast milk and whether this might pose a risk to a nursing infant. To help answer this and other questions about polyurethane-coated implants, FDA is requiring the manufacturer to conduct studies on these implants, analysing blood, urine and breast milk for TDA.

Birth Defects

Because there is not enough research to show whether or not silicone gel-filled breast implants cause birth defects, FDA has required manufacturers to conduct further studies on this issue and submit them to FDA for review.

SALINE-FILLED IMPLANTS

Although the safety of saline-filled implants has not been proven, leakage or rupture of these implants results in release of salt water, which is not foreign to and does not remain in the body. But because saline implants use a silicone envelope, whose long-term safety has not been demonstrated, the saline-filled implants may not be entirely without risk.[5]

If a saline-filled implant leaks or ruptures, it deflates and usually must be replaced. A woman who is considering saline-filled implants should discuss this possibility with her doctor beforehand.

[4]In the USA.

[5]FDA are currently reviewing the safety of saline-filled implants.

OTHER FREQUENTLY ASKED QUESTIONS

How long do the implants last? The life span of the implants is not known; future studies should help to answer this question. Implants can last from a very short time to many years, depending on the patient and the implant. In any case, breast implants should not be considered "lifetime" devices.[6] Women should be followed by their physicians for as long as they have their implants.

What about the problem of implant rupture? If a gel-filled implant has ruptured it should be removed. Signs and symptoms of rupture may include breast pain, tingling, numbness, burning, changes in breast size or shape, and changes in sensation.

An implant may rupture without causing symptoms, but women should not have routine mammograms (breast x-rays) just to detect these "silent" ruptures.[7]

What factors increase the chance that an implant will rupture? The chance for rupture may increase the longer the implant has been in the body. Injury to the breast also increases the chance of rupture, as may closed capsulotomy, a technique to correct capsular contracture by squeezing the breast to soften the scar tissue. Closed capsulotomy was commonly practised in the past, but is not currently recommended.

Should a woman with gel-filled breast implants nurse her infant? It is not known whether the small amounts of silicone that "bleed" from all gel-filled breast implants can find their way into breast milk and, if this were to occur, whether it could affect the child. Further study is needed to answer this question.[8]

[6]Women who opt to have breast implants should be aware that it may be necessary to have further surgery to remove or replace the implants.

[7]Most implant ruptures do not cause symptoms, and are detected at subsequent surgery. Neither mammograms nor ultrasound will definitely detect a ruptured implant.

[8]Because it is not known whether silicone appears in breast milk of women with breast implants the New Zealand Ministry of Health recommends that women with breast implants consider the potential risks and benefits of breast feeding.

Are there concerns about the children of women with implants? Some women are concerned that health problems in their children could be linked to exposure to silicone during pregnancy or nursing, although there is no scientific evidence at this point to prove that this can occur. FDA will follow any research in this area and will provide this information to women as it becomes available. Parents who are concerned about symptoms in their children should consult their doctors.

Is there a test to detect silicone in the body? Is there one to determine whether an individual is sensitive to silicone? There is no widely available, standardised test to detect silicone in the body. Some large, sophisticated research laboratories are able to detect the presence of silicone or silicon (an indirect measure of silicone) in blood, tissue and urine, but the meaning of these test results is unknown.

Even if simple techniques to detect silicone were available, they might not be useful in detecting a rupture, because small amounts of silicone ordinarily "bleed" even from intact implants. Further, since silicone is found in food and many products, including commonly used medicines and cosmetics, the tests would not easily be able to determine whether the silicone came from the implant or another source.

Determining that silicon or silicone are present in body fluids does not indicate whether a person is sensitive to these substances or at risk for any specific disease. There is presently no test to determine if a person reacts to silicone or silicon.

How can a woman find out what kind of implant she has? The information should be in her medical records. She can contact the facility where the surgery took place, or ask her surgeon. Women with implants who want this information should seek it soon, since physicians and hospitals do not necessarily keep medical records indefinitely.[9]

Should a woman have her breast implants removed? FDA is not recommending that women have their implants removed if they are not experiencing any problems. But they should be alert for possible problems. If they experience any symptoms they feel may be related to the implants, they should contact their personal physicians,[10] as they would with any illness.

[9]This information also applies in New Zealand. To find out about her medical records, a woman should approach her general practitioner, surgeon or hospital for further information if required.

[10]General practitioner or surgeon.

ADVICE FOR WOMEN CONSIDERING IMPLANTS FOR RECONSTRUCTION

Breast implants have been available in the United States since the 1960s. As of 1992, approximately 1.5 million women[11] have chosen breast implants either for reconstruction or augmentation.

About 20 percent of these implants[12] have been used for reconstruction of breasts after mastectomy (surgical removal of the breast due to cancer or injury), or to correct other deformities. The rest have been used for augmentation (to increase the size or improve the shape of the woman's natural breast(s)).

Making the decision to have reconstruction with silicone gel breast implants

Learning why some women choose reconstruction with implants and why others don't, may help you decide whether this surgery is for you. The reasons are varied and highly personal:

- to replace an external breast prosthesis
- to avoid being constantly reminded of their cancer diagnosis
- to allow for a more comfortable active lifestyle
- to avoid embarrassment in public dressing areas
- to help create a look that makes them feel more comfortable with or without clothes.

A few reasons why some women decide against reconstruction are:

- they may want to avoid more surgery
- they feel the risks outweigh the benefits
- they are happy with their external prosthesis
- they are concerned over the unknowns about breast implants.

[11]In the USA.

[12]In the USA.

Although breasts reconstructed with implants aren't the same as natural breasts and are sometimes troublesome, many women have reported they are happy with their appearance, size, and feel or texture.[13]

Existing studies of the long-term psychological benefits of breast implants are inadequate. These studies have concentrated primarily on mastectomy patients. FDA believes that more information on long-term psychological benefits are needed. For this reason, FDA has required manufacturers to continue psychological studies and report the results.

SPECIAL MEDICAL CONSIDERATIONS

Before making your decision, you should discuss with your doctor the following important medical matters and how they might affect your decision:

- whether only the initial surgery will be required or if additional corrective surgeries might be needed on your reconstructed or other breast
- the possibility of rupture of your implant(s), signs to watch for, and what is involved if your implant(s) ruptures
- gel bleed (the sweating of microscopic amounts of silicone through the implant envelope) and how it might affect you
- capsular contracture (the tightening of scar tissue that forms around implants) and how it might affect you
- open capsulotomy (the surgical removal of scar tissue surrounding an implant)
- closed capsulotomy (the forceful squeezing of the breast to loosen or break up scar tissue surrounding an implant)
- what is currently known about an association of autoimmune disease with silicone gel breast implants
- the effect of past or future radiation (x-ray) therapy treatments for breast cancer
- your personal or family history of immune-related disorders, such as scleroderma and lupus
- the effect of medicines, especially any taken for chemotherapy

[13]The New Zealand Ministry of Health is aware that some women have not experienced these benefits and express dissatisfaction with their breast implants.

- previous problems with breast implants you may have had
- the movement of your implant when you lie down or raise your arm
- discomfort when lying on your stomach
- your breast's response to heat, cold, touch, and sexual activity
- effect on breast feeding
- the chance that you may be able to feel the edges of the implant
- the appearance of your cleavage
- matching both breasts.

ADVICE FOR WOMEN WITH IMPLANTS

Examining the Breasts

Like all women, those with breast implants should perform regular breast self-examinations and seek regular examinations by their personal physicians, their surgeons or other health professionals trained in breast examination.[14] For women with breast implants, these examinations take on added importance because they can help to detect complications that might be due to the implants.

Women with implants should examine their breasts on a monthly basis so they become familiar with how their breasts normally feel and can detect changes. For women who menstruate, the best time to examine the breasts is two or three days after the menstrual period ends, when the breasts are least likely to be tender or swollen. Women who no longer menstruate should examine their breasts at the same time each month.

To examine your breasts, first stand in front of a mirror and look for anything unusual, such as changes in the shape or appearance of your breasts or nipples. Then with your right arm raised above your head, use the flat surface of your fingertips of your left hand. Move them in a circular motion in a clockwise fashion around the breast to feel for any unusual lump, swelling, or mass under the skin of your right breast.

You should also feel for any swelling of the glands or lumps in your armpit. Follow the same procedure for the other breast. Repeat while lying down.

Pay particular attention to changes in the firmness, size or shape of your breasts. Be attentive to pain, tenderness, or colour changes in the breasts area, or any discharge or unusual sensation around the nipple. Any of these changes should be reported promptly to a physician, as should any other concerns about your breasts.

[14]Initially, ask your surgeon for guidance.

Getting Mammograms

Women with breast implants who are in an age group where routine mammograms are recommended should be sure to have these examinations at the recommended intervals.[15] (Those who have had breast cancer surgery should ask their doctors whether mammograms are still necessary.)

It is important to ask whether personnel at the mammography facility are trained and experienced in the special techniques needed to perform mammography on patients with breast implants. If these techniques are not used, there is a greater chance that breast cancer will go undetected.

Women with implants should always inform the radiologist and technician about the implants before mammography is performed. That way they can be sure to use special techniques for detecting breast abnormalities, and can take extra care when compressing the breasts to avoid rupturing the implant.

Dealing with concerns about autoimmune-like disorders

The possible link between gel-filled implants and autoimmune-related disorders is unclear. Nevertheless, women with implants should be aware of symptoms that can occur with these disorders. These 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. People who have immune-related disorders, which are relatively rare, generally experience a combination of these and other symptoms.

A woman who experiences these symptoms should see her regular doctor if the symptoms do not subside, because these complaints could signal a variety of health problems, not just immune-related disorders.[16] Depending on the situation, her doctor may refer her to a rheumatologist or other type of specialist for further evaluation.

Removal of the implant

There are a variety of problems that could require removal of the implant. These problems include rupture from a sharp blow or from normal wear over time, as well as adverse effects such as severe capsular contracture and calcium deposits. It is not known how many women have had to have their implants removed because of implant rupture or other problems.

[15]In New Zealand the Ministry of Health's policy is to recommend that women who are under 50 should not have routine screening mammograms unless they have known risk factors for breast cancer. The risk factors include a strong family history of breast cancer, previous breast cancer, or breast histology demonstrating an at risk lesion.

[16]If a woman experiences these symptoms it is important that she tells her doctor that she has breast implants.

ADDITIONAL NEW ZEALAND INFORMATION

Product liability

Specific information about an implant is usually provided to the surgeon by the manufacturer of the implant. In some cases the manufacturer may include a statement which exempts it from liability or limits its liability in respect of the implant.

This may complicate your chances of legal recovery against the company and/or your surgeon if you go ahead and have a breast implant inserted and then experience complications.

You should ask your surgeon to show you the manufacturer's statement concerning liability in their data sheet on the particular implant that you are considering. If the surgeon is unable to show you any documentation then you should ask him or her to find out whether the company concerned attempts to limit its liability. If you have any concerns in this regard you should discuss it with your lawyer without delay, and before undertaking any surgery.

The data sheet may also state what action should be taken if the implant ruptures. This should be discussed with your surgeon. Does the manufacturer make any comment about replacing the implant if it should rupture?

Your surgeon may have additional information for you about silicone gel-filled breast implants, and you should discuss any concerns you may have before consenting to the operation.

Durability of implants

Implants can last from a short time to many years, depending on the woman and the implant. They should not be considered as lifetime implants. Check the data sheet provided by the manufacturer for the "life expectancy" of the product that is being recommended for you. You can get the data sheet from your surgeon.

Copy 1 (to be kept by the patient)

DECLARATION

- I have read the information in this booklet about the use of breast implants. I understand and accept that it is possible that other side effects may come to light in the future.
- I have read the information about product liability and have had an opportunity to discuss it with a lawyer, if I so choose.
- I recognise that the use of breast implants is not endorsed by the New Zealand Government, whether through the Ministry of Health or otherwise, and that the safety of such implants cannot be confirmed.
- I agree that the information in this booklet has been explained to me to my satisfaction by my surgeon and that I have had an opportunity to discuss any concerns with others. (These could include your legal adviser, general practitioner or counsellor.)
- I understand that the Ministry of Health requests that the surgeon carrying out the operation keeps a register of the names and addresses of women who receive breast implants and details of the implant(s) fitted.
- I understand that the presence of my name on this register authorises my surgeon to contact me by mail with significant new information which may arise about the safety of my implant(s).
- I understand that if I agree to my details being recorded on the register it will be my responsibility to provide updates of any changes to my name or address.
- I agree to the inclusion of my name on the implant register maintained by my surgeon.

_____ _____

Witness *Patient's signature*

_____

Date

Copy 1 (to be kept by the patient)

BREAST IMPLANTS - REGISTER ENTRY

Name and address of patient _____

_____

_____

_____

	Patient's left	*Patient's right*
Brand name and type of implant	_____	
Lot number	_____	
Volume/size	_____	
Date inserted	_____	
Hospital (postal address)	_____	
Surgeon's name	_____	
Patient's signature	_____	
Date	_____	

Copy 2 (to be kept by the surgeon)

DECLARATION

- I have read the information in this booklet about the use of breast implants. I understand and accept that it is possible that other side effects may come to light in the future.
- I have read the information about product liability and have had an opportunity to discuss it with a lawyer, if I so choose.
- I recognise that the use of breast implants is not endorsed by the New Zealand Government, whether through the Ministry of Health or otherwise, and that the safety of such implants cannot be confirmed.
- I agree that the information in this booklet has been explained to me to my satisfaction by my surgeon and that I have had an opportunity to discuss any concerns with others. (These could include your legal adviser, general practitioner or counsellor.)
- I understand that the Ministry of Health requests that the surgeon carrying out the operation keeps a register of the names and addresses of women who receive breast implants and details of the implant(s) fitted.
- I understand that the presence of my name on this register authorises my surgeon to contact me by mail with significant new information which may arise about the safety of my implant(s).
- I understand that if I agree to my details being recorded on the register it will be my responsibility to provide updates of any changes to my name or address.
- I agree to the inclusion of my name on the implant register maintained by my surgeon.

_____ _____

Witness *Patient's signature*

_____

Date

Copy 2 (to be kept by the surgeon)

BREAST IMPLANTS - REGISTER ENTRY

Name and address of patient _____

_____

_____

_____

	Patient's left	*Patient's right*
Brand name and type of implant	_____	_____
Lot number	_____	_____
Volume/size	_____	_____
Date inserted	_____	
Hospital (postal address)	_____	
Surgeon's name	_____	
Patient's signature	_____	
Date	_____	

CHANGE OF NAME OR ADDRESS ON THE REGISTER

If you change your name or address, remember to advise your surgeon of the details so that the register can be amended.

If your surgeon is no longer practising you should advise the surgeon who has taken over the care of their patients.

The Royal Australasian College of Surgeons (New Zealand Section of Breast Surgery) and the New Zealand Association of Plastic and Reconstructive Surgeons have agreed to hold the patient register entries of any of their members who are no longer practising, if their practice has not been taken over.

The Ministry of Health could forward your changed name or address to the appropriate organisation so the register can be amended. The address to write to is:

The Manager
Therapeutics Section
Ministry of Health
P O Box 5013
WELLINGTON

Make sure you also include the name and address of the surgeon who performed your operation and the date of the operation. (It would be helpful if you could photocopy the register entry in this booklet and enclose it with your letter.)