

INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you concerning breast implant removal and capsulectomy, its risks, as well as alternative treatments.

It is important that you read this information clearly and completely. Please initial each page, in the bottom right-hand corner, indicating that you have read the page.

GENERAL INFORMATION

The removal of breast implants that have been placed either for cosmetic or reconstructive purposes is a surgical operation. Breast implant removal may be performed a single surgical procedure or combined with additional procedures, as follows:

- Simple breast implant removal, without removal of capsule tissue around implant
- Removal of tissue surrounding the breast implant (capsulectomy)
- Removal of escaped silicone gel in breast tissue (extracapsular, outside of capsule layer) from silicone gel-filled implants (breast biopsy)

Implants that are found to be damaged or ruptured cannot be repaired; surgical removal or replacement is recommended. There are both risks and complications associated with this operation.

ALTERNATIVE TREATMENTS

Alternative forms of non-surgical management include not undergoing breast implant removal, or other procedures to replace, or revise existing situations when patients choose to continue with breast implants. If breasts are sagging, wearing supportive undergarments to lift breasts may be considered. Risks and potential complications are also associated with alternative forms of treatments.

RISKS OF BREAST IMPLANT REMOVAL AND CAPSULECTOMY SURGERY

Every surgical procedure involves a certain amount of risk, and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your Plastic Surgeon to make sure you understand all possible consequences of breast implant removal and capsulectomy surgery. Risks include, but are not limited to, the following:

Skin Wrinkling and Rippling:

Visible and palpable wrinkling of breast skin can occur. This may require additional surgery to tighten loose skin following breast implant removal surgery.

Ruptured Silicone Gel-Filled Breast Implants:

As with any man-made object implanted in the human body, device failure can occur. It is possible that an implant can rupture causing silicone gel to be released from the implant. Implants also can rupture during the removal process. If implant rupture has occurred, it may not be possible to completely remove all of the silicone gel that has escaped. The implant shell material of textured breast implants may be impossible to remove completely. Calcification around implants can occur and may require removal of the scar tissue surrounding the implant (capsulectomy). It may not be possible to completely remove the scar tissue that has formed around a breast implant, implant parts, calcifications, or silicone gel. Additional surgery may be necessary in the future.

Change in Nipple and Skin Sensation:

You may experience a diminished (or loss) of sensitivity of the nipples and the skin of your breast. After several months, most patients have normal sensation. Partial or permanent loss of nipple and skin sensation may occur occasionally. Changes in sensation may affect sexual response. In rare circumstances the nipple may be lost entirely.

Skin Contour Irregularities:

Contour and shape irregularities may occur. Visible and palpable wrinkling of skin may occur. Residual skin irregularities at the ends of the incisions or "dog ears" are always a

possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

Breast Disease:

Current medical information does not demonstrate an increased risk of breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes. Individuals with a personal history or family history of breast cancer may be at a higher risk of developing breast cancer than a woman with no family history of this disease. It is recommended that all women perform periodic self-examination of their breasts, undergo routine mammography guidelines, and seek professional care should a breast lump be detected. In the event that suspicious tissue is identified prior to or during breast surgery, additional tests and therapy with corresponding expenses may be warranted.

Aesthetic Outcome:

Removal of breast implants, with or without capsulectomy, can sometimes result in a less than ideal aesthetic outcome. The following aesthetic outcomes are common post explant surgery:

- Loss of breast volume
- Skin laxity issues, significant droop to breasts
- Uneven, or asymmetric breast shape and size
- Dents, folds, or tethering of the breast and/or scar tissue
- Nipple retraction / inverted nipple
- Exaggerated or visible breast surgical scarring
- Breasts appearing significantly different to 'pre-surgical state'

As such, it is important to be fully informed of the potential for these outcomes occurring and there is no guarantee of final aesthetic result.

Breast Implant Illness:

Although not recognized as an official medical condition, some patients may feel that their implants may be causing a range of illnesses and unpleasant symptoms. This may influence a decision in removing breast implants. There is no guarantee that removal of breast implants will resolve any or all symptoms associated with breast implant illness.

Anaplastic Large Cell Lymphoma (ALCL):

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a very rare type of lymphoma that can develop in the scar capsule near saline or silicone breast implants. In instances where implants are being removed and there is a query of BIA-ALCL, pathology will be taken. Most cases can be cured by removal of the implant and the capsule surrounding the implant; however, rare cases have required chemotherapy and/or radiation therapy for treatment.

GENERAL RISKS OF SURGERY

Healing Issues:

Certain medical conditions, dietary supplements and medications may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming apart, infection, and tissue changes resulting in the need for additional medical care, surgery, and prolonged hospitalisations. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as swelling, bleeding, and the length of surgery and anaesthesia that include a longer recovery and the possibility of additional surgery, prolonged recovery, colour changes, shape changes, infection, not meeting goals and expectations, and added expense to the patient.

Patients with significant skin laxity (patients seeking face lifts, breast lifts, abdominoplasty, and body lifts) will continue to have the same lax skin after surgery. The quality or elasticity of skin will not change, and recurrence of skin looseness will occur at some time in the future, quicker for some than others.

There are nerve endings that may become involved with healing scars during surgery such as suction-assisted lipectomy, abdominoplasty, facelifts, body lifts, and extremity surgery. While there may not be a major nerve injury, the small nerve endings during the healing

period may become too active producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often massage and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with your Plastic Surgeon.

Bleeding:

It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood, or you may require a blood transfusion, though such occurrences are rare. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time.

Do not take any blood thinning medications for at least seven days before or after surgery, as this may increase the risk of bleeding. Non-prescription vitamins and dietary supplements can increase the risk of surgical bleeding. Haematoma can occur at any time, usually in the first three weeks following injury to the operative area.

Please advise your Plastic Surgeon if you are regularly taking any blood thinning medications such as Heparin, Warfarin, Cartia, Aspirin, Nurofen or Ibuprofen medications and fish oil products.

Infection:

Subacute or chronic infections may be difficult to diagnose. Should an infection occur, treatment, including antibiotics, or additional surgery may be necessary. Individuals with an active infection in their body should not undergo surgery. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time after surgery. It is important to tell your Plastic Surgeon of any other infections, such as ingrown toenail, insect bite, tooth abscess, or urinary tract infection. Remote infections (infections in other parts of the body) may lead to an infection in the operated area.

Scarring:

All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different colour than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is the possibility of visible marks in the skin from sutures. Scars can become hypertrophic or keloid, please notify your Plastic Surgeon if you have a history of keloid scarring. In some cases, scars may require surgical revision or treatment.

Firmness:

Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatment including surgery may be necessary.

Change in Skin Sensation:

You may experience a diminished (or loss) of sensitivity in areas that have had surgery. After several months, most patients have normal sensation. However, diminished (or loss of) skin sensation may not resolved entirely after a scar revision surgery.

Skin Contour Irregularities:

Contour and shape irregularities may occur. Visible and palpable wrinkling of skin may occur. Residual skin irregularities at the ends of the incisions or “dog ears” are always a possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

Skin Sensitivity:

Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolves during healing, but in rare situations it may be chronic.

Major Wound Separation:

Wounds may separate after surgery. Should this occur, additional treatment including surgery may be necessary.

Skin Discolouration / Swelling:

Some bruising and swelling normally occur. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

Drains:

During your surgery, your doctor may find it necessary to place a drain(s). A drain is a small tube that drains fluid out from the operated area. You will be instructed on how to use your drain. Placement of the drain may require a small incision. The drain will be removed when your doctor feels it is no longer necessary and covered with a waterproof dressing. Please do not remove your own drains.

Sutures:

Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires suture removal.

Damage to Deeper Structures:

There is the potential for injury to deeper structures including nerves, blood vessels, muscles, and lungs (pneumothorax) during any surgical procedure. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

Fat Necrosis:

Fatty tissue found deep in the skin might die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is the possibility of contour irregularities in the skin that may result from fat necrosis.

Seroma:

Infrequently, fluid may accumulate between the skin and the underlying tissues following surgery, trauma, or vigorous exercise. Should this problem occur, it may require additional procedures for drainage of fluid.

Surgical Anaesthesia:

Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation. Please advise your Plastic Surgeon and your anaesthetist of any prior adverse reactions or allergies.

Shock:

In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

Pain:

You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist for an undeterminable amount of time following surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

Cardiac and Pulmonary Complications:

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 emboli can be life-threatening or fatal in some circumstances. 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. Please advise your Plastic Surgeon of any past history of swelling in your legs or blood clots that may contribute to this condition. Cardiac complications are a risk with any surgery and anaesthesia, even in patients without symptoms.

If you experience shortness of breath, chest pain, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

Allergic Reactions:

In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur in response to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment. Please advise your Plastic Surgeon of any known allergies.

Asymmetry:

Some breast asymmetry naturally occurs in most people. Differences in terms of breast and nipple shape, size, or symmetry may also occur after surgery.

Unsatisfactory Result:

Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. You may be disappointed with the results of surgery. Asymmetry in nipple location, unanticipated breast shape and size, wound disruption, poor healing, and loss of sensation may occur after surgery. Breast size may be incorrect. Unsatisfactory surgical scar location may occur. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. It may be necessary to perform additional surgery to improve your results.

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Vape, Patch, Gum, Nasal Spray):

Patients who are currently smoking or use tobacco or nicotine products (vape, patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying, delayed healing and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally,

smoking may have a significant negative effect on anaesthesia and recovery from anaesthesia, with coughing and potentially increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication.

Please indicate your current status regarding these items below:

I am a non-smoker and do not use nicotine products. I understand the potential risk of second-hand smoke exposure causing surgical complications.

I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

I have previously smoked and stopped approximately _____ ago. I understand I may still have the effects and therefore risks from smoking in my system, if not enough time has lapsed.

It is important to refrain from smoking a minimum of 6 weeks prior to your surgery. I acknowledge that if I continue to smoke within this time frame, I am at risk for a number of significant complications and understand that for my safety, the surgery, if possible, may be delayed.

Medications and Vitamin Supplements:

There are potential adverse reactions that occur as the result of taking over the counter, vitamin, and/or prescription medications. Aspirin and medications that contain Aspirin interfere with clotting and can cause more bleeding. These include non-steroidal anti-inflammatories such as Ibuprofen and Nurofen. Be sure to check with your GP about ceasing any regular medications and any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your Plastic Surgeon 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.

Sun Exposure – Fake Tanning:

The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, colour changes, and poor healing. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

Patients are advised to avoid all fake tanning products for a period of 6 weeks from the date of surgery.

Body Piercing / Jewellery:

Individuals who currently wear body piercing jewellery in the surgical region are advised that an infection could develop from this activity. Please remove all body piercing jewellery in applicable areas prior to surgery. Jewellery should not be brought with you at the time of your surgical procedure. Items, such as earrings, wedding rings, and necklaces should be removed prior to surgery.

Nails:

To determine your vitals status during surgery, your anaesthetist may require access to your finger or toenails for monitoring. Make sure to have either full fingernails or toenails free of nail polish, acrylics or gels.

Work Commitments / Travel Plans:

Any surgery holds the risk of complications that may delay healing and delay your return to normal life. Please let your Plastic Surgeon know of any major work commitments, travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

Patients are encouraged to take a period of two weeks off work, this includes ‘working from home’ situations.

Long-Term Results:

Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, or other circumstances not related to your surgery.

Future Pregnancy and Breastfeeding:

This surgery is not known to interfere with future pregnancy. If you are planning a pregnancy, your breast skin may stretch and offset the results of surgery. You may have more difficulty breastfeeding after this operation.

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. Activity that increases 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 intimate physical activities until your specialist states it is safe.

FEMALE PATIENT INFORMATION

It is important to inform your Plastic Surgeon if you use birth control pills or estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

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 your Plastic Surgeon 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.

DISSATISFACTION WITH COSMETIC RESULTS

It is important to communicate what you are hoping to achieve with your surgery to your Plastic Surgeon so both parties have a clear understanding of your goals. It is important to discuss with your Plastic Surgeon realistic expectations regarding what you are wanting to achieve taking into account your original anatomy and what is possible.

REVISION PROCEDURES

There are many variable conditions that may influence the long-term result of breast implant removal and mastopexy surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of the breasts. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with breast implant removal. 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. In some situations, it may not be possible to achieve optimal results with a single surgical procedure.

PATIENT COMPLIANCE

Follow all specialist instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed

by your Plastic Surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. Patients are advised to refrain from strenuous physical activity, including swimming, heavy lifting, and resistance work for a period of 6 weeks from the date of surgery. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

HEALTH INSURANCE

Most private health insurance companies exclude coverage for cosmetic procedures. If there is an applicable MBS item number for your surgery, please ensure you have checked your coverage with your private health insurance prior to surgery as there may be additional hospital fees. In the absence of private health insurance, patients are responsible for all costs associated with surgery including any hospital and anaesthetist fees. Cosmetic surgery is not covered by Medicare.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your Plastic Surgeon, the cost of prostheses if applicable, anaesthesia, laboratory tests, and hospital charges. These fees can vary depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery will also be your responsibility.

For your Plastic Surgeon's fees (only) please refer to your quotation. Details can also be found in here regarding deposits and payments required and payment dates, and refund of deposits.

The cost of follow-up care is included within your surgical fees. Your Plastic Surgeon may suggest that you purchase some support garments to aid your recovery.

In the event that revision surgery or additional treatment is required, the costs of this will be in addition to your current surgery.

In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risks and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

I acknowledge the below points:

I understand that with undertaking surgery, I am responsible for the surgical fees quoted to me, as well as additional fees for anaesthesia, hospital, and possibly laboratory, imaging, and pathology fees.

I understand that hospitals often have rules that certain tissue/implants removed during surgery must be sent for evaluation which may result in additional fees.

I understand that the surgery deposit I have paid to confirm surgery is non-refundable.

Should I cancel my surgery without an approved medically acceptable reason, submitted in writing to the Plastic Surgeon within 2 weeks of the scheduled surgery date, the surgical fee is forfeited. While this may appear to be a charge for services which were not provided, this fee is necessary to reserve time in theatre and in the clinic, which are done when I schedule.

I understand and unconditionally and irrevocably accept these conditions.

PLASTIC SURGEON PERFORMING YOUR SURGERY

Dr Robert Choa (MED0002049063) is a Specialist Plastic Surgeon both in Australia (FRACS) and the UK (FRCEd Plast), who has been working in Perth since 2016. He has gained significant exposure to all aspects of aesthetic plastic surgery. He is a Consultant in the public health system, working at Fiona Stanley Hospital, Rockingham General Hospital and the Fremantle Hospital Hand Unit.

Dr Choa has recently joined Rodin Clinic in Nedlands, but also has clinics in Mandurah, Geraldton and Sorrento. He is accredited to undertake plastic surgery operations – both medical and cosmetic at St John of God Hospital Mount Lawley, The Park Private Hospital in Mount Lawley, Glengarry Private Hospital in Duncraig, and St John of God Hospital Geraldton.

Dr Choa attended Liverpool Medical School in the UK, graduating with honours in 2005. During his time at medical school, he undertook an additional degree in Anatomy, obtaining First Class Honours. Throughout his training he has worked at a number of prestigious hospitals, including the Queen Elizabeth Hospital in Birmingham, Chelsea and Westminster Hospital in London, and the Nuffield Orthopaedic Centre in Oxford.

In 2014 he attended one of the top 25 business schools in the world, Warwick Business School, and obtained a Masters in Business Administration (MBA). His thesis looked at how LEAN principles can be applied to plastic surgery services and was awarded a Distinction.

Dr Choa currently has 18 peer reviewed scientific articles and numerous national and international presentations on a wide variety of plastic surgery topics. He is keen on training junior surgeons and has set up the Fiona Stanley Hospital Plastic Surgery OSCE exam. He is also an examiner for the Royal Australasian College of Surgeons clinical exam.

In 2016 Dr Choa travelled to Perth to gain further exposure to complex microsurgical reconstructions at Fiona Stanley Hospital. Following his fellowship he returned to London to undertake an aesthetic fellowship at the London Clinic on Harley Street, working with and learning from world-renowned surgeons – including Paul Harris, David Ross and Charles East. In 2020 Dr Choa was awarded the FRACS qualification – the benchmark qualification for specialist surgeons in Australia and New Zealand.

COMPLAINTS PROCEDURE

Patients who are dissatisfied have the right to make a complaint. There are a range of complaint mechanisms available, including but not limited to:

- Raising and resolving the complaint directly with your Plastic Surgeon who performed the surgery.
- Accessing the complaint process of the clinic's location where you were consulted or hospital where your surgery was performed.
- Making a complaint to The Health and Disability Services Complaints Office (www.hadsco.wa.gov.au).
- Making a complaint to Ahpra is an alternative.

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(s), including no surgery. 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. Your Plastic Surgeon may provide you with additional or different information that is based on all the facts in your particular case and the current 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.

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.