

**INFORMED CONSENT:
BREAST IMPLANT EXCHANGE (INCLUDING OPEN CAPSULECTOMY)**

INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you about breast implant exchange and open capsulectomy, its risks, and alternative treatments. It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your surgeon.

GENERAL INFORMATION

Breast implant exchange and open capsulectomy is a surgical operation performed to replace damaged breast implants, treat scarring which occurs around breast implants and to place new breast implants. Individuals with old, damaged or broken implants may consider breast implant exchange and open capsulectomy as a procedure to maintain the long-term results from their original surgery. You may be advised by your surgeon to consider replacing of your breast implants with new ones, irrespective of how long you have had them. Breast implants do not have an indefinite lifespan and will eventually require replacement surgery.

Scar tissue, which forms internally around a breast implant, can tighten and make the breast round, firm, and possibly painful. Excessive firmness of the breasts can occur soon after the original surgery or years later. The incidence of symptomatic capsular contracture can be expected to increase over time. Capsular contracture may occur on one side, both sides or not at all. Calcification can occur within the scar tissue that surrounds breast implants. Treatment for capsular contracture may require surgery, implant replacement, or implant removal.

Depending on the extent of the scarring problem, it may be necessary to place the implant in a deeper location, underneath the pectoralis muscle on the chest. Incisions for the open capsulectomy procedure may be placed in different locations than those used for the original surgery. If the breasts are not the same size or shape before surgery, it is unlikely that they will be completely symmetrical afterward.

Patients undergoing open capsulectomy surgery with breast implant exchange must consider the possibility of future revisionary surgery. Breast implants cannot be expected to last forever.

ALTERNATIVE TREATMENT

Open capsulectomy with breast implant exchange is an elective surgical operation. Alternative treatment would consist of removal of your breast implants. Risks and potential complications are associated with alternative treatments that involve surgery.

RISKS of BREAST IMPLANT EXCHANGE (INCLUDING OPEN CAPSULECTOMY)

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with breast implant exchange and open capsulectomy.

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 your surgeon to make sure you understand the risks, potential complications, and consequences of breast implant exchange and open capsulectomy.

Bleeding:

It is possible, though unusual, to experience a bleeding episode during or after surgery. Should postoperative bleeding occur, it may require treatment to drain accumulated blood (haematoma). Do not take any **aspirin** or **anti-inflammatory** medications for ten days before surgery, as this may increase the risk of bleeding. The incidence of bleeding during this procedure is approximately 1.5%.

Infection:

Infection is unusual after this type of surgery. It may appear in the immediate post operative period or at any time following the insertion of a breast implant. Subacute 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 tissues. 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. It is extremely rare that an infection would occur around an implant from a bacterial infection elsewhere in the body, however, prophylactic antibiotics may be considered for subsequent dental or other surgical procedures. The incidence of infection during this procedure is approximately 1%.

Recurrent capsular contracture:

Excessive firmness of the breasts can recur soon after capsulectomy surgery or years later. Scar tissue may form again around the breast implant; it can tighten and make the breast round, firm, and possibly painful. The recurrence of symptomatic capsular contracture following capsulectomy is not predictable. The incidence of symptomatic capsular contracture can be expected to increase over time. Capsular contracture may recur on one side, both sides or not at all. Treatment for recurrent capsular contracture may require additional surgery, or implant removal.

Inability to remove capsular scar tissue:

It may not be possible to completely remove all scar tissue that has formed around the breast implant(s). It may not be possible to completely remove textured implant shell material that has become adherent to the scar layer.

Damage to adjacent structures:

Scar tissue may be adherent to breast tissue, muscle or the chest wall. These structures may be damaged during capsulectomy surgery to remove the scar capsule. Escaped silicone gel material- In situations that involve damaged, leaking, or ruptured silicone gel breast implants, gel material can escape into the space inside the scar capsule layer around the breast implant. In other situations, gel material may have escaped outside of the scar capsule layer into the breast and other tissue. Additional surgical procedures may be needed to remove escaped gel material. It may not be possible to completely remove escaped gel material discovered during surgery.

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.

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.

RISKS of OPEN CAPSULECTOMY WITH BREAST IMPLANT EXCHANGE SURGERY (continued)

Implants:

Breast implants, like other medical devices, can fail. Implants can break or leak. Rupture can occur as a result of an injury, from no apparent cause, or during mammography. It is possible to damage an implant at the time of surgery. Damaged or broken implants cannot be repaired. Ruptured or deflated implants require replacement or removal. Breast implants cannot be expected to last forever.

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.

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 consequences of this are unknown.

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.

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 may be necessary to remove and examine calcifications.

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 saline-filled implants or thin breast tissue. It may be possible to feel the implant valve. Some patients may find palpable valve and wrinkles cosmetically undesirable. Palpable valve, 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.

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 implant(s). 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.

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 from 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 of 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 this is a problem.

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.

**RISKS of OPEN CAPSULECTOMY WITH BREAST IMPLANT EXCHANGE SURGERY
(continued)**

Implant displacement:

Displacement or migration of a breast implant may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape. Difficult techniques of implant placement may increase the risk of displacement or migration. Additional surgery may be necessary to correct this problem.

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.

Chest wall deformity:

Chest wall deformity has been reported secondary to the use of tissue expanders and breast implants. The consequence 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.

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.

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 periodic self examination of their breasts, have mammography according to the National Health Service Breast Screening Programme, and seek professional care should they notice a breast lump.

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 open capsulectomy with breast implant exchange. Breast sagginess may normally occur.

Thrombosed veins:

Thrombosed veins, which resemble cords occasionally develop in the area of the breast and resolve without medical or surgical treatment. Immune system diseases and unknown risks- 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. To date, there is no scientific evidence that women with either silicone gel-filled or saline-filled breast implants have an increased risk of connective tissue 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.

Additional surgery necessary:

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 open capsulectomy with breast implant exchange; other complications and risks do 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 any guarantee or warranty expressed or implied on the results that may be obtained.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical operations and any complications that might occur from surgery. Some insurance carriers may possibly exclude breast diseases in patients who have breast implants. If you have private health insurance, please carefully review your policy terms and conditions or contact your insurance company before you undergo surgery.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. This includes fees charged by your doctor, the cost of implants and surgical supplies, anaesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed. By consenting to the surgery you accept that you will be responsible for all charges incurred.

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). 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 surgeon 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.

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.

CONSENT FOR SURGERY / PROCEDURE OR TREATMENT

1. I hereby authorize _____ and such assistants as may be selected to perform the following procedure or treatment:

BREAST IMPLANT EXCHANGE (INCLUDING OPEN CAPSULECTOMY)

I have received the following information sheet:

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2. I recognize that during the course of the operation and medical treatment or anaesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgement necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.

3. I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involves risk and the possibility of complications, injury, and sometimes death.

4. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.

5. I consent to the photographing of the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.

6. I consent to the disposal of any tissue, medical devices or body parts which may be removed.

7. I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.

8. I realize that not having the operation is an option.

9. I AGREE THAT MY SURGERY HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:

- a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
- b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
- c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9). I AM SATISFIED WITH THE EXPLANATION.

Signature of Patient or Person Authorized to Sign for Patient

Printed Name of Patient

Date _____

Signature of operating surgeon