



THE PLASTIC SURGERY CENTRE

Informed Consent – Breast Augmentation Mammoplasty

Instructions

This is an informed-consent document that has been prepared to help Dr. Waslen inform you about breast augmentation surgery, its risks as well as its alternative treatments.

It is important that you read the following information carefully and completely.

Introduction

Breast augmentation mammoplasty is a surgical procedure performed to enlarge the breasts for a number of reasons:

- To enhance the body contour of a woman who, for personal reasons, feels that her breast size is too small.
- To correct a loss in breast volume after pregnancy.
- To balance breast size, when there exists a significant difference between the sizes 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 following surgery.

Breast enlargement is accomplished by inserting a breast implant either behind the breast tissue or under the chest muscles. Incisions are made to keep scars inconspicuous as possible, usually under the breast, around the lower part of the areola, or in the armpit. The method of inserting and positioning breast implants will depend on your preferences, your anatomy as well as Dr. Waslen's recommendation.

Risks of Breast Augmentation Mammoplasty Surgery

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with this surgery. An individual's choice to undergo a surgical procedure is based on the comparison of the risks to potential benefit. Although the majority of patients do not experience the following complications, you should discuss each of them with Dr. Waslen to make certain you understand all possible consequences of a breast augmentation.

Bleeding – It is possible, though unlikely, that a bleeding episode may occur during or after surgery. Should post-operative bleeding occur, it might require emergency treatment to drain accumulated blood or a blood transfusion. Do not take any aspirin, anti-inflammatory medications or Vitamin E capsules for 2 weeks prior to surgery as this may increase the risk of bleeding.

Infection – Infection is unusual after this type of surgery. Should an infection occur, treatment, including antibiotics or additional surgery may be necessary. It is extremely rare that an infection would occur around an implant from a bacterial infection elsewhere in the body.

Sensation - Changes in nipple and/or skin sensation. Breasts are normally sore following surgery. Some change in nipple sensation is not unusual right after surgery. After several months, nipple sensation should return to normal. Partial or permanent loss of nipple and/or skin sensation may occur occasionally.

Capsular Contracture – Scar tissue, which forms internally around the breast implant, can tighten and make the breast round, firm and possibly painful. Excessive firmness of the breasts can occur soon after surgery or years following. Although the occurrence of symptomatic capsular contracture is not predictable, it generally occurs in less than 20 percent of patients. The incidence of symptomatic capsular contracture can be expected to increase over time. Capsular contracture may occur unilaterally, bilaterally, or not at all. Treatment for capsular contracture may require surgery, implant replacement, or implant removal. External pressure (closed capsulotomy) may break up scarring, but can potentially rupture the implant.

Scarring – Excessive scarring is uncommon. In rare cases, abnormal scars may result. Scars may be unattractive and of a different color than the surrounding skin. Additional treatments including surgery may be necessary to treat abnormal scarring.

Implants – Breast implants, similar to other medical devices, can fail. Implants can break or leak. When a saline-filled implant deflates, the body absorbs its salt-water fluid. Rupture can occur as a result of an injury, mammography, or from no apparent cause. It is possible to damage an implant at the time of surgery. Damaged implants cannot be repaired. Ruptured or deflated implants require replacement or removal. Breast implants do not have an indefinite lifespan and will eventually require replacement surgery.

Surgical Anesthesia – Both local and general anesthesia involve risk. There is the possibility of complications, injury and death from all forms of surgical anesthesia or sedation.

Delayed Healing –Wound disruption or delayed wound healing is possible. Some of the operative areas may heal abnormally. Some areas of the skin may die. This may require frequent dressing changes and/or further surgery to remove the unhealed tissue.

Smokers have a greater risk of skin loss and wound healing complications.

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.

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.

Mammography – If you are over 50 years of age, pre-operative mammography is recommended prior to surgery. Post-operative mammography is performed according to American Cancer Society guidelines. Breast implants may occur from breast compression during mammography. Inform your radiologist of the presence of breast implant so that appropriate mammogram studies may be obtained. Ultrasound, specialized mammography and MRI studies may be of benefit to evaluate breast lumps and the condition of the implant(s).

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.

Pregnancy and Breast-Feeding – There is insufficient evidence regarding the absolute safety of breast implants in relation to fertility, pregnancy or breast-feeding. While there is no convincing evidence of any special danger of breast implants for pregnant women or their children, studies are continuing to look for possible problems.

Calcifications – Calcium deposits can form in the tissue surrounding the implant and may cause pain, firmness, and be visible on mammography. Should this occur, additional surgery may be necessary to correct this problem.

Immune System Diseases and Unknown Disorders – 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. These symptoms include joint pain or swelling, fever, fatigue, thyroid problems, breast pain and musculoskeletal pain. 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 effect of breast implants in individuals with pre-existing connective tissue disorders is unknown.

Unlike silicone gel-filled implants, the saline-filled implants contain salt water. Any risk related to silicone gel would not be associated with saline-filled implants. However, gel-filled and saline-filled devices have a silicone rubber envelope. An increased risk of autoimmune disease is possible even from saline implants. Reliable medical laboratory tests to determine antibodies to silicone do not exist. It has not been proved that there is a relationship between silicone antibodies and disease in women with breast implant(s) and scar tissue capsule(s) will alter autoimmune disease or prevent its potential occurrence.

In very few women who have breast implants, a variety of other symptoms and conditions have been reported, suggestive of an auto-immune multiple-sclerosis like syndrome. Additional complaints involve the musculoskeletal, skin, nervous and immune systems. The relationship of breast implants to these conditions has been hypothesized, although not scientifically proven. Because such disease states are rare, they are difficult to research. There is the possibility of unknown risks associated with silicone breast implants.

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.

Chest Wall Deformity – Chest wall deformity has been reported to the use of tissue expanders and breast implants. The consequences of chest wall deformity are of unknown significance.

Activities and Occupations – Activities and occupations that have the potential for trauma to the breast could potentially break or damage 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 American Cancer Society guidelines, and to seek professional care should they notice a breast lump.

Allergic Reactions – In rare cases, local allergies to tape, suture material to topical preparations have been reported. Systemic reactions, which are more serious, may occur to drugs, used during and after surgery, and prescription medications. Allergic reactions may require additional treatment.

Pulmonary Complications – Pulmonary complications may occur secondary to both blood clots (pulmonary emboli) or partial collapse of the lungs after general anesthesia. Should either of these complications occur, you might require hospitalization and additional treatment. Pulmonary emboli can be life threatening or fatal in some cases.

Removal/Replacement of Breast Implants – Future removal or replacement breast implants and the surrounding scar tissue envelope involves a surgical procedure with risks and potential complications.

Long-Term Effects – Subsequent alterations in breast size may occur as a result of aging, weight loss or gain, pregnancy or other circumstances unrelated to breast augmentation.

Pain – Chronic pain may occur very infrequently due to nerves becoming trapped in scar tissue following surgery.

Other – You may be disappointed with the results of surgery. Asymmetry in breast shape and size may occur following surgery. Infrequently, it is necessary to perform additional surgery to improve your results.

Additional Surgery

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 augmentation surgery. 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.

Health Insurance

Most health insurance companies exclude coverage for cosmetic surgical operations such as a breast augmentation or any complications that might occur from surgery. Please carefully review your health insurance information pamphlet.

Financial Responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, anesthesia, laboratory tests and possible outpatient hospital charges 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. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day surgery charges involved with revisionary surgery would also be your responsibility.