

BREAST IMPLANT EXCHANGE/REMOVAL/CAPSULECTOMY

MAKING AN INFORMED DECISION

This is an informed consent document that has been prepared to help inform you about breast implant exchange or removal, its risks, and alternative treatments.

It is important that you read this information carefully and completely. Please initial each page, indicating you have read the page and sign the consent for surgery as proposed by Dr Linsell.

GENERAL INFORMATION

Breast implant exchange or removal and capsulectomy is a surgical operation performed for a number of reasons:

- To replace or remove breast implants and their capsules (scar tissue surrounding the implants) for medical or cosmetic reasons
- One or more breasts have become firm or distorted due to capsular contracture
- One or more breast implants have ruptured
- To balance breast size when there exists a significant difference between the size of the breasts.
- As a reconstructive technique for various conditions.

The shape and size of the breasts prior to surgery will influence both the recommended treatment and the final results. If the breasts are not the same size or shape before surgery, it is unlikely that they will be completely symmetrical afterward. Remember 'your breasts are sisters; they are not identical twins'.

Breast implant exchange is accomplished by removing the existing implant as well as the surrounding scar tissue (breast capsule) and replacing it with another implant, either in the same or a new pocket. Breast implant removal simply removes your existing implants with or without the surrounding breast capsule.

Incisions are made to keep scars as inconspicuous as possible, usually through the existing scar under the breast in the breast fold. The method of inserting and positioning breast implants will depend on your preferences, your anatomy and your surgeon's recommendation.

Patients undergoing breast implant exchange must consider the possibility of future revisionary surgery. Breast implants, even when replaced, cannot be expected to last forever.

ALTERNATIVE TREATMENTS

Breast implant exchange or removal is an elective surgical operation. Alternative treatment would consist of the use of external breast prostheses or padding, or the transfer of other body tissues to enlarge breast size. Removal of breast implants is not possible without an operation.

PLEASE INITIAL HERE TO INDICATE YOU HAVE READ AND UNDERSTAND PAGE 1 OF THIS CONSENT FORM:

RISKS OF BREAST IMPLANT EXCHANGE OR REMOVAL

Every surgical procedure involves a certain amount of risk, and it is important that you understand the risks involved with augmentation mammoplasty. Additional information concerning breast implants may be obtained from the implant manufacturer, or other information pamphlets available online.

An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of women do not experience the following complications, you should discuss each of them with Dr Linsell to make sure you understand the risks, potential complications, and consequences of breast augmentation.

Bleeding

It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it might require emergency treatment to drain accumulated blood (haematoma) or blood transfusion. Do not take aspirin or anti-inflammatory medications for ten days before surgery, as this may increase the risk of bleeding.

Infection

Infection is unusual after this type of surgery as you are routinely given antibiotics for 10 days after your procedure. Nevertheless, it may appear in the immediate post-operative period or at any time following the insertion of a breast implant. Sub acute or chronic infections may be difficult to diagnose. Should an infection occur, treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary. Infections with the presence of a breast implant are harder to treat than infections in normal body tissue. If an infection does not respond to antibiotics, the breast implant may have to be removed. After the infection is treated, a new breast implant can usually be reinserted.

Capsular Contracture

Scar tissue, which forms internally around the breast implant is a normal occurrence. If the scar tissue stays soft the breasts are soft. If the scar tissue tightens around the breast implant, it may make the breast firm and possibly painful. Excessive firmness of the breasts can occur soon after surgery or years later. Though the occurrence of symptomatic capsular contracture is not predictable, it generally occurs in less than 10 % of patients. The incidence of symptomatic capsular contracture can be expected to increase over time and increases with the number of operations on the breast. Capsular contracture may occur on one side, both sides, or not at all. Treatment for capsular contracture may require further surgical implant replacement, or implant removal.

Change in Nipple and Skin Sensation

Some change in nipple sensation is not unusual right after surgery. After several months, most patients have normal sensation. Partial or permanent loss of nipple and skin sensation may occur occasionally. Sometimes the sensation is actually improved.

Reduction in breast tissue

The breast capsule can be inseparable from breast tissue, hence removal of the capsule (capsulectomy) can lead to significantly reduced breast tissue, reduced breast size and unevenness in the breast.

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Pain

You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist following Breast implant exchange or removal. Dr Linsell has a comprehensive program to minimise your pain and you are advised to follow this religiously. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue after implant exchange which may require treatment with drugs or further surgery.

Skin Scarring

Excessive scarring is uncommon. In rare cases, abnormal scars may result. Scars may be unattractive and of different colour than surrounding skin. Additional surgery may be needed to treat abnormal scarring after surgery.

Implant Failure

Breast implants, similar to other medical devices, can fail. Implants can break or leak. Rupture can result from an injury, unapparent cause, or during mammography. It is possible to damage an implant at the time of surgery. Damaged or ruptured implants require replacement or removal. Breast implants cannot be expected to last forever.

Implant Extrusion

Lack of adequate tissue coverage or infection may result in exposure and extrusion of the implant. Skin breakdown has been reported with the use of steroid drugs or after radiation therapy to breast tissue. If tissue breakdown occurs and the implant becomes exposed, implant removal may be necessary. Smoking may interfere with the healing process.

Mammography

Breast implants may make mammography more difficult and may obscure the detection of breast cancer. Implant rupture can occur from breast compression during mammography. Inform your mammography technologist of the presence of breast implants so that appropriate mammogram studies may be obtained. Patients with capsular contracture may find mammogram techniques painful and the difficulty of breast imaging will increase with the extent of contracture. Ultrasound, specialized mammography and MRI studies may be of benefit to evaluate breast lumps and the condition of the implants. Because more x- ray views are necessary with specialized mammography techniques, women with breast implants will receive more radiation than women without implants who receive a normal exam. However, the benefit of the mammogram in finding cancer outweighs the risk of additional x-rays.

Skin Wrinkling and Rippling

Visible and palpable wrinkling of implants can occur. Some wrinkling is normal and expected. This may be more pronounced in patients who have thin breast tissue or have undergone capsulectomy. Some patients may find wrinkles cosmetically undesirable. Palpable wrinkling and/or folds may be confused with palpable tumours and questionable cases must be investigated. An implant may become visible at the surface of the breast as a result of the device pushing through layers of skin.

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Pregnancy and Breast Feeding

Although many women with breast implants have successfully breast fed their babies, it is not known if there are increased risks in nursing for a woman with breast implants or if the children of women with breast implants are more likely to have health problems. There is insufficient evidence regarding the absolute safety of breast implants in relation to fertility, pregnancy, or breast feeding. Some women with breast implants have reported health problems in their breast fed children. Only very limited research has been conducted in this area and at this time there is no scientific evidence that there is a problem. Nevertheless, pregnancy will change your breasts as they will get larger and possibly more droopy. After pregnancy your breasts will have changed and you may require a further procedure such as a breast lift. This will require further expense.

Asymmetry

Many women have naturally asymmetrical breasts. Although surgery will attempt to correct the difference, asymmetry may continue to be present following surgery. Should this occur, additional surgery might be necessary to improve the differences. Additional costs may occur.

Calcification

Calcium deposits can form in the scar tissue surrounding the implant and may cause pain, firmness, and be visible on mammography. These deposits must be identified as different from calcium deposits that are a sign of breast cancer. Should this occur, additional surgery might be necessary to remove and examine calcifications.

Implant Displacement

Displacement or migration of a breast implant from its initial placement may occur and can be accompanied by discomfort and/or distortion in breast shape. A tear-drop shaped implant may rotate and implants can 'bottom out' (double bubble) or shift to the side. Additional surgery may be needed to correct these problems.

Implant sitting high

It is normal for implants to drop down over about 6 months. Sometimes one or both implants stay high and the breast droops lower over the implant. Additional surgery may be required to correct this problem.

Surface Contamination of Implants

Skin oil, lint from surgical drapes, or talc may become deposited on the surface of the implant at the time of insertion. The consequence of this is unknown. Dr Linsell uses a no-touch technique for insertion of the implant using an especially designed funnel to minimise the risk of any contamination.

Degradation of Breast Implants

It is possible that small pieces of the implant material may separate from the outer surface of breast implants. This is of unknown significance.

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Surgical Anaesthesia

Both local and general anaesthesia involve risk. Dr Linsell only uses high quality anaesthetists however, there is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.

Chest Wall Deformity

Chest wall deformity has been reported secondary to the use of breast implants. The consequences of chest wall deformity is of unknown significance.

Unusual Activities and Occupations

Activities and occupations which have the potential for trauma to the breast could potentially break or damage breast implants, or cause bleeding.

Allergic Reactions

In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions, which are more serious, may result from drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

Breast Disease

Current medical information does not demonstrate an increased risk of breast disease or breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes. Breast disease can occur independently of breast implants. It is recommended that all women perform self-examination of their breasts, have mammography according to the Australian health guidelines, and seek professional care should they notice a breast lump.

Seroma

Fluid may accumulate around the implant following surgery, trauma or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation around breast implants.

Long Term Results

Subsequent alterations in breast shape may occur as the result of aging, weight loss or gain, pregnancy, or other circumstances not related to augmentation mammoplasty. Breast sagging may occur normally.

Thrombosed Veins

Thrombosed veins, which resemble cords, occasionally develop in the area of the breast and resolve without medical or surgical treatment.

PLEASE INITIAL HERE TO INDICATE YOU HAVE READ AND UNDERSTAND PAGE 5 OF THIS CONSENT FORM:

Breast Implant Illness (BII)

Some women with breast implants have reported symptoms similar to those of known diseases of the immune system such as systemic lupus erythematosus, rheumatoid arthritis, scleroderma, and other arthritis-like conditions. Some people refer to this as Breast Implant Illness. A connection between implanted silicone and connective tissue disorders has been reported in the medical literature. To date, there is no scientific evidence that women with either silicone gel filled or saline filled breast implants have an increased risk of these diseases, but the possibility cannot be excluded. If a causal relationship is established, the theoretical risk of immune and unknown disorders may be low. The effects of breast implants in individuals with pre-existing connective tissue disorders is unknown.

Current studies have only looked for the symptoms of known autoimmune diseases, rather than the variety of symptoms that women report experiencing. Some of the reported symptoms include:

- ♦ swelling or joint pain or arthritis like pain
- ♦ general aching
- ♦ unusual hair loss
- ♦ unexplained or unusual loss of energy
- ♦ greater chance of getting colds, viruses, flu
- ♦ swollen glands or lymph nodes
- ♦ rash
- ♦ memory problems, headaches, brain fog
- ♦ muscle weakness or burning
- ♦ nausea, vomiting
- ♦ irritable bowel syndrome
- ♦ fever

Currently, there is insufficient evidence to state that there is a health benefit from removing either breast implants and scar tissue capsules or that removal will alter Breast Implant Illness or autoimmune disease or prevent its potential occurrence. Nevertheless, if at any time you would prefer to have your implants removed, Dr Linsell will do this for you. He will generally perform a partial capsulectomy at the same time, but usually does not perform a full capsulectomy and this has NOT been shown to provide any health benefit, yet significantly increase the intraoperative risk for a patient.

Please note that there is the possibility of as yet unknown risks associated with silicone breast implants and tissue expanders.

Anaplastic Large Cell Lymphoma (ALCL)

In recent years a small number of women with breast implants have developed a type of cancer of the blood named Anaplastic Large Cell Lymphoma (ALCL). This appears to be more associated with certain types of textured implants. It develops an average of 7-10 years after breast implantation and most commonly presents as a swollen breast that continues to increase in size. Early stage disease is curative with surgery alone. Disease which has spread through the capsule forming a mass or which has spread to local lymph nodes, carries a worse prognosis. For more detailed information please visit the website of the Australian Society of Plastic Surgeons at <https://plasticsurgery.org.au/protecting-patient-safety/bia-alcl/>. If you have any concerns, contact Dr Linsell immediately.

PLEASE INITIAL HERE TO INDICATE YOU HAVE READ AND UNDERSTAND PAGE 6 OF THIS CONSENT FORM:

Toxic shock syndrome

This is an extremely rare complication following breast augmentation, reconstruction, or tissue expansion with silicone implants.

Unsatisfactory result

You may be disappointed with the results of surgery. Asymmetry in implant placement, breast shape and size may occur after surgery. Unsatisfactory surgical scar location or displacement may occur. Pain may occur following surgery. It may be necessary to perform additional surgery to improve your results.

Removal/replacement of breast implants

Future removal or replacement of breast implants and the surrounding scar tissue envelope involves a surgical procedure with risks and potential complications.

Deep Venous Thrombosis, Cardiac and Pulmonary Complications- Surgery, especially longer procedures, may be associated with the formation of, or increase in, blood clots in the venous system. Pulmonary complications may occur secondarily to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anaesthesia. Pulmonary and fat emboli can be life-threatening or fatal in some circumstances. Air travel, inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of blood clots, swollen legs or the use of oestrogen or birth control pills that may contribute to this condition. Cardiac complications are a risk with any surgery and anaesthesia, even in patients without symptoms. Heart attack or stroke could occur due to strain on the heart. Should any of these complications occur, you may require hospitalization and additional treatment. If you experience shortness of breath, chest pains, or unusual heart beats, seek medical attention immediately.

Intimate Relations After Surgery- Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Increased activity that increased your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery and control bleeding. It is wise to refrain from sexual activity for about two weeks after your operation.

Medications- There are many adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Be sure to check with Dr Linsell about any drug interactions that may exist with medications that you are already taking. If you have an adverse reaction, stop the drugs immediately and call Dr Linsell for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Mental Health Disorders and Elective Surgery- It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with Dr Linsell, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

PLEASE INITIAL HERE TO INDICATE YOU HAVE READ AND UNDERSTAND PAGE 7 OF THIS CONSENT FORM:

HEALTH INSURANCE

Medicare item numbers exist for complications that arise with breast implants, notably capsular contracture. Consequently, there may be health insurance may cover some (but not all) of the cost of breast implant exchange or removal and capsulectomy Please carefully review the information provided by your health insurer regarding breast implant exchange or removal and capsulectomy

ADDITIONAL SURGERY NECESSARY (RE-OPERATIONS)

Should complications occur, additional surgery or other treatments might be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with breast implant exchange or removal and capsulectomy Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty, expressed or implied, on the results that may be obtained.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by Dr Linsell, the anaesthetist, the surgical assistant, the implants and hospital charges. There may be Medicare item numbers for breast implant exchange or removal and capsulectomy however this will not cover all of the fees. Additional costs may occur should complications develop from the surgery. Whilst Dr Linsell will generally perform revisional surgery within the first 12 months for a small out of pocket cost for his fee, there may be charges for the anaesthetist, assistant and hospital. If you choose to go larger or smaller, or have your implants removed at a later date, you will be responsible for all charges.

DISCLAIMER

Informed consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment. The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Dr Linsell may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

NO SURGERY IS GUARANTEED.

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

PLEASE INITIAL HERE TO INDICATE YOU HAVE READ AND UNDERSTAND PAGE 8 OF THIS CONSENT FORM:

CONSENT FORM – BILATERAL BREAST IMPLANT EXCHANGE/REMOVAL

The following form acknowledges my willingness to undergo the procedure of Bilateral Breast implant exchange or removal and capsulectomy, performed by Dr Malcolm Linsell.

Initial:

I acknowledge that I have consulted with Dr Linsell and I have a good understanding of the operation and the expected outcomes.

Initial:

I acknowledge the cost of the procedure has been explained in detail and that there will be fees for surgeon, anaesthetist, assistant surgeon, the hospital and the breast implants.

Initial:

I acknowledge that this is real surgery and any surgery carries with it the risk of complications.

Initial:

I acknowledge Dr Linsell has explained the most common complications that can arise from this procedure.

Initial:

I acknowledge and accept that some complications can interfere with my expected outcome and no guarantees have been made as to my outcome.

Initial:

I acknowledge I have been given ample time and opportunity to ask Dr Linsell questions about the procedure, my expected outcome and the possible complications.

Initial:

I acknowledge that photographs of my breasts will be taken before, during and after the operation and agree to the use of my photographs to follow my own progress and (without being identified) to share with other patients to help them with their decision-making.

Initial:

I agree to the potential use of my photographs (without being identified) in medical conferences and publications.

Initial:

I agree to the potential use of my photographs (without being identified) on Dr Linsell's web page, Facebook page, Instagram page and other online forums to help other patients with their decision-making.

Initial:

I acknowledge every effort has been made to choose the size of the implants that will give me my desired outcome.

Initial:

After the procedure is complete, I acknowledge that if I choose to go larger or smaller, this will be at my expense. I understand this would involve costs for the surgeon, anaesthetist, assistant surgeon, hospital and new breast implants.

Initial:

I acknowledge that during the course of the operation, unforeseen conditions may necessitate additional or different procedures to those outlined. I authorise and request that Dr Linsell perform such procedures that are, in his professional judgement, necessary and desirable.

Initial:

I acknowledge blood products or derivatives are occasionally necessary to administer during and after the operation.

Initial:

I acknowledge that in the event of one of the hospital staff coming into direct contact with my blood, blood samples will be taken from the staff member and myself to test for infections such as Hepatitis and HIV.

Initial:

I acknowledge a revision surgical procedure is occasionally necessary for up to 12 months after the procedure. If required, Dr Linsell will do this for a small out of pocket cost for his surgical fee, however there may be fees for anaesthetist, assistant surgeon and hospital.

Initial:

I understand I have the right to change my mind at any time, including after I have signed this form, but preferably following a discussion with Dr Linsell.

Initial:

I understand and acknowledge that no surgery is an option.

Initial

My signature below confirms I have read and understand the information provided and hereby consent to the procedure.

Print name:

Signed:

Date:

Dr Malcolm D Linsell

Signed:

Date: